Joe Lewis – Managing Director, Life Sciences Supply Chain Practice, Deloitte, USA



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23.11.2020

Tags: USA, Deloitte, Supply Chain, Manufacturing, Logistics

Joe Lewis outlines the key concerns of Deloitte's pharma clients around manufacturing and supply chain operations in the wake of the COVID-19 pandemic, how companies can come out of the crisis stronger, and highlights some of the major issues surrounding vaccine allocation and deployment.

Joe, could you introduce your responsibilities and roles at Deloitte?

I am a managing director in Deloitte's life sciences supply chain practice in the United States. I started my professional career as an engineer, moved into consultancy in 2000 and joined Deloitte a little over 14 years ago. I have a couple different roles within Deloitte. Firstly, I oversee the supply chain consulting services that we provide to a number of large pharma manufacturers. Additionally, I have been leading the supply chain aspects from a COVID-19 response perspective, helping to drive collaboration both amongst our manufacturing clients and across the broader ecosystem of stakeholders that Deloitte as a firm is engaged with. This includes both international and domestic agencies, providers, hospital systems, and other potential vaccinators such as large pharmacy chains.

A lot of my background over the last number of years has been in global supply chain transformation: helping clients drive global scale changes to their supply chains, which is increasingly being driven by a transition to digital capabilities. I also help clients identify, develop,

and then deploy those capabilities globally. I also have a breadth of experience within the planning space, helping clients develop and deploy integrated business planning or sales and operations planning capabilities at global scale. I have also helped clients do things like develop vaccine allocation algorithms to help them determine how they're going to deploy vaccines, like the flu, as they become available, but I have worked across the breadth of the supply chain spectrum.

COVID-19 has impacted all aspects of life and work as we know it this year, with global manufacturing and supply chain operations perhaps being one of the most severely hit sectors. What kind of needs are you seeing from your pharma and healthcare clients?

The first thing I would do is differentiate the non-COVID versus COVID responses. Looking outside of COVID-related therapies and vaccines, the majority of the pharmaceutical supply chain, while challenged, has remained largely robust in the face of this increasingly challenging global pandemic. If you look at how pharmaceutical supply chains have traditionally been managed, they do carry reserves of inventory that have enabled clients to largely meet the current demands of products. There have been exceptions, particularly for products under investigation for use in a COVID context, but by and large, the pharmaceutical supply chains have remained fairly robust.

The concerns we do see are in a couple of different areas:

- Understanding one's upstream supply chain – not just direct suppliers, but your suppliers' suppliers, so to speak. Going upstream two, three, four plus nodes has become increasingly important. In response, Deloitte has expanded our capabilities in this area, and we have some unique offerings to provide visibility to clients or to industry stakeholders.
- More real-time visibility of one's internal supply chain, both from a logistics and distribution perspective, and from a manufacturing perspective, i.e. how much raw materials inventory do I have to actually make product.
- More real-time visibility of product moving through the transportation network, given that we have seen pretty radical changes, particularly in international air freight capacity, which is one of the primary modes for moving product

As companies reacted to the initial waves of COVID, a lot of what they were focused on was this sort of internal visibility of inventory and the corresponding allocation decisions about where a product could or should be sent. For many, while the capabilities existed, they were, by and large, very manual and very labor-intensive. There has been a recognition that enhancements of those processes, and the underlying technologies and capabilities to support improved integrated

business planning, are essential.

It is reassuring to hear that existing industry distribution and supply networks have generally remained robust. A hot topic, especially this year, has been this idea that the US should be repatriating manufacturing back into the country. How realistic or feasible is this?

This is a story that has yet to be written, and the outcome of the recent US election could certainly impact this debate to some degree. My personal view is that pharmaceutical supply chains are organized the way they organized today for a reason. Those reasons are a combination of calculable variables, such as actual demand, the size of the markets served, and the scale efficiencies of production. Where the math has traditionally led the pharma industry is a more concentrated degree of global manufacturing than in some other industries. As we see the expansion of the middle class across a variety of geographies and in association, increasing access to healthcare, a more regionalized view of manufacturing actually becomes efficient at the scale required to produce pharmaceutical products.

One of the key drivers influencing manufacturing decisions is related to tax policy. That being said, we did not see the degree of manufacturing network adjustments after the latest tax legislation that we had expected.

Another consideration is how rapidly it is to shift production? It takes time to build and certify pharma manufacturing sites. There is a realistic limit in terms of how fast such transitions can be.

Certainly, markets like the US are large enough to support a certain volume of production, especially if you consider the entire North American region, but any movement towards that would take perhaps more time than expected or desired by some.

You recently wrote an article about the rule of threes, using wilderness survival principles as an analogy for pharma companies looking to survive the COVID pandemic, identifying the needs across inventory, distribution, manufacturing, and planning, across different time horizons. Based on this framework, how well do you think the industry in general have prioritized the right aspects in their COVID responses?

We are actually working on research outlining the lessons learnt from the first wave of COVID. One of the most common questions we received from clients is, who responded the best during the first wave of the pandemic? The answer is simple: the companies that had invested the most in supply chain processes and capabilities before the crisis. Companies with more robust and mature supply chains were able to better respond to the unusual degree of volatility that the industry experienced during the early phases of the pandemic.

It is generally recognized that we are not through the COVID pandemic yet, and looking ahead, especially as we enter the winter season in the Northern hemisphere, we expect to see increased demand and supply volatility. In terms of where we expect clients to invest, it comes back to looking at one's maturity and identifying the aspects that would make the biggest impact in terms of your ability to maintain continuity of supply during this period.

The first thing we see clients investing in are aspects like supplier illumination and visibility to better understand the potential risks their network of suppliers face. The next is improved visibility of one's internal supplies, whether they are owned or already shipped to a customer. The third would be the digital and analytics capabilities to rapidly present information to decision makers so they can effectively make better supply chain decisions amidst significant variability and volatility.

Many industry leaders have highlighted the unprecedented scale of collaboration between companies and other institutions for the R&D and manufacturing of therapeutics and vaccines. How challenging has it been to integrate all the relevant manufacturing and supply chain systems and processes?

It has been very interesting. For COVID-related production, what we are seeing today is that governments and other public entities have commissioned a vertically integrated R&D, manufacturing and distribution network, and the major pharma manufacturers are effectively acting as contract manufacturers for these national and international entities. Within the US, that is Operational Warp Speed, who has procured large volumes of material, and globally, there is the COVAX facility, and of course, others.

These do present unique challenges. The main question that we have been grappling with surrounds clear decision rights and governance, i.e. who should be making what decisions. While many companies have the capacity and certainly deep experience in making all these decisions for themselves, they now need to collaborate with others to ensure the consistent delivery of product into the market.

When that product is a COVID vaccine, companies also need to account for the many differences that exist, for instance, in the regimens and the distribution requirements of different vaccine candidates. Against the backdrop of those differences, an important consideration is how to minimize the degree of variability that frontline healthcare workers have to deal with so that the vaccination process can be more efficient. Given the importance and scale at which COVID vaccines would be deployed, it is essential to minimize the opportunity for human error, which can occur if an individual is confronted with multiple decisions to make.

Another interesting aspect is the decisions of many pharma companies to invest in so-called ‘at risk’ manufacturing to ensure that a vaccine can be deployed as soon as it is approved. What do you see as the downsides of this?

While we do not have insights into the details of these agreements so we can comment on them specifically, I would say in general, the idea is to look at the broader picture. What would ultimately be the final cost per delivered dose of a vaccine (candidate) and is that a reasonable price to bear in the context of the global pandemic?

You highlighted having worked on vaccine allocation mechanisms for the flu vaccine. Could you outline some of the considerations that would or should be going into these decisions?

In the US, a lot of these decisions are being made based on the Advisory Committee on Immunization Practices (ACIP) guidance that has been delivered at the Federal level. Within that, the States are the ones with the task of identifying the relevant patient populations and then ultimately determining the final allocation methodology. From a theoretical perspective, state-level allocation depends on a number of fairly tangible factors such as population distribution, size and characteristics of at-risk groups, and so on. These are the quantifiable bases on which state-level allocation decisions are made.

Where it gets interesting is allocation below the state level, i.e. which hospital system the product should be sent to? That can, in theory, also be determined through factors like the vaccination capacity of each hospital systems, which, in turn, depends on the distribution requirements of the product. For instance, a product that has to be maintained and distributed at -70 degrees C is much more challenging to work with. A single-dose vaccine regimen likely requires less

complicated planning than a double-dose vaccine regimen.

Another really interesting consideration comes in when a governmental agency may start calculating optimal distribution based on forecasted infection rates, with the idea that they could actually redirect vaccines into a specific area in advance of a predicted spike in infections. That is much more complicated because it is based on modeling and forecasting instead of quantifiable and observable elements, which means there could be different degrees of precision based on the tools used and the extent to which we are looking ahead into the future. Deloitte actually has a tool called , that can be used to forecast infection rates several weeks out, but if we want to optimize allocation decisions in order to preempt disease spread in the future, we would need tools that look beyond three or four weeks, which Deloitte is also in the process of developing.

The challenge with such an approach is that it becomes much harder to explain why a decision was made. A much higher degree of trust within the population is required, particularly in the institutions and stakeholders undertaking such decisions.

You mentioned the distribution requirements of vaccines being a consideration when it comes to facility of use and deployment. Taking into account the global scale of the COVID-19 pandemic, how would the need to, say, store a vaccine at negative 70 degrees Celsius affect its manufacturing and supply chain planning process? What should the companies that supply them and the health systems that would acquire them think about?

The important question that we have encouraged companies to ask is not how a COVID vaccine would be similar to what exists in the marketplace but rather, how it would be different. I think about this in terms of a ‘distributability index’: the more distributable a product is, the more people that product can reach. A product that has to be maintained at negative 70 degrees Celsius and requires 22 kilograms of dry ice to keep the freezer cold could be really hard to administer outside of large population centers. That being said, these are engineering challenges that have solutions and there are robust precedents for products with similar requirements being successfully deployed.

The real issue is not actually delivering the product into the market, it is ensuring that individuals are successfully vaccinated. For COVID, we are talking about huge numbers of people that would ultimately need to go through the vaccination process. Beyond the delivery of the actual vaccine to be used, what processes and pathways are involved in the vaccination of an individual? We need to

have healthcare personnel ready to administer the vaccine, we need to get the individual to the vaccination center, and so on. It is much easier to get the individual to the center once than to have him return in a few weeks for a second dose. This is the kind of concern that stakeholders need to look at.

Just looking within the US alone, we have a wide variety of population groups with different characteristics that need to be vaccinated. People in rural versus urban areas, people within at-risk populations, homeless populations, and so on – all have different access levels and behavioral factors that affect the likelihood of their being vaccinated successfully. In general, a product with a higher distributability index would be able to access a large portion of the overall population, whether we are talking about individual countries or the world as a whole.

As a hypothetical scenario, assuming that we have a number of approved vaccines with similar efficacy, I think it is reasonable that products with a lower distributability index could still be deployed within populations that are easier to reach, such as frontline healthcare workers. It is all about looking at the available vaccine options and then assessing the optimal portfolio and distribution of products based on the needs and characteristics of the population groups that need to be vaccinated that would ultimately improve community health outcomes.

Of course, the calculus becomes much more complex if different vaccines have different levels of efficacy, and especially if it is up to the frontline worker delivering the vaccination to select the right vaccine for the person in front of them. Here again, we return to the question of trust: the public would need to trust that the decisions being made are optimal for them and their communities. One critical aspect to remember here is that we are talking about complex manufacturing processes, which could come with challenges and missteps, so it is even more important for companies to build and then maintain public trust as they navigate these processes.

In your opinion, can the new models and levels of collaboration we have seen in the global COVID responses be transferred to other disease or public health areas that have thus far been neglected, like antimicrobial resistance (AMR) or other infectious diseases?

One clear trend is the evolution of public-private partnerships. From that perspective, vaccines have always been an underfunded space, just like the area of anti-infectives. For manufacturers to invest at scale is challenging because the returns are so uncertain. Another area with a different sort of challenge is orphan disease, where the cost of R&D and manufacturing is so much higher. In

that sense, I am optimistic that public-private partnership arrangements have been identified that could support the advancement of other therapeutic areas.

Another pattern is the increase in the rate of digitalization within manufacturing and supply chains. We have demonstrated many capabilities, including remote work, and so on, and I believe this will continue in the future. In association, we are also seeing the acceleration of investment in business process improvement and business continuity planning.

Moving from vaccines, cell and gene therapies is a space where manufacturing and supply chain aspects are much more central to the overall development process, and many have said 'the product *is* the process'. What are some of the important considerations in this space?

Certainly, as you alluded to, the degree of supply chain synchronization required to effectively deliver cell and gene therapies is really unparalleled across industry. Given that the pharma industry has lagged behind in terms of investment in supply chain, there is a gap that will likely need to be bridged so that cell and gene companies can move to the forefront of supply chain capabilities.

Currently though, cell and gene therapy manufacturing still operates on a relatively small scale. The bespoke solutions we currently have are adequate, but are relatively expensive and perhaps not as efficient as they could be. However, as the therapies mature and the volume of patients grows, corresponding increases in supply chain expertise and sophistication will be required. That is both a challenge and an opportunity that our life sciences clients do understand and are generally trying to tackle. We have had many conversations with them regarding both real world deployment of cell and gene capabilities as well as the development of these capabilities in the future.

Cell and gene companies will likely need to invest in their supply chain capabilities well in advance of the normal industry timelines. We are working with companies much earlier in the product life cycle, and much earlier in their business life cycle than we ever have in the past, because they have recognized the need to put these cutting-edge capabilities in place from the get-go in order to support bringing cell and gene therapies to the market.

To wrap up, digital transformation is a huge topic, and it has been accelerated by the COVID pandemic. What are the key aspects companies should be aware of, and how can Deloitte help them along this journey?

We are seeing clients pursuing digital transformation across multiple fronts. You can say it is the right step to take but you can also say it is the only logical step to take in order to stay competitive.

We are helping companies improve their visibility of their upstream and downstream suppliers and contractors. We are helping clients identify and then prioritize leading-edge technical capabilities that enable them to move product through to market with higher efficiency and less waste, and waste can be product, carbon emissions, and anything that costs a business.

We are helping clients shift their workforces away from more manual and labor-intensive processes, leverage the digital capabilities that exist to drive decision-making for the business, and move away from operations that do not add value.

Where Deloitte is really stepping in is to help clients not just define their future in this digital state but also helping them execute that vision pragmatically. We excel in that space. Many of our clients have what I consider a mature vision of where they want to be, and they just need help with organizing and driving alignment around that vision. Other clients do need a thought partner and an external organization that can challenge their thinking and bring new ideas to them.

In terms of digital transformation, a really important question clients are asking is, do I need to own and operate that specific capability internally or can I rely on an external partner? Increasingly, the client answer is, no, so that is an area where Deloitte is increasingly stepping in in order to provide these requested services.

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