Considerations in Over-the-Counter Hearing Aids: Past, Present, and Future

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Today's course is considerations in the over the counter hearing aids, past, present and future. It has been said that innovation is seeing what everybody has seen and thinking what nobody has thought. This month on audiology online, we're celebrating innovation in the hearing industry with our third industry innovation summit. Thank you for joining today, and we hope to see you in other summit courses which you will find in our course library. We would like to thank our title sponsor, care credit, and all the companies who are participating in this 2024 summit.

And now it's my pleasure to turn the microphone over to Dr. David Akbari, who will let you know a little bit more about himself. Welcome, Dr. Akbari. Thank you very much, Vaughn.

And for those of you who are joining, it's great to be with you.

So this is a course that I am pleased to give. And what we're going to do to start is I just want to lay out kind of the scope of what we're going to talk about today. So we're going to start just with a brief introduction, and then I'm going to get right into it with the over the counter hearing aid history, timeline, and impetus. And by impetus, I mean, why did we need this? What does it come from?

Following that, what I'd like to do is discuss a little bit of the over the counter hearing aid legislative outcomes and some of the technical details. And when I say technical details, I'm not necessarily speaking at this bullet to the electroacoustic piece, but more so the regulatory piece, kind of the technical aspects of the regulatory piece, and legislative outcomes. Then what I'd like to do is present you with a contemporary analysis, is what I'm calling it. And it's just going through the existing products that are out there today. These are products you might see in the clinics that you're in, or some of your settings as appropriate.

And then we're going to get a little bit more detail where we look at the electroacoustic test methods supporting self fitting, some of the wireless test methods supporting self fitting. And then we're going to answer your questions and get into more of a general question and answer period. So strap in. We're going to get ready to go here. To start with, you might ask yourself, who am I?

Who is this guy? Right. Well, I'd love to tell you about that. So this is me. This is my family up here.

And I am currently the chairperson of the ANSI ASA s three working group 48. It's a lot of words, but this is the group that authors the ANSI S 322 test standard. That's the standard for measurement in the coupler, the two CC coupler that we all learn in our audiology training and what have you. But I find myself fortunate enough to lead this fine group, frankly speaking, the finest minds in the world, as far as I'm concerned, from all the different manufacturers working together to make reasonable accommodations for standard testing. So I also happen to be a us delegate for the ANSI Technical advisory group to IEC.

That's a great privilege. I also received the Academy of Doctors of Audiology Industry Leadership award in 2022, 1st time it was given to ten years and the first individual to ever win. What an honor that is. That's me pictured with Victor Bray here. I also happen to be an advisory board member for the hearing review, been on several podcasts.

And of course I am an employee of IntRaCON Corporation for additional disclosures. I think they're in the course description. But that's enough about me. Let's talk about you, and let's talk about OTC hearing aids. So what we're going to do here is talk about the impetus and the timeline.

So why OTC hearing aids? Why do we need these? Wasn't everything perfect? And so forth? Well, starting as early as 2013, Ian Windmill and Barry Freeman, and more recently, Victor Bray and Amin Amlani have looked at the workforce projections, as well as the population incidence of those who can dispense hearing aids for the hearing impaired.

In a lot of words, the summary is that they are finding that there is a huge and growing unmet need for hearing health care in the United States. So you can see at the bottom here we have a couple figures. On this left hand figure, you can see the horizontal axis is looking at the year index, and then the vertical axis is number of people. And what you can see here is there is a huge growing estimated population in the United States with impaired hearing. But at the same time, you could see on the right hand graph that the projected and actual labor market for the licensed healthcare profession, specifically audiologists, is actually going down, or some estimates have it being flat.

So the idea here is that the projected need for hearing health care far outweighs the projected growth of hearing healthcare providers. So this has created a problem that we have to address. Well, you might ask yourself, why don't we have more audiologists, right? I mean, the audiologists, of course, and I would agree, are the gold standard. And the reason we don't have more is because they're simply insufficient clinical placements.

That's probably the number one reason. It requires a year of an internship or externship, as you call it. And frankly, many audiologists do not want to intern, especially if they're selling hearing aids, unfortunately. Also, the university audiology training programs are very people and money intensive, so the student faculty ratios often end up sort of unfavorable. And the university doesn't like that because they're wanting to get people licensed and certified and make sure they're meeting the requirements.

And it's a great thing that they do. And also, of course, many programs have difficulty attracting patients for the student training, not all of them, but some. And so it kind of creates this environment that you are seeing. And so if you look deeper into this data about the audiology and AUD programs, what you start to see is from the period year 2009 to 2010, there's about 70 programs. You have about 3200 applications, with the program capacity close to 800.

Your enrollment is about 787. So your total enrollment, United States 2600, with 548 degrees awarded in this year. And then you can see it's kind of somewhat flat. Although the applications have increased by a lot, the program capacity between 2000 and 910 and 2014 15, they are about flat. And enrollment and so forth is somewhat flat.

Total enrollment growing a little bit, a little bit more degrees being awarded. But really, data provides the answer on this. There's about 71 AUD programs, give or take, in the United States, 8.7 students program, about eleven capacity in each program, sort of 80% of them maybe graduate. You got seven per year graduates, and 20% maybe you got attrition. Maybe half of those people go to selling hearing aids.

Half go into other areas of the profession. So you can start to see the picture that emerges from this data. So in light of this, you'd ask yourself, well, how do we get to where we are today, then, if that's the case? So, in light of this data, there was the national advisors in science, engineering and medicine in 2014, which was commissioned by then President Obama, and they held a workshop on hearing loss and health, aging. And that's when I first got kind of involved in this sort of thing, as well as with the pcas.

So this is becoming more formalized at this time. In 2015, the president's Council of Advisors in Science and Technology issues this report. And what you saw in that report

is kind of what we just talked about, that there's this projected need and demand, but the supply in terms of the providers just are not going to not only meet that, but they're going to be very short. So for that reason, they recommended, based on the risk classification, to create this category of over the counter hearing aids. From there, we had an FDA workshop streamlining good manufacturing practices for hearing aids.

And then in 2016, the nascent released a landmark report which was hearing health care for adults. Priorities for improving access and affordability. Those are really important words around the conversation of over the counter hearing aids is access and affordability. Around this time, as well as those of you who were dispensing hearing aids at the time might remember, the FDA stopped enforcing the medical clearance requirement for adults. In other words, if you remember, we used to have to do waivers, and you say, hey, can you sign this form that says that you're waiving the physician evaluation prior to receiving hearing aids?

And that was a big deal at that time. And this is all related to this concept that we're iterating on. From there, the Federal Trade Commission had a workshop where they had to now hear this competition, innovation, and consumer protection issues in hearing health care. And then finally, the over the counter hearing David act was passed and enacted as part of the fedara, which is the reauthorization act that we had. But having that, of course, in between here, we had something called Covid-19, a very little thing that some of you might be familiar with for that reason, perhaps, and others.

FDA missed the statutory deadline to issue the proposed over the counter hearing aid regulations. So this is the time period, I would argue that people started to get a little nervous, but thankfully, we've moved on from that. So on July 9, 2021, President Biden issued an executive order urging the FDA to issue the proposed rule finally, on this over the counter hearing aid within 120 days. So they had created the need to do the over

the counter hearing aids, but they didn't finalize the details at that time. So now President Biden comes and says, please do that.

We really need those details. So following that, the FDA issued the proposed final OTC rule on October 17, 2021, which led to a robust public comment period. Just to give you an idea, with these public comments on the proposed OTC hearing aid rule, there was this period of time between October and January, October 17, 2021, January 18, 2022. There was many, many comments. I think just to give you a perspective, there was close to 2000 comments that were submitted in the public docket.

Normally, for a proposed regulation that comes through FDA, my understanding is that number is closer to 150. So we were very much, and that's kudos to all of you and others in the professions who have a stake in this and are very energized to talk about this. So it's actually quite an accomplishment for our profession. So amazing, really, if you ask me. But anyway, so that was the public comment period.

And then, following the public comment period, the FDA issued the final OTC hearing aid rule on August 17, 2022. And then, of course, the rule takes effect, meaning that it would be enforceable on or about October 17, 2022. So exactly a year to the day after issuing the proposed rule and the details therein. So, the bottom line is this. Even if every single AUD program in the country had 100% graduation rates, which doesn't happen, and all audiologists work dispensing hearing aids full time, which also doesn't happen, and hearing instrument specialists did the same thing, there'd still be a huge and growing unmet need for hearing healthcare services in the United States.

This is the impetus for OTC and why we need it. So consider that this is not taking patients away from you. I think that's an important point to make to this group. This is not taking patients away from you. These are people who would not otherwise be seen.

Think of it more as these are people who could see you. These are your potential patients that you wouldn't otherwise have access to, and they otherwise wouldn't have care. So, when we talk about access and affordability, that's an important piece as well. So what actually ended up happening? Let's talk about the over the counter hearing aid legislative outcomes and some of the technical details, just to give you some color on this.

So, as mandated by Fedara, which is the Food and Drug Administration Reauthorization act of 2017, the FDA's task was to provide greater access for hearing aids than were currently available at the time. Provide affordability for hearing amplification help. And by the way, this is not the government coming in and telling you what to set the price are. The idea is here, with affordability, that market forces in our system of free markets would help to create downward pressure on price, thereby increasing affordability. So it's not government controls the price, it is market forces here.

And then, of course, also implicitly, to increase use of hearing aids by consumers, which we all win from. All of us win from that, especially the public. So, in an effort to improve affordability and accessibility as key goals of the final OTC rule, they created what was called chapter 21 of the Code of Federal Regulations 830. So, that was a new rule, and this is a slide you might pay attention to. If you notice, there's something up in the top corner here.

This might be important later. Anyway, so what they did with this rule was to maintain the existing definition and medical device classifications for hearing aids. So we had class one and class two. Class one is kind of like the non wireless, the stuff you plug in. And class two would be the wireless.

Of course, there's another class, class three, you might be familiar with that stuff you implant. That's like implantables. So they did this as consistent with the Food, Drug and Cosmetics act. That's what FDNC act is. So what this, David, was it created a category of OTC hearing aids in addition to regulatory controls and conditions for sale.

And that was mandated by Fedara. They had to do that. What it also did was it noted the fedara's federal preemptions for OTC hearing aids. We live in the United States. They kind of had these debates some hundred years ago, several hundred years ago, where this idea of federalism anyway.

But they did have to decide what those preemptions were going to be. They also did something which they did not have a congressional mandate to do, which was they created a category of prescription hearing aids along with their regulatory controls and conditions for sale. So despite the fact there was no congressional mandate to do it, perhaps the FDA saw that as a great opportunity to create this new regulatory classifier such that there was clarity around the rules and differentiation between over the counter and prescription hearing aids. Those hearing aids you were prescribing and dispensing prior to the OTC rule probably are now prescription hearing aids, but you ought to check, because this is all new. So consider that along with the OTC hearing aid final rule, they've also kind of created the prescription hearing aid rules.

And so what this has also done is it's replaced chapter 21 Code of Federal Regulations 801 four 20, which previously was the prescription hearing aid regulatory box, if you will, the statute, and it repeals the conditions for sale for hearing aids and created under a new chapter 21 of the Code of federation 801 four two one. So it repealed the conditions for sale as restricted devices. That's the idea. So that they took them off the restricted list, which where they had been, by the way, for quite some time. And keep in mind, there was no mandate to do this in fedara, so they did that anyway, perhaps because it was convenient time to do it.

And so what they've done is they've removed federal preemptions and 40 year old exemption decisions for restricted hearing aids. This is an arguable thing, but what I would say here is that's what they did. Whether we debate it now or not, that was their choice. That's the world we live in. So the FDA did exceed Congress's mandate under the OTC Hearing act of fedara by eliminating the current restricted category of hearing aids associated regulations and creating the prescription category of hearing aids.

That's why this is important to know. So class one and two prescription hearing aids did not exist before. Now they do. So this is a little table here. You can see to show the difference between over the counter hearing aids and prescription hearing aids.

The over the counter hearing aids is a category that never existed before. It's defined by its technical specifications and intended use. So consider that. We'll talk more about that in a minute. It may be dispensed by a licensed or unlicensed person, but you can't make yourself, you can't say that you're required to be dispensed by a licensed person, but you can still advertise.

If you are licensed, you can say, yeah, I offer OTC hearing aids. That's fine. And the federal preemptions here are strong. By contrast, prescription hearing aids are also a category that never existed before for air conduction hearing aids. They're also defined by their technical specifications and intended use, and these must be dispensed by a licensed person as governed by state law.

So where you've got the federal preemptions on OTC, prescription hearing aids still firmly fits in the state piece. So just keep that in mind, and this is a good reason to be involved in your state organization. And as well, consistent with that point, federal preemptions are limited on the prescription side. So as a result of the new OTC final rule, both OTC hearing aids and a newly created class of prescription hearing aids were

defined. And I'm not going to read this to you, but it's important here to know that this is an example of the intended use here, or I guess this is not, but I'm jumping the gun here.

But it's an air conduction hearing aid that doesn't require implantation or surgical intervention. It's intended for use by a person 18 and older. Keep that in mind to compensate for this idea of perceived mild to moderate hearing loss. Not automatically confirmed. It's an important detail, and they're saying this device, through tools, tests, and software, which is sort of a bucket term, allows the user to control the hearing.

David. And customize it to the user's hearing aids. This could be self fitting. It could necessarily not be self fitting. And we'll talk through those details as well.

The device may use wireless and it may include tests for self assessment. It's available over the counter without the supervision, prescription, other order and so forth. So that's the idea, is it's over the counter. By contrast to prescription hearing aids, a hearing aid that is not an OTC hearing, David, and does not satisfy the requirements. So it has its own regulations.

In other words, what they're saying. So there was a clear mandate that over the counter hearing aids will be available to consumers through in person transactions by mail, online without the supervision, prescription, other order of a licensed person. Doesn't mean you can't advertise it, but it just means it's not, you can't make it required. There is also an express federal preemption which prohibits state or local governments from establishing or continuing any law specifically applicable to hearing aid products that will restrict or interfere with the servicing, marketing, sale, dispensing use, consumer support or distribution of OTC hearing aids that's not identical to the term. So what does all this mean?

I'm going to boil this down for you. The idea is this, that as you have your consumer products that have things I think of like your apple Watch or something, you've got this increasing medicalization of consumer products. At the same time, what you've got happening is you've got a consumerization of medical. You know, I think a good example is your pulse or something on your apple Watch or something like that. What happens in the middle here is you've got this increasing category of regulation.

And that's just an unfortunate consequence or civic or perhaps fortunate for what happens as a result of this desire. You have a great idea, you want to bring it to market. You think you can help.

So that's what kind of. In a nutshell, that's what that means. So in summary, over the counter hearing aids are a medical device, an electronic product. They're for people 18 years and older. For those with perceived mild to moderate hearing loss, you got to have somebody that's 18 years or older to buy it with no medical exam prescription, no fitting or need for a licensed seller.

But a prescription hearing aid is also a medical electronic product. Anybody can have it of any age, as you know, including those younger than 18 years, perhaps especially those younger than 18. And for people with any degree of hearing loss, including severe, you need a prescription, you need to be licensed. These are both different from the PSAPs or the personal sound amplification products, which are electronics, but they're not a medical device, that's a key thing. And so these are just meant for situational listening.

And there is no applicable FDA requirements regarding the conditions for sale. Just a note here. Before we get into the analysis, I do see some questions coming through. I would be delighted to answer them at the end when we get into our q a period. And thank you for asking them.

I am aware that they're happening. So from here. So we talked a little bit about kind of the regulatory landscape and the legislative outcomes. What happened as a result of that. What I'd like to do to make this more accessible for you that are on this call are to discuss the contemporary analysis.

In other words, what's out there and how do you kind of make sense of it? Because there's emerging resources about this. I want to help you navigate that. So now that it's here, OTC, what's out there? Well, all the hearing aids sold in the United States fit into one of the three letter product codes as defined by FDA.

So they're not meaningful in themselves. They're not acronyms, they're not anything like that. They're just a placeholder for categorization of devices that are the same in a regulatory sense. These product codes are searchable and public. So this is a direct link from the FDA's website.

You can search them. I also saw one on hearingtracker.com. That was nice, that had kind of a list of them by product code. But kind of the key point to make here is that not all OTC hearing aids are considered self fitting. This is a very common misconception I encounter when I discuss OTC hearing aids.

They are not all considered self fitting. In order to be legally marketed in the United States, all self fitting hearing aids need to have a 510K marketing clearance prior to sale. And that's where I'll talk a little bit more detail about that in a couple of slides here. But I want to just make the point here that the FDA does not approve or endorse any product. They only clear them based on claims and intended use.

So if you take anything out of this talk, take this, be wary. Anytime you see the phrase FDA approved. You know, now that you've been in this talk, that is nonsense because

they do not approve anything. They do not endorse anything. This is only cleared based on your claims and intended use.

It's a very important point. So here's examples of the product codes. You can see them kind of on the left hand side of the screen here. And these are all the hearing aid air conduction product codes in the United States. So I've kind of used different colors here to highlight them.

And in a nutshell, the Q, UF and Qug product codes are non self fitting, over the counter products. These are products where you would buy them off over the counter, but they might have like two or three program settings in it, like kind of a generic setting for a hearing. David. And these are the ones that you might decide not to service them in your clinic or whatever, but you ought to know that they exist. And the only difference between QF and QG is whether it's wireless or not.

That's the idea. So you can see here, QG, it says with wireless, QF is a non wireless. So this is the idea that they're medical products. They're intended to compensate for impaired hearing, unlike a PSAP, but they are non self fitting. The Quh and QDD product codes are self fitting over the counter and prescription, respectively.

So QDD, one of the probably most common products under that code is that Bose sound control product that I don't think it's on the market anymore, but that was the first one, and it's in the QDD product code. There are others now, but you can also have a prescription hearing aid that's self fitting as well, as long as it meets the regulations. And you've got the quh, which is the self fitting, over the counter wireless OTC hearing. David and then this code, OSM and ESD, those are the product codes that refer to prescription products that you're probably used. So OSM being the wireless version, and then the ESD is a non wireless prescription hearing aids.

So those have been around for a long time. So in a nutshell. And then you can see here, this is the regulation number. So this is kind of the statutory, the law that is required. And then it shows you the device classification here.

So you can kind of see that all the class ones, none of these are wireless or they shouldn't be wireless. Yeah. So none of these are wireless. That's right, because the class two makes it a wireless, and that has to do with the risk classification. So as I mentioned a minute ago, what is a mean?

We ask yourself, what is that? Well, a 510k, which you might hear of in the news or on press release, whatever it refers to, section five hundred and ten k of the food, Drugs and Cosmetics act. And what it means is that a medical device has been deemed by FDA to be substantially equivalent to another already legally marketed medical device. So the key element of substantial equivalence is with respect to a device being compared to a predicate. It has either the same technological characteristics or has different technological characteristics, but does not raise different questions of safety and effectiveness.

In other words, like you're fitting to NaL NL two prescriptive targets. And yeah, your algorithm works a different way, but you still get there reasonably close in the same way. Right? So that's the idea. You have different ways to get there, different implementation details, but you're still treating hearing loss, you're still meeting targets or whatever.

This is the idea that you're able to make this claim. And frankly speaking, another way that you might simplify this of substantial equivalence is, you'd say, with respect to performance, to recognize voluntary consensus standards. So let's say you measure the ANCS 322 standard, for example, measure in the coupler, it has output and gain, and you've got total harmonic distortion, things like that, and you're showing that it's

equivalent on that, in that axis, right? So that's the idea, is you're trying to say it's perhaps different technologically, but it doesn't raise any new questions of safety or effectiveness. Two different questions, by the way, effectiveness and safety.

So when you look by product. So this is a list right here. I've gone through and done the search for you. This is the product code, Q-U-H. So these are all the self fitting over the counter hearing aids.

Actually, there is one more. I looked last night. There is one more that should be on this list that just happened. And so forgive me for omitting that, but I did have to submit these slides some amount of time ago, so you can't track in real time. But just keep in mind, at the time that this slide was created, there was nine of them, I think now there's ten.

So there's not a lot of them. Right. There's not tremendous amounts of them. But what's important to show here is that they have a 510k number. You can see here.

And also you can see that there's only a couple that are both in the OTC and prescription category. So previously, people have kind of made the decision, is it either over the counter prescription, how is it marketed? And there's only a couple that are in both categories. But this is kind of the list, as it were. And then here's the product code, QDD.

So these are the prescription self fitting ones. And you can see that. I'll go back one slide, but you can see that the Luma 155 SF and the Jabra enhanced plus these are the only ones that are in both categories. So here you've got the Bose sound control, the Braun bha series 100 clear hearing aids, and so forth. And then this is the previous slide again.

So the quh product codes are self fitting. The thing about the self fitting is it's just a regulatory bucket that they put this. So it's the reason that they use the code quh is specifically because of how it's classified. So in this case for quh, it's OTC. That's one part of it.

It's self fitting, it's wireless, and it's an air conduction hearing aid. That's what makes it a quh as opposed to the QDD. It's self fitting, it's wireless, but it's prescription. Right. And it's an air conduction hearing aid.

So the regulatory classifiers, in terms of the three letter codes are really just a bucket. And I'll go back a couple of slides here just to show you that, again, that these different product codes, all they refer to is the device type and classification, just to be clear. Okay, so we're moving on here, looking deeper at this, and this is what I would encourage you as clinicians to do, is when you click, and I'm sorry to jump around here, but just to go back one slide here, you can see this 510K number. You can kind of see they actually are a link. Each 510k number here has a link.

If you click on the link, you'll see this. So this is an example, and I'm going to use this example of the lumen 155 SF for self fitting. I happen to know this one pretty well. So if you click on the summary here, it actually goes through the clinical data that was required to establish substantial equivalent. So when you talk about safety and you talk about effectiveness, those are two things you kind of have to prove clinically.

So safety typically means it can't go above a certain amount, and effectiveness means, can you match what you expect to match if it's a prescriptive target or not, whatever that is. But if you look at the summary, you can see an example of what the statistical analysis was, what the study design was, and so forth. And actually, I'm going to go through that with you. But looking deeper in OTC, all 510K cleared OTC hearing aids have to provide clinical data, robust labeling claims and intended use, which all of them

are evaluated by FDA. Each cleared 510K has a publicly available summary posted on the searchable database that is required.

So that's why it's important, because if you know how to navigate this, you as clinicians can go through and evaluate yourself with your advanced training and credentials. You can look at this stuff and see what you agree with, what you don't agree with, and maybe it spurs you to do future research. Maybe it helps your understanding. For whatever reason. I think knowledge is power, and it'll help you.

But here's an example. I didn't go through some of the statistical detail on this example, but this is the indications for use just as an example. But it goes through a whole summary, and FDA is very serious about that. So when we talk about self fitting, what do we really mean by that? Going deeper.

All but one of the cleared self fitting devices is based on the NAL NL two fitting rationale. The sole exception that I'm aware of is the one I just showed you, which is not based on NL two. So all clinical data summaries typically use deviation from the NAL NL two prescriptive targets, along with a similar performance, to recognize consensus standards, to establish substantial equivalents. So when they look at like, self fitting, and how do you show benefit? Typically the primary endpoints are something like the AFAB, the abbreviated profile of hearing aid benefit, or other similar self reported outcome measures, along with the real ear.

So here's a table that summarizes for the product code. Q, uh, how they did their study in order to validate their self fitting rationale. And the self fitting rationale, the way they do self fitting is different on all of them. I mean, some of them, it's like a slider. They call them a dimension reduced controller.

So what that means is you might have compression gain and output limiting all tied to one knob, for example. That's like the bose kind of did that. I don't know if it's exactly that, but the idea of a dimension reduced controller is certainly from Bose. But others might do something where they'll do like an insecure audiometry, and then they'll fit based on that, based on hearing aid. So the self fitting itself means different things to different products.

And that's why I would encourage you to look at the summaries, because that'll tell you exactly what individual self fitting is on a different product. But to go into the interpretation of the different products and how they validated them, so you know that they actually went through this study. We'll take, for example, the Santro. They're using the NL NI two fitting rationale for their self fitting. And the way they validate it was through AFAB quicksin.

And they showed some real ear measurements. And their predicate was Bose. It's really important to kind of show this spread, because as you go through the summary and interpret it, this is kind of what you get. The one exception, of course, the Lumen 155 SF, that's kind of based on this. It was a paper published by researcher Celeti and flame in 2008.

And then there was this national help survey based data. The idea was that you could kind of have like six audiograms for men, like six audiograms for women, twelve audiograms for men. Overall, kind of. The broader idea is that a large amount of audiometric space gets converted into a much smaller amount of prescribed gain space. That was kind of the idea with this one.

That's just a general fact about our hearing aids in general. And so the endpoints we use for this one were the AFAB, the SSQ twelve, which is the speech, spatial and

qualities index. It's twelve questions. And did some real ear. This one used a dual predicate, so it was using the new Hera IQ buds.

Even though the product is a BT product, you can still leverage an IT product as the predicate, just showing equivalent performance. And also reference the Bose. And this, by the way, this Bose, the k number here, this is the special five hundred and ten k that followed the de novo. Just so you're aware, the Bose, what they did is they had this kind of neck band looking thing. They did a de novo on that, meaning it was a brand new.

And then they followed that with a special 510K, which was the BTE styled product. So you're allowed to do that. You can see. That's why predicate selection is very important. Hui Zhou.

They're also using NL two. They used Afab and real ear. They referenced the Bose device, the intrasound tuned Lumen 155. This is from a group in Israel. They're using the nal nl two fitting rationale as well, with the insitu audiometry aided by some AI, and they use the real ear mean absolute difference.

So they're looking at when we measured in the real ear, how different was it from what we expected on NL two? And kind of, you'll see that as a common theme, this idea that profit versus a self fit, what does that mean in terms of real ear performance? Or in other words, what SPL are we delivering to the eardrum? They also chose to use the client orientated scale of improvement in the international outcome inventory for hearing aids as subjective questionnaires, just to support the benefit statement. And their predicate was the Braun Bha 100.

Moving on. And these are other products, just to show you the all day clear product. Once again, based on nl two afab, the quicksin real ear. They reference the Bose Lexi lumen. They use an NL two based fitting rationale.

They use the AFab, the international outcome inventory, quicksin. They use digits and noise. It's a nice test. And then they reference the Braun as their predicate, ergo, five and six. As you might know, that's the small it product.

And they use a proprietary self fitting rationale. But it's based on l two proprietary. In this sense. They've optimized it for their form factor. So they've got this really tiny ite style product.

What they did is they just optimized it for that. Things like occlusion and what have you. And so they used Afab and aided speech recognition as their way to show the endpoints. And they referenced the Bose, the new hero IQ buds. That's an NL two based thing.

Again, the group in Australia there, HP branded, and they use an AFAB SSQ twelve, the BKB syn, just a little bit of a different word recognition, speech and noise test, and then real ear measures. They also use a dual predicate using the Bose, the de novo. In this case, that was the neck band one and the Braun predicate. And keep in mind, the dates matter at the time this was released, perhaps the Bose special 510K had not been done yet, because this takes a lot of effort to do a jabra enhanced plus. That's the NL two based, and they're using AFaB, quicksand, and real ear with the Bose de novo as their predicate.

So when we're talking about substantial equivalents, and how do you show that the product's effective or even safe? What methods might we use to support the idea of self fitting? In other words, when you give the controls over to the user, whatever those

controls are, of course, it's always going to be less than you can get from an audiologist. That's kind of an important talking point, but you got to make sure that the product is still safe and effective when the person is not there. In fact, the impetus is much more because there's not an audiologist.

So, once again, you might notice the top right corner here. This might be an important slide later, but a key aspect for determining the 510 key marketing clearance and achieving substantial equivalence is by showing similar results to recognize consensus standards. So there's really two of them in terms of electroacoustics that we use for air conduction hearing aids. And these are the ones that are typically leveraged in a ANSI asas 322. So this standard details methods for evaluating hearing aid electroacoustic performance in a coupler and is used for both prescription and OTC hearing aids.

And it's used, the scope really says it's for outgoing quality control inspection. In other words, when you measure this test, the idea is you're trying to trace as a manufacturer if there's something wrong with the hearing aid before it goes out the door. This is a lot for manufacturers. This is what we do, statistical process control. So a manufacturer will set a limit based on what's called an operational qualification.

That's where you measure a sampling distribution of hearing aids. And you say because there's variability in the manufacturing process, what are the reasonable limits for things like gain and output and so forth? And these are based on how you seat the components in there at a very micro scale. So it's very technical and detailed. But in any way this standard is leveraged for that.

And it's used for both prescription OTC hearing aids. The other standard we use for electroacoustic performance is this ANSI CTA, which is the consumer Technology association, and it's this 2051 standard. And this standard references s 322 for most of its methods. When it talks about electroacoustic, it references ANSI S 322. And then

what it does is it adds several criterion reference values, meaning that there is a right answer, that they say the manufacturer does not set the limit here, where the manufacturer does set the limit on the S 322.

And that's true for prescription as well. So this standard was designed, the CTA 2051 was designed with psaps in mind and it's now used as part of the test requirements for OTC hearing aids. In fact, the FDA is quite keen to see results to the ANCT standard when they're evaluating a, they're pretty serious about it. And it's the things like they have, for example, an output limit and total harmonic distortion plus noise and so forth, different limits that they set their criterion reference S 322, both prescription OTC, ANSI CTA 2051 was, it's just OTC and it was designed with pseps in mind. So that gets us into the wireless.

And this is one of the things that you might not think of as important to FDA, but it's very important. Actually, I was frankly surprised going through the, on several of the products I showed you that they were really interested in this piece. Once again, there's a little bit of indication in the corner that this is important. But as part of the test requirements to maintain that, consumers will be able to realize safe and effective OTC products. Wireless testing is really a huge part of FDA's concern, and there's a couple of reasons for that, and you'll kind of see that as we look through the standards at a high level.

So among the many potential wireless tests the FDA may require, depending on the product, there's really two major ones. The first one is the ANCI c 63 27. So that's a lot of numbers and words, but what that test is, it's to show wireless coexistence in a medical device. In other words, coexistence is how does the hearing aid operating conditions where there are numerous wireless signals operating while the hearing aid is also trying to operate? What we mean by that is specifically like Wifi or Bluetooth.

You might think of something like hospitals or high density housing, where there's just a lot of stuff going on, a lot of wireless transmission. And one of the key points is that they're protocol based, so that you think of using a bluetooth, for example. Everybody's using Bluetooth. At the same time, how do you make sure that the product works as it's intended when there's all this other electromagnetic energy going on in that environment? So the failure condition really, for this test is that the hearing aid cannot operate in the presence of competing wireless signals.

And of course, success is that the hearing aid's design function is unaffected in the presence of competing wireless signals. So a summary for this test, you got to do it. It's found in all applicable OTC hearing aids, user manuals. So keep that in mind. A user manual is not just a throwaway.

There's a lot of regulatory detail related to tests like this one that's required to be in the user manual. So keep in mind the key takeaway here, c 63 27. That's the coexistence test. Another test we have is the c 60 319. So this test is really used to document wireless radiated immunity in a medical device.

So that focuses more on the hardware susceptibility, like the antenna, for example, to its unintended wireless signal. So think of the idea that you need to go into airplane mode, begin the airplane, because the pilot doesn't want to hear your, you used to hear that, right? That's the idea of that. You've got immunity from those types of signals. The technology has improved quite a bit, but it's still a concern, especially on hearing aids.

That are kind of a low powered device embedded system. So, unlike coexistence, where there are discrete levels that are documented, wireless rated immunity gets what's called an m or t rating. And that's exactly what you might think. It's microphone telecoil, and it's in the range one to four, where a higher rating means that the device is

resistant to increasing levels of magnetic field strength. In other words, you might think we're talking about Star Trek.

No, we're talking about magnetic induction, things that we have on hearing aids. So, as I mentioned, m ratings are for the microphone, t ratings for the quail. This is just sort of a reference in terms of category boundary here at the bottom, m one m 235 volts per meter. And I tried to convert this into decibels, but it's not so clean. I think the 31.6 milliamps per meter, that's equivalent to kind of our saturation lower 90 db inputs, but it scales differently, you know what I mean, from decibels.

So it's a little bit harder to say. But these are the category boundaries for the c 60 319 test. So if you want to achieve an m four, the highest level immunity, you have to make sure that it's not susceptible. At a field strength of 45 volts/meter it's a little bit hard to meet, but, you know, it's a good product in terms of wireless. I mean, another example would be like, you go into like a target store or something or Walmart or whatever, and you got those things at the front, those inventory control sensors.

Those are things that if you're not sufficiently immunized against in terms of wireless radio immunity, you'll hear that through the hearing aid, especially if you're in like a telcoil or a mixed mt kind of a mode. So it's important to know for hearing aids, both prescription and OTC, but especially if you end up start seeing telecoils being used in the OTC hearing aids. So in any case, wireless radiated immunity, this slide is important, is the c 60 319. This slide might be important if it wants you take the test. Right.

So that gets us into answering some questions. I know there's a lot of questions, and that's okay. It's okay to have questions, and I really appreciate your questions, by the way. I see them popping up in the chat. I will try to get to those.

But first, what I wanted to do was answer some of these questions that I got from some of my colleagues. These are common questions that I get asked and I think they're worth going through as we get to your questions as well. So, general knowledge, how do they work? What capabilities? What's out there?

One person was curious about the average sale price, typical age of those purchasing and return rates. These are great questions. So most hearing aids that are over the counter work the same as prescription hearing aids. They have the same components, the same hardware, but the key difference is the software, whether it's self fitting or the interface. Labeling and intended use.

Labeling and intended use are huge in this, and I'll explain why I think in a slide here. When in doubt in terms of how it's working, I would recommend you measure SPL on the real system. I mean, it's the best way to handle this as a black box is you check against what you expect from the NAL NL two prescription targets. In fact, as you saw in a previous slide, I went through a table for all the products that are out there, it's pretty reasonable to use NAL NL two because to my knowledge, all the ones that are commercialized are based on NAL NL two. So there you go.

That could be a good takeaway from this, is, if you're not sure, just test measure twice, cut once. Maybe is another way to say it. We don't want to cut people up. But anyway. So average sale price per pair, that was a question.

It kind of goes on product codes. So, like the Q-G-Q UF, the non self fitting customizable ones, they're a little bit cheaper, 299 or so from what I could see. Maybe it's higher now with inflation, whatever. And then you get up to maybe $1,100 quh QDD products with options kind of at the 799 99 price point. That's stuff like the Lexi Lumen and Lexi B one B two, those kind of products.

But those are more. You can see there's kind of a spread. What I can tell you from some of the price elasticity studies is people would love these to be about $300. You'd sell a lot of them. But of course, what does that mean in terms of quality?

And of course, your time, especially if you're an audiologist and you're servicing these at any level, doing real ear or whatever, your time is worth something, right? You're just going to expect to work for free anyway. So the typical age of those purchasing tends to trend older than we'd like. That was part of the question. Typically, these people are 75 plus as opposed to the 55 plus.

This gets into the idea of the self perceived mild to moderate hearing losses. When you have these people that have audiometrically less hearing loss, perhaps their expectations of fidelity are higher. It's just a fact. And so I think that's an important detail as we look through the future of OTC hearing aids for manufacturers and others who are interested in this space to consider return rates here. This is actually a really interesting point.

It's a big mystery. And the reason for that is that the HIA Hearing Industries association is kind of like you're sort of asking the retailers what you're doing, because previously, the HIA was kind of the source of truth on this for prescription hearing aids, or at least to some extent. But what I can tell you is that the business model doesn't work. If you get 50% of them back, and you might say, oh, we got some top line revenue, we're selling them out the door, but we get half of them back. Okay, well, then you didn't really make so much money in the bottom line anyway.

So returns are as high as 60%, though, and that's a big problem. The business model ain't working, but it can get as low as sub 10%. And I could tell you those are situations where we're leveraging things like the pharmacy tech, because they kind of sell them at the pharmacies. Actually, they call them over the counter. Well, if you

actually go to a store, like a Walgreens or something, they actually have them behind the counter.

You can kind of see them up on a shelf. And when those people are doing the counseling and whatever, that can be as low as 10% return rate, because people just need a little bit of help and orientation. This could be an opportunity for those of you who are in private practice to diversify your revenue model. And so, another question here. Even though they're not approved, I'm going to get to labeling.

Even though they're not approved for children. This was asked to me by an educational audiologist. Families are going to try. Okay, that's important. We got to acknowledge that it's a case in point.

I have a couple of families at my school talking about it. Therefore, how can educational audiologists best counsel families regarding appropriate amplification? Ergo, you need to know what is inappropriate about them in order to adequately counsel someone. Fair point. I would assume this is the first and foremost to the inability to acoustically adjust them and to algorithms and self fitting devices not being targeted to children.

But I will defer the. Okay, let's see here. So, with the self fitting ones, they can be adjusted but frankly speaking, the best counseling advice you can give is really to point to the labeling and intended use. So using a medical device outside of its intended use can have really big consequences. And so I like to use the example of a bottle of Tylenol as an example of labeling.

So you buy Tylenol at the pharmacy, over the counter you buy at your store, it says, don't take more than x amount over y hours. What does that mean? It means you can't stop someone taking the whole bottle if they're determined to do it. But you can point

to the labeling and you say, look, you got to use this as intended, as indicated, or it's soft label, right. You take the whole bottle, you might hurt yourself.

Same thing with over the counter hearing aids. You really got to look at the labeling and intended use for that. So you can't stop someone taking the whole bottle, but you can point to labeling. In the case of over the counter hearing aids, FDA has done the best they can to require it. And I don't want to get into the debate about the output limits and stuff, but the FDA decided on what they believed was an appropriate level such that people were not going to damage their hearing as a result of wearing over the counter hearing aids for an extended period of time.

Right. So here we go. Next piece to this. This is the same question. Another thing to consider is the fitting rationale.

As you saw, almost all the self fitting products are based on NL two. Keep in mind, if you're an educational setting, NL, NL two as a rationale, has a goal of comfort. That's the goal of the rationale, and it's for comfort for adults, frankly. By contrast, the DSL, the desired sensation level fitting rationale, has the goal of audibility for everybody. You can use it for adults, but that's why it tends to be favored in the school system.

It's really for learning and for access to language. So once again, when in doubt, the real ear system can be a very powerful tool, even if you don't know the thresholds. Showing SPL can help. At least it can help you if your goal is to understand. Maybe, for example, they come to your clinic and they're not wearing in the right product for them and you know better.

Well, there you go. You have a nice counseling tool in your realtor system. You can show them, look, this SPL, it's really not doing what you need it to be doing. I can give

you something much better, for example. So I want to give you this case, example here of how this can be confusing the clinic.

And one of the things to consider this was from the clinical study or clinical trial on the centibar lumen 155 sf example I gave this was 83 years old male, and we did a profit versus self fit. You see here the serial audiogram in the right ear, and these are the thresholds in DBHL. So this is SPL. And the verifit, you can see left side profit not doing real good for low level inputs, right? I mean you're not even close, but that's what they get.

It's perhaps beyond the limits of the product here. With the self fit, which was not based on NL two, you can see that we did much better for lobby. So it's still not great as far as thresholds, but better than it was. And you can see that we did a little bit better for louder sounds and of course for mid level inputs, a little above threshold. So keep in mind, this is a very complex relationship between manufacturer based auto fits and what you might see in a self fitting.

So when you look at the idea of self fitting, it's not necessarily based on an audiogram. It might be some kind of a dimension reduced controller, it might be just SPL. I mean, think about the idea that some audiologists think we should just do away with DBHL and just do everything in SPL. It's a little bit confusing, right? But within the madness, there might be some truth there anyway.

But the idea is that you need some way, some physical unit of reference in terms of SPL to be able to show apples to apples, what's really going on in the ear. And it helps you as a clinician make the best decision you can. A couple of people mentioned working with student aged 20 to 21 in educational training transition programs. They assume they'll probably encounter them at some point. Maybe we ask to support them in some way.

So how do you do it with OTC hearing aids, care and maintenance? Well, in this case, because the person's over 18, the use of an OTC hearing aid is consistent with labeling antenna use. But of course it's never going to be as good as a licensed professional performing evidence based best practices. As I said, the best thing you can do is leverage your real ear system and you may also get into features and lifestyle for things like this. So, including the use of remote microphones, let's say you're in a large age, 2021, you're in a large auditorium style learning environment.

You might use a remote microphone or something like that. It might help you with similar noise another thing to consider about OTC hearing aids is their intended user is someone with self perceived mild to moderate hearing loss. So what I tell audiologists in other settings than education is your time is worth something. You can explain care and maintenance, sure. But I would suggest a fee for service model.

If you can do it in your setting, your time is worth something. And really, you are the best option as far as somebody who can service and handle OTC hearing aids, being the expert on all hearing aids. And so that's the thing I would suggest. If you can do fee for service, you could also say, I'm only able to produce best practices with what I can give you. Keep the ones you got.

You bought those OTC, keep them. But if you want the best results, use the ones I give you. For example. I mean, this is something you might do, and maybe it's not kind of a take it or leave it, but this is how you get them into your revenue model, how you get them into your setting, such that you're able to make the business model make sense for you. Okay, continuing on here, what algorithms are used for self fitting?

This is a good question. I think you just told me the first self fitting is coming out now. I wonder if they're confused with jabra. Nonetheless, pediatric audiologists are very concerned about audibility and fitting. So curious.

Okay, great question. This is the reason I went through this in detail on slides 29 and 30, I believe it is of this presentation, because it is really an important detail. Like how are they self fitting? What is the algorithm actually doing? In a lot of cases, it's nal and I two.

You can see, in fact, in almost all cases, what that means is they're sort of creating. Either you input the audiogram yourself, you put the thresholds in, or it measures it yourself, or there's a dimension reduced controller, some combination of those. If you start going down the path where it's customizable, where it's like you say you have eight settings or something in the hearing aid, you could argue that that's not actually a self fitting. And FDA actually said that in the final rule. I think they used that example.

I think they said less than six or less or something. They. David, you actually can't consider that self fitting probably have to have about eight or something like that if we're being realistic about the diversity of hearing profiles you might see. But nonetheless, they're all using NL NL two today, and they're just kind of getting to that fitting a little bit differently, whether that's kind of a speech test or a threshold based test. It's dependent on the different product, and I'd encourage you to look at those.

But anyway, the concerns of pediatric audiologists are quite valid. I would validate those. Any use of any OTC product by a minor person is considered off label use, and I would say it's not recommended. Realistically, you can provide evidence based reasoning against over the counters and peds by showing difference in prescriptive targets between NL two and DSL, theoretically. And then you show stock real ear, for example, to demonstrate using OTC product, what's missing?

So while SPL, the sound pressure level should be sufficient, you could use something like a speech articulation index or other index measures to kind of demonstrate. You kind of say, this is what you're leaving on the table if you continue using your over the counter hearing aids. Continuing on this question here, as mentioned, NL two has the goal of comfort and DSL has the goal of audibility. So one example you might say is you can drive to get groceries in your luxury party bus with couches, or you can drive to get groceries using a sedan or suv. Use the right tool for the right job.

If you want to learn more about this topic and others. This is kind of a very high level overview, gets into some of the standards. Feel free to reach out to me. Connect if you want, on my LinkedIn page. Check out my articles, podcast, appearances, quoted attributions and more.

If you have other questions that are not answered, you'll send those. I think fauna or others will take your questions at customer service@audiologyonline.com. And with that, I would like to start looking at questions from the question and answer box. So thank you for your patience. And of course, also thank you for being here.

So first question, federal preemptions are strong. You don't understand this. Okay, so federal preemptions, what that means, and I kind of alluded to this when I was talking about the idea of federalism before. Federal preemption means that the federal law trumps estate law. So what that means is that when they say that the OTC hearing aid specifically cannot require a licensed person to dispense, that's an example of a federal preemption being strong.

You can't say, oh, I live in such and such a state. They require a license to sell OTC hearing aids. Federal government said no to that. And this is something I think George

Washington and others historical figures in the, you know, they've settled this in the federalist papers. The idea of federal government.

So the idea that federal preemptions to state laws, maybe that's the missing term, federal preemptions to state law are strong. Hopefully that helps you understand that. Next question. How are quh hearing aids self fitting? Ok, so the quh hearing aid self fitting, what that means is it's the three letter product code based on the product feature.

So quh, for example, is a wireless based self fitting. So that means it's air conduction, it's wireless, it's self fitting, and it's over the counter. So the quh sort of unpacks into that. That's how it's considered self fitting. I can see a follow up question.

What does self fitting mean? Okay. Self fitting means that the person selects the setting. They're ultimately going to listen to themselves. So you could facilitate that as an audiologist.

But most likely what's happening here is that the person is getting either a dimension reduced controller, that they're adjusting something like on a smartphone, for example, or they're inputting an audiogram or something, or they're taking some sort of an NCU based test, something like that, that's trying to fit the hearing david themselves without the involvement of a licensed professional. So self fitting specifically means without the involvement of a licensed professional. Next question. Following up, do self fitting hearing aids create some kind of a personalized audiogram, either for the patient to enter or that they enter automatically? Yeah, I don't know if it's so automatic.

Right. Because you got to have, there's some response level here. You talk to these legendary people who teach us about audiology. They'd say that when you press the button, it's activating both the afrin and efferent nerve pathways. Right.

Because you have to hear it through your ears. It goes to the brain, comes back down and you press the button because you've understood to activate your muscles, you have the innervation on both ends. So it's not automatic. There is some level of response that is required. So what they'll do is.

Yeah, it's not necessarily an audiogram. You might think of it as it's like device settings, which you could say it correlates to audiogram. And that's why I advocate using SPL and I did so in this presentation as well, because sometimes you don't know. That's the big takeaway, I think, to some extent from this. If you hadn't heard this before, the idea that a large amount of audiometric space when you fit the hearing, David gets converted to a much smaller amount of prescribed gain space.

And it's just due to the nature of how hearing aids work. When I first heard about that, it's kind of a mind blowing thing for me, but that's the idea, is that however they get there because of how compression works and what have you, it's very complex. And frankly speaking, even the relayer system has its own limits because we're using our eyes to evaluate what's happening with the sound. So hopefully I answered that question appropriately. And so that's all we got.

I really appreciate. Oh, we have more question coming in. We have 1 minute left. Do you anticipate telehealth remote services for OTC hearing aids? That's a great question, and I think the question really is going to be, the answer to that is going to be downstream of what the kind of payment reimbursement services are for that.

So you're a provider, your time is worth something. Can you get paid to do it? I think to some extent the idea that federal preemptions say you can sell these direct to the consumer via the mail. Why wouldn't an audiologist want to do that? It does get a little

bit, though, into the states thing, like the interstate commerce things and stuff, and some states do have a position on that, but it's hard to say.

I think what's going to happen is you're going to see telehealth kind of emerge as its own separate thing, not with respect to OTC or prescription, but as its own thing, as the public awareness increases for hearing aids generally in terms of its public health outcomes. Because OTCs are just a vehicle, keep in mind, I mean, really what we're talking about is not a device. We're selling a process. We're trying to sell people on better health outcomes. And so certainly as the technology improves, I can definitely see telehealth remote services for otcs.

I also would see more of those for prescriptions, probably first. But you might say, look, I'm an audiologist. I'm going to give you the best treatment recommendation I can, and that may or may not include hearing aids at all. And if it does, these are the OTCs that might work for you. I might be able to help you or not, but this is the best prescription for you and kind of leverage you as now becoming the opportunity to reinvent being a doctor, if you will.

Because think of like the 1970s, right? We were in a situation where it was unethical, or seen as unethical to both attest for the diagnostic piece and dispense a hearing aid. Well, now we've moved past that, where I feel like we're in a similar era at this time. And so as the technology improves, definitely I could see opportunities for that. But I think it's going to be downstream of some of the reimbursement, because audiologists are treasured, precious and valuable resource.

And thank you for this question.

Turn it back over to fawn. Yes. Thank you so much, Dr. Akbari, for a great talk today. Just a quick reminder, once we close the classroom, the exam will be available in about 15 minutes.

So just that quick reminder. Thanks again for sharing all your knowledge with us today, and I hope everyone joins us again on continued. Thanks, everyone. Thanks. Great to be with you.

Bye.