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In this episode, Taren Grom, Editor-In-Chief of PharmaVOICE magazine, meets with Laura Shafner, Co-Founder, AiCure.

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

Laura: Thank you very much for having me.

Taren: It's our pleasure. Laura, your entree into the pharma ecosystem is a very personal journey. Would you be so kind to share your experience in the role of medicine and behavior play and how that led you to where you are today?

Laura: Yes, in my personal experience, medicine and behavior intricately linked. People's perception of their illness, how they understand their illness, the response to the illness are as important as understanding the efficacy of the drug. In addition to those individual parameters outplayed, there is a much larger ecosystem in which we all live and all impact our ability to really understand the illness and respond to it, and it's that interface between the two that I find particularly interesting.

Taren: And didn't you have a family member where this really came into play?

Laura: Yes, my father, who himself is a psychiatrist, also suffered very much from bipolar, and I saw growing up how his perception of the illness very much impacted the degree to which he was able or willing to take treatment and benefit from it. Having effective drugs out there was not enough and it was a terrible tragedy that the way the healthcare system is built is not built with a 360 view of the patient. It's very much targeted on the disease itself. And one of the reasons why we started AiCure was to get a much broader and fuller understanding of the patient and being able to better characterize where they sit in, in terms of their illness. In the hopes of better treating it, I think that would have helped him greatly.

Taren: Let's talk about starting the company, and that was back in 2009, so congratulations on 10 years. And as you said, you founded the company with Adam Hanina and this is before AI or artificial intelligence, is where we know it today. So talk to me about founding the company and what led you to it and what was its original mission? And has that mission changed?

Laura: The company was founded in 2009. The three of us were co-founders – Adam Hanina, myself, and Gordon Kessler. And my own background was very much in finance and public

health, but the link between the two was the interest in predicting human behavior. Whether it's human behavior in the financial market or in public health, the idea was how can you accurately predict behavior and the fact was that, in order to predict it, you needed the best data possible. And where do you get the best data possible? Probably from being right with the person, the person whose behavior you're trying to predict.

The early concept of the company was to take a very simple concept of nurse interaction with the patient where the nurses really collecting data from the patient, creating insights based on years of experience, and trying to assess risks and react accordingly. And so the idea was how can we scale this environment through technology and the early concept of the company was capturing patient or operational data to create a much fuller view of risks and being able to predict how that risks will pan out and if you can predict it, you can hedge it. And that was the initial kind of driving force of the company and it remains today, that's very much still our work today in both pharma and in real world setting.

Taren: Excellent. And so the technology in artificial intelligence in particular is really a hot topic now. What barriers do you think need to be overcome before some of these technologies for predictive analytics and behavior indications can really become mainstream in the pharma industry?

Laura: I think the tools are there, the mass is there. A lot of the work will be in really understanding the datasets. We can capture mountains of data, but is the data we're capturing really relevant? Does it have direct clinical relevance? How do you clean it? How do you interpret it? And how do you translate it into use? Every day, there seems to be a new conference around the AI in healthcare or AI in pharma, AI in any industry. I think we're now at the point where the real leap will be translating those insights and validating those insights into actual use. Once we are able to overcome that barrier, it will become very much mainstream.

Taren: Excellent. And so what kinds of technologies are you working on now that can help us better understand the science behind the human response to illness and treatment? Is it basically capturing those insights in a person-to-person or is technology really going to be a driver of this?

Laura: Well, it's both. So you need the tool to be able to cut the mechanism to which you are able to obtain the data. The closer you are to the patient, probably the more accurate the data, the more you will be able to understand or characterize their response to treatment. So a lot of the AI today sits on structured datasets like electronic health records or other large datasets that really are a derivative of patient performance or operational performance, but they are not a direct observed data point from the patient.

So what we set out to do is try and capture the patient in their moment where they're at, either when they're taking their medicine or being able to directly assess how they look as they take their medicine or some questions in their own environment, to get a much more realistic and

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objective view on how they are living their treatment and their illness, to be able to better understand what it means to them specifically. Once you start being able to capture the data on an individual basis, personally you can calibrate it, you can annotate it, you can structure it, and then you can start to articulate what you're seeing. And it's how we articulate the value of the data that is particularly important in connecting how patients respond to almost new treatment. The AI component of that is twofold, one is just helping to scale the very capture of the data themselves and the second component is the algorithm, providing the insights that lie on top of the structured datasets.

Taren: It's exciting. So what are some of the most exciting outcomes you're seeing from the technology or you're doing with AiCure?

Laura: Right now, what's really exciting is, it's taking years and years to build these huge datasets that we've accumulated across 50 plus trials, many sponsors, different types of trial designs, large patient populations. Once you start growing these datasets, you can start to better see how they all fit together. Typically, what we've seen in pharma is a lot of these datasets are quite siloed. They're interested in the patients and then some other stakeholder is interested in high performance and yet another stakeholder may be interested in the statistical value of the data that is a very siloed lens. What we're trying to do is aggregate these datasets and really present this 360 view of the trial itself or even at the portfolio of performance and all of these datasets feed into each other. It gives them much more nuanced view and a much more accurate view on how the trial is doing and how it's progressing.

I think where AI comes into it is, you can start to model what something may look like without even having to run the trial. So an example of this is we've been running a lot of CNS trials in one indication, particularly in ADHD, and we've recently started an ADHD trial, but we've had so much data already in these patient populations from the patients themselves to the sites, to the performance of the site that we were able to model ahead of time what the trial might look like. And you can only do that once you've accumulated enough data and you've annotated and structured it to make it really be search grade, and that's exactly what we're doing.

Taren: That's exciting. Are clients coming on board? Are they seeing that this could potentially be revolutionary for them?

Laura: They are. They're realizing that these sites are absolutely necessary. I think we're just shining. It's not revolutionary in the sense that these data and these risk points have always been there, but we're able to now shine a light on them. And if you can see them, you can quantify them and you can build them into how you operationalize your programs and I think that's what revolutionaries at.

If you take an industry like finance, the idea of the hedging risks is absolutely central to the way the financial markets behave and one of the ways you have to risk is be able to quantify it and define very specific instruments to hedge that risk. But in pharma, those instruments have not

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really been available yet. At the pre-clinical stage, everything is done to avoid risks and they only move from pre-clinical to clinical once they're really quite certain of how the drug works. But once the compound moves into clinical stage, suddenly they expose themselves to an enormous amount of risks. A lot of it is because while, yes, the compounds are tested within the confines of clinical trial, it really is a real world environment. The patients are mostly at home. It's on the outpatient basis. The sites function in the real world and all of the variants that comes from being in the real world presents risks and is brought in to the trials. So I think if we can pinpoint all of those risks in real time, we can give pharma the tools to hedge them and that is a very good concept.

Taren: That is very exciting. So thank you so much for sharing that information with me. I don't know if you get too much involved in the STEM movement, but I'd like to talk to you about technology since your company is really going forward with new technologies and looking at how technologies going to change the landscape. Do you have programs within the company that address how maybe STEM can be brought to a broader field of girls and how industry can incentivize more girls to move into the field of technology?

Laura: Yes, for me, this idea of STEM where pharma is at today feels like where finance is at. Years, back, I remember when I was at UBS, you had a trading floor with 700 people and then 12 women. At still at the executive level, there is a dearth of women in pharma. And what I found in finance was one of the barriers was that there was just a lot of use of jargon. The concepts themselves were simple. It was quite a binary motion. The markets went up, they went down, but there was an enormous amount of jargon and it gave a false sense that you required a lot of expertise to be able to give value in these areas. But once you stripped down the concepts and stripped them free of the jargon, you realize that things actually got much more interesting and more nuanced. And I think that as women enter the tech industries, I think there's a lot of room to broaden these STEM fields.

While it is the application of science and math, I think the applications really target human behavior or the real world functioning, those require much broader lens. And I think if we can only encourage women to enter a field that may, at the outset, seem like it's very binary and even simplistic in some way just because it's applying math or models to characterize environments, but I think if we can bring women in to broaden how we view these fields, it will be much richer.

And that's where we're seeing is women – more and more women enter the tech field and even finance, the insights are that much richer. Our algorithms are only as good as the datasets that go into them or in the interpretation of those datasets. If the datasets only include half the world population, the extent to which that are generalizable or even correct is questionable. So it's imperative to bring in the other half of the world into what's becoming a very important tool across all industries, AI or STEM, and even more so AI.

Taren: Excellent. Well, thank you so much. I love that. Some of this is just based on jargon and the nomenclature and the words that we use that create some of that gender gap. So that's an interesting insight. Thank you. And so talk to me about how you define success for yourself. You've had a very successful career. It's been multifaceted. When you look back and think about what you've done, how do you define success for yourself?

Laura: I think it's more of balance than success. I think personally, it's hard to define, but balance across the environments in which I function, I think that it could be work, it could be family, the broader environment, living in the US at this particular time. While sometimes, any one of those components may take over. If success is the right word, I feel most at ease or most balanced when there's a certain equilibrium and sometimes it's difficult to find, but I think it's essential for success to not overtaking any one single area.

Taren: I like how you use that it was equilibrium rather than balance and I think we hear so many women talk about having that work-life balance, but I like that term equilibrium better because it has a broader application to one's whole life.

Laura: Yeah, I think it's equilibrium also, for me, it allows for the concept of change. The equilibrium may change. The variables that enter into the equilibrium may change, and their ways may change over time as you step from one day into the next. But it is always the sense of equilibrium and if it's not there, I find that it can negatively impact any corner of your life, but it's not easy to achieve.

Taren: No.

Laura: I think you can strive towards it. And different people need different equilibria in different ratios. And I think it's recognizing that that equilibrium is different for everybody is extremely important in the culture and how we work and how a company function.

Taren: Excellent. Finally, can you identify one wow moment from your career that either impacted you or changed your trajectory of where you were going?

Laura: Actually and coincidentally, we had a full board meeting this morning in the offices and then I presented a lot of the ideas that have been growing for years in the company that we've all been spending many, many hours working on, brainstorming on, talking through, really trying to understand how all these datasets relate to each other, so years and years of work. I placed hard work because pioneering in the areas that at first may not seem obvious in the pharmaceutical industry and I presented a lot of those ideas this morning and it culminated into a real validation of a direction that we need to go in and it was incredibly satisfying and it was 10 years in the making. Yes, actually that was my wow moment just this morning.

Taren: Congratulations. I feel that this is a perfect time for our conversation. That's wonderful.

Laura: It's perfect.

Taren: Well, congratulations to you and congratulations to the company for 10 years of success, and I wish you continued success, and thank you so much for sharing so many of your insights with us. It's been a delight to speak with you.

Laura: Taren, thank you.

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