

West Pharmaceutical Services: Former Chief Scientific Officer Discusses **Destocking Concerns**

Former Executive	Moderated Call Moderator: Shane Sullivan February 23, 2024 16 Min Read							
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Fran DeGrazio, Former Chief Scientific Officer - West Pharmaceutical Services

AGENDA

- What is causing destocking by select customers of West Pharmaceutical Services? When could destocking abate?
- Could destocking become more widespread beyond the five to six core customers that have been identified?
- Why has West Pharmaceutical Services seemingly lacked visibility into its order book?
- What are the implications of GMP Annex 1 regulations to West Pharmaceutical Services?
- How is West Pharmaceutical Services positioned in the long term to participate in high-growth categories like GLP-1s?

HIGHLIGHTS



66 "I have no reason to believe that [destocking] shouldn't go back to normal in the second half of the year."

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Shane Sullivan: Hello, everyone. Good morning. Thanks for joining us on today's call concerning West Pharmaceutical Services.

Before we get started, if anyone in the audience has any questions that they would like me to pass along to the Advisor on an anonymous basis, you can email me directly at SSullivan@Guidepoint.com and I would be glad to do so.

With that, Fran, it's a pleasure to have you again today. Thanks again for agreeing to participate. To begin, would you mind introducing yourself and providing us an overview of your background, please?

Fran DeGrazio: I'm Fran DeGrazio. I retired from West as the Chief Scientific Officer in 2022. I worked there for close to 39 years in a series of various analytical, technical, scientific, and commercial positions, and quality and regulatory.

Shane Sullivan: Thank you for the intro. Just a bit of background, West cut guidance for this year from October, a plurality of which was driven by worse-than-expected customer destocking, which seems to have begun in September, October and accelerated toward the end of last year, per comments from West's management team. I want to start with just a basic topic, and then we can get into the destocking itself. How do customers determine acceptable safety stock levels for the types of components that are supplied by West: your plungers, your stoppers, your seals, and such?

Fran DeGrazio: Typically, each customer and pharmaceutical company will have their own perspective on that, however, quite often, it's going to be based on the history of lead time. That's how long it would take for them to place an order and actually get product in. Generally speaking, over the years, the stocking time, and how long they're holding stock has shortened up, but they will adjust that based on the lead time of getting the product. Typically, you're talking anywhere from six months to a year of product they may be holding on to.

Shane Sullivan: One of the takeaways from West's recent call was an apparent abruptness, let's call it, in certain customers pushing inventory management. Any thoughts on why customers might be doing so now, in summary, the timing of it all?

Fran DeGrazio: My guess would be that it really relates, again, back to the COVID side of things where they had anticipated needing more product, whether it be for vaccines or other related drug products. When they realized that even though the vaccines were going to taper off, that all dropped dramatically compared to what they initially anticipated. My guess is that's really what drove the majority of this impact. Now, that's part of it.

The other piece of it is the fact that West's lead times, because they grew capacity, also shifted back down more toward normalcy. In doing that, that means now that the customers, the pharmaceutical companies are adjusting their order patterns back to more regularity. When the lead times were very long out of West, there's



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always concerns, and many of these companies are, what I would call, over-ordering to make sure that they have enough on hand. With the adjustment of West's lead times, that also had an impact.

Shane Sullivan: The COVID piece definitely makes sense. West's management team has talked about better lead times, to your point. What types of products would be affected by this across West's portfolio? We can draw distinctions between different product categories and different product lines, your bulk or standard stuff versus your high-value components, under the scenario you talked about.

Fran DeGrazio: I would believe it would cross all of those types of products. The greatest impact from a smaller quantity move is going to come from the HVPs. So because the HVPs are higher value, if a customer now decides I'm pushing out my order for another six months, you're seeing more of that adjustment on the sales line.

Certainly, the bulk may be some larger quantities, so that has an impact in a little different way but relates to maybe larger quantities of products. Certainly, many of the vaccine-type pharmaceutical companies will use, some of them are still using bulk products because of the large quantities that they utilize. They may be a portion of that, although, certainly, that's not all of the vaccine companies.

Shane Sullivan: West has identified, thus far, five to six customers as being responsible for 75% of destocking. Is it reasonable to be concerned about destocking spreading to additional customers?

Fran DeGrazio: I would assume that the ones that have hit are the ones that are larger companies, so there's more of a significant impact seen. Most likely, everyone, to a certain extent, are doing some adjustments though. Really, one of the challenges with a mid-size to smaller company is that they may have been challenged more to get their hands on product, to begin with, during the COVID period because of challenges with capacity. They may not have stocked up to the same degree as a larger company would have.

Shane Sullivan: West has sized this impact as a 2%-3% headwind to their original guidance. More importantly, they expect this destocking to abate in one or two quarters, or at least improve markedly by the second half of this year. Does that seem reasonable to you?

Fran DeGrazio: Yes. I don't think that the stocking was so overboard that it would go past that period of time.

Shane Sullivan: Is it fair to question West's visibility into its order book? Meaning, if current destocking was not really predicted, again, the theme seems to be the suddenness of it all, can they really accurately predict the second half of this year? I'm just wondering how that all works, that visibility.

Fran DeGrazio: It's always a bit of a challenge for a couple of reasons. One is, to be quite honest with you, many times, the pharmaceutical companies themselves don't necessarily know how things are headed, what they're forecasting is not necessarily then what happens as it gets closer in time periods. That is always a challenge.

The other thing is, a lot of times, demand is going to be based on history. That also can be a challenge



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depending on what's going on from a historic standpoint. Certainly, I know there is a high priority at West, historically certainly there was, with engaging with the major pharmaceutical companies to understand and try to get alignment on what the forecasts were. A lot of that, as I'm saying, is unpredictable because the industry itself as a whole is unpredictable.

Shane Sullivan: Do you agree that destocking is most likely an industry-wide phenomenon and not indicative of share losses, for example, by West?

Fran DeGrazio: Yes, I believe that's true. West, through the years, we've had similar situations where stocking, customers built up stock for various reasons and then we went through a downturn until they worked that out of the system. This is not really unusual. It's probably the first time something like this has happened in the last maybe seven or eight years since the management team that's in place now has been there. Going back into history, we went through these kinds of cycles in the past.

Shane Sullivan: I don't think destocking commentary - and I know I ran a question by you suggesting the contrary, potentially. I know Gerresheimer has been talking about some destocking dynamics as well, and they're obviously in a different segment, in containment. Where else would you expect an impact across the wider packaging industry just in terms of product categories and companies that are exposed to this destocking situation?

Fran DeGrazio: Well, it does make sense that a company like Gerresheimer because really the glass vials go with the rubber stoppers. I would anticipate that possibly, I know it was tough, there was a period of time when it was very tough, especially through the beginning of COVID, for companies to get their hands on glass. I'm sure that there was some over-ordering done during that period of time.

Those would be companies such as Schott, Stevanato possibly, and Gerresheimer they all produce glass vials to not the same extent because, relating to the COVID vaccines specifically, they were out in vials on the most part. If there's been any move for any of the latest vaccines that are out there now to go into pre-filled syringes, then you could have an impact on some of the syringes and syringe components also.

Shane Sullivan: Can I just clarify two of the comments that you've made earlier? Please correct me if I'm wrong. You said that you would expect less of a stocking impact from some of the smaller to mid-size customers because their ability to stock, to begin with, negatively impacted by scarcity of available products. Is that accurate?

Fran DeGrazio: Yes, that's how my perspective on it would be.

Shane Sullivan: The stocking situation then would be most likely limited to larger pharma if you think about just customer groups.

Fran DeGrazio: Correct.

Shane Sullivan: You also mentioned at the outset of this call stockpiling products to accommodate demand for

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COVID vaccines or COVID products even, that totally makes sense. Could it also be the case, and I say this because West's commentary has said, "Oh, we're seeing it in pharma. We're seeing it in generics. We're seeing some of it in biologics," which implies a wider scope. Would customers also have been inclined to stockpile products, not for COVID products at that time, again, driven by potentially product scarcity, as you mentioned, or other stuff? I just want to make sure I understand that as well.

Fran DeGrazio: Yes, that's true. Absolutely right, because all of them are also making other drugs, and so, they would be ordering across the board. You also need to understand, quite often, especially in these larger companies, they may be using the same type of components across multiple drug products. They could be using the same packaging components for a vaccine as they are for some other type of drug product that they're making. I could definitely see it could be, or the impact, or the ordering process would have been more broad than just solely the vaccines.

Shane Sullivan: Glad we captured that. This might be tangential, but can these products sit on the shelf indefinitely or do they have a limited shelf life? Especially, I don't know, stuff with coatings. I'm just curious.

Fran DeGrazio: Well, typically, unless things have changed recently, many of the HVP products that have been, for instance, ready-to-use, so any of the products supplied ready-to-use would have a two-year shelf life on them. The product as is from West sitting in the bag supplied by West would have a two-year shelf life on it. There are associated validations to prove that out.

Now, for a bulk product that has not gone through any of the HVP post-treatment processes, that would have even a longer shelf life. That would be more closer to five years, I believe.

Shane Sullivan: Once again, if anyone has any questions, shoot them in by all means. You mentioned improving lead times and obviously West has made investments. Is it reasonable to think that stretches across the entire industry? Do you think lead times not just for West have reached normal levels? Or do you think there are still pockets where that might be a challenge? You mentioned glass vials, I know shortages were a challenge for a while.

Fran DeGrazio: My guess is that that's back to normal, just because I know there was such a push on growing capacity by multiple suppliers once COVID hit. My guess is, by now, they have that capacity in place.

Shane Sullivan: Just to summarize everything we've talked about, Fran, because I think this is the verdict people want. One, is the second half of this year reasonable? Two, is it reasonable to expect that this won't get worse and potentially introduce downside to what management is expecting now?

Fran DeGrazio: My belief is I have no reason to believe that it shouldn't go back to normal in the second half of the year. As I mentioned earlier, I do believe that if this destocking issue was to hit it, it would have hit already. It's not something that I would expect to be turned on more broadly as the year goes on.

Shane Sullivan: We have an audience question, Fran, so I'll read it verbatim. "Maybe this is too simplistic, but West knows the quantity of stoppers they send to a particular pharma client. With that info, could you calculate

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when the pharma client would be forced to buy more? I'm trying to get a sense for how well West can track inventory once it leaves West's door and goes to pharma."

Fran DeGrazio: A great question. Certainly, I can tell you back when I had marketing for a period of time, we actually tried to do that. The challenge is really on the use side of it. One of the things I could tell you that we tried to do was to track prescriptions, and understanding what components went on what drug product, and how much of this drug gets prescribed, and then understanding that upstream. The problem with all of that is that inventory levels within each company are different and how they manage their inventory is different. There's also a certain amount of, for instance, loss. Where if you send them 100 pieces, they aren't always using 100 pieces. They may use 80 and throw away 20 or something like that. There's a lot of detail that you really just don't have the ability to track without working with individual companies.

I know that there certainly is work directly that occurs between purchasing organizations and West's supply chain and demand planning organizations. Those relationships are there, it's just a matter of the accuracy of what gets conveyed.

Shane Sullivan: We have another audience question, Fran, two actually. "Many experts say that lead times were brought back to normal in the summer of 2022. If that's the case, why is destocking happening now?"

Fran DeGrazio: I'm not sure that all of the lead times went back to normal at that point in time. That would be one question that I would have. Lead times on some components probably were back to normal and not on others.

The other thing is you still need to understand that the destocking aspect is controlled by the pharma company. It's when they believe internally then that they're, "Ok, we're not going to be using all of these components in the next six months because the demand isn't there." Then they have their processes that they start to back down or push out their orders. It's really driven by the decision-making within the pharmaceutical company.

Shane Sullivan: Is there any impact from IDVR or MDR?

Fran DeGrazio: Doubtful that there's a substantial impact there. They continue to push dates out on things in relationship to that because there have been struggles. They're not, as far as I'm aware, there has been no impact to product going out to the marketplace.

Where I would anticipate that there would be more of a challenge is with new products. That when companies are deciding their regulatory strategies for a new product approval - especially around the areas of combination products, which are quite common now - they may choose to start in the US versus Europe because there's still a lot more complexity in the regulatory approval processes out of Europe for combination products.

Shane Sullivan: One other question from the audience, Fran, thanks for addressing all of these. I'll read it verbatim. "In talking with pharma, will the supply chain person at pharma always be truthful? Do they have any



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incentive not to tell you at the last minute?" I'm trying to think through this. Would you think that they'd be upfront with West and not hide their true intentions? Is it a bit messier, perhaps?

Fran DeGrazio: Genuinely, I think they're trying to be as honest and open as they can be. I'm not aware of any situations, in history at least, where they would pull that kind of a thing purposefully.

I do believe, at times, though, they don't have a great sense as to, especially when you're talking about the launch of a new product or things like that, that they think, "Hey, this one's going to be a blockbuster," and it turns out for some reason it isn't. I think that those are honest conversations.

You've got to remember, West, of all of these companies that we're talking about, has a very long history with all of these pharmaceutical companies. At the heart of that certainly is a certain amount of trust just between the companies themselves.

Shane Sullivan: Let's see if anything else comes in at the last minute. I had one separate question from all of this destocking stuff. West has been talking a lot about a new regulation, GMP Annex 1. What are the implications for components sourcing and potential upgrades to higher-value products, in your view?

Fran DeGrazio: Annex 1, this was approved or it came fully into effect this past year, I think it was August of 2023. It talks a lot about two things in relationship to components. One is the need for a contamination control strategy by the pharmaceutical company. How that relates to West and components is that they're going to need HVP-type products because of their cleanliness and associated quality.

The other piece is around what's called container closure integrity that relates to keeping the sterile nature of an injectable drug product. West's components, and the control around those, and also the testing support that West can provide, all those things play right into this direction of Annex 1. From my perspective, that offers West continued opportunity for HVP growth.

Shane Sullivan: With that, Fran, we're just about out of time. Anything else you'd mention particularly around destocking before we close out?

Fran DeGrazio: No, I don't think so. I think that's it.

Shane Sullivan: With that, we can wrap things up here. Fran, once again, thanks again for participating today. I'm glad to have the opportunity to speak with you again and a helpful discussion. For those in the audience listening in, if you'd like to schedule a follow-up call, please get in touch with your Guidepoint representative. Also, I'll be following up on this topic next week, so I hope you'll tune in. Otherwise, thanks so much again, Fran. Have a nice weekend.

Fran DeGrazio: You're welcome. Bye-bye.

Shane Sullivan: Bye.