

March 17, 2021

Welcome to WoW – the Woman of the Week podcast. This episode was made possible by a generous sponsorship from AstraZeneca. For more information, visit astrazeneca.com.

In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE Magazine meets with Michelle Hefley, Co-Founder, Managing Partner and Chairman, Optime Care.

Taren: Michelle, welcome to our WoW podcast program.

Michelle: Thank you for having me. I'm really looking forward to our conversation.

Taren: Excellent. Michelle, you have worked for most of your career in that specialty pharma rare disease space. Why is this area of focus of such interest to you?

Michelle: Well, I'd have to go back to early in my career in the 80s and I had been working in different jobs, but mostly just working to earn a living, and I had the good fortune to go to work for a pharmaceutical company that had two products even way back then in the orphan space, one for hemophilia patients and one for primary immune deficient patients. And if you put that in context at that time no one was developing or had much interest in orphan products or orphan patient population. And it really wasn't in the dialogue or discussion in the pharma industry at all. But this company had two of them. And the experience I gained there in working with orphan patients and started getting to understand the struggles they face, at that time and unfortunately even now has taken an average 10 years for them to get a diagnosis and then once they got a diagnosis if there was a medication, then they had to struggle to get access to the medication. And also getting involved with the patient advocacy organizations at that time and sort of seeing the dedication and passion firsthand, I was hooked. That was kind of it for me, that sort of moment, light bulb moment in your career. That pharmaceutical company was sold to another big one and they lost focus in the orphan space as kind of happens. But as I said, from then on from that experience I was dedicated to trying to work and find ways to support patients, orphan patient populations as best we could because I had seen firsthand sort of the real tangible impact that could be had in a positive way on patient lives and I want to be a part of that.

Taren: That's awesome and what a worthy pursuit. You talked about jobs because it was just part of your career, but what initially drew you to the life sciences industry? You could have applied your talents to any industry I would think.

Michelle: Well, when you're in school I gravitated and had an affinity for classes like biology and microbiology and anatomy and physiology and some chemistry. I really liked those. They really interested me. And so when I was going to college I looked at sort of paths directions I could take that had a lot of course concentration in those type of courses and that ended up being in

healthcare and life sciences. The bonus has been that I got to take those courses and enjoy my college career but then spend my life sort of working in the life sciences.

Taren: Wonderful. Well, we're glad you did. You also are a bit of an entrepreneur if I can say so. You started a couple of companies and as one of the co-founders of Optime Care, what led you to take this entrepreneurial leap again to start this company?

Michelle: Well, the group of co-founders is Optime Care, for the most part we had worked together at Centric Health Resources, which was a company that like Optime was focused on providing support for patients with rare and orphan disorders and working with the pharmaceutical companies that were bringing those products to market. We've recently moved on from that previous company and we were all sitting around the table and reminiscing as you do and talking about the fun we've had and what great people in the patient communities and the pharmaceutical industries we've gotten to know and had been inspired by... and we're talking about all the things we had accomplished, but also in that we started talking about the things that we would still like to do. And the more we talked we came to the realization that there was still some contributions we felt like we might be able to make and that our work just wasn't really done. So I'd have to say sitting around that dining room table, mine, with a few glasses of wine in hand and some scribbles on a scratch pad and inspired by our past experiences Optime Care was born and that was in 2011. So five and a half years later, we're still here.

Taren: Congratulations. I've heard some similar stories where companies are born around a glass of wine. I think the vintners need to go into a different – they can use that as a marketing ploy for themselves. That's awesome. Five and a half years, starting a company, it's not easy. What are some of the biggest lessons you've learned along the way?

Michelle: I think in Optime Care the biggest lesson we've learned is even though you think you've been at something for decades and that you have things figured out, that this ever evolving healthcare market is always going to throw you a curve. So you've got to bring those skills of staying focused and adapting and always looking forward to the next situation and for a creative solution that served you well the last time, you've got to continually apply those. So the bottom line is when you think – ever think you've got something figured out, you don't.

Taren: I love that and that's so true. But to be an entrepreneur, it does take a certain amount of grit and resilience. What other characteristics would you define yourself as to being an entrepreneur?

Michelle: I think being an entrepreneur is first just truly believing in what you're doing and not letting anything dissuade you from that focus. And I'll take you back to when we were at Centric. When we founded Centric, we founded it with a similar focus as Optime Care as I said, and we were focusing on very small, rare and orphan patient populations. And even then in 2004, orphan really wasn't in the dialogue too much. There were a few more products in the market and there was some background noise about orphan, but nothing that anyone was really paying attention to, and we started that company with that focus. A number of people tried to

dissuade us and say why don't you broaden your focus, why don't you be like every other specialty pharmacy and we didn't. We stayed true to what we knew and we stayed true and focused on where we thought we could have an impact. And ultimately, the market I'd like to say caught up with us and by the time Centric was sold, orphan was all the rage in the thing and everybody was focused and everyone was talking about it.

Taren: So you really were a trailblazer in this space and as such, what are some of the biggest trends you're currently tracking? What lies ahead?

Michelle: Well, in the rare disease orphan space in particular we're still challenged with the things that were challenges all along and that is the identification, the diagnosis and access to therapy for patients with rare disease. It's just long been a struggle and still is.

But in addition, the pharmaceutical industry in particular are faced now with the best way to support patients after they started therapy and everyone has come to realize and then even payers are having a focus on okay, you have this medication, but how does it work. Do patients stay on it? What does it mean long term? And so finding a partner to help you support that part of the continuum of healthcare for a product is still, you know, pharma companies are evolving to it, but it's still relatively new and it's historically been out of their purview. So that is still a key area that we work with pharmaceutical companies in in trying to find a solution.

Taren: Fantastic. And as you said, there's been a lot of focus recently on the orphan and rare disease space. You would think that you would see the needle move a little bit quicker – that's a mix metaphor, sorry about that – but what are some of the things that are still holding patient access back?

Michelle: It's a multitude of things. If you've been taken still today years and years to get diagnosed and then you finally get a diagnosis after years and years and then you need to go on a medication and you need to navigate that healthcare landscape and anybody who has spent any time even just going to a doctor realizes the complexity involved in doing that. It's just beyond most people that are already stressed with a new diagnosis around an orphan and most of the time chronic disease in their families. So supporting that access to the therapy by helping someone navigate the healthcare landscape, by interacting with the payer world and supporting them in terms of getting that medication to a site of service, whether that be the home or a hospital or a clinic can make a tremendous difference in supporting the access to a product.

Taren: Fantastic. Do you think there's also an added complexity because so many rare diseases impact children and they just – they have parents who have to care for them and so having to act as a patient advocate is also just double with what's on their table?

Michelle: It's absolutely a huge component because if you're a family and a parent and oftentimes have other children and a work life and then having to navigate and access and advocate for your child just the barriers are huge and also the landscape is alien to most people.

Taren: Sure. I mean most doctors haven't even seen some of these diseases, so that's the diagnosis part and why it takes so long. Do you have an optimism for the future? Do you see that we're going to be able to get to a place, and I don't want to say soon, but in the not so distant future where it won't be such a struggle?

Michelle: Well, I'm by nature kind of always optimistic – the answer is yes. I mean with the continuing discussion around orphan, interest in orphan and rare diseases and those products, with the increased understanding at a general population level, at the third party payer level and in the healthcare community we're gradually seeing a shift in terms of either recognition or understanding and by the pharmaceutical companies that bring their product to market an understanding of what I discussed earlier that there might be a need. There is a need for a support system to get patients the sort of things they need to access products, to navigate third party payers and to live the best life they can.

Taren: Wonderful. Well, thank you for continuing to do and serve this patient population so passionately because they certainly need champions like you in their corners. To switch tacks just a bit, you sit in a C-suite role now. You were a founder to a previous company, but you were also the president and CEO at Orphic Therapeutics for a number of years. And as you know, unfortunately, there still aren't that many women sitting in the C-suite roles. What was that role like for you at the time and what lessons did you learn in being the president and CEO of a pharmaceutical company, biotech company?

Michelle: Based on when my career started, I was definitely the only woman most of the time, lady at the table, so to speak, and sadly even now I'm usually one of few at the table. I guess I could safely say I've seen a lot and experienced a lot, but I would say that what I found was that to succeed you need to keep your focus. You can't let anyone take your voice away. In other words, speak up. Don't be shy about being heard. Stay the course. There'll be challenges. There'll be issues. There'll be uncomfortable situations. And I also for me personally found that if I brought a sense of humor, it really came handy in navigating sort of stressful situations.

Taren: I think that is a key piece of advice. Sense of humor will take you a long way for sure. How would you describe yourself as a leader?

Michelle: I would describe it is what I would call adaptive. That word comes to mind. And what I mean by that is I've learned you need to treat and recognize the person in front of you as individuals and identify what attributes they have that you can tap into. And just by that simple recognition it can be very motivating for individuals because how often do we actually get seen and heard. But also there's some very simple things and they're often neglected like you need to have a clear, concise communication style regarding what your goals and expectations are for the company, but even most importantly down again to the individual. And then it creates a reward system, whatever that may be that is consistent with both of those things. And too often you see sort of a divergence in all of that, or not a clear communication which only causes confusion and creates a lack of motivation.

Taren: And as leader, how do you find your way through some of those tough situations where maybe it's not the right communication or maybe the employee hasn't heard it in the right way and you have to have those difficult conversations. How do you manage those kinds of stressors?

Michelle: I found being very straightforward and not being cruel or demeaning, but very straightforward and just clearly communicating things as simple as 'I don't think that we're communicating here. Let's go back over what we've talked about' and then also hearing what may be a barrier for that individual in accomplishing what all of us like to do for the most part and that is to succeed and feel like we've made a contribution.

Taren: Absolutely. Earlier on in our conversation you talked about an aha moment in your career when you joined the pharmaceutical company that was focusing on that rare disease space, but I have to ask you is that the same as your wow moment of your career, that moment that either shaped or helped transform your career?

Michelle: I would have to say that definitely is the wow moment in my career. It shaped everything from then on and it's been sort of my focus and abiding passion since then. And I feel fortunate to have had a passion. Some people maybe in the don't ever identify one or get there, so that's definitely a wow moment. But I would also say that it started with my parents and what they made clear to me from day 1 is that I should be able to do anything I wanted, but that it was up to me to accomplish it.

Taren: Isn't that a nice open highway to have. Some women haven't had that kind of encouragement, and I think that's a limiting factor too in a lot of ways. Do you find yourself as a mentor or a sponsor to other women who are looking to you as a role model?

Michelle: I have never embraced that formally in any sort of outside organization, but I have certainly worked to be that within the women in the companies that I've worked with and just spending time offering mostly just an ear if they're interested and some feedback if they ask for it.

Taren: That's wonderful, but what about your statute as a role model, do you consider yourself to be one?

Michelle: That's an interesting question. I don't think I've ever really thought of it like that as a role model. I've thought of it more as I have this experience and these experiences and I'm happy to share with anyone sort of what's worked for me or what hasn't or what the path has been that I've been on, but a role model I guess so.

Taren: I would say so. You've started several companies and now you're sitting – and you were a head of a pharmaceutical company, so I think that's pretty role model-ly. That's awesome.

Michelle: Well, you have a point.



Taren: Thank you so much, Michelle, for sharing some of your experiences with us and shedding a light on where the rare disease space is right now and for continuing to give us some hope for the future for these patients who are in such desperate need for treatments. Thank you what you do for the industry, and thank you for being with us for our WoW podcast program.

Michelle: Well, thank you very much for having me. It's been a pleasure.

Thank you for listening to this episode of WoW – the Woman of the Week podcast. And thanks to AstraZeneca for making this episode possible. For more information, visit astrazeneca.com. And don't forget to check out our other WoW episodes at pharmavoice.com/wow.