



Actionable Advice and Resources for Knocking Down Obstacles to Trial Participation

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Andrew Schorr:

Hello from Carlsbad, California, near San Diego. I'm Andrew Schorr from Patient Power. Welcome to today's Patient Empowerment Network program, clinical trials myth busters and actionable advice, resources for knocking down obstacles to trial participation. I wanna thank the companies that have provided financial support for this program. They have no editorial control, but we definitely thank them for their support. Those supporters are AbbVie Incorporated, Astellas, Celgene Corporation, and Novartis.

Okay. We have a lot to talk about. First of all, I'll just say I've been in two clinical trials; one Phase II many years ago at MD Anderson for the leukemia I have, chronic lymphocytic leukemia. And that gave me tomorrow's medicine today. It worked, but I had travel far to do it and there were costs involved.

And then I was in a second Phase III trial close to home, and that was good too, and discovered another cancer that I have, myelofibrosis, through the monitoring in the trial. So, I'm a believer, but there are obstacles, and let's talk about some of these. And we're gonna give you some very specific resources to overcome these obstacles, so that hopefully, if a clinical trial is right for you, you can participate, you can feel good about it, and you can move medical science along to help everyone who is dealing with that condition.

So, what are some of the issues? Financial, of course; logistical issues, of course; distrust, are they really gonna take care of you or are they gonna protect your safety? Is it really right? And are you being given the straight scoop? What about travel costs? I went from Seattle to Houston, Texas a few times. Costly, okay? Stay in a hotel. It's costly. Get a babysitter, leave work; costly.

The guinea pig syndrome; you've heard about it so many times. Are they gonna experiment on you, and are they really protecting you, and are you a number, or you are a person with cancer, or your loved one? And then is your medical team that you're talking to about your treatment, are they informed about clinical trials? Or are they pooh-poohing clinical trials because they don't wanna do the paperwork, or it's happening down the road and not at their clinic. Lots of issues; we'll talk about that.

Okay, I got some great helpers. So, first let's go to Asheville, North Carolina, and you used to live in Charlotte. Reina Weiner joins us. Reina, welcome to our program today. There we go. Say that again, Reina, you were muted.

Reiner Weiner:

Thank you.

Andrew Schorr:

Okay. Now we should tell you that last June, well, June of 2017, Reina had a autologous transplant for multiple myeloma. And along the way, leading up to that, over many years she was in four trials. So, first of all, Reina, let's start with what's most important. Post-transplant, how are you feeling today?

Reiner Weiner:

I'm feeling very well. Thank you, Andrew.cis

Andrew Schorr:

Okay, and what's coming up at the beginning of September?

Reiner Weiner:

What is coming up at the—oh, a big party is coming up. Our children are throwing us our 50th wedding anniversary party, so that's been cool.

Andrew Schorr:

Yeah. Well, congratulations. And you've been dealing with what became multiple myeloma since 1999. We're gonna come back and track that in a minute, as far as the steps along the way, the concerns you had or not at different times about being in four clinical trials.

And now let's go up near San Francisco in the East Bay of San Francisco Bay, Danville, California. Dana Dornsife. And Dana is the Chairman of the Lazarex Cancer Foundation. Dana, thank you so much for being with us.

Dana Dornsife:

Thank you, Andrew.

Andrew Schorr:

Okay. Now ladies and gentlemen, I want you to know Dana and her husband and her family, overall, they're incredibly philanthropic across a number of issues that are faced globally, and also in the US. But one of them is helping people with the financial issues that prevent them from being a clinical trial. So, Dana, this is a personal story for you, so maybe you could just tell us why did you start the foundation? It was a family issue.

Dana Dornsife:

It was a family issue, and that family issue really revealed to me a gap that exists in cancer care for advanced-stage patients who want to remain in their battle with cancer through clinical trial participation. My youngest sister's husband, Mike, was diagnosed with pancreatic cancer in his early 40s. He was given one-half of 1 percent chance to

live, and at the time 35,000 people a year were diagnosed, and 35,000 people a year were dying from pancreatic cancer.

So, we decided as a family that if Mike wanted different results that we would need to do something different. And Mike and Erin went ahead and pursued standard of care, and I was tasked with identifying clinical trial opportunities for Mike. And, of course, that sounds very linear, but in fact, for a layperson it was a very difficult task to undertake. I did identify some trial opportunities for Mike. He did participate in a trial and responded well for a period of time, he had good quality of life.

And during that period of time he was meeting people who were asking him, “Hey, what are you doing? I wanna do what you're doing.” And he would say to them, “Oh, just call my sister-in-law, Dana. She'll help you.” And that's literally how this organization began. Through those phone calls that I was receiving from other pancreatic cancer patients, I began to understand that Mike was able to take advantage of medical breakthroughs in clinical trials because he had a family who could afford to support him through the process. And all of these other families that I was talking to, they just didn't have the financial wherewithal.

So, we started Lazarex in order to fill that gap and help people identify clinical trial opportunities, and then provide financial assistance to them to help cover the out-of-pocket expenses that create huge barriers for patients who are already experiencing financial toxicity due to their disease.

Andrew Schorr:

Well, thank you for what you do. And we're gonna talk a lot along the way about resources. There's a downloadable guide that you'll be provided with, along with a link to the replay of this program. And that's gonna have specific resources that you can access, whether it's financial issues, other issues you may be facing. So, look for that.

Today we're really focused on actionable resources. So, let's go to Reina for second. So, Reina, you had been in the pharmaceutical industry.

Reiner Weiner:

Yes, I had.

Andrew Schorr:

So, you knew about drug development, and you understood about clinical trials. So, I'm willing to bet you were pretty proactive. People who weren't in the field, they don't know from clinical trials, and maybe they'd been worried about it. They've worried would they be experimented on, would they be a number and not name, would they get quality care. But you were probably, I have a feeling, pretty proactive. And you write about that. I know you have a book as well. So, is that step one for people to speak up for themselves?

Reiner Weiner:

It is step one; absolutely, step one. And what I found is, first of all, people don't know about trials. And if you go to a small community practice where they're very busy, they don't have the time, they don't have the staff to really educate patients about trials, the best, best step for patients to take is to ask, “Is there a clinical trial that might be appropriate for me?” That's huge.

Even when I went to a very well respected hospital and there was a researcher who was following me as I had smoldering myeloma and the numbers kept going up and up and up. I said is there – because I was living close to the NCI—is there a trial that would be appropriate to me at the NCI. And he said just a minute, turned around, went to his computer, found the trial and that's how I got in.

Andrew Schorr:

But it wasn't at where you were receiving care or being monitored at that time. It was somewhere else.

Reiner Weiner:

It was not. It was at somewhere else.

Andrew Schorr:

Okay. Dana, is one of the obstacles, not just financial, or maybe it's even the business of cancer where if an oncology practice that you're going to that's maybe close to home is not doing the trial, maybe it's not even in their financial interests to tell you. I mean, is there an awareness issue, do you feel?

Dana Dornsife:

There's a huge awareness issue there, Andrew. And it all starts with knowledge is power, right, so I completely agree with Reina's comment about one of the first questions you need to ask is, is there a clinical trial out there for me because many doctors who are in community environments don't offer that information. It's not what they do every day. They're there to administer standard of care. Only 6 percent of doctors actually engage in conversation with their patients about clinical trials, and that's usually the 6 percent who are associated with research universities, right?

So, knowledge is power. If the patient doesn't know about a clinical trial, they're never going to participate. But once you find out and once you've identified an opportunity, the second biggest hurdle is that out-of-pocket expenses associated because most patients have been dealing with their disease for a longer period of time, and they're basically broken in every way: physically, emotionally, spiritually, and, sadly, financially.

So, patients start to make decisions about the outcome of their care based on the size of their checkbook, and not focused on what's best for them. And so, Lazarex eliminates that financial barrier as well to help patients say, "Yes, I can participate," and we can get them where they need to be when they need to be there.

And that's just the tip of the iceberg, Andrew, because there are many other barriers that exist; socioeconomic barriers, language, culture, historical barriers. And we are tackling all of those barriers one at a time. But really, the biggest two barriers are knowledge and financial.

Andrew Schorr:

Right. And you mentioned about the historical barriers. Some people know about the Tuskegee experiments with African-American people, so in the African-American community, there still is a distrust among some people. Yet if you think about it from the FDA's point of view where a company that's developing a drug, or the NIH, they say okay, how does it work on broader populations or different ethnic groups or different ages or genders, et cetera?

They want to understand that data, and so not just having a number of people participating in the trial, but having it reach people who are in different situations, if you will. And so...

Reiner Weiner:

...and if I may—oh, I'm sorry.

Andrew Schorr:

Reina, please, go ahead.

Reiner Weiner:

Well, if I may say that because people don't know about it and the trials, the best trials, are trials with a variety of patients, but they do try to accrue populations who are certain ages, certain genders, ethnic groups, whatever they can get. And only 3 to 5 percent of patients participate, cancer patients, participate in clinical trials, and so much is lost if people don't participate.

Andrew Schorr:

Here in San Diego it's sort of a pocket of a lot of medical research. There's a lot up in your area, Dana, in the Bay Area, San Francisco Bay Area. I mean, it's in North Carolina in the research triangle where that's home state for Reina. And not to disclude others, and then certainly up around Boston. There are like companies all over the place and many of them are in earlier drug developments.

So, when you talk about immuno-oncology now, can we harness our immune system with the help of some medicine to fight the cancer, and I know some people who've received it; lung cancer patients who are living, et cetera, melanoma patients who are living for an extended time. These companies can't move forward unless there're people who are in the trials. So, the FDA says where's your data? And they're saying well, we're trying, but we haven't been able to complete this trial. Right, Dana? So, we can't move towards cures unless we all come together.

Dana Dornsife:

That's exactly right. So, let me just throw a few statistics out at you that I found astounding when I learned of them. So, we have a 48 percent failure rate of clinical trials, and it's not because the drug didn't work. We will never know, quite frankly, if the drug would have worked or not. And we will never know because there weren't enough patients enrolled in the trials to find out.

So, 11 percent of trials never enroll a single patient, if you can believe that. So, here we are with an almost 50 percent failure rate, and yet we have 600,000 patients a year in this country who are dying from cancer. So, there's this incredible disconnect between the thousands of patients who would participate in clinical trials if they could, and the thousands of clinical trials that need patients to participate in order to succeed. And without successfully completing those trials, those drugs are never going to get market to help the cancer patients that they are intended to serve and help.

That's why Lazarex Cancer Foundation exists, and that's why removing the barriers to clinical trials is so important. Our process does not lend itself well to that. And I just want to take a step back, Andrew, to address the minority participation in clinical trials. We all understand because of epigenetics and, yeah, advances in medical science that we need to have the full spectrum of our population participating in clinical trials. But that doesn't happen. When you look at the 5 percent of patients who actually participate and you break it down ethnically and racially, less than 5 percent are from minority communities combined.

So, in theory, though we say we understand the importance of that, we're actually not in practice doing what needs to be done. And so a lot of our work is also focused on reaching out to those socioeconomically challenged and racial and ethnic minority communities to raise awareness and help people like you're doing on this program dispel the myths around clinical trials, so that they're more inclined to ask better questions.

Andrew Schorr:

Right. So, so important, and I applaud for that work. We're gonna talk about the financial process in a second. Reina, so you were involved in a National Institutes of Health or National Cancer Institute trial.

Reiner Weiner:

Yes.

Andrew Schorr:

A couple of them, I think, and one at Memorial Sloan Kettering in New York's premier resources. So, we talked about your tip was you gotta speak up and ask about trials, where they're at that center, wherever you are, by XYZ oncology in a suburban area, whatever it is or not. So, what's Step 2? So, for instance, now I understand there are people – and Dana, I'd like your comment on it too.

At some clinics now where there are clinical trial—there are nurse navigators, but often sometimes there are clinical trial navigators too, but often you gotta ask about that too, right, Reina? I mean, it's speaking up and looking for the resources that are available to you there or wherever you choose to go, right?

Dana Dornsife:

Yes, and there are organizations like Dana's who help people do clinical trial searches because that's a bit overwhelming when you are already frightened, you already have the financial issues coming up. And like you mentioned, logistical issues. So, there is Dana's organization; therefore, myeloma, the SparkCures. There's the MMRF. There's the International Myeloma Foundation. There is something called CISCRP. And so, they will help you find a trial.

And there are lots of regional trials groups, so you may not need to go to the big, big research center. They might be able to do it locally for you. But I always want to bring up the fact that there's so much misinformation about trials and what it entails. There's a tremendous amount of fear. And when I went on the first trial, as I wrote about a little blog recently, everybody said to my husband—well, not everybody, but an awful lot of people said why would you let your wife going in a clinical trial? She's definitely gonna be a guinea pig.

And I can tell you very, very, very clearly that you get so much care. There's so much documentation. And the patient's health is never sacrificed for the research ever. And so, and you sign a consent form, so you're very clear about what is going to happen. And yes, there's more there's more blood work. Yes, there are more biopsies. And it's part of research. And when you sign up, you sign up. And I had more than I'd like to even talk about, but I feel very grateful and very humbled for the care that I received.

And I can tell you, too, that I talked to other people on the trial. And yes, they hope to gain better control of their cancer. But, in addition, they really hope to help the next group of patients who are coming up, so that these new treatments actually happen.

Andrew Schorr:

I feel the same way. I was in a trial at MD Anderson in 2000, and the three-drug combination I got was not approved till 10 years later, but they learned a lot. And you were on a three-drug combination, which I think still has not been approved for first line, but it's widely used, I think.

Dana Dornsife:

Right.

Andrew Schorr:

So, in multiple myeloma. I wanted to mention some other resources, The Leukemia & Lymphoma Society also has a resource center. You can call them. So, there're these different groups that help you identify a trial, and doctors who specialize, so let's say pancreatic cancer, you mentioned earlier Dana. I got a call from a friend in Miami, "How do I

find a pancreatic cancer specialist?" And I connected them with PanCAN, Pancreatic Cancer Action Network in Los Angeles, who knows who are the doctors who have the most experience with that.

Now, Dana, so then the next thing comes up is alright, I've identified the trial, but it's not where I am. So, now we talk about logistics and finance. So, let's say somebody calls your foundation. Tell us how it works. So, I don't have the resources. Maybe they live in Northern California and the trial is in Southern California or in Salt Lake City. What happens next?

Dana Dornsife:

So, Andrew, in some cases it's not even that distance. In some cases, it's getting from Sacramento to San Francisco, which is literally a one hour, one-and-a-half hours without traffic, in your car. And sometimes it's a tank of gas, a bridge toll, and parking. I mean, we're not talking about thousands of dollars in some cases, but it's still the difference between life and death.

When someone calls Lazarex Cancer Foundation, they can contact us directly. We have a financial application that we use to determine the degree of eligibility for patients to get their out-of-pocket expenses reimbursed. Or they can be referred to us by their social worker at the institution where they are receiving, or thinking about participating in a clinical trial.

We take a look at the household income of the patient, and I believe our guidelines are very generous. We go up to seven times the federal poverty guidelines for patients. And we arrived at that number through trial and error. Our goal is to help as many patients as possible participate in clinical trials, and turn away as few as possible. And then we reimburse on a sliding scale from 100 percent to 75 percent to 50 percent depending upon your household income.

And it's a pretty easy process to go through in order to be enrolled and receive the reimbursement. And then we reimburse our patients monthly, on a monthly basis. And in some cases, we've been working with patients, we follow them, like Reina, through two, three, four clinical trials. And we've been supporting them in trials for years. And without doing what we do, they may not be here with us today.

Andrew Schorr:

Well, I'm sure you've saved some lives and lengthened some lives. Reina, so you were in the pharmaceutical industry and in oncology, I believe, before all of this started happening to you. And you've continued teaching nurses and devoting yourself to education and your book and your blogs. Thank you for all that. Maybe that's what life's about.

But knowing on the inside there are pharmaceutical programs, in some cases, I think, particularly for rare cancers where they may provide assistance. They can't pay you to be in the trial, but there are at times assistance and travel logistics, particularly for rare cancers where maybe the trial is not, not one hour away. Am I right, Reina? Are you familiar?

Reiner Weiner:

Oh, there are. And sometimes when I was working, there would be a patient who had a cancer that really was not aligned with a particular treatment that would be effective for them. And so, the doctor wanted to try an off-label use of a product, and so then they would come to me and asked me if I could get the pharmaceutical company to provide the drug for free.

And sometimes it takes a little doing, but I was concerned about the patient and hoping to get them a better quality of life, if not an extended period of life. And so, yeah, the company would do that—not every day, not all the time. But if the company had evidence that this was a patient who would benefit from the off-label use of a product, then they would help them out.

Andrew Schorr:

Okay. So, Dana, related to other organizations providing assistance, and I recently interviewed someone from the Family Reach Foundation where they help with rent or things, groceries, things like that. So, somebody says, "Oh my God, I'm afraid of a trial, I can't go there," or if they hear about it and they say, "Hmm, well, maybe I could, but I'd have to leave work, or maybe my spouse would have to leave work, we'd have to find somebody to pick up the kids from school, oh my God." There are organizations that can help with some of these family processes, aren't there?

Dana Dornsife:

Absolutely. And I think we've provided the Patient Empowerment Network with a list of those. 21st Century C.A.R.E. is an organization that provides patients with immediate financial assistance for expenses related to active cancer treatments. Cancer Care provides assistance for cancer-related costs. There's a Cancer Care Co-Payment Assistance Foundation. We get that question a lot.

We'll help with the out-of-pocket travel expenses, and in fact, some of the medical and diagnostic expenses that aren't covered by insurance. When you're participating in a trial, sometimes you have to get more stems than insurance will cover or whatever. But co-pays are a big deal for people to be able to afford those, and so, that is another organization that can help. Patient Advocate Foundation, which is an underinsured resource directory.

So, there are a lot of you nonprofits out there who exist to support patients through the fifth process. It's just a matter of helping patients really understand and put together all of those resources in a way that they can access them.

Andrew Schorr:

Okay. So, Reina, you've been through it four times, and you're a pretty savvy person. Not all of us know as much, so help us now. So, one of the questions in a trial is, and in cancer, am I gonna get what I describe as the good stuff, knowing that the good stuff that's being tried may not be good. I mean, it may not work out. There are trials that go bust. Not just for not getting people, but they got people, but it wasn't as effective as they hoped it would be.

But let's say we've done our homework and we go to a certain clinic, but it's some sorta controlled trial. We don't know whether we'll be in the arm. So, was a concern for you? Were you gonna get the good stuff, and why do it?

Reiner Weiner:

Well, no, really, Andrew, because I know that like if it's a Phase 3 trial, so you're comparing standard of care versus the newest and hopefully the latest and greatest. If it turns out that one arm of the trial really shows a significant improvement, patients are always switched to the more effective arm of the trial. They don't leave you on this arm of the trial thinking well, what the heck, we'll just leave you there and see how the research pans out. So, they are always switched over to the most effective.

So, I wasn't really concerned about that. And in the Phase 2 trial, it's just seeing if the product was effective. And so, that was obviously not a concern for me. So, it worked out, and I do think, though, like what Dana does is absolutely wonderful at totally, totally, totally past wonderful.

But I always try to let people know who have friends and family who are facing some chronic significant illness that don't just call and say let me know, let me know if I can help you because that's so ambiguous. And most people will not call, because they have pride, or they think they can do it all by themselves.

So, I always try to suggest to people that if you're calling somebody who you think might need some help, be specific. Call and say, "Can I walk the dog? I'm going to the grocery store in an hour. Is there something I can pick up for you? Can I mow the grass?" Anything that will help, but make sure that you are specific in your offering.

Andrew Schorr:

I want to talk about a related issue. You use the word pride. Some people, maybe in some cases it's even shame. They developed a certain cancer. Where these are maybe middle class people who've had some resources. They've been paying their mortgage. They've been paying their expenses, making do. But now they get hit with a cancer diagnosis, which is catastrophic, and there is help available, Dana, but they're too proud to ask for it when this could happen to anybody. And maybe you've even countered that along the way or know there're people out there. What would you say to people, to not be shamed and to speak up?

Dana Dornsife:

Yeah. Well, sadly, one in three women will be diagnosed with cancer, and one in two men. And so, this is not an uncommon scenario, right? The likelihood of knowing someone who will receive a cancer diagnosis is very likely. So, I think that patients have to understand that pride doesn't help you in your process with battling this disease. You have to take advantage of every opportunity that's out there in order to come out on the positive side of this experience. And if you don't take advantage of every opportunity, you may not.

And so, it's one of those things that we just have to deal with right from the beginning, and just say okay, again, knowledge is power. I'm going to surround myself or engage with the people that are around me who want to help me. And you have to put that team together, because you will need your team with this disease.

Andrew Schorr:

Okay, so great advice. Reina, part of your team maybe could be the first doctor you saw who gave you the diagnosis, but they might not be the one where a trial was offered. So, first step is you talked about speaking up, but it takes a lot of courage to say to the doctor in the white coat with all the letters after their name, you know, thank you so much, Doctor, and I've either found out about a trial, or your turned and typed it in somewhere else. I hope you don't mind, but I am going to go over there. Maybe you can advise me along the way.

But that takes courage because people are terrified, and they may be bold in principal in that situation with the person in the white coat. What advice would you give?

Reiner Weiner:

Oh, well, that's a big one for a lot of people. And, really, you know what, I imagined that it would be people who are older, who come from a generation where the doctor has the final word. But what I found out when I was writing my third book is that there were younger people who also feel very uncomfortable speaking up, asking a doctor, and so forth. But really, what to really put in your little mind and in your heart is this your life.

This is not just kind of a trip to the mall. This is really important for you to either improve the quality of your life or extend the quality of life, so take a deep breath, be very polite, and I think most doctors who are professional and open-minded will hear what you have to say if you present it in a way that they can hear. And if they really don't hear you then it might be time to have a look around to see who will.

And, really, the bottom line is you need to trust yourself. And if you feel that this is really right, that there is a clinical trial that you would be eligible for and you can participate in with Dana's help, with the financial, with the logistics, and so forth. Like I said, you just take a deep breath. And most doctors, like I said, really want the best for you.

Andrew Schorr:

Okay, let's talk about something that comes up. One of the things for people is the criteria of different trials. Dana, I don't know if this is in your area, too, related to financial, but people let's say okay, I wanna be in a trial, but the criteria are so narrow that I really wanna be in the trial, but they say I can't.

Dana Dornsife:

Yeah, so that is a sad reality in many cases. And I refer to this as Clinical Trial Nirvana Syndrome where as a drug sponsor for trial, you want to attract the healthiest patients you can to participate in your trial, so that you have the greatest chance of success. But, unfortunately, in many instances, in most instances, a cancer diagnosis is accompanied by other comorbidities like heart disease or diabetes or other maladies that would preclude a patient from being able to participate in a trial.

So, that is an area that we are looking into and trying to—we have several proposals out there with various aspects of our government to try and really take a closer look at that, to try and make the trial makeup in relation to patient participants better mirror the realities of our situation, because the likelihood of someone, if the drug gets approved, taking that drug and having a co-morbidity is pretty likely.

And yet we won't know what will happen there, right. So, we have to drill down on these issues and it's a great, great issue to bring up. So, we've got a lot of work to do ahead of us.

Andrew Schorr:

Right. And another thing that comes up too, and Kevin sent in a question. Kevin, thank you for this, matching what's available in clinical trials to where you are in your journey with an illness. So, on day one, you're diagnosed. I know Esther and I, we were crying and almost on the floor. And I thought I would be dead the next day. And it really took a while to overcome the terror of the diagnosis. And so, we were not even—well, the doctor wasn't talking about trials; we wouldn't have been hearing it anyway.

And some of us, thank God, with some trials, with some cancers now, are blessed with living longer and we start to learn. And then we want to know, in our situation, what applies to us. So, I know there are a lot of efforts being made to match trial offerings to where you are and what you might need to know now, what might need to be offering.

And some of you have heard this term, artificial intelligence, where we in the Internet business are all trying to fine-tune what we're suggesting or putting in front of you based on who you are and where you are, recognizing privacy and all those kinda things to make it more manageable.

We still have a long way to go. I mean, we have clinicaltrials.gov, but it's not tied to where I am, who I am, where I am in my journey. It's just what's being done in a certain illness, right, Reina?

Reiner Weiner:

Yes.

Andrew Schorr:

So, we have to refine our tools.

Reiner Weiner:

Absolutely.

Andrew Schorr:

We have to refine our tools. Well, we've been getting in a number of questions. So, here's one. So, David; so, he says as the excessive use of CT scans in clinical practice moves away from being the norm, have they lessened their use in clinical trials? In other words, this is about testing, and maybe it's about the requirements.

Dana, I don't know if you have feelings about it, but the scientists who are doing these trials, they wanna know everything. They would like to test us. So, the CT scan, and I mean I'm gonna have one next week, but it has radiation, right?

Dana Dornsife:

Right.

Andrew Schorr:

So, let's do a bunch of CT scans. No, let's do a bunch of bone marrow biopsies. No. So, I'm saying I'm sorry. Not just do I have to pay something for these tests, or is there a co-pay or whatever, but also am I gonna be radiated? Am I gonna be poked? So, what about those issues? Is there dialogue going on, not just to help us financially, but also make it less onerous, I guess?

Dana Dornsife:

Yes, in fact there is dialogue going on about that, and it's good, heartfelt dialogue. And it's coming from a myriad of stakeholders, right, not just from patient advocacy organizations, but also from within industry insurers. And the whole goal is to okay, let's stop looking at patients as a chart or a number on a piece of paper, and let's understand that these are living, breathing human beings who are voluntarily participating in this clinical trial process for the benefit of not only themselves, but future patients to come and our industry.

And let's start treating patients as humans who are participating, and let's see what we can do to lessen the number of visits or minimize the number of scans and blood work, et cetera. So, there is active dialogue around that, and I think there's a much higher degree of sensitivity on behalf of the teams who are actually putting the protocols together now.

Andrew Schorr:

All right, I think so. And I know in some cases they're doing what's called trial simulations with a panel of patients and saying okay, we're trying to answer these scientific questions and see if this drug that's in development can do better for patients and would require so many office visits. Or so many, you come to the site, but so many could be done, maybe with your local doctor if that's closer to home. So many blood tests, so many CT scans, so many biopsies. Imagine lung cancer patients with another lung biopsy. Not fun, and often not available.

So, there are all these kind of questions. And I think that's going on, although it needs to happen more. Now, Dana, do you talk to the pharmaceutical industry? We had a question from Vi Life wanting to know related to trial awareness. Beyond the financial, do you work with pharmaceutical companies at all, as you are now, today? I mean, what we're doing here is just to raise awareness about trials or other programs that you may do.

Dana Dornsife:

So, we are engaging with pharma right now. We were very fortunate to work with the FDA earlier this year in securing language around reimbursement of patients' out-of-pocket expenses associated with clinical trials. There was some very nebulous language out there that was really preventing pharma from being able to support programs like ours.

And what we're doing now is, in addition to we're bridging this gap for patients that exist every day by reimbursing patients, but that is not a sustainable business model. It's noble, but we have to have our tin cup out every day. And the number of patients we can help is directly related to the amount of money that we have in our account, right?

So, in addition to that program, our Lazarex Care Program, what we are also doing is trying to fix this problem and do it in a sustainable way. And in order to do that, we actually have to shift the burden from the patient back into industry, right, and help industry understand why they should include these out-of-pocket expenses as part of the clinical trial protocol every time, right, so they can enroll trials on time, on budget, save R&D dollars, preserve patent years, right?

I mean, there are a lot of reasons why pharma would want to participate in a program like that, in addition to the fact that it's the right thing to do, right? And then we get more drugs to market faster, and we provide a platform of equitable access for everyone. So, we are engaging pharma in discussions right now about funding this program, we call Lazarex our IMPACT Program, that's being rolled out at comprehensive cancer centers across the country. And it stands for Improving Patient Access to Cancer Clinical Trials.

It has been received very well and I'm happy to say that Amgen actually stepped up and funded this, so we are rolling it out here in California, and we are hoping that we'll have similar opportunities in a couple of other areas in the United States. So, they are interested, and they want to improve clinical trial enrollment retention, and especially minority participation.

Andrew Schorr:

Right. Boy, that you. Again, I keep saying thank you for what you're doing, but you're a real leader in the field. I'm going back next month to the Biden Cancer Initiative Summit continued by Vice President, Biden, former Vice President Biden, and his wife who continue to do leadership in this. And there'll be a lot of senior people there, and I'm hoping we can talk. And I know this issue of how can we advance cancer care through research in partnership with patients is a big one. So, Dana, thank you for helping lead the way in getting this going. And thanks to Amgen just as an example.

Reina, so, we talked about the cultural differences of people being in trials. We talked about the pride people may have in asking for assistance, the fear people have maybe participating in trials. You still have a—not now. I mean, you're doing so well and you've been through trials and it's worked out well. But there must have been some bumps along the way. Were there any misgivings at different times? And if so, how did you overcome it?

Reiner Weiner:

Oh, yeah. Well, there were definitely misgivings, I am sure. The first trial was when I asked the doctor if there's something going on at the NCI. And there was no misgivings about that because that was a very observational trial. The second trial was much more progressive, and I felt kind of a little uncertain about it, and so I asked the researcher at this well-known institution if I should participate because the trial, I should back up a little bit, that was for either smoldering myeloma patients or active disease patients.

At the time I was smoldering, and most physicians didn't believe that that was a good idea to treat smoldering and wait until it became active. So, I asked this one researcher and he said absolutely, not, do not participate in the trial. And then I called someone else also from a very respected institution where I had been, and he said well, if you join that trial you'll be crossing the Rubicon, which I didn't even know what the Rubicon was at the time. I had to go look it up.

But, basically, once you start treatment, you kind of go on that journey and there's no way to step off. But then I thought about it, I thought about it, thought about it, and finally I decided to trust myself because I had been to the NCI. I felt very safe there. And I decided to move ahead with it.

So, yes, I had plenty of misgivings about that. The other trials, not really because that trial changed my life and it gave me a very reasonable complete response. And the other ones, like I said, they just kinda fell in with the collecting a good amount of stem cells for a transplant and so forth.

Andrew Schorr:

I wanna talk about family issues. So, the decision to be in a trial affects the family, whether it's somebody's driving you to the doctor, somebody's taking off work, their worry, how they feel about trials, their own view of it, family logistics, costs, et cetera. We've talked about that. So, you wrote this blog about people questioning your husband, I guess, was your wife gonna be in a trial? So, how did you overcome that, whether if not with your husband, just with your community that you weren't like crazy?

Reiner Weiner:

Well, they already know I'm crazy, so that's a total aside. But, really, trying to educate people about the misinformation about trials; say, look, I will never be a guinea pig, because that's not what trials are about. And it's very well controlled, and there's a lot of data that follows you. The care that I got was excellent.

And I try to dispel, like I said, a lot of the myths; that you signed consent form, which clearly explains what the trial is about, what your commitment to it is, and you can also drop out for any reason. There was hope that you don't because they would like to have some results that then will lead into future treatments for patients. But you can drop out, so, really, taking that opportunity to educate people about what a clinical trial is like and that there are no guinea pigs.

Andrew Schorr:

I wanna just—oh, yes, please, Dana.

Dana Dornsife:

Yeah, if I could just offer something in that regard. For people who haven't gone down this path, the journey with cancer, having a cancer diagnosis is not like other chronic diseases, right, like diabetes, for instance, that you can typically control with insulin or whatever, right? For a cancer patient who has failed standard of care, who's gone through maybe second- or third-line treatment options, but still has progressive disease, that patient will die if they don't do something, right?

And so, clinical trials offer tomorrow cures today in some instances, right, and we don't always have positive results in clinical trials. But for a patient who's at that crossroad where their doctor has delivered those words, "You need to get your affairs in order," right, it's not a matter of am I crazy if I participate in a clinical trial. What it is a matter of is do I wanna live? And if so, what clinical trial can I participate in? It's a very different decision tree.

Andrew Schorr:

Right. And I certainly say that all the time. I got a call, as I mentioned, from a friend in Miami. The mother has a very serious cancer. And I said part of the initial discussion, even the initial discussion, Dana, can also be are there clinical trials that we should consider along with standard therapy? So, certainly, if you've failed or they've failed you, the treatments no longer work, what is the 360 degree view? And if you don't do it here, so they do it down the road, or do they do it across the country? And what are the issues for you participating?

So, a lot of thinking, but it's gotta be part of the discussion. So, so sadly now, what are we seeing; 3 percent, 4 percent, 5 percent of adults participating in cancer clinical trials in the US. Not good at all. And are we hurting ourselves with the chance of future therapies that can be more effective, or even cures, because some of these companies sometimes are venture-backed. They don't have money forever, you know, and they're trying to get to the goal line to go the FDA.

Look, here is another question we got in. Tamara, our producer, just sent in. She says well, what happens when you join a clinical trial and it doesn't have a beneficial impact? So, Reina, they didn't know that the trials would necessarily work out for you. So, what happens then? Do you go on another trial? What do you do?

Reiner Weiner:

Well, if it doesn't and you don't seem to be responding to the therapy on the trial, or you find it intolerable yourself, then they will always return you to your oncologist who you had been seeing previously. But, on the other hand, they may offer you another trial that's available that you would be eligible for as well. So, I mean, I really try to stress to people that the researchers are looking out for you. They want the best income, in addition to accruing the data that they hope.

And I can tell you that when I was on a trial at the National Cancer Institute, when I had questions, especially about the trial with smoldering versus active disease for myeloma, they would spend a couple of hours for me, explained with me, can I say that, right? Yes, spent a couple hours with me explaining all of the aspects of the trial, so yeah.

Andrew Schorr:

I wanna point up an example that some people have heard of a woman I've become friendly with in the myeloma community, Reina. Cherie Rineker. So, Cherie's down in Houston, and she was dying of myeloma. And she'd been in trials and treatments. She was at MD Anderson. Bob Orlowski is one of the top doctors in the world, and her doctor. And she was in different trials and then things were not working.

And she was put in touch with another researcher doing this CAR-T investigation for multiple myeloma, which is pretty new, pretty new. And they're learning a lot. It's not a slam dunk, but so far it's worked for her. It saved her life. She went to Nashville, Tennessee from Houston where she lives, and maybe I'm not sure the financial issues, Dana, about going. But that's where she'd been in successive trials. And some were not working or no longer were working. There was another approach.

I wanna ask about another concept I've heard called siteless trials. And I don't know, Dana, you're nodding your head. Maybe you are familiar with this. One is a siteless trial because we talked about these trials going on at these academic medical centers, but not much elsewhere.

Dana Dornsife:

So, I have tell you, I don't have a lot of experience with siteless trials, but there is a lot of dialogue taking place around rather than having the patient go to the trial, bringing the trial to the patient, and I think that's the impetus behind a siteless clinical trial.

I think cancer has some unique challenges, especially blood-based cancers in clinical trials, and the oversight of patients participating in those trials that make siteless trials a bit of a challenge. But I think the place to start is in other diseases, or perhaps where you have a cancer diagnosis that's not a rare form of cancer, whatever that requires, a high degree of oversight.

But the whole goal in doing this is to understand how we can get more people into these trials and make it less obtrusive on their life, right, so that more patients would be inclined to participate, increase our enrollment retention, our minority participation, and, ultimately, reduce the burden on the patient to participate.

Andrew Schorr:

Esther and I've given a lot of talks at different conferences, and we said you have to see patients who might be considering or are in a trial as investors. So, they're gonna invest with their body, their time, sacrifices, and other things in their lives for the hope of being cured if they could, or doing better.

And there needs to be the communication, financial support, logistical support in really treating people with a lot of respect as a person. Reina, do you agree with that, that we have to get to that concept where we're taken care of? And you felt that way, but we need to do it for more people and have more people feel confident that it'll work out that way.

Reiner Weiner:

Oh, certainly. Certainly, I do. And the education is really essential. And after I was in the first trial, I talked to everybody who would listen to me. And even if they didn't, I would talk anyway just to try to say this is a place where you can go where you will receive what is hopefully the newest and the best treatment that's available. That you will be cared for as well as you can possibly be, and that everything is documented. You know all the options that you have staying on the trial, giving consent, making sure you have all the information that you need to feel comfortable.

And Dana's organization, hopefully, helping people out financially and logistically. There are ways to get into trials that at times are very successful. For me personally, I don't know that I would be alive now if I had been on that trial, and that's really my claim to fame, what can I say?

Andrew Schorr:

And, Reina, I would say the same thing. Had I not been in a Phase 2 trial for chronic lymphocytic leukemia in 2000, I wouldn't be around to have had retreatment last year, which has work quite well; 17-year remission. And I wouldn't have been able to do this, and really have a purpose in life. So, I'm very grateful for being in the trial.

Dana, I can't tell you—we were talking about gratitude, for you; came up in your family. You saw the gap for, not so much your family, but so many other families. The issues, financial issues, and you've been very philanthropic and, obviously, trying to have leadership in getting at some of these—we have a very imperfect system right now, so we have a long way to go. But for our viewers, if you're living with cancer now, if your loved one is living with cancer, there are resources, people like Lazarex, people have been through it, like Reina.

We're gonna give you this downloadable guide. And you're gonna connect with these resources. Don't—put your pride away. Dana said it so well. There's a very high likelihood we're gonna be affected by cancer in our families, and there is help to navigate what's kinda complicated right now, but is doable and can offer you the chance of doing better. Dana, did I say it right?

Dana Dornsife:

You did. You did. You did a great job, Andrew. Thanks.

Andrew Schorr:

Okay. Well, thank you. And thanks to the Lazarex Cancer Foundation and, really, all you're doing. And let's hope that we can improve this process, increase participation, and have so many of these companies and the government that are trying to get scientific answers. We participate as respected patient investors. And we do better well. Reina, any final words from you with your 50th wedding anniversary coming up?

Reiner Weiner:

I'm very grateful. I'm very grateful to be here. I'm grateful for all the clinical trials, all the physicians who have taken care of me and who listened to all my concerns and fears. And I am super-duper grateful to my husband who has supported me, helped me, been there, been my caregiver, and washed the food for me when I had the transplant, and really, all the people who have been on the journey with me. So, if you are considering a clinical trial, if there is one that you might be eligible for, give it some thought. It's a really important choice for you to make.

Andrew Schorr:

Reina, thank you so much, all the best. Happy anniversary, early. Dana, best to you. Dana Dornsife, joining us from the Lazarex Cancer Foundation in the San Francisco Bay area. Dana, good health to your family, and thank you for all you do. Thanks for being with us, Dana.

Dana Dornsife:

Thank you.

Andrew Schorr:

And, Reina, all the best, and thank you for those great words of wisdom. And we'll meet in person sometime, and I'll give you a big hug, okay?

Reiner Weiner:

I hope so. I hope so. You take care of yourself, Andrew. Thank you so much.

Andrew Schorr:

Thank you for joining us for this Patient Empowerment Network program Clinical Trials Mythbusters. We hope to do more. I wanna thank the companies that have helped provide funding for it; Abbvie Incorporated, Astellas, Celgene, and Novartis, for their support.

Thank you for joining us. I'm Andrew Schorr from Patient Power down near San Diego. Remember, knowledge can be the best medicine of all.

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