Midlife Clarity with Dr. Tracy Page

"Clarity Changes Everything"

Hosted by Dr. Tracy Page

Episode #17 — The FDA Peptide Hearing

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[00:00] Hi, I'm Dr. Tracy Page, and welcome to Midlife Clarity. When I think you have clarity, everything is simpler. And so that's the reason for this podcast: to create clarity around topics I think that are important for my listeners and for my patients who are in midlife. And today we're gonna talk about a topic that I have done a series on. So I've done a whole series on peptides, try to educate you on what they are and what they are used for, why we use them, and so forth.

[00:28] And I wanted to conclude that series with the recent two-day hearing by the FDA about peptides and just kind of give you a summary about that hearing, what was concluded or what do we know from the hearing, and really just kind of give you some insight on this topic. So the hearing was July 23rd and 24th of 2026, depending on when you're listening to this podcast. And the second day of the hearing was a Thursday. And in the afternoon, in the middle of the hearing, but while I was in clinic with patients, my phone buzzed. They sound vibrate because I typically don't look at my phone when I'm in the clinic, but I have it with me in case I need to look something up or, of course, just in other emergencies.

[01:14] And within about an hour of these two texts that I received, they were from two different patients, two completely different people, but they were both aware of the FDA rulings. And so they were reaching out about the same event. Okay. The first patient, she's 52. And you've met her in one of my previous podcasts, at least her symptoms, because she's a patient that it was on a peptide, or is on a peptide called larazotide. So she's very similar to my podcast on leaky gut or larazotide. She had bloating, food sensitivities that came out of nowhere. She was in her late 40s, brain fog, joint pain that couldn't be explained by rheumatology or primary care.

[01:59] She had gone to many other doctors, but no explanation in a protocol that now includes peptides. And for the first time in years, she feels like herself. And that particular peptide for her is larazotide. Her text to me said, I just saw the headline that says the FDA is voting on my peptides. Or I think my peptides. Are they about to take this away? Am I not going to be able to get it? Okay, so that was her text. Then the other text I received was from a guy. His name is Paul.

[02:30] He's 58, former college wrestler. In his 30s, he basically sat behind a desk doing his desk job. Then he had a rotator cuff injury, actually a tear, during something that was very undramatic. As he was reaching the backseat of his car, he tore his rotator cuff. And likely he had degenerative tendons in there, and they just tore. Surgery,

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physical therapy, and a shoulder that two years later still would not do what shoulders are supposed to do. So we had pain with movement. He started a recovery peptide protocol probably about six months ago. And in his words, he got his arm back.

[03:08] His text to me read the opposite of my other patient. He said, I saw the FDA thing on the news. Does this mean it's finally legit? Can I stop feeling weird about it, about taking my peptides that are helping me so much? One patient was afraid the door is about to slam shut, and she'll lose her peptide. The other patient was hoping it was finally about to open. And this is kind of the interesting thing about these two texts. They were both watching the exact same voting thing. They were both partly right and partly wrong. Because what happened this week was not a door slamming, and it really wasn't a door opening.

[03:47] It was something more subtle and, honestly, hopefully more important than either of them realized. So here's why I told both the patients in almost the same words. What happened on July 23rd and 24th was not the FDA approving peptides. It was not the FDA banning them either. It was an advisory committee, a panel of outside experts with no legal power to make anything happen, voting on whether seven peptides should be allowed to be made in licensed compounding pharmacies. And here's the thing: six of the seven got a yes, including the two you've heard me talk about, BPC-157 and TB-4, or otherwise known as TB-500, and only one was turned down. The FDA's own staff scientists had argued against every single one of the peptides. And now a process begins that will take somewhere between one and two years before anything actually changes about what is legal.

[04:47] So nothing's been taken away today. Nothing is fully, quote, legit either. What we have is a movement in a direction that if it's handled well, it could be one of the better things to happen to peptide safety in about a decade. And it's interesting because I've had with them now for over five years. I did my peptide training just before I opened WIFM. And so I've really got to see the progress and the progression and stopping and starting of peptides. It's very interesting. So today, no single molecule.

[05:19] Today we talk about the news itself. We're not going to talk about a specific peptide because you're going to see the headlines, and half of them are written to scare you. And I think the other half are written to sell you something. So I just really want to make a lot of clarity around this. I want you to walk away from this episode with clarity. What actually happened, what it means, what it does not mean, and what you should or should not do about it this week. Whether you are a woman in

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perimenopause or a man trying to get his shoulder back or whatever diagnosis you have, I think you need this information. Okay, so what happened in that room? Let me give you the facts. I'll try to do them cleanly because the facts are actually not complicated when someone lays them out in order. Okay. So on July 23rd and 24th, a group called the Pharmacy Compounding Advisory Committee, I'll call it the PAC, PCAC, PCAC, so the PCAC, because that's what everyone in the room called it. Okay. So they met, this advisory committee met to consider seven peptides. The question in front of them was narrow, and it was very specific. Should these substances be added to something called the 503A Bulks List? Hold that phrase because I'm going to explain properly in the next segment, because it's the single most misunderstood part of the whole story. So I want to make sure you really get this part. Okay. Over two days, they took seven peptides in two groups. On day one, they considered four. BPC-157, which was nominated for ulcerative colitis. KPV, nominated for wound healing and inflammation.

[06:59] TB-500, nominated, I would say, for wound healing. And they also did MOTS-c, nominated for obesity and, listen to this, osteoporosis. Okay. On day two, they turned to three more: a sleep and withdrawal peptide, emideltide, also called delta sleep-inducing peptide (DSIP), and two brain and nerve peptides called Semax and Epitalon. So here's what the committee did on day one. They voted yes on all four of the peptides I just mentioned. And I want to give you the actual numbers because the numbers tell a story that the headlines aren't going to really tell you. BPC-157, 8 in favor, 6 against. KPV 8 to 6 again. TB-500, the recovery peptide, the one my patient, the guy with the shoulder, is on, 8 to 6 again.

[07:51] And MOTS-c, 7 in favor, 5 against. Okay? So notice something. Not one of those votes was a landslide, right? 8 to 6 is not a room full of true believers. It is a room that was generally deeply split. With a meaningful number of experts voting, I would say no every single time. Okay? When a headline says FDA panel backs peptides, what it is describing is a slim majority on a divided committee.

[08:20] Remember, it's a committee. They can't make any legal decisions. Not a scientific consensus. Those are very different things, and differences matter when you're deciding what to put in your own body. So that's why I'm bringing this up. Day two brought the other three peptides on board, the sleep and nerve compounds. And this is where it got a little bit more interesting than most people expected. Two of them also advanced. Epitalon, a peptide nominated for insomnia, got a yes.

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[08:47] Seven to four. Semax, a brain and nerve peptide, got a yes, 8 to 5, and only one peptide in the entire two days was voted down: DSIP that I just mentioned, and it's like a sleep and withdrawal compound, which lost by a single vote, 6 to 7. So the confirmed final headline is this: six of the seven peptides recommended for inclusion, one was rejected. All right? Now, the part almost no headline led with is the FDA's own scientific staff, the career reviewers whose entire job is to evaluate this kind of thing that we're talking about. So they recommended against every one of these peptides, not some, all of them. One of the agency scientists said, in essence, that the field had never been before faced the basic problem of not being able to answer the question, what even is the substance? Because for several of these peptides, there isn't a single universally agreed-upon chemical definition. Another committee member warned that the panel risked responding to what he called market-induced demand. In plain English, deciding something is worth allowing mostly because a lot of people are already buying it rather than a decision based on solid science. So that's where they were coming from. So the real shape of what happened in this is a divided outside panel voted by slim margins to recommend six of the seven peptides directly over the documented objections of the FDA's own scientists. That tension between demand and evidence, between panel and the agency is the entire story that we're going to talk about, okay? And it's a tension, but my patients both felt in their guts without having words for it, okay, because patients are benefiting from these peptides.

[10:35] And if you're not a functional medicine physician and haven't used them, and you're a scientist sitting on FDA who has no clue what they are, you know, they're going to be very adamant about not using them, right? So let's talk about the jury and the judge and what the vote does and doesn't do. This is the segment that will save you from 90% of the misleading headlines you're about to see, at least I hope so. Because the single biggest misunderstanding about this week's, I would say, ruling is the belief that the committee approved anything because it didn't and it can't. So the FDA scientists on the committee, they didn't approve anything, and they can't. Neither did the other pharmacy committee members approve anything. They can't. This is not what the committee is for.

[11:21] Okay. Think of a jury and a judge. So I think I like this analogy. An advisory committee is the jury. It hears the evidence, it deliberates, and comes back with a recommendation. But the recommendation is not the verdict. The FDA is the judge. And in this system, the judge is not even required to follow the jury. So that's interesting, right? The agency can accept the recommendation, modify it, or reject it entirely. And it has

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done all three, and it's the history of peptides. So when you read FDA panel votes to approve peptides, mentally translate it every time to the jury has recommended, the judge has not ruled. Okay. That one substitution will keep you oriented through every article you read this month or everything you hear. Because again, remember, there's a lot of marketing around peptides. And I'm going to tell you why, because so far you're hearing me and you're probably thinking, well, maybe I shouldn't be taking these if I'm taking them, or maybe she doesn't think they should be used, and that's not what I'm saying, because I want you to listen through the entire podcast so you get the gist of what I'm saying, okay?

[12:27] Let me explain the 503A Bulks List, because once you understand it, the whole hearing snaps into, I think, a better focus. There are two kinds of pharmaceuticals. There are FDA-approved drugs, the ones that went through full clinical trials, the ones with a brand name and a package insert, and then there is compounding. The centuries-old practice of a licensed pharmacist mixing a medication to order for an individual patient based on a prescription. Compounding is how a child gets a liquid version of a pill they can't take or swallow. It's how someone allergic to a dye gets their medication without a dye. Compounding pharmacies are real.

[13:06] They're licensed, regulated pharmacies. They're not gray market. So they're a licensed pharmacist. And what they've learned is to make products individualized for patient and patient needs. Okay, but a compounding pharmacy can't just build anything it wants. Okay, I should say it can't build with anything it wants. The raw ingredients the pharmacy is allowed to use have to come from an approved list. So this is important. The list is the 503A Bulks List. So the entire question in that hearing was not do these peptides work?

[13:38] That wasn't the question. And it was not should these peptides be approved as drugs? That wasn't the question either. The question was narrower. Should licensed pharmacies be allowed to keep these peptides on the shelf as legal ingredients to compound form? Okay. So they need the ingredients to compound them. So picture a licensed, inspected commercial kitchen. I'm going to use this as an example. It can cook almost anything in that kitchen. Okay. But it can only use the ingredients. So think about this: on its approved supplier list. Ingredients whose identity and purity can be verified. The 503A Bulks List is that approved ingredient list. This week's vote was a recommendation to add four new items to its list. It was not a Michelin review of the dishes cooked in the kitchen, right? It was not a promise that the food is good for you or bad for you. It was a decision about what the kitchen is allowed to keep in the pantry.

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Whether any given dish belongs on your plate is still a conversation between you and your physician or provider. So that's the difference, right? So they're voting on can they keep it in their stock to make it. But whether or not it's right for you is still, again, a decision between you and your physician based on your diagnosis and clinical history and so forth. Here's why it's even more narrow than we realize. Technical questions matter really enormously in this scenario, especially for safety. So right now, because these peptides they're not on that approved list. Most people who use them are not getting them from a licensed pharmacy at all. Now, I'm happy to say that's not the case here at WIFM. We use only licensed pharmacies. I sat next to the people that run these pharmacies in my own peptide training. I know they've had peptide training. But patients who are not getting them from licensed pharmacies they're buying them online from websites that label the vials as for research use only, not for human consumption. And that's how they're dodging the legal system, okay?

[15:36] So no pharmacist has looked at them. No prescription, so they're not coming from a physician or provider. No verified dose. No verified purity. That is a status quo the FDA scientists and the peptide advocates are both, in their own ways, trying to fix. They just disagree profoundly about whether there's a right way to fix it. Because people- physicians or providers who are using peptides- they don't want to see their patients getting them from poor sources. And we could talk about it till we're blue in the face, but they just don't really understand that anyone can put anything in a vial and label it and call it what it is.

[16:12] And it might not have the right ingredients or the purity that you will get from a licensed pharmacist. So what's the real debate? It's access versus evidence, right? So we have two camps, and I want to look at both of them because you deserve, I think, what's considered the honest version of each camp, not a cartoon about something like we should dismiss. Like we really need the right answers, okay? So the access camp, that's one camp, right? Which includes a current Health and Human Services Secretary who has publicly pushed to expand peptide access.

[16:46] And they make an argument that's, I think, generally compelling. It goes like this. Hundreds of thousands of adults are already using these peptides. This is not in dispute. The only real question is where do they get them? Do they get them from a stranger's website with no oversight or from a licensed American pharmacy with a pharmacist, a verified dose, and a physician's prescription? Prohibition hasn't stopped use. It has just pushed use to the least-safe possible channel. So that's what they're arguing. So again, this is the Health and Human Services Secretary is arguing that peptides are being used,

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but they're not being used legitimately. And by keeping them not on the 503A list, then they're going to keep coming from these unverified sources, when And they could be getting them from a licensed pharmacist, a verified dose, and a provider or physician prescription.

[17:37] Okay? So imagine your neighbor is buying a medication out of the trunk of a stranger's car in a parking lot. You can stand there and tell them it's illegal and unproven, and you'd be right. But they're going to keep doing it, right? Because it's helping them and they have nowhere else to go. The access argument says the humane, harm-reducing move is to let them buy it at the pharmacy counter instead, where at least someone checks what's actually in the vial. And I think that's not a crazy argument because in the world of real human behavior, it's a serious one. Like, we are humans. And if something's helping us, we're going to go buy it from the trunk of someone's car if it's going to help us, right? I mean, that's human behavior. And especially too, when it's helping you and then access is denied, it makes you even more adamant to want to have it, right? Because that's human behavior, right? Now, let's go over and argue the evidence camp, because there is, you know, because really these are the two arguments in my view. So the evidence camp is the FDA's own scientist, and their argument is equally serious, and I hold it with just as much respect, because I think it's important. It goes like this: moving a substance to the pharmacy counter implies to the public that it's safe and it works. And for most of these peptides, we simply do not have enough human data to say that it does. Let me give you the specifics that they put on the record because they're a bit sobering. BPC-157, the gut and repair peptide. The agency could find essentially one human study; it had about 46 people, and it was delivered as an enema, not the injection almost everyone actually uses. One small study, wrong delivery route for a condition that already has FDA-approved treatments. Okay. TB-500, so that's the recovery peptide.

[19:26] The reviewers found no human trials supporting its use for wound healing at all. The evidence is animal studies and, famously, decades of use in racehorses, actually. It's also notably on the World Anti-Doping Agency Prohibited List for Athletes. For KPV, the anti-inflammatory peptide, no human trials were identified. And at one point, the people who had originally nominated it actually withdrew their own nomination, which is interesting. And for MOTS-c, the metabolic peptide, no human evidence, and FDA reportedly could not find a record of any outsourcing facility ever compounding it at all. Alright? So this is a map drawn from the animal tracks, is how I describe it. The

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preclinical data on these peptides, the rat studies, the mouse studies, the racehorse data, is often generally very impressive.

[20:12] Actually, the data is really impressive. It's a detailed, hopeful map, but a map sketched from animal tracks, not the same as a road that has been driven which are humans, right? The mechanism can be beautiful, and the human proofs can still be thin. Both of these things are true at once, and any honest guide has to hold them together. This is exactly the, I would say, tightrope. I try to walk with my own patients because I have read the animal studies. I have seen the results in patients, the clinical improvement. I've seen a clinical improvement in myself. I've used these peptides, so I won't deny that, right?

[20:49] But the FDA does argue some good points. So I think this is generally, like a difficult, it's difficult, this question and these answers, right? Both camps are trying to protect people. One is trying to protect them from unsafe supply chain, right? Because it's unsafe if we ban it and they get it out of someone's trunk or their car off a website. The other's trying to protect it from taking something that hasn't been proven in humans, right? So there's not really any good guys or bad guys, right?

[21:17] There are two legitimate definitions of safety and drug collision. And then this week, undivided vote, because there was some division. So the access definition- let's supply access, I think won the first round of this match, okay? Okay, so what does all this mean for peptides? You've actually heard me talk about, and some of you are taking. So let me bring it home to the molecules some of you are already on and considering because this is where my patients' questions finally get real answers when they reach out to me. Two of the six recommended peptides are ones we have covered in depth in this peptide series.

[21:55] TB-500, the recovery peptide that travels through the bloodstream to wherever the body is calling for repair. The one Paul used to his shoulder back was recommended, 8 to 6. And BPC-157, the local repair and gut healing peptide. I've talked about that in the gut repair. It was recommended, 8 to 6. KPV, the anti-inflammatory gut peptide I've mentioned as part of the, I think even glow peptide stack, was the third. So three of the six peptides that got a yes this week were molecules that sit right in the middle of the connective tissue gut repair work that I and many functional medicine practitioners do every day.

[22:33] Okay. So what changes for you today if you're on one of these? I would say, practically speaking, nothing. And that is a sentence I most want you to hear correctly.

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A recommendation is the first step of a long process, not the last. Nothing about the legal status of your protocol changed this week. What changed is the direction it's traveling. And this is the honest nuance I owe you. And it's the same thing I said in the TB-500 and the Larazotide episodes that I taped a while ago. So long-time listeners will recognize what I'm going to say.

[23:09] The regulatory story and the biology story are two different stories, and you have to keep them separate in your head. The biology of why repair slows in midlife has not changed since last week. The tendon healing capacity still drops roughly 15% per decade after 30. Collagen synthesis still declines about 1% per year after 25. With an extra drop for women in their first year of menopause, and a skin wound that healed in a week at 25 takes two to three weeks at 50. Those facts are why these peptides are interesting in the first place. And no committee vote adds to or subtracts from them. Okay, so hear that.

[23:49] What the vote changes is, I would call the plumbing, where the molecule can legally come from. And who has to stand between you and it? That's what this vote's about, okay? And on that front, I'll tell you plainly where I land as a physician. I want more oversight, not less. I want peptides to come from licensed compounding pharmacies with verified potency and purity, prescribed after real testing, monitored over real time. Not ordered from a website that calls for research chemicals to avoid what's right in the law. If this process ends with that outcome, it will make what I do safer, not more dangerous. And that is the version of the news worth being cautiously encouraged about because that's what I think all functional medicine practitioners wanted to go to.

[24:38] So remember my patient, the former athlete, where the two rule books get concrete? On the very same day, TB-500 was recommended for legal compounding for patients. It was recommended. It remained on the World Anti-Doping Agency ban list for competitors, so it must work in some aspect, right? One molecule, two rule books. If you're a master swimmer or you compete with anything drug tested, my doctor can't prescribe it, and I'm allowed to use it in competition, are two completely different questions with two completely different answers. Know which rule book you're standing in before you assume the news applies to you.

[25:15] So yes, if somebody is a master swimmer and they're competing, then they cannot use TB-500, and it will remain on the anti-doping list, right? But if it's a patient with an injury that hasn't healed and they're looking for recovery, you know, right now,

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there's no reason I wouldn't give it to them. I've seen it work. Okay. So what do I do with all this information? So I will share with you, this is my playbook. It's the same whether you're navigating perimenopause or a shoulder injury or whatever it may be.

[25:46] I always have my patients on a provider / physician because we have really great nurse practitioners who are providers. I don't want to say just physician-supervised peptide protocol. So if you're somebody who's on a peptide protocol, you don't have to panic. You don't have to change anything on your own based on a headline. Nothing about your legal access changed this week. So you still talk to your prescriber before your next refill- the person who's prescribing it for you. Not because there's an emergency, and you should talk to them because it is the moment to confirm your source, and it's coming from a licensed compounding pharmacy and not a gray market. So with them, we only use licensed compounding pharmacies. That's it. If your clinic can't tell you which licensed pharmacy fills your prescription, I think that's a real risk in your life. And you should actually find a different physician or provider or have them make sure that they give that information to you. Okay. Second, if you are peptide curious because of the buzz, let this news push you toward the front door, but not the back alley. Okay.

[26:49] The temptation when you hear the FDA panel back these is to feel permission to buy them online. But please hear me, that is exactly backward, okay? The whole point of this hearing was that the online supply is the unsafe part. If the news makes you interested, the right next move is to find a physician or provider who works with peptides from licensed pharmacies, right? And get proper testing and don't just add it to a cart online, okay? Remember that the foundations do the heavy lifting no matter what the FDA decides. This is the least glamorous thing I say always on this show, but it's always the truest. Protein in every meal because connective tissue is protein built. Vitamin C, zinc, copper as the cofactors your body needs to actually make collagen.

[27:40] Sleep because the bulk of tissue in your mouth happens overnight. And movement because mechanical load is what tells the body where to send repair. So if you never use the body, it doesn't know where to send it. Okay. For the gut and hormonal picture, that means anti-inflammatory basics, addressing the perimenopausal hormonal shift with a real clinician, with labs to document where you are, and not asking any peptide to outrun a diet and sleep because that will just work against you. There's no molecule on the 503A list, approved or not, that works without building materials in place. So you have to do the work.

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[28:15] You'll hear me say that in every podcast. The final thing, the mindset piece. Watch this process with interest, but don't outsource your clarity to the headlines. Over the next 12 to 24 months, you will see articles that say peptides are now legal and articles that say they've been banned. Sometimes in the same week, they'll both come out, often about the same molecule. Most of them will be describing some small procedural step as if it were the finish line, and it's not. I call this the bridge that's being built while you're standing on it. The panels, yes, were the first support going in.

[28:52] The start of a rulemaking process that typically runs 12 to 24 months before actually anything is legal and can be compounded and added from the list. The bridge is not finished. You are standing on it while it's under construction. The move is not to sprint across the bridge. That isn't done. It is not to jump off it either, because peptides are helping a lot of people, right? So you don't want to panic. It's to keep doing the same thing, supervised, foundation first thing, that we're smart before we vote and we're still smart after it.

[29:25] So you want to do your foundations, all the things I always talk about. And if your prescriber is giving you peptides and it's working with no side effects, no adverse events or anything, and it's helping you, then you're fine. Just stay exactly where you are. We're going to let the construction of the bridge finish at its own pace, and we'll all find out what's on the other side. Okay? So I told my patients basically what I just told you. No one's taking your protocol away today. If anything, the long-term direction of this is toward the thing that you should want most.

[29:54] Your medicine is coming from a licensed pharmacy made to a verified standard, prescribed and watched by a provider / physician who knows your labs. And also, I have to say in the same breath, the peptide is not fully, quote, legit in the way you meant. That was my second patient. Not yet, anyway. But you can stop feeling like you're doing something in the shadows because the whole country just spent two days arguing out loud and on record about how to bring what you're doing into the light. So that's what was the whole point of the advisory committee. And I'm really grateful there are many functional medicine physicians I've been able to be in the same room with.

[30:35] They were there fighting for patients and for peptides and sharing examples, sharing patient experience, the things that happened, how they were able to help patients. And so I'm very grateful to know those people and to be aware of their presence and the fact that they went to the FDA ruling, and they spoke on our behalf, all the functional medicine and integrated medicine providers and all the patients

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benefiting from peptides. So keep this clarity in your mind; make it loud. What happened was not an approval, and it was not a ban. It was a divided expert panel voting by slim margins and over the objections of FDA's own scientists to recommend that six of the seven peptides be allowed into licensed pharmacies. That recommendation now begins a slow journey through a system built, for good reason, to move carefully.

[31:24] Your job, in the meantime, is unchanged. Stay supervised. Stay sourced from real pharmacies. Keep your foundation solid, because that's the root of everything, and keep your head while the internet loses it because it will it's going to be all over the place the biology of midlife and repair of the body it hasn't changed at all these knowledge tools haven't changed what's changing slowly is whether you can get them from a pharmacy instead of a stranger or online vendor that's worth watching it's not worth panicking over and it's not worth reckless clicks and getting medication or peptides that are not sourced well you just need clarity right i hope this episode gives you that. I hope it helps you make some sense about the confusing information this week if it confused you. And I hope that you will give peptides a chance if your provider recommends them based on your clinical scenario, with you doing your foundations, and if they are helpful. Okay, so if you have questions, you always can send them to info@wisconsinfunctionalmed.com.

[32:26] Thanks for listening to the peptide series. I hope you go back and listen to all about all the different peptides and what they do. And I look forward to seeing what happens on the other side of this journey together. That's all. Thanks for listening. We'll be heading into some new topics coming up, some on the fear of estrogen and some other topics I think that will be helpful on this stage of midlife. Take care. Talk to you soon.

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