

Contract Packaging – H2 2021 Market Update & Competitive Dynamics – 24 May 2021

Disclaimer

The information, material and content contained in this transcript (“Content”) is for information purposes only and does not constitute advice of any type or a trade recommendation and should not form the basis of any investment decision. This transcript has been edited by Third Bridge and may differ from the audio recording of the Interview. Third Bridge Group Limited and its affiliates (together “Third Bridge”) make no representation and accept no liability for the Content or for any errors, omissions or inaccuracies in respect of it. The views of the specialist expressed in the Content are those of the specialist and they are not endorsed by, nor do they represent the opinion of, Third Bridge. Third Bridge reserves all copyright, intellectual and other property rights in the Content. Any modification, reformatting, copying, displaying, distributing, transmitting, publishing, licensing, creating derivative works from, transferring or selling any Content is strictly prohibited.

Specialist: Dan Marasco (DM)

Title: Head, External Supply Leadership at Takeda Pharmaceutical Co Ltd

Moderator: Arelis Agosto (AA), Third Bridge Sector Analyst

Agenda:

1. Contract packaging industry overview and competitive landscape across key players such as UDG Healthcare (LON: UDG), Sharp, PCI Pharma, Catalent (NYSE: CTLT) and Patheon
2. Biologics and cell and gene therapy growth
3. Commercial vs clinical packaging contract and pricing dynamics
4. Continued impact of serialisation
5. H2 2021 outlook

Contents

Q: Could you give an overview of some developments or trends in the contract packaging industry?	4
Q: What’s your take on the greater push towards large-molecule products, given you’ve mentioned getting closer to the patient as well as global regulatory changes? What do you think this will entail for the contract packaging industry? We’ve heard mixed reviews in past Interviews, with some saying this might entail greater industry decentralisation vs others who don’t believe that will happen.	4
Q: Could you expand on the increase in changeovers? To what extent are truly different companies at play here? What informs your outlook on further industry consolidation and more end-to-end models, particularly in more complex fields such as cell and gene therapy?	5
Q: You mentioned different criteria between small biotech and large pharma, with some nuances in modality or the complexity of that modality. Could you describe those differences in criteria between a large pharma and a small biotech, perhaps mentioning factors such as price and footprint?	5
Q: Could you expand on the contract packaging competitive landscape? Who comes to mind as the key players of excellence, given the criteria you highlighted?	5

-
- Q:** What do you think would be the benefit of increased packaging services? Increased conversion has continued in the pharmaceutical supply chain's contract inputs. Thermo Fisher with its Patheon vertical announced plans to acquire PPD in April 2021, and Charles River on the pre-clinical side acquired Cognate in manufacturing in March 2021. You mentioned that Patheon or Catalent might have simpler packaging abilities, but how beneficial for price and strategy would increased packaging services be for customers? 6
-
- Q:** What are your thoughts on Sharp and UDG's combined business and the news in May 2021 of UDG going private? Chairman Shane Cooke said the company has transformed since disposing of its supply chain business in 2015 through a combination of sustained long-term organic growth and acquisitions. Where do you think UDG plays? What potential risks would you identify in its positioning? 6
-
- Q:** What do you think are the UDG-Sharp portfolio's potentially weaker areas that could continue to be improved, particularly as we expect a more competitive landscape? 6
-
- Q:** You mention PCI Pharma, which has a CDMO [contract development and manufacturing organisation] vertical, and that this might not be a draw. From your perspective of large pharma criteria or for contract packagers, to what extent are some of those services utilised and what potential conversion could there be between the two services? What does that indicate for a larger CDMO aiming to expand its CPO [contract packaging organisation] services? 7
-
- Q:** How would you quantify the outsourcing rate for clinical and commercial contract packaging? How do you expect that to trend for the next 12-18 months? 7
-
- Q:** Could you give a range of where the outsourced rate is, across verticals such as biologics, small-molecule, commercial and clinical? How much would you expect it to increase? 7
-
- Q:** Could you elaborate on how the increased importance of serialisation might have impacted industry pricing or other selection criteria? How much more impact would you expect, and how much has been already absorbed? 8
-
- Q:** You mentioned the cost piece as it relates to regulatory changes. As other companies start or continue to adopt a similar regulatory framework, what impact might that have on cost structure, given the more complex serialisation requirements? 8
-
- Q:** Could you elaborate on the longer-term considerations you mentioned for increased contract packaging outsourcing and the greater investment you expect from pharma for in-house services? What modalities or segments would you expect greater investment for in-house packaging in? Where might there be a slower uptick in outsource packaging? 8
-
- Q:** Is increased investment in device assembly a matter of complexity or of pricing and a lack of contract players? 9
-
- Q:** You mentioned complexity being one of the key criteria for devices being kept in-house. How far can we extrapolate that into therapeutics and the cell and gene therapy industry, which continues to be regulated with increasing rigor? What players do you think might be best-positioned to limit some of that greater uptick in-house? 9
-
- Q:** What are your thoughts on potential outsourcing for clinical vs commercial in cell and gene therapy? CDMOs' outsourcing rate for cell and gene therapy is quite high in the pre-clinical and early clinical stages and then drops off as it continues through the clinical process into commercial. Might we expect a similar dynamic in contract packaging? Are there any potential risks to those assumptions from an allogeneic model? 9
-
- Q:** What do you think greater decentralisation or the need to have a stronger, more broad geographic presence could mean for larger players such as Sharp, UDG and PCI vs smaller players? Might this dynamic

be an opportunity for some smaller packaging players? What are the considerations for working with a larger company with a large presence vs a myriad of smaller companies to reach a similar footprint? 9

Q: How might a greater reliance being needed from smaller, more local packaging players, especially for the fill finish portion of the segment, impact pricing? 10

Q: Could you describe a packaging firm's perspective on this growth strategy and having a more localised footprint? What challenges might packaging firms face in taking on that strategy and how far away are they from cost or operational savings materialising? 10

Q: Do you think coronavirus has highlighted the importance of a more decentralised model? If so, to what extent? What are the broader considerations as to the pandemic's impact and any potential longer-term effects? 10

Q: How do you think supply vs demand constraints might shape contract or pharmaceutical packaging in the longer term, as coronavirus vaccines are pushed? There was commentary at one point around a Coca-Cola model, where the fill and finish is done at a more local level. 11

Q: Are there any smaller companies that we should be aware of or that you think might pose a longer-term threat to incumbents such as PCI and Sharp-UDG? 11

Q: What are your pricing expectations for the contract packaging industry? You mentioned expectations for new players and what that might mean overall. Might there be a pricing increase in the next couple of years? 11

Q: What further regulatory changes might the contract packaging industry experience? You mentioned recent regulatory changes in Canada, and we touched on materialisation expectations beyond Europe and the US. Is there anything we should continue to monitor that could shift the pricing profile or the overall supply chain? 12

Q: Could you expand on the potential for industry consolidation and where that might continue? If increased efficiencies or offerings from CDMOs and CPOs continue, might there be a greater uptick or acceptance of this model that would warrant increased M&A? 12

Q: Are there any further considerations being driven by increased focus on patient adherence or similar factors that we have yet to discuss? 12

Contract Packaging – H2 2021 Market Update & Competitive Dynamics

Transcription begins at 00:00:02 of the recorded material

AA: Welcome to Third Bridge Forum's Interview entitled Contract Packaging – H2 2021 Market Update & Competitive Dynamics. I am Lis Agosto and I'll be facilitating today's Interview with Dan Marasco, Head of External Supply Leadership at Takeda Pharmaceuticals.

Dan, before we start today's Interview, please state I agree or I disagree to the following statement: You understand the definition of material non-public information and agree not to disclose any such information or any other information which is confidential during this Interview.

DM: I agree.

AA: Thanks, Dan. Could you begin with a brief introduction to your background?

DM: Again, Dan Marasco. Lis mentioned my title. I've been working in the industry, in pharma, for just about 25 years coming in July. I've worked at Merck, Merck & Company, Bristol Myers Squibb, Shire, which is now part of Takeda, in varying roles. Started as a packaging engineer, spent time in procurement handling packaging materials and contract packaging. A couple of years in operations, back in procurement handling, again, both contract manufacturing and packaging. Currently, spent the last three-and-a-half, almost four years in a contract manufacturing packaging operations role.

[00:01:34]

Q: Could you give an overview of some developments or trends in the contract packaging industry?

DM: I think what everyone has seen maybe over the last 10 years, and I think it will continue, is there are still plenty of blockbuster products out there, but the high volume, it's all relative, I suppose, but that high-volume, small-molecule product, set up and run it for a week or two or maybe even for weeks or months on end, those kinds of products are gone, at least from the innovator pharma side, have gone by the wayside. We still continue to see much more pinpointed medicines with much smaller volumes. Those are some of the big things. I would say the last two years, we had serialisation. Just saw a new requirement for Canada 2D barcode, took us a little bit by surprise, but, nonetheless, I'm sure we'll be able to comply in time, certainly. I've seen, certainly, more of a focus on risk management and with companies having multiple sources of supply, especially as we get closer to the patient. Those are just some of the major trends. Another couple other things I guess I'll mention around digital printing, we're seeing a lot more of that and I'd like to probably see more myself, digital printing in the marketplace, especially as it seems to be a perfect fit for our lower-volume, higher SKUs types of products that we're seeing.

[00:03:49]

Q: What's your take on the greater push towards large-molecule products, given you've mentioned getting closer to the patient as well as global regulatory changes? What do you think this will entail for the contract packaging industry? We've heard mixed reviews in past Interviews, with some saying this might entail greater

industry decentralisation vs others who don't believe that will happen.

DM: Packaging has definitely become much more regional, perhaps, than it used to be, closer to the patient. I'm not saying you're going to see a packaging location in every country, but, certainly, regionally, a primary hub in the US, Europe, for sure, maybe Asia. As far as a split between small molecule and large molecule, what I've seen is there's still a fairly even split, but, again, regardless of the modality, I think they call it, whether it's small molecule or large molecule, there are still, generally, low-volume products that, again, require a lot more changeovers. I think the industry has to continue to get better and more efficient there, keep costs down when it comes to that.

[00:05:27]

Q: Could you expand on the increase in changeovers? To what extent are truly different companies at play here? What informs your outlook on further industry consolidation and more end-to-end models, particularly in more complex fields such as cell and gene therapy?

DM: I think we'll see that, more consolidation, more, perhaps, companies becoming more vertically integrated. I see, for smaller companies that are more the, say, small to mid-sized pharma, sponsor companies, seeing that as a big advantage, being able to go the one place, you're dealing with folks in those companies that are wearing multiple hats and they don't necessarily have the time to pick and choose the individual companies for each of the steps of the operation. I think what I've seen in my past and what I still see with big pharma is the selection of what is deemed, say, a centre of excellence for API or bulk drug substance manufacturing, but a separate one for drug product and a separate one for packaging. On occasion, you'll see the drug product and packaging together, but not necessarily a driver for that, but, again, I might just re-emphasise the regionalisation and the need and preference for packaging sites closer to the customers. Even, potentially, companies like a DHL that offer more secondary packaging services, so they're maybe not so much in the primary packaging arena, but also can offer an order fulfilment capability as well that I think some of the contract packagers are getting stronger in that regard as well.

[00:07:50]

Q: You mentioned different criteria between small biotech and large pharma, with some nuances in modality or the complexity of that modality. Could you describe those differences in criteria between a large pharma and a small biotech, perhaps mentioning factors such as price and footprint?

DM: Just from my procurement background, what's instilled in me is that the main categories, and, of course, there are subcategories to each of these but I group them into assurance of supply, quality, service, cost and innovation. Those are the main categories, of course, I would say, in commercial, big pharma, again, the innovator companies, assurance of supply and quality and technical capabilities are probably, by far, the most important. What often happens in those cases, though, is you may have a few companies that are running neck and neck in those major categories. Often, at times, cost may become the differentiator in the end, while ensuring all those other boxes have been checked. Commercial vs clinical, certainly, I described the commercial. I think, with clinical, timing is probably much more important in how quick you can meet their timelines. Obviously, get the product to the market sooner, no one wants to be sitting around. I would say those are probably the key differences between commercial and clinical, it's all about timing.

[00:09:46]

Q: Could you expand on the contract packaging competitive landscape? Who comes to mind as the key players of excellence, given the criteria you highlighted?

DM: The major contract packagers, certainly, a major presence in the US, Sharp and PCI. As another, perhaps stronger in Europe, Almac, I would throw in there as well, as a larger contract packager. Certainly, many of the others, like Lonza, Patheon, Catalent, Delpharm, Corden, companies like that, that I would say are stronger in drug products and maybe even some API. They can also package, just they're perhaps not what might be considered the centre of excellence for packaging. They can do more of the basic bottle, basic blister vs if you have a complex need or if you're a smaller company and you just don't know what you need, you may air on the side of going with a Sharp and PCI that can provide perhaps a more full breadth of capabilities packaging.

[00:11:10]

Q: What do you think would be the benefit of increased packaging services? Increased conversion has continued in the pharmaceutical supply chain's contract inputs. Thermo Fisher with its Patheon vertical announced plans to acquire PPD in April 2021, and Charles River on the pre-clinical side acquired Cognate in manufacturing in March 2021. You mentioned that Patheon or Catalent might have simpler packaging abilities, but how beneficial for price and strategy would increased packaging services be for customers?

DM: I think as a customer, the expectation is, "The more business I give you, the better the price should be." It may also help with hand-offs and I'm not saying we've quantified exactly the cost to manage each relationship, but many of our supply chains have, if you look at APIs or product packaging, have three different sources of supply for each one of those nodes, but it could certainly simplify things and perhaps cost us less overall, maybe even less resources to manage one site or maybe two sites of the same supplier vs having three distinct separate sources of supply. That would probably be the main area that I would see could be viewed as an advantage to that, but, again, my past experience, it has often been looked at, each one of those nodes separately, literally separate RFPs for each of those. We tried to pick the best one. Again, I think that's just from a big pharma standpoint. As I mentioned earlier, the smaller companies might rely on going with one because it's just simpler and easier for them to manage.

[00:13:29]

Q: What are your thoughts on Sharp and UDG's combined business and the news in May 2021 of UDG going private? Chairman Shane Cooke said the company has transformed since disposing of its supply chain business in 2015 through a combination of sustained long-term organic growth and acquisitions. Where do you think UDG plays? What potential risks would you identify in its positioning?

DM: I'd like to know a little bit more about the acquiring company. I know it still has some time before it will be fully approved and all, but I would expect it to go through. Certainly not surprised. I think by going private, it might actually help with being able to focus on the more long term and making decisions, not necessarily based on, I've heard people call it the 89-day cycle to when the next earnings, you're always looking to when the next earnings are. You have to have an eye on the long term, but you also have this focus that's taken away by the very short term and you're forced into making short-term decisions, just because you have to meet the numbers. I kind of like it. Like I said, I'd like to look into it a little more, this acquiring company or the private equity firms getting into this. Obviously, they don't keep companies forever, but Sharp or UDG has been a high-performing company. Again, based on my perspective, hopefully, they also leave things alone. From a risk standpoint, I hope there's not too much tinkering.

[00:15:26]

Q: What do you think are the UDG-Sharp portfolio's potentially weaker areas that could continue to be improved, particularly as we expect a more competitive landscape?

DM: I know they have expanded the business and continue to invest in the Allentown area. I think they just acquired another location, which was just recently made public. I think just continuing to understand what the customer demands are and being able to perhaps plan ahead further with those vs, again, being restricted by, “We can’t make that move yet or expand this capacity here or bring on these additional resources because it might affect our numbers for the quarter.” Again, I think it’s just help them with being able to be more long-term focused and customer-focused. Ultimately, it’s all about the patient. The whole industry, every single one of them talks about how the patient is at the centre of it all.

[00:16:48]

Q: You mention PCI Pharma, which has a CDMO [contract development and manufacturing organisation] vertical, and that this might not be a draw. From your perspective of large pharma criteria or for contract packagers, to what extent are some of those services utilised and what potential conversion could there be between the two services? What does that indicate for a larger CDMO aiming to expand its CPO [contract packaging organisation] services?

DM: I guess I’d continue to say that I don’t necessarily always see a huge advantage to it. It could perhaps help the pharma company reduce some inventory, again, from a CMO management standpoint, managing two sites vs one or, again, managing it all under one umbrella. When I place a PO, it’s for the finished packaging, so you CMO can decide when to make it and, then, ultimately, when to package it, as long as you meet our delivery date. I guess there are probably some advantages there as well, just from a management standpoint. I would imagine we’ll see more of it, especially with CMOs that have figured out packaging very well, perhaps, there’s another play there, say, in the sterile fill finish or something like that, where, yes, while there are several players out there, perhaps getting into, say, small molecule may not be the best move, only because of the number of other players that are out there in the small-molecule space vs, again, I think it’s more limited as far as sterile fill finish. Although, again, big barriers to entry to get into that, you just don’t buy a filler, buy an isolator overnight and think companies are going to show up. It’s the chicken and the egg kind of thing. What’s going to prompt that leap into becoming more vertically integrated? That’s the question.

[00:19:33]

Q: How would you quantify the outsourcing rate for clinical and commercial contract packaging? How do you expect that to trend for the next 12-18 months?

DM: I would continue to see it growing. I think, also, there are probably some dependencies on some particular companies and their internal network, but, overall, I would continue to see it growing. You don’t see pharma companies making big investments in drug products or packaging manufacturing, maybe there are some small pockets of that, unlike investment that has happened over probably the last five or 10 years by big pharma companies in, say, bulk drug substance, biologic manufacturing, let’s say, for example, because of the very limited capacity on the outside, or when it does get built, it’s consumed in a matter of what seems like months.

[00:20:49]

Q: Could you give a range of where the outsourced rate is, across verticals such as biologics, small-molecule, commercial and clinical? How much would you expect it to increase?

DM: I would struggle with giving a number. I’ve seen some different reports that have said around the continued growth of around 7% or something like that, but, again, just based on some reports I’ve seen in preparations for this call, each company is obviously going to be a little bit different there, but, like I said, I continue to see the growth. I’d see, if anything, the internal pharma networks will probably continue to shrink

over time.

[00:21:51]

Q: Could you elaborate on how the increased importance of serialisation might have impacted industry pricing or other selection criteria? How much more impact would you expect, and how much has been already absorbed?

DM: It was certainly a lot of fun with the recent FDA and then the most recent EU FMD that was put in place. Certainly, there were some costs associated with that. I don't see much more happening there. China has their own unique requirements with serialisation. I've been told by some serialisation experts that, eventually, the expectation is, probably, all countries will have some serialisation, but many of them will either adopt something similar to what the FDA or EMA have in place. I don't expect there to be that much more disruption in that regard, other than the initial start-up and qualification part of it. Hopefully, that helps.

[00:23:36]

Q: You mentioned the cost piece as it relates to regulatory changes. As other companies start or continue to adopt a similar regulatory framework, what impact might that have on cost structure, given the more complex serialisation requirements?

DM: There's, typically, a cost per pack associated with that, that could be an add-on. I think now that serialisation, you have the two major markets, again, with the US and EU being in place, there's an experience there now and I guess the feeling, from a big pharma perspective, is that, "Look, this is part of the cost of doing business." Again, I guess there's that initial set-up and qualification work that needs to take place and there probably, rightfully, should be some costs associated with that, but it's almost like serialisation has become part of, "This is GMP now, guys. It's part of the requirements, it's part of doing business."

[00:25:04]

Q: Could you elaborate on the longer-term considerations you mentioned for increased contract packaging outsourcing and the greater investment you expect from pharma for in-house services? What modalities or segments would you expect greater investment for in-house packaging in? Where might there be a slower uptick in outsource packaging?

DM: I think the contract packaging world is good at and getting better at device assembly. Many of these biologics and perhaps even oncology products are, through a product lifecycle eventually, they typically start in a vial and maybe go to a syringe or start in a syringe and end up in a device, again, if it makes sense for self-administration for that product. I think device assembly might be an area where you might see more internally, depending on perhaps the complexity of it. That would then perhaps pull with it the packaging portion of it as well. I really can't see any other areas where pharma is saying, "We've got to do this, we've got to bottle or we have to blister," I doubt that, or blister wallets. Certainly, compliance packaging is still something I think that is I wouldn't call it a hot trend anymore, but still something that is a demand out there. Device assembly, I would say, is the one area where there might be some investment.

[00:27:04]

Q: Is increased investment in device assembly a matter of complexity or of pricing and a lack of contract players?

DM: It could be the complexity of the device and/or it could just even be a risk management play as well. Again, as I was saying before, I've seen to, compared to, say, 15-20 years ago or maybe even 10 years ago, the increase in having dual sourcing. You might have a CMO in the US and an internal site in Europe or vice versa. I've seen supply chains that are completely externalised. I would say price is necessarily a driver, it's just, perhaps, again, risk management, complexity of the device and just, again, there are also some strategies around, for new products, you want to have one node internal, a control measure and being in full control of capacity in the event of significant growth of the product. As we know, the forecast for, I'm sure everyone can appreciate, the forecast for in-line products that have been in the market for even years are still a little wacky and not too accurate, to say the least. Certainly, in launches, it can go either way and we certainly don't want to run short.

[00:28:57]

Q: You mentioned complexity being one of the key criteria for devices being kept in-house. How far can we extrapolate that into therapeutics and the cell and gene therapy industry, which continues to be regulated with increasing rigor? What players do you think might be best-positioned to limit some of that greater uptick in-house?

DM: I think it's a little too early to say or at least, from my perspective, it's hard at this point. When we talked about low-volume products and with gene therapies being almost down to individualised medicine, I think it just adds to the complexity of control and being able to do changeovers in extremely efficient manners. I can't see why a CMO couldn't do it just as well as internal operations, so I don't see that impeding on external growth, I think everyone is going to have to figure out how to do that efficiently, if you're doing a set-up of potentially one, so it should be interesting.

[00:30:33]

Q: What are your thoughts on potential outsourcing for clinical vs commercial in cell and gene therapy? CDMOs' outsourcing rate for cell and gene therapy is quite high in the pre-clinical and early clinical stages and then drops off as it continues through the clinical process into commercial. Might we expect a similar dynamic in contract packaging? Are there any potential risks to those assumptions from an allogeneic model?

DM: I would expect it to be similar. Just thinking about this more, perhaps there would be maybe even more regionalisation of the packaging node with regards to gene therapies, meaning even more locations to do the packaging, potentially. Again, I'm just thinking out loud vs having a hub somewhere and then shipping to multiple countries, but, yes, I would expect that to be the same. I've seen that as well, that nearly almost all clinical supply is externalised and I believe, primarily, on the stance of or on the basis of just risk management, that especially for new products, big pharma would like to have some control of some of these key growth products. That's why they'll do at least some of the work. Again, I don't think it's going to hurt the CMOs long term or short term, for that matter. I think it'll just continue that way as it has.

[00:33:23]

Q: What do you think greater decentralisation or the need to have a stronger, more broad geographic presence could mean for larger players such as Sharp, UDG and PCI vs smaller players? Might this dynamic be an

opportunity for some smaller packaging players? What are the considerations for working with a larger company with a large presence vs a myriad of smaller companies to reach a similar footprint?

DM: I think your available footprint is probably going to matter or I would say wait and see and let the customers drive the need here. If it's, "Look, I need you to establish a facility in Canada or a facility in certain countries in Europe," as examples, perhaps, that may need to be the investment that happens down the road. Yes, I think that could be what we see in the future, is establishing locations even closer to the customer. Even, as I said before, making sure you continue to develop that order fulfilment capability as well, receiving orders directly, perhaps through our system, to be able to do fulfilment work. That, I could see being an area of growth as well. Again, what's happening now is our contract packagers are shifting to a UPS, as an example, and they may be doing some of the fulfilment work. There's no reason PCI or Sharp can't be doing more of that and I think they are, we're just not taking advantage of it this much.

[00:35:32]

Q: How might a greater reliance being needed from smaller, more local packaging players, especially for the fill finish portion of the segment, impact pricing?

DM: Again, I think the expectation is by perhaps having more under one roof. There should be some efficiency there and expectations for a lower cost. Again, some efficiencies on all ends and perhaps a win-win, but nothing drastic, but that would be what I would expect.

[00:36:30]

Q: Could you describe a packaging firm's perspective on this growth strategy and having a more localised footprint? What challenges might packaging firms face in taking on that strategy and how far away are they from cost or operational savings materialising?

DM: That's a good question, the timing of it. I haven't been too close to it yet, but as far as the cost and investments that may be required, as I think I was saying, if I understood the question right, that there would be perhaps a need to buy more or less warehouse-type facilities that probably exist. I don't think there's necessarily a need for greenfields or anything like that, bringing that facility up to GMP, GDP-type standards and going from there, although, again, it's not a field of dreams type of situation. I think let the customers drive that need, if that is truly the requirement.

[00:38:16]

Q: Do you think coronavirus has highlighted the importance of a more decentralised model? If so, to what extent? What are the broader considerations as to the pandemic's impact and any potential longer-term effects?

DM: I think it has been interesting, to say the least. I haven't seen any significant impacts due to a COVID outbreak, let's say. Certainly, there's talk about operations for the next pandemic and when's the next one going to come? I think that's going to be in people's minds for a while, but I think if there's an outbreak somewhere and you've got centralised operations, certainly, that can be an impact. I don't know if it has been just purely luck that we haven't been more affected by that. Again, there have probably been some pockets of it where there has been more. We had a case or two in a warehouse and we had to shut down for 10 days and we couldn't ship certain products, but, fortunately, not all products went into that one site. For certain products, we couldn't ship for 10 days and, unfortunately, we obviously had enough inventory in the supply chain to manage through that, but it could have been worse. It could have kept going. Certainly, decentralising is probably something that will continue to be a need.

[00:40:17]

Q: How do you think supply vs demand constraints might shape contract or pharmaceutical packaging in the longer term, as coronavirus vaccines are pushed? There was commentary at one point around a Coca-Cola model, where the fill and finish is done at a more local level.

DM: That's a good question. I think, yes, there's this concept of postponement that, perhaps, the filling into a vial or a syringe happens somewhere and then all of these filled containers are kept somewhere, as they call it, bright stocked, and then get packaged later, as needed. I don't know about what the impact will necessarily be, other than some potential treatments for COVID. I haven't been directly involved in any supply of COVID-19 supplies or vaccines. Certainly, I think the vaccine seems like it's the answer at this point and, fortunately, we were able to develop something quickly there and get it out. Had there been delays with the vaccine, I personally wish there were certainly more treatments around COVID, but, again, I'm getting away from my areas of expertise. Again, I think, potentially, the bright stocking model could be an area of opportunity, again, if we go that route, it could be an opportunity for the contract packaging business and being able to assist, just like other pharma. Merck, I believe, they're going to fill some of the Pfizer vaccine, I believe, just like why couldn't PCI or Sharp help Pfizer or Moderna with packaging? They may already be. Again, I'm just not close enough to it. I would think there could be some advantages there.

[00:42:59]

Q: Are there any smaller companies that we should be aware of or that you think might pose a longer-term threat to incumbents such as PCI and Sharp-UDG?

DM: I mentioned DHL earlier. It's just a small pocket, but perhaps other distributors like that. I don't know. Amazon is always talking about getting into everything and taking over the world, but I think other players, like a DHL, a UPS, could get perhaps more involved in the industry as far as secondary packaging. If the strength is believed to be that we need to rely on their capability and fulfilment capability, so, again, perhaps, I guess, for some of the contract packagers out there, perhaps to avoid that is to eat some of their lunch and get better at the fulfilment part of it and that capability, so that business isn't potentially lost there. There are some other small players, nothing to necessarily note that I have direct experience with, just companies I've talked to, so I hesitate from providing any other names, just because I don't have that direct experience. Okay, great, this sounds like they have interesting capabilities, but I just can't speak to their performance, which, ultimately, matters.

[00:44:59]

Q: What are your pricing expectations for the contract packaging industry? You mentioned expectations for new players and what that might mean overall. Might there be a pricing increase in the next couple of years?

DM: Just in general, certainly, there's a lot more talk about inflation. It certainly doesn't help, all the money they're printing either, but I think labour seems to be, especially in the skilled areas, like packaging mechanics, let's say, packaging equipment mechanics that is, and there's high competition there that's probably driving up the cost of labour. Probably, in lesser-skilled areas, there still can be a relatively high demand. It seems like everybody's hiring these days and people are coming and going, but, yes, certainly, there are economies of scale and ways to become more efficient, but, yes, I would expect to continue to see price increases over time, short, medium, long term.

[00:46:29]

Q: What further regulatory changes might the contract packaging industry experience? You mentioned recent regulatory changes in Canada, and we touched on materialisation expectations beyond Europe and the US. Is there anything we should continue to monitor that could shift the pricing profile or the overall supply chain?

DM: Not especially. It will be interesting, though, since in the last 15 months or so, many of the health authorities have not done in-person audits and I just wonder if they're chomping at the bit to get into CMOs and pharma companies and start issuing 43s. It's their job to ensure the safety of their citizens and such, but I wonder what that dynamic's going to initially be like once they're released out into the world again to be able to perform in person audits. How much can they really assess through paper audits? Maybe that also changes the way they do things, maybe for certain low risk and they've already, depending on the risk of the operation, I've seen or heard of contract packagers not getting health authority inspections for three or four years, maybe four years or beyond, so whereas it typically was in the 2-3-year time frame in the past. That'll be interesting, but not other major regulatory... is there some new theme that's out there? Anvisa, obviously, cross-contamination is one of the big areas for them, they're a stickler for, but, no, nothing else.

[00:48:36]

Q: Could you expand on the potential for industry consolidation and where that might continue? If increased efficiencies or offerings from CDMOs and CPOs continue, might there be a greater uptick or acceptance of this model that would warrant increased M&A?

DM: I'm just thinking out loud, as you're asking that. I think I could see companies, again, like Thermo, or Patheon or Catalent, perhaps, buying more into packaging. I think it's probably a little harder for packaging to go up, maybe packaging goes, I shouldn't say down, but packaging more downstream, as I was saying before. Small-molecule API, there certainly is a lot of competition there with India and China. Again, I think of areas that have perhaps lesser so capabilities or capacity, as I said before, sterile fill finish, but, again, it's a big leap to get into that if you're not already there. I see maybe there being some strategic partnerships between some companies, perhaps, as a way to go down that road. Yes, nothing else to add there.

[00:50:30]

Q: Are there any further considerations being driven by increased focus on patient adherence or similar factors that we have yet to discuss?

DM: I think, as I was saying, for the right products that require perhaps a monthly treatment and can be self-administered, I still see the pen injectors, those types of medical devices that are bought, are going to be looked at more for certain products. I'm surprised and maybe there's still more to come, a more significant use of phone applications or phone apps to enhance compliance and the patient experience. I think there are probably still a lot of areas to learn there on how those developed and how pharma convinces health authorities to enable the use of those. Those are probably the couple big areas, I think. One other area I've seen more of is just in systems that enable collaboration between customer and CMO, so that sharing of information can be... Something as simple as having a SharePoint site, but also systems that allow for forecast sharing and perhaps the status of production or lease vs picking up the phone and finding those things out, so just on a real-time basis, being able to see a quick snapshot, a quick picture, where things are. Again, just to help with the planning process. I also mentioned the digital printing earlier as well that I personally would like to see a lot more of that applied to these specialty-type products, where you might have one of a kind or you only need to package 20, 30, 40 packs, there certainly could be some cost efficiencies there and speed as well.

[00:53:08]

AA: Dan, this seems a perfect place for us to conclude our discussions. Let me just close by saying thank you so much for your input today. Clients, if you would like to speak to Dan in a private call or meeting, please let your relationship manager know. Thank you, clients for joining Third Bridge Forum's Interview today. Dan, thank you so much.

DM: Thank you.

Transcription ends at 00:53:19 of the recorded material