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Research QuickTakes Volume 5: OTC Hearing Aids - Background, Optimization, and Delivery Issues to Consider

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OTC HA's - All About the New Product Category

- Welcome back, everybody to another Research Quick Takes. We're on volume five, believe it or not. I'm Brian Taylor, and with me today as usual is Gus Mueller, our independent consultant. Welcome back, Gus.

- Yeah. Yeah. I can't believe it. I don't know if we're counting episodes, but on volume five, I think we're probably in the twenties or so.

- At least the twenties, yeah.

- So, yeah.

- Close to 30.

- And I don't know if we've been renewed for another year or not, but we'll keep working on it.

- We're gonna say, yeah, we are. And we're gonna talk about a really hot topic today, over the counter hearing aids and some of the things that people need to know as they navigate some of these new product categories. So I thought maybe we could kick it off, Gus, by maybe you talking about your perspective on this.

- Yeah, well it's interesting. The first thing that I noticed, now and then I follow some of the social media sites for audiologists and HCPs and so on. And when this first all, when it came out recently, back in, I guess it was back in October or so, it was just filled with comments of like, "Oh my God, I hear the sky falling." And, "Oh no, is this the end of our profession?" And on and on. And so the first thing I thought about was, this really isn't anything new. It shouldn't have been a surprise. I know you've been following this too over the years, as you've worked in industry. I mean, it all started back at an NIH conference, which stirred up a lot of talk way back in 2019. Then it got

picked up again a few years later. And the big thing was this NASEM, I don't know how to pronounce that acronym, but-

- Yeah, NASEM.

- The Academy of Science, Engineering and Medicine. They used to be called something that was a lot easier to-

- Institute of Medicine, IOM.

- Yeah, yeah, that was a lot easier. Anyway, they came up with recommendations, 12 of 'em, and that then really got the attention of everybody, professionals and politicians, which I guess are also maybe professionals. But what that led to then was the introduction of the hearing, this act by Senators Grassley and Warren, which as I recall, was tacked on to something else so that it was like a given that it was gonna go through, because whatever it was tacked on to was like almost a hundred percent gonna go through and so it just slid right along with that. And then, it was signed into law by Trump, and it was, "Okay, we're gonna have OTC hearing aids. The FDA will have all the guidelines out in August of 2020."

Then the pandemic came along and things got delayed. So it wasn't until I think Biden actually said, "Hey, you guys, speed that thing up." And then in October of 2021, there was a draft regulation that was put out, and over 100 comments were submitted. There was some speculation about where all these comments came from and if manufacturers were behind something inappropriate. But I doubt that that was true. But anyway, a lot of comments. And finally, finally, on August 16th of 2022 at 8:45, we were all sitting waiting, and it had actually then went into effect on October 17th.

- I noticed you even had the time on that last slide, so.

- Well, I couldn't resist. After waiting from 2009, you know.

- Yeah, it's been-

- And so now, they're here. And I know you've been following this all along, so maybe you want to talk about-

- Sure.

- What ended up.

- Well, I think it's still a little bit-

- We have new categories.

- Yeah. I think it's still a, as far as the details, we don't have to get into the details here. First of all, we've been talking about OTC for about 10 years and we didn't have an OTC until October. So now we can actually talk about hearing aids that can be sold over the counter. And the important thing to remember, I think if you just look big picture here, is that there are two major categories of over the counter hearing aids. There are basic, or what some people call preset OTCs. They're essentially, as the name would imply, there's not a lot of adjustability and the output is a little bit lower. I think the maximum output is 111 on a basic OTC.

And that differs from what we would label or call a self-fitting OTC, which as the name implies, has a little bit more adjustability usually on a smartphone app that allows somebody to kind of go through the whole process of fitting that hearing aid in a way that maybe, and we'll get into this, I think over the next volume here, that maybe

simulates how you might do some of those things in the clinic. And of course, the self-fitting OTC has a higher maximum output. I think it's 117. So, did I miss anything there, Gus?

- No, I think covers, well, I don't know, I don't know if it specifies if the output varies from self-fitting versus basic, but how it does vary, I think, we have gonna talk about that a little bit. It does vary, whether it's linear, has compression, for sure, The self-fitting ones, it's pretty hard to be self-fitting without compression. And with compression, it goes up to one 17. So I think just the way it's gonna turn out that the self-fitting ones will be 117.

- Right.

- 'Cause my bet is they're gonna be compression. Yeah.

- Right.

- The one thing that I wanted to mention relative to the self-fitting is, I don't know that this has to be true for every product, but they have to show research that shows that it is more or less equal to a traditional hearing aid. And that these research studies have been done, a lot of 'em have been done affiliated with major universities. So a lot of the manufacturers have taken this background research pretty seriously.

- We'll talk about that, I think, in one of the upcoming volumes.

- Yeah, yeah, yeah, exactly.

- Yeah.

- Prescription hearing aid, I guess they had to come up with a new name because we got this hearing aid and a hearing aid and a hearing aid and so they, supposedly, this would make things clear that they're gonna call, or are calling what we've always called hearing aids now, prescription hearing aids. So that would be what we all call a hearing aid, historically. I'm a little concerned, and some state licensed people are concerned that there are some states where there are rules about who can write a prescription. And I think some of that's gonna have to be cleaned up. But I think, that's already happening.

- Yeah, and I think probably the best advice that we could give anybody right now as we record this in March of 2022, is that you should check with your state licensing board to see what they say about prescription hearing aids and OTC hearing aids.

- Yeah. Yeah, I know the Academy of Audiology has written some memos on that particular thing. And then we have these other products which haven't gone away, which we commonly call a PSAP. And these look like hearing aids. They walk and talk and quack and everything like a hearing aid. But most of them, they're not really supposed to be hearing aids. Technically, they're for non-hearing impaired, but that hasn't stopped people from marketing them as hearing aids.

- Right.

- Over the years, actually. And in fact, some people call PSAPs over the counter hearing aids before we had over the counter hearing aids.

- Exactly.

- And then we have this new category. There's this whole area of devices that are called wearables. And part of the wearable area is what we call hearables. And it's

something that sort of is, well, I guess it could be a PSAP, depending on how you define it. A lot of these categories sort of overlap.

- Exactly.

- I dunno what's your thought on hearables, Brian?

- Well, I think it's a marketing term. I think there's a British guy by the name of Nick Hunn that coined the term hearable about 10 years ago. And some people use it. I think the important thing to remember about a hearable is it sounds like a cool term, but there's no regulation behind it. It's just a marketing term. And PSAPs have been around for a long time, sort of like ALDs have been around for a long time and because PSAPs are unregulated and the intended user is somebody with normal hearing, the quality varies a tremendous amount. And there's been several studies that have looked at PSAPs. Some are kind of perform close to hearing aids, most don't really help or actually make things worse, so.

- Yeah, there was something published three, four years ago that I think Mike Valente, A. U. Bankitis, and some people were involved in, and they looked at like 20, 24 of 'em. And I think outta that whole group, there was only about two or three that could actually be programmed to work.

- Exactly, and I don't think that's probably changed much since they published that.

- Probably not. This is just an example of probably the most popular or talked about hearable, I guess, if we want to use that term. And I put this in simply because the folks over in Australia at the NAL just published something last year where they did some speech and noise testing, some other testing, and it was, "Yeah, wearing these, it actually does improve speech and noise." Now it was set up with speech in front and

noise directly from behind, as I recall. But at least some of what they claim it does actually happens. And we're looking at \$249.

- Yeah, it's a good product. Actually, as a side note, Gus, last year, AAA, 2022, AAA, we did a poster that compared the AirPods to a pair of Signia Silks. And when it comes to audibility, there's not many differences. The problem with the AirPod is it had very primitive noise reduction.

- Yeah. Well, we'll see. And it's hard to keep track of what fits where. I tried to do it on this little chart of what is regulated by the FDA and what is direct-to-consumer, just so you can sort of go down the list. If it isn't regulated by the FDA, then it isn't an OTC because by definition, an OTC is regulated by the FDA. So if you mail off for something that's not, you can't, I mean you can call it whatever you want, but technically it's not an OTC. And then of course, what we're gonna, there was a talk at one time that once OTCs came out, all the PSAP manufacturers were just gonna move in and become an OTC. But I don't know if that's gonna happen or not. You know?

- Well, I think because the regulations, many of them probably will not because they can't meet the regulatory requirements-

- Right, right. Yeah, which we didn't mention, but there are some 2CC coupler requirements that you have to meet for the FDA to give them the stamp of approval. But then we say, well, prescription hearing aids aren't direct-to-consumer. So just in preparing this slide, I just went to eBay and typed in Signia. I don't remember what I typed in, but there you can get this Styletto AX, which, what, Brian, that came out just a year ago or so, right?

- Two years ago.

- Two years.
- Is that the Styletto? No, just in the last, within the year.
- That's what I was thinking. Yeah, this is the Styletto.
- Yeah, the ^Styletto, yeah.
- And I'm guessing, now, this is not supposed to be direct-to-consumer, but I'm guessing if I click buy it now and put in my visa number, I'm thinking it's gonna show up in the mail.
- Probably.
- And I'm a consumer, so therefore it's direct. So who knows.
- There's a lot of examples like this with, is it still a prescription hearing aid if it's remotely fitted? You know, so we have those companies.
- Yeah.
- Lot of conditions. And then we have this category to even add to the confusion, these are products that you can get four hearing aids for 499. They're not prescription 'cause they're not signed by a license so they're not prescription. They're not OTC 'cause they don't have FDA approval and they're not a PSAP because they specifically are designed with hearing loss. So we gotta make up our own category for those, so.
- Yep.

- It's hard to even have a conversation when all the categories overlap.
- There's a lot of fuzziness in the market around direct-to-consumer for sure.
- And supposedly, we're experts on this. Imagine a consumer who's trying to buy some, they're going, "My god, they're everywhere."
- Hmm hmm.
- Wow. So anyway, and I put in quotes here, intended, these are the intended candidates. And this is, you had mentioned earlier about the overall output, Brian. First of all, the person supposedly is 18 years or older. I seriously doubt they're gonna check your ID at Best Buy to see if you're 18 or not. And then the regulation that I'm sure is being, well, I would guess is being followed that the SPL for the linear processing cannot be higher than 111, no more than 117, for devices with input compression, which I'm guessing will probably be more likely to sell fit. There is no restriction on gain. But indirectly, it'll be controlled. It's gonna be controlled by the maximum output, obviously. If you can only get an output so high, you're only gonna be able to have so much gain.
- Right.
- And I believe, 'cause I've seen walking around, people walking around with the earplug not even in their ear canal, I'm thinking gain's also gonna be controlled by feedback because most of 'em are not gonna fit very well.
- Feedback and poor insertion, exactly.

- Yeah, exactly. Exactly. So, but the other point is people like to say, well, these are only for mild to moderate, people 18 and over. Basically they're for whoever buys 'em, you know? They're being sold everywhere. And as I think I put a note in here, if dad thinks his one-year-old needs hearing aids, he can walk down to CVS and buy a pair of hearing aids for his one-year-old.

- Right.

- Speaking of that, where are they sold? You might have some places here that I didn't think of, Brian, but Walmart, Best Buy, CVS, Walgreens, Sam's Club. And my favorite, if you live in Iowa, you can get them at Hy-Vee grocery stores.

- So is it Hy-Vee only in Iowa, or is it Hy-Vee anywhere that has a Hy-vee-

- Well, the thing I read specifically was Iowa, but you could say, "Hey, honey, honey, I'm here at Hy-Vee. Yeah, you needed some raspberries. And I remember we needed mushrooms for tonight, dinner. I was also gonna pick up some hamburger and there was something else. What? Oh, a pair of hearing aids. Yeah, now I remember. Yeah. Okay, I'll be home shortly." And there you go.

- Well, you know what makes it so confusing is, well, take for example, Walmart. You could go into a Walmart 10 years ago and they had a number of different PSAPs that you could buy.

- Right.

- And now they just add a couple of OTCS. So it just adds to the confusion, I think, for consumers. They see multiple products.

- Well in somewhat of defense of my grocery store comments, the Hy-Vee does have a huge pharmacy section to it.

- So maybe it's in the pharmacy, right?

- It's probably not out with the raspberries. It's probably in the pharmacy section.

- And of course the biggest place you would be able to buy these would be online.

- Yes. Yeah. These are just the stores that you can go to.

- Brick and mortar, right?

- Yeah, exactly. There's been some early partnerships. Did I get these right, Brian? Is there somebody-

- I think so. And I think this is one of the things that to me is a smart, you can see how both the hearing aid manufacturer and some of these larger consumer ear audio brands are sort of combining forces and they're collaborating and sharing their expertise. I think that's kind of a smart move so.

- Yeah, you're on the road talking to Signia customers a lot. Do they think this is an okay thing that Signia/Audiology and Sony have this partnership?

- I think so. I think most people I've talked to, the response has been really positive. I think they see it as potentially a win-win where it brings more traffic into the clinic inquiring about things like this. It gives some people maybe younger, that wanna dabble with something before they go into the full prescription mode of buying. And with multiple visits, they can try something from the comforts of home. And that's an

option. I think some clinics see that as a nice little revenue stream, for lack of a better term.

- Yeah.

- So I think it's a positive. We'll see how it all shakes out.

- Yeah, well, and Sony's a big company and who knows. They may have something they have to offer that could make prescription hearing aids better. You never know.

- Exactly. Well, so what do HCPs actually think about all this? Our friend, Abram Bailey, over at the HearingTracker, did a survey. Now this was shortly after the news came out. So I don't know if things have changed, but at least we can go back so it's a decent end here. He had 730. What we have is 26% said they plan on selling. 55%, they plan on providing support. And then 19% said they did not plan. So if you take selling and support, we're talking about 80% are gonna be involved with OTCs. It's like, at least that. They also rated, this maybe a little misleading 'cause I think Abram had about 20 different things that they could rate. But these were the ones, the four that were rated the highest by, in other words, why do HCPs think you could run into problems or how the patients are gonna run into problems.

So I just listed them there. Obviously number one is they're gonna have to struggle to identify common problems. I mean, anybody listening who is selling hearing aids know that you have some patients that you see every six months because of a plugged receiver. As an OTC user, are they gonna know that it's a plugged receiver when they call the help line at Best Buy? Is that person gonna know it's a plugged receiver? Where are they gonna go? Well, where are they gonna go? As we'll get to in another episode, they might go to an HCP and it might be a new patient screen.

- Hmm hmm.

- Ah! And how about this? Everybody thinks that these over-the-counter hearing aids are something new. Brian and I know, you were there firsthand 21 years ago, right?

- Yeah, 20 years ago.

- Had an idea. Now Mead sort of had a motive because I think that was about the time that he had his own ESAP. I think the Bean was in its infancy then or something. But anyway, it was also good thinking on his part that he decided to go to the FDA and petition the FDA to approve OTC hearing aids. This is, actually, 21 years ago. But there was a little bump in the road when the FDA reviewed it and it was denied because you had to have a medical clearance. Now, of course, the FDA probably didn't know that almost everybody just signed a waiver and didn't have the medical clearance. But it sounded good that everybody had to have a medical clearance and therefore OTCs were rejected.

Of course, as you all know, the medical clearance thing, the FDA said, well, you don't really have to have it anymore which then paved the way for OTCs to be approved this time around. I was working at the Hearing Journal back in those days and we did an annual survey. So this survey now was in 2023, 20 years ago. And we asked both Audiology, well, we asked all of our subscribers, this is like a huge hand of well over a thousand people, I think. And these were the responses. Really no difference between audiologists and hearing instrument specialists. And we asked, should the FDA approve OTC hearing aids? And you can see, there aren't very many, well, there aren't any high bars over on the right side of this chart. Sort of yes and definitely yes, you put those two together and it adds up to about 10%. I think overall, HCP says no by an eight to one margin. That was 20 years ago, so.

- That's pretty interesting.

- Again, this isn't something new. It's been going on for quite a while. They're here, they're not gonna go away. So we need to decide how we deal with it. What are the potential problems? What could be the success stories? And do we want to put all this into our practice?

- Yeah, and I think it's interesting how we say that they're new. I'll just kind of end and say that, in the 1990s, about seven or eight years, I spent time at a place called Rockford Clinic in Rockford, Illinois. And anyone that was in the industry back in the nineties knows that the home of mail order hearing aids is Lloyd's in Rockford, Illinois. And it was a very obvious, it was not a well kept secret that Lloyd's was down the street. We would even tell people, you can go to Lloyd's. And very few people went there because they knew, even though they were getting a lot lesser, they were paying a lot less, that they were getting a lot lesser service, a lot lesser qual, much poorer quality. So again, I think maybe the same thing with OTC. People know it's there, but they also know that it's worth the extra money. They bet the quality's better, the outcomes are better when they work through the hearing care professional, so.

- Yeah, well, I hope so. But I have one quick story from that same timeframe.

- Hmm hmm.

- Back when I was at the Hearing Journal. Somebody was a well-respected researcher, was hired to do a survey of Lloyd's patients and compare the results and I think it was like on the AFAB and something else to prescription fit hearing aids by HCPs. And the findings were no difference and nobody would publish it.

- Well, and they still put that on their website, actually. I was on it a few weeks ago. And they show the market track satisfaction rate of about 58%, which I think is like from market track two.

- Well, this, yeah, well, that's when this was done, yeah.

- Yeah, so.

- No, it was, it was 20 years ago or so.

- Well, for those that pay attention, the market track satisfaction numbers are over 80%. So they're not 58% like it says on their website. Anyway, on that note.

- All right.

- Thanks, Gus. We'll see you for five-

- Hey, yeah, let's do this again before too long. All right.

- Sounds good.

- See you next time.

- [Gus] Okay, thanks.

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OTC HAs - A Good Fitting Without the Help of a Professional?

- Hi everyone, and welcome back to "Quick Takes." We are on volume 5.2 and we're talking in this edition about OTC hearing aids, and today we're gonna tackle the question is it possible to get a good fitting without the help of the professional? So with me, as usual, is Gus Mueller. Gus, welcome back.

- Yeah, thank you. Thank you. It's been a few weeks and when we did episode one and I think we're just gonna keep moving on this topic. It's a fun topic to talk about and very timely.

- Exactly, exactly. So I think today we're gonna talk more about what could possibly go wrong.

- Yeah, yeah. You know, there's a lot of things, a lot of, you know everybody's saying, "Hey, they're gonna be more affordable and they're gonna be more accessible." But that only matters if they're fit correctly. Right? And I know you and I talked and you had a few things that, what could go wrong?

- Well, when you think about all the possible things that could go wrong I think you have to start with do we want people or can they do the self-guided hearing test? So many of these devices the ones that are labeled self fit allow people to do a hearing test. And of course with that, people have to get the instrument in their ear seated properly. They have to kind of go through the process. So whatever the instructions might be on the app to do the test. And of course it relies on those settings that you come up with to determine the gain in the output of the instrument. So I think that's a big issue. Gus, do you have anything that you wanna say about that?

- No, you know, I've, unfortunately I haven't had my hands on a lot of these systems. I've done some of, you know, some of 'em you can go online and do a hearing test and

I've played around with that. I never have personally done one using the app. So I don't have a good sense of how that works.

- Well, and I think some of 'em, some of the devices, it's more like traditional audiometry where you are prompted to listen for a tone. Others are very different. There's a couple that use some new kinds of approaches where you basically wait for the beep to get it. It happens much faster. And so, it just, I think it takes a certain amount of skill to go through the test. I know that they say many people can do it, but I would be, I'm a little leery that a lot of things can go wrong when you're trying to do a self guided test and you don't have any experience doing it.

- Yeah, and that's just the beginning of the problems.

- Right. So go ahead and you wanna? What are some of the other problems, Gus?

- Oh, okay. I know that the next one is one of your favorites. So I was gonna give that to you, but, it's one of my favorites too. And that is that even if you enter into the correct hearing loss, you're gonna have to rely then that this presetting, whatever shows up as, call it a first fit, is going to be fairly close. I would bet most anything that it's gonna be under fitting just because people don't wanna shock somebody with too much gain. And then the question becomes is what is the range of adjustments and is there enough adjustment to turn it into a good fitting? And we have a case study for that that we're gonna go into later.

And then along with this same line is let's say you have a big range of adjustments. Is the average person going to do the adjustments to the point that you're gonna have a good fit? Do they know what's best for them? You know, I was in the clinic giving away hearing aids in the Army, selling them for five years in private practice. And I mean, I

don't have a lot of faith in patients picking the hearing aid that's best for them. They tend to under fit themselves in my experience.

- Right, and I think we have some studies that kind of illustrate that point.

- Yeah, we actually do. And we, and you mentioned a little bit Brian, but there's a whole host of potential problems other than the fitting itself. But for right now, let's talk about the fitting itself. And so you have to say, well, we're saying a good fitting. What is good? Well, I would challenge anybody to show me evidence that shows that the now fitting is not a good starting place. And I'll get to some evidence that shows that indeed it is. Now granted, this is the average starting place. Statistics tell us that six, if you go plus or minus one standard deviation, you have a window of about plus five and minus five from the now. But it's a starting place and it's a pretty good starting place.

Almost always, when there's been a head-to-head competition the now has essentially always won. Usually because it's been compared to a manufacturer's first fit, which tends to under fit people. And I also should mention 'cause we're talking about the NAL, but just in case Susan Scully is listening, and I know she is, the NAL for adults is very similar to the DSL for adults. And so if the NAL has worked in all these studies, if you're a big DSL fan, I'm pretty sure the DSL will work too. In fact, one comparative study averaged five different types of audiograms, and they looked at the NAL versus the DSL and the difference in the SSI was 0.01.

- Yeah, so they're pretty much the same.

- So I don't think we have to spend a lot of time.

- No, either one would work.

- So most people do use the NAL, which is why I use that as my reference most of the time. Well, let's just talk about some research that has happened using the NAL. Here's one from Catherine Palmer, which happened to be with Siemens hearing aids trainable Siemens hearing aids of maybe 10 years ago or so. What she did is she sent people out, fitted to the nail but these were very trainable hearing aids plus or minus 12 dB. They also could train compression meaning you could increase gain for average and decrease gain for soft if you wanted. What she found at the end of two months the SII, was just reduced a little, 2% for one group, 4% for the other group.

And interestingly, as many of you know she was fitting here to the NL1. The NL2 actually reduced gain by about 2 to 3 dB, which means that where they trained to would be very similar to the NL2. So to me that's a definitely a study that would say the NAL's a pretty good place to start. Here's some research that I did with Ben Hornsby at Vanderbilt. I'm sure we were having some serious we're probably planning the study right in that photo. Who knows?

- Looks like it.

- Anyway, this is a real fun study because we looked at a group of people who'd been all been using hearing aids for two years. They were all happy. And because we knew how the hearing aids were being fitted at that clinic, we knew that they were all under fit. So we took them and we gave them trainable hearing aids. They could train plus or minus 16. So by the way, we keep talking about self fitting, but self fitting isn't really anything new. I mean, you can call it machine learning or whatever you want to, but it's been around for quite a while. And Signia, Siemens, that company was the first really to introduce it in several different models.

So this again, was a Siemens hearing aids. And I wanna show you the results of it in that if you look at this, what you see is what they started with. This is their average

output. And you see for soft, average, and loud and most the point I want to make the most is what happened for soft inputs. Notice that before the fitting before they were trained and went out to train, they were using about 65 dB on average. That was the blue curve. After training, they essentially were the same as the NAL. So again, these were people that were happy being under fit but yet when we gave them the opportunity to train and we programmed them to the NAL, they ended up training to the NAL.

And there's one more. This was actually done by the people at the NAL. They had people who trained for three weeks. They trained for six different listening situations based on the classification system of the hearing aids. Again, this was done with Siemens hearing aids. And what they found was that the people only train down by 1 or 2 dB from the NAL. So based on all that you can say, "Yeah, that's great. The NAL really works and that's a good thing." But, here's the problem. This is another study that we did. What was that Brian?

- No, I just, wanna make sure that I wanna emphasize the point you made I thought was really interesting. The study that you did with Ben, those were people that were under fitted primarily for soft sounds and they were okay with that, right?

- Oh yeah, we did a satisfaction testing. To be into the study they had to score a four on a five scale in satisfaction. So yes.

- Right, so they were relative, they were satisfied with the fitting but then when they were given the opportunity to train it, they actually trained it so that they gave themselves more gain, especially for soft sound. That's a really

- Yes, and importantly, we fit, we brought them in, we tested to see what they'd been wearing, then we fit them to the NAL and sent them out. But it was plus or minus 16.

So they could have gone home and said, "Wow these soft sounds are terrible. I'm just gonna turn this down and train them right back to where they're listening." I can only guess that what happened is they went home and said, "Wow, these soft sounds are annoying but wait a minute, I'm hearing some sort of good things. This isn't so bad, after all." They'd never had the opportunity before.

- Right. So anyway, that's a good point. Continue.

- Yeah, so that indirectly ties into this because this was a crossover study that we did and we wanted to see, well what happened if we didn't start at the NAL? So this is, and again, this is crossover. So these are all the same people. So this isn't two groups it's the same group who had two different fittings. In each case were the hearing aids for a month with trainable hearing aids. So you see, first of all, that there's a lot of variability. There was one guy who ended up plus 14 and one that ended up at minus 14. But if you take an average look where it lands up, lands up right at the NAL, which are those triangle there.

But here's the main point that I'm showing you this is that look over on the far right and you see that group of 24 people, and you see they started out fitted 6 dB above the NAL, and you see where they ended up, about 3 to 4 dB above the NAL. Then we took those very same people, well they didn't all follow the same order, but the very same people were fitted 6 dB below the NAL, which is the far left dots on the screen. And so now they were fitted 6 dB below, and look where they ended up, minus 5. They stayed below because they didn't experience the louder sounds. And it's like, "Yeah, I guess this is okay." But these are the same people.

So depending on how we started them out, there was a difference of 8 dB all for the same people. But I have to tell you, although we didn't do any word recognition testing relative to this, I can assure you that the people over on that right column would do a

lot better understanding speech than the ones over on the left column. But it just mattered where we started them. So the moral of the story is you gotta start them at or near the NAL 'cause I don't think they're ever gonna train to the NAL if you don't. So let's see where we're starting people. This is just an end of one, one product I mean. But some I'm guessing it's not that different from many.

This is from our friend, Dr. Cliff. If any of you wanted to actually watch the complete review on this, Brian and I didn't have a chance to run any of this ourselves before we put this together. Something we'll be doing shortly and maybe down the road we can compare six, seven different products or something like that. But for right now, we'll go with Dr. Cliff's stuff. This was the audiogram of the woman that he used as the patient. And so notice that this would be a good candidate for OTCs, therefore the mild to moderate. And her hearing loss is in the mids there, is 40 to 45. So one might say, "Yeah, that's what OTCs are for." So they did.

She's actually, I think she's an audiologist actually. So I'm guessing that she did a very reliable hearing test using the app. And what happened then is they did probe mic. What you see with the dotted blue line is the NAL target. And what you see in the solid blue line below that is the first fit. It was the preset based on the audiogram that she entered. Okay? As we would predict, very conservative. Somehow I cut off the frequency on here, on the bottom. So that's why I said I put in that that peaks at 2,500.

- Oh yeah, you can see.

- In case you're wondering where it's at, it's at 2,500. That peak stays with us here for this whole thing. I'm not too sure might have something to do with the receiver that's being used in the product. At any rate, so I mean, if you gotta have a peak somewhere I guess 2,500 isn't terrible. Better than a peak at 250. But no notice that we're way short of gain in the high frequencies. Now in this case, Dr. Cliff did the programming and it

took him some time but he did treble control and gain control and he ended up with this. And I wanted to point out that that peak is still at the same place, but he got everything else pulled up and pretty close to target. In fact, I actually went frequency by frequency and calculated the RMS error, which is a very respectable 3 dB. So if this were in your clinic and you were doing this, you would pat yourself on the back and say "Gus good fitting. Darn good fitting."

- Yeah, but I think the key point though, Gus, is that that's with everything maxed out on the adjustments, right?

- Yes, yes. This was with treble maxed out and I think maybe gain was also maxed out.

- So there's no room to move it up even higher.

- No, and again, remember that that NAL is for average. So some people are gonna want 5 dB higher than the NAL. And right now it bothers me that this 4K area is 5 dB below. I'd really want to go in and pull that up, but I don't think you could. I think treble was maxed out. In fact, I'm pretty sure he said treble was maxed out.

- Right.

- And the other point then, you know that I have is you have to ask yourself if this patient is sitting at home doing this, and they don't have Dr. Cliff programming for them. You know, if they start out here are they gonna program up to here? You know, I think so.

- Based on what you said before, it's probably not likely.

- No. They will tend to stay where it starts. Here's some data that, you know, we talked about this way back in one of our other episodes, Brian last year sometime, but it's worth to go back to it again. This is from the big Larry Humes study where he had the three different groups of the clinician fit the people who fitted themselves and then a placebo group who had 0 dB of gain. And what, what they did is they looked at these are the number of ears that you're seeing over in that chart on the left. And they had the audiologist pick out what they believed would be the best fitting for the patient. But, and then the patient that these people, this is the group that was all self fitting, you can see what the patient picked out for themselves.

The interesting thing is that when the audiologist looked at it, 61% of the 102 ears, the audiologist picked out the hearing aid that had the medium amount of gain. So there was three hearing aids that they could self fit themselves with, mild, and I mean none of 'em had a lot of gain, but there was three levels of gain. The patients only fit themselves with medium amount 14% of the time. And rather 62% of the time they selected the mild gain. So we're going back to what we're seeing. When they actually looked what the audiologist would've fitted them with versus what the patient picked for themselves, they were only in agreement 28% of the time. And there's more. Part of this Humes study.

Everybody paid for their hearing aids at the beginning but they were told that at the end of the study they could get their money back. Of the people who fitted themselves, only 53% chose to keep the hearing aids compared to 81% of those fitted by an audiologist. It's a pretty, pretty big difference. And of course, here is maybe the most interesting part of the study. The placebo group were fitted with 0 dB gain. So basically they didn't have insertion loss, but they had no gain. So wearing the hearing aid, everything was the same as if they weren't wearing a hearing aid. 36% of them kept their hearing aid. They didn't want, they could get their money back but they, "No, I'm gonna keep this." I just put this in to say people aren't very good judges, so what's

best for them? If they wanna pay that much money to keep a hearing aid with no gain, wow.

- Well, it shows you the value of the professional and also if anybody is an over the counter hearing aid manufacturer, it shows you that expect a high return for credit rate if you don't have a commission involved in the process.

- And also suggests you might get lucky one third of the time. Right.

- Lucky and they don't have any gain in their ear.

- Yeah, but you know, I joke, but we shouldn't because I mean we're, you know all these things we know about the link with dementia and social activity and all these things they only apply if you have a hearing aid that's giving you appropriate amount of gain, you know?

- Exactly. And it's really hard to get that without a professional guiding the ship here. So this is like an interesting slide. What do you have to say about this?

- Well, you might remember this, Brian from back when you were in high school or something, and wide dynamic range compression was introduced. Actually it came out in 1988, I think maybe '89. The K amp was the most well known wide dynamic range compression circuit. But what we talked about in episode one was that many of these OTC products will be have linear amplification simply because that's the cheapest way to put something out. And here's yet another potential problem in the fitting and something we've known for a long time, which is and why we have WDRC in essentially all our prescription hearing aids today. And that is, if you look at this chart over here and I'll help you with it in a moment, and that it look at the top chart, when

average inputs are set just rate for, in other words, for average, you say, okay this sounds really good.

What's gonna happen for soft? They're gonna be too soft by about 20 dB for this particular person. Well, what happens? It's loud when average speech is set just right. Loud sounds are gonna be too loud by about 20 dB. I know because I'm old enough to have fitted linear processing hearing aids. What is that patient gonna do? They don't like those loud sounds. So they're gonna turn gain down because of the loud sounds and now average won't even be correct and soft will be 100% inaudible. How do you fix this? There's no way to fix it. If you have linear processing, you're not gonna fix it.

- Fast finger on the wheel.

- Yeah, yeah. Beat Killian actually had an acronym for that I think.

- Yeah, probably

- DIGTADAWAY I think was the acronym, which that stands for a whole bunch of different words that we won't get into. So the way we've been fixing it since 1990 or so is we just use WDRC processing but we don't know now how many of these products are going to be coming out that we're going backwards 30 years, 40 years.

- Well, it's a good bet that some of the basic preset OTCs are going to be linear and have this.

- I would think so. I would think so. Maybe not. You know, it's early. We're still finding all that.

- Yeah, we don't know for sure. But the self fitting I think are more likely to be the WDRC.
- Right, absolutely, yep. So there you have it. Those are all kinds of things that could possibly go wrong. But I heard, correct me if I'm wrong, Brian, but we're going to dig and come back in a few weeks with some things that might go right
- Right, well I guess today the glass was half empty.
- Yeah, it was almost, there's just like a dribble in the bottom I think is all. It's like.
- Next time we'll be more optimistic. So, yeah, thanks for going through all that.
- There is some good news. There is some good news.
- Really interesting. You went back about 30 years on some of these things, so.
- Exactly, yeah.
- Thank you for all that and we'll see you next time.
- Okay, sounds good. Alright.

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OTC HAs - Some Encouraging Self-Fitting Research Findings

- Hi everybody, and welcome back to another Research Quick Takes. Today we're gonna be talking about OTC hearing aids, and with us today sharing some encouraging findings on the self fitting research is Gus Mueller. Welcome back Gus.

- Hey, thank you. Thank you. You know we did this a few weeks ago and we were doing the glass half empty I think on that day of all the possible things that could go wrong which we'll review in a second here. Today we're gonna be a bit more optimistic and try to present our listeners with some things that maybe will be okay and maybe things won't be quite bad as we thought they were gonna be. So let's jump into that. So, as I just mentioned in episode 5.2, we had these things. Brian, you came up with some of these, so.

- Yeah, we mentioned these last time and it's probably bare some repeating, and that is, there's a lot of things that could potentially go wrong when it comes to self fitting an OTC device. You have to be accurate in the way that you do the self test. And then we know that a lot of people have a tendency to, well, first of all we know that hearing aids in general when they're first fit tend to be under fitting, and the range of adjustments sometimes is not even getting them close to where they really need to be, ideally with the now. So I think it's safe to say that many people that would be self fitting would be under fitting.

And we know that a lot of patients are not always a good judge of what's best for them. And I know you, I think made that point pretty well in the last episode in 5.2. So today, Gus, now that we talked about the glass is half empty last time I'm hoping in volume 5.3 you can give us some reasons to be optimistic.

- Yeah, well, I did some digging and there some data that are more positive than what we talked about the last time. And one of the things we've talked about now a couple times is the big research projects that Larry Humes did published back in 2017 where

he had the three big groups of people fitted differently. And one of the findings of that was the group that fit themselves tended to fit under fit as usual, and their SII's were lower than the group fit by an audiologist by six to 7%. And when the audiologists actually looked to see what they believed was the best hearing aid for the patient, they only and compared to what the patient picked for themselves there was only agreement 24% of the time.

And the reason there was poor agreement is that the patient almost always picked a hearing aid with less gain than what the audiologist believed was right. So that was sort of where we ended back in our last episode. But now I wonder, I dug a little deeper. This article is 27 pages long, so there's a lot of place to dig and I looked at the real world self-assessment inventories. Now, you know, logically you'd say, you know, these people are going out with 5 to 10 dB less gain than they need. I mean they 5 to 10 than they should have compared to this group. You'd say, oh my God, they're gonna notice that there should be huge differences when you actually look at the real world.

And that really didn't happen. Satisfaction did win or best practice I mean did win by a slight margin for satisfaction but for benefit use and reduction of handicap based on the HHIE there was no difference. So, you know, why is this one reason could be what we think and I don't know what this we is but at least the two of us, what we think matters. Maybe it doesn't matter as much as we think maybe 5, 10 dB isn't as big a deal or it could be that these inventories just aren't sensitive enough to pick up these differences that really were, you know, happening. I don't know, Brian, your thoughts on that?

- Yeah I mean I think that that's probably, there's some truth to both of those. In my own experience I think many people are just happy to be able to hear something again and they don't really have a good judge of how well they should hear. So something is

better than nothing and therefore they often rate some of these things maybe higher than what we expect.

- Well, back when I only ate my mom's cooking and had never gone off to college I liked my steaks well done And that was easy to please.

- Right?

- But I didn't know you could make a medium rare. Nobody ever told me that. But we can fit hearing aids medium rare. I know we can. Anyway, but you know what, one final thing that's relates to this is it wasn't done in this particular study but relative to my second point are the self-assessment inventories sensitive. There's this whole thing now that's commonly used called ecological moment analysis, EMA.

- Momentary assessment.

- Yeah, assessment. And where people are doing these ratings, they don't sit down and fill a questionnaire and have to go back and remember how they did in the grocery store. They actually take out their smartphone and make the rating while they're in the grocery store. And I think those ratings turn out to be a little more valid

- Right?

- So here's a study that was done. This is an interesting one, because they were all fitted with the same product, and some were about half were experienced half were new users and they all sort of did the fitting themselves but then some of them needed assistance and 14 of them to be exact. So what was happening then out in the real world for 12 weeks, 38 or using what was called user driven, meaning they did the threshold measurements the fitting and everything themselves, 14 of them is being

labeled clinician driven because they were given some help. Interestingly, if you go back down to the fourth bullet on the bottom that irrespective of hearing experience the type of fitting either user, clinician driven had no effect on the gain that they ended up using on their laboratory speech recognition score or their self-reported benefit and satisfaction.

So this would be something to indicate that yes indeed, if these people have the right product this was a very adjustable product. That maybe things can turn out okay. And then we have a series of studies that if nothing else is just interesting because of the name, the Goldilocks approach, which is an adaptive method of fitting hearing aids. So it indeed is a self fitting and it's been developed it's been around now for almost 10 years, but the whole why it's called Goldilocks is of course the Papa's porridge was too hot and Mom's porridge was too cold and baby bear's porridge was just right. So what we're looking for and this is to come up with adjustments to get the right fitting.

This was all came up with by Arthur Boothroyd, a well-known researcher and that his group probably has five articles or so on this topic. And I pulled out a few that I thought you might find interesting. Now I have to say that this is probably more sophisticated and way more controlled than what we're going to see with OTC hearing aids, but forget about that for a second and just to see indeed does it, does it work? So this is just something from their software that the patient uses where the patient makes a judgment of fullness, loudness, and crispness. And then you see down on the bottom you're seeing the results of what these adjustments were for those three things when the patient reached a decision of where they wanted to be.

So high frequency boost obviously is crispness. You see, that didn't take very long before the person decided where they wanted to be. They had some trouble deciding the best loudness. And on low frequency cut, they had about eight changes on that ended up pretty much where they started. The whole hearing aid was fit by 44 steps

while the patient's listening to speech, okay? So that's sort of the idea. And this would in most definitely be a self fit report. So this is a study then using this particular approach, they started with a generic level that was somewhat below the NAL. And then they had people do those adjustments I just showed you. And they had them do two different trials.

So they fit them, then they waited a while did a second trial, and then at each time they calculated the SII. And what I'll show you here in a chart that by the time they got to the second adjustment the SII was the same as what you would get for the NAL.. And it didn't matter whether it was new users or previous users, it was essentially the same as what you would get for a NAL fitting. Now some of you, if you haven't thought about the SII for a while, you might say, well wait a minute, those numbers are only 75 to 80%. When we're looking at the SII, just as a reminder if you're up at 75, 80% patients are going to do very well.

They should score about a hundred percent for words and sentences. That's the top blue dotted line. And even for single syllable words, which is that red line they should be getting around 90%. So that would be a good fitting if you're up that high. And so that was a very positive result was the author's conclusion. And I would agree. Here's another study that was related to that except now rather than the SII, this is a different group of people, but rather than look at the SII we're looking at output and what you see there on the bottom was where they started the orange is the NAL and the blue is where they ended up. They actually were a tad above the NAL.

I would argue that they didn't really start that far away from the NAL. Which was a topic that we had in our last episode is what happens when you get away from the NAL. And just to take us back to that I'm gonna bring this slide back that we used before. This is from a case study from Dr. Cliff showing a first fit from an OTC product. And that's the starting point. And the question then becomes are they gonna program up to the NAL

target? Now, if you looked at the starting point for the Goldilocks study that we just looked at on the previous slide, not only did it follow the NAL pattern, the starting point, but it was only about 3, 4 dB below the NAL.

So it's a good sign that shows people can fit and do it right. But we have to say, will they do that in the real world and will they do it if the starting point is not close to the NAL? Well, to answer the question about the starting point we have this, did you have anything on Goldilocks?

- No, I just, I think that it shows you if you have the right controls in the person's hand that you have better chance, better success maybe of getting them closer to that NAL starting point.

- Yeah, and of course this was in a laboratory, you know where they're sitting there and they're focused is not gonna be the same if they're sitting out in a restaurant or something like that. So but here's a study, and I'll point out shortly why this is interesting and relates to the very topic that we're at. And that is the study, I'm just calling it the Bose study because, well it was done by Bose people and it was then the results of which were submitted to use, but for use with the FDA which is now another company has taken those data and that approval and is selling a hearing aid advertised what Bose technology, Bose processing something like that.

- Right?

- So they had a elaborate self fitting mechanism that was in 12 different frequency bands. Everybody was first fitted using clinical practices and they had just a bit of time to use hearing aids fitted to target. But then they changed and half of the people half of the people went back to the self fitting. And some of the other ones the other half stayed with best practices. What makes this interesting is for the people who were self

fitting they started them off with zero dB gain, okay? So I've been talking about the starting point does matter. They started out at zero. So where are they going to end up? Then they also did a lot of outcome measures. We'll talk about shortly. So what happened when they started them at zero? The final fitting actually ended up fairly close to the NAL, excuse me, I need to cough for a second.

- Oh.

- Thank you. I needed that. They were, as you can see here 50% of them were within 2.6 dB, 90% were within 6.7. That's not too bad really not as good as the people, the best practice group. Now the best practice group also were allowed to adjust their hearing aids with the volume control and they ended up a little closer to NAL. But the authors report, that this was not a significant difference. In other words, if you are making a claim which was does to the FDA, you could say that the self fitting turned out as good as best practice because there wasn't a significant difference relative to as good compared to gain. I do wanna mention though that the fit to target that these other people were using wasn't a true fit to target in that the clinician did change the gain of the hearing aids based on the subject's request, and in most all cases it was a change downward.

So when we're saying they were within 1.9 well let's take the first group, they were within 2.6 dB it was 2.6 dB of what they had after clinician adjustments, not 2.6 dB from the NAL. So that is a difference to keep in mind. Other outcome findings, they did a A/B comparison. A lot of people didn't notice this is done in the field. A lot of people didn't notice a difference but when they did notice a difference, they almost always favored the self fit, that could just because they're saying I did it so it must be good. They did standardized outcome measures. No difference. They did speech recognition and there was no difference. My only question here, which I find a little odd is that they reported they did it at 60 Db HL did not report the SPL, but I would guess that the way

most things are calibrated it'd be around 72 to 75 dB SPL, which is pretty loud to do aided testing. You don't see that in much research. And of course that would add some forgiveness for the under fitting because the speech is so loud you don't need as much gain.

- Exactly.

- Yeah. And finally, while they were in the field for various listening tasks, they had this app of course on their phone and they could do star ratings like you rate your Uber driver. I'm always scared if I don't rate them well well then he like, give me a one and I'm in trouble. They say they don't know, I don't know, I'm always worried. I always give them fives just to be safe. But anyway, these people didn't give many fives. But what you hopefully do see on that chart is if you compare best practice to self fit, notice that when you get out at the four and four and a half you see a lot of orange bars out there.

And in fact, I did some calculations. Only 26% of the participants in the best practice group had an average star rating of four better, whereas 57% of the self fitting group so again, these are two different groups, remember. And so the self fitting people are pretty happy about how things are going. Thoughts on this Brian?

- Yeah, I think this is a really interesting study and there's a couple of questions that I have about it. First of all, I think that it was great that they went from zero dB as a starting point rather than the target. But I wonder if, because all of them were originally clinician fit, right? So they had some training and coaching and they probably had some encouragement to go and I think that's why you might see that difference. That's one thing

- They had some some experience of what was good. before this.

- Yeah. Yeah. So, but that doesn't really reflect how it happened in the real world necessarily. So I think that's one of the drawbacks of the study. The other thing, if I remember correctly is they didn't report any data for soft sounds.

- I don't think so.

- And you know, if you go back to 5.2 of our volume on this we know how much people tend to be under fitted for soft. So that's another thing that I would wonder about as well.

- Yeah, I don't recall that there was a chart showing soft in there, which of course now you know, you could if this is wide dynamic range compression, which it is. You could say well they probably would be close to okay at soft. But we know ourselves, some of the studies that we've done is you can you can NAL things at the average and be off by 10 dB at soft if the compression ratios are set pretty low and you basically have a linear fitting even though it's WDRC processing.

- Yeah. It would be nice to know what they did or see that.

- Yeah.

- Well our final thing on this, has to do with a topic that there has been one study related to this and many of you listening have heard about locus of control and that is do you think that you're controlling your life? Are other people controlling your life? Or do things just happen by chance? So this whole logic of locus of control has related to the health field. There's in general health things, there's a lot of studies that have been done relative to locals and control. And so if it's internal, you believe that you can take

care of things yourself. If it's external, well then you believe that you really need other people. 'Cause other people are in control and they they take care of you.

And a given individual can have an external and for some things and internal for others, you know, if you think you're too chubby and you need to lose some weight, you can say I can handle that myself. I'll just not eat as much. Whereas if you get diabetes, you might say, okay that's far enough, I'm heading to a doctor now. So you can have internal and external depending on what the pathology is. We're talking about the pathology of hearing loss of course. And not surprisingly, there is one study done with over the counter hearing aids, and they actually looked at the health locus of control and they found what the people who were the most apt to request assistance were the people who had the external health locus of control.

Conversely, although they didn't exactly say this, but it had to be true when you look at their data. The people then who didn't need assistance were the ones who were most apt to have an internal locus of control. And that makes sense. And I think you all will see this when you see people have success or failure really with any hearing aid or, but certainly more so even with over the counter products How's your locus of control going these days Brian?

- I try to go towards the internal side of things, but I don't know.

- Well you got Google, you could, what is Google count? Is that internal or external?

- I think that's, I would put it as internal, but I

- I would put it as internal too yeah.

- You know, I think this is interesting kind of, because I think it this is a great example I think of what you might see down the road with decision trees that one of the factors you look at in deciding do I go to see somebody or do I buy something online and I could see a few questions in a self-directed survey that might ask this. And if you're internally controlled it'll say you're a better candidate for OTC than if you're external.

- Yeah, exactly. You know, I was just reading this article the other day and I think we're gonna do one more of these guys. One more in this series. So in episode four I can't resist but toss this in. There's a study that we can talk about in episode four Where recently published where they looked at what was the probability that you would buy something online? A hearing aid, not something but what's the probability you'd buy a hearing aid online? And interestingly enough, for every year of age it goes down by 5%. That's what they reported in that study. So wait until you get to be my age, you know You won't even buy pajamas online anymore, you know.

- Not that you do now I'm not making judgements. All right that might be a good ending point.

- That's a good place to end.

- Once you get to pajamas, you know it's probably time to call it a night.

- We know we've been at this so long. It's time for bed.

- Yeah .

- All right, these quick takes are turning into medium size takes, I think.

- All right.

- Well that's okay. All right Gus, great seeing you.
- We'll call them sort of quick takes sort of quick.
- We got one more left in this series so I'll see you next time.
- Okay, good. I'll see you then, whenever that might be.
- Sounds good. Bye.

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OTC HAs - Practical Issues Related to Sales and Services

- Welcome back, everybody, to Research Quick Takes. We're on volume 5.4, and the topic of volume five is over the counter hearing aids. We kind of talked about the good and the bad side of fitting OTC products the last couple of episodes, and today we're gonna be talking about some of the real world practical issues that revolve around the sales and service of these devices. And with us today, as usual, is Gus Mueller. Gus, welcome to the program.

- Yeah, yeah, thank you. This has been a fun topic and certainly timely. You know, we're sort of gonna go full circle for the listeners who have gone through episodes one, two, and three. Way back at one, we talked about a hearing tracker survey that showed that roughly 25% of HCPs say they're gonna be selling OTC products themselves. Another 50% say they're gonna be servicing them. So we've already talked about potential problems, potential solutions, and now we're gonna get to the real nuts and bolts of the practical thing for those of you who are going to be either selling them or servicing them. So, we're gonna start off by just in general, Brian, I think you have a list here of six or seven or eight things that, just in general, why this could be good things surrounding the OTC product.

- Right, it's probably, I think a lot of people are familiar with at least some of these things, but it's a good reminder, I think. The first is affordability. I think that there are people out there that want something that costs less. In fact, I know just from the last few months of the Sony devices being on the market, the leading reason those that have purchased that device, when you ask them why they purchased it, the leading reason by a lot was that it costs less. So we know affordability is an issue. And then we have accessibility. We know that there are a lot of folks out there, older people, low income people, people living in an area that's more rural, it's difficult to get to an office where they can get hearing aids not only one time, but then two or three times over the course of the first few months of use. And we know that research has shown that about 90% of Americans live within five miles of a pharmacy, and about 50% of the

population lives within a mile of one. So that might cover a lot of people, but there's still people that could be left out.

- Sure, yeah. You know, in fact, as we mentioned back in episode one, you know, pharmacies, whether they're at Walmart or at CVS or wherever, is gonna be one of the leading places that are selling this. In fact, there's been some work with audiologists. I know the Pittsburgh people, they're doing some work where they're actually working with pharmacists. So that's an important statistic.

- Right, and I know other parts of the world too, they have pharmacies more involved in dispensing those kind of products. And another one is market penetration or the uptake rate, that people that need hearing aids don't use them. And the numbers vary somewhere between 20% and 40% of people that have hearing loss actually own hearing aids. So there's some ideas maybe that an OTC product would be attractive to people that need one, but for whatever reason haven't purchased one.

- You know, the question that always comes up here, and I think you probably know the numbers, but when we talk about market penetration, if we go to a country where hearing aids more or less are free, or at least they're free to a large percent, how much does that increase market penetration?

- Oh, maybe 10%. 10 points maybe. But it's not as dramatic as many people think.

- Yeah, so it'll be interesting to see what happens. This isn't free, but it's a sizable reduction in cost, so it'll be interesting to see if it indeed makes a difference over time.

- Well, public awareness is a big one, I think. I think there's a lot of lack of awareness. I know of one recent study from some researchers at Mayo Clinic that both the public in general and medical professionals are not aware of the various treatment options

available, and that includes hearing aids. So there's some room to be optimistic that OTC might drive public awareness.

- Sure. You know, and let's assume that people walk through these stores and there's racks of hearing aids. You know, again, there's actually a name for this, but if you don't think anybody else owns a red car until you buy a red car, and all of a sudden everybody has a red car. Well, if people start seeing hearing aids in a store, they're gonna say, "My God, I'm seeing hearing aids everywhere." And that might get them excited.

- Right, and I can tell you, just to follow up on that, my friends in the industry that are still dispensing hearing aids tell me every time they talk about hearing aids on "The Today Show," five people show up the next few days asking about hearing aids, and so they love the fact that they get a lot of traction. Another reason is basically just increased competition. I think the more players you have involved, it kind of raises the stakes for others that they wanna bring something more innovative to market. Maybe some company that we don't even know about yet will bring something really unique and innovative to the market that people will gravitate towards and that could improve the uptake rate.

So another, I think, good thing that kind of surrounds the idea of OTC in the marketplace. And then I think another reason is kind of as far as like competition raising your level of play, is it forces more hearing care professionals to follow best practices. You wanna be able to demonstrate that what you do can't be duplicated in the OTC market. And I think that might force more and more people, if they wanna stay in business and be better than OTC, to actually implement best practices throughout their clinic.

- Yeah, you know, obviously I've for years have been a fan of probe-mic measures and have advocated for their use, and it hasn't gone incredibly well because they still aren't used that much. But here's something where if somebody walks into your office and they need your help, you have to be able to do something that they can't do for themselves. They already have a self-fitting hearing aid, you know? So somehow you need to do something that can make things better. And it's gonna be hard to do without the use of probe-mic measures, I think, so we'll see what happens. And let's see, we've got one more here.

- Well, that's around the idea of unbundling services. And I know there are some people inside the profession that are huge proponents of unbundling. It's a way to kind of show the value of the service. You know, I think most people know that when you bundle, it has a tendency to devalue the service because people don't see it on their invoice and they kind of take it for granted and assume that it's part of the product that they're buying. And the idea here is you might have more and more people coming into your office that have already purchased these devices, or they're at least inquiring about them, and then it's an opportunity to offer some service that stands apart, that's unbundled and separated from the sale of the product. And, you know, for the profession, that could be a good thing.

- Yeah, we'll see. Well, so then the question is, why would you? So some of these are relative to servicings only. Some are related to sales. And so I think this came from some type of study where a group of audiologists or something sat down and came up with ideas why they might want to sell an OTC product. So I'm gonna just go through these briefly 'cause there is some overlap. So let's start with the patient who is just gonna walk out the door, and you wanna retain them. Certainly this product might be a way to just get them to know you, to get them on board, and sort of start them on their hearing aid journey.

There's some people who might come in, in fact, I know there's people like this, who say, "You know, I don't need your help. I know how to fit hearing aids. I just need to buy something and I can go home and I can fit 'em myself. I don't really need your help." This would be particularly true in an unbundling approach where they say, "I don't need all that stuff, you know? Just give me the hearing aids, and, you know, what do you have?" There's some people who think little loss, little costs. You know, "Why am I paying \$6,000 for a pair of hearing aids, which is big money, when I just have a little hearing loss? I should be paying little money for little loss."

And this could be something that would help these people get started using hearing aids, and then hopefully they would eventually move into prescription hearing aids. Sometimes, in some places, you just want a variety of price points in your sales. One could argue that with some of the basic intro models that are prescription hearing aids, you can pretty much match the OTC product. But I think in some cases, you know, the OTC product might be a little lower than what you'd be charging for a prescription hearing aid. You might want something for everybody who walks in the door. As Brian just said, people are asking about OTC products. If you don't sell them to them, they will go someplace else or they'll order 'em online.

And sometimes, you know, these OTC products we're seeing more and more, many of them have a pretty unique style. You know, we were just talking in one of our last episodes about all the hearables, which some of them may end up with FDA approval and they would be considered an OTC, and they have some very unique styles. And some people might want that style rather than the more traditional products. So there's a lot of things that could be done.

- Yeah, I actually think that one of the more important reasons wasn't on the list, and that is I think there are a lot of people out there, and it has to do with sort of the psychology of hearing loss and the fact that a lot of people are aren't aware, some

people say they're in denial about it, they don't think it's that big of a deal. And I think that if you provide somebody with a product that they can just kind of dabble with from the comforts of home without having to go to somebody and acknowledge that they might have a problem, I think that's a great way for people to sort of get started with hearing aids in a kind of a low risk kind of a way without having to see somebody and kind of try it on their own to see if it actually works.

- Yeah, I think it was the last time we were out having a beverage together, you were telling me a story about hearing loss in dogs. What was that?

- Oh, that's another reason, I guess.

- Well, it ties into what you were just saying though, right?

- Yeah, I think for anybody that's a dog owner out there, or just a pet owner, you might find this interesting. It was published in one of the medical journals, Otology & Neurotology, by Sarah Sydlowski, who was the past president, maybe the current president of AAA.

- Past.

- Past president, not that long ago though. She was one of the authors of the study. They surveyed, I wanna say, about 1,200 middle and older aged adults, 50 to 80, and they asked them a series of questions about how important it was to do certain things with their health, in relation to their health, like get their blood pressure checked, cholesterol checked. One of the questions was get your hearing checked and another was to take your pet to the vet. And people were twice as likely to say they would take their pet to the vet than to get their hearing tested. So that kind of shows you that

there's a lack of awareness or a lack of priority around having your hearing periodically checked. So I think OTC might be an avenue to kind of improve apathy around it.

- Yeah, exactly. And, you know, I'm all for taking dogs to vets, but having good hearing's important too. Well, I know there's a lot of people out there have said, "You know, I don't even want these people coming in." This is 25% of the survey people. "I don't even know what I would do for them." So I sat down and thought, "If I were in private practice, what could I possibly do that I could bill for," obviously. You're not gonna be doing it free like you would if you had sold hearing aids in a bundled manner. So I came up, and there's probably more things than this, but this is just a few things that I thought of.

I think a lot of people are going to wanna come in and get a hearing test. Even if they decided on OTC, they'd like to have a test so that they really know if they need hearing aids or not. Which takes us to number two, is you could actually do some candidacy counseling. You could certainly do the QuickSIN, which you would give the patient a good idea how well they're doing in background noise. There is a ton of research that shows that their score on the HHIE is a good indicator of whether or not they would be successful with hearing aids or need hearing aids. And these are all things that you could do for that OTC person, even if you're not selling OTCs.

In fact, in particular, if you're not selling 'em. A lot of people are gonna be overwhelmed. I mean, this has only been around now for, what, four months, and already we see probably 20, 30 FDA approved OTCs. If I were thinking about buying one, I'd gladly pay somebody for an hour of their time to sort through all the different products out there and tell me what would be the best for me. Once I get it, gee, I'd like to have somebody help me learn how to set up the app and do the streaming and get it in my ear and all of those kind of things. Quality control. I could see wondering, "Is this thing really working the way it should and the way it was advertised?"

2-cc coupler measures would be a nice service that could be provided. Now there's gonna be some people who say, "These really aren't working right. Is it possible that you could program them?" And you say, "Well, of course." So you could actually program them, if they're adjustable enough, and hopefully at least some of them will be, that you could actually fit them to probe-mic targets. As they're using the hearing aids, you could help the patient determine if they're providing benefit by doing unaided and aided testing or unaided and aided APHAB, or by doing an IOI-HA, or by doing a COSI that you can provide all these services for the OTC user the same as you would for a prescription fit.

And as I mentioned here, again, you could look at satisfaction and benefit in the real world, 'cause we have the tools to do that. The patient probably isn't gonna be doing them themselves. And of course, finally, there's all kinds of new exciting things related to rehabilitative audiology, computer assisted methods where you can do auditory training and so on. There's no reason that an OTC user wouldn't want to do this as much as your prescription hearing aid users. In fact, maybe more so because they might just have a hearing aid that isn't fitted as well, and they need more training than anybody. So to me, you have a whole, I think I named nine different things that you could offer.

You could have a menu at your front desk and the patient just decides from that menu what they need, what they like. I'm not in private practice. I was for a while. But I think it would be sort of fun to offer these services. And also on the same, you do a good job, you get to know the person, they'll probably be moving into prescription hearing aids before too long.

- Exactly, and it's a great opportunity for each one of these to use best practices.

- Yep, exactly, exactly. Don't ask me what billing code each one of these fall under.

- Not me either. You can find that easily.

- But there are experts out there that can tell you that. I'm not one of them. So here was an interesting study. This was just published a couple months ago, I think, right, Brian?

- Yes, 2023.

- Yeah, Sumit Dhar, I know, is one of the audiologists on this. They asked people what their preferred pathway was, whether it was through an HCP in person, whether it was online, or it was an online that requires a hearing test or online that does not require a hearing test. The good news for all you listeners is that 84% wanted the in-person pathway. That was their first choice. Now, we're not saying that's what they're gonna do, but that for sure was their first choice. And interestingly enough, they found that for every additional year of age, the odds of purchasing hearing aids online decreased by 5%. So I guess by the time you get 80, it's down to zero or something, I don't know.

Or negative numbers maybe. And they also rated their comfort in purchasing hearing aids online, which takes us to this chart right here, which I think is pretty interesting because first, look at the orange. So these are saying, if you have a hearing test, if you already have a hearing test, how comfortable will you be? Well, notice that even with a hearing test, only about, what, 30% or so are going to be comfortable. 20, 10, well, maybe 40%. But look what happens if they don't have a hearing test. All of a sudden, you look at the blue bars, everything's down on the left extremely uncomfortable part of the chart.

- [Brian] All of the above.

- And again, that's why I think the world still needs us, because we can fill that gap that they need.

- Well, it shows you the value from the consumer's perspective, shows you the consumers value the test by and large.

- Yeah, yeah, exactly, as they should. We've talked about in this all of these OTC segments we've been doing, Brian, many of them we've mentioned this study from Larry Humes back from 2015 where he had three different groups. And at one point, the point we were making that it was sort of bad news because the people who fit themselves didn't do as well. But there's actually some good news that Larry has written about more recently, although I think it's all from that same study. But here's one that he found from the consumer decides. In other words, these were people who fit themselves. That 50% indicated at the end of the six week trial, they did not want to keep their hearing aids, okay?

That was our point earlier, saying this isn't good because people don't want to keep their hearing aids when they fit themselves. But over 90% of those opted for a four week follow-up trial after they were refitted best practice. Point being, many of these people who might not be happy might be coming to you to be fitted. And there's indications in this case that most of them do want to be fitted by a professional. So it could be that even if that first initial fit isn't good, there still might be hope. He also had a placebo group. These are the people who were fitted with zero dB of gain. And so after the first six weeks when the study was concluded, 33% of these actually chose to keep their hearing aids.

But the more interesting thing is when they were refitted employing best practice, the success rate went to 92%. Again, shows you the value of the HCP. And actually, you

know, I say this placebo group were fitted to zero dB gain. It's very possible that some of these OTC users will be fitting themselves to zero dB gain. That wouldn't surprise me at all. Well, I think this is one of our last shout outs to Larry. And he pointed this out in an article recently published in Canadian Audiologist. This was of 40 people for the self-fitting group. So he pulled out 40 of them and they were asked at the end of the study how confident they were in the fitting.

Remember, they fit themselves. And they rated this on a 1 to 10 scale. And so then what he did is the fitting confidence was compared to whether the participant chose to keep hearing aids. Remember, 50% of them did not keep their hearing aids on the initial go. And what we see is the confidence in the self-fitting had a big factor. So look at this chart here on your left. If we look on the two bars to the left, that's if they had a fitting confidence of five or greater, nearly 80% of those people kept their hearing aids. But look over to the two bars on the right side. These are people who had the fitting confidence below five, only about 20% kept their hearing aids.

And so it really shows that fitting confidence, fitting confidence is a big player here whether people keep their OTC hearing aids. And we know that a lot of 'em out there are not going to have a lot of confidence at the fitting. And who are you gonna call? Not Ghostbusters, but your neighborhood HCP. And I really see that happening.

- Yeah, that's interesting because in volume 5.4, you showed some research around health locus of control. And now you're showing some research around confidence. So again, you can kind of see how there's a picture emerging where there's these decision trees that could be put together where you're asking questions that have nothing to do with the audiogram and have to do with somebody's confidence level and their locus of control, so that's interesting.

- Yeah, absolutely. I was thinking you could almost have a questionnaire in your clinic to look at those kind of things.

- Exactly, right, it wouldn't be that difficult to do.

- You could then pair up with the audiogram, yeah, exactly. So we finished our whole whole big volume of quick takes on OTCs, and so if we go back to the first slide of episode one, whenever we did that sometime ago, the thing we talked about then was social media was filled with sayings like, "Oh my God, OTCs are here. This is the end of our profession. The sky is falling. I hear the sky fall." And it goes on and on and on. There was many more of those kind of comments than, "This is a great thing." But hopefully in this short little quick takes that we just finished now, maybe OTCs and the HCP is a better fit than a lot of people believe. So we certainly hope that's the case, 'cause they're not gonna go away and we're not gonna go away. So it would be nice if we all got along.

- Yeah, and maybe there's volume eight or a volume 10 of Quick Takes where we kind of go back and see where the research takes us and the market takes us over the next couple of years.

- Yeah, and you know, the problem now is that there has been some research published to say, "Hey, we're comparing prescription fit to OTCs," except they really aren't OTCs, they're PSAPs, so I think we need to give it a year or so so the real OTCs are out there.

- Well, not only the technology itself, but also the way it's bought. I think a lot of these studies, they were actually set up in the clinic, and they weren't in the wild, so to speak, where people actually buy them on a website to take them home without any involvement from a professional, so more to come.

- Yeah, it's gonna be an exciting time, and you're right. Let's see, we're on volume five now. Yeah, you're right. I'd say about volume 10 or so, I think we'll be ready to come back.

- Well, again, thanks for all your time and expertise, Gus. See you next time for volume six.

- All right, can hardly wait.

- All right.