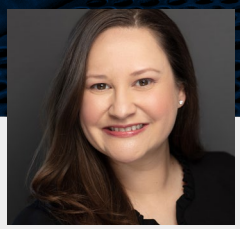
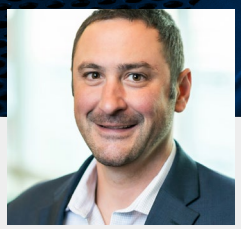
The road to a COVID-19 treatment launch

How pharma's supply chain partners are paving the way for coronavirus therapies

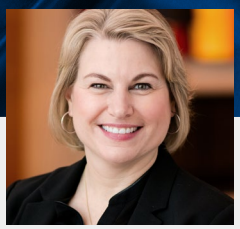
Beth McMahon,
Vice President, Specialty and Branded Sourcing



Summer Richoux,
Vice President, Sales, Specialty Distribution



Matt Sample,
Vice President, Manufacturer Operations and Supply Chain



Heather Zenk, PharmD,
Senior Vice President, Secure Supply Chain

What will it take to bring a treatment for COVID-19 to market? What have we learned from efforts to ensure supply chain stability at the height of the coronavirus pandemic? Leaders from AmerisourceBergen's Strategic Global Sourcing team share their perspective on how we'll make sure the right pieces are in place as manufacturers seek to commercialize new therapies.

Q: Reflecting back on the supply chain at the height of the COVID-19 pandemic, what have we learned that will inform our partnerships with manufacturers as we focus our efforts on emerging treatments for coronavirus?

Heather Zenk, PharmD, Senior Vice President, Secure Supply Chain: I think one of the main lessons we've learned is that we're much more resilient than we thought we were — the whole supply chain is very resilient. I think we should be proud of the resiliency. I think we should be proud of the innovation. I think the other lesson we learned is that, even though we're all really big companies, we can act very nimbly, very fast. And I'm not sure we thought that before COVID-19. We were used to a normal rhythm of contracting and product launches.

While we know some teams will want to follow the clinical data, when it comes to truly launching a new product, perhaps we don't need 18 to 24 months. We've proven we don't. We've done it super successfully multiple times now during COVID-19.

What COVID-19 taught us is that, if we really need to, we can really do some fantastic things and some very innovative things quickly.

The other thing we have to consider is the number of products that continued to launch, particularly in the oncolytic space, during this time. We saw significant product launches, even in a time of what I would call "un-normal" disease state progression and developments. That is pretty amazing — our manufacturer partners launched something like 20-plus products during the pandemic.

What we've shown is that the resiliency of the supply chain and the speed can happen if we have partnership in this and we're all rowing the boat in the same direction.

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Beth McMahon, Vice President, Specialty and Branded Sourcing: That's something that even the manufacturer would say. Typically, they're working with 18 to 24 months to launch a product in their pipeline. Well, in some of these pandemic-related cases, we've compressed this timeline to 30 days or 45 days or less with emerging therapies or therapies with COVID-19 indications. And so now we are all retooling the norm. Why does it take 18 to 24 months for a product in their pipeline? Should it take that long?

I think manufacturers are going to start rethinking launch plans and timelines, and whether we really need that much of a window. I think there's been a new norm set, and people are working faster, smarter, more efficient. We've been at our best operating with these hard deadlines and cutting out all of the red tape.

Q: What made COVID-19 significant in terms of forcing innovation in the supply chain?

Zenk: I think it's a combination of factors — we know the timeline crunch really helped, but it could also be that pressure of the government being involved. There's also a tremendous sense of urgency and passion knowing that everybody knew somebody who was touched by COVID-19. All of us know someone who tested positive or had a COVID scare, whether it was a family member or a child's teacher. Somehow, I think the massive disease state of COVID-19 and the amount of people impacted gave it a different level of urgency for the whole supply chain. We know it should matter the same for other diseases, and we've learned a lot that we can apply to chronic disease therapies, but COVID-19 really did trigger what we, as an industry, we need to reset our thinking on.

Summer Richoux, Vice President, Sales, Specialty Distribution: It was remarkable to see that sense of urgency carry over into our associate base. We had associates who thought it was so important to be a part of this that they shifted roles and responsibilities to help. That's just one of the ways we were able to be really nimble.

McMahon: It became more personal for all of us. We share a purpose with our manufacturer partners of creating healthier futures. I'm in awe of all of the science from our manufacturer partners with their product innovation and readiness, and I am truly humbled when we can partner together to bring life-saving treatments to the market. There's definitely a benefit of working with an organization with the size, the scale, the resources that are behind AmerisourceBergen. We have the bandwidth to repurpose and reprioritize based on the emerging therapies coming to market. In that respect, we stand ready for anything.

Q: How has the emergency use authorization for certain products impacted distribution planning, operations and inventory? And how has AmerisourceBergen pivoted to meet these new circumstances?

Zenk: The emergency use authorizations (EUAs) we've seen are very specific to the site of care where the product must be administered to the patient and attributes that must be met in order to use the EUA. That's really how the partnerships we've forged started: manufacturers are asking for some pretty specific guard rails around sites of care where their product can be administered. The EUAs also come with specific reporting requirements.

Matt Sample, Vice President, Manufacturer Operations and Supply Chain: Specifically, some of these EUAs actually call out that the allocation and distribution of that EUA-issued product will be managed by the government. We adapted by setting up a process by which we not only limit how we distribute and who we distribute to, but we also work with the federal government, and more importantly, the state departments of health. For example, the federal government would say Pennsylvania, you get 3000 cases of Product X this week. From there, the state would then work with us to actually identify the target hospitals for the EUA and what products actually shipped there. We had to build this process from the ground up.

McMahon: Both the EUA and the product attributes are driving the distribution channel strategies and the solutions that we've put in place for manufacturers and customers to receive life-saving products.

Q: What important industry partnerships have we tapped into in order to get new treatments to the patients who need them?

McMahon: Not only do we work with 99 percent of all commercialized manufacturers today, we've also leveraged our relationships in Washington, D.C., and with our customers, like the Department of Defense, to bring all these solutions and the products to market.

Sample: We built upon those existing relationships and then even developed deeper and new ones with the Department of Health and Human Services (HHS), the Assistant Secretary for Preparedness and Response (ASPR), and the departments of health, just on the process and allocation and delivery of medicines.

Richoux: We very much expanded what I would call our government footprint.

Q: How are we preparing for what's next? What new solutions or processes have emerged from our need to adapt to EUAs?

McMahon: In these instances with the EUAs, we're seeing the government intervention upfront because of the scarcity of product, or government intervention while there is scarcity of product, where they are driving the allocation and therefore taking that burden off of the manufacturer and/or the distributor.

Richoux: We are seeing the government take part early on and help allocate, but we adapted very well when it came from multiple teams coming together. So you've got Matt's team in Manufacturer Operations that is helping very much with the analytics and the data and helping us actually build the templates that we would arm state departments of health and customers — hospital entities in this instance — with so that we could get their orders. And then we had a very warm handoff from his team to my team when it comes to customer facing sales where we're working to actually make sure the product is going to where it's needed the most.

Zenk: At this point, we've seen multiple iterations of how a product comes to market when it gets EUA. From helping ship into hot zones to advising and partnering with state and federal agencies to build the process Matt mentioned, then outlining how to transition back to a full commercial state, we're experts at this. Our partners got to see that in real-time as we got product to patients.

It was all about being nimble. We're calling these health systems directly saying "you've been awarded allocation. Do you have enough physical space? Do you feel you have the clinical need for it?" Some of our customers are taking less inventory because they have limited space, while others are giving inventory because they think it's in short supply and they're acting as a community to ask us to reallocate it to somebody else that might need it more. Some are telling us yes; they need all they've been allocated. We have the capability that, if there is an emergency or something that pops up unexpectedly outside of this, we can modify our cycle of working with the state and the hospitals.

McMahon: The other important piece is our footprint within health systems. We have access to 99.9 percent of health systems today. Knowing that, manufacturers can be confident that their specialty distributor has nearly complete coverage of all health systems and locations on a national scale. And for any outlier, it takes us less than 24 hours to set up a new customer.

Richoux: One thing I've noticed that is really key is that this "dream team" we've built demonstrates our ability as a large organization working with another large organization, like the manufacturer and then the government, but still being able to be very nimble. That is key here. We were able to pivot and contact the customers really quickly, really efficiently. And again, everyone had the same goal and it was to get the product — the very, very important product — where it's most needed. I think we can all agree that happened, and it was because of everything we built through the process.

Q: How has the perception or understanding of AmerisourceBergen's role in healthcare evolved as a result of our efforts, both at the height of COVID-19 and as brands look to launch new therapies to treat the virus?

McMahon: There's been continuous improvement on the processes and the procedures that we were able to implement and realize. For example, we discovered certain processes for shipping weren't ideal, the partners we were working with weren't set up for that. But then we could partner with the states and say, well, we'll do it for you.

Richoux: We bridged the gap between what the manufacturer's capabilities were and what the federal government's capabilities were. We really were that glue that held the supply chain together. Without us, neither the manufacturer nor the government would have had a partner to execute on EUAs.

In addition, even though we may have been expected by manufacturers, as well as the government, to execute a certain task — getting the product to where it's needed — the fact that we were able to actually collect really pertinent customer insights along the way became an asset, too.

Sample: We really saw evolved expectations from manufacturers because of what we were able to do. I don't think it was the expectation upfront.

Zenk: Absolutely. It might not have been expected initially, but now we're getting calls from manufacturers and we are being seen as an industry expert or leader here. We have subject matter expertise about the various stages and steps. We're actually seeing that some of the questions our manufacturer partners are getting from the government stem from our insight on how the allocation process could be improved.

Q: What could this evolution mean for the future of other therapies?

Zenk: The fact is, these capabilities are here for any new product launch. While COVID-19 was certainly a deep situation, these are things we can execute for any new product. We're raising the bar for supply chain sophistication and efficiency.

If we can pivot for COVID-19 and multiple products in this disease state, think of what we can do for other critical and chronic illnesses. Our sales teams become almost an extension of the manufacturer sales organization.

Richoux: We can do this for any product, and that's the beauty of it. We can be this nimble for any product segment — cell and gene therapies and other emerging treatments. We absolutely are ready to be that essential partner for commercializing these new drugs.