Over the Counter (OTC) Hearing Aids: Misperceptions and Misinformation

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- Welcome to today's course. We're so delighted to have you with us. Today, we're gonna be covering OTCs: the misperceptions and also misinformation by Dr. Tom Powers. It's been said that innovation is seeing what everybody has seen, but thinking what nobody has thought. So this month in February on AudiologyOnline, we are celebrating just that, innovation in our hearing industry. This is our third year holding the summit, and we're so glad that you're able to join us today. We hope that you enjoy this course and be able to catch the recordings of the other summit courses in the AudiologyOnline Course Library. We wanna thank our title sponsor CareCredit, and all of the other companies who are participating in this year's summit. At this time, it's my pleasure to hand the mic over to you, Dr. Powers.

- Thanks a lot, Christy, I appreciate it, and thank you for getting this together. I think is quite an event. And thanks to everybody who's joined us today for a little discussion about over-the-counter hearing aids. I'm going to move on to my disclosures here. You can certainly read those. And as you know, I have my own consulting company and do work for a variety of companies within the hearing healthcare space. So with that, we'll move a little bit further on. The learning outcomes. Describe and discuss the FDA regulations for OTC devices and changes to the hearing aid distribution. Compare the facts and misperceptions regarding OTC devices. And review hearing professional choices of OTC devices and personal sound amplification devices.

So with that, we will move on. So the path to OTC hearing aids, I think, was very well illustrated, and of course, I think it was held last week by Dr. Alani and Kevin Libby from Health Hearing. They went through the entire pathway from the early PCAST through the regulation, the FDA, and how all that worked. I'm gonna do a brief summary of that in just a minute, but I think by way of getting ourselves ready for our discussion here, some of the perceptions I think that went into creating the OTC category of hearing aids by the FDA certainly were cost. We continue always, and I think even now we

continue to hear issues related to cost, whether that's the prescription side or the OTC side.

Access to a professional was certainly a big driver in some of the early meetings, both PCAST, NASM, FDA, FTC, and a growing body of research and awareness around associated comorbidities. I think one of the ones we're seeing mentioned most is certainly the comorbidity related to dementia, cognitive decline, and potentially Alzheimer's, but mostly cognitive decline. We know from the Lancet from a while ago, treating hearing loss is one of the modifiable risks for cognitive decline. And so this has generated a lot of interest. Also, I think in some ways, it's also generated some of the either misperceptions or misinformation that we're seeing out there in the marketplace. And we'll touch on some of that in a little bit.

One of the other pathways, of course, is the lack of coverage within Medicare. Since 1965, the original Medicare statutes excluded hearing aids and hearing aid related services from coverage as well as dental and vision as we know. And I think back then, there certainly wasn't enough information about what hearing specifically could do in terms of those comorbidities or related to how it may help people in terms of their communication needs, both partners, work, play, et cetera. Coverage is limited to some degree what coverage there is for hearing imbalance exams, cochlear implementation, osteointegration devices for those who meet those criteria. So with with limited coverage, of course, we move backups up to the first point, which is cost.

Insurance coverage is also somewhat limited. We do see an emerging access through Medicare Advantage plans. I'm sure those of you that watch anything on television have seen ads for a number of the Medicare Advantage programs, which includes certainly hearing, vision, and dental to some degree, one or more of those as a way to gain membership in those plans because those are attractive things and certainly healthcare issues that are not covered under Medicare at the present time. So this is

some of what drove that. And again, if you want a more complete description, I encourage you to take a look at that other course that's out on AudiologyOnline related to OTCs. In terms of the timeline, in terms of how we sort of got here, just briefly, there was a lot leading up to the first line here, which was the legislation.

And I mentioned a few of those, which is the workshops held by PCAST, National Academy of Science, Engineering and Medicine, FDA, FTC, just to name a few. Eight or 10 meetings in total, probably. And originally, of course, there was an NIH meeting in 2009, which really was the impetus and sometimes isn't mentioned much, but that was really one of the early meetings dealing with the access and affordability issue, which is what drove the OTC regulations. So those were passed in August, 2017. We know, those of us that have been around the industry for a while. It was due in August of 2023, years after the legislation was signed. However, due to the pandemic and a number of other factors within FDA, it took a little bit longer, almost five years to get us the proposed rule.

And then the comment period, which closed in January '22. So as you see there, a five year gap. The final rule was published with changes and/or comments, if you will, in August. And then a 60-day implementation or effective date is now October 17th. So since October 17th, 2022, the sale of OTC devices and their variety of farm factors and et cetera were available to the public. I think two very important parts of this, and we'll come back to this in terms of discussing the implementation, and it may also be a CEU question, you'd never know, are the compliance dates for both the existing companies as well as new companies. As you see their compliance date one for hearing aids not legally offered prior to the effective date, which again is October 17th, are required to submit new 510 s before they could start that, while they were looking at the rule and understanding what the rule was.

Or any time after then, of course, they could submit to the FDA. The second one, which I think is as important, and may be more important, for those products that were legally offered prior to the date, which is again October 17th, they have a compliance date of April, 2023. What that means is those devices that were on the market that had already applied to the FDA for their approval or release to market. Again, the FDA doesn't really approve devices. They let you go to market. Have till April to be in full compliance with the rule. That means the labeling, the packaging, the documentation, the technical specifications, et cetera. So there are some information out on the internet, et cetera, that some companies are not complying with the rule because their packaging isn't appropriate, if you will, for OTC devices.

But those probably, and we'd have to look them up and see when they were on the market, have until April, 2023. This is sort of the standard thing within medical device industry. When a new rule like this comes out, if you're in the market, the FDA generally gives you a grace period to reprint your information, create your new packaging, make sure it's all in compliance. And to ensure that when the date occurs, April, 2023, you are in full compliance with the new regulation. As I mentioned, if you were not on the market, then you must go through and complete whatever requirements are, whether you are an OTC or a self-fitting OTC or if you even wanna become a new prescriptive device.

Those are important dates that you must complete and comply with in order for you to get approval or release, if you will, from the FDA for a go-to-market strategy. Move to the next one. We've mentioned a couple of the agencies, if you will, that are involved at the present time or will be involved, if you will. The first and foremost certainly is the FDA, the Food and Drug Administration. Their primary charge is to ensure the safety and efficacy of medical devices and products here in the United States. They do have authority also to go outside of the United States for inspections, should companies sell

here and/or manufacture both here in the United States and/or have manufacturing facilities.

Outside of the United States, they do have the right to inspect those facilities to ensure that they are complying with what we call GMPs or good manufacturing practices. And they do inspect those facilities on a fairly regular basis, typically every two years. They're looking for record keeping, they're looking for that you've got the right information in your files on a variety of aspects of good manufacturing practices, quality control, et cetera. The other aspect within the FDA is enforcement. There are several branches within the FDA, the Ear, Nose, and Throat division, which is what hearing aids are classified under now has their own enforcement group. Before, it used to be one big enforcement group. But a year or so ago, they split that group up and assigned several of the enforcement folks to each of the branches within FDA to take a look at if companies were not complying with the existing regulations and reach out to them to first notify them that they weren't.

And if that seemed to be enough, then they have full enforcement capabilities to close a facility and encourage and force, if necessary, products off the market. So the FDA has a fairly big role in hearing aids, of course, as we all know. And they will, I think, continue to evolve both their safety and efficacy role, but also the enforcement role. The second agency is the FTC, the Federal Trade Commission. Their mandate is to prevent unfair or deceptive acts or practices, and that primarily revolves around advertising, marketing claims, et cetera. Their role came out in the eyeglass business several years ago, as was discussed during the OTC period leading up to the regulation. Would the FDA issue a ruling similar to what they did back eight or 10 years ago for eyeglasses and contact lenses where if you go for an exam, you must receive a copy of your eye exam test prior to any discussion about whether you're going to purchase eyeglasses and/or contacts from that facility, doctor, et cetera.

And so it sort of is referred to as the eyeglass and contact lens rule. And the question was, would they do a similar thing? They have not up to this point, although that's still within their purview to do that are my expectation. And others, I think, is that they're sort of looking at how this whole OTC rule is playing out, and is there a need for them to move in that direction? We'll see. One thing that may be of interest, of course, is a new compliance guide that was issued by the FTC back in December, 2022. This was a guidance document issued by FTC, primarily for health products as it relates to claims and advertising. Normally, those are pretty broad and don't have anything specifically to do with our industry.

However, there was one example of the 50 or so that was in that document, which related to the use of the term doctor as it relates to professions including audiology. And that the term doctor should only be used in association with the specific specialty. So in other words, doctor of audiology, Dr. Thomas Powers, PhD, audiologist, or Thomas A. Powers, PhD, audiologist, or a number of ways in which that can be done so that the consumer is not confused with that title, thinking that someone is a medical doctor or in some other way, a specialist that they are not. Now at this point, this is just a compliance guide, and for those of you that haven't read this or are unaware, I encourage you, you can go to the FDA site, search health products compliance guide and you can find that document.

It's another pretty big document like the FDA one, but it is worth a read. The third component is the state regulations. I'm sure all of you who are out in your practices are aware of state regulations both for your licensing, but also the more important one as we talk about these other agencies are usually it's a consumer protection agency that's looking for deceptive practices as they're referred to. This relates primarily to advertising and/or material that might be on your website that either might be inaccurate, confusing, or outright untrue. And so there are state regulations as well as

federal in regards to how we portray both ourselves as professionals but also the messages that we send to consumers.

So these are some of the agencies that are looking at and have regulatory responsibility within our industry. So around OTCs, what are the regulatory requirements for the devices? We mentioned earlier these two compliance dates. Pre-market approval, usually referred to as 510 . That's the section of the document within the FDA regulations that refers to a set of documents that a manufacturer must submit prior to getting the FDA to tell them that, yes, they fulfilled the requirements and they can go to market. So the 510 has been a requirement for most hearing aids. Most class one, class two devices are exempt as long as they are, in quotes, "Substantially equivalent to other devices on the market." You can then indicate that in a series of documents, have that in your FDA files within your regulatory framework within your company.

And so if you're inspected, you just have to produce those documents. So it is not required 510 for OTC hearing aids, but it is required for self-fitting hearing aids. So those of you that have read the document, I'm sure have read in earnest those two, the differentiation between those two, and we'll talk about that in a second. But again, here are the specifics of this compliance data. And I think it's important because as consumers begin to arrive at our office with some of these devices and bring in whatever materials come along with them, some OTCs they may have purchased online, it's important we understand what they may or may not be bringing with them to the office.

So again, hearing aid not previously offered for sale or those that are required to submit a 510 must comply before marketing the devices on or after the effective date of the rule, October 17th, the 17th October, 2022. Those that were offered before must comply with the newer revised requirements within 180 days of the final rule.

Non-enforcement, if hearing aid meets a certain criteria. So as long as you meet the existing criteria, the only thing you might have to do is redo your packaging, redo all of your literature, make sure the labeling that's required, and specifically the wording that's required in the FDA regulations is complete and is in your documentation that you provide with that device. And doesn't matter who provides the device, it's the manufacturer's responsibility to comply with those requirements.

So if it's a previous device, you can still sell those in existing packaging that was available prior to the date. If it's a new device, excuse me, a new device, then you're gonna have to completely go through a 510 if you're a self-fitting device. And remember, regular OTC devices, which are those that primarily just have a preset, are not required to file a 510 . Those companies still do have to register with the FDA as a medical device company here in the United States. They may be located overseas, but in order to be able to sell devices, even though the 510 is not required, they must register as a medical device manufacturer or seller. And that list is available on the FDA site.

So if you'd like to find it, you can certainly look it up and find those devices, listing of those devices out on the FDA site. So what are the technical specifications within the OTC? And I put these up because we will see that some of these get misreported and some of them, the information that's out there, output is 111 for linear devices, if you will, with 117 SPL allowed for those with input compression. There is no limit or any requirements or anything even mentioned about gain in the file, no regulation. This certainly was issued a lot of debate within the comments that were submitted. Those of you that followed this know that were well over 1,000 comments submitted to the FDA on this proposed regulation.

They responded to those in the final rule. And that's in that 200 or page document or 40 pages, which is if you read the one on the federal register. So those are the

amplification. The insertion depth is another sort of interesting ones. It shall remain at least 10 millimeters from the tympanic membrane. This also generated a lot of discussion because we're wondering how consumers might know and/or measure this. It's kind of an interesting part of the regulation that manufacturers I think have struggled with, certainly the existing manufacturers and certainly others. As do you measure from the outside, where, let's say for ARIC device, the bend of the tubing goes into the ear to the end of the receiver and assume that your device is 15 millimeters long and that the average of your canal is 25.

And therefore, you're 10 millimeters from the tympanic membrane. If someone has a longer your canal, then you're great. If someone only has 23 millimeters, then in theory, you are not in compliance with the insertion depth. I think this is one that we may see the FDA come back, they're not required to. There is some indication that, you know, a year or so out, they may take a look at at all of these specifications and make some modifications if they feel it's necessary. Self versus OTC. Self-fit primarily enables the user to independently customize their devices and the settings in a manner that personalize those settings to their audiometric profile through the use of presets or let's say an app or some other tool to do that.

OTC devices typically and in regulation are those that have presets. So one for listening and quiet, one for listen and noise, one for your TV, one for, whatever ,outdoor listening to birds, et cetera. Whatever it is that that manufacturer decides the presets will be. And what really, really sets these two apart are those independent adjustments the users can make. One of the big concerns here is, of course, will device manufacturers try to skirt the 510 requirements of the FDA for self-fit devices and only submit them as OTC devices? We've yet to see how this is gonna play out. If anybody's tried to do that, most of the devices that are currently categorized as self-fit already have have received clearance from the FDA.

And that's sort of the term. They clear the devices for market, they don't approve them. So if you see devices that have approved by FDA, you know that's untrue because they don't approve devices. Some definitions, mild to moderate hearing loss is not defined, of course. That's another big point of debate. People tend to estimate, underestimate the severity of their loss because nobody wants to have a hearing loss, nobody wants to get devices in general. I should say, nobody, most people don't wanna do that. And so we now have two categories, OTC and prescriptive devices. And even within those categories now, we have a very long description of what these devices are. And so I think I thank Hearing Tracker here.

If you wanna take a look at the long list of devices that have already received clearance and/or are registered with the FDA, Hearing Tracker has that out on their website. And there may be a place you can look that up also on the FDA side itself. But you see here, the product codes that have been assigned to the five different types of OTC devices. I know I mentioned there were two but there are different codes within this OTC and self-fit. So the first one, and there's no, I don't think rhyme or reason that at least I can decipher, the QUF and the regulation number you see there, it is OTC. Those are preset OTC devices, air-conduction.

Pretty simple description. The QUG has a different regulatory number. These are presets, OTC hearing aids that have air-conduction with wireless technology. So this would be analogous. In the sort of previous regulations, we had Class one and class two devices. Class one were were regular air-conduction devices. And of course class two have wireless, which have some communication between the two devices for changing volume, changing your presets, exchanging data for directionality, et cetera. Those of us that are fitting hearing aids know about the wireless capabilities of today's instruments. The third one there. You see QDD. Not considered OTC but is considered a self-fitting hearing aid that may be sold online. Little bit different classification, QUH.

Again, these all have different regulatory numbers. The number is the same as you notice for the QDD and the QIH. This is gonna get confusing, but it is an OTC, and it's a wireless self-fitting OTC that may be sold online and stores and pharmacies, et cetera. So the way we differentiate, really, these two devices, which could be similar devices is how it's sold. You see on the first one, the QDD, it may be sold online, and the other device can be sold in other types of establishments. OSM, the last one. These are the new product code and regulatory number, which are a no because these are the prescription wireless air-conduction hearing aids. So these are the ones that we're most familiar with that we've been dispensing and fitting over the years.

And so those are the new product codes that are associated with those. Where will these devices be sold? We've already seen sort of an explosion, if you will, since the 17th. But hearing care professionals can dispense both OTCs and prescriptive devices. In the previous course, I mentioned Dr. Alani talked about, they did a poll, I believe in their course of the attendees of who already is and will and might sell OTCs. It looked at about 55 to 60%, I think. Of the people attending the course said that they were already or might dispense OTCs. And so I think is a growing trend that professionals will dispense OTCs in their practices. There's some caveats and things we'll talk about in a little bit.

But I think one of the real challenges here is the changes in the regulations as it relates to prescriptive devices versus OTCs and state regulations. This creates a little bit of a dilemma, if you will, for hearing care professionals. If you are an audiologist or hearing care professional and you are licensed in the state and you display your license on your wall, then if you sell a prescriptive device, you're certainly within your scope of practice and within your licensing scope. If you sell an OTC device, then you've already identified yourself as a hearing professional. And it could be that depending on how your state regulations and licenses are done, you may be required, even though the

manufacturer of the device doesn't provide a trial period or return, you may be regulated by those state regulations.

Remember the FDA decided against requiring a return for privilege as a part of the FDA. They felt that because this was going to be primarily, if you will, a consumer device sold over the counter that the manufacturers and/or the sellers, which could be different, would make those decisions. It isn't quite so clear for audiologists and hearing care professionals because their license, sometimes their return privilege flows through the licensing requirements. And in some cases it, it flows through consumer protections in other part of state regulation. It's gonna become a little confusing as we see states now trying to figure out how their licensing laws and/or some of these consumer protections will operate when the federal requirements go away.

So in other words, the requirement used to be to see a physician, sign a waiver. That's gone because it's no longer in the guidelines. However, that may exist in state regulations. And because there is no federal preemption, by that means federal law supersedes state law, state law starts to come into play. So it's kind of confusing. It's a topic for another day. But those of you that are dealing with that, I'm sure you understand how that's gonna affect you. Retail stores are another place we're going to see with various price points. And again, if you've already seen the other OTC lecture, you know from some of the screenshots they showed, it's all over the place in terms of the price points for OTCs from 59, $79 to a couple thousand.

Pharmacies offer OTCs. We've seen a few that announced soon after the OTC regulation became final, that they were gonna offer models in various price points. Online, of course, you can find these, and these should be OTC models, not PSAPs or hearables. PSAPs, hearables, and consumer products like earbuds, these are not considered even OTC devices. These are consumer electronics. But specifically, PSAPs are not intended for people with hearing loss. Excuse me, an association with

the OTC regulations. The FDA did issue an update, its guidance document on PSAPs to reinforce the fact that these are for specific listening situations and primarily for people with normal hearing levels for activities like bird watching, et cetera. And they are not intended.

You see that in quotes. That's the FDA's language for what the intended use is for a device. For example, you know, pacemaker's intended use is to help your heart work. PSAPs intended use are not for people with hearing loss. If you have hearing loss, the intended use is either OTC devices, a variety of categories, or prescription devices. So they're not intended for that use. We do use them, of course. We use things like pocket talkers, et cetera, potentially in nursing homes or even in counseling sessions to allow patients to hear better. But that's not necessarily the intended use for long-term wear for people with hearing loss, at least according to the FDA. So what support are you going to need if you decide to bring these in?

There was a new standard that's proposed for professional offices. In other words, you are gonna sell these in your practice. You see it there: ANSI/CTA-2051-2017. This is a standard primarily devised or developed, if you will, for PSAPs. However, because it gives you a better way to compare between devices because it requires that the manufacturer of the device provide things like the smoothness of the response and the distortion, et cetera. It makes it easier for, they feel, the FDA for consumers to compare devices. The current ANSI spec is a manufacturing specification primarily used in manufacturing. And this is our specification, we meet those specifications, we test a couple hundred devices, and then lot test them to ensure they meet the specifications.

In theory, these consumer devices will have to have a different set of testing that will be required. We're also gonna have to understand the presets in the self-fitting process of a lot of these devices. So I think in many ways, we'll see that OTCs will follow in the sense of prescription devices and that most handle one, two, maybe three brands, if

you will, of devices. And we'll see the same, I would think, with OTCs. Because while they don't have programming software like traditional prescriptive devices, and that requires you to learn three or four different programming softwares, you are gonna have to understand how these devices all work because if the consumer wants you to help them and you've sold it, then you need to be able to provide that support.

Online, in retail, many of the OTC companies have customer support and fitting support, whether that's audiologists and/or hearing care professionals or dispensers. So I think one of the issues we saw in the beginning is that a lot of, I think, people thought there would be very little or no support. And in some cases, there is not. It's only customer support if you have a warranty issue. But we're seeing more and more of them expand that customer support to have professionals involved to help consumers with the self-adjustment, if you will, or the fitting process. But maybe put that in quotes, the fitting process for those OTC devices. You're going to have to provide programming or adjustments.

And again, the support may be handled by any of these groups. So in other words, professionals, audiologists, dispensers, hearing care professionals in general, will be able to program the devices if they have programming or probably more help them with the self-fitting and/or adjustment process. The consumer may take that role themselves. We see in the latest Market Track that consumers about half, I guess about half of them are comfortable doing some of the tasks that would be required. And that is to take a test online to potentially use an app to adjust the device. The things that they seem least interested or want to do is the troubleshooting, et cetera, of the device. But that's something that if they feel tech savvy enough that they could do.

And in the third case, of course, the seller of the device may have support either within their company or from the manufacturer. You know, I mentioned that these could be two different things. And we see that in the case of devices being sold in places like

Best Buy, and Walgreens, and CVS, et cetera, the manufacturer is different than the seller. The seller is Walgreens, CVS, Best Buy, whoever. And the seller could be all of the companies that are currently out there selling devices within those establishments. So let's get to... So that's how we got here. Let's spend the rest of our time taking a look at what I'm referring to as misinformation, misperceptions, and misinfoceptions. That's a word I made up, so don't try to look that up in the dictionary.

It's not there. Misinformation, if you look it up in the dictionary, is providing inaccurate information. Misperceptions potentially is confusion about information you may have had or you just are misinterpreting it either unintentionally or intentionally. And the last one, of course, is when both occur, and that is you provide misinformation to consumers that are, in this case, looking for OTC devices and then they become confused because they received misinformation or inaccurate information about a particular device feature or how they all work. So the way that these all came about, if you will, before we go into the first one here, is Google, of course, lets you set up all kinds of alerts to give you information about gazillion things that are happening out there.

And it's setting up my alerts related to OTC. Every day, you know, I get a whole bunch of 'em and I sort of look at them. And when they seem interesting or truly are either misinformation or misperception, I drag those into a special folder, thinking that someday I might need them. And of course, I need them today to be able to continue the rest of our talk here today. So these all come from actual either websites, interviews, TV or radio, or discussions with professionals about OTC devices. And I think it's telling in the sense that because we're so new in this, it's easy to have either misinformation or misperception. So let's sort of take a look at the first one here.

This was a statement that about 48 million people in the U.S. alone need hearing aids. That was the first part of the statement, which is probably true. I mean, we don't have a

count. It isn't on the census or anywhere. But NIH and IDCD and a lot of folks have tried to estimate about how many people in the U.S. have hearing loss. I mean, we have survey data from places like NHANES and all kinds of places. And the numbers seem to be about 35 or 38 to 40 to 48 million people in the U.S. have some type of hearing loss that's causing miscommunication, which seems to be okay. However, the second part is the lion's share of those, 94% have mild to moderate hearing loss, which makes it the target market for OTC hearing aids.

Now, I guess we could do a poll, but then it might take a little bit too much time, but I'm sure many of you are thinking about that. Maybe that seems a bit high. Well, in essence, it is. This is a chart that you probably see in a lot of lectures. It was developed by using data primarily, I think Goldman Sachs was involved in the original creation of this, but it's also fed into data from Market Track and from a number of different sources to try and look at the, if you will, the market potential between unaided and aided for each degree of hearing loss. And what's most important here is we take a look at the market potential for mild to moderate is about 70% by this chart, would be the target group, if you will, for mild to moderate hearing loss.

And again, this is perceived now. So you know, obviously that number might even be smaller because everybody's gonna underestimate their hearing loss. But if we actually could run out and test those people and use some data to look at, it's probably more like 70. So in this case, I think we have a little bit of maybe misinformation trying to push the idea that these devices are just about for everybody. Now, I'm not too sure people in the severe to profound category would probably find a significant amount of benefit from the devices we are seeing, primarily because of the limited gain and output. But also their speech understanding capabilities, et cetera, don't usually make them ideal candidates, and I'll use the word ideal candidates for OTCs.

So again, a consumer sees this and says, well, gee, 94% of the people have hearing loss, I have hearing loss, I must be able to get an OTC. Probably some of them really should be in a professional's office dealing with their hearing loss if it's that extensive. So first one, this came from an interview that was done on a TV station, we won't say where it is to protect the innocent or guilty. One interesting thing, and I'm gonna read this because this is an exact quote. "One of the really interesting about the OTC devices is this was one of the rules that was part of the FDA guidelines was that they have to be sold for the same price wherever they're sold.

So if you go to Best Buy, Walgreens, or CVS, it's any place selling these devices, they should be the same price wherever you go." Well, if you remember my early slide in terms of what the FDA's responsibilities are, they are safety, efficacy, and enforcement. The FDA does not have any jurisdiction over pricing of products in the United States. So I'm not sure whether this was just a misinterpretation of part of the regulations in terms or that someone has seen that the prices are about the same in some of these devices. And we sometimes refer to as MSRP, manufacturers suggested retail price and suggested is the key phrase there, but it's just not true. The FDA doesn't control prices and certainly this could be construed as a violation of anti-trust in terms of price fixing.

So I don't think that this is something that we should continue to promote, that there's part of the rule that says they have to have the same price everywhere. This was part of a discussion at a professional meeting. Somebody came into my audiology office with an OTC from a company that's been selling in the DT Channel, DTC channel and is now OTC. None of the packaging has the required labeling from FDA, should I report them? Well, after some discussion, I made them sort of come in to understand that since they're existing, and you remember early on, we mentioned that there's a grace period for existing companies that we're assuming have the required regulations or registration, I should say, with the FDA, and that they're now selling these devices

during the grace period, during which time they are proceeding with revising their packaging, revising their labeling, et cetera.

So the answer to this question, of course, is no. If you do have somebody that comes into your office with an existing OTC product and the labeling isn't appropriate. And again, if you wanna see what the labeling is, you need to go out and get the FDA regulations. There are very specific wording, in regards to how you may assess your hearing, in regards to the warranty, et cetera, and what needs to be included in the packaging and the labeling. And so some of these devices until April will still look like they have been since October or when they're selling 'em. So no, we don't need to report them yet. Let's wait until April and then we can get on with that.

This is, again, another interview that was done on some local TV. So these devices are small earbuds. They've been on the market for a while and could not be marketed as hearing aids. There's a standard of care that comes with these, screening, fitting adjustments, expert assessments. OTC devices do not; users are on their own. There is no ongoing care after purchase. Again, I believe this is probably misinformation, in my opinion. I think an attempt to indicate that there really should be a professional involved and we can all agree that that's probably the best standard of care for people with hearing loss would be to at least see a hearing professional, have a hearing test, ensure that they do have a mild to moderate loss that would allow them, if you will, to purchase an OTC device and expect to receive benefit from it.

To indicate that there is no ongoing care is simply not true. There are companies selling, you know, used to be Lively, which is now Jabra Enhance. A number of the companies out there have audiologists and hearing care professionals on staff to provide support for people who are purchasing these devices. So I think we do ourselves a disservice when we provide and make statements that would lead consumers to believe that and then they find out that there is support. It doesn't go to

having a good professional image as providing good care to consumers. Another one, there is evidence that self-programming technology, one-size-fits-all, can be harmful. There was no data provided with this and I agree, that in some cases, it can be.

Second statement there, of course, that amplifies too much to further damage your hearing and an ill fitting hearing aid can create discomfort. Well, I don't disagree with that. I've had a number of people we've seen over the years and in my own private practice before I joined the industry, you know, once in a while, you have somebody that has issue with their ear mold or an allergy or something. And yes, we can create discomfort. Inappropriate amplification will not help enough and will not slow down the progression of your hearing loss. I'm trying to... I was trying to understand if this indicated that if you have appropriate amplification, you will no longer have any progression of your hearing loss, which I think is certainly inaccurate and misleading and potentially unethical.

Hearing loss will change whether or not you have amplification or not. It may change more rapidly if you have poor amplification and if you decide to listen to anything too loud. We have a lot of examples with that in consumers and probably the one that we don't like to have that information about is kids that have been wearing earbuds and headphones, et cetera, way too loud for way too long. That information's been around for quite some time. Brian Fielder published a lot of that data a number of years ago to show that there was some temporary and/or permanent threshold shifts from children who were wearing headphones back in the day. Those of you that might remember things called Walkmans.

But even now, you know, iPads and their phones, they're listening to things that are too loud. So again, I think we need to be careful with some of the statements that we make here that may come back, if you will, to bite us, in a sense. This is another, again, a series of of quotes that were... Or information provided in an interview. Consumers may

think their loss is mild, but they really don't know. And when you pick something that has amplification 3, 4, 5, or 10 times more than you need, you put that in your ear and you're actually causing damage. The implication here, if you will, taken at face value is that all OTCs, if you put them in will cause damage to your ear.

We know that's not the case because the FDA has issued safety regulations, and tried to limit the output. Maybe not as much as some of us would like, that's for sure. But irreversible damage is not necessarily an outcome if you use an appropriately-fit OTC device. So again, I think here, if we want to call this misperception, misinformation, or misinfoperceptions, my made up word. These are things that I think consumers just shouldn't see from hearing professionals. To maximize comfort and functionality, hearing aids must be custom fit to each individual and programed to their lifestyle. I agree in the prescription area... In the prescription devices, yes, we should make sure they're custom fitted, et cetera. The OTC devices, I think we see a number of individuals who are what I call situational wearers.

And that is they may wear them when they go to dinner, they may wear them at family functions, they may wear them at other places, at work, et cetera. And it's because in those situations, they have difficulty because of background noise. And for those folks, they may not need to be comfortable for more than a couple hours at your dinner meeting. So the next one that only a trained audiologist or hearing institute specialists can do this. Again, might be true in the prescriptive side, but in an OTC environment and for a situational where this may or may not be a true statement. And only audiologist can verify the improvement of your hearing, monitor your progress over time, make fine tunings to meet your personal listing needs.

Absolutely. I see here. This is with the capabilities to do real air measurements, although probably aren't done as much as some of us would like to see on every single patient. It is true that audiologists and hearing care professionals, we should include,

they can do probe mic measures. So, you know, what we see here is, it's a mix, if you will, of appropriate and maybe I'll call it inappropriate meetings, inappropriate information, you know, from some folks who are being interviewed either for paper, print, or TV media applications. So those are a few of the, what I'll call misinformation and misperceptions. I'd like to think that by highlighting some of these, and my intent here not was to call people out or anything else, but yes, to call out the misinformation that potentially is out there because I think we do ourselves a disservice as a profession if we don't provide fair and unbiased information about the devices.

We know these devices have been cleared by the FDA, they are safe and effective for the use they are intended for. And so we need to start testing the devices, providing clinical data on these devices, and find the devices that can help our patients either in that situational need or in a long-term and everyday wearing need that'll meet their expectations, and potentially their budget. We haven't talked about that. We've mentioned cost in the beginning and there are individuals that cost continues to be an issue. So how are we gonna get these devices into our practice? The existing prescription manufacturer/suppliers have just about all come out with devices either themselves or potentially in collaboration with some fairly well known consumer brands.

And I think this is potentially a good thing. Consumers don't, in general, we know this from Market Track, the latest Market Track, which was just published in seminars and hearing. Back in November, about 30% of those individuals surveyed for Market Track knew the brand of device they were wearing. And I'm sure those of us have a list somewhere of all the butchered names I'll call them for the manufacturers they think they're wearing. So for consumer devices to come into this space potentially gives consumers some maybe additional confidence or at least recognition that they know that brand and that they know they're not going away. They may not know all the brands of hearing aids, per se, but they might know those consumer brands.

So in the OTC area, it's probably much more important than maybe the prescriptive side. And since they already are now selling those devices primarily through professionals, but some are selling online. There are a whole bunch of new OTC companies. And again, if you wanna list, I would encourage you to look at a variety of places. But Hearing Tracker has one that just has been published recently that lists just about everybody who has registered. When you're looking at devices, make sure you exclude PSAP devices because remember these are not intended for that use. And if patients ask you about PSAP devices and they indicate they have a hearing loss or you've tested them, we need to indicate to them that this really is not an intended use of that device.

They might be better served by an OTC device, whether that's OTC or self-fit or potentially even an entry level prescription device. But we need to be, again, factual and unbiased in our information. For those of you that may or may not seen this, near the end here, I wanna talk just quickly about the customer experience. And Stephen O. Frazier who published on HTTM gave OTCs several months to sort of ramp up, if you will. And then he embarked on a journey in his local area and tried to find out what was happening in terms of OTCs. And it's a fairly lengthy article and I'm just gonna give you some very quick highlights here, which I think give us a confirmation that we're still very, very, very early in this whole OTC area.

He visited a couple pharmacies, and first was, yes, we have them, they're in the pharmacy department. When he went to the pharmacy department, he said, "Yes, we have one box. I don't know why we don't sell them." He asked if they had been trained, he said, "No, why would we be trained? We don't sell hearing aids." And again, I don't mean this to pick on pharmacies, I mean to show that we need, we still have a long way to go in terms of trying to get these OTCs out and available and also in a way that

consumers can understand what they're getting. He went to an electronic store, he said he was interested in smart hearing aids.

I can't tell you much. There's something new for us. There's a video training course on these, but it's not required so I haven't taken it so I can't really help you is the end of of that story. He went to a mobile phone store that was selling them. Asked if they had any in stock and they were told they have a single pair, they're not for sale. You can certainly look at them, but you can go take a test and then you'll be contacted by the device manufacturer and seller. Again, the experience is that it's still very, very early and even though these were announced way back in October, we still have places that we think are going to be selling these devices that still need to ramp up.

And again, training individuals, if you're talking about pharmacies, you know, 15, 20,000 pharmacies with 40, 50, 60,000, how many pharmacists work there? It's gonna take some time. Same with electronic stores, same with mobile phone stores. These folks have as their primary business something else other than hearing aids. So if you haven't looked at it, it's a very interesting article. And then I'll let Steven's description talk for itself. So summary, read the FDA regulations. If you're going to provide information to your print media, to interviews, et cetera, be sure you know what the regulations are, and more importantly, what they're not. Be sure that you give accurate information to our consumers out there, our patients, our customers, whatever you like to call them.

Decide if they're right for your practice. They may or may not be depending on what your model is. As I indicated before, probably about 60% or so of professionals that viewed the previous course in their poll said they might or are going to be selling OTCs. And I think the most important part here is you have to develop a pricing model for OTCs. It's a different product. It's a different time element, of support, of follow up, et cetera. And there was a really great talk at ASHA last year. Some of the hospitals in the

Boston area that were deciding to go into OTCs took almost a year and a half to evaluate how to do that, especially in light of the insurance.

The number of insurance that they participate in, you may or may not participate in as many as, let's say, a hospital-based system, but you are going to have to take a look at your entire practice and decide does an unbundling model, for example, work for you as it relates to OTC and then how does that relate to your prescriptive side. So with that, thank you very much. My email is there. And I think there might be a few chat questions I see, but I'm gonna let Christy handle it and she's been looking at them and see if there's something the most few important that we wanna handle. So I'll turn it back to Christy.

- [Christy] Thanks, Tom. All right, we've few in the queue here. I wanna get through as many as we can.

- Sure.

- [Christy] We have a question here from Emily. How will a consumer know when an OTC is appropriately fit?

- Wow, that's a great question. Well, first, I guess, they need to try it in the environment that they feel they need the most help in. And I'm gonna assume here that the question was sort of around those that are trying to do it on their own. So they go buy one online or go to a store and they did that because they're having trouble, let's say at dinner or when their grandkids come, for example, that's the time that you need to try it and see first if it provides you benefit. In terms of is it appropriate? And are they appropriately fit? I mean, we really only can tell if we can actually do probe mic measures.

And if they're not seeing a professional, then that's out the window. So I think the main thing is are they getting help from it? And does it improve their ability to communicate in the environment that they're trying to use that device in? And I think that's probably the best way that I can give advice to consumers. And I've talked to, you know, a few friends who have thought they were going to do it and they know I'm an audiologist and that's what I tell them. Listen, if it's for going to dinner, then go to dinner and see if it works. You know, the other thing is, of course they sit in the wrong place, and of course, they have a directional microphone, it doesn't work 'cause they're sitting with their face to the noise. So we need to be advocates and try to help them down that road. But I think that's about the best we can do for those that will be both trying it on their own.

- [Christy] Thank you, Dr. Powers. All right, we have another question here. Let's see here. Are PSAP devices not considered part of the OTC category?

- They are not. They're considered a separate class of devices. PSAPs are not in the OTC category. Certainly, they're not prescriptive devices, but they're not even in the OTC category. They have their own guidance document for personal sound amplification products. And again, the most important, I mean, it's, I don't know, 15, 20 page regulation. But the most important part of that is this intended use phrase is that PSAPs, the intended use is not for individuals with hearing loss. So you need to go to the FDA and find that PSAP guidance that came out around the same time as the OTC regulations 'cause that was required in the law that they update their PSAP guidance. So no, they're not OTC devices.

They have a separate category, which of course there's another separate category which is not even controlled by the FDA, which are the hearables and any AirPods and all those. Because again, the intended use for those is to listen to music and your phone calls. It is not intended to provide any help for people with hearing loss. So

those are outside also, at present, the FDA. Who knows if any of those will submit? But right now, they're outside of their regulatory purview.

- [Christy] All right, Dr. Powers, we have time for one more question here. A member asked what is the difference between an OTC and a self-fit OTC?

- Yeah, that's probably the most confusing part of this regulation. In brief, OTC devices are considered those that, in essence, don't have any way for the consumer to adjust them, and they wear them, I'll call it out of the box. So you take it out of the box, you put it on whether it has a battery charger or whatever you put it on, and it probably has either a button or something for you to go through presets in the device but you can't really change those in any significant way. So again, listening in quiet, listening in a background noise, maybe restaurant or maybe it's gain and frequency response changes. Self-fit OTC devices will have some mechanism for the patient or the user to change the parameters of the device.

So typically, this is through an app so that you can go in, potentially have... You know, listening to TV, listening to music, listening to whatever the signal is, and you can adjust, let's say in the example, you know, you might have a base and a treble or maybe several bass and treble type controls on a frequency in your phone. Let's say you can look at these and move these little sliders around. You might be able to create separate environments on your own for listening, let's say, in background noise. So you could go in and say you wanna create background noise and cut out all the lows. You move the sliders. You probably don't know to do that if you're a consumer, but you might.

You might know that you don't wanna listen to that background noise. So the real difference is the OTCs have presets. They could have just one. I mean, you may not have any, but you might have one or two or three presets. And the self-fitting devices

have ways for the consumer and/or the professionals to help the consumer with some type of application that lets them configure their device more appropriately, if you will, for their hearing loss. And some of 'em actually allow you to do an in situ hearing test, do a first fit and then make those adjustments. So we're beginning to see some pretty sophisticated type adjustments in some of the OTCs.

- [Christy] Thank you so much, Dr. Powers, for your insight and for your time. This is a really hot topic and I think you were just the right person to speak on it. So we thank you for your time. We appreciate everyone who attended today's course. We hope that you tune in for the following courses during this month for the summit. Thank you, everyone, and have a great day.

- Thanks everybody for attending. Thanks, Christy.