Your Medication Is Only as Safe as the Pharmacy That Made It Transcript

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Opening on CGMP and FDA inspections

CGMP was literally like learning a whole new language. Things like auger plates and equipment validations and smoke study. All these things were like, what is going on?

And that first inspection by the FDA was, let's just say, very uncomfortable. But we've evolved through that and have had fantastic inspections since then.

But it's very rough. And a lot of people, a lots of pharmacies went through it. They're like, oh, I'm going to sign up and be a bee. Then the inspection came in and it was so hard on some pharmaces, they couldn't recover and they ended up shutting down.

Welcome to Beyond the Scale, where real health gets deeper than just the numbers. I'm Dr. Darren Dubiak. And I am Alexandra Dubyak, and we are not only partners in life, but also passionate partners and integrative care.

Blending faith, family, functional wellness, And a little life with our dogs. Because true healing happens beyond the scale. All right guys, happy afternoon.

I'm pretty excited to actually, I am really excited. i've known this guy for over 15 years. He has been such an incredible person and not only as a business advocate for body by aim, but just as person.

Podcast intro and guest introduction

And I can't thank him enough. So in today's conversation, this is going to be really, really important information. so it's someone joining us who brings a rare.

first-hand perspective on one of the biggest turning points in compounding pharmacy history. So Dan, I want to read a little bit about you because I love this.

He was actively working in a compound pharmacy when the 503b outsourcing facility regulations were created. right as the industry was being reshaped in response to safety concerns and the need for higher standards.

While many people understand that there is this 503A and B from the outside, he actually lived through that transition and he's going to talk a little bit to us today about that.

Now he spent more than 15 years of experience in the field. He's also a leadership coach and professional speaker And who helps businesses grow, communicate effectively, and he's wonderful because he really leads with intention.

That's why I love this guy. So today you'll hear just not definitions. You're going to hear a real world insight, right, on why these differences matter.

Guys, look no further. Mr. Dan Powell. Thanks for joining us today. Thanks so much, Dr. Deer. I appreciate it. Thanks for the kind words. And I'm looking forward to sharing what I know with you.

Yeah, thanks for having me. Appreciate that. Dan, this is such a big topic, and I don't think people really understand why it is a such big a topic. But today, guys, we're going to talk about compounding pharmacies because not all compound pharmancies are the same, right?

So first and foremost, Dan, We have this 503A and 502B verbiage. What's the difference between the two? That's a great question.

503A vs 503B compounding pharmacies

And let me start by saying back before the rules changed, back, before The 503Bs were created, the really only differentiation in compounding pharmacies was whether you are a sterile compounder or not a steril compound.

That was kind of when I got into the industry back then. There was about 10,000, think of this number, 10 thousand steril compounders across the country.

When they came out with the 503b level of pharmacy, which we'll talk about in just a second, that number shrunk from 10,000 to about 80. And there's only about 90 to 100 502b operating 504b pharmacies in the country today.

So the bar was raised and it is a high bar. So to jump into the differences, 503A and 502B pharmacists, they both compound medications, but they operate at very different levels of scale and oversight.

Think of 504A pharmacies like this. They're typically patient specific. You have a patient who needs a custom medication. They don't fit in the box of what's out there in a manufacturer world as far as dosage, that kind of thing.

So they can create a very patient-specific medication, and it's an individual prescription. And the 503As are primarily regulated at the state level. 503Bs are also referred to as outsourcing facilities.

They are federally regulated. And they follow what's called current good manufacturing practices, or we abbreviate that CGMP. Similar to pharmaceutical manufacturers, they can produce medications in large batches, which allows for greater consistency, stability assurance, and standard processes.

So they both have important roles, but how they're used and what the industry they serve is very different. And that's when I try to let my patients know, you know when you're getting some of these formulas from Body by Aim, and it's not taking away anything from the little guy in the neighborhoods.

Trust me, I started as that little guys. But I want people to know about the sterility, the safety of these products, and that's why we utilize the company you've been with for so long, because there is just such a prowess and a premise of, hey, there's so many regulations to make sure your patients are getting the safest products.

Correct. Yeah, and that's exactly right. Ed, you've been with us at our pharmacy. And we're just not mentioning the pharmacy, Nick, because this isn't really about a pharmacy ever.

It's about the industry. So we've got the A's and you got B's. There's very few pharmacies that do it this way, where we have both an A and a B pharmacy So what does that mean for the end user?

So whether you're buying medication for office use or you are buying a patient specific, you can count on when a 503B pharmacy also has a 5003A, what the regulations allow them to do is make the pharmacy, make them medication at the B pharmacy.

but fill prescriptions through the aid. So whether you're buying office use medication or whether your buying a patient prescription in that situation, it's all being made under the 503B CGMP level of compounding, which is, I don't know if we can get into more of the details of that.

And that's what I want to ask you.

Why 503B regulations were created

Why were these categories of 502A and 504B even created? Well, that's a great question. So back in 2013, when the Drug Quality and Security Act, or DQSA as it's called, was signed into law, I think, late in 2014. And the reason that came about was there was a pharmacy in Massachusetts.

They were making a drug called methylprednisolone. It's a anti-inflammatory, steroidal medication. The thing that

they were doing is they weren't making it as an intrathecal, meaning it was injected directly into the spine.

What ended up happening is, they released a batch of medication that was contaminated. Wow. And that contaminated medication got out to surgery centers and places like that, and they started injecting people in the spine with this medication and hundreds, hundreds of people got spinal meningitis and 60 some people actually passed away.

They lost their lives because of this. So the state of Massachusetts said, Hey, this company is acting as a manufacturer so the FDA should be having oversight over them.

but they're not registered as a manufacturer. They're registered has a compounding pharmacy. So the state of Massachusetts should be have oversight. Say went back and forth for a while and finally the FDA stepped in and said, okay, listen, people lost their lives because of this.

We need to make a change. And the change they made was by coming out with this designation called 503 B pharmacy, having it operate under CGMP guidelines, which is the same as pharmaceutical manufacturers.

That's why we went from those 10,000 sterile processes down to about 80 to 100 right now is because they raised the bar so high, but that's why I was for patient safety and it was the event that happened up in Massachusetts.

Gotcha. And I don't think patients really understood the differences in oversight or why that happening. Quite honestly, Dan, I think people even realize the terminology in our world, 503A or B, but I constantly speak about it to my patients every time they come in because we are so proud to deal and have a relationship with a company like you guys.

I want to go on to this. So the FDA oversight and rigor, how difficult has the FTA approval been over the past 10 to 15 years with you, guys? That's kind of a loaded question because when we first signed up, Yeah, it is.

It drives me. When we decided, you know, back when all this changed, we had to make a decision. Are we going to go 503A route or are we gonna go five or three B route?

And we really didn't know.

FDA oversight and the challenge of compliance

We debated this for weeks, maybe even months. And then we decide to to 502B. So how do you get started with that? You fill out an application, and you said the FBI forget how much money it was.

I may say, okay, yeah, your registered outsourcing facility. and we were first like, Oh, I was easy but then came the inspection right then the FDA showed up and they inspect you and oh my gosh I could tell you that at that time we knew 797 which is what the state regulators of course.

CGMP was literally like learning a whole new language. Things like honor plates and equipment validations and smoke study, like all these things were like, what is going on in that first inspection by the FDA?

was, let's just say, very uncomfortable. But we've evolved through that and have had fantastic inspection since then, but it's very rough. And a lot of people, a lotta pharmacies went through, that they're like, oh, I'm gonna sign up and be a bee.

Then the inspection came in and it was so hard on some pharmancies, they couldn't recover and they ended up shutting down. Wow. So let me ask you this.

In doing so, what do you guys have to do from a pharmacy standpoint to stay on the up and up, we'll say? We have a whole team of people. We've got a legal team, a regulatory team and they are at all the pharmacy conventions, all of the legislature.

They are up to the minute on all new regulations. So, you know, that's forward looking. But what we have to do from a pharmacy standpoint to kind of stay in operation and stay up to par with the CGMP regulations.

We have do things like vendor qualifications, where we get our API from. So our raw pharmaceutical ingredients, we just can't buy that from anywhere. And we to buy the ingredient from the FDA inspected and approved supplier, no matter where they're at in the world.

The whole process starts before we even begin to make the medication. And then we have all these equipment validations, room validation, smoke studies, employee validators, method development, methods suitability, all of these big words, batch testing, clean room, 24-7 monitoring to finally bring that drug product to market that is given to the patient.

So that leads me to this, you know, I always tell people it's about safety, sterility and testing, so you just led me into my next question. What happens before that medication even gets to the patient, right?

Right. So the first thing we have to do, like I mentioned, we got to validate where we're buying our raw ingredients from. By validate, that means they have send us a whole bunch of information.

We have look at it. But here's the next thing that happens. Once we say, okay, yeah, you match all the qualifications here, your FDA approved and inspected.

Now go ahead and send us your whatever API. I mean, by let's say it's, I don't know, let say its Tory, right? So that gets in house. Then what we have to do, even though we the paperwork, we then take some of that Turing or that powder.

We send it off to an independent third-party lab to basically say okay. You say it's this. We're doing our own testing and we're going to make sure that what you say, it is and what our test comes back is make.

Testing, validation, and sterile manufacturing

Sure it matches. And that's before we even start to compound the medication. It's all these validations that we have to validate equipment to make sure like, for example, all of our equipment has to be sterilized before it's used in the clean room.

And we put that equipment a lot of times into what we call a dry heat oven. We have do a equipment validation, meaning, okay, the manufacturer says this dry-heat oven takes 30 minutes to get to temperature and it maintains this temperature throughout the whole oven, That's great.

That means we can buy it, but then we have to do our own validation. We have temperature probes all inside this oven or all different shelves. And we to run a validation to make sure that what the manufacturer says, it actually meets that performance.

Every piece of equipment that we use in the creation of a compound, the medication has to go through that level of risk. I mean, guys, right there, if that doesn't tell you.

Why there's only 70 to 80 of these five or three B's. I don't, you know, got me right then. That's a lot, but it's for our safety. And, I'm going to get to this at the end of the conversation, one of reasons I wanted you on this program so badly today was how many people are buying some of their medications, peptides, or whatever they are on these online stores.

With having no doctor oversight and Dan even further yet, they don't even know where these products are coming from. Right? I mean, if that's not a Russian roulette, I don' know what is, right?

You're absolutely right. And here's what I think it is. Some of this I'm going to say is just. from where i'm sitting and the people i know who buy medications like especially when the glps came out yeah people love the results right

they love their results and they get you know they almost get desperate to get that medication so they when they reach out to these online telemedicine practices or online pharmacies, wherever they're buying it from, they are thinking in their mind, a lot of the patients think like, this is coming from a doctor.

They've done their due diligence. So I feel safe when that's just not the case. That is just nothing. As a matter of fact, when I go out and I speak in front of different groups of physicians and prescribers, one of questions I always ask, if I'm speaking about 503A and B pharmancies, I say, Show me how many people, raise your hand, how may people know the difference between 503 A's and 502 B's?

And these are rooms full of practitioners, prescribers, and usually it's about half. So about a half of the physicians are well versed on 504 A and Bs, so they're patients Normally, it's a smaller percentage.

Now, there are some patients who do their homework, and I applaud them because they need to, because there's so many ways to get this medication where it goes through who knows where.

The wrong ingredient comes from who know where, ends up at a pharmacy. Who knows? You can't be too careful, especially with the peptides and GLPs and all those things that people are desperate to give.

I think they sometimes overlook the inherent dangers of doing that. I agree. And again, I want to be very clear. I'm not saying all online pharmacies or how people are doing this are wrong, but there's a lot out there that are do it right.

But there is a whole lot that is doing it very wrong. Like you said, Dan, you know, i've had patients even tell me just to save a hundred dollars. they're going through these hoops just to get some of these things.

I'm like, your life is worth more than $100. It still blows my mind. But the efficacy, the safety, and the reliability of products coming from a reliable compounding pharmacy like yourselves, it's almost like my warm fuzzy blanket, Dan.

And I want my patients to feel the same because they have to know that I am on a lot of the things that do talk about. You know, all the practitioners when they're developing programs for our patients, you know these are some things that we are on.

So I would never put my patients in harm. And again, I'm such an outspoken person as people know.

Risks of online pharmacies and unsafe sourcing

But on my social media and all these other videos, I'm just sick and tired of people buying these things and having no idea what the hell they're getting, where it's coming from, and they don't even know the safety of it.

I mean, let's put it this way, Dan. What should these patients watch for if they are not getting it from a lower standard pharmacy? Like, what should they be looking at?

Contamination. There's incorrect dosing some of these people do. It's crazy to you. right just not me it is and you know i have to get my hats off to you because you have always been one of the physicians that not only stays up to up-to-date on the medications and what they do and whatever for but you also care about where it comes from because you care about your patients.

And we need more people like you and Body by Aim in the industry that are like, hey, we're not only patient outcomes, but patient safety. You're a pioneer in that industry as well, and you're the type of practice we like to work with.

But the things that patients need to look for is when they're online, find out where that medication has come from. When you get the vial, look at the label.

because that could make sure it's coming from a reputable compounder within the United States, preferably a 503b because here's what happens when the medications are made by 50 3a's and there's a big point of separation.

By no means are we saying anything poor or badly about 503A's because there are great 502A pharmacies out there. But for example, a 504A pharmacy can only make a batch size, and a bad size is a certain number of vials.

They can make only a badge size based on what they're currently selling. So if they are selling 500 vial a month, their batch size can be 500. As a 503B manufacturer, you can make 5,000, 10,00, 20,0000 vials at a time, send those out for testing, and you know that every vial that comes out of that batch has been made the same way with the oversight, the equipment, technicians, so you it's uniform throughout the entire batch.

When you're doing smaller batches like that, It's tough to be uniform with every single batch of medication. And patients might say, hey, this medication worked great this time, next time it's not working so great.

Why is that? And it is because there's some fluctuation in things like the potency of the ingredients. Those are the things that, okay, the potent C is probably not going to hurt anybody.

The things sterility, endotoxins, those things can make you sick. I mean, you have to think about it. People ask me, well, how does it impact patient outcomes?

Well, do you think it's going to impact them? You just answered it if the, and you know, Dan, my, My staff laughs at me because I have this saying, I always say safety over shortcuts, right.

And quality over cost all the time. Right. There's no reason to skimp on anyone's safety, including my own, as I'm doing these things and to make sure there there's companies like yourself.

to make sure we are being held to a high standard as well, I appreciate that. I have a last couple of questions for you, and you could take this how you want.

And I'm going to let you go with this. With compounding pharmacies, what do you see is the next thing? What's happening next? Are you seeing that there's going be more for us to be able to use medication wise, peptides wise?

Where do see the future of these compound pharmacy is going over the four or five years? Yeah, I'm gonna answer that very carefully because there's a lot of rumors out there right now and we're hopeful for a lotta things, but we don't have a crystal ball to see what's really gonna happen.

So I'll tell you what we are excited about right know. You know, one of the things that's good is RFK is now in office and he's kinda pioneering a little bit of kind of loosening up those regulations.

Batch consistency, potency, and patient safety

So one of the things that we see coming down the pipe is, peptides are going to be made available on the 503b bulk substance list. What is the five or three B bulk substances list?

The FDA basically gives us a list of medications that says, hey, you can make these items, drugs that contain these particular ingredients. And right now, The peptides, things like BPC 157 and CJC 1295, they're not on the 503b list yet.

There are rumors that they are coming and they'll be coming soon. So we are hoping that that happens and those will be a huge thing for the five or three B industries to be able to make those in mass quantities.

And that 50 3 B list of allowable drug substances is always growing. You could hit on something that's really a game changer. Some of the amino acids that haven't been able to be compounded in the past are now becoming available for compounding.

Things like gamma, ambiotronic, it's great for relaxation and sleep. That's also been approved for the 503b list. When things like that start happening, that is when we get excited.

We're like, wow, this opens up a whole new door to treatment of different patient afflictions. You know, anymore, Dan, when you're saying that I'm listening to you, it's almost like the patients are driving the market.

Right. And I really hope for ourselves and our patients that some of these things come to light because we've seen in the past, the incredible impact they've made from a health standpoint.

They've been unbelievable. If a patient doesn't call Body By Aim 360, Dan, what should every patient understand about a 503? Like more or less is what, which should they know?

What should ask their provider if they're not coming to Body by Aim? Well, let me say something about what you're doing. What you guys have been doing is what leadership really looks like in health care because you, guys, are intentional about the decisions patients may never see.

But they're trusting you to get it right. And that's very important. So being able to have a provider, trust the provider who's this involved and this knowledgeable about the industry is a big plus for safety.

But for patients in general, if they don't come to the body by aim, what do they do? Ask your providers, where does the medication come from? Are they intentional about every step of your care, including the pharmacy partner they use?

Because the outcome isn't just about what medication is being prescribed. It's also about how and where it's made. And that's what they should really pay attention to.

No, agreed. I thank you for the compliment. Dan, any last words on our podcast today about this? Any highlights that we haven't covered yet, sir? You know, it's just so important just continuing to do education like this for patients to educate themselves, providers to education themselves so they know what to look for.

I'll give you a little story about us when we became a 503B and this is one of those things that I hope puts into perspective the level of detail we have to put in So there's some vitamin mixes that we make that have five or six ingredients in them.

Future of compounding pharmacies and peptides

Those are all mixed together and they're sent off to a third party lab and are tested for potency, sterility, endotoxins, pH, all those different things.

And on the potence of medications, you're allowed a little bit of Wibble Group, usually from 90% to 110%. on those five or six ingredients, but sometimes before we got really good at making large batch medications, we would make 5,000 vials of medication, let's say, and maybe one of those six ingredient came back at 89% instead of 90. That whole batch of 5 thousand vial has to go in the trash.

You can't, there's nothing you can do about it. Wow. Yeah. And you imagine how much money that is, but that's the way it is because the FDA could come in and say, well, let me see your batch records on that.

Well, this was about 89%. Now show me your destruction log. And that better be on the destruction log and not in your dispense log or your big trouble.

And it's really that fine. You might think, oh, he's overemphasizing it. No, I'm not. 89%, 89.9%, the bar is 90. it goes in a trash. And that's the kind of world we live in that, you know, that level of detail.

But that is important for healthcare. That's super important, for patient and patient outcomes, to for patients to get consistently potent and sterile medications.

So those are the kinds of things that we do as 503Bs. I love it. Dan, I, you know, each time I talk to you and I I learned more and more every time. I talked to as well.

And, You know I hope everyone understood this episode and why it was so important. It was one of the top episodes that I wanted to shoot. and Dan you've known this for a while when we started our podcast because there is such a relevance in people knowing, Hey, I need to make sure it's safe.

I needed to. Make sure that I can take these things for a long time. And it some, you know, something where it coming from very reputable where people are regulating these.

What patients should ask providers

Because like I said, anymore, it everywhere online and I don't think people understand the safety. However, today, Dan, I hope they do now. But guys, Dan Powell, a leader in the industry, have phenomenal speaker.

I would applaud you guys to check him out as well. Dan, I am humbled you said yes to being on the show today. Thank you so much, sir. And it's always great to see you.

Thank you. Thanks very much. I love talking about the industry and sharing my knowledge, especially with yourself and have yourself a great Easter and I'll see you soon.

Guys, next time Beyond the Scale, if you guys love this episode, please be sure to share it. Have a good day, everyone. Bye now.