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In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE magazine, meets with Ubavka DeNoble, M.D., Chief Commercial Officer at PAREXEL Informatics.

Taren: Dr. DeNoble, welcome to the PharmaVOICE WoW Podcast Program. We're so excited to have you be one of our honored executives.

Dr. DeNoble: Taren, thank you so much. Thank you for having me here, and I'm really excited that we will have our conversation today.

Taren: Ubavka, you were recently named Chief Commercial Officer of Informatics at PAREXEL. Can you tell me about your new role?

Dr. DeNoble: Yes. I'm very excited about this as Chief Commercial Officer of the PAREXEL Informatics. I'm responsible for commercial strategy and development of PAREXEL Informatics organization. My focus is related to marketing, field product development, and I am trying to work with my customer and work on the business growth and try to increase the market share of my organization, but this is not so dry. Actually, it is always exciting that you analyze and interpret changing market and industry dynamics and industry trends.

I think that this is something that everyone is talking about and then that you can determine the effect of the current business that you have and use this information and work with your team to have right commercial strategy intact. I'm really excited about this anytime when I'm doing and starting to build something from the beginning. I have this sense that I am privileged to have such assignment and then you start with this basic task then you like to do development of strategic sales and marketing, but the beauty of this process is that you have opportunity to work with team and you are focused on this collective work where you need to set up priorities, you need to set up standards, and at the same time you need to motivate your team and ensure effective control of the commercial team results, and this is where you are building a successful team. Every team that starts to work in such a way is actually vesting to be successful.

Taren: It sounds like you have to wear a lot of hats.

Dr. DeNoble: This is very new. This is why I'm telling you – and actually we clearly define pillars that they have in our company, and one of three is commercial pillar. I got opportunity really to work with my colleagues that are responsible for operations and my colleague who is responsible for technology. I was very excited.

Taren, you know, in my life, I had quite a few similar assignments but then I have the opportunity to hand pick my team and then I have opportunity to guide them and make them motivated and enthusiastic because I think you must have a team that will buy in your concept and your vision, and I think that when you have opportunity to build something, this is absolutely fantastic.

Taren: It sounds exciting. Let's talk about that vision. What do you hope to accomplish within the coming year?

Dr. DeNoble: I have two goals. First one is to set up everything that I just shared with you and I think that this is not a small assignment. This is an assignment that requires a lot of cross-functional work, a lot of thinking, and at the same time you need to bring business in the company and to be sure that you have commercial team results that are expected based on the company strategy, but regarding long-term vision, regarding technology impact on the industry and patients, I am a strong believer that the future of drug development will be based on real-time patient data. This is why I'm so excited to be on this side right now because I am physician. I worked for many years on drug development and now I got opportunity to observe and find out what is going to be the best technology that we can apply to clinical trials to accelerate drug development to simplify this process. I don't want to say that we will make drug development more cost effective, but certain stages of drug development we will for sure make more cost effective, and it will help us to better recognize a good candidate for drug development.

I think that technology is going to be based on real-time data. I also know that it's not going to happen tomorrow because right now – and I had opportunity to work on some trials within my company, we have trials that are incorporating wearables and I think industry prevalence is approximately 10-15%. We use mainly exploratory data, but I believe that we will move from this exploratory data to secondary and eventually primary endpoint because using technology and using sensory wearables because everyone is talking about virtual trials is going to be our reality, and I definitely want to be there. And I remember – I really, really remember when we started to talk about devices and you remember that we didn't have very good devices, and now the quality of patient devices is improved significantly, and what is happening right now, many of these devices are recognized by FDA and this is something that was so exciting. I believe that

having ability to monitor and prove that medication has positive impact on patients in real life and then that you have a combination of I like to call this physiological data, you will have opportunity actually to really assess effectiveness of the drug. So far, it was under certain conditions, and we talked about safety profile, we talked about efficacy, but how this impacted and how effective was the drug on patient's day-to-day life was a completely different story.

Taren: I think it's exciting. I think that your take on how real-time data is going to transform the industry is spot-on. At the same time, I do have to play devil's advocate and say are companies or the pharma sponsors, are they ready for this, or are patients ready for this? So what are some of the challenges you still have to face and overcome?

Dr. DeNoble: I think you know that we all understand that you will always have challenges. I had the opportunity to talk with some of my clients that is using some exploratory data with certain devices. Everyone has understanding that this is not going to be a process that we will go through relatively quickly, but on the other side, you need to understand what are the tactical challenges that you will face. I think that many smart companies are investing in this.

Your question was related to how are we ready for this. I will answer in the following way. Companies, they understand the importance of digitalization. They understand importance of wearables. When you talk with them and you spend a lot of time talking with them verbally, they're all ready to embrace this. In reality, this is a little bit different.

Regarding the patients, I believe because we have millennial generation and in general we can agree that younger patient population are going to be more receptive to use wearables, but I think since this process is going to be a continuum, that many of this representative of young generation today will be a targeted patient population. I think that you also have issue that is related to geography because it is different what's happening in the United States than in some underdeveloped countries, but this is a completely different story and then you have to ask yourself what we will have, we will have sensor, we will record data, we will have very good and clear data sets.

Taren, I am also very focused on telemedicine and I am following very carefully what's happening there simply because I believe that this is going to be a very important part of the clinical trials going forward. This is going to be very important especially for patients that are facing some rare diseases and that are living in some places that are not easily accessible.

And if I can bring one more aspect that I want us to talk, this is aspect related to partnering an evolutionary pharma tech partnership because we are not talking about this in the way that we talk about other aspects of digitalization, but I think that this is happening in front of our eyes. For me, the outcome of this partnering is going to be very important to find out really what's going to happen because machine learning and artificial intelligence, everyone is talking about this; pharma is making partnership with small start-up companies sometimes. This is done in the way that this is not publicly announced. Everyone has expectation and you remember what happened when we had this situation with IBM Watson and when they believe that machine can be better in diagnostic process and then we know what happened after that. But I am just interested, and I don't know what is your opinion. In this extent, digital companies are going to invest on expertise because my expectation was that they will pull in much more subject matter experts than what they did so far. They have that. They have significantly more than before they realized that they must have that means they would like to do certain things, but do you believe that this is enough?

Taren: I think it's going to be interesting to watch. I too am cautiously optimistic and I do hear a lot of chatter about AI and machine learning, and companies are jumping in, but I have seen this happen before and I've been long enough in the business to have seen what happened with EDC 15 years ago when electronic data capture was supposed to be the panacea, and yet 10 years later, clinical trials are still being conducted on paper. So I am cautiously optimistic and I think it's going to take a few companies to really have some early win and we will see then what happens. I think that's what's going to be key.

I do want to touch upon the point you made about some of the underdeveloped countries. I think there is an opportunity there because if they are starting from nothing, then they're not going to bring an old process. They're going to come with what the latest is. So they may already have an advantage in some ways from some other countries, so we'll see what happens. I too am watching what's going on.

Dr. DeNoble: This is really a good point. When I'm thinking about this, I don't know, in this extent, young generation in certain countries, I'm not talking about – if you talk about China and cities in China and rural China, you have like two different aspects. I'm thinking if we have this orientation especially for drug development, how many countries we will be able to use, and I'm carefully following this because access to technology is so appealing especially for this young generation that I expect that we can have a really positive effect more than anyone originally anticipated.

Taren: I agree. I think it's going to allow larger groups to participate in clinical trials which would then exponentially improve the process. Instead of doing it one by one,

maybe we can do 10 by 10 or 20 by 20 by doing it in a different way. I think that there are certain rules obviously in place, but with technology, some of those old paradigms don't need to even exist anymore because there are – and I hate to use that phrase, but there are some game changers out there.

Dr. DeNoble: Absolutely. We are witnessing this every single day. I can tell you in that I talk with clients every single day for different reasons that you do, but there is a strong realization. One phenomenon that is actually present today that we have a technology that is well developed but not embraced by industry in the extent that you will expect when everything started.

Taren: Interesting. I think that there is a ways to go, but I am as I said cautiously optimistic. One of the areas that you guys are really looking at is the impact that technology is having on post-marketing patient engagement, and talk about why that's important. I think we focused a lot on the clinical trial, and then once the trial is done and the product is out in the market, not that it gets forgotten but there is less attention, so why is post-marketing patient engagement so important?

Dr. DeNoble: I think that digitalization – and let us talk about virtual trials. They have very positive impact on patients with different diseases. What I see is that we will have opportunity to observe patients in their natural environment and then that we will collect some data – and I called this, I told you, physiological data – that will give us a very good sense about effectiveness of the drug because as we know drug development is not anymore about regulatory approval, it is about making formulary, but even when you make a formulary, you have competitive drugs, and with collection of this type of data, you will be able to prove, together with witnessing of the patient, that your drug is very effective.

Taren: Interesting. Is that an increasing focus of PAREXEL Informatics in that post-marketing arena?

Dr. DeNoble: Recently, we are thinking about this as everyone – we are trying to work with our partners to have a certain partnering with our client, but this is a work that requires as you know many tactical tuning and virtual trials and this surveillance of the patient of the drug is approved is definitely our focus, but in extent that I will tell that this is the number 1 focus, we still didn't reach this level.

Taren: Fantastic. I want to switch tacks a little bit. I love speak to you about industry trends all day, but I really want to talk about you now a little bit, and I want to hear about your journey and how your career has evolved over time. I know you're originally from

Sarajevo. Talk to me about how having this international perspective has influenced your career journey because you didn't get that accent from Jersey, I know.

Dr. DeNoble: This is a journey, but my story is one of the million stories that you have in the United States. I came in 1992. It was a time that it was war in Yugoslavia. My husband is Croatian and I am from Bosnia, and that was not a good combination. At this time, we had the opportunity that presented itself because my husband was here a collaborator at Duke, and this is how we came in the United States.

Taren, I would like to tell you how I had a good vision, what I would like to do, and how I would like to develop in United States. Being a physician, you have to go through the USMLE and then go through residency again, but I didn't have the time to go through residency again. I am more satisfied in internal medicine, and at this time, I had my son and I had a new country, I had to adjust to all these, and then opportunity presented itself and I joined the industry. I have to admit the fact that I didn't know anything about corporate world on one side, and fact that you have this I will call this survival instinct actually was very beneficial for me because I didn't understand or accept obstacles that you are facing when you are in some new environment. I knew that I needed to work hard. I knew medicine. I joined this industry as a product safety associate. It was entry-level position. It was a lot of differential diagnoses. I enjoyed my work because you're affecting new medication then you compare safety profile of comparators.

For me, it was absolutely amazing and entertaining, and it was a realization that I'm working very hard and obviously my productivity was significantly higher but not because I wanted this intentionally. I thought that when you are in America whatever came on your table you have to finish this, and I remember that first year when I worked in the industry, I used to stay in my office from 7 to 7, sometimes even more, because I was processing serious adverse events that were related to clinical trials.

My point is you need to have this drug and you need to find things that you like to do because every drug has some aspects that are not very appealing and some that you really enjoy. I always try to do things that I don't like first, and this is my philosophy all my life. All subjects that I didn't like I did first, and then you have to enjoy things that you really like. I grew up through ranks really very quickly, and it was time that coincided with the growth of industry. It was a lot of opportunities. I always used to say that I stay in one office and have the opportunity to go through several mergers and acquisitions. Every single merger and acquisition and change of management, I learned something new. I relatively quickly came to vice president level. After that, I really thought and it was probably something that I didn't know that my work and outcome of my work that if you define my future and my professional development. In other words, I didn't

understand the importance of certain things like lobbying. I made all mistakes that females that are in my industry and some other fields are making. You actually waited for somebody to recognize you, and of course, as we all know, this is not the right way.

Taren: That's right. That is true. So you've been PAREXEL now for a little over eight years about?

Dr. DeNoble: Yeah, it is about eight years. It is a phenomenal company. Taren, I came in PAREXEL after my previous company was acquired and I really didn't have some extraordinary expectation. I just wanted to be part of a big company to see how it is and to have some stability and to have opportunity to grow. This company actually gave me such exposure, opened so many doors, and I'm even today absolutely fascinated with the profile of the people that we have in this company. There are so many companies that you can work eight years and still be surprised, and I know that you know some of our people and that you understand what I'm talking about. At PAREXEL with introduction of this diversity and inclusion initiative that is here for 5 years, you can see how the company is transformed, how people think differently, how people respect this cultural difference because culture that I'm bringing on board and culture that you have in United States are not the same, but they are very comparable, and I think that this diversity is actually very important for us.

Taren: That's wonderful. You know I do talk with a lot of women who are involved with their companies, inclusion and diversity employee resource groups, and I do know that PAREXEL has made some tremendous drive as you said in the last five years. So it's very encouraging to hear somebody at your level seeing that there is such a difference being made.

Dr. DeNoble: Yes, and at least in fact we are listed as one of the top 100 companies to work for.

Taren: Yeah, it's good to go to work at a company that believes in the same things that you do.

Dr. DeNoble: And I can tell you when I put all elements that they can use for this judgment, there is only one aspect that is really striking and this is diversity, this is inclusion, this is respectful approach to all people that are part of our company, and this is something that makes me proud. I have to tell you when I go to work, I'm happy to go to work. My life philosophy is if I don't like to go to work, there is no money that somebody can try to compensate for this, but if I like to go to work, then this is a different story, and this company is such that I like to go to work. I'm so proud of

unbelievably smart people that are top-down that you can meet every single day and then you have some undiscovered role and then you try to process this.

Taren: That's fantastic. To bring our conversation back to like the beginning when we started talking and all of the things that are on your plate in putting together the teams that are going to be necessary to execute on your vision in your new role, how would you describe your leadership style?

Dr. DeNoble: I have to confess. When they did a survey, they always told that I'm very demanding, that I have a high standard, but that I lead by example and that I am fair and that I don't have hidden agenda. To describe my leadership, I will tell you that after so many years of experience, I can describe this in the following way: I like smart people. I absolutely prefer to have three A+ people than people that are below this level with full understanding that you need that in many instances you have bell curve.

But I like to explain to people what are objectives. I like to tell them what is our mission because our mission is to help patients. Our mission is to do this with heart and with a belief that we can do it to energize them and to set up expectations. When you have a team that buys in, there is absolutely no single thing that is impossible. This is why I believe that for example when you go through pain and you always go through pain, it's a new health turmoil, I don't have a turnover. I have a very loyal team. Everyone is going to tell you that I'm demanding, but turnover in my business, businesses that I ran over 20 years was minimal.

Taren: Yeah, you can't ask for better than that. One of the other questions I asked is if there is one word that best describes you. I know the word I would choose, but what is the word that you think that best describes you?

Dr. DeNoble: It is a very tricky question.

Taren: That's all the questions I have for tricky questions.

Dr. DeNoble: Yeah, this is a very tricky question, and if I have to describe this in one word, it will be fearless.

Taren: And my word was courageous, so there you go.

Dr. DeNoble: Okay, courageous and fearless, but when I'm talking about fearless, I think you know that I am very pragmatic. I need to understand circumstances. I'm a believer that you need to try certain things, and I always tell my people how you know if you

didn't try. I also think that if certain things happen and if some people did certain things, that there is no reason that my team and myself cannot repeat this and introduce something that will make us even more effective. I think that during this trust, you need to preserve your integrity. When people trust you and then they know that you are doing something because this is in our interest, interest of the company but ultimately interest of the patient, then this is a winning game.

Taren: It comes through. To put a bow on our conversation, what one accomplishment could you identify as the WoW moment that helped shape your career?

Dr. DeNoble: I don't think that this is one moment, but I think what shaped my career is exposure. Every time I went outside of the comfort zone, I discovered some completely new world. When I was in medical field and did safety both medical monitor and things of such nature, it was a world that I was very comfortable. Then when opportunities called me to go outside of my comfort zone, I realized that there are so many different things, and when you combine your previous knowledge and then acquire skills if you would, then you open so many new doors.

Personally, what I think is my biggest achievement, this is my participation in the woman leadership board. This is the Women and Public Policy Program at Harvard Kennedy School where I had the opportunity – and I'm sure that you know many of this people – to meet this exceptional women starting from Iris Bohnet who is academic dean of Kennedy School or new chair Carol Hamilton and people that really have amazing biography behind them. To be part of such group and to be part of their meeting and to be part of the conversation that we have about the position of women today and what we did and what we would like to do is definitely for me personally my biggest achievement and when I think about myself since I focus my energy on developing young people because I always have a few people that I mentor not because they need my mentoring. I just want to help them not to make same mistakes as I made.

I think you know that every time I elevate them to the next level, I feel such gratitude and I think that this is one of things that will definitely define my legacy, but if I want this to be something to be my legacy, it is that I helped development of undiscovered talent.

Taren: That's excellent. That is a mic-drop moment. I want to thank you so much for being so open and transparent and explaining your vision for the organization and for your passion in developing others. You are a fearless leader. I'm honored to know you, and it was great fun having you part of the podcast program today.

Dr. DeNoble: Thank you, Taren. Thank you so much.



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