West Pharmaceutical Services Inc. - Former VP Device Technologies at Amgen

Interview conducted on August 29, 2022

Topics

Injectable Packaging, Pharma Outsourcing, Primary Packaging Suppliers, Biotech Modalities, Innovation, Sustainability

Summary

In conversations between a Tegus Client and a former VP Device Technologies at Amgen, various topics related to the injectable packaging industry were discussed. The expert provided insights into West Pharmaceutical and its transition from a stopper seals company to a complete delivery system solution company, as well as the decision-making process for pharma companies to outsource packaging material manufacturing. Factors such as cost, quality, and the ability to use the product in manufacturing suites are taken into consideration when selecting a supplier. The expert also discussed trends in the industry, including the increase in new therapeutics and modalities available to attack diseases, the need for increased diversity in containers and primary containers, and the issue of a finite supply of pharmaceutical grade glass.

Expert Details

Former VP Device Technologies at Amgen, a partner of West Pharmaceutical. Expert can speak to WST and its senior leadership team.

Advisory Board Member at Stevanato Group S.P.A. Expert is responsible for supporting C-level staff on creation of new capabilities, industrialization of existing capabilities and business development and acquisitions.

Special Advisor to CEO and Advisory Board Member at PBS Biotech. Expert is responsible for supporting the CEO and C-level staff on organizational and governance systems design and corporate financing.

President at an executive Consultancy leveraging broad leadership and success in the biopharma space leading highly complex and global projects over a broad spectrum of technical, strategic and organizational initiatives in Operations and R&D. Engagement and leadership of C-level staff to assess, identify and deliver on successful organizational design, strategy and goals.

Former VP Device Technologies at Amgen, Inc., a partner of West Pharmaceutical. Expert was responsible for Primary Container Science and Engineering, Packaging & Labeling, Human Factors, Device Engineering, and Advanced Device Technologies. Expert launched 9 new combination products in 4 years including 2 wearable drug infusion devices, 1 reusable auto-injector and 6 single use auto-injectors. Combination products were accountable for over 60% of Amgen sales in 2018. Expert developed and launched Nuelasta Onpro (wearable SC infusion pump) and ENBREL Mini with AutoTouch (reusable electromechanical autoinjector), two unique combination products, resulted in the protection or growth of over $500M in revenue per product. Expert also led the cross-functional, global team that designed, developed and launched the first wearable combination product. Expert designed a new operating model for collaborating with suppliers to execute co-development of drug delivery systems. This model was applied across Amgen’s supplier network to accelerate development timelines and supplier reliability.

Q: Do you have a good understanding of the competitive dynamics within the elastomer and glass components niches of the injectable drugs packaging industry?
A: Yes- I have worked with West Pharm at my role at Amgen. If you work with a pharmaceutical company, it's pretty inevitable.

For AMGEN I was accountable for post formulation and managed all of the devices and different packaging. We were customers.

Q: Have you worked closely with WST's senior leadership or have insights to share about the management team and the culture at WST?
A: Don Morrel and I are still good friends. I can speak to a lot of the folks on their past/current senior leadership team.

Tegus Client
Hi, thank you for taking the time to speak with me today. For context, we are interested in learning more about West Pharmaceutical and the injectable packaging industry in general. So I wanted to start off with any insights that you may have on both the current management team as well as the past management team at West?

Former VP Device Technologies at Amgen
So the past management team, the one before the previous one, which Don Morel was the CEO of, is the group that actually took the company public and really transferred them from a stopper seals company to more of a complete delivery system solution company. During his time though, they acquired rights to Daikyo's CZ plastic containers.

They acquired rights to a couple of different devices, wearables, one of which is used by Amgen and called Pushtronex by Amgen. I think it's called SmartDose by West. And they acquired just a whole set of patent suites around drug delivery systems. The German who is most responsible for that, Eric Resnick, with their Senior Vice President of Innovation.

And he ran that whole side of the company for Don. It's interesting when you look at West, it's like two companies that were smashed together. There's the old guard stoppers and seals group and then there is a new group, which is more on the innovation side around drug delivery systems, the containers, stuff like that.

Since Don left, a gentleman named Eric Green took over as CEO probably about five or six years ago. And actually, just to go back for a second with Don, there were not a lot of issues, but sufficient enough issues between the two companies, Amgen, which I was representing and West that we decided to really restructure the way we ran our relationship.

And we put in place this engagement model between the two companies. But actually, we presented as combined companies at one of the PODD meetings in California. I can't remember which one. So that's out there. And it was really just a different way of looking at the partnership.

We're in the middle of trying to develop this wearable device for a monthly dose of Repatha, and there were some issues there, and we decided to bring together teams from both companies and really integrate them to the point where it really felt like it was the same company that Eric and I are running it. And that to me was probably one of the most successful engagements I ever had with the supplier from the Amgen side, at least.

We did similar engagement models with Flex and Nypro, Jabil, a few other companies like that. When Don left, Eric Green took over, and this is post IPO post expansion of the company into drug delivery systems. And Eric's been I think, very good at stabilizing the company, integrating better all the different components because it didn't feel like things were integrated when I was working with them a lot.

It felt like, like I said, like two separate companies that worked together, but didn't always think about each other, for instance, when you are developing a device with Eric, it was easy to have the conversation that some that needed to be done, and the work would start and we would figure out the PO and the cost as we were going, so we didn't lose time.

If you do that with the stopper, seal part of the company, they don't do anything until they have a PO sign, stopper work, everything. So very, very different. I think both of the CEOs, Don and Eric both very fair people. I found them both very easy to work with. Also very competent. Don has since joined the Board of Directors of Stevanato Group and was instrumental in helping them go public. And he also brought Bill Federici, who was their CFO at West, his CFO of West over to the Board of Stevanato also to help with that.

Tegus Client
Anything about the company's culture that you could share with us based on your past experience?

Former VP Device Technologies at Amgen
Yes. I mean like I said, I felt like it was almost two separate companies. It was the one that was extremely well integrated with the partner companies, and then there was the older business, the stoppers and seals. One of the very low margin business, the stoppers and seals. And then there is the device side of it, which is a very high-margin business. And I just never felt like those two groups, I mean, they worked together, but I never felt like it was very well matched that there was a similar culture between the two companies.

I always felt like there was two separate cultures going on, one of a very typical low-margin manufacturing company, on one side and the other one of a higher margin tech company on the other side, with the tech company being more open to partnerships and working together and sharing of information and really trying to get the best for the client in the business that we're working with, whereas with the stoppers and seals side, the lower margin part of the business, it always just felt like you are buying widgets in a bag at a hardware store.

So it's hard to get information from them when something went wrong to get batch information was difficult. On the innovation side, very easy, very simple to do. And in the end, what I ended up doing was leveraging the information side. So my corporate partner at West was Eric Resnick, and when I had a problem getting information on stoppers and seals, I just called him and let him deal with it for me. And that was very helpful.

Tegus Client
And is Eric Resnick still at West? Or has he left?

Former VP Device Technologies at Amgen
No, he has since left the company, I do not know who his replacement is, to be honest.

Tegus Client
And the low-margin business that you were referring to is stoppers and seals. So the way West reports its financials, they have two reporting segments. One is the proprietary product segment and the other is the contract manufacturing segment. And so I was wondering if you were referring to the contract manufacturing segment or were you actually referring to stoppers and seals?

Former VP Device Technologies at Amgen
Yes, we never really called it either. When I was working there, and I knew there was the innovation part and probably one of the people in charge there now is a guy named Jeff Kyle. I know he's headed the Wearable Drug Delivery Systems projects. And he was always very, very helpful.

There's a guy named Atul Patel, who is the Vice President for I think Devices & Delivery Systems at West. So I always think of it in that term. I don't think of it in terms of contract manufacturing or I'm sure most of the devices are in the contract manufacturing space because they do make one-off products for us for the pharma industry.

Tegus Client
I'm assuming you're still on the Board at Stevanato.

Former VP Device Technologies at Amgen

Former VP Device Technologies at Amgen Board. Not the Board of Directors.

Tegus Client
So I'm not sure if you're aware, but so West announced their partnership with Corning and it seems to me that they are trying to get a pre-filled syringes market, which is currently dominated by Becton, Dickinson, I believe, and they have an exclusive contract with Aptar, quite all the elastomeric products for that. So I was wondering if you had any thoughts on whether or not West is likely to be successful?

Former VP Device Technologies at Amgen
The thing that I always told was good about West is that they were container-agnostic. Unless all the other glass manufacturers are signing up to a specific stopper company, I don't know why you would do that if you are West. I think it limits them. It already puts them at odds with other companies, if they're that close to Corning because, quite honestly, most of the other glass companies don't much like Corning.

There is this sort of, I think, tendency in the industry space right now to try to have complete solutions available for sale. But it is pretty different the elastomer, and the glass space, the making of those things are very different. Even when West started to make it their own CZ cartridges based on the Daikyo process and formulation. But it took them a while to be able to do that.

I can't imagine or see them ever getting into the manufacture of glass, syringes and vials, that's so far out of their space. But the partner, if the deal is that Corning has to use their stoppers, but they could provide stoppers to other solutions, then I think it's fine for us. But if it becomes something where it becomes a one-to-one relationship, that is severely limiting for West because quite honestly, Corning doesn't have a large enough market share to justify that. I think they'll get it, to be honest.

Tegus Client
Also, how would you describe West relationship with Stevanato? I think a few years ago, they had announced a partnership like Stevanato and West announced partnership for EZ-fill vials. And so I was wondering if you could comment on West relationship with Stevanato and then how this new partnership with Corning might impact that relationship?

Former VP Device Technologies at Amgen
I mean I think it's okay. I wouldn't say it's the best corporate partnership I've ever seen. It's not bad. They have a partnership. It's basically the co-package, their stoppers and seals where they're ready to use stuff. That's the startup choice for those things. But I do think this move to support Corning in a unique way, probably makes Stevanato question the commitment West has to them.

Also, if you look at West and Stevanato, Stevanato has the glass containers, the devices doesn't have a polymer part, the stopper, seals, that type of thing, those plastic manufacturing now. It's got systems engineering, so it can actually do the assembly equipment, all that stuff, inspection equipment, all those things. All right. West on the other hand, has everything but the glass. So there is each missing one component to be the complete solution space for the pharma industry.

Tegus Client
Would the industry even want that like so just from a risk mitigation standpoint, as I say, you're buying all the rubber products from vials and stuff from Stevanato and others. But if one company is providing everything like so from a risk management standpoint, your pharma companies would have second thoughts about having too much reliance on one supplier.

Former VP Device Technologies at Amgen
That's the same thing with BD though. If I buy a BD syringe system from BD, I don't get the rubber from BD. Rubber comes from another company, it's a one-to-one relationship. But West maybe seven or eight years ago was more risky as a single supplier to the industry, but now they have a few plants that make the same things with the same coatings that are geographically separated.

So if their plant in Florida goes down, they have one in Singapore now or you know what I am saying. So as long as you didn't do your regulatory submissions and tie yourself into a bind, where you're saying we are buying stoppers from West on this line in the plant in North Carolina or whatever, then you're probably okay. If you say we're buying X352 stopper from West, and we've qualified that across multiple sites, you're okay. So is it the best risk mitigation?

It's always good to have two companies. There's business risk. There are other opportunities that could be bought out. It's been taken over, it could fail as a company whatever, although I don't see that happening to us anytime soon. But it could happen. So yes, it's always to have a second source that's financially and business model independent. But having a source that has multiple production sites is probably okay. I mean, it's sufficient mitigation to make you sleep at night.

Tegus Client
I wanted to tap into your experience with West versus Amgen. So the next two questions are going to probably be on West's relationship with its customers and so on. So before I get into that, I just wanted to get a general understanding of how pharma companies make the decision whether to produce packaging material in-house or outsource it to someone like West?

Former VP Device Technologies at Amgen
What aspects of packaging are you talking about primary container, secondary packaging, thermal containers? There is a lot of packaging.

Tegus Client
Yes, primary and secondary packaging materials, so like vials and seals and stoppers.

Former VP Device Technologies at Amgen
Right, I don’t know any pharma company that is based on vials and seals. It's so far out of the realm of what these companies do. I mean the farthest I would go to say is that there are some pharma companies that produce their own auto-injectors. I mean, Novo Nordisk was very well known for that, although they sold that capacity off and I think two years ago signed an agreement with SHL to use SHL auto-injectors instead.

But there are still a few that make their own. Before I left Amgen, we had an innovation group that was designing a fully-owned auto-injector for Amgen, that Amgen probably would not manufacture that, they would contract manufacture it out, but they would own the intellectual property. So there's a little bit of a difference between me owning the intellectual property and me making it myself or having a contract manufactured out or not only the intellectual property and buying the parts from somebody else.

But then you have even with that realms of where do you do final assembly. So SHL, for instance, when I first started working with them, and I think only one website when I first started working with them, nobody at SHL and only one side of West had the ability to handle drug product. So you have to have a facility that's licensed to do that. And then that puts you under a much stricter regulatory inspection set.

So there are pros and cons. If I'm selling you a complete solution, you give me your filled syringe bodies and plunger rod and I assemble the whole device for you, that's a good margin product. It's a way to raise the profitability of the company overall. But it increases risk because you're now handling drug product, you are more responsible and accountable. And when issues happen, there's more places that the issue could have had its beginning.

So for instance, if an auto-injector stalls, I could think of a ton of reasons for that to happen, okay? It could be that the syringe has a pebble on the inside, a little bump in the glass that pass the stopper and could be that the variation in the strength of the spring or whatever the drive is gas spring electromechanical is not strong enough to push against viscosity of the product. The variation and you're at the low end and maybe you're at the high end of viscosity for a drug and install. It could be the drug itself.

So if you don't properly handle especially the biologics space, protein solutions, and they are out of temperature range on the high side. They tend to get more viscous. So I've had an instance where a plastic

part inside an auto-injector, the angle of one of the arms is off by like 0.5 degree in the production of the plastic, and that's stalled it. There's so many different places you can go with this.

So I always thought my target was always, hey, if I could either have a company where the primary packaging, the secondary packaging, the device itself and everything was done by them, then I only have one person to point to as a problem when something goes wrong. So what most companies do is they buy the device from one company, the unassembled device, maybe it's a drive unit and a base that syringe gets into it. You buy the glass from somebody else. The stoppers and seals come from somebody else.

And the stoppers have huge variation in them. You fill the drug itself. And even though you have your own stability, most people don't actually go back and recheck the scarcity as part of stability. They have to see where the drug is still worth. But they don't necessarily go back and say, "Oh, it's getting a little bit more viscous, which would change the drive unit power.

So you put this complex thing together. And when something goes wrong, there's a lot of different places you could point. And most pharma companies don't like to point out themselves. So they point everywhere else first. You got to check the glass, you got to check the stoppers, you got to check the drive unit, you got to check the plastic parts, you got to check the springs, you got to check all those other things. But I've seen it be any of those things.

So if you go back to the original question, if a drug company has that expertise, yes, it would be great to do. But to install a bunch of glass forming equipment in a place, get it up and running, acquire your own cane from one of the five or six suppliers in the world that make cane and be accountable and responsible for all of that, that would be really hard for companies to do. And it's so far out of their wheelhouse of what you do well.

Tegus Client
So once the company has decided to outsource the manufacturing of packaging material, at what point in the drug development cycle, is that decision made?

Former VP Device Technologies at Amgen
In reality or what, would the preference be, the people making combination product. I mean the best of all worlds and some companies do this, not all, would be to at least have your final presentation available for your Phase III trials. Unfortunately that doesn't always happen, because you don't want to invest a whole lot in your product until you know it's going to be successful.

So a lot of companies wait and wait as long as they can before they make that decision to pull the trigger and then it takes a while to develop an auto-injector for a drug. I mean sometimes the drug has very similar characteristics. It's the same filled volume, it's close to the same viscosity and you can leverage in other products, auto-injector to do it.

But most auto-injectors don't have this huge range of power that can power everything. So it takes time. Most companies actually at Amgen, a lot of what we did was due to the clinical trials with the pre-filled syringe or vial and then do a bioavailability study to show that the auto-injector did the same thing as the vial and syringe. It's less risk.

But there are companies that do the whole thing with the trial with the device that's intended to be commercialized. Now if you can do it, it's great because you learn a lot about the performance of your device. And from a regulatory standpoint, you have a commitment with FDA to continuously improve your device.

And it can be simple things, too, by the way. You might not even change the device. You might just change the instructions for use. I can tell you, if you look at the registry of adverse effects at the FDA, it's amazing how many people do, how many weird things with auto-injectors. You would not believe some of the things that people think might make the auto-injector work, okay?

I remember seeing complaints where a person injected their thumb and said the auto-injector didn't work because what they did was they took the cap off and they put their thumb over the whole where the needle

comes out, taking that, that was the button to start the auto-injector and then press the button, which is at the other end, down on their skin, which activated it and injected the pump. So a simple thing there. Have the end be different colors or a big, this side down or no. But you don't know that until you start doing it with patients.

Tegus Client
I was curious about the selection process for the packaging supplier like what does that look like? Is it like a typical RFP process that suppliers go through like in other industries? Or is it more like a customer approaching West and saying, "Hey, we are trying to bring this new drug to market.

Can you give us a quote for this particular drug and basically make sure that the drug has a minimal amount of interaction with the packaging material and all that stuff. Can you talk about that process a little bit?

Former VP Device Technologies at Amgen
Yes. I would say for secondary packaging, thermal packaging, all that type of stuff, it's more of an RFP type of thing. But quite honestly, you get to a point where you've platformed a lot of this stuff anyway. So for instance, I can't recall any time that Amgen reached out for a singular drug, unless it was a very unique product that needed a unique container to get something new from a West or Stevanato Group or BD or anybody else.

Typically, what happens is in research, or at like the toxicology, preclinical and maybe in Phase 1 level. What we did was we had a platform formulation that was a frozen liquid for biologics at least, and they were put into vials, a standard SCHOTT vial with a West stopper and seal, and we just use that.

As you move into doing a commercial formulation process with the exception of formulations that delaminate glass, where you probably need a more expensive delamination-resistant glass container, you would just probably go with whatever syringes you had in production. At least that's what we did. And then you would negotiate annually or semiannually or whatever through your sourcing group contracts with your glass suppliers, if we hit certain milestones of amounts and numbers, then we will reduce the cost by x, something like that.

Tegus Client
And my understanding is, I think you alluded to this as well a few minutes ago, but for every packaging component or drug containment solution is like a primary supplier and a secondary supplier?

Former VP Device Technologies at Amgen
Usually. Not always. Again, we used a lot of the West stoppers and seals and when we did our risk mitigation exercises around that. Part of that with that West agreed to have a second site that could produce the stoppers that we use. So that didn't make us think we had to go out. Now certain applications have very unique things. 3 ml glass cartridge or plastic cartridge, if you're designing something from scratch, you might go out to Datwyler or Daikyo or somebody else and ask them to develop something that's unique for you.

When you get to why diameter cartridges being able to stop with and container closure integrity is difficult. So you might go to a couple of different stopper suppliers and try a few different ones out before you decide on which one to use.

Tegus Client
So it seems like at Amgen, you were predominantly using West products. But I was wondering if you could touch on like what are the different factors that are taken into consideration and selecting that primary packaging supplier? Is it speed to market?

Former VP Device Technologies at Amgen
Well, speed to market usually isn't that big of a deal unless it's something that you're asking a few companies to try to independently develop is something that doesn't exist. How quickly they could do it and

to what quality and get into production and industrialize it and all those types of things is something that would have an impact, especially if you don't want to delay your drug launch because of something like that.

I think if you're going with something more standard, it probably comes down to cost and quality. So if I have experience with a certain set of vials. And I know one of them maybe cracks a little bit more often or has defects more often from a factory, and that could cause a recall for me. The cost of that recall is probably in the $40 million to $50 million plus probably lost business, if there's a competitor in the market, whereas the cost of vial is pennies. So when you fill these primary containers with product, they become very expensive.

So the last thing you want to do is lose out on that. So there's probably a balance when you do a total cost of ownership assessment where you look at the overall quality of the product, your ability to use it in your manufacturing suites because you don't want to have to change anything if you don't want to. And then the total cost of ownership. So again, would I pay double for a vial if I knew, it was always going to be 100% correct? Probably not. Will I pay a cent more? Maybe.

Tegus Client
So how does West stack up against, there is a Swiss company called Datwyler and then there's a U.S.-based firm, I think out of Chicago, Aptar and that also has elastomer products. So I believe they are the two main competitors for West. Do you mind comparing West to these two companies and tell us more about how West stands out in terms of quality or anything else that you think is important?

Former VP Device Technologies at Amgen
Yes. I don't know the one in the U.S. very well at all. Datwyler is somebody who we dealt with on occasions. Most of our stuff was from West. Datwyler has a reputation of being at higher quality and higher cost. So to me, again, it comes down to where is that total cost of ownership line that you're drawing.

What we did do is when we had something that was a unique primary packaging configuration, we would go to West, we would go to Datwyler. We would go to Daikyo in Japan, sometimes also, even though they have with West to ask them to all design the best solution and then get some of that tested on our own equipment and see how well it worked.

Tegus Client
So would you say like West differentiation is probably just quality and the global manufacturing scale?

Former VP Device Technologies at Amgen
Yes. It's quality and ability to deliver product to us. Again, you don't want to delay a launch because you don't have stoppers. If you look at the biggest issue of today, COVID. Moderna and Pfizer both. Let's think about this. The largest biotech product up until COVID came out was a TNF inhibitor, I think, at like $15 billion a year. COVID vaccine and mRNA vaccine for Moderna was $17 billion, and I think for Pfizer, it was $30-something billion. Those companies would have taken any container and any closure they can to get it out in the market.

Because if you think about it, you went from an industry that tries to keep its capacity utilization in the 80% range, and you just plopped on top of it 5 billion doses globally of something. It spread across many companies, yes, in some cases, really focused into two. But those companies could go anywhere to buy glass and they would use vials from three companies, if that's what it took to get it out there.

So the urgency for them was very different than when you have a more of a planned progression. So when I was buying glass from vendors, I had a fairly good idea of what my pipeline looked like we probabilities it. We try to find what we thought was the mean demand and be an Amgen who has never shorted the market for any patient ever. We always err on the side of the high-side case to get ahead of that.

Right now, it's pretty hard to do that because there's just not enough glass manufacturers in the world making glass. There's not even enough cane manufacturers really at the moment. They're struggling to get new furnaces up and running. And my guess is even for the closure part, there's issues there also. So if I'm sitting in Pfizer or Moderna right now, I'll buy it from anybody and I don't really care what the cost is. For

Moderna, this is my chance to print money instead of being a start-up.

Tegus Client
How easy or difficult is it to switch suppliers for primary packaging suppliers?

Former VP Device Technologies at Amgen
That actually is hard, not so much that as hard as expensive. So even if you buy vials that are the same configuration made from the same original cane, you still have to go through a whole set of studies to show approved to the FDA that what comes out of that vial ends up being the same as what came out of the way you used before.

So I would always tell my friends at Stevanato, they'd be like, well, everybody is going to switch to this. This is a far superior product that I'm thinking, well, if I don't have the problem that you're fixing, I'm not going to switch right? So if you come up with a vial or a syringe that reduces silicon particulates, is that a good thing to have? Yes. Is it something you would want for all future products? Probably it just takes one risk out of my process development time.

But if I'm selling billions of dollars of a product then I have a few particulates, do I switch? Because the switch for a biologic, you have to do engineering runs on your equipment that you're going to have to do qualification runs. You have to put that on stability. You're going to have to file something with the FDA. It might just be a 30-day review or a 60-day review is probably not a year review, but you still have to do it. All that costs a lot of money.

And probably the most expensive part of it is the drug you put into the container to put on stability while you wait to see if you get the same stability that you got with the old container. So unless I have a problem that I have to fix, I probably wouldn't change. Now if I was starting new with the product, I would qualify it probably in two different sets of glass. I do that upfront. But a lot of companies don't, you would be surprised how many companies just have one glass supplier and all their products are in that same glass, and that's it.

Tegus Client
Are there specific areas of improvement that you could point to for West, things that they can do better in the future?

Former VP Device Technologies at Amgen
I don't know what's changed today. I mean I haven't interacted with them for three years as a primary customer. But I think how Eric and I ran the partnership was actually very, very good. It's a model that I would want to follow. I don't know if they still do that and still allow that to happen.

I do think the people there are very capable. I feel like sometimes they used to get caught up in their own culture of, again, this low-margin mindset versus this high-margin innovation mindset. And to me, getting as much of the company on that innovation high-margin mindset as soon and as quickly as possible would be a very good thing to do.

Tegus Client
You mentioned biologics a minute or two ago. I wanted to get your thoughts or opinion on whether the growth in biologics, I guess that's sustainable. So this biologics business is growing at a pretty rapid clip. And just wondering like how sustainable is that? How COVID driven? And if you look out like two or three years, the growth is going to decelerate significantly. So do you mind sharing your thoughts on that?

Former VP Device Technologies at Amgen
Yes. Well, it's hard in my mind to predict that right now, we saw COVID coming. And my guess is with global warming and all the issues that are happening from a technological side of it, more animal/human contacts going to happen and more viruses are going to jump post. So with that in mind, I think, yes, COVID will go down, and there will be a small decrease in some companies' sales if they're a supplier mainly because of COVID.

But the reality of it is, in my mind, at least, is that in five years, it's not going to be COVID, we're worried about, it's something else. So take that off the table. They have a pretty solid base of companies and products that use West stoppers and seals to start with. The United States is one of the outliers from the standpoint of ongoing COVID vaccinations.

It was like 68% or 69% of Americans got the 2 doses of a vaccine but only like 25% or 30% have gotten a booster. That's not the same in most of the rest of the world where boosters are actually being allowed. So yes, it's got to decrease some depending upon what percentage of their total volume is COVID-based. It's going to slow down the virus right now.

The trend is to modify itself to mutate towards something that's less deadly and more infectious. And that's probably what happened with quite honestly, the Spanish flu back in 1980. It just went away. So will it go away 100%? I don't think so. Will this demand go away 100%? I don't think so. Are you going to need the full amount of capacity that you've allocated to it? Probably not. But I do think there's other diseases coming up already from monkeypox, let's just throw out one. But there are other viruses out there that I think are being identified and picked up.

Tegus Client
You have a more favorable view of biologics growing at the high single, low double-digit rate?

Former VP Device Technologies at Amgen
I mean look at Merck, Merck was always a traditional small molecule company, but they're getting more and more into biologics. They're starting to develop an internal capability in combination products. So I think biologics in the whole mRNA cell therapy, you just go down the list of types of therapeutics, they're all in that same realm of liquid or frozen liquid formulations that need to be delivered.

Tegus Client
How do you think about the risk of an Asian manufacturer, let's say, someone in China or even India entering the developed markets and competing aggressively with someone like West just on price while being able to match them on quality?

Former VP Device Technologies at Amgen
Even if they do match them in quality, West does produce in India, and in China. It's reputational. When I was at Amgen, one of the heads of quality that was there, absolutely refused to let us source anything from China. In this line, that was a bad thing to do. And if you didn't have to do it, why do it?

Now that being said, it's like 75% of the medications sold in the United States from China and India now. So hard to keep that mindset up if you ever want to take a drug. So is it possible? Yes. Is it going to be difficult? I think it will be more difficult, but there's a large amount of production going on right now in China and in India. And a lot of those products are being used with glass produced in India and stoppers produced in India and China.

But I don't see U.S.-based companies who are saying, no, I'll give up on West and these other companies. Again, the margin is small, the cost is small per unit. Do you want to put something in risk for such a small cost?

Tegus Client
So we talked briefly about biologics, which seems like a long-term secular trend within the industry. But are there any other key trends impacting the injectable drugs packaging industry over the next five to ten years that you didn't really talk about?

Former VP Device Technologies at Amgen
Well, yes, I mean, you're going to see, I think, a lot of options around in glass silicon, silicon-free, minimal silicone, which will require coated stoppers in different formulations for that. I think plastic is going to become more viable. I was actually talking to a company a start-up that has a flexible plastic container that

they can actually then put aside a rigid plastic container and make it like a plastic single-use vial that actually has a whole bunch of applications from the standpoint of lyophilization and things like that.

So I think there's some pretty cool trends out there. But blow-fill-seal was a pretty good trend just a little while ago and really hasn't taken off except for really, really inexpensive term world applications. Again, if you have capital equipment in place that fill vial syringes and cartridges, do you really want to change out of that. So I think plastic might become more and more applicable.

But plastic in and of itself has its own issues. It tends to attract particulates because of its static charge. It does have higher potential for oxygen and other gases to pass through it. We looked at actually putting Epogen into a plastic pre-filled syringe a while back like a Luer-Lok syringe that was in a dialysis center instead of injecting it through a port at dialysis point, you would just Luer-Lok it to it and push it. But the product became so oxidized so quickly in the plastic syringe that it wasn't a viable alternative.

Tegus Client
Is that why the CZ product that West has to that Japanese partnership that they have, have not been super successful?

Former VP Device Technologies at Amgen
I just think the pharmaceutical industry is a bunch of creatures of habit. So the plastic is more expensive than the glass. If it goes in glass, why switch? I mean I had a job before the final product technologies job, it was called external supply. And we used to buy basically any raw material that went into a production suite at Amgen.

And some of the stuff we bought was for our labs. And we realized that pretty much every scientist who developed an assay at Amgen had a preference for the type of pipette, the type of test tube, the type of this, the type of that. And it's what they learned and used in their labs when they were in college and they just still bought those and used them.

Honestly, I can’t give a good reason that I have to have five different brands of test tubes. They all made with the same glass for the most part. I've never heard of a test tube being the reason why something fell. And it's the same thing with primary containers. Again, creatures of habit. If something does not delaminate glass, then I don't need a low alkaline vial.

I'll go with the cheapest alternative, and I'll put it in there, and it's probably something I'm already using on my line, so I don't have to worry about a testing and making sure it works right and all that stuff. So even with Stevanatos ready-to-use EZ-fill stuff. I already have a washer and a deprioritization of tunnel and all this other stuff set up, and I still buy bulk vials, why do I go to ready-to-use vials, basically writing off equipment, and I'm paying more for the vial.

Now if I'm building new lines, well, yes, and it might be worth it or if Stevanato wants to say, "Hey, we'll buy back that washer and tunnel from you and if you buy our glass, maybe I'll think about it. You're going to also compensate me for a requalification of a new vial, then yes. But if I don't have to, why do it. It's amazing.

A lot of people on the primary container space come up with some great ideas, but they're typically an idea that needs a problem. One company might have the problem. It's really bad for you to assume that the solution came up with is going to be solved everybody's problems.

Tegus Client
Can you comment on how the regulatory environment has changed specifically for the primary packaging industry for drugs over time. And given what's happening on the regulatory side, do you expect more and more pharma companies to outsource manufacturing or packaging components over time?

Former VP Device Technologies at Amgen
I always looked at contract manufacturers as a really great flex space for me. I have a couple of colleagues and friends who are involved in trying to start up a contract manufacturing company for cellular treatments. And I can't figure out the business model. Just dumping a lot of capital equipment down for processes that

are unique and very specialized. So probably every time you build a suite, it's going to work for on cellular therapy and not for another.

In the case of fill-finish and formulation, it's a little simpler. But again, it has to be the right type of capacity at the right time. So let's take COVID vaccinations, the amount in multi-use vials frozen, very wasteful because if you froze the vial, you have a certain amount of time to use it and if patients don't come in that day, you toss whatever you have left in the vial. So there is a trend for both companies, I believe, go to single-use containers or vials or syringes.

But when you think about it, if you go from filling one vial for ten doses to ten vials per ten doses, that really increases the amount of capacity you need to be able to deliver products in the marketplace. As COVID vaccines get out of government reimbursement and pay for into regular reimbursement, the waste becomes a bigger, bigger issue. So you do want to go to single-use stuff, but finding the capacity is probably going to be problematic. I think on the vial side, it's probably sufficient.

But if you want to go to pre-filled syringes, it's probably not. So yes. If I'm a start-up company, I'm a small company. I don't have my own production facilities. I definitely would go to contract manufacturers to do some of the stuff for me. But if I'm in Amgen, I probably I'm thinking about utilizing my internal capacity as maximally as I can. And Amgen is building two sites in the United States now for fill-finish and for packaging.

I tried to convince a few executives at Amgen who wants to actually regionalize final packaging. So what I thought would have been the best solution would have been and whether you contracted it out or built it yourself, didn't matter. But you have Amgen now, I think, operates in 150-something countries. Up until ten years ago, it was only probably about 45 or 50 where Amgen actually operated.

And that rapid expansion, you start to look at the demand numbers from each of these countries. And they're highly variable. And if you have a central production sites in Puerto Rico that makes the drug, puts it into a, let's say, a pre-filled syringe. And then has to send it to a country, you have to label it at that point.

Now think about what would happen if you weren't doing individual runs of labeling for every country out of the 140 or 50, because you start to carry inventory at each of those finished product levels and at the WIP stage before it. If you were to regionalize that final pack out and the regions was to get a demand to your filling company, you would actually decrease the overall inventory you have because you would do just-in-time labeling in a region.

It would decrease your cycle time to get product to the market, and you would probably also have a fairly large reduction in the overall inventory you hold at the WIP stage and at the label stage. But Amgen never wanted to do it. They wanted to keep their big manufacturing plants and do it that way, do it the way they do it now. And then they distribute the label final package stuff to a distribution center in the country and then have it delivered that way. It's not very efficient.

So again, if I'm a small company, I'm probably yes, I'm definitely going to outsource it. If I'm a large company, it really depends upon my demand, what my capital utilization is at the moment, how much that I have sunk into the company. It's more of a business decision than an operations decision.

Tegus Client

Is there anything that you think is important about West or just the industry in general that you didn't touch upon?

Former VP Device Technologies at Amgen

I do think, as time goes on, you've seen these great consolidations through time, the traditional pharma then biotech blew it out and got really big and lots of company start-ups and that collapsed down. Now you've seen it with cellular and gene therapies and mRNA therapies and that will eventually class down.

I think the number of new therapeutics and the number of new modalities is huge. Right now, especially the modalities, the number of different ways you can attack a disease today is much bigger than it was 30, 40 years ago. Just in the biotech space, you have mRNA therapies, you have cellular therapies, you have traditional protein therapies. You have monoclonal antibody therapies. You have BiTEs, TriTEs, all these

different things that are existing now that give you multiple ways of attacking an issue and a problem.

So I don't think that's going to change. I think that's actually just going to increase. So the diversity of containers and primary containers is probably going to have to increase with it. But I'm just not sure where that's going to go yet. I do think also the whole concept of we can put pharmaceutical products and glass whatever, has got to change.

Now, this glass shortage is now, everything from pharmaceutical grade glass to buy windows to redo your house. And it's not an infinite resources. It's definitely a finite resource. And so to me, I think one of the game-changers would be figuring out how to recycle that glass, how do we use it? How do we use polymers, that type of stuff. But I don't think anybody has even looked at that yet, really. Some of the regulations on it, it's really not going to be a simple thing to do just because of the amount of anxiety, it will cause people.

Tegus Client

Interesting. I appreciate you sharing your thoughts and insights with me. Thank you very much. This was very helpful. Bye.
