



## SoundBites Podcast Transcript

### Episode: Brandon Sawalich on new OTC regulation

Dave Fabry: Welcome to Starkey Sound Bites. I'm Dave Fabry, Starkey's chief innovation officer. This is a special edition of the podcast that follows on the heels of the FDA's final regulatory guidelines for the new over-the-counter hearing aid category that came out of Washington in mid-August.

Hearing care professionals have been seemingly waiting for forever. It's been a little bit like Waiting for Godot since 2017 when the bill was first passed, but now we have better insights into the direction and guidance that the FDA is providing for this new hearing aid fitting category. Joining us today on the podcast is Brandon Sawalich, Starkey's president and CEO.

Brandon. Welcome back to the podcast.

Brandon Sawalich...: Well, thanks Dave. I appreciate it. And a lot of good things going on in our industry that require a good conversation because it's opportunity.

Dave Fabry: Well, yeah, and we've seen and heard an awful lot about these FDA final regulatory guidelines and first of all, I'd say, should we just roll up the sidewalks? I guess we're just done now, right? If all of the worry and fear over the last few years, I guess let's just go home.

Brandon Sawalich...: Well, I started at Starkey in '94, and I remember hearing those comments. You and your career have heard those comments ever, it's nonstop. And quite frankly, we know the industry, we know the patient, which is more important, and we know what better hearing looks like.

And if anything, over the counter, it's a new category. It's not like it's something new that we haven't been around in the last 20 years where there's catalog sales and such. So, okay let's get more people into the wanting better hearing and amplification and then educate them on what the options are because others have it wrong.

Dave Fabry: Yeah, and I think you raise an important point and a good reminder for those of us who've been in this industry for a long time. We have to remember the sobering statistic is our biggest competitor is not brand A, B or C, but non-compliance.

Two thirds of the people who have hearing loss don't do anything about it. And so if this new swim lane, if this new channel does raise awareness for the importance of hearing and gets more people to consider using amplification, we believe as you've emphasized and been dead fast on this all throughout this process, our technology in the hands of the professional delivers the best



outcomes. But now that we have this new channel, if it raises awareness for and adoption of hearing aids, then it's a good thing.

Brandon Sawalic...: It's a great thing. I mean, if the VA is not our largest customer and more and more veterans need hearing in 10 years, I hope they're not because we can do so much on the upfront to help active military men and women. The same thing goes with what we're looking at here is where people assume they know the industry and the patient, and then hearing loss and it makes for good articles. And it's like our industry's kind of becoming a little bit of some of the media on TMZ about hearing aid cartel. And it's laughable because you have to care.

And at Starkey, we care about the technology and helping more people. It's not profit over people. It's helping not selling. And we provide the products that they're deregulating and our only concern for seven years and even previous as this has come up has been the confusion that this is going to cause with seniors from bad actors, right? The \$100 amplifier that they call a hearing aid is not a hearing aid that you buy from a professional hearing healthcare provider.

Dave Fabry: So, well, let's look under the hood a little bit. You've had a front row seat to all of this with your role as CEO and president at Starkey, but also your past chair of the Hearing Industries Association. And you've been involved in this from the start. What happened in the final regulatory guidelines, anything surprise you or anything that you want to raise to our listening audience?

Brandon Sawalic...: I believe the FDA did a good job for the task they were asked to do. They didn't come out with this law. This has been what, six years in the making and it's complex and they're trying to, what we know is not a commodity, trying to make it a commodity and a consumer electronic.

And I believe that we provided good insight on the output with your help and what that means to somebody looking for better hearing. Nobody knows what mild and moderate is. It's not a cholesterol score for your hearing. So the two things, it's the preemption and by states where that's going back to the '70s and '80s of really, again, the bad actors that could mislead people and really I'll say provide a bad reputation for hearing aids.

And then the unlimited gain. That's surprising, because we know what Apple or even other consumer electronics do for their products. Why would a hearing aid have unlimited gain? That one was a little surprising, but again, they were tasked with a hard job and as I said, they did the best they could and we adapt.

Dave Fabry: Yeah. I share your opinion on the gain. I was pleased that they responded to the science and the input from the professional communities that provided evidence, that those output levels that originally were drafted by the FDA were too high for someone with perceived mild loss who may have normal audiogram, audiometric thresholds. And so bringing that down a little bit, I think



will provide some patient safety. The gain, as you already mentioned, remains a concern.

I think there's going to still be some voices heard from those attorneys general who had spoken up previously and wanted to be able to provide consumer protection at the state level, from those bad actors that you mentioned and really the lack of clarity on a return policy could mean that someone might spend less money overall, but without a well defined return policy that is in play, they could be out more money out of pocket ironically than if they'd gone through the professional channel and had that professional work with them to achieve an optimal result. So TBD on that.

Brandon Sawalic...: And I think from when this bill started to where it's at now, there's a lot of unintended consequences and it's going to happen and nothing's ever perfect, but it's also others that don't know what the patient as you do, somebody's sitting there that really needs that hearing help, you're not going to get that off the shelf. And I don't care if it's mild or moderate, you've got to make sure that every ear, as we know, we've talked about many times is different, but you've got the right product.

And the other word and interesting to hear your perspective too, is the other word that has been coming up in the last two weeks because of this came out the media and the interviews, prescription. It's like, this is a commodity, it's a pill or it's write a prescription for your hearing aid. And that's not the right terminology. This isn't a prescription. This is something that you're going to see a professional about. And you're choosing based on your lifestyle and that professional's choice of what you're going to do right there in the office. You're not going to write a prescription and then just go to the pharmacy and pick it up.

Dave Fabry: You raise a really important point. And just for clarity, I'll back up one step. So for those who haven't been following this as closely as we have, the over-the-counter category that the FDA created really has two subcategories, there's over-the-counter hearing aids, and then there's non-self-fitting and self-fitting devices. And then the other one, as you mentioned, the traditional channel that we've known, and that has been regulated by the FDA in the past, now they've referred to this as a prescriptive category. It involves the professional doing the diagnostic testing. Interestingly, because as you say, the prescription really is whether an audiogram serves as the central point.

We know all too well from the work that Starkey's done around the world, that the audiogram is an overly simplistic assessment of a person's disability that they have with their hearing loss. Most of what we're hearing it would be as if you went in for an eye exam and they just shine very faint light to see what you could see instead of asking you to have acuity on the Snellen chart.

And there's so many things that the professional can do to really assess the individual's difficulty that they're having, that go beyond the audiogram or the prescription. So even in that respect, but simply put, the prescriptive category and the label that's on that isn't like a medication, but rather it's the auditory and non-auditory challenges that a person who is having hearing difficulties or hearing and balance difficulties experiences, and that differentiates now from over-the-counter self-fitting and non-self-fitting category. And I won't go deeper into the weeds on that self-fitting, non-self-fitting because it's really for the regulatory agents and the attorneys to hassle over what's self-fitting and what's non-self-fitting.

Brandon Sawalic...: And the prescription and I bring that up because of the media, the interviews I've been doing, that's what they go to. And again, that's where the unintended consequences of they think they're reporting on so much other health and other news, they hear the word prescription. That's what they easily relate it to and then that causes confusion. And that is not our industry and how we look at it.

An opportunity for us to educate? Absolutely. Hearing healthcare professional associations should be stepping up and I hope to do the same thing, because it's their profession, they're the provider. So it's not that we're against it. We just want it done right because patient satisfaction is at an all time high of 88%.

Dave Fabry: Absolutely. And I think there's also this impression that while accessibility and affordability are very important barriers for some people, there isn't this expectation that we're going to go from 37% of the people who have hearing loss and don't do anything about it now will suddenly those other 63% are going to all wear hearing aids because you and I both know, stigma still remains, challenges still remain for beyond the accessibility and affordability.

I'm all behind anything that improves access, but safety and accountability is important as well.

Brandon Sawalic...: Stigma is number one. I mean, we give hearing aids away for free. Countries around the world, as we've mentioned many times, and others didn't seem to want to listen or hear that, but their states, Medicaid, other types of programs that give them away for free. People don't want one until they have to have one. And it's usually for their career, their family, it's a certain age that okay, time to do something about it because you're not going to die from hearing loss. Right?

Dave Fabry: And so I guess our advice then for people who think that they have a hearing loss, if they're listening and they've been confused by what they're hearing in the media or what this category creates, you can go to [starkey.com](http://starkey.com) and take a screening test. You can go see a professional. I mean, I realize, again, for many, that's been a barrier that this OTC channel is created by, but if you want to just do it from an app or from a website, you can do that at [www.starkey.com](http://www.starkey.com).



You can go and get a test from professionals in your area. We can refer you to one, if you want to do and even if you don't want to do anything. But then any other advice for patients or end users who are contemplating trying a hearing aid and want to try out this new channel, when it becomes available in October?

Brandon Sawalic...: Ask questions, be curious, know what the service levels are. What's the warranty, what's the return policies, because that's where, as we mentioned, companies put profit over people and this industry is about service and care and if they're looking into this new category, make sure you're just being curious and asking the right questions.

Dave Fabry: And any advice for professionals as to how they're going to navigate this new environment. Should they be considering stocking over-the-counter hearing aids in their practices?

Brandon Sawalic...: Yes, they should have an option in their practice and advertise it on their website, or however they do it in their community. Because if it's a new category, a hearing professional should have that as well, because it's about the art, right? You provide the science, but the hearing professional is about the art of the fitting and understanding and connecting with that patient for them to hear better and then they get to live better.

Dave Fabry: And for those who do work with us professionally, thank you for your partnership if you're listening to this, but we will provide guidance moving forward as to how they should set a value for the role of the professional service, for someone who tries over-the-counter hearing aids and how they can engage with patients who suddenly will realize the benefit of professional service when they want access to the latest technology, but don't want to do it themselves.

Brandon Sawalic...: All right. Well, thanks for the discussion, Dave, and thanks again, too yes, for all those listening, whether a hearing healthcare, professional, or patient, there is better hearing out there, just know your options, educate yourself, and there are really good people there to help.

Dave Fabry: Well, and thank you, Brandon, for being with us to talk through this and thank you all for listening to this special episode of Starkey Sound Bites. And if you enjoyed this conversation, please rate and review us on your preferred podcast platform. You can also follow us or hit subscribe to be sure that you don't miss a single episode, and we'll look forward to hearing you and seeing you next time.