



SoundBites Podcast Transcript

Episode: Michael Scholl

Dave Fabry: Welcome to Starkey Sound Bites. I'm your host, Dave Fabry, Starkey's chief innovation officer. And today my guest is Michael Scholl, Starkey's Chief Compliance Officer and Executive Vice President of Corporate Relations. Michael joins us today to talk about developments in Washington D.C. regarding what has become a buzzword in the hearing aid industry, OTC, or over-the-counter hearing aids. He's here to help us make sense of some of the policy changes and what to expect in the months ahead. Michael, I'm glad you're with us today.

Michael Scholl: Well, Dave, thanks for having me. It's great to be here. It certainly is a timely topic with everything that's happening in Washington.

Dave Fabry: Yeah, I mean, I've been an audiologist for nearly 40 years this year, and for many of those I've sort of arm wrestled with patients to get them to use hearing aids. And although we know that accessibility and affordability is a major concern and we welcome that opportunity to provide new pathways for patients or end users, consumers, to get hearing aids, we also know that stigma remains a big part of the reason why our biggest competitor is non-compliance. The other issue is, is I think we said, "Oh, you know, hearing should really be recognized as an important health concern." And I file that under you better be careful what you wish for, because since the PCAST hearings that began during President Obama's term, and then continuing into President Trump's term, when he signed the OTC legislation into law, and then continuing recently when President Biden issued that executive order to hasten things along a little bit, I would say that we've achieved that goal because hearing has certainly got the attention in Washington D.C.

Michael Scholl: Well, when you have the President of the United States starting a speech talking about hearing aids, you know it's certainly a topic for discussion. So to your point, over the last decade, hearing aids continues and has been an issue that's now at the top of the list for policy makers in Washington.

Dave Fabry: No question. And for many years we've seen slowly insidiously hearing loss and hearing aids has crept into television and movies. I mean, A Quiet Place. And some of these places that have hearing loss or hearing aids, or these hybrid sort of cochlear implant devices featuring prominently in the role. I saw on a recent Saturday Night Live, it led with a joke about hearing loss and hearing aids. So it seems as though it's everywhere. And so we're delighted to have you on board to serve as our eyes and ears to what's going on in Washington D.C. But I think for those people who don't know you and your background, would you talk a little bit about what brought you here to Starkey?



Michael Scholl: Yeah, yeah, for sure. So as Dave mentioned, I wear a couple of hats. One is our Chief Compliance Officer and then our Executive Vice President of Corporate Relations. My background before coming to Starkey is really on the policy making regulatory front, working with organizations, both on the for-profit and nonprofit side in Minnesota, my native state of Ohio and Washington D.C., working with members of Congress and advocating for different policy changes over the last 20 years. I came to Minnesota. My wife is a native Minnesotan. So here I am in Minnesota. And when I moved here in 2008, I got to know the Starkey and the Austin family and the Sawalich family. And then came in house almost five years ago and now serve in the roles that I mentioned earlier. And it's exciting because on the compliance side, that's really the work that is done after the sausage is made, so to speak.

So having my hands in policies, related to hearing health, but just general compliance policies and healthcare, it's making sure we as a company are adhering to those policies, our own policies that we have. But then on the other side, on the corporate relation side, that is that's the exciting side, the government relations and interacting with elected officials, not only in Washington, but in each state. As you know, issues come up at the state levels that impact our industry, but some other exciting things.

Some of our partnerships that we have with organizations, I have an opportunity to lead up our Starkey Cares program, which is our corporate social responsibility program that we've recently relaunched here this year. And we've got some exciting developments coming early next year. So it's exciting not only on the compliance side, but the people and individuals, the policy makers that we get to interact with on a seemingly daily basis. And you participate in some of those meetings, Dave. You're a great ally to have when we're talking with elected officials.

Dave Fabry: Well, as they say, my expertise is a mile wide and an inch deep. And so I'm really glad that we have someone like you who can really help us stay the professionals, hearing care professionals, really see how these policies impact us in our profession.

Michael Scholl: Well, if you think about it, I mean, Starkey investing in somebody that does what I do and investing with people in individual states, and we have teams that we work with in Washington, it's really for the professional, right? Because, you know as the largest U.S. hearing aid manufacturer, there's a lot that happens that impacts us, right? And impacts our customers all across the country. So, we need to ensure that they not only have a voice in the industry, but they have a voice with policymakers in their home state and in Washington. So, I think it's something that we've been able to do over the last four to five years that's been a resource to the profession that they might not otherwise have.



Dave Fabry: Yeah. And we're going to get to OTC in a minute, but I think you just raised an issue regarding the impact of legislation and of uncertainty on the discipline. And OTC has been hanging over our heads for a long time the last several years. And I think entering into 2020, we all thought that the worst case scenario was that we would have to address this issue, which was the big unknown at that time. But boy were we wrong that ... and you really were instrumental during the COVID pandemic in the early days when there was a lot of legislation about HIPAA compliance and telehealth and all of that-

Michael Scholl: And all the executive orders.

Dave Fabry: a few times with all of those executive orders. Talk a little bit about that.

Michael Scholl: Well, I think Starkey got out ahead of the game and again, bringing resources to our customers. There was so much uncertainty happening in the country, in our industry at that time. At one point the number that sticks in my head is that there were 935 executive orders across the country. And the question was how do these impact our industry, right? How do these impact professionals? How do these impact retail shops across the country? People still need to hear.

And we hosted town halls where we talked about this. Our team analyzed to the best of our ability how these executive orders or these CMS changes to telehealth might impact their business. But I think what I'm most proud of during that time is working with our President and CEO, Brandon Sawalich and you, and our Chief Health Officer, Archelle. We took the lead that hearing is essential.

Dave Fabry: Yes.

Michael Scholl: That was a line that we drew in the sand and it became-

Dave Fabry: It became a flashpoint in 2020.

Michael Scholl: ... a flashpoint.

Dave Fabry: That the essential nature of hearing and many state governments tried to say that, "Practitioners were non-essential." And I think throughout the year, I mean, we saw in quarter two of 2020, the industry in as a whole was off about 80-85%, but it came roaring back such that by 2021, and we continue obviously with COVID during the year 2021, but our numbers now have shown that hearing indeed is essential on the basis of how many hearing aids are likely to be dispensed this year.

Michael Scholl: And look, I think states listened, right? I mean, if you look at the executive orders and the way states reacted and they would close down certain industries and certain groups, but I think only one state specifically prohibited hearing



professionals to open a retail or keep their retail locations open during the pandemic. And a lot of that was the work that we did educating those elected officials on the importance of hearing and the fact that hearing is essential. So obviously-

Dave Fabry: Yeah. And, and I'll just interrupt for a minute though, but although the eventual result was that everyone did recognize the essential nature. You were the calming force during the early days when there was so much uncertainty, many practices were uncertain, how they were going to continue to put food on the table. And the other thing I'll say is I've heard personally from many of my colleagues who said that, "How helpful it was to have you on," guiding them through the process as to how they could get the small business loans. And again, I'm not meaning to just say, but you were really out in front on that and guiding people through that process for how they could keep their doors open. Keep themselves and their patients safe.

Michael Scholl: Well, the PPP program that you're referring to, I mean, you may recall Dave, we had one of our leadership team meetings early on where we had Senator Marco Rubio, right? Join us on that call as he was the chief author of the PPP program in the Senate at that point. Right? And getting guidance from him and sharing that with our customers. I know many of them took advantage of the PPP program and to your point, they were able to keep their employees working and on payroll during that time. So, a lot of that, I think that just shows our commitment, Starkey's commitment, to ensuring that we provide as many resources and as much guidance, not only how it impacts our us as a company. Right? And all of this stuff does.

Dave Fabry: For sure.

Michael Scholl: But how it impacts our customers and making sure they have, up to date information on things that's happening, that impacts our-

Dave Fabry: Yeah. Ultimately, coming straight from Mr. Austin, the company's founder and continuing through our CEO and President Brandon Sawalich, focusing the needs on what will benefit the patient, the end-user, as well as our partners will generally win the battle. And while you may lose a few skirmishes along the way, but you'll generally win the war by focusing on the end-user and the patient. And then as well, our partners who serve that valuable role and the important and essential role of identifying, diagnosing and treating their patients with our products.

So let's a little bit into that area and in the same way, but not to the same degree, but I think there's been a lot of anxiety over OTC. When is it going to happen? And now we know it's no longer an if, but when, and we have a better idea on the timeline, and I wondered if you could talk a little bit about the situation and the timeline we're in and the uncertainty that's being removed, if



you will. We're getting more certainty as we move into this next phase with OTC.

Michael Scholl: Yeah, no, for sure. So I started in February of 2017 full-time on the inside and that's right in the heart of the OTC discussion in Washington. So, if we fast forward, the OTC legislation was eventually signed and passed in August of 2017 or passed and signed by President Trump in 2017. And the window in that legislation was for the FDA. They had four years, right? August of 2020 was their deadline. And you mentioned earlier President Biden's executive order. It was not until July of 2021 when the president issued an executive order related to hearing and 78 other different issues. And that's where I reference on, I think it was July 9th. The president started a press conference talking about how this executive order is going to help people get hearing aids at a lower cost.

And we knew something was coming. We knew we would see a draft regulation from the FDA likely within his 180 days, which he outlined in the executive order. So October 18th is when we first saw the draft regulation. Remember they had been working on this for since August of 2017. It's 114 pages as you know, Dave-

Dave Fabry: Yep. Every one of them.

Michael Scholl: every page. And so where are we today? So the regulation came out on October 18th and it calls for a 180 ... or it calls for a 90 day public comment period. And followed by 180 days for the FDA act. So that 90 day public comment period puts us somewhere around the January 18th, 2022 timeframe. So obviously Starkey, the Hearing Industries Association, our customers, patients, other industry groups, we're all working feverishly to make sure we draft our comments and make sure to make sure that they're submitted by January 18th. So, and we can come back and talk a little bit about what we're doing related to that, but from a timeline perspective. So January 18th is when the submissions are due. And then that 180 days that I referenced earlier kicks in. The FDA then has 180 days to review all of those comments and then release their final regulation, which will then go in effect 60 days after that regulation is released.

Dave Fabry: So we're looking at July, August, somewhere in that timeframe of 2022.

Michael Scholl: Summer of 2022. Let's be clear, this is certainly a priority of the President. So when we look at that 180 day timeframe that the FDA has, now if history repeats itself, they took more time than they were originally allotted. Right?

Dave Fabry: Okay.

Michael Scholl: So will they take the entire 180 days? We don't know they could move-

Dave Fabry: It could be faster than 180 days.



Michael Scholl: It could be faster than that, right? If they decide that it only takes them 60 days to review all of the comments and then release their final regulation, it could be spring of 2022.

Dave Fabry: Okay. So that's good clarity.

Michael Scholl: Good clarity. On the long end, late summer. It could be as early as spring of 2022. Chances are that July timeframe I think is probably going to be the sweet spot.

Dave Fabry: So can you talk a little bit about from the role of the industry, from the professionals and from end users, consumers of this category? Certainly we welcome and embrace the accessibility and affordability and the new competition that will result from this new channel. But what about safety and efficacy that concerns you, and I know you're not speaking in a formal capacity for anyone, but you are a chief compliance officer. And ...

Michael Scholl: Well, if we look back, back in 2017 and even before, Starkey was never opposed to expanding access, right? We just wanted to work with Congress, the Trump administration at that time to make sure that we did it the correct way. And that really led to the consensus paper, which came out in 2018, Dave, which you are-

Dave Fabry: I was part of.

Michael Scholl: ... played a very big role, and you're very familiar with, and that was the document five key points in that consensus paper that really focused on patient satisfaction, safety, above all, making sure that there were consumer protection elements that they were labeling, right? Efficacy. There were five major points that we used as a company and the industry used and other organizations that supported that.

Dave Fabry: Yeah. You said consensus documents. So in addition to the HIA representing the major manufacturers-

Michael Scholl: Manufacturers.

Dave Fabry: ... it also included ASHA, the American Speech Language Hearing Association, American Academy of Audiology, American Doctors of Audiology And IHS, The International Hearing Society. Was-

Michael Scholl: And HLA I think-

Dave Fabry: HLA, yes. Yeah. Hearing Loss Association.



Michael Scholl: ... supported it. So that document is what we used in 2018, 2019, when we would meet with individuals at the FDA, right? You're now tasked with drafting this regulation. We encourage you to follow what is laid out in this consensus document. When we would meet with members of Congress or others on the Hill, we would have that document in hand. And we would encourage, if you're weighing in with the FDA, these five points are how we believe we can go about creating a safe and effective OTC category. And now if we at the regulation, the proponents, Senator Warren, Senator Grassley, others who really push this, they're focused on access and affordability.

Dave Fabry: Correct.

Michael Scholl: Which, obviously we support greater access and, affordability for hearing aids. But we can't forget about safety and satisfaction. We can't have access and affordability if it means compromising revising with safety and satisfaction. So, I'll speak to a couple of the kind of high points in the OTC regulation and feel free to chime in with your expertise. But from our perspective, we really break it into three categories, right? That safety and satisfaction category. The consensus paper had a recommendation of a maximum output of 110 decibel and a maximum gain of 25. As you know, Dave, in the regulation that has been released, you have the ability to have a maximum output of up to 120 DB, and they do not include a maximum gain. I think what's even more surprising is if we recall this category, this product, is designed for individuals with perceived mild to moderate hearing loss.

Dave Fabry: Correct. Let's go back though for a second to the 110 to versus 120. Now, professionals know that that 10 DB difference on a logarithmic scale is a big difference. A layperson might say, "Oh, 10 decibels. What's that?" Barely noticeable. Well, two sounds that differ in their intensity by 10 DB will sound twice as loud. One will sound twice as loud as the other. And we feel plays considerably greater risk to the individual if they're listening at 120 decibels over the course of a day than if they're listening to 110 decibels of output. So we'll come back to that. But I just, I want to frame that within the context of 10 DB, what's the big deal? That's a big deal.

Michael Scholl: And so our task now is to educate the FDA, educate elected officials who will formally weigh in on this rule for them to understand the impact of 110 to 120, Dave, you may recall we were recently at a football game, right?

Dave Fabry: Yeah.

Michael Scholl: And inside the stadium on third down the home team, they always crank up the music and the crowd goes wild and they have decibel readings, readers. And recently I saw it as high as 119 decibel indoors. And there were people around me that were commenting, "Boy, it's loud in here."



Dave Fabry: People covering their ears.

Michael Scholl: People covering their ears. Right? And my thought, and I told you, "Well, think about it. This could be an over-the-counter hearing aid."

Dave Fabry: Right. It absolutely could. And 120 decibels, in addition to that, that crowd noise during that point in the game is similar to other sounds being in close proximity to jet aircraft and firearms. And it's getting in a level that can not only be damaging to the ear, it can be downright painful to some people.

Michael Scholl: But difficult for people to realize-

Dave Fabry: To comprehend that.

Michael Scholl: To comprehend that. Right.

Dave Fabry: Yeah.

Michael Scholl: Right. So, the safety piece obviously is primary. We have to educate. We have to make sure the FDA understands going to 120 and not having maximum gain could have some real negative impacts and could actually cause more damage to somebody's hearing. So that's a takeaway of the regulation as written. Another area is preemption. So what does that mean? Well, right now, states really regulate hearing aids sales, licensing across the country. The FDA has some regulatory authority, but it really relies with states. And as you know, there have been 17, 18 state attorneys general who have weighed in over the last year about companies selling over-the-counter hearing aids before that category even exist.

Right? So that just goes to show you of the state's authority in this area. So one of the provisions in the original OTC bill was a simple paragraph that preempts state law. So, this new category will now preempt any state laws governing over-the-counter hearing aids. So, we were expecting for this new over-the-counter hearing aid category, that it would be pretty clear that you wouldn't have to be licensed, right? You wouldn't have to see a professional, that it would preempt some of those burdens, because this is now an over-the-counter hearing aid. Our concern with the way the preemption language is written is there's the potential to preempt state laws that regulate any hearing devices. So it sets, the OTC regulation creates two categories. It creates OTC hearing aids, and then a new category of prescription hearing aids where everything else. And then there's PSAPs over here. Don't forget we have to talk about.

Dave Fabry: What's a PSAP?

Michael Scholl: So, the personal sound amplifier, right, is just that. It amplifies. It's not designed as a hearing aid. You can't market it as a hearing aid. It's not designed to help



somebody with hearing loss. It's simply... a lot of bird watchers and folks use them to amplify noise. So with the OTC regulation, one of the asks was to finalize a PSAP directive that came down in 2013, which the FDA does in addition to the OTC regulation. But I want to come back to this, this preemption piece, think about it. If this regulation were to preempt state laws governing hearing devices, then not only professional involvement, but return policies, warranties, anything that a state currently governs may go away.

Dave Fabry: It goes away. Yeah.

Michael Scholl: And the FDA is already ... and this would move hearing aids from restrictive devices into a category of non-restrictive devices. So the marketing claim enforcement, et cetera, it would be left to the FTC, right? The FDA and states are losing a lot of authority with this. So this is really concerning because we know how important that these laws are there for a reason, right? So now if you've got people buying products and that they don't work, and there's no mechanism for return or for refunds, that's not only going to hurt that person by not getting the help that they need, but the industry in general. It's going to impact the reputation of the industry. And you know, Dave, what the last more market track, it's 89%,

Dave Fabry: 83%.

Michael Scholl: 83%.

Dave Fabry: But that's higher than cell phones. It's higher than a lot of consumer electronics.

Michael Scholl: So, when we talk about safety, we talk about satisfaction because people that are getting the help that they need, they're satisfied with that help. So that preemption piece and how it impacts states will play a ... it's something that the FDA needs to clarify of what is preempted for OTC categories and what is not preempted for traditional hearing aids? And then the final piece, I hit upon this a little bit that I think we certainly will weigh in on is the consumer protection piece. Making sure that the right labeling requirements are in place, right? These are designed for somebody who has perceived mild to moderate.

Dave Fabry: Right.

Michael Scholl: You don't have to take a test. Really, the only guidance is looking at the labeling on the outside of the package, right? The FDA believes that you can pick up the over-the-counter product, and you can say, if this causes more damage or you don't get the help you need, return it if doesn't work or find something else, that's the only mechanism for individuals to buy this. You have to be above 18, but there's no enforcement that that will ...

Dave Fabry: Just the labeling. The labeling.



Michael Scholl: It's the labeling, right? It's not behind the counter where you have to show your ID to buy this. So the only really consumer protection is the labeling. Not only on the outside that's on the inside of the package. Well, if I buy it online, Dave, how do I read the outside of the package? Right? We've got to be clear that there's some mechanism to ensure that the patient is protected. So from our perspective, and I know Dave you're doing a lot of work with HIA, and obviously internally at Starkey, but that safety satisfaction, this issue of preemption and who now has enforcement authority, and then just the consumer protection. Those are three buckets that we will certainly be weighing in with the FDA on.

Dave Fabry: Yeah. And I would just add that last part that you talked about, perceived mild to moderate loss. We were a little surprised that there wasn't more clarity precision regarding the definition of mild to moderate. And a lot of attention has been focused on the upper end of that in that maybe those individuals with more significant loss who might need the help of a professional, because they have more complex listening challenges provided by their hearing loss.

I think another part that has been not been given enough attention is on the low end. That if someone perceives that they're having difficulty in the four environments that are in the bill at the present, the regulatory guidelines, that maybe they have normal hearing. And then go back to that situation where we were in the stadium, and it was close to 120 decibels. The implication is, well, if you try these over-the-counter products and they don't work, no harm, no foul. Then you can go see a professional and get more help if needed. But the issue is, is some damage may already have been done if you're listening at levels that could cause hearing loss.

Michael Scholl: Well, absolutely. Right? And then the other piece is if you buy this product and it doesn't work and it doesn't help, are you truly going to then go see a professional, right? Or have you bought a hearing aid and it doesn't work? That goes back to the satisfaction piece that we talked about earlier, but I think it's a major concern. And I think the FDA, I hope they embrace this, but being that it is perceived mild to moderate and the way this is currently written with output and gain, you're the expert, but you could go out and purchase a product that could absolutely cause more damage to your hearing.

Dave Fabry: Yeah. I mean, I make the analogy. I mean, you can buy over-the-counter Tylenol rather than prescription strength Tylenol, and it is still possible to overdose on over-the-counter Tylenol.

Michael Scholl: Right.

Dave Fabry: Similarly, it is possible at these levels with this output level for someone unknowingly to listen at levels that could cause them to overdose on audio, and provide a noise induced hearing loss that ironically OSHA or NIOSH would protect workers in noisy environments from levels that are going to be possible



in these over-the-counter devices. And if someone has just a little bit of hearing loss, but they perceive that they're having more difficulty, it makes them especially vulnerable to more damage that occurs and that's ... Again, I go back to the safety and satisfaction or safety and efficacy issue.

Michael Scholl: And we get one opportunity, right? We get one opportunity to get this right. Professionals won't be involved with these over-the-counter products. So, we've got to ensure that all of the guardrails are there to make sure safety and efficacy is incorporated.

Dave Fabry: Well, thanks for going over those details and for additional details on this. I know that you've led the development of Listen Carefully, an advocacy program. Talk a little bit about what motivated you to want to have this resource available. And how do people find it?

Michael Scholl: So, over the last few years, certainly back in 2017, but then in '18 and '19 as developments would occur or issues would pop up at a state level, I often get calls or e-mails from customers, patients, what does this mean? What can I do? And our own team internally asking, "Well, what do I share with our customers?" And it was pretty clear to us, Dave, that I harken back to that president's speech when he talked about hearing aids, that this was going to continue to become a topic. So, what tools could we put together where folks can go to on a regular basis to get the most up to date information? And that's why we decided back in August to launch Listen Carefully and it's listencarefully.org.

And it is designed to be a repository for anything and everything that's happening right now in Washington. But as we get into 2022, that's when the state legislatures start to come together and they may have legislation that impacts our industry. So, right now it's designed to focus on what's happening with over-the-counter hearing aids, Medicare, which we can talk a little bit-

Dave Fabry: Mm-hmm (affirmative). Yeah, lets.

Michael Scholl: ... if we have time today and then even hearing protection, right? What can we do on hearing protection to prevent some of this hearing loss? So listencarefully.org is that repository where whenever something happens in the industry, that's going to be the first place where we update. And we've had over 6,000 emails go to elected officials on the Medicare topic because that's what we were focused on until this OTC reg came down.

And so after the holidays, after Thanksgiving, we're going to move, listen carefully from a Medicare focus to an OTC focus from the perspective of taking action. Right now, if you go there, you take action. It's focused on Medicare, but I just walk through those three buckets of concerns. There will be documents and information on Listen Carefully after the holidays where people can go and



they can start submitting letters of the record of their own letters to the FDA as to why we should take into account the 110 max output, or there should be a max gain. So, we need all of our customers. We need patients with hearing loss to proactively participate in this FDA comment period and the tools and resources that you need to submit a letter will be there on listen-carefully.org to continue through with that process.

Dave Fabry: Fantastic. Well, and we'll stay tuned to keep watching for updates, which are made as they happen.

Michael Scholl: As they happen. And many folks have signed up on the e-mail list. So there's e-mails that come from Listen Carefully and from Starkey. So when it's ready to have folks start submitting comments, we'll absolutely alert you. And look, we have what we suggest that you say, or at least include. And as patients, individuals with hearing loss or professional, we encourage you to include your own comments, right?

Dave Fabry: Yeah.

Michael Scholl: If you've got stories or if you've had patients that have come in and they had an experience with an over-the-counter product that didn't work, absolutely you should include that. But as an industry, we need to make sure that we have as many people as possible submit comments with their own unique experience.

Dave Fabry: Excellent. Well, you mentioned Medicare expansion. We know the OTC legislation has been signed into law. Now these final regulatory guidelines are unfolding. Talk a little bit about Medicare expansion. I know there's a lot more uncertainty with that because it relates to big dollars and being included, really. It's a small component of much larger Medicare expansion bills. But talk a little bit about what that means for the hearing industry, for patients again, and for professionals. Potentially.

Michael Scholl: If OTC wasn't enough, we have to deal with Medicare. At the same time, we could spend another hour talking about Medicare, but high level where we stand. The expansion of Medicare to cover hearing, dental and vision has been something that has been pushed for the last decade different members of Congress, specifically Senator Sanders, Bernie Sanders of Vermont. This is a priority for him to accomplish. So, everybody's talking about this BBB, this Build Back Better. I call it the reconciliation package because that's what it is. This is a package that Democrats, since they control the United States Senate, and since they control the House of Representatives, they can pass without Republican support. But they have to have every single Democrat in the Senate support that. So, there's a reason why over the last couple of weeks or months, really, you've been seeing so much attention focused on Senator Manchin from West Virginia and Senator Sinema from Arizona.



Because if they lose either of their votes, then they don't have the 50 votes that they need to pass this. So the Democrats or the party in charge can pass reconciliation once a year. So they have one opportunity to do this. So when this topic came up, again, August timeframe that there was this consensus of a framework of a reconciliation package, that framework back in August included Medicare expansion for hearing, dental and vision. And it was clear to us that we needed to do everything that we could do as an industry to make sure if this is going to happen, it happens in a way that both benefits the end-user, the patient, but ensures that hearing professionals are accounted for as well. Right?

Dave Fabry:

You mentioned earlier about the satisfaction with hearing aids being 83%, according to the latest Markettrak survey of potential hearing aid users and existing hearing aid users. The other thing that often is overlooked is that that satisfaction with the hearing care professional was just as high. So they really existing hearing end users, even some of those PSAP users that you mentioned said that they feel that the role of the professional was as critical as the technology. And I think that's something that the Medicare expansion really needs to ensure as you said not only the payment for the devices, but the support for professional services.

Michael Scholl:

Well, exactly. And the way that the legislation had been drafted in previous Congress, there was a lot of uncertainty around that. So as an industry, we made the decision that if this is going to take place, we have to ensure a couple of things. We have to ensure that a hearing aid is a prosthetic device, and it's not a cane. It's not durable medical equipment. It's something that you can constantly refine and tune and make better. So, it has to be a prosthetic device. Number two, individuals have the ability to upgrade, right? I mean, Medicare may cover X product. And if you want more, a premium and more features, you have to have the ability to upgrade out of pocket like you can today with many third party and insurance programs. And then finally from an access standpoint, if we want to improve access, we need to make sure that individuals with hearing loss have as many access points as possible.

So, not only can you see an audiologist, but you have the ability to see a hearing instrument specialist to be tested and fit for a hearing aid. So, those were three big issues that we pushed for. A lot happened over the months. Right? Manchin said this, or Sinema said this, and it was in, it was out. But at the end of the day, the version that passed the House of Representatives recently does include Medicare expansion for hearing. And those three pieces that I mentioned are included in that. So, you know, it's encouraging. Yeah. I think as an industry, we really did a good job of educating elected officials. If you're going to expand Medicare coverage for hearing, then you have to do it this way. And that's what they've done thus far, but it's only passed the House.

Dave Fabry:

Yeah. The Senate is an uncertain future.



Michael Scholl: The Senate is an uncertain future. I was on the phone this morning with folks in Washington trying to get what's the latest lay of the land. And the House passed the bill. It goes to the Senate. As you might imagine, people are on recess now, but they're going to review all of this. And the Senate will adopt their own version. I think it'll be pretty similar to what the House adopts. And then the question is, can they get the 50 votes to pass the broader package, reconciliation package. But we'll continue to work, continue to, to do our best as an industry to make sure that the language is as tight as possible. Because with anything dealing with Medicare, Dave, Congress can only go so far. And then it goes to the Centers for Medicare & Medicaid Services.

They really dictate the final regulation and how it's implemented. So, we want to get as much in statute as we can to make it clear, these things have to be part of the process, but then CMS has the ability to finalize how it will be implemented and how it will impact providers. So, I think we made a lot of good progress, but question number one is, will it go into effect? And if it does, then we need to spend a lot of time working with CMS to make sure the final regulation is as we see. Similar to OTC, right? Congress passed it, but yet it's left up to FDA to write it. Well, this is a similar situation with Medicare coverage for hearing.

Dave Fabry: Yeah. And so stay tuned to listencarefully.org for updates as they happen. And I think I'm sure that the industry and hearing care professionals feel the impact of these disruptions. Disruptive innovation has become a buzzword, but we feel like our traditional model where it is, professional driven in the healthcare system, and then on the other end, OTC is creating this non-prescription approach that doesn't necessarily involve the role of the professional. And the professionals probably feel like they're being squeezed in the middle by this. But the beneficiary in my mind, long-term, can potentially be the patients in the sense that if it provides access, affordability, while ensuring safety and satisfaction, that if more than a third of the people in the U.S. who have hearing loss use hearing aids, everyone will win. And I think for professionals and for the industry, it can potentially end up being the best decade ahead if we're raising awareness even further and reducing stigma around hearing loss and the use of hearing aids. And it can be good things.

Michael Scholl: Yeah, but I just, again, a plug for Starkey, I mean, it's really important the work that we're doing, right? Because if we weren't at the table in Washington, in these state capitals, who knows what the final regulation for OTC would look like, who knows what the Medicare regulation would end up looking like. Right? So again, because we're active, because we've invested time and resources and energy to working with members, I think we may end up to your point having the best decade in a long time.

Dave Fabry: Seat at the table may not always be comfortable, but I'd rather have a seat than be in the other room. Absolutely. So with all of this experience and your five



year, six years at Starkey, can you talk a little bit about what advice you might give professionals based on your experience? What pearls of wisdom do you have other than those that you've already dropped here?

Michael Scholl: Well, when I've given talks on this topic before, I don't want to sound repetitive, but I can't highlight how important this is for folks to be involved at their state level. Right? Everybody has a member of Congress. Everybody has two United States senators. Those people have a lot of influence. And I think Starkey has done a good job at setting the groundwork. If you talk to your member of Congress, if you talk to your Senator, I bet they know who Starkey is. I bet they know a little bit about the hearing industry that they wouldn't have known five years ago, but we're just one manufacturer. And I know it may be for some uncomfortable and out of their comfort zone, but really reach out and try to build a relationship with your elected officials at the federal level and the state level. Having that seat at the table that you just mentioned is so important.

And hearing from a manufacturer is one thing, but hearing from professionals who see patients every day and know the trials and tribulations and the stories that these people are going through and how getting the proper hearing help impacts their lives, that's so much more powerful. So, reach out. Reach out to me. Reach out to our team. And we can help you put you in contact with these people. Some of you know, I reach out if we have something in a certain state and proactively say, "Will you help us with this or help us with that?" But being involved, that's how we influence the future of our industry and the regulatory regime that we may, or may not see. It's so, so important.

Dave Fabry: That's great, Michael, and you can be reached at Michael underscore, S-C-H-O-L-L@starkey.com.

Michael Scholl: That is correct.

Dave Fabry: So, advocacy starts at home and in your backyard. And so people can, if they're looking for ways and they're really not certain what to do, I just gave them your e-mail so they can get to you.

Michael Scholl: There you go.

Dave Fabry: Okay. So, we call this podcast Sound Bites. So a thing I'd like to do is maybe hit you up on a couple things of what are some of your favorite sound bites? And let's start with one in terms of, I've always said that movies without music really would be a very different experience. And whether you're thinking of a movie soundtrack, like something, my personal favorite would be Purple Rain. I don't think that's your favorite, but what's your favorite movie soundtrack?

Michael Scholl: Yeah, that's a good, I'm going to give you two answers.



Dave Fabry: Okay.

Michael Scholl: One is going to be the easy answer. Anything that John Williams had a hand in, right? To me it is unbelievable. We had an opportunity. He was touring some years ago where he would travel around the country and conduct the local orchestra and then do all of his movie scores. Right? And it was an unbelievable experience. And now having young kids who are watching the Harry Potters and the Star Wars and the Jurassic Parks, I get an opportunity to relive some of those. The other one, Dave, you know, I'm kind of a music person.

Michael Scholl: I think it's hard to beat the soundtrack from Saturday Night Fever. I think the Bee Gees are probably the most underrated band of all time, even though they're top five and all-time album sold. And number three in number one hits. That soundtrack just has so many classic hits on it. It's hard to beat.

Dave Fabry: Well, it sets the tone from the moment the movie opens and John Travolta's walking down the street and you just see his legs and walking to the beat of the original, the opener song. And so I'd agree with you on both accounts.

Michael Scholl: It did not win an Oscar. The Bee Gees won every award possible. And that was the soundtrack that was up for an Oscar. And I don't remember what did win, but it did not. They did not win an Oscar for that soundtrack, but ...

Dave Fabry: Good trivia. Okay. So now what about when you think about the power of the spoken voice to communicate? And we talk about Helen Keller's words that is, vision bringing in the beauty of the outside world and hearing connecting people to each other. When you think about your favorite celebrity voice, whether it's in commercials or whether it's in movies or whether it was a character that they play, do you have a favorite celebrity voice?

Michael Scholl: I mean, I think it's pretty hard to beat James Earl Jones. I mean, his voice stands out as I think heads and shoulder above others. The other voice, and I'm not going to get the name. You may know, Dave, that's more recent is, you speaking of commercial, and he was in the series Billions, is the Home Depot commercial. The voice of the gentleman who does the Home ... If you heard it.

Dave Fabry: I'll be listening for it now. Yeah.

Michael Scholl: He's in a couple of a couple of different commercials, but I think generally, I mean, James Earl Jones is hard to beat.

Dave Fabry: Yeah. I mean, Darth Vader. I mean, how can you beat him on that? As well as all the other voice work that he's done. Okay. Last one, what is the quietest place that you've ever been or that you can ever remember being the quietest place that you've ever been? Natural or otherwise.



Michael Scholl: Quietest place?

Dave Fabry: Mm-hmm (affirmative).

Michael Scholl: Certainly not my house.

Dave Fabry: Nope. Mine neither.

Michael Scholl: I would say probably hiking or in the Tetons. Right?

Dave Fabry: Okay. Yeah.

Michael Scholl: In the mountains, naturally quiet. Not a lot of or no people around. Right? Occasionally you may hear a bird or a waterfall, but it's just, it's extremely quiet.

Dave Fabry: Excellent. I had an opportunity to interview Gordon Hempstead, a guy that does a lot of movie work with audio recordings. And he is in a search for finding the quietest centimeter on earth. A centimeter being roughly the diameter of the microphones he's using. He'll never reveal because he wants to keep them free of noise pollution. But I got kind of a wink when I suggested that the Boundary Waters Canoe Area in Northern Minnesota is one of those quietest places.

Michael Scholl: What is your-

Dave Fabry: I've been there. That's my place.

Michael Scholl: That would be yours. The Boundary Waters. Yeah. So we're not-

Dave Fabry: We're not far off.

Michael Scholl: ... too dissimilar there. Yeah.

Dave Fabry: Yeah. Nature.

Michael Scholl: Right.

Dave Fabry: So, all right. Well, to our listeners, I want to thank Michael on their behalf for what you've done for the industry, for Starkey. And as a colleague, I can really say that I've enjoyed working with you these last five years. And I look forward to the future as well. We've got a lot in front of us, but with that uncertainty, I think, as I mentioned at the start, you are a calming influence and with your connections and with your experience, just keep me from being... I come from a long line of overreactors and I awfulize everything when I first hear about it, but I really appreciate what you do to bring that stable force and a sense of direction as to the uncertain environment that we live in. So thanks for sharing that with us today.



Michael Scholl: Well, thank you. Thanks for having me. And as you mentioned, there's a lot happening. I'm most certain that we'll have opportunities to do more of these down the road as things continue to change, not only in Washington, but across our country. So thanks again.

Dave Fabry: I look forward to that. And to our listeners, thank you for listening to this episode of Starkey Sound Bites. If you'd like to learn more about Listen Carefully, please visit listencarefully.org. If you've enjoyed this conversation, please rate and review Starkey Sound Bites on your preferred podcast platform. You can also hit subscribe to be sure you don't miss a single episode. See you next time and thanks for listening.