

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[APPLAUSE]

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

Panelists:

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

Moderators:

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

ELLEN CONNELLY: The regulation panelists could come forward.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FRANK LIN: Can I clarify one question? Sorry.

ELLEN CONNELLY: Sure, of course

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

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

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

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

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

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

RICHARD CLELAND: Well, stump the chump.

RICK GILES: Sorry.

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

RICK GILES: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

ELLEN CONNELLY: Anyone? Frank?

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

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

ELLEN CONNELLY: Rick.

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

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

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

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

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

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

RICK GILES: I understand that.

FRANK LIN: Yeah.

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

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

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

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

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

DAVID SCHMIDT: Ian.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ELLEN CONNELLY: Ian?

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

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

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

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

ELLEN CONNELLY: Thank you. Frank?

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

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

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

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

ELLEN CONNELLY: Richard.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ELLEN CONNELLY: Give it now.

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

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

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

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

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

ELLEN CONNELLY: Sure.

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

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

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

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

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

[APPLAUSE]

[MUSIC PLAYING]

[SHORT BREAK]