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I'm Deepti Babu, certified genetic counselor and NSGC member. A quick note that I'm very excited to share with you. For 2020 I'll be hosting the Genetic Counselors and You Podcast, so every two months we're continuing to bring experts in to help break down complex topics in genetics that are making people curious, with the goal of turning that curiosity into knowledge that you can apply in your own lives. If you have an idea for a topic that you would like us to explore, please email the show.

It seems that new at-home genetic tests hit the market all the time. In response to consumer interest and demand, but is that changing? In January of this year, two major at-home genetic testing companies laid off staff in a response to a slowdown in sales. If this is a real trend, why is it happening? Well, one possible contributor is increasing concerns from consumers about the security and privacy of their genetic information with these at-home tests.

Today we're talking with an expert who can give you insights to help you separate fact from fiction. Before we get started, we wanted to acknowledge the challenging and surreal times that we're all in with the Coronavirus pandemic going on right now. We hope that you're staying healthy and staying safe and thank you for listening, because time is trickier to manage these days than ever before.

Okay. Onto today's episode, we're talking with Dawn Barry, the president and co founder of B Corp, LunaPBC who launched LunaDNA, a community owned platform for health research. Dawn has done a lot of thinking about health data sharing, community ownership, and a person's control over their data. Welcome, Dawn, and thank you for joining us.

Thank you so much for having me.

I wanted to say off the top that we're talking about at-home genetic tests today. These are not the tests that you might get through your healthcare provider and the healthcare system. Those tests might be used to diagnose a genetic condition, or your risk for one, and those are very separate from the conversations that Dawn and I are going to have today. With that in mind, it's interesting to see how popular at-home genetic tests have been and actually how that might be leveling off. Do you think that bubble is bursting?

It's interesting. We've had a, certainly a long run of these direct to consumer genetic testings that are not of the clinical variety. I believe the market started in about 2013. And really took off in 2018, 2019. I think it's safe to say that we may have plateaued out in terms of that demand. And some of the contributors that we've heard about have been people's fear of learning they have a genetic disease. To insurance discrimination, understanding family secrets that they otherwise wouldn't have wanted to learn. Certainly challenging family perceptions and nationality perceptions. But I think there's also a case to be made for perhaps the recent law enforcement uses of those databases, as well as the sheer fact that perhaps we're just running out of a certain percentage of the population that has that discretionary income to spend on these tests. I do think there is a case that we are plateauing out in terms of demand for a product that's more of the entertainment variety than as you described, of the clinical variety.

Can you dig to this issue about privacy? Because I know that's something that you in particular have spent a lot of time thinking about and doing good work about.

In the case of any innovation, you don't really know what questions to ask and I think in the more recent years it's become more clear, this notion of you are the product. That and the companies that do sell these direct to consumer DNA testing kits are also selling the de-identified data. The increased recognition that can genetic data really be de-identified? I mean if it's being used in law enforcement, is inherently identifying characteristic. And even if, if there is consent for that is it being used for the

research purposes that you intended. And so these are some of the implications when people think about privacy, is my identity being protected? Is the intent for which I shared it being honored? And are copies of my data being propagated such that even if it is de-identified, and I say that in air quotes, is the data then also creating copies in other people's hands that aren't honoring the same policies. So I think what we're seeing is a heightened awareness of these further considerations that are downstream of just getting that report and learning about health clues and ancestry.

I mean I recognize that there is an increasing awareness and I'm really grateful for it as a genetic counselor. This is something that we talk about with families when we talk about genetic testing in the healthcare system, for which there are laws in place to allow for privacy to be maintained as much as possible. But I do think the average person really doesn't have a sense of that possibility of their DNA being used and shared without their permission.

I would agree with that. And I think just the implications of that privacy. There's genome protections for health insurance and employment discrimination, but there still are open spaces in various states for life insurance, disability, longterm care. If you're part of an employer, less than 15 people, the protections in those categories still do lack. And I'm not sure there is a complete awareness of that.

So for the at-home category of testing really kind of all bets are off in terms of that. Because there really are no legislation frameworks in place to protect people's privacy. Is that based upon whatever the company's policy is then?

Yeah, you've got to look through privacy policies, terms of use, and consent documents. That can be quite a lot to read through just in terms of the breadth of content, but then the ability to truly comprehend what all of that means can be very overwhelming. And I do think some folks perhaps just click through to I agree, without taking the time to fully read and comprehend what all of that means. Especially when a product is very popular and people are talking about it. There's a, maybe you're less diligent when you see the wave of consumers purchasing these products, but they really should be read and understood.

And it is really tricky to understand them. Legalese is not most people's first language.

Absolutely.

I wanted to bring up this Paris poll that your company had commissioned in February. It said roughly a quarter of the people that participated were concerned about the fact that their insurance company could access results. Now this is for at-home testing. That's a significant amount of people who were concerned about their privacy then. I imagine that's going up now.

Yeah, there's concern about a quarter of the respondents were concerned about finding that they carry a genetic disease. About a quarter of the respondents, as you mentioned, were concerned about insurance discrimination. Others, I think about 20%, were concerned about uncovering family secrets, or law enforcement using the information. And then about 17 to 15% were worried about their information being used to make a clone, as well as their nationality being challenged. And I think we giggle when we think about clones, but there are some companies that do keep residual specimen on file. And so it's, I believe people, they know that it's more than just a file or a digital copy of their data that might be stored, and that can be extrapolated to think, if my specimen still is on file, what could be done with that physical specimen?

Thinking about the golden state killer being identified because of information used that was allowing for DNA matches to occur from ancestry based data, that law enforcement had access to, which was for the purposes of their investigation. But the people who provided that sample were not intending that purpose when they did it.

That's correct. And, those, the law enforcement teams are doing what consumers are doing, which is looking for mathematical matches between others in the database. So this idea of creating communities within the consumers of that product to see if you can find relatives. Those law enforcement folks are just using it to do the same, just matching the specimen left behind at a crime scene and saying, does this crime scene have any relatives in the database? It's certainly the technical use of those platforms, but probably not the intended use, when people came to those platforms to think that would be the purpose.

Have companies started to adjust their policies to build more language around this?

Yeah, I would say they're being much more clear about that as a possible use case for the platform. So one in particular, Family Tree has come out very strong that they think this is a good use of the database. And the CEO is very proud that they've helped solve some major cold cases because of it. And so I think they're being extremely clear that this is their stance and they support the use of this. And if you go to their webpage, you can see there's even support pages for folks that are used in law enforcement. And I think you can agree with that or disagree with that. But the point is they're being very transparent and upfront, and clear and people can make the choice if that's the right product for them. So I think that's the right thing to be as transparent as they're being.

The reason why you're doing the test needs to match with what the company is intending to do with your data.

Absolutely. A lot of the companies talk about the opportunity to contribute to the understanding of disease and that's the intended use. When people click the button, sure, I'll support research. But does that extend to extreme inbreeding studies, or behavioral studies, or research into gay genes? Is that what people understand to be the intended use? And does that align with the reason for being of the entity for which you participated in a product? I think these have to always be continuously aligned and checked for clarity.

Absolutely. And there's so much we don't know and that's actually what I love about genetics and partly what led me to join the field of genetic counseling. Is because I knew I was never going to be bored. I mean it is constantly evolving and no pun... Maybe pun intended, but that also means we potentially uncover new learnings and findings with every question we ask. I think another point you brought up was really interesting, which is not everybody feels the same about all parts of the data that could be learned. They might be really comfortable if it's a medical trait, they might be less comfortable if it's a personality trait. Have you found that in your research and the work that you've done with consumers?

Certainly, being in the genetics equipment space for as long as I have, and seen the birth of the direct to movement. And reading the stories of incidental findings, that I bought this product thinking I would get one experience and I really got another. I think that the best practices around purchasing these products, really understanding first you, what do I want to learn from this product? What do I really want to learn, and what do I not want to learn? And then to not buy something based on how popular it is. Really understand yourself and your goals, and I guess your fears or the things you just don't want to learn about. And take the time to look into that deeper detail. I think a good product, for example, won't put a propensity or a risk in front of you. That's something that should never fly up in front of you without knowing, the consequences of learning that information. And also, and why I appreciate NSGC, is it's really engaged the experts here.

There's great resources that you guys have and there's also great genetic counseling resources to help you on this journey of self discovery. So do your research, read the fine print, and most importantly understand the answers that you're trying to achieve in pursuing such a purchase.

The Aboutgeneticcounselors.com website is a great place to go to explore a lot of those things that Dawn just mentioned. So thank you for the plug. So I want to talk a little bit about your company's business model. And what got you revved up to co-create this company.

I spent, gosh, 12 years at Illumina, which is one of the most prominent DNA sequencing companies in the world. And got into that space because always believed in health and quality of life advancements through science. And after many years working there, making the generation of DNA data less expensive, faster, higher quality. Just became frustrated that we weren't seeing the same velocity in discoveries.

And then observing that are behaviors around data, specifically data siloing, institutional, geographically et cetera, was really hindering the ability for research to achieve that scope, scale, depth, diversity, longitudinality, that we all need makes for statistically robust research. And is required by tools like AI to solve those discoveries that we really want to see. And recognize that in this increasingly digital world and with the legal rights of access to data that so many pioneers have fought for us for, that people really are the missing piece in discovery. And so with that in mind, started Luna towards the goal of, we like to say promoting people from subjects of research to partners in discovery. Giving one a place where their privacy is protected, where they have true control over their data, where they have the transparency to contribute their data for research and of life advancements, in a way where their data stays in the system and research comes to the data.

So we believe in the ability for research to be much more expeditiously and efficiently conducted. But we also believe in the power of people and their valuable data to advance medical discovery. And especially in the backdrop of COVID, the ability to do these studies as digitally as possible, leaving people in their homes to participate in research and not always have to come to a clinic to check in for studies. So COVID really demonstrates that self-reported, people permission, digitally collected, privacy protected data can really make a difference in discovery.

I think I've heard you use the word inversion. Going from the typical kind of a model in a research study where the individual is a participant to sort of driving and furthering that process. Can you tell us what that looks like? When you talk about the ways that these individuals can sort of control the sharing of their data with your platform?

We typically wait for a research question to arise, and then a grant to come, and then a budget so that people can be recruited and data can be generated. And that data, maybe it's shared, maybe it's not, maybe it's published, maybe it's not. And it's a very linear process that gets truncated at the end of that process. And we've heard the term data is the new oil, it should be data's the new renewable resource. We should be able to generate data once, and have it be used over and over again. And ideally that data being more valuable as it's further contextualized. And so the inversion is really recognizing people and their ability to permission their data, the ability for them to allow as many research questions to come to the data as possible. That follows along a charter for health and quality of life advancements. Full stop, nothing beyond that.

IRB approved research to come to that data, at an aggregate de-identified level. And then for the ability for those folks who have opted in to be able to be contacted for other research studies that may require a little more granularity about them, about data that they need to share. The thesis is really if we can bring people together in aggregated, organized, properly structured and permission data, could we get to the point where we're just waiting for questions to come to the data, versus waiting for an interest in questions to happen?

The individual can choose to put their anonymized, de-identified data into the platform and then when a researcher or some other group would like to access data, that might be part of a group that fits into their particular interest, that individual gets to say yes or no.

The first discovery, at a de-identified aggregate level, that's IRB approved. That's the inherent permissions when people come in.

Okay.

The opt-in is for them to participate more in a study that requires perhaps for them to do additional surveys, or maybe the opportunity to have, get a kit and do a microbiome study. Or potentially the opportunity to enroll in a clinical trial. At that time, and if they wish, they can take those choices or not, identify themselves or not. These are the things that the system does. We don't put ourselves in the middle of that. The system is organized to enable that type of communication and opting in or not opting in.

The theme that I'm hearing from you through all of those interactions is control. And in that case it's the control that the individual has. Whether they were exerting that at the beginning when they chose to engage with the platform, or later on. That's particularly resonating with me right now in this pandemic time because it feels like so many things are out of our control.

As an industry with GDPR and CCPA, these are the privacy protection laws coming from Europe and from California, that are really enforcing one's ability to clearly understand where their data is being stored, why it's being stored, an understanding of what is being stored, and the ability to get that data un-stored if they wish. That's a great first step in our platform, people and only people, so not institutions on behalf of people, but people, permission a single copy of their data, whether that's electronic health records, DNA, self-reported data, et cetera. That single copy is under their control in the system. They can delete themselves and that file at any time, and questions come to the data and only answers leave. And so that in addition to the oversight of the platform, the ownership that people can take in the platform through data sharing, these are all elements of control, so that's it's transparent and so that the promise we make can never be changed.

Well, I think you're leading me right to what I kind of wanted you to sum up for us here is how do we turn these into takeaways for folks?

Yeah. So I think in terms of the empowered consumer to read that fine print. And here's a hack. If it's too long and you're not getting through it, I think any platform worth their salt has a little talk bubble in the corner that you can chat with somebody and get your question answered from a live human. If the documents are just too long or too legalese. Ask the questions: am I clear and the intent of this institution? How is my data being stored? Who has access to it? Can I get my data out of that system if I want to? Is my data staying in that platform? Are other people getting a copy of it? And then decide if that is right for you.

Some of these companies offer consultation with a genetic counselor, and that could be something that you consider, if you can get it before the testing is done, just to sort of have that individual really flesh out things for you.

And if you've already purchased that product, go back to the website where your profile is held, and make sure that what you opted into or have been opted into is still what you wish. I would also say, health data has value and it can be used to accelerate medical discovery. So download those files so you have... Whatever's being stored, you have a right to a copy too. So in the case of consumer DNA testing, get a copy of that DNA file. There are telegenetic counselors that may be able to grab some clues. You can't practice medicine off of those files, of course, but there may be some insights from there that are worth following up on.

And so grab a copy of that file. It's not a huge file. And keep that one for yourself because it does have value and it can be used for other purposes, including contributing [inaudible 00:21:34] or discovery. Those are the things I would do.

Yeah, that's great. That's really nice, practical advice. Thank you for making that a bit easier for us. It's been a great conversation. I've really enjoyed it. Thank you for being with us, Dawn.

Thank you for the invitation. I really enjoyed the chat today.

Thank you for listening to this episode of Genetic Counselors and You. For more information about genetic counselors, and to access tools and resources mentioned in this episode, visit [Aboutgeneticcounselors.com](http://Aboutgeneticcounselors.com).