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In this episode, Taren Grom, editor-in-chief of PharmaVOICE Magazine, meets with Jessica S. Scott, MD, Head of R&D Patient Engagement office, Takeda Pharmaceutical Company.

Taren: Jessica, welcome to the PharmaVOICE WoW podcast program.

Dr. Scott: Thank you.

Taren: I am so excited to talk to you. I love that you have both a medical degree and a law degree, and want to really explore how that duality has impacted your career. I know that you are credited with leading the organizational culture change at Takeda – from developing medicine for patients to developing medicines with patients. And that's not just a subtle change; that's a huge shift. Can you tell me what impacted you to move in that direction?

Dr. Scott: Yes. It's been an interesting evolution in my career, and I think we'll get into that a bit more in a few minutes. But as I moved into the pharmaceutical industry, I noticed that there was a keen interest in focusing on patients and yet, patients weren't a part of research and development. The challenge was to help shift the culture from believing that patient centricity and patient-focused meant developing medicines for patients. In other words, coming out the other end, the medicines will be taken by patients to an organization where there's real partnership in the process of research and development, bringing that patient perspective much earlier on in the 10- to 15-year development cycle for a new medicine.

So the action that I took at Takeda is to really embed the mindset of including the patient perspective earlier on in research and development. And the results so far, are quite rewarding. We are seeing evidence of the impact on our pipeline. Study teams are having those aha moments when they interact with patients, which is really rewarding. We're not waiting to see the return on the engagement, if you will, but we're doing it because we believe it's the right thing to do and that we'll see an impact, it will be valuable. But we don't know whether it will be really measurable. And that's okay.

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Taren: That's interesting considering everything in development is measured. So how did you change the culture to have leadership have faith enough to take this leap?

Dr. Scott: Well, one of the reasons I joined Takeda was actually that there was the beginning of this mindset shift culture change within the organization that really drew me in. So our President of R&D, Andy Plump, had already worked with a task force to begin this transition. They had developed what they had called, last year, key performance indicators for the R&D organization to instill a patient-centric culture the values and beliefs for the R&D organization that are more in tune with the patient perspectives.

So the KPIs for last year were that each employee would fulfill three patient-themed activities. And those are activities that are meant to really bring the individual closer to patient perspectives. It might be through volunteering at a patient organization event, or reading a book, or hearing a presentation in our auditorium by a person living with a condition sharing his or her experience.

And so those as patient-themed activities were really valuable to our organization and inspired and motivated many people throughout R&D. And that was the beginning. This year, we've moved further by embedding a patient engagement KPI where we're focusing on a smaller subset of the broader culture shift, and that's really for engaging our pipeline program teams with patients during the process of research and development.

So I came into an organization that was ready and forward-thinking and it was about really operationalizing and bringing this kind of mindset, the culture change that's more of a gauzy idea into a reality for the organization. And I would say that we're not there yet, but we're well on the way. We're doing it now. We're not waiting, because we believe it's the right thing to do. It aligns with our Takeda priorities to put the patient first and start there that will help bring trust, build reputation, and ultimately, will drive business.

Taren: Excellent. Have you run into any resistance? And if so, how have you overcome some folks who maybe just don't buy into it?

Dr. Scott: That's a great question, because the reality is, there are going to be some people who get this concept right away and see the value. And then there are going to be others who are willing to take the ride and remain open. And then there's still others (and this is not an insignificant number) who believe we do get the patient perspective, and we get it through the eyes of physicians already, and we have for quite some time in industry.

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However, getting the patient perspective through the physician community, or through the literature, doesn't get to the depth of insights that we can get when we have a two-way dialogue with patients in a patient engagement activity, as we define it at Takeda. There's so much value in really understanding in a deep way what the patient experience is like, and that can only happen in a dialogue where we're really open to learning about what we don't know and what we know we don't know.

If we start out with a survey, we're asking questions from the framework of 'we know, we don't know this, but we're want to ask you specifically about these questions and hear what you have to say,' that's a more limited kind of scope for insight, for obtaining insights. And so the value of patient engagement as a two-way dialogue really opens up for discovery and innovation in a far larger way than we have before. And that's why we've defined it as such for Takeda.

And to answer your question more specifically, for those late adopters, not having experienced the value of this kind of two-way interactions, it's hard to kind of see what kind of value would add to spend the time and the effort that's needed to put into these engagement opportunities until you've done it. And then those who have done it, they begin to see "Oh, okay. Now it's clear. I get it. And we need to do this. And we need to do it for this reason, and for that purpose, and in this country and in that country." So it's very helpful but this culture change, it does take time and conversation and collaboration.

Taren: Excellent. For some of your peers who are listening to this podcast who also are striving to make culture changes within their organizations to become more patient-centric, since that seems how the industry needs to move for sustainability, do you have any words of advice to them that you've maybe learned as you've been going through this process that could help them? And I'm not talking about proprietary secret sauce here, but as an assist.

Dr. Scott: I've really learned that shifting the mindset needs to happen through a push and a pole. And what I mean by that is, by embedding patient engagement in the structure of R&D at Takeda through the KPIs (key performance indicators), we've given a little bit of a push. This is an important push because for our organization, the entire R&D organization has bonuses tied to successful completion of KPIs. So it really is a push.

But even more importantly is the pull. By not being prescriptive about how and when and why to engage patients in patient engagement activities, that two-way dialogue, we're leaving it open to study teams to be really innovative, and what would be a value to them. They develop their informational need. And then as a patient engagement office

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sitting with R&D, we help to brainstorm and flesh out that idea and then the activity that would help provide those perspectives from people living with the condition and a diverse group that would appropriately meet the informational needs of the team.

So my advice is to create the openness for discovery, but to trigger that need for innovative thinking by a bit of a push. And then I would follow that with clear communication of the value of the engagement, so that the broader organization is learning by the activities that are being conducted by the early adopters.

Taren: That's excellent advice. Thank you so much for sharing those insights. And I want to turn to a little bit of another innovation that you're responsible for. I understand you started a video series. Talk to me about this mode of communication and how it's working for you and what impact it's had.

Dr. Scott: Yeah, so that really goes to the last point about communicating the impact of the patient engagement activities across our internal organization. So we're creating a library of examples where we're sharing a five-minute news room format video, where we're actually using avatars to portray news anchors from the patient engagement office to kind of guide viewers through the experience of the patient engagement activity, what the challenge was for the team, what the activity that was conducted consisted of, and then finally, the results, the impact, all through the eyes of the program lead – the individual who led the study team in developing the activity and implementing it in collaboration with the patient engagement office.

So the idea is that these are easily relatable, easy to watch, that they're sticky and memorable, and even that there's a little bit of humor, because these avatars are portraying the patient engagement office and even some of our key leaders like our chief medical officer, so that people really want to tune in. They're looking forward to the next episode, and they hear about an activity and think about how it might apply to their study team.

Taren: I love it. That sounds really clever.

Dr. Scott: The other thing it does is it allows us the ability to share an episode that describes a particular activity that's relevant for a given internal colleague or stakeholder. So recently, I was in China and Japan, and talking about patient engagement and exploring the landscape, both internally and externally in those countries for patient engagement. And I was able to use several different video episodes to show how the engagement with patients and patient organizations effected change in the primary

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endpoint for a study that was accepted by the regulatory authority because of the patient engagement.

And another example where we engage patients with a project team in early research before even clinical development. In this example, the project team wanted to understand if there was an unmet need for patients living with spinal cord injuries. They hadn't gotten from physicians or the medical literature that there actually was, that this symptom was adequately addressed with current treatments. However, they had an intuitive thought process that maybe they were missing something.

And so with a patient engagement activity, we had people living with spinal cord injuries meeting in person around a table with a study team. And when we spoke directly in a very trusting, safe environment where we were really collaborating together, it became very apparent that this symptom was so important and there was no current treatment available, that these individuals would rather have that symptom effectively addressed than to be able to walk again. And we hadn't gotten that from the medical community.

And that really describes the value of patient engagement, and if we share this, and our project team lead did share this on an episode of the Newsroom Update, it really resonates. It really does demonstrate the value of engagement activities, even as early as research phase of drug development.

Taren: Yeah, that's a really powerful example. Again, thank you for sharing that. It does prove the power of engagement. And I think the things that you're doing are really quite ground-breaking at this time. Do you feel that? Do you feel like you're breaking new ground?

Dr. Scott: I feel that we're breaking new ground in that we're very comprehensively and strategically developing our capability and culture change for engaging patients in R&D. Other organizations are really wanting to get into this space as well. And they are. They are piloting different activities. Some of them are prescribing patient engagement needs to happen at the study design phase of drug development. So there are different ways that other organizations are trying to progress patient engagement.

I feel really proud of what Takeda has been able to do in terms of really embedding it more comprehensively within the organization and culturally progressing very quickly toward really doing what we say we're wanting to do.

Taren: Excellent. And in your work, in terms of patient engagement, how closely do you work with patient advocacy groups?

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Dr. Scott: Very important question, because from a patient advocacy organization perspective, having multiple people from Takeda reaching out and without a clear connection among the individuals who are trying to work with that organization, it looks fragmented, and like one end isn't talking with the other. And so it's really important that our patient advocacy colleagues internally maintain that ongoing relationship and coordinate what's happening from a Takeda perspective with that organization.

So we work very closely with our patient advocacy colleagues and want to respond to organizations that are keenly interested in collaborating with us in research and development. This isn't necessarily an interest for all organizations. But for those where it is, we'd like to work with these organizations to identify potential advisors for the various patient engagement activities, including having ad hoc members of study teams, where there's a longitudinal relationship with patients during the drug development process.

So our advocacy colleagues are really key and helping us to navigate which organizations have interest and could collaborate, and where we have mutual interests with those organizations in different geographies. So key internal colleagues to collaborate with. They have a particular job and we have a particular job. Ours is more focused on R&D and collaboration within the drug development process. Advocacy is more about relating to the patient organization and is a bit more focused also on pre-launch and regulatory approval, and then post approval as well.

Taren: Thanks for providing clarity around that. I appreciate it. You know, you noted a little bit earlier that you're well on your way; you're not all the way there yet. Have you set yourself any benchmarks in terms of metrics of where you want to get by any certain period of time in terms of your long-term strategies for the patient engagement office?

Dr. Scott: Well, I referred to the KPIs for our R&D organization. And this year, we are focused on having 100% of study teams identify a patient engagement activity in our goals tracker so that we're really changing the mindset of each and every project team. We also have a KPI this year where 30% of the study teams will develop an overarching plan, a roadmap for how we'll engage patients and also patient communities (so that involves our advocacy colleagues), and other functions across the value chain of drug development in developing this roadmap with an eye toward each of the phases of drug development, and even commercialization.

So this year, as we start with 30%, our goal is that next year, we will move to 100% of our study teams. And this will give us an ability to coordinate and leverage the different

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activities going on across a given study team, but even across multiple study teams where we're engaging with the same patient population. It will give us a way to optimize each engagement activity with an eye toward what's happening next, and what's happened in the past so that we can build upon insights that we've gained and think forward. Is there a new patient reported outcome measure that we need to develop a new tool? Is there evidence that we need to develop that would help address a patient's need for decision making, and whether he or she would want to take a new medicine? That's different from whether there's a regulatory approval for certain new medicine in development.

Taren: Sure. And it sounds like a lot of this works because it is centralized under the patient engagement office – meaning that there aren't clinical teams doing ad hoc activities, and with little to no coordination. And because of your officers' shared resources, there are best practices I would assume, and then the same tactics have been developed by one study team could be adopted by another study team. So there's not that reinvention of the wheel but a continual evolution. Is that a fair statement?

Dr. Scott: It's very fair. In fact, you're exactly right. By having a centralized function, we can share these learnings and best practices. And we can also share what's happening externally, you know, what are the developing quality criteria? For example, the patient focused medicines development work and the seven quality criteria developed in that guidance are incorporated into our internal guidance for how we conduct patient engagement activities. It's important to connect with the rapidly evolving external landscape in this space and share those best practices that are evolving and also the lessons learned – both from the external environment but also internally across geographies and across therapy areas.

So it's also important that we have this centralized function within R&D. It doesn't fit within our communications group or government affairs or even public policy. It doesn't fit in the commercial organization at all. This is about bringing patient perspectives into our research and development.

Taren: That's excellent. And obviously, there's a commitment by Takeda because there's a budget for it – and that's the other tricky thing sometimes when you're looking at patient engagement. Oftentimes, it's one of the first things cut when things get tight. But it looks like there's a true commitment.

Dr. Scott: Yeah, and I have to say that at the bee farm meeting a couple of weeks ago, Andy Plump and I were talking during a fireside chat on day 2, and Andy said that the patient engagement office and I will have a job for a long time. So I think that was the long-term commitment made very publicly that I can rely on.

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Taren: That's excellent. Nothing like saying it on a public forum, right?

Dr. Scott: Yeah. He also said that he watches each of the patient engagement videos, that he really enjoys them, and that they really hit the right tone and the right content in a very concise way. So I'm really happy to have his clear endorsement for the work that we're doing and also the way we're doing it.

Taren: Congratulations, and I wish you continued success. Yeah, I think it's important, and I want to thank you, too, for sharing some of these really great insights to help other folks who are looking to start an internal movement, if you will, in their own organizations.

Dr. Scott: I really see this as beneficial to patients. And there are so many passionate people in various organizations who want to do this, and we need to do it together – share learnings, and it's in the best interest of patients and really, the whole industry.

Taren: Couldn't agree with you more. To switch facts a little bit, let's go back to what I alluded to at the beginning of our conversation about your MD and JD degrees, and how your role as a doctor and a lawyer. How did you get into healthcare? What is driving your passion around the field of patient engagement?

Dr. Scott: I will take them one by one, break it out a little bit. How I got into healthcare: When I was a teenager, my sister was diagnosed with cancer, and she was treated in a very highly respected academic medical center. My experience as her sister going through the process, was that she was treated for her cancer and from the oncology perspective, but not necessarily as a whole person and certainly our family. And the needs of the family going through this really difficult and painful process wasn't addressed either.

I wanted to go into medicine not to cure cancer, although increasingly, I've gotten closer and closer to being part of delivering medicines that can cure cancer. My initial feeling was I want to be a different sort of physician. I want to go into medicine and take care of the whole person and the whole family. And so I went into family medicine, and that's how I got into healthcare initially.

Taren: Was she treated successfully?

Dr. Scott: No.

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Taren: Oh, I'm so sorry.

Dr. Scott: It was three years and she did pass away. So that was a huge impact on me and my family. But really, I just felt like our whole family was out of focus for care. And she was treated as an oncology patient – a number really, actually. And in fact, in a clinical trial. So it was hard. It was a hard learning experience, but it inspired me to become a family physician. And I didn't know what family medicine was.

I grew up in the New York metropolitan area and we didn't have family physicians. We had a specialist for everything. You know, if you sneeze it's like, okay, do you need an allergist or an ENT? So when I got to Tufts Medical School, and we had a brief presentation by a family physician in the first semester, I was just captivated and thought that's exactly what I want to do.

To answer your second question, how did my career evolve, as a physician, I very much enjoyed that biopsychosocial model, taking care of the whole person in the family context, and increasingly felt that there was a need for improvements to healthcare on a broader level, on a policy level. And for me, this meant going to law school. Law school was a really valuable experience, and what I learned was clarity of thought and communication, advocacy, reasoning, and the use of laws and regulations.

The policy in healthcare to improve our US healthcare system was something that I enjoyed coming out of law school. And it was US-focused, and there are certainly a lot to fix with the US healthcare system. But then a colleague suggested a career in industry where I could combine my background in a really unique way. And it's really true.

I moved into the pharmaceutical industry initially in medical policy and advocacy, and developed kind of a global perspective with a lot of external collaboration based on the skills that I had learned in law school about interest-based negotiations and the value of collaborations. My specific area of interest in law was collaborative law, which really builds on those exact skill sets. And I missed that more direct patient interaction that I had enjoyed in medical practice.

So it really combines both of those trainings and expertise in a single field where I am able to bring that patient perspective and that deep knowledge and understanding of the experience that patients have had, how to work with patients, how to interact directly with patients, and the value and deep insights that come as a result, but also to help navigate an innovative new approach to bringing those perspectives into the pharmaceutical industry where we really do need to navigate laws and regulations as well as cultural issues on a global scale.

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So I love the way these two have come together in my career, and it's certainly inspiring and really aligns with my values and my passion.

Taren: Well, thank you for sharing such a personal part of your career journey. I can't imagine that any of that along the way was easy. Medical school is very hard; law school is very hard, and then combining the two to give you a really unique perspective. And I think from our conversation, it's one that you're really bringing to the forefront to benefit patients. So it's working out for you so far, right?

Dr. Scott: Thank you. Yes, I'm very pleased at having the opportunity to do what I do.

Taren: Not everybody has the opportunity to be both a lawyer and a doctor. But along the way, what are some of the lessons you learned that helped you progress your career? Any lessons that you can share with our audience?

Dr. Scott: Yes, I'm happy to share this. I appreciate in my career when others have shared their perspectives on exactly this kind of topic. So thanks for this opportunity. I think to reach the executive level, you really need to uncover what it is you feel passionate about. Let yourself explore what inspires you and realize that you won't always know where it's going to land, and you evolve as a person so be open to it. Be open to where it might take you, but follow and continuously try to uncover where your passion is.

I would say the second thing is to do your homework and really develop your expertise. Always be well-prepared, be curious, learn, explore. But always get your work done and done well, which doesn't mean being a perfectionist.

And the third thing I would say is to have courage – courage to speak up, ask questions, be curious, share your perspective. And having courage can also mean being open to others' perspectives and supporting others' views. Even having courage about changing your own perspective based on the views of others, including your career path. Reflecting back, I realize it did take some courage to change from medicine to law, but I felt really passionate about it and really curious, and I didn't know where it was going to take me and how I would combine the two fields. But I'm really thrilled that I did make that leap because in the end, it came together beautifully.

The last thing I would say is to be a strong leader as a woman, you need to realize that your voice as a female is really important, and not as interpreted by the more masculine perspectives of what's important in the executive level, but from what you feel in your

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heart is important to express. Both perspectives are really important but there is value in the female perspective that we need to bring to the table as women.

Taren: I couldn't agree with you more. That emotional quotient or that EQ that we talk about and we hear about is becoming even more important, it's becoming even more valued as a skill set in the boardroom.

Dr. Scott: It's so true, and to be a bit more concrete about that point, I would really emphasize that we should think carefully about what we say and how we say it. We don't need to equivocate. We don't need to sugar-coat. We don't need to use the word "just" – "I just want to say" or "I just need a minute". What we need to do is stand up and say what it is that we're thinking.

Taren: Excellent advice. Too often we hear that or we ask for permission, or we then apologize for interrupting. "Sorry, I just need to say this." Right? Words that should be eliminated from our vernacular.

Dr. Scott: And you have to be intentional about it because it doesn't necessarily come naturally. Yeah.

Taren: Yeah, it takes practice. Given that, what is one piece of advice that you would give to your younger self, something you wish you knew then that you know now?

Dr. Scott: I would identify moments where I feel uncomfortable as moments for learning, where I feel things aren't right. Those are some of the key times in my life where I've had deep introspection about what's important to me to help me with my path forward, both personally and professionally. I think when you're uncomfortable, then you can give thought to: is this something I want to do something about? Is this something I care enough about to take action, to have this be one of my priorities moving forward, when something is discordant and doesn't sit well? I think those are opportunities – not negative things, but positive.

For example, my daughter, my eldest child is in her senior year in college. And she's relayed to me discomfort with injustice on certain issues, like in criminology, and that laws and policies lead to recidivism because we're not helping people coming out of jail or prison re-enter society, and that puts them in a disadvantage. And that's something that made her uncomfortable and something that she feels quite passionately about, and is really an insight and a motivation for her to then go to law school.

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And for my middle child, my son, it's about wanting to think about engineering differently, and being innovative, because things aren't as good as they could be, and/or isn't as new and novel and better. And he is passionate about improving and innovative in a mechanical way.

And my youngest, for her, she's inspired to be a ballerina, and she's highly successful in that route now – already dancing professionally in her senior year of high school. So my advice to my younger self is to find those areas of passion and discomfort and learn from them. And that's the advice and what I'd hoped my children would find. And I think that they are already finding that.

Taren: Congratulations to you. That's not an easy thing to do. So congratulations to you to giving your three children that groundwork and that framework to figure out what it is they want for their future.

Dr. Scott: It's true. I guess I bring it up because success to me in my life is both professional and personal. So in my career, I would like to help transform our industry to really collaborate more with patients in drug development, because I believe, it will lead to more medicines of value to patients where we're really addressing unmet needs. And it will also lead to measures that matter most to patients for their decision-making about whether or not they want to take a new medicine. And it will also expedite how fast we get medicines to patients because we'll have more of a partnership in drug development, more participation in clinical trials, more retention in those trials because they'll be more patient-centric and easier to participate in and less burdensome. And we can only do that together. So that's professionally what I see as what I want to achieve when I look back at my career at 80 or 90.

And then personally, I would say that family is incredibly important to me, and that balance between my professional and personal life is an ever-constant opportunity and challenge. But to see my children following their passion and whatever that might be, and it's diverse as you can see. If they find careers where they're as inspired as I am in mine, I will feel like that has been a success for me.

Taren: Excellent. Finally, what is the one WoW moment that changed or enhanced the trajectory of your career?

Dr. Scott: Well, to borrow a term that's been coined by someone else, there are crucible moments, and I think about that after reading that particular book where I recall career-shaping incidents. When I mentor others, I share, "okay, thinking back on something that

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made you extremely uncomfortable, what was it about the situation that made you uncomfortable and what do you want to do about it?"

For me, I recall, when I was between my first and second year of college, my first experience in the healthcare community. I worked as a phlebotomist in a local hospital, and I recall stepping into the elevator. And as I pressed the button for the sixth floor, I had this feeling about needing to draw blood from an elderly woman who was days from dying. At the time, morning labs were routine and taken regardless of any sort of decision-making that would result from the lab test.

In this situation, I felt very uncomfortable that I had no ability to decide not to draw the blood – that was my job. And I knew in that moment that I needed to be a decision maker. I needed to be able to make the decision that it was not the right thing to do and to do it differently. And that meant for me going into the medical field and being a physician, and mentoring others who are deciding between becoming a physician's assistant or a nurse practitioner versus a physician.

This is something that, for me, was a crucible moment in my decision-making for my career because I knew, for me, my satisfaction would be out of having the ability to decide on treatments, rather than following through with the treatment that had been prescribed by someone else.

Taren: That's an extremely poignant example. And again, I want to thank you for sharing something so personal. You know, I don't know that there are many 16-/17-year olds that would have come to that same conclusion.

Dr. Scott: Admittedly, I did graduate from high school year early, but I will tell you, I'd say I probably was 20. So I'm not 16 or 17.

Taren: Okay, sorry. Even so, even at 20. I mean, that's not something that a lot of 20-year olds think about, and to think about it with the empathy and the compassion to your patient. You were born to be a doctor.

Dr. Scott: Thank you.

Taren: There is so much focus now on patient engagement, but I think you bring up a really important point that no patient is usually alone. And that involved in that care are family members and caregivers. And yet, that seems to be one of the pieces of the equation that still isn't being addressed.

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Dr. Scott: When I refer to the patient or the patient perspective, I'm using the term broadly, because in our advisory boards, for example, we often will include a care partner or more depending on the context. We may include a patient opinion leader or a member of a patient advocacy organization. Very often, we want the perspective of individuals living with the disease or condition, and it may be that they're early on in the disease progression or later on, or that they're younger or older or male or female, or from a rural area of the country or urban. There are just lots of diverse criteria that will lead us to select the right mix of that patient perspective for an individual activity depending on the context. It's very contextual, which makes it incredibly interesting and challenging.

Taren: Jess, I can't tell you how much I've enjoyed our conversation. Thank you so much for sharing so many of your personal insights, and for providing so many great tips to others who are also looking to improve that patient engagement experience for their companies. It's been wonderful.

Dr. Scott: Well, thank you, Taren. I really appreciate the opportunity to speak with you and I enjoyed it as well.

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