Regenerative Medicine Revealed: What's Fact, What's Fiction? Transcript

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Intro and Podcast Banter

Well. Neuropathies is a stomach disease. It may not be manifesting in their hands, but it's certainly affecting the nerves in their hands. Yeah. Neuro apraxia is a specific focal defect in the outer third of the nerve, and that outer third of a nerve is dense, irregular tissue.

It's actually collagen based. And as a matter of fact, it's type one and type three collagen. And so can you apply a biologic for a focal deficit in a cartilage based structure.

You can't. Right. You can't say that you're imparting a biologic activity. And you're going to treat neuro proxy. But could you apply a human cell and tissue product to a cartilage based defect in a peripheral nerve.

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Hi, welcome to the Recharged Biomedical podcast. I'm your host, Ed Park, and today we're very lucky to be joined by Doctor Scott Martin. Hey, Scott. Hey, doctor Park, how are you, handsome?

Good. Thanks. So, as it happens, you know, I was on Facebook doomscrolling several months ago, and I said, oh, Dubai. I'd like to go see Dubai. So I went to Dubai and I met Scott, who was lecturing.

He gave a couple of brilliant lectures. And then for some reason, they like to kind of my job or the book. So they said, why don't you lecture two? So a month ago or so we were in Cancun and he was on the dais at stage, and I was talking and, we had a good time and got to drink tequila and sing mariachi and learn more from each other.

But I think I learned more, from him than vice versa. So I'm very happy. I don't know, I think everyone should know that the the the esteemed Professor Park gave his entire lecture, two of them in Spanish.

It was, it was absolutely stupendous. Very, very humbling. Well, I mean, thank you so much. It was, on the wake of some cognitive decline from my fire in the apartment.

It wasn't great, but, you know, I probably only lost ten words. And so they were really fun to interact with. So today I thought we could cover things that come up a lot for both patients and for doctors.

And you excel in the latter? You have a Facebook group called the Institute of Regenerative Education, mainly aimed at practitioners, and it's been a great resource.

Stem Cells and Regenerative Medicine Basics

You give many lectures, expanded lectures about a lot of things, which we'll get into. But I think from the patient perspective, when they're using well, you know, as well as I was certainly in stem cell and an exercise and a freeze dried exosomes and PRP, you know, and so the question out of people's mouth is also is it safe?

Is FDA approved. So these are topics that we need to kind of, dissect out of it. But I'd like to start the 20 minutes

we have ourselves with the quote by Upton Sinclair, the author who said, it's very hard to get a man to understand something if his salary depends on him not understanding it.

Oh, how true that is. Wow. And so we see this quote. Yeah, well, I think it's true. And you and I both have affiliations with companies that produce biologic.

So we are not immune from this as well. But I think there is a higher calling to the truth. And that's why I like the company I work with currently, because I asked him, hey, do lifelike accents work?

And he goes, yeah, they're probably 80 plus percent viable. So he's not going to sit there just because he doesn't have a bio, lifeless product or freeze dried product and say that they don't reconstitute.

They do. But, as we sit here in the market, you and I have seen and we were just talking before the show companies have come and gone. Companies that have been led by scientists and not.

And so there's a lot of shifting sands. So how can the consumer possibly figure out what company is legit? So what I, what I like to say is first, it's imperative that a patient understand the difference between a pluripotent stem cell and a differentiated mesenchymal stem cell.

Now we're going to start with a little story. Almost everyone recalls that we cloned a sheep. Now I mean that was very very big back in around 2010. To test all that we cloned a sheep dolly. Right.

Really amazing. And she was cloned with pluripotent stem cells. Now pluripotent stem cells have the ability to turn into anything in the human body. In we've seen their use aggressively for things like, you know, making additional organs, making, you know, lenses for the eye.

And that was going to be the panacea. Everyone was going to get stem cells. It didn't matter what you had, if you had lupus or if you had liver failure, if you had kidney failure, if you had diabetes, we're going to cure everything.

And then you've got a little quiet right? And it got a little quiet because Dolly died of metastatic cancer at the age of four and a half. And unfortunately, Dolly had five baby sheep and all five of her babies.

She died of metastatic cancer within a year of life. Yeah. And so the whole pluripotent stem cells are going to be the panacea of, you know, eternal life.

That whole movement cooled a little bit. All right. That brings me to the point of kind of this introductory paradigm. When we talk about Stem cells, there are, unfortunately, providers whose pocketbook and companies who pocketbook depends on patients intentionally misunderstanding what stem cells are.

They are not a Harry Potter wand, right. We don't just, you know, when got oblivious and we just elevate everybody's health, right? Yeah. And suddenly because we got an IV of stem cells or exosomes, disease is cured.

That doesn't happen, right. And I think there's this wonderful intentional discord in some doctors are selling stem cells because they're selling the miracle cure.

Yeah, but that's not what it is. Now, if you have a complex disease process, please, for the love of God, see a doctor who's going to practice medicine.

And what I mean by that is, if you have end stage renal disease, please see into for ologist, please get into for all just opinion right it if that's coupled with very bad diabetes please for the love of God see a very good qualified endocrinologist.

Yeah. Now can you support that medical care with certain biologics on an experimental basis? Of course, because yeah, if, you know, I think it's say stage five kidney disease, what else do we have?

I think that's a great way to to describe it. And as you mentioned in when your lectures in Cancun, the doctor asks you, well, what can I do for appendicitis?

You just recoiled, saying, well, appendicitis is an acute surgical or at least medical emergency. Don't start. Maybe waving here. You know what? So I think it's a good thing. So.

But patients do hear the miracles they want to believe. And there's reason to believe. So if people want to understand stem cells, what pluripotent versus adult okay.

Autologous versus allogeneic. They can pick up my book, exosomes Science of Healing. It explains it in a simple way. And doctors can go to your Institute of Regenerative Education group on Facebook.

But the long and short of it is, you and I have been in this space for several years, and we know that you, as a pain management and rehab doctor, you've always looked for ways to not just cover up the pain with opioids, but to actually support the patient in alternative therapies.

And I think, I think you'll agree that we do have a real boon, a real gift. But you're right. It needs to fit into their treatment plan. You have to know, do they have renal failure to have cancer?

What's your plan? How do you know if it's the endpoint is good and it's a great point. But when patients look at this they do conflate. They say oh stem cell. What's the difference being stem cells.

Next cells. Why should I go to Panama or Costa Rica. Cayman. You bet. Yeah. So but let's go back to the FDA because I get every week as to you, oh, so-and-so has an FDA letter.

And, you know, I was just that the doctor who in Cancun, who shall remain nameless, was kvetching about her FDA letter. And so it's kind of like a badge of honor or disgrace.

So the FDA rolls up on all these manufacturers and says, we don't like this, this and the other thing, but from 10,000ft, let's talk about the FDA, the Food and Drug Administration.

Right. So food that Galen said that would be diminished. And now that RFK is in there, he's trying to take out red tide number 30. They're trying to take out high fructose corn sirup.

And for a lot of years there's been stuff in the food supply that's not been good. But as long as agribusiness and the lobbyists want atrazine or glyphosate in our food, it's going to be there until people act up.

So I think people really underestimate the degree to which, regulatory agencies are captured by corporations.

FDA Regulation and Biologics

And I think that was pointed out by Marcia Angle of the New England Journal, medicine. She wrote a book, how at least half of the studies in science and academia are fabricated.

So I think that shocks people. And I think it shocks people because they assume that the food and Drug Administration has our backs. And if there was something that was really working to help people with, you know, just simple MSC or neuro stuff, FDA would be championing that.

But they really don't see that. The FDA is also an organization for intellectual property, and it's pay to play. The majority of the budget is from the companies that want to spend $2.3 billion over seven years for a 17 year patent.

But, you know, we know that most drugs and conditions are not, you know, single pathway magic bullet problem. So the whole thing about, you know, is the FDA approved small molecule drugs or even now, biologics for the last 15, 20 years.

Is that really going to cure disease? So tell us what five 351 and 361 was intended to do and how it's being applied in our space. So if you've seen any of my lectures, you will hear me say, the FDA is your friend.

Now, that may like put people on their on their heels and other people want to fight me when I say that within the realm of biologics, we have two types of biologics we have in body biologics, right?

Those in body biologics are your blood, your bone, in your fat, out of body biologics typically come from umbilical cord source, the umbilical cord that attaches mom to baby.

All right. Those products are all under a regulatory framework described under section 361. Section 361. At its simplest, elementary basic understanding is if I have torn a ligament in my knee, right, I have missing damaged deranged tissue in allograft means that I will take like tissue with like structural properties and like mechanical function, and I will harvest it and put it in place of that missing damaged arranged tissue.

So, for example, I tear my ligament, I get a catastrophic ACL. That's what you're talking about. That is an out of body or an allergenic allograft. Right.

So that's how human cell and human cell tissue product from not great. But now they're applying that to something that arguably I've heard people say is a secretion like in non pasteurized milk you have exosomes.

In fresh lettuce you have exosomes. And some people are marketing plant exosomes. So you know, do you think that a secretion of a cell is subject to 361 or that's not for us to decide.

It's not really a cell in tissue product. It's a well, what I'll say is this all right. Section 351 and section 361 or different. Section 351 denotes drugs.

Drugs with biologic active Vicodin. Right. I take Vicodin, it works on new receptors. It reduces pain. That's a biologic activity. I put cortisone in my knee.

I get a anti-inflammatory response, but I also get a systemic response. Meaning if I've got inflammation in my shoulder and I've got inflammation in my knee, if I inject cortisone in the knee, some of the inflammation in my shoulder may get better.

If in section 361, I put a porcine ligament in my knee for a ruptured ACL. If I have a torn rotator cuff, there's no way that that porcine ligament in my knee is going to suddenly make my shoulder better.

All right. And so they have to work in that regard. The warning letters that doctors get, the warning letters that companies get hopping when they make claims, and they equate a human cell and tissue product, a graft, let's say, with having systemic ability to treat disease, meaning if I put platelet rich plasma, most people have heard of PRP in the knee.

If I were to claim that that's going to treat osteoarthritis well, anyone with osteoarthritis knows that it doesn't just affect their knee. When they get up in the morning and they roll over and they feel like the Tin Man for an hour and a half before their joints finally loosen up.

Right? It's not just the knee that hurts, it's the knee, the left knee, the right knee, the ankles, the shoulder, the back, the hips, maybe even the neck.

Right? Yeah. And so where companies get in trouble is they want to sell more product in the easiest way to sell product is to market to diseases that ring the bell with people.

Oh, I have osteoarthritis. That's on my report. So. Oh if you treat with stem cells osteoarthritis I want that product. Yeah. And this is why the FDA exists in the field of biologics.

They're not there really. As a police officer pulling out their Taser and shooting companies, they really just put up

roadblocks, almost like the little rubber bumpers.

When you're bowling, they're trying to make sure you don't get a gutter ball. But if you are throwing the ball as fast as you can at pins, right, and hurling it down the lane, they're going to pull you off the bowling alley.

We age because our telomeres shorten and our stem cells to deplete. But what if we could support both? I've been taking tier 65 for 17 years. It's the only supplement I trust to support better mood, better sleep and exercise recovery.

At age 57, I don't have any gray hair and I don't need breathing glasses to 65 is available now. Go to Recharge Biomedical E-commerce to iPhone 65 and enter promo code Recharge ten to save 10% off.

Yeah, you know what I means. So for doctors who are kind of, a little gun shy as they well, should be, you spent time defending doctors through the FDA, and it looks like there are different levels of, you know, adjudication.

There's even the hidden star chamber. So, you know, talk to us a bit about the terms of art. We can use as practitioners, like, nurse practitioner, general malaise.

I guess you could argue. I mean, there's three main hammers that can hit you, right? There's the FTC if you go online and advertise curing of disease.

Correct. There's the FDA. If you go and say, I'm curing disease, preventing disease. They don't directly enforce, but they can get you both through. We had one huge, massive art manufacturer that sold out their, practitioners.

So, you know, you can get in trouble if the, manufacturer that you buy from shares your name with the FDA, they can shut the whole thing down. And, of course, the medical boards regulate in 50 states are sure.

If someone says, I don't like the kind of your jib doctor Park, you know, that could also bring us down. But, you know, I think that. Yeah. I mean, I tell people this is not FDA approved, but, you know, tell us about practice.

You tell us about general malaise. Why do you think those terms are helpful? Instead of saying, oh, osteoarthritis, how is that going to protect us humans selling tissue products are FDA cleared.

The biologic is FDA cleared. How you use it is not a case in point. If I were to use bone marrow aspirate concentrate and I was to tell efficient, I'm going to treat your ALS by spinning those bone marrow derived stem cells down, expanding them, and then giving them to you.

IV all right. You are imparting a biologic activity on a human cell and tissue product. We talked about the graft for the knee. Right. A porcine graft for the knee has no biologic activity.

It's not going to treat the degenerative joint disease in the knee. And so when doctors ask is this FDA approved? It's not FDA approved. It's FDA cleared.

Everyone forgets that PRP, Bmcc stromal vascular fat. These are kits. They're 510 K cleared kits. So the little plastic kit is cleared by the FDA. No different than, say, A2E needle due to an epidural or a cannula to do liposuction.

All right. Once you combine that kit with blood bone fat. Now, what's a biologic and what you claim about it to a patient in what you market in. Advertise about it right now can either get you in trouble or allow you to practice medicine.

The point is that every doctor can practice medicine. You're allowed to prescribe gabapentin for failed back syndrome. They may not be indicated for that, but you can practice medicine right now as long as it's not grossly out of the scope of your practice.

Can you use a human selling tissue product, whether it's in body or out of body, to supplement to cartilage based defect focus locally, yes, but you can't make claims about it.

You can't say, I'm going to treat your arthritis. I'm going to dramatically improve your well-being. I'm going to treat your pain. These have specific diagnosis codes.

Diseases ICD 910. Yes, absolutely. So in terms that the terms that you've come up with while working, both from the doctor and FDA side are neuro apraxia, which is, I guess, restoring the collagen around the myelin or the nerves, general malaise is not a disease.

And, it's limit inflammation. So these are things that we can kind of scribble in. Yes or no. See. See, you have a patient that presents with numbness in their feet.

There could be all sorts of reasons for numbness in their feet. Apple. Right. So if you were to tell a patient look we're going to treat your neuropathy well.

Neuropathy is a stomach disease. It may not be manifesting in their hands, but it's certainly affecting the nerves in their hands. Yeah. Neuro apraxia is a specific vocal defect in the outer third of the nerve.

And that outer third of the nerve is dense irregular tissue. It's actually collagen based. And as a matter of fact it's type one and type three collagen.

And so can you apply a biologic for a focal deficit in a cartilage based structure? You can't. Right. You can't say that you're imparting a biologic activity.

And you're going to treat neuro apraxia. But could you apply a human cell and tissue product to a cartilage based defect in a peripheral nerve. You should put right I think you're not important right.

Yeah. Yeah I think it's important. Like you know, people talk about the, Covid mRNA products. They were never FDA approved. They were FDA emergency use authorization.

And did the correct initial iterations are now FDA not approved, and they're trying to roll out subsequent versions. There's been some pushback because some people believe they may have done more harm than good.

But I think oh. Edit sorry.

Clinical Use, Scope, and Warning Letters

Oh, you're back. Okay. We're here. Yep. Okay. But I think that the point that the lay person struggles to parse out is that the FDA is the big brother that protects us in anything science based and beneficial will eventually make it to the FDA to help us because they're looking after us.

And, you know, I don't think they see the big picture in terms of how the money flows. So we and our personal experience with our ends of one and our patients with the miracles, you know, we don't get out there and say, oh, I'm going to cure your disease.

But on my consent, it says, this is not FDA approved, not center of care, something that people who take my online provider training course can download, customize.

But it's very important to have that fig leaf. Does that mean a person can't sue you or regulatory agency can't come after you? No, but I think it's important to realize that there is a scope of practice.

And what used to be arguably it's been damaged, but there was a sacrosanct patient. You know, physician relationship. It's not like the power of attorney, which is tantamount to the power of God.

But there was a relationship. And if I said to you, I want you to do deep box breathing and meditate on gratitude. I'm not practicing some kind of craziness.

If I told you to drink cat poop coffee from barley also. Okay. But, you know, people have a trouble seeing that like something that is standard of care reimbursed, like, epidural steroids has never been FDA approved, and it's probably harmful, according to the Concord Collaborative and Scientific Research.

But, you know, that's the thing. People defer to authority. And so it's very hard. It's a hard sell. But, you know, we definitely don't want to take advantage of people that are desperate.

But, I think it's a it's a fine line to walk. You know, if somebody is the commissioner of the FDA like Peter Marks in this region and, you know, his mom has a problem, you know, it's like abortion in the 40s.

If you needed it, you could get it. But we're trying to walk a line where in the 1940s, I mean, we're trying to walk a line where, you know, these are available.

Like we don't ruin the party for everyone. It's not all about the money, but there are a lot of data points in our anecdotes. You know, that support this.

So how do you some wonderful anecdotes. Yeah, there's some wonderful anecdotes. Look what I would suggest to a general patient is if you're going to see a doctor who's going to, you know, offer you a regenerative medicine application.

First things first, right? What product are you using from what company in the patient can do a simple Google search? Do they have a warning letter from the FDA?

Or if they have a warning letter from the FDA, I would probably not consider using that product or seeing that provider. Right. Okay. I mean, just a general thought in point, right.

Number two. All right. Understand that if you are sick, all right, no regenerative medicine application is necessary. These are all elective procedures.

All right. Nobody needs a breast augmentation. Sorry. Nobody needs a breast augmentation. You may want one, but that's an elective procedure. All right.

Do I think in the next five, ten years, the use of allogeneic allograft in autologous allograft will become more standard of care. And we won't use steroids.

We won't use hyaluronic acid as a first course application for somebody with a cartilage based defect in their knee, cartilage based defect in their shoulder.

I think that will happen. But right now, the studies that we have to do to get that approval process are drug studies. You have to do a drug study. And how do you do a drug study on a human cell and tissue product?

Well, it's a little bit rigged. Yeah, it's a great point. Like I was at a conference this Monday to announce it. Enhance cure STAT has a product which is the secret tome of immune cells to cure muscle atrophy.

But, you know, people are like, I think rightly. And, you know, I was talking to one of the founders of the first exosome company, and they say that they're combining their phase one or safety with their, you know, their complicated phase two studies to a because the traditional model of a small molecule, billion dollar blockbuster is not really needed here.

I mean, the power analysis, the numbers you need to show a benefit are de minimis. So it's kind of a new frontier for the FDA. But again, as Upton Sinclair said, you know, it's not Pfizer or Merck writing a check for eight figures on it.

But these companies are about at least 12 or 14 studies going to the FDA, probably more. And so they're starting to cast checks and they're starting to think, you know, we'll look at this, but I have the bigger question of whether someone can even own a human product.

You know, the myriad genetics, the BRCA one, the Supreme Court shut that down. So, you know, the FDA is always in sort of this dance with taking money and persecuting companies.

And regarding the FDA warning letter, there are most there are a lot of companies that have come and gone, as we know and some don't even make their own product.

They white label with someone else. So how could they get a warning letter if they're just a marketers? So, you know, I think that it could be a badge of honor.

You have to read the context, but I think most of the people that are trying to do this, the FDA tries to color them. They put the electronic dog fence around them, they inspect them.

So yeah, there are a lot of reasons why I would stay away from companies. But, again, nobody has a final answer. You know, Peter Marks doesn't have people, you know, in his lab.

You know, I think Peter Marks is a brilliant man, and I think he's trying very hard to police in industry. You know, just osteoarthritis of the knee is a 5 to $15 billion industry a year when there's that much money involved.

And we're not talking about neuropathy or back pain or anything. It's really high dollar just osteoarthritis of the knee. It's 5 to $15 billion a year. All right.

That's a lot of secondary game right in one actually I just got I got a patient wrote to me about $2.5 billion market for, life sized cosmetics herself from fat Korean dudes.

You know, it's like, this is big money. And people are playing this game. But, you know, unfortunately, apple, apple juice, apple chips, you know, they're all comparing stuff that's not really comparable.

So I love the fact that you are always able to explain both at a strategic level, but at a granular level, what the actual differences in terms of the legal language and the science, I think that's really missing.

So when I write the next version of the book or the course, we're going to have you weigh in, but I'm just kind of wrapping up the talk. What are the general things that you can tell people about regenerative medicine?

I mean, we don't know where the headwinds are. The tailwinds are in terms of approval. But can is is something that's going to be available only overseas, or is it something that's going to be shut down?

And you I mean, I think I think in general, I truly believe that people think that RFK Jr is just going to make it a panacea. And everyone can get stem cells everywhere.

All right. He's not going to do that now. He doesn't have the unilateral authority to usurp the FDA's power. All right. What I hope happens, there's a law in the state of Utah that states that a doctor within the scope of their practice can practice medicine.

And if they want to use stem cells, meaning not pluripotent stem cells, which have been illegal since George W Bush was president. But right. Stem cells. Right.

Or they want to use peptides, or they want to use alternative therapies to try to improve the quality of a patient's life when they've either reached a plateau, when their medical progress or there are no other options.

They have the ability to practice medicine in the medical boards. Not going to come after them. My hope is that becomes the law of the land, that we don't have these frivolous attacks by medical boards that are trying to make

money just like everybody else, because medical boards run on investigations.

That's how they make their money, right? By investigating doctors and making them go through expensive courses and things. Sure. What I hope is that doctors are able to practice medicine.

Future of Regenerative Medicine

I actually hope that the FDA keeps up the barriers so that we don't have people making crazy claims and waving magic wands and intentionally misleading patients about what the potential benefits are right in.

What I hope most is that we have more collaboration. You know, you have you have very staunch proponents of biologics, whether they're autologous and allergenic.

You have people that swear that they're awful and they're the devil. And then here in the middle where you have all of these people that really like allergenic in autologous, they're either purely autologous or purely allogeneic, and nobody wants to work together.

What is needed desperately are two things. Number one, better communication between providers and better collaboration between providers. That's number one.

But number two, what is needed are large scale observational studies, not drug studies that we do with 351 large scale observational studies that no matter what you're using as a provider, we can compare apples to oranges, right.

With this same outcome measure. I don't care if you use PRP or if you use Wharton's jelly, if you're applying it to a cartilage based effect of the knee, which works better.

We don't know, right? No, no, I think you get your point. Combined Morton's Jelly and PRP, we don't know, but it would be great to know if there was a level playing field and financial interest was removed.

That's right. Yeah. No, I appreciate that. And that was what you said. And what I tried to say in Spanish is that in this field, you know, the one eyed man is king.

And as long as we keep our one eye on the prize, which is what is the truth, what works, we'll figure it out. But, yeah, unfortunately, there are a lot of people who fall prey to salesmanship and talking about numbers of exosomes.

I mean the truth. You can't even you can't even count exosomes directly. But nobody talks about that. But I think, you're a voice of reason, both for doctors and for, end users.

And I think, we need more of that. Just more light and less heat. But again, like Upton Sinclair said, if a man's salary depends on him not understanding, they could be pretty obstinate.

But, let's, wind up and just say that your Facebook page for mainly doctors, right. You do a vetting process is the Institute of Regenerative Education.

It is dozens of interesting little breakout sessions. You know, I tried your technique at the Microneedling at 0.25 without anesthesia. We all loved it.

So I'm going to pivot, you know, because not that crazy, right? Well, I wouldn't say that. But even a blind the is humble. Oh yeah. And very grand gesture of respect from you know my little phrase it goes a long way. Namaste. Great. Yeah.

Well they say a blind squirrel is right twice a day, right. So no, but I thought the BLT. Yeah, I guess it probably could be toxic to exosomes. I had a point to five.

We barely thought so. Thank you for that. You know, it's interesting watching you do demos, live demos in Dubai. I was there so many points at which I would have done things differently.

And it just goes to prove that there's no one way to get up the mountain. There's many different techniques, and the best part of being a doctor in some ways is helping people in a way that's personalized, improvised.

OOP. Sorry, I get it. Oh, that's the best. And I think the best part of being a doctor is that we can personalize, we empathize and we can improvise. And so things change.

And that's really the fun, creative, delightful part. Yeah. All right. Well Scott, thank you so much. And we hope to see you again at another thing. And hope to get our tequila and our mariachi out.

I really thank you. Namaste. Christ, my absolute pleasure. Thank you very Park. Have a pleasure. Okay. Thank you for tuning in to Doctor Talks. We hope today's episode has enlightened and inspired you on your path to optimal health.

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