PSC Partners Patient Registry: Interview with North Star Review Board (Transcript)

Rachel Gomel: I am Rachel Gomel, the founder and director of the PSC Partners Patient Registry. The registry, which was the result of years of collaboration with the NIH, is celebrating its 10th anniversary this year. The registry currently houses data of 2,500 people with PSC and has the important mission of amplifying the patient voice and facilitating, expediting and driving PSC research. I'm joined today by BT, also from PSC Partners and Dr. Rosenfeld and Ms. Seymour from the North Star Review Board. Could you briefly introduce yourselves?

Stephen Rosenfeld: I'm Stephen Rosenfeld. I'm the Chair of the Review Board. We'll get into what that means later in our discussion. I'm trained as a hematologist and spent about 19 years at NIH. But for the past 16 years or so, I've been in the institutional review board or IRB space. Most of that time doing what I'm doing now, which is sort of overseeing the review boards.

Patricia Seymour: Hi everyone. My name is Pat Seymour, and I'm the Director of North Star Review Board, and I am the person that you would call if you have any questions. So I'm sure Rachel will share my contact information with you and I look forward to hearing from you. Thanks.

Brian Thorsen: Hi everyone. I'm Brian. I'm the Registry Analyst and Webmaster. So I manage the new registry site, keeping it updated with the latest news on the registry, including clinical trials in support with other registry communications. I also work as an analyst for the research arising from the de-identified information, which registry participants provide in the registry.

RG: Thank you. We're very excited to have you here with us today. The North Star Review Board is an important presence in the PSC Partners Patient Registry, as IRB review and approval are a requirement for every research initiative that involves interaction with patients.

With their team, Ms. Seymour and Dr. Rosenfeld have been the ones reviewing and annually monitoring every survey that you see in the PSC Partners Patient registry. Even though they're so present in the

registry, the IRB or Institutional Review Board often remains obscure and invisible to the most important registry users. That is, you, the participants and those who contribute their information for research.

I have a quick story to explain how North Star IRB became our valued research partners. Six years ago, at a large rare disease conference, I heard Pat Seymour speak about the true partnerships, their ethics board formed with rare disease organizations. After the session, Pat Seymour was instantly surrounded by a crowd of enthusiastic people who seemed somehow to know her intimately. I sought her to understand why their IRB provided what other IRBs did not. My conversation with her determined our move to North Star Review Board and to the start of a much-treasured partnership. To us Pat and Stephen at North Star represent the ultimate example of partnership between a rare disease organization like PSC Partners and an IRB where both entities have the safety and ethical protection of patients at heart.

We have prepared a few questions for you, Pat and Stephen. We're eager for our community to learn about your role as an ethics review board for the PSC Partners Registry and all patient-focused research. I'll start with the first question. **What were your reasons for founding an IRB? And how can you describe your role?**

SR: We'll probably ask that question of each other a lot during today's discussion. And before I talk about that, I just want to make one remark, which is, I think it's such a great thing that PSC Partners is doing this. Because the whole purpose, and we'll talk about this, the purpose, the reason, the mission of the IRB is to protect the interests of the people who are participating in research. And there's irony in the fact that most people don't even know that such a process or such institutions exist. And I think IRBs in general would be greatly improved if they actually had some accountability to the people they're supposed to protect. So I think this is a great first step. So that having been said, we founded IRBs... So let me give you a little bit of context. So most IRBs are associated with institutions like universities or hospitals, or our commercial for-profit companies. Academic and hospital IRBs typically review the research they do. For-Profit IRBs typically review research that's conducted by drug companies and medical device companies. And their review fees realistically reflect the resources available to industry.

We founded North Star really for two reasons. First, we really believe so, IRB stands for Institutional Review Board, it does not stand for independent review board. And I think that name is enshrined in regulations, so we're stuck with it. But if I went back, I think they should be independent. We believe North Star should be independent, any IRB should be independent of the institution conducting the research. There are lots of incentives that reward institutions simply for doing research. And this creates unavoidable conflicts of interest for IRBs that are made up of employees and researchers mostly from that institution. For-profit IRBs have comparable conflicts. Their success depends on the profit they make on reviews, and that means they have to have a very strong incentive to please the people who are submitting studies to them, which is the industry sponsors.

Again, you, as research participants get left out of all of this, which is really why we felt that the IRB should sit apart and should be structurally able to make decisions through recommendations in the best interest of participants. I think the other reason is that there are a lot of smaller foundations and other entities that are not in institutions, things like PSC Partners, that don't have the resources available to pharmaceutical companies. So they don't have access to institutional IRBs, and the commercial for-profit IRBs really don't have a fee schedule that's appropriate to their resources. Which just means that, that's a showstopper for important research that needs to be done. So given the importance of conducting research ethically and in compliance with research regulations, in all research, we felt there was a need for an IRB that could help such entities. Pat, do you want to add?

PS: Another very important aspect of this is that, for IRBs that are very large and are serving big companies, like all the sponsors who do biological research or biomedicine, when they have a study that they submit, they don't necessarily need to ask any questions. But what I've found over the years is that, people in smaller organizations or entities don't often know what the IRB process is, and then they're kind of stuck because they don't have anybody to talk to about, "Well, what should I do about this? Or can I have a study that includes that?"

So it's always been very important to me to patiently answer questions of anybody who asks them. And I think that is something that's been lost in our present space, and I believe very strongly that I want to be available to people who are new to research or people

don't have a lot of experience, and especially to participants who might have questions and they're very intimidated by some of these big companies. So for the most part, if somebody contacts North Star, they'll contact me and then I'll find answers if I don't have them. So that's another thing that I really like about what we do, is that we're real people with real lives and you're free to reach out to us on any basis that you want to.

SR: I'll add one thing to that. So that's true for the researchers. So we try to explain why we make our decisions. We don't see ourselves as sort of a compliance thing, you can't do your research till we stamp a form. If you're asking us for how we evaluated a protocol or what our findings were, we take pains to explain it to you, to the researchers, because I think from the board's perspective, that builds trust and a sense of partnership.

BT: That transparency is so important in the research process, absolutely. **Just wondering, Pat and Dr. Rosenfeld, if you could speak a little more to what your specific roles are, what your day-to-day looks like in your jobs?**

PS: Sure, I'll start. My day-to-day looks like very much like this, talking to people. I get lots of emails, I get lots of phone calls, requests for meetings, and usually it's about, there are from people that just want to talk about their research and sometimes I do get participant calls and they come at all times of the day and night and that's perfectly fine. So mostly my role is to make sure that the operations are running as smoothly as possible and that we have enough support for our board to make the appropriate decisions and for them to be able to not worry about the nuts and bolts of getting a letter out or revising a consent.

So, that's mostly what I do, but what I like the best is talking to people and coming up with solutions. That's so much fun and it's so rewarding, because if I were at a big IRB and I've been to many and had different roles at IRBs, there's one person who does one job and another person does another job. So when you call, you might not get the right person, but when you call us, you tend to get the right person. Because there's very few of us, and we all work very closely together.

RG: **Other than you, are the people reviewing each study?**

SR: So, this gets into a little bit of regulatory stuff. So there are multiple levels of review that are dependent on how risky is, what the risks are presented by a study. So if we get a study that involves the drug or a device intervention, it goes to what's called the convene board. And we have a board of, I think it's almost 20 people now from all different spheres, I mean mostly biomedical. And we're actually planning to post that roster on our website because I think it really speaks to our strengths. If something is relatively low risk, like a registry. Or is submitted as a change to something we've already seen and the change is minor, it doesn't have to wait for a group of people to meet and for the minutes to be reviewed and for everybody to agreed. That level of complexity is only appropriate if it's justified by the risk.

So what I do is, if we have a high risk study and we have one of those meetings, I chair those meetings. And it's my responsibility to see that we are led to a conclusion that we agree upon and that responds to the requirements of the regulations and appropriately protects participants. If it's a low risk study or a minor change to anything, it goes through what's called expedited review, which means, one board member reviews it. And to be honest, most of the submissions to North Star fall into that category, at least to date.

I review many of those, so much of my time is spent actually doing the reviews. And I have to say along the lines of what Pat said, I think you can only be good at things that you love doing. And I've done a lot of different things. And one of the things that I love about being an IRB chair, is every study you get is an opportunity to learn and every recommendation you make goes to the human side of science. Which everybody has their own reasons for doing what they do, but I find that sort of the most interesting place of all. So I am not sure that's all responsive to your question, but.

RG: Yes it is.

BT: Could you elaborate on what makes a study or proposal high risk versus low risk?

SR: Sure. So some of it is obvious if you are doing something... So the way the regulations are written and it's my personal opinion, that they need to be revised, but that's not likely to happen anytime soon. But they were written traditionally, the whole history of research oversight, is about people getting hurt, primarily. That's really what gets people indignant and what is the source of why we have

regulations at all. So the highest levels of risk are those associated with physical harms and even unknown the potential for physical harm. So pretty much anything with a drug, unless that drug has been on the market for 20 years and it's being studied for an indication for which it's approved, would be considered high enough risk to go to a board.

Many of the things we deal with today, everything's changed, have to do with data collection and risks of data breaches and privacy and how people use or misuse your data. Use of AI, none of those things lead directly to physical harm, so they all fall very neatly into things that require much less rigor in review. That's the way it's set up. I'm not sure that that's appropriate anymore, but that's how it works. So most of the things, like registries, the risks to the people who contribute to the registries is that their data will be misused. They'll be identified from the data that we say is de-identified, but we know that you can combine credit card databases and phone records and re-identify almost anyone, if you want to. And so as part of our role is ensuring their protection's in place and at least are statements that people won't do that. The IRB sits outside, we can't in a study with physical contact and drugs administered and that sort of thing.

All we can do is make sure that the protocol says what it needs to say, the actual conduct of the study and whether people transgress what the protocol says is kind of out of our control, although we can react to it if we find out. So the best we can do with data is really to ensure that the protections are in place and that people you share data with have said they won't do this or that. But yeah.

PS: I think another risk that's not well understood is the risk of genomics. And Dr. Rosenfeld I think is the best person to talk about that. But I think people don't understand how, especially in the rare disease community, genetic testing can really reveal a lot more and a lot more easily about the identity of a person. So Dr. Rosenfeld, could you talk about that?

SR: Sure. Mean, so that just opens a door. I mean, again, the research regulations were written when things were pretty straightforward. Most research was interventional trials or observational non-medical research. And it was all about individual people. So the research regulations are written for the protection of individuals. You get into genomics and first there's the identification piece. I think we hear this in the news all the time, that someone was usually, it's a good story.

That someone who had committed some horrible crime was found 10 years later because a cousin submitted their DNA to 23andMe or Ancestry.com or something, and law enforcement has access to that and they put things together. But I think that speaks to the fact that, most of those people didn't even have genetic testing. In today's world, when you submit your biospecimen, your blood or your cheek swab for genetics, genomics, there's no question that at some level that identifies you.

For years, we put in our consent forms, and I'm not sure that this is really appropriate any longer in these days of gene therapy. We used to put language that says, "What are genes? Genes are what make you are and who you are." Well, if that's true, then they're obviously identifying. And quite frankly that regulations don't catch up with that. So we're very careful to make sure people know about that. There's one other piece that I think genomic research opens the door to. And that is the implications of a person's participation for everyone else in their family and in potentially their ancestry. So suddenly you are learning information that isn't restricted to that individual. And we have no official process to recognize that. I mean, you can't ask everyone for consent. I'm not sure other than telling people that this is what they're doing and letting them make that decision on behalf of the people to whom they're related or if they have children.

If you're a parent and you get a genetic test, you're learning a lot that's going to potentially color the lives of your children. And, I mean, gene therapy takes that to another level. But there are all sorts of interesting implications to that for which I don't think we have clear answers. So the best we can do is make sure they're openly discussed.

BT: There's an interesting point on the point of identifying information, even aside from bio data, if you have, for instance, I just looked this up. If you have the county, someone lives in their gender and their date of birth, that identifies 18% of the US population. When you add in that someone has a rare disease, it's a much narrower, you have to be really careful with what you're revealing and sharing with researchers in that case.

SR: So that doesn't mean that they will identify you. I mean, it's really important, that's absolutely true. And I think, with basic census data that's available to the public, you can re-identify an extraordinary proportion of people. So what we try to do is make sure people say they won't do that. That at least can't be the intent. And we're not

naive enough to think that that will never happen. I think data is a valuable product these days and there are lots of incentives to share and sell. But again, we need to make... And people, that's not necessarily a showstopper. People may want to make that... I think many, many people do want to make a contribution to research even knowing that, but they still need to know it.

RG: **And what are the rights of patients when they participate in a study? What can they expect?**

SR: I'll give you my, I mean there are regulations which say what you have to put in the consent form and all of that. And I don't think that's the right way to explain it. I mean, I think that the challenge to the role of the IRB is, you have investigators. Whether it's medicine or behavioral science, they typically know more about their field. We hope they know more about their field than people who are participating in their research and they are subjects to test something on. There's always going to be that disconnect. And when you get into medicine there further, there's the doctor-patient relationship. There are power structures in society. There are all sorts of things that make the researcher have an underappreciated-- I think, just from being a researcher-- level of influence over the participant. And so part of what the IRB does, is take what the researcher wants to do and write in the protocol and bring another set of eyes that represent the interest of the participants.

And that's not because the researchers are untrustworthy or covering things up or whatever, but they're scientists. That's what we want them to do. We want them to design good studies and ask great questions until IRBs were required, we trusted that they could also discharge conflicting duties to the humanity of the people they're working with. And I think the vast majority of them can, but it's sort of trust and verify. You trust the investigator, then you have a step to just make sure. And I think we don't see a lot of studies that would egregiously harm anyone really. I think investigators do a good job and are well-meaning, but every once in a while, they'll miss something because that's not what they're supposed to be thinking about. And so that's where we come in. So at some level it's sort of a paternalistic, or I guess what word is parentalistic now, role that we play mediating sort of this knowledge gap.

The other thing though is that when you get to the rights of participants. A study can be great, to answer a really important

scientific question. But that almost never justifies using people to answer it without their consent. And for them to say yes, they have to understand what they're getting into. And they may not have to understand the deep pathophysiologic models, they have to understand what it will mean to them in terms of the risks they take on, what benefits they might get, what burdens they'll take on. And we have to make sure it's very important that that information is shared neutrally and not with a bias towards participation. So, we make sure that the question that the investigator asks, is a reasonable thing to ask people to do. But then we also have to make sure that each person gets the information they need to decide whether or not to be part of that research, given their values, their background, their life experience, all of that, their socioeconomic status, they need to know what the impact is for them.

Even if we think it's a worthwhile study. That doesn't mean you should be part of it. You have to make that decision for yourself. The corollary to that is once you make that decision, it can't commit you for the rest of your life. I mean, you change, knowledge changes, your circumstances change, your health changes, you have the right to say, "I don't want to do this anymore." And so we have to make sure that where there's not risk involved, people can just step away whenever they want to. And we have to tell people, particularly in something like a registry, some registries retain the data, some registries will get rid of all the data they've accumulated thus far on a person who withdraws. People need to know that to make their decision. And then if it is something that could hurt, if someone is on a drug trial with safety monitoring and such and they choose to withdraw, that's their right. But there better be circumstances in place to provide them what they need to stay healthy if that happens. So it's complicated.

BT: On that note, I just wanted to share something for the PSC Partners Registry participants. If you have any questions about that, you want to no longer be a participant, just reach out to us and we can clear your information. We have information for that on our website. I'll have the link in the video.

SR: Pat, do you have anything to add?

PS: I would say the most important patient right, is that you have the right to say no. The person conducting the study isn't going to be mad at you. They're not going to change any of the relationship that you have with them. Sometimes, for example, with doctors, people say, "Well, if

my doctor says I should do it, then I guess I should." That's really not what research is about. So you have the right to ask questions. If you're reading something and it seems really complicated and you don't understand it, I would just plead with you, please ask questions. Don't just sign something or agree to a study that you don't understand or they use technical or legal terminology. And we work very hard on our consents and with our partners, our collaborators like PSC Partners, to make sure that the consents are understandable. But if you don't understand, you have to ask questions.

And you also have to, as Dr. Rosenfeld pointed out, if you just can't do it anymore, it just doesn't work for you, you can always just withdraw. And again, nobody's going to be mad at you, there's not going to be any consequences, there's no negative consequences about it. Sometimes the data is kept, sometimes it's discarded completely, so it's all up to you. I mean, you have more power in authority than you might believe.

I know sometimes when you're in a situation where there's a medical issue and you're seeing a lot of doctors or you need a lot of help, it doesn't seem as if you have that kind of right because you're so dependent on other people for help. But in the case of research, you always have the right to say no, to ask questions and to withdraw.

SR: And I would just add, yeah, I hope it doesn't happen with the consent form that we produce. But if we start to review complicated interventional trials, it might. Consent forms can be 40 years-- 40 years? It doesn't take you that long to read them. Can be 40 pages long and full of arcane terminology. They can be organized so that they meet certain compliance requirements, obviously. And so there'll be sections that don't make any sense to you as a participant, but have to be there or the information has to be there and they're written so that the reviewing IRB knows it's there-- not so they're more transparent to participants. So if you are faced, and unfortunately this circumstance happens typically when people are sick, and they're faced with this document that they don't want to read because they want to move on with things. And I would just encourage you, the answer to that is whatever is in the document, it's that conversation you have with the researcher that should leave you feeling you really understand what's going on.

So if there's anything that's opaque to you in a consent, in any study, an interventional trial, a drug trial, a survey, if there's something in the

consent that you don't understand ask, it is really the obligation of the doctor, the researcher, whatever, to make sure you really understand and choose to do this with your eyes open.

RG: And how would people connect with you if they have a concern about a study and they want to go beyond us, for example, they want to reach you the authority to understand?

PS: Well, the information on how to contact us is always in the consent. So there's an info at northstarreviewboard.org and some consents have a phone number. That phone number is actually an answering service, but it rings through to me. So honestly, I am available anytime. So please feel free to use that information and contact us. I'll get right back to you with an email or a return phone call if you leave a message.

RG: It is on our consent form.

BT: So just speaking back to the adjustments that you might make, the "trust but verify", what are you looking for when you're reviewing research? Do you have an example maybe for a survey or something where you would intervene to make something more patient friendly, more protecting the patient's rights and privacy?

SR: Well, I think we're looking for some things. Here's what we're looking for. So first of all, the question has to be worth asking. It's a waste of everybody's time and money and resources and everything else to ask a question that if you answer it or if it's already been answered, that's probably more common thing. Is not going to make any difference. So, I think that's the first bar. And then, every study involves some inconvenience, at least to research participants, whether it's taking half an hour to fill out a survey and putting their data potentially at risk or whether it's taking an experimental drug.

And so those different levels of risk and burden have to be balanced by the importance of the question. It's fine to do a SurveyMonkey survey to answer a question that's sort of interesting but not impactful. It's a totally different thing when you're giving someone an intervention that could harm them. Or asking questions that could put them at, if revealed could put them at risk of losing their job or social stigma. So, we have to have, what we're looking for is a balance. The question and the likelihood of answering it. So it's not just the importance of the question, it's how well the study is designed.

Because studies may great questions, if they're designed in a way that you can't answer the question, it's useless.

That's the piece on the research side. I think for participants, we want to make sure, again, get back to that idea. We want to make sure that if you're asked to participate in a research study, it's a reasonable ask. Doesn't mean everybody should do it, doesn't mean anything like that, it just means it's worth asking people. That's the first bar and that's where that science piece comes in. We also have to make sure... Science in its best state is curiosity driven. And we've certainly seen protocols where, I think in all our roles outside North Star too, scientists are data hungry. And when you get to medicine, data collection sometimes involves interventions and invasive things. So we have to make sure that the things that we do to people are only in service, or things we ask people to allow us to do to them, are only in service of what the protocol says.

You can't take a piece of the liver and store it for future research without any idea just because you're in there anyway. It is that kind of thing. And that's not to say you can't have biobanking, there are ways to do that, but there have to be real reasons to do it. And that's very common. And again, it's driven by the fact that, scientists are curious and they know they're going to have new ideas tomorrow, and that's just how it works. And we want them to think like that, but we have to get in their way in certain circumstances. And then I think the other piece is, what's in the consent form? We have to make sure people... And not only what's in the consent form, but how that, what that opportunity is like to discuss what's in the consent form and how it'll be presented to people.

We often go back and forth when we get a new study and we ask people to say explicitly things that they didn't even think to put in the protocol, because we can't tell. I think it's rare for us to ask for changes in the protocol. It's not rare for us to ask for changes in the consent form. Pat, would you say that's accurate?

PS: Yes, I agree.

RG: **How are you working with the PSC Partners Patient Registry to protect Registry participants?** We say something, but you could explain it much better.

SR: Well, so everything we just talked about, but I think it gets to another point. I mean, we have reviewed and approved the registry in transfer several years ago. We have an ongoing responsibility. So, it used to be, that all research, you had to come back to the researchers every year and say, "What's happened?" Are there changes? How many people have you recruited? Are things going as planned? Because there are things that are informed by that. If a study anticipates that to answer its question, and this is much less true of registries, but bear with me, that they need 100 patients a year and they get five, then you have to go back. Because those five patients and the five patients they're going to get next year are really being asked to enroll in a study that can't answer the questions that it seeks to ask.

So that's less of an issue with registries, particularly rare disease registries. PSC Partners, for a rare disease registry, is pretty large. There are diseases that have 200 people worldwide affected, and those registries are going to be very, very small. So that's less of an issue. And in fact, the regulations were changed in 2018, so that if you're a low risk study, you don't even have to do that. We don't have to ask you. We ask you anyway because we think that that's an important thing to check in every year. I think it's less about, there are a couple of things we want to know. Yes, we want to know if you're recruiting, but again, that's not a big thing for a registry. We want to know if anyone's withdrawn and why. So people may just withdraw because it's a burden, people may withdraw because they had a bad experience, people may withdraw because they feel used by the researchers.

So we want to know that because we can ask the researchers to... We can require changes to the protocol and the way the research is conducted if we see things like that. The other thing we ask for typically every year, because we see hundreds of protocols all on different diseases, we don't take on the burden ourselves of keeping up with that literature, I think it would be impossible. So we ask the studies that we review to tell us if there've been any changes in the science in the past year or if the registry is published. So this is another thing that I think we do, but I'm not sure other IRBs do. I think when a study we oversee, like a registry, if the registry leads to publications, I want our board members to see those publications, because I think it closes the loop. They're all reviewing the science, and I think it's not a patient rights issue, but it's an IRB issue. I think, they should feel included in the conduct of the study and its outcomes. Pat, anything I forgot.

PS: I think that, one of the things that we do is that we serve as a resource for Rachel and Brian. And that's important too, because they're representing you as the patient and your families. And sometimes they're not sure if a path that they're considering is ethical or is it according to regulations? But both of them always have the ability to email us or call us. And Dr. Rosenfeld and I, for example, are often on the phone with many of our clients, our registries, to give them advice to kind of do a reality check both ways, we learn a lot from them too. And so that resource is very important because it keeps all of us communicating, it keeps us on the same team. And it builds that trust, I think that's so important. And I think that's something that we're pretty proud of because there's very, very few IRBs where the clients can actually get on the phone with the executive chairperson on a regular basis. And our clients really appreciate that and have come to depend on us for that service.

SR: And as Pat says, we both learn, both sides learn from that. I mean, I have to say, not at North Star, but in previous roles, similar roles at other IRBs, you'll go back and forth with emails that will say, we need this, we need that, we need this because this. And people ask why and why isn't this sufficient? And once it gets to a certain point, you schedule a call and it typically takes 10 minutes and it would save so much time from the beginning and be so much more respectful, anyway.

PS: In fact, in some of our letters that we said to the researchers will say, "This might be best answered by a phone call." So that we really want to be part of a solution and not just perpetuate this ongoing exchange of information that's not getting us anywhere. It saves time for everybody and it brings you the study or the survey to the patients or participants much more quickly.

BT: This has been fantastic, Pat and Stephen. **Is there anything else you'd like to add about your work?**

SR: I'll go back for a moment to our reasons for founding North Star, which are really, one way to look at it is to try to let us make decisions outside of structural conflicts of interest. So I would just encourage you, and certainly anyone who's participating in a study, whether it's reviewed by us or someone else. Every IRB has the obligation to be responsive to you. So if you don't understand why something is being

done, those conflicts or structural conflicts are real. I think we have less of them than anyone else, but they're real for everybody.

And if you feel like someone is not serving your interests, you should ask. You should push back and you should call the IRB. I think it's the Declaration of Helsinki, which is sort of a foundational international medical ethics document, has a line, and I'm not going to quote it verbatim because I'll make a mistake, but it basically says, "The goal of research is the advancement of knowledge. But that can never take precedent over the rights and interests of the research participants." And I think that's just really important. And you as a research participant, should not be intimidated by the institutions of science and medicine.

PS: Well said.

BT: Well, thank you so much, Dr. Rosenfeld, and Seymour for joining us today. It's really been a pleasure learning about your work. On behalf of the Registry Team, we're really grateful for all that you do to support the Registry's work and protect the rights of registry participants.

PS: Thank you.

SR: Thank you. We're doing the things we love to do. I hope it's true for you guys too.

BT: Absolutely. Yeah.

RG: I echo Brian's words of gratitude to you for joining our community to explain how you protect people with PSC who contribute to research. And if you, the audience, haven't visited pscpartnersregistry.org, you'll find it to be a most valuable educational resource. The website will show you the importance of participating in the PSC Partners Patient Registry, and in being a crucial voice in the search for solutions for this rare disease. Thank you.

BT: And if you have any questions, don't hesitate to reach out to us. And Pat sounds like you're more than ready to be available with questions too.

PS: I am.

BT: We'll have your information too. Yeah.

PS: Yes. We'll work together to get your answers.

SR: And thank you for the opportunity to talk to the participant community. Because we very rarely get that, and I think it's really important.

PS: I think we should have a group hug.

SR: There should be a Zoom thing for that.

PS: Yeah. Thank you everybody.

SR: All right, thank you.

RG: Thank you.