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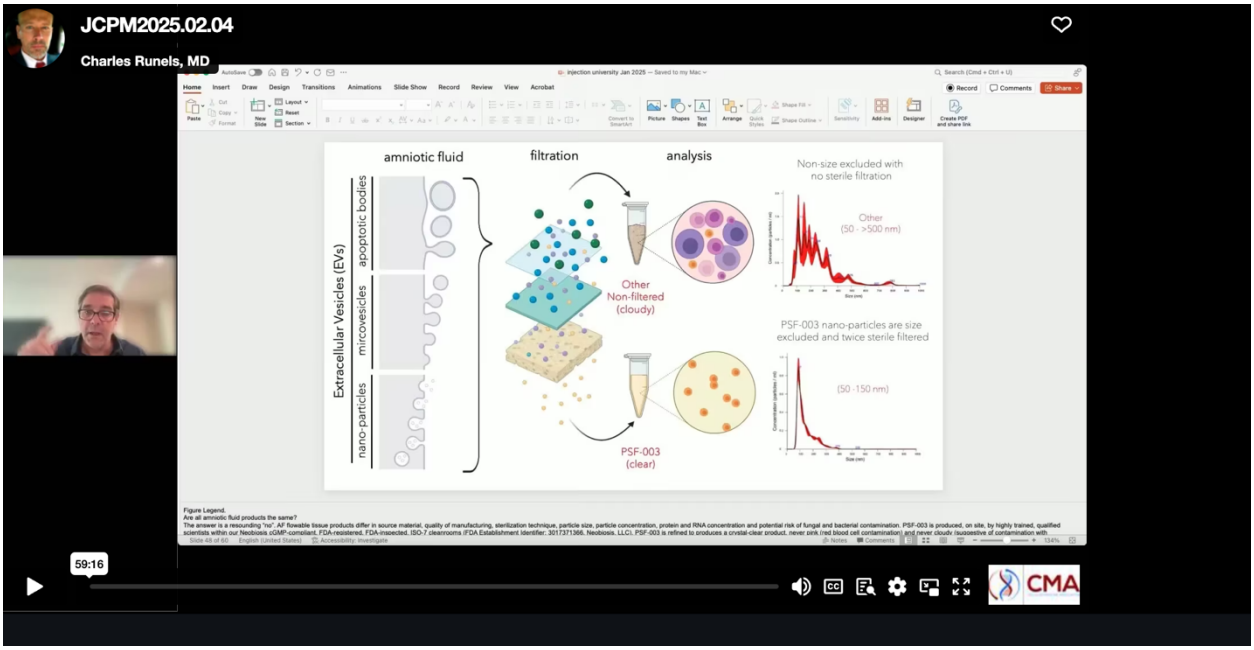
The following is an edited transcript of the *Journal Club with Pearls & Marketing* (JCPM) of February 4, 2025, with Charles Runels, MD.

>-> The video of this live journal club can be seen here <-<



Topics Covered

- Trends in biologics
- What is aging, and where does it decelerate?
- Heterochronic Parabiosis
- Klotho

Charles Runels, MD
Author, researcher, and inventor of the Vampire Facelift®, Orchid Shot® (O-Shot®), Priapus Shot® (P-Shot®), Priapus Toxin®, Vampire Breast Lift®, and Vampire Wing Lift®, & Clitoxin® procedures.

Transcript

Charles Runels, MD:

Today, we have a very special guest, Dr. Ian White, PhD.

Probably two years ago, I was at a conference with Karen Rae, who's in our group. She has a very, very popular course where she teaches PRP injections. She teaches our procedures, but she also teaches injecting the joints. And she has a Regen summit every year, which I attended. And I saw Dr. Ian White, PhD who has a PhD in regenerative medicine, which is very rare. I was super impressed with his credentials. Without a doubt, he knows more about regenerative therapies than anybody else I've ever heard lecture. He's worked with Harvard and Dartmouth and had many, many multi-million dollar ideas, and I think he has a way of helping you flush out the wheat from the chaff.

At least once a week, probably more than that, I probably get at least eight offers per month of someone wanting me to promote some sort of biologic with you guys. Either it's exosomes, or somebody has a new Wharton's jelly or something, and they offer me money to promote it. But just so you know, I don't take any money from any product distributor of any type. No centrifuge company, no biologic, nobody.

And that keeps me, I think, neutral so that when I do say, "Here's someone you should pay attention to," you know it's because they stand out with their knowledge.

And as you guys know, I have not promoted any sort of biologic or even talked about it except just to tell you not to talk about it for at least the past five years. But I heard Dr. White lecture again at Karen ...

By the way, if you want to learn to inject a joint, Karen Rae. She's in our group and she does the best joint injection course using ultrasound of all the people I know.

Anyway, so Dr. White blew me away again. And here's the thing that's happening, and he'll tell you more about this, much more than I know, but not only does he have, I think, the premier knowledge base and company to manufacture some of the more powerful biologics, but he's also because of his expertise communicating with those in political power to help decide what's safe and how we can help our patients. As you know, it's one of my big pet peeves.

The last time I looked, somewhere around 35,000 people per year die from just GI bleeds from non-steroidal.

[I quoted the wrong number here; the actual number of deaths per year from GI bleeds from NSAIDS is closer to 16,000[1]]

I was a resident about the time that Advil became a non-prescription drug. Some of you guys are old enough to remember when to get Advil, you had to write a prescription.

[1] Wilke and Hirschowitz, "Minimizing the Risk of NSAID-Induced GI Bleeding."

And when it went non-prescription, I had an attending who was a nephrologist who just shook his head and just was so disturbed by that because, as you guys know, if you go to any dialysis center, you're going to meet people who lost their kidneys by the combination of Tylenol and Advil for headaches.[2] [3] [4]

And yet, even in the face of over-the-counter Advil, Google has killed our ability to have a click ad for freaking PRP! (With millions of PRP injections per year for multiple indications, you will have difficulty finding more than a dozen significant adverse events secondary to the injection of PRP. And the ones you find usually involve a non-licensed person doing something stupid)[5].

And I think our FDA is needed and is necessary, but the legal structure has been, I think so in favor, I hate to say it because it sounds cliche, but you're seeing it now play out as Kennedy tries to get approved.

The pharmaceutical companies do wonderful things for us and bring to us wonderful drugs, but they also have their thumb on us. And so, you can advertise on TV about Advil, which puts people on dialysis and kills 16,000 people a year with GI bleeds. But you can't do a click ad about PRP, and you can't talk about biologics.

But I think that's about to change.

And so with that change, with Kennedy probably about to be approved. And when you look at the picture of the guy without his shirt, thank goodness, I think you should have to pass a physical fitness test and be able to play a musical instrument to run for office. I mean that's one thing I liked about Clinton. He could play the saxophone. Instead of the Republican Party and the Democratic Party, I think it ought to be the Jazz Party. You got to play an instrument and you have to be able to walk at least three or four miles without getting out of breath. Then you can run for office. And that's what you got with Kennedy. You've got a person who has a mission and I think you're going to see some changes. It's already happened in some of the states and I think it's going to be easier for us to do the things we know will help our people.

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[2] de Vries, Setakis, and van Staa, "Concomitant Use of Ibuprofen and Paracetamol and the Risk of Major Clinical Safety Outcomes."

[3] Honma, Onda, and Masuyama, "Drug-Drug Interaction Assessment Based on a Large-Scale Spontaneous Reporting System for Hepato- and Renal-Toxicity, and Thrombocytopenia with Concomitant Low-Dose Methotrexate and Analgesics Use."

[4] Yue et al., "Association between an Excess Risk of Acute Kidney Injury and Concomitant Use of Ibuprofen and Acetaminophen in Children, Retrospective Analysis of a Spontaneous Reporting System."

[5] "Don't Fear the Vampire Facial. Just Keep It Safe."

So I've rattled on long enough except to tell you that out of the past 15 or 20 years you're about to hear the man I think understands both the politics and the science better than anyone else I've ever met. And so I think with that, let me make sure, are you there Ian? Are you still with us?

Dr. Ian White, PhD:

Yes, I'm there. Can you hear me okay?

Charles Runels, MD:

Yeah, we can hear you. Yeah. And see you. So take it away and take as much time as you need. We have some of our top people on the call and of course this will be recorded and go to the rest of them.

Dr. Ian White, PhD:

Well, Charles, thank you so much for that introduction. It was very kind of you to invite me to address your group today. It has been a pleasure getting to know you and meeting with you. I have a lot of respect for everything you've done for this industry, and it's a real honor, I would say. I speak all around the country to a lot of different audiences, but this is a real honor to be here today. So thank you very much.

So these are just some disclosures and they're often a good idea to help introduce myself a little bit. What I'm going to do today is somewhat rapid form compared to normal, although I'll try not to skip over anything important is give everybody an idea of the types of study that we are doing in the field of regenerative medicine and longevity so that they can get an understanding of what the mechanisms are that cause the process of aging and how biologics could possibly Interfere with that process and why therefore we use biologics in order to promote tissue regeneration, tissue regrowth and also accelerate or slow down the aging process.

So I'm the CEO of Neobiosis,[i] and in Neobiosis, we manufacture perinatal products. So biologics from birth tissue, that includes exosomes, that includes Wharton's jelly. These are products I've been working with for many, many years now. And just see in the presentation as we go forward, we've done a lot of research on these products and on these tissues. And we were recently awarded a FDA approved IMD. It's a very long and laborious, and expensive process to demonstrate to the FDA that you have safety and efficacy in your product. And then they would [inaudible 00:07:43] laboratory and either approve or not approve a clinical trial. Recently, we were approved for a clinical trial with our products, and I'll talk a little bit about that.

I'm also the Chief Scientific Officer for Ways2Well, and if you're not familiar with Brigham Buhler, I strongly recommend that you look up Brigham Buhler, Ways2Well, and Joe Rogan and hear what Brigham has to say on the Joe Rogan Show about the healthcare system in the United States.

I'm also the founder of the Space Aging Research Institute, where we focus on the mechanisms behind aging, and the Vice President and member of the board of directors of the American College of

Regenerative Medicine, which is a non-for-profit organization where we communicate regenerative medicine to the general public and to lawmakers.

Further talking about lawmakers, I'm also an advisor for the Alliance for Longevity Initiatives, where we've just established the first bipartisan caucus on longevity research. So, what does it take to understand and study longevity? How do we fund that kind of research? And how do we apply that to patients for their benefit?

What is Aging?

The purpose of this presentation is to introduce you to the idea of what aging is, why it's a disease, and why there are potential products that exist that we manufacture that can have beneficial effects on patients. How do they have beneficial effects? What is it we're actually doing to the biology of the patient? So we'll ask the first question of why are we interested in age-reversal at all? Then we'll look at whether it's even possible and then we'll talk about the path forward.

So, this is where I would like to start. It's a crazy slide when you think about it, but what this demonstrates is that we as a nation spend about $4.8 trillion a year trying to treat all the various symptoms and diseases associated with aging. So if you are over 65 years old, you have an 80% chance of succumbing to one of these various aging-related diseases, whether it's cardiovascular disease or neurodegeneration. And in fact, you have a 68% chance of developing at least 2 of these diseases. So what we want to do is try to address this 4.8 trillion cost on the American people that doesn't seem to be getting addressed efficiently right now.

So we all know in the field of longevity, these various aspects, these hallmarks of aging, but when there are groups that are trying to study aging, what it ends up happening is that we have this sort of whack-a-mole situation where we know that we've got to take vitamin C for this and BPC-157 for that, but nobody's really addressing the entire aspect of aging. It's all one aspect, telomeres or mitochondria dysfunction or something like that. So what we really need to do is understand how the aging process works rather than just trying to treat each individual symptom by itself.

So in the field there's been a little bit of exhaustion. People feel that we're running out of ideas, but we're absolutely not. This is actually the prime time for studying regenerative medicine and longevity, but the narrative has to change. For a long time, we've understood or we've been told that aging is inevitable. Biological aging, so that the age of our tissues is connected with chronological aging. So how many birthdays you've had, but we're learning now that actually aging is not in a linear form, it's actually fungible. You are able to modify it and I'm going to give you some examples of that.

So in nature we have this phenomenon called matriphagy. And in this case, what happens is that an individual will mature to sexual reproductive age, it will reproduce, have babies, and then undergo this switch, a switch that accelerates the aging of the individual so that the mother of these spiders ends up dying and becoming food for her offspring. So it's an accelerated aging that benefits the next generation by providing resources for her offspring. And something similar happens with Pacific salmon. Once they spawn, they reach sexual maturity, they spawn, they undergo accelerated tissue degeneration due to an accelerated aging and their tissue liquefies, they end up dying and freeing up resources for the next

generation. So we're kind of the same thing. We reach sexual maturity and then we accelerate our aging, although we don't really notice it as rapidly as these species, we are accelerating aging to exit us from the gene pool so that we can free up resources for the next generation. We are just seeing it an accelerated form in some of these species.

But we also see it in an accelerated form if we send people to space. If you go to space, you age much faster than you do on Earth and you're not going to be able to see the details of this slide, but it's on the NASA website if you're interested. But these are pointing at different areas where scientists have studied aging in astronauts, whether it's the eye, the brain, reproductive organs, all these different organs accelerate aging in space and it's unclear why. It's not just due to the exposure to radiation. There's something unknown about being disconnected from gravity that actually accelerates the aging.

So aging is fungible and this was demonstrated very interestingly recently when Doug Hurley entered the space station, bumped his head on the capsule. And while that was not necessarily a big deal for him at the time, if he had been on the space station longer, that little bump that caused a small bleed could have been very dangerous because in space, not only do you age faster, but your skin, your tissues heal less fully, less rapidly. So an injury like that could have become infected, our immune system is compromised in space and it could have been a life-threatening injury for him if he had been on the space station longer before he actually bumped his head.

So we know that aging can be accelerated, and there are detrimental effects to that. But what about slowing aging? Well, there are many examples in the animal kingdom of decelerating aging. So this is Jonathan. He was recently inducted into the Guinness Book of Records for being the oldest living vertebrate. In the black and white photo there, he was already 50 years old and today he's almost 200 years old. So that's an individual that's lived through the equivalent lifespans of about 20 billion human beings. So all the population of the Earth who have experienced a full lifespan and have had grandchildren and whose grandchildren have had children, all of those lives have been and passed in Jonathan's lifetime.

That's 20 million human lives that he's lived through because of this ability that he has to slow the aging process.

There are other examples too. And in fact most people don't know that lobsters for the most part are immortal. They don't show any signs of aging whatsoever. They just keep growing bigger and bigger. And the only time they die is if they get disease or if they are captured or if they die under their own weight. They just get so big they can't molt anymore, and the energy expenditure required to malt is too great and they end up dying in the malting process. But if you look at their cells, if you look at their reproductive organs, they are no different from if they were one years old.

And that's the same for this buffalo carp as well. A 100-year buffalo carp is just as reproductively active as a 1-year-old. And in fact their cells look no different than if it was a young individual. It has the ability to pause the aging process. Yes, they get chronologically older, and they have more birthdays, but biologically, they do not age. They have no aging mechanism in their body at all. It's quite a phenomenon, but it means that in nature, something exists within the DNA that can be captured and taken advantage of. So that's going to be relevant for the discussion later on.

But this species is even more interesting. We've talked about slowing and pausing aging, but what about reversing it? Is that even possible in the realm of physics, biology, and chemistry?

And the answer is yes. A species called Turritopsis dohrni, also known as the immortal jellyfish, does not die and does not age. What it does is that it lives until reproductive age, it reproduces. And rather than accelerating the aging process like other species do, it de-differentiates its tissue. So when you're young, you are differentiating, your cells are becoming specialized into hair and eyes and organs. But in this case, once it's an adult, it de-differentiates. It takes all of those specialized cells and puts them back into an embryonic-like state and it becomes a baby again. And it just keeps doing that backwards and forwards forever until it dies of a disease or it's injured in some way that it can't recover. But there are estimates that some of the jellyfish, these specific jellyfish exist in the ocean today that were born over 5,000 years ago. So something like that existing in nature for somebody who studies aging is fascinating.

So the story there is that biological aging can be uncoupled from chronological aging. Just because you're getting older with every birthday that passes, it doesn't mean you have to necessarily get biologically older at the same rate. And that's what we're going to get into. So again, all of these symptoms that you recognize as associated with being older, neurodegeneration, cardiovascular disease, hypertension, they're all due to this process after reaching reproductive age, after we stop growing, we start turning everything off, we lose the ability to repair and regenerate our tissue, which is why we get wrinkly, which is why our joints hurt and which is why we need more surgeries and we're spending almost $5 trillion a year on these different aspects of aging. But what's fascinating to me is that these species that exist that are able to manipulate the process of time are not unique. We can do it ourselves as a human species.

And in fact, this research here by Shinya Yamanaka won the Nobel Prize in 2012 where he demonstrated that you could take old skin cells, keratinocytes, fibroblasts, and you could de-differentiate them, you could take them from their old differentiated state and with only four growth factors, turn them all the way back to the beginning and make them embryonic-like stem cells. They're called induced pluripotent stem cells. So, this old cell was made to look like an embryonic cell with zero markers of aging. And it's amazing that we don't really talk about this more, but we see this phenomenon every single day. If you take a 40-year-old woman and you take a 40-year-old man, they're both born with their reproductive cells. Yes, a man makes new spermatids every day, but that comes from the sperm stem cells in his gonads. With the mother, she's born with all of the eggs she's ever going to have in her lifetime. So once they reach 40 years old, all of the cells in the body are aging, all of the systems in the body are 40 years old.

But somehow miraculously in this miracle of birth, those 2 40-year-old cells when they come together turn into a 0-year-old cell and they make a 0-year-old baby. And it seems silly, but when you think about it, it's actually quite amazing that through 40 years our bodies have been aging, we're getting older. And in fact, once women reach 40, 50, 60 years old, they're no longer able to have children because their eggs have aged so much. Yet if they reproduce in time, those cells revert to zero. So there's something very special in the birth process that has a switch, a signal, a growth factor, something that is able to turn back the clock on our aging cells and make them young or even zero again.

And so there's been a lot of research done on this. And in fact, these experiments essentially established my scientific career. This was not my work. This was done by scientists at Harvard University a couple of decades ago. But these experiments are called heterochronic parabiosis. And what these scientists did was they sutured together, they stitched together two mice, one old and one young. And to cut a very long story short, what they observed was that the young mouse experienced accelerated aging, but the old mouse actually got younger. All of the markers of aging reversed. Grip strength came back, cognitive ability came back, the hair color of the mouse went from gray back to its original color. So all of these markers of aging were reversing, and at the time they called them rejuvenating factors. But what we know now is that they are exosomes. And in fact, you can take those exosomes from the young plasma of an individual and inject it into older individual and see a lot of the same phenomena that you would see if you sutured the two individuals together.

So with that principle, I started a lot of my research and you're probably not going to see this very clearly. I don't know how clearly you're able to see it, but the publication is there. It's also on my LinkedIn. All my publications are listed there if you'd like to follow along with my research. But I just wanted to tell you about this in particular because what I did here was I listened to nature. I understood that these young signals have the capacity to affect all the tissues. And in the United States and around the world, cardiovascular disease is one of the biggest killers because the heart does not have the ability to regenerate and repair itself.

But what's fascinating is that the heart in utero during fetal development, can regenerate, can repair, and in fact, it keeps that regenerative ability for the first two days after birth. And I've won awards from the American Heart Association for this work. I was featured on the cover of Circulation Research, which is one of the number one medical journals in the world for cardiac research. So please, I would urge you to go read that work if you're interested. But what I demonstrated here was with just a few young growth signals, I was able to take a heart out of a mouse, a young mouse, put it in a Petri dish and observed one or two things. If I did nothing to it, it necrosed very quickly and died. And on the very left panel you can see as we zoom into this histology that the tissue is completely necrosed.

But if I give those young signals, those very specific young signals, what you can see is that actually I can keep the heart alive and in this case, up to a month or more. And if I'm able to play this video and if you're able to see it, this is one of the hearts in the Petri dish still beating. So not only did it not die, not only did the cell survive, it's still functional after all this time just with young signals. If you're not able to see that working and you're interested, I'd be happy to share that with you offline. So let me see if I can progress.

But I was able to take a step further. So yes, I was able to keep a heart alive for an extended period of time, which has huge implications for cardiac or tissue transplantation because we struggle right now with keeping tissues alive. But I was able to take it another step further and actually demonstrate regeneration. So if hearts don't regenerate in the adult, but they do only in the first two days, is there a way that I can give those two-day signals to the heart and induce it to regenerate? And that's what I ended up seeing.

I took the heart out; I injured the ventricle of the heart, I put it in a Petri dish, and I changed the growth factors. And over the course of 21 days, you can see that the heart regenerated itself, it regenerated that injury. If you're able to see that panel on the bottom middle where it says EDU, that triangle is full of red dots. Those are proliferating cells. Remember the heart can't regenerate itself. It only has that capacity for the first two days. But after 21 days, we were able to induce that regenerative response and get a regenerative outcome in that cardiac tissue.

Heterochronic Parabiosis

So we were the first then to sort of make this connection between heterochronic parabiosis, so suturing a young mouse and an old mouse together, which of course is not practical from a medical perspective, but we were the first to publish that pregnancy is actually a natural form of heterochronic parabiosis. You have a young individual and an old individual sharing a blood supply, and that blood supply is full of exosomes. So the amniotic fluid that the baby is sequestered in, accumulates exosomes from the baby and from the mother. The baby consumes them, the baby's bathed in them. And without access to these exosomes and without access to these growth factors, the fetus doesn't actually grow properly. What's amazing is when the baby consumes the exosomes, they're actually able to get into the blood supply of the mother. And it's not just the consumption, it's actually the respiration as well.

Although the baby's not breathing, the chest movements draw the amniotic fluid into the lungs and it's able to pass that blood barrier and get into the mother's circulation and through the placenta, and it actually changes the mother's physiology as well. Her heart increases by a third in volume in the last trimester and the quality of her skin, her eyesight, hair quality, everything improves during pregnancy so that she can deal with the rigors of pregnancy the baby. It gives her the tools and the resources that her body needs to deal with this additional stress.

But what's fascinating is that we're able to harvest that amniotic fluid once the baby's born, a full-term healthy pregnancy, a cesarean section, we're able to harvest what's left of the amniotic fluid. We can purify it in a proprietary method in our CGMP-compliant laboratory in Gainesville, Florida. And we end up with this purified exosome product. And you can see here on that graph, those exosomes are between 50 and 150 nanometers. We've cleared out all of the junk and all of the other non-regenerative vesicles, and we're left with this pure population of exosomes surrounded by all of these soluble growth factors that are perfectly designed by nature, over 7 million years of human evolution to grow tissue and to modulate inflammation.

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So let's talk a little bit about the skin and how the skin might benefit from something like this because we know in utero, if the baby is not exposed to amniotic fluid, the skin does not mature properly. And we've done that in experiments with sheep and other species. But here's a quote from Dr. Orgel at Harvard University where he says, "The body's capacity to repair the skin diminishes as we get older. There just aren't as many growth factors and stem cells in the skin." So we all experience sagging skin, wrinkles. We all experience the lag in repair, if we injure ourselves as we get older, it hurts more, it

takes longer to heal because we don't have the growth factors and we don't have as many stem cells in the skin as we did when we were younger.

And in fact, as soon as we are born, we lose the vast majority of our regenerative ability. When we're neonate, we have this huge capacity to repair and regenerate. But even in our teen years, we've lost the majority of that. And by the time we're in our 40s, 50s and 60s, it's almost completely gone. So our theory was if it works in mouse models of heterochronic parabiosis, maybe we could confuse the skin, maybe we could confuse the organs of our aging bodies into thinking they're younger. So if we can take that heart that would otherwise not survive and give it those young signals and suddenly it thinks it's still two days old and so it repairs like it might have done before, can we do that with other tissues?

So one of our first experiments was in collaboration with a team at Harvard University where we did what's called in vitro wound healing assay. It's a monolayer of epithelial cells and we put a gel block in the middle and that circle is where the gel would sit. Once the cells reach confluence, so once the dish is full of cells, we remove that gel so we're left with a circle that doesn't have any cells, and then we add in control items like saline to see what the cells will do. So under the control setting, which is at the top, the cells just sit there, they don't do anything, they don't respond just like old cells might do. But if you give them the signals from amniotic fluid, purified amniotic fluid, and we've designated it ViX001, and we'll get into that in a minute. That's the designation of the product we have the FDA approval for our clinical trial.

If you provide this product, the epithelial cells that would be responsible for repairing injury and skin, activate and they start migrating and they close over that wound. So we know that there are growth factors and exosomes that are present in this product that theoretically can activate the epithelial cells and they do so in vitro. But what about in vivo? What about in animal models?

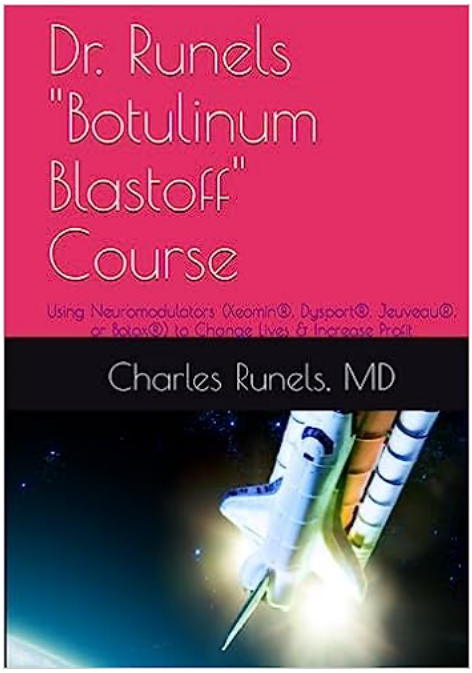
Now, this is a mouse model of wound healing. We injured the back of the mouse, and although mice naturally heal very fast, what we were able to observe here was that with the addition of this product, we were able to accelerate the healing. It would be great if the mouse didn't heal, but they do naturally heal very fast. But as you can see in this assay, whether we add Wharton's jelly or we add the ViX001, which is the purified amniotic fluid, the healing process is accelerated.

And so we thought, let's translate this to the bedside. Let's try this in a clinical setting. And this was done in collaboration with the University of Miami. You can read about it in all of our publications. We publish all of our work. This is a diabetic ulcer, so a recalcitrant diabetic ulcer. You may know that most diabetic ulcers do not respond to treatments, and in fact, this injury, this ulcer was not responding to treatment. And so this patient was on the road for an amputation. However, we applied the product and just like in vitro assay and just like in the mouse model, the tissue was able to respond to the growth factors and heal. We were able to revascularize, we were able to grow new nerve endings and we were able to grow new tissue in the absence of scarring. Now, it did take a few months. In this case, this took three months, but the alternative would be a progressively large ulcer and ultimately amputation.

Here's another example. This is another diabetic ulcer on the achilles. Progressively got worse in hospital, no treatments were working. We applied the product topically and over the course of two

months, it completely healed. Baby soft skin, revascularization, de novo nerves and pain was eliminated immediately.

A couple more examples. This is a thermal burn. So a firework had exploded on the back of this lady's leg and received second and third-degree burns. The prognosis was two to three months recovery with extensive skin grafting. She was in 10 out of 10 pain, but she happened to work in a provider who uses our products. And so they sprayed just topically, no injection, just topically sprayed the product over the wounds. And instead of two-to-three-week months recovery, the injuries healed Within six days.



Her pain went from 10 out of 10 to 2 out of 10 within 30 minutes. She was off opioids, they were able to debride and she was able to sleep and go back to work much, much faster.

Here's an example of autoimmune disease. This was in this case, delivered intravenous, so systemic. This woman had been suffering from this disease for five years, steroid withdrawal syndrome or also known as red skin syndrome over her face, her arms, her legs, and then within one week of administration, this is the result with her feet and you can see her arm there and that's two weeks later. She did need a couple of additional boosts, but after one year of four treatments, she was completely in remission and she had regained her life.

A couple more examples. This is an undiagnosed, so we call it [inaudible 00:31:37], but it wasn't officially diagnosed. We have published on it though. This was a dog bite that progressively got worse. No antibiotics helped. They were going to amputate the leg. So she was an amputation candidate already, and she agreed to do a test with the product. We applied it topically and after one month, the infection resolved and the skin grew back.

So that's the clinical side of things. I want to just touch on a little bit of the science before we go on to what's next on the regulatory side, but we don't actually know how a lot of this works obviously. We are learning as we go, but it's no different than something like breast milk. We've been studying breast milk for decades, not us personally, but other scientists and we still don't know what's in it. We still don't know how to reproduce breast milk, but it's great. And we have formula and we utilize breast milk all the time, but we don't know what's in it. That's the same thing with amniotic fluid. We just don't know what's in it. So we don't want to be purifying out all the goodies. We want to keep those growth factors and those exosomes present.

Klotho

But one thing we've learned recently is that there's a protein called Klotho. And if you are interested in longevity and health span, I certainly urge you to research more about Klotho. There's a great book by Dr. Cleaver about the anti-aging power of Klotho. But a long story short, basically scientists discovered

that this gene, this protein that we make is able to slow down the aging process if it's over-expressed in mice and if it's blocked in mice, if it's knocked out in mice, mice die much, much faster. But the amazing thing is that the fetal baby, the fetus in utero in the amniotic fluid, their kidneys make this protein in abundance. And it's probably one of the things that contributes to the growth of the baby and the physical changes in the mother. So when we harvest the amniotic fluid, it's actually abundant in this amniotic fluid. So not only do we have the exosomes, which are an amazing source of signals and anti-inflammatory [inaudible 00:33:34], we have all of these growth factors that are solubilized in the amniotic fluid as well as hyaluronic acid, chondroitin sulfate, but we have this Klotho present as well.

So we're really excited to pursue this further. If any of you are currently using biologics and you're using purified exosomes from a source like MSCs that won't contain Klotho, that won't contain any of these other bioactive growth factors because they're purified out. The monolayer produces the exosomes, they're collected, they're washed, and then they're re-suspended in saline so you're not actually getting any of these additional goodies that are likely doing the majority of the work.

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So is there a path forward?

Well, we've been working for many years. My partner is Dr. Pascal Goldschmidt, who's the Dean Emeritus of the University of Miami Medical School. So he on the MD side and myself on the PhD side have started this company, Neobiosis, to bring transparency to the biologics industry because we saw how disrupted it was previously. And one of the ways that we can do that, one of the ways we can bring transparency is to publish. But another way is to apply for clinical trials. And it's quite hard for a biologic to get a clinical trial. But working with the FDA, they inspected our lab, they audited us for two weeks, and then they awarded us through an extensive application process, an IND to study the purified amniotic fluid IV in a cohort of patients. So we're very excited that we're pushing the frontiers of biologics in the right direction with the appropriate approvals in place.

So I've been doing a lot more to influence this industry as well. I've worked with the government in The Bahamas, and recently, they've changed the law in ***The Bahamas to allow regenerative medicine to be practiced in the absence of FDA approval.***

So before, when individuals would go abroad because they weren't able to practice certain aspects of regenerative medicine in the United States, they would go to Mexico or other countries where it's completely unregulated, and they have no idea what they're getting. But in this case, the Bahamian government recognized the potential of regenerative medicine, but also recognized how difficult it is for people to have historically had access to regenerative medicine.

So, in September of 2024, they enacted a new law to allow anybody in The Bahamas to have access to regenerative medicine by going to a licensed healthcare provider. And so we were able to achieve that so we're very excited, but that's not where it ends. We have a new government now, and this individual, Brigham Buhler, who I mentioned previously, has previously testified in front of the Senate on the healthcare system in the United States and on regenerative medicine. He's appeared on the Joe Rogan Show several times. I've been given the honor of serving with him as the Chief Scientific Officer for

Ways2Well as they are advising RFK in his transition to establish a new FDA. So moving forward, I'm very confident that we're going to be in a situation where finally the FDA understands the safety and efficacy of these biologics and we're going to have a much easier pathway through to product approvals.

I've also been very busy with other lawmakers. And as I mentioned, I'm on the scientific advisory board of the Alliance for Longevity Initiatives where we've established the first bipartisan caucus on longevity research. So the study of aging, how do we study aging? What is aging? And how do we deploy countermeasures against aging? That now has a lot of interest on Capitol Hill with a lot of different lawmakers who are putting their names behind this and that there is myself with a former Speaker of the House, Newt Gingrich.

I didn't have anything to do with this, but this is a very exciting piece of news that Utah recently passed a law very similar to The Bahamas, allowing physicians in that state to practice regenerative medicine without FDA approval. So we hear a lot about this is dangerous, we don't know how to regulate it, but lawmakers are now understanding how much data actually exists around these products, particularly our products and how safe they are and how effective they are. And they're taking a unilateral decision here and following the medical marijuana model and saying, "We are going to allow it in our state, and we're going to see how that develops." And a lot of states are now adopting that policy too. So even without this change in the administration, it's likely that we would be seeing this change on a national level starting at the level of the states.

So before I sort of wrap up with some other ideas, this is basically where we're at currently. We're looking at a complete new HHS with RFK coming in and becoming the new health secretary. He is very pro-biologics, safe biologics. We've had many conversations, our network, about how we need to regulate the field of biologics more appropriately. And he's very on board and he's picked Jim O'Neill to be his number two who used to be the CEO of SENS, and they're an organization dedicated to the research of aging and how aging affects our health span in the United States. And then finally, Marty Makary will likely be taking over as the new FDA Director, and he in the past has been very vocal about his support of regenerative medicine. So we're very confident that this field is finally going to get the attention that it needs and we'll be able to explore a lot more of this industry.

So before I finish off with a few more slides, we're back to the beginning. We're spending $4.8 trillion currently on all these different diseases of aging, but my company, Neobiosis, is looking way, way upstream. We're looking at the causes of aging. Can we give the signals the body needs and the body can respond to so it can heal before it even gets sick, before it even gets injury, before it starts developing wrinkles? Can we slow that aging process by giving these young signals? If you've got an injured knee that's not responding to treatments and is going to require surgery, can we trick it into thinking that it's young again, give it those young signals that it needs, those was building blocks and allow it to heal? And these are the things we're seeing. These are the publications we're making, and we've deployed over 50,000 vials of these products so far.

A lot to the NFL. We're talking about concussion, we're talking about injuries, we're talking about torn achilles tendons. I'm not going to mention any names, but these athletes that are recovering magically

that nobody can understand why they're recovering so fast, it's because they're using our products, but they just can't talk about it unfortunately.

So this is where I'm going to start wrapping things up, but I want to wrap things up in a slightly different way than I would normally. And what I would like to do is demonstrate that not all biologics are created equal. Some of you are familiar with the biologics field and maybe using exosomes already, you're likely interacting with a lot of sales reps and their job is to convince you to make a purchase. Their job is not to communicate the science and their companies often are not in the business of science. They do not understand how to manufacture these products, and they're simply a distribution company whose sole purpose is to make you buy their product. And we started Neobiosis for completely different reasons. We understand the science, we understand the potential, and we want to give you the transparency to say this is the right way and this is the wrong way. So Charles, if it's okay, I'll continue with this explanation.

Charles Runels, MD:

Absolutely. We have questions that I think you're probably about to answer, so go for it.

Dr. Ian White, PhD:

And if I don't answer those questions in this section, I'm happy to stick around to answer questions afterwards.

Charles Runels, MD:

Sure.

Dr. Ian White, PhD:

So this is an example of question that I get all the time is how are exosomes derived from MSCs different from exosomes that are derived from amniotic fluid? And I could talk for maybe an hour by itself on the differences, but the long and the short is when you're culturing MSCs in a Petri dish, first of all, they're stuck to plastic. This is a very artificial environment for them. And so they're not responding the way they should be responding because they're stuck on plastic. They're not in the body, they're not associated with blood vessels like they would normally. So the signals they're packing into their exosomes aren't necessarily the best signals that you would want in an exosome.

Also, those cells can only make so many exosomes as a monolayer. So you get a much reduced number. And these types of products, you typically would get maybe 5 billion exosomes per CC. In a purified amniotic fluid product, you might end up with 400 billion exosomes per CC. So you're getting not only a greater number of exosomes, but also the diversity is there. You're getting exosomes from all these different cells in the growing fetus and embryo that are designed to grow tissue and to change the physiology of the mother. So all those signals are in all these different exosomes, which you don't see in a monolayer of exosomes from MSCs. Not to mention these MSCs are bombarded with artificial growth factors to just try to keep them alive, whereas of course, we're taking these fresh exosomes from the amniotic fluid. So it's exactly the signals that the body needs.

This is just another representation of this example. So I believe this is being recorded. So you can zoom in and take a look at a lot of these differences between the purified exosomes from MSCs versus the exosomes from purified amniotic fluid.

The Scams

But this is something you might actually see in your practice, if you are using biologics already, if you're thinking about using biologics and you're going to get hammered by reps potentially, this is why I'm here. I'm trying to communicate the difference between a rep knocking on your door and speaking to the CEO of a biologics company that was established to bring rigor and transparency to the industry. On the top there is a product that exists in the market. Now we purchased that product and we tested it, and you can see all those different peaks there. Below is our product. You see a single peak. That means that we've purified the exosomes in that product and we have only exosomes that are between 50 and 150 nanometers. That's the size of exosomes. So when you're getting all these other peaks, that's non-regenerative junk, that's [inaudible 00:43:52] bodies, that's other vesicles that don't have the regenerative capacity exosomes have and in fact could be detrimental and could be dangerous to use those.

So we purify out all of that. Other companies do not. And often when you hold up the vial, we'll see that it's cloudy. That's because they don't filter it. And so without filtering it, the danger is that it could be contaminated with bacteria. We do a double redundant. We do a redundant sterile centrifugal filtration at the very end of our processing, not that anything's contaminated. We have so many different redundancies all the way through our process to make sure the product is safe. But we end up with this purified product, double sterile filtered. When they don't their product, they have to try to sterilize it some way and the way they do that is by irradiating it. So they'll put it under UV irradiation to try to kill any bacteria that are there. But of course, the way that works is that the irradiation damages the DNA in those bacteria or those viruses, but that's what the exosomes are made of. The signals inside the exosomes that are doing all this great work are made up by RNA. And if you are irradiating them, you are killing all of the exosomes.

But these companies just don't understand that because they're not founded and run by scientists and physicians. They're run by businessmen who see the opportunity, they hire a biologist that doesn't know anything about these subjects, they give them a protocol and they say, "Go away and do this." And this is what they end up with. A product like that.

If you are approached by a rep, always ask for data. This is data from our Wharton's jelly product. We have two different Wharton's jelly products. We have an acellular, so without cells, and we have a Cellular product. And in the cellular product we demonstrate with these kinds of data and we work with independent labs, so there's no bias. This is the University of Florida data showing all these different cohorts of cells that are present in our product. And then if you look at the bottom right-hand side, what you can see there is this is all of the live MSCs that are present in our Wharton's jelly product. Companies just generally don't do that because for the most part, they kill their cells and you'll end up with just debris in those products. You don't end up with actual live cells. But we're demonstrating here that we do have live cells in these products.

In addition, over 300 bioactive growth factors, we have independent labs testing for the growth factors that are present in our products. But unfortunately, we go against things like this. There's a company out there right now who are doing very well for themselves, but this is how they behave on social media. They put up signs and they tag our company because we are a legitimate company, they call it, as you can see there, I'm not going to say it out loud. But this is part of their marketing strategy and this industry doesn't need that. We are trying to demonstrate to the entire industry, the entire world, to lawmakers that this is a legitimate industry with safe and effective products, but we are dealing with jokers like this all the time.

So we don't do that. We don't talk like that. We do things like this, which are to go through the FDA and get an IND approved by the FDA, which we've done. We publish our results, we do the studies and we publish them in peer-reviewed journal articles. We don't write white papers, we publish them after they're peer-reviewed, and we talk about the mechanism of action.

Again, these guys online, on social media talking about how rich they are, how extravagant they are. This is not an appropriate way to behave in this industry and it risks the entire industry and it risks your practice. If you're associated with these guys, they have a huge target on their back and if they go down, you go down. And so we don't want to be working with individuals like that. I would hope you would want to be working with individuals like us where I have a PhD in regenerative medicine from Cornell University. I've been studying these biologics for 20 years. We have complete transparency. Pascal is the Dean Emeritus of the University of Miami Medical School. We brought our expertise to make you the best product, that is the safest. We don't take shortcuts, we don't take risks. You know that when you use these biologics that your patient is safe, they're getting a safe and effective product.

Here's another example of things that are problematic in the industry. That particular company purchased a whole lot of out of date biologics. So you can see here in the top right-hand side, the date this particular biologic was made was 2020. They were selling this in 2024, so 4 years later. So after the expiration date, they relabeled the vials. And then if we zoom in, you can see that they just changed their name on the official sterility record. You can see that by the font change that they just copied and paste their name into the sterility document, change the labels. This is what's going to end the industry. This is what's dangerous for the industry. This is what happened with Liveyon and now John Kosolcharoen is in jail. They put 19 people in the hospital. You cannot mess around with these biologics. You've got to do it right or everybody goes down. And so that's just a word of caution.

But let's take a quick look into the inside of the labs. This is a different lab, but these products are still out there. And if you go to conferences on regenerative medicine, antiaging, they have a booth there and they're selling products. This very day, I was able to get a photograph inside one of their rooms, and you can see there, there's some food on the table, there's some Petri dishes. If we zoom into the top right-hand corner there, that is a instrument warmer. It is not a validated incubator. This is an instrument with a Petri dish on top that contains a sample of the product they made to see if it was contaminated. We send our products, we take our lot that we manufacture in our CGMP compliant clean room, take 10% of everything we make, and we send it to an independent third party clear certified laboratory to do official testing on our products to make sure that there weren't any mistakes or any problems.

You cannot validate that the product you are giving to humans is safe when you just put a Petri dish on top of something that's not validated for temperature, and it's just in a lunchroom. These are products that are out there right now. I just want to draw the comparison that this is our lab. This is a CGMP compliant ISO 7 certified CGMP ... FDA registered and FDA inspected laboratory. You can see on our website that we have the date of the inspection. A lot of these companies say, "Yeah, we're inspected, we're CGMP certified." None of it's true. If they've been visited by the FDA, they will have dates and they will have a form that's called A482. So just be aware that there are differences in the market. And the reason why Charles and I are having this conversation is because I've spent my entire career trying to promote this safe and effective product and demonstrate that it can be made in a way that protects us, it protects you and it protects the client, the patient, but there are risks out there.

So that's the end of my presentation. Our product is called Lilium. We also have this new aspect of Lilium with the Klotho being present. It was a brand new observation. We're very excited about it. If you're interested in these products, I'd be more than happy to answer any questions. And I believe we have Bill Hart on the call who is our distributor for these products, and you can access them through him. So I hope that was informative. I'm happy to take any questions. And Charles, again, thank you so much for the opportunity.

Charles Runels, MD:

Thank you for being on the call Ian. Last week when I was in Florida at Karen Ray's Region Summit, I had a chance to have sit at the table for lunch with Ian. And I said, "Well, what are you doing for marketing?" And he said, "Nothing." And that alone made my respect skyrocket. As you guys know, Elon Musk never really marketed the Tesla because it was good enough that people just knew. And when you compare what's going on, and I haven't spoken, as you guys know, I just don't talk about non-autologous products. And part of the reason has been that it feels to me like back in the 1980s, I don't know if you remember, but when weightlifting was just sort of catching on, if you go back to the 60s, people thought weightlifting was not a good thing to do for athletes.

But then these health clubs started showing up where they would sell you a lifetime membership. And what they would do is they would collect many hundreds of thousands of dollars in lifetime memberships and then just shut the business down and go to the next town. And I get that same sort of feeling of hucksters that are just, it's part of the reason I don't talk about non-autologous stuff is I haven't really found anyone who gave me the confidence to say, "Okay, here's a company that's doing something that is well researched and well thought-out, and well and truly inspected by the FDA."

Now, put contact info. I'm not saying you go put a big banner on your website about how you're going to cure cancer with biologics. There still has to be a degree of intelligence about the way you think and talk about them. And you're looking at a man who does zero marketing because the way to be safe about it is to have individual conversations about what do you have in mind with your product, and then how can talk about it so that everybody's who's involved is being benefited and no false claims or dangerous claims are being made. And so I've put some contact info there, and I think the time is finally right to start thinking about it.

Of course, our group was based on the use of platelet-rich and I'm sure Ian would agree, autologous, homologous use of platelet-rich plasma is still a very viable tool. But I've always said, I mean, this is why I jumped into the platelet-rich plasma arena, is you watch to see what NFL athletes are doing, and you watch to see what are veterinarians doing to race horses that cost $100 million because they know before the FDA ever knows, before physicians ever know. And so you're looking at the premier top of the pyramid, I think mind when it comes to this product or to this arena, not just any one particular product there. I don't know if you know, but there's less than a dozen people out there who even have a PhD in regenerative medicine. So you're looking at a rare person who is talking with people at the top of our political and scientific pyramid when it comes to this idea.

And again, we talked before this webinar and I said, "I want no commissions on this. I just want to tell what I think about you and your company and then let people decide how it might fit in their practice." And there are more scary things that can't all be said on camera about what some of the companies are doing, but I guarantee you'll see some more people disappear from the market pretty soon, just like those lifetime membership people did, because there's some people making some fast money that are going to have to go hide in another country pretty soon, I think. Anyway, so we had a question here from James Panter who said, I don't know if you can see it Ian. Can you see that question? Says, "Does your purification ..." I think you already answered this, "Remove spike protein?" And then the second part of the question, "Do use mRNA vaccinated donors?" I know you were very careful about your donors. Maybe you could talk about that some.

Dr. Ian White, PhD:

Yeah, we have very strict inclusion-exclusion criteria and it's often difficult to get the right tissue because we have to reject a lot of tissue that we're offered. Companies will take anything that they can get, but we're very, very specific about what we take. We often get the question about COVID spike protein. We don't test for it. It's not very easy to test for in this case. But there is a lot of research out there, independent academic institutes that demonstrates that the spike protein does not pass the placental barrier and end up in the birth tissue. Now, if a mother's vaccinated, the antibodies can get around her body and into the fetus. That's the antibodies. But as far as the spike protein is concerned, the research seems to suggest that it does not. But it's not even possible for us, especially now where almost everybody has either been exposed to COVID or has received the vaccines, it's going to be impossible to generate tissues in the absence of those. But again, the research supports the fact that it doesn't pass the percentile barrier.

Charles Runels, MD:

Beautiful. And then one last question, unless your colleague wants to say something. We have a very informed and very courageous and smart group and I don't know. Obviously not this day, but in the future it might be interesting, we already have a mechanism, we're already surveying patients in a HIPAA-compliant way for the whole group. It might be interesting to see if we could include maybe multiple centers from our group in a future study. I think that might be ... in an actual IND, FDA approved IND in a future study. I could supply you with literally hundreds of people for a study like that.

Dr. Ian White, PhD:

Yeah, that would be great. Of course, as our clinical trial that's currently approved by the FDA expands, we're going to need multi-sites and many recruited patients. But in the meantime, once we do start the phase one, we can actually write and apply for single patient INDs or other examples like what's the name of it? The pathway? Compassionate use and things like that where we're able to, on a single case by case, apply to the FDA and that you can demonstrate that on your website. We have an active single patient IND and here are the data. So it's a very exciting opportunity for anybody that's interested in publishing and demonstrating that they're associated with a legitimate biologics product that's going through the regulatory pathways, that they're associated with it, they're working with it and they're getting results.

Charles Runels, MD:

Beautiful. I think that's all I have, unless your colleague Bob has something to say. I don't see him.

Dr. Ian White, PhD:

[inaudible 00:58:16] see if he was on the call. I'm not sure. Yeah, he says he's on, but he's muted. Is there a way we can unmute him?

Charles Runels, MD:

I can unmute him, yeah, if he wants to jump on. Let's see. Okay, Bob, you should be able to speak.

Dr. Ian White, PhD:

Bob, are you there? Well, Bob is the contact person to reach out to if anybody has questions about how to access the products. Of course, Charles, anytime you have any questions from your group that you feel that I could be helpful with, please reach out and let me know. But as far as access to products, we have inventory, we have the ability to ship anywhere in the country on dry ice overnight, so Bob would be the contact person to reach out to.

Charles Runels, MD:

Beautiful. So we'll end with that. I have Bob's contact info, phone number and email and the website for Dr. White's information. And I think with that we'll end the day. I sure appreciate you Ian. I would like to sit with you for several days and take notes, but I'll take what I can get. So thank you for being on the call.

Dr. Ian White, PhD:

You're very welcome. And I look forward to that day that we can do that.

Charles Runels, MD:

All right, bye-bye.

Dr. Ian White, PhD:

All right, thanks. Bye.

Contact Information for consultation regarding the products provided by Dr.White's company, Neobiosis: Bob Beilhart, 727-728-4000, sales@keystonebiologics.com

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Tags

Charles Runels, Ian White, regenerative medicine, PRP injections, exosomes, biologics, Wharton's jelly, FDA approval, longevity research, Neobiosis, Space Aging Research Institute, Alliance for Longevity Initiatives, stem cells, tissue regeneration, clinical trials, Klotho protein, anti-aging, neurodegeneration, cardiovascular disease, wound healing, diabetes ulcers, amniotic fluid, growth factors, autologous treatments, orthopedic applications, Utah regenerative medicine law, biologics regulation, medical innovation, patient safety, clinical applications, healthcare policy, RFK, Joe Rogan, Brigham Buhler, Ways2Well, stem cell therapy, aging reversal, telomeres, mitochondrial dysfunction, scientific research, medical ethics, biologics transparency, alternative medicine, athlete recovery, NASA aging studies, immunomodulation, regenerative therapies, inflammation modulation, tissue engineering, exosome purification, CGMP compliance, medical marketing, physician education.

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[i] Bob Beilhart, 727-728-4000, sales@keystonebiologics.com