NOVEMBER 2020

Pharmaceutical® Executive

MASTER THE SCIENCE OF SUCCESS

Virtual Drug Commercialization: Connecting with Customers in the Era of COVID-19

This custom ebook is sponsored by AmerisourceBergen and presented in partnership with *Pharmaceutical Executive*.

AmerisourceBergen®

The Pharma Supply Chain: Responding to COVID-19

Heather Zenk

Assessing evolving practices in protecting the supply chain amid pandemic, including partnering and planning for what's next.

Every day, pharmaceutical distributors ensure the safe, efficient, and reliable delivery of 92% of the medicines purchased in the US, reportedly connecting 180,000 providers and pharmacies with 1,300 drug manufacturers nationwide. Now, amid the COVID-19-a global pandemic for which the world was not ready-it is both humbling and an honor to continue this work, despite many challenges. The US healthcare system, from pharma manufacturers and distributors to providers and pharmacists, has come together to make sure as many critical medications as possible reach the patients who need them most.

As we look to the next phase of the pandemic response and maintain our long view on protecting the supply chain, it's critical we take stock of what has already evolved and how distributors can continue to provide stability. That work includes protecting in-demand medicines, ensuring safe product handling, and supporting clinical trials. It also means partnering across the supply chain to anticipate the next set of provider and patient needs and planning for them now.

"Distributors needed to evolve their allocation strategies to reflect the specific realities of a pandemic, such as the emergence of 'hot zones.'"

Safeguarding In-Demand Medicine

When products are in or have the potential to be in short supply-either due to a surge in demand or a loss of production-distributors will often put those products on "allocation." This means any one site of care can only order a certain volume of that product, based largely on its ordering history, so all sites of care can maintain a level of access.

Using a "fair share" allocation program helps ensure that well-meaning health systems, pharmacies, and providers do not unintentionally overstock a product out of fear of a shortage and, ultimately, cause an access issue at another site of care. These programs also help prevent the over-concentration of resources at any one site of care and allow the supply chain to maintain its flexibility and responsiveness.

In March, distributors saw unprecedented "surge ordering" across distribution networks. All at the same time, pharmacies, hospitals, and health systems throughout the US placed orders at volumes above historic purchase levels. For example, over the course of a three-day period, between March 12–15—from the day the novel coronavirus was declared a global pandemic and when stay-at-home orders started rolling out across the country—AmerisourceBergen saw a nearly 50 percent surge in orders and distribution. We quickly responded and went from distributing approximately four million products per day to nearly 6.5 million.

As a result, distributors needed to evolve their allocation strategies to reflect the specific realities of a pandemic, such as the emergence of "hot zones." AmerisourceBergen realigned allocation programs to provide additional support in regions reaching the top of the COVID-19 curve and accounted for an increase in ICU beds and "pop up" clinics or hospitals in certain locations.

Now, we are seeing the supply chain continue to stabilize. But, we still face potential challenges with key products such as: ventilator and intubation drugs; sedatives; azithromycin; insulin; injectable narcotics; and experimental COVID-19 therapies.

As the pharmaceutical supply chain collectively navigates forward, distributors, drug manufacturers, and sites of care will need to continue to communicate and collaborate as clearly and often as possible. Together, these parties will monitor inventory levels and purchasing behaviors, so they can manage supply and demand updates.

But, most importantly, this partnership is what will allow us to continue to quickly meeting patient needs, however they may evolve.

Ensuring Product Handling Safety

Additionally, at the start of the pandemic, distributors were-and remain-acutely aware that every shipment contains products that eventually treat patients, many of whom could have underlying conditions that make

them especially vulnerable to COVID-19. Not to mention, distributors' own associates are part of the front-line workers who are making sure warehouses stay operational and the supply chain, as whole, remains functional. Meaning, it is critical these individuals stay healthy in order to continue ensuring essential medicines, such as those for heart disease, diabetes, cancer, and other conditions, reach patients.

For all of these reasons, product distribution centers (DCs) across the globe implemented and have now fully adopted additional cleaning measures.

For example, all of AmerisourceBergen's healthcare distribution facilities have been using Shockwave and other powerful EPA-approved disinfectants to clean multiple times a day for several months. BruTab 6S is sodium dichloro-s-triazinetrione (NaDCC) and is included on the Environmental Protection Agency's (EPA) list of approved disinfectants. It produces an available chlorine solution proven very effective as a disinfecting and sanitizing agent against a broad spectrum of micro-organisms, including COVID-19.

Teams at DCs continue to be extremely diligent in disinfecting associate working areas daily, while also increasing screenings for visitors, couriers, and partners. In addition, all drivers must confirm that pickup or delivery contacts are not known or suspected to have COVID-19 and arrange for contact-free deliveries or pickups whenever possible.

Documents signed by shipper or consignee and retrieval of monitors, packaging, or return shipments are also being arranged in a way that avoids physical contact whenever possible. For example, shippers have been avoiding the use of sharing pens by waiving the signage requirement or asking the consignee to use his or her own pen. Even when protected, though, one of the most universal directives is limiting person-to-person contact. In some cases, that means creating processes that involve as few points of contact as possible.

Supporting Clinical Trials

At the same time that patients are being asked to stay at home, pharma manufacturers are working to find a COVID-19 treatment while also advancing care for all other diseases-and one way is through the use of clinical trials. To protect these trials and ensure patients are able to participate, many manufacturers are working with their logistics partners to explore or implement new models, including direct-to-patient (DtP) options.

Recognizing clinical trial participants are often patients with chronic conditions or part of particularly vulnerable populations, DtP services allow patients to remain at home, following the current guidance of public health officials (i.e., social distancing and self-isolating). Patients can continue to access novel and life-saving therapies without having to put themselves at risk by traveling to hospitals and infusion clinics for treatment, and manufacturers are still able to collect critical data that will ultimately support the approval of their innovative therapies. This approach has proven so successful that specialty logistics providers

are able to map increased interest in DtP services in correlation with the spread of COVID-19. The industry first saw an increase in the use of DtP models in China and Europe and is now seeing those same inclines in North America.

Looking ahead, though, just as specialty logistics providers are tracking and anticipating rising interest in DtP models, patient support services companies are also seeing an increased need to support patients in coping with the other effects of COVID-19, including economic hardships.

Deploying Critical Patient Support

A record number of people lost their jobs in the US as businesses temporarily closed in the wake of "stay at home" guidance. In fact, more than 43 million Americans have filed for unemployment aid since the US declared COVID-19 a national emergency-the highest loss of jobs since the Great Depression. This economic downturn has created a significant spike in uninsured and under-insured patients, which has also created an increase in Medicaid claims and higher demand for patient assistance programs (PAPs) or patient copay programs.

Patient support providers are a vital link that enables the type of industry-wide collaboration that's needed to address patient access, affordability, and adherence issues now to make a substantial impact in the future.

Pharmaceutical manufacturers have already begun working with PAP providers to understand the scale of need within their specific patient populations and developing plans for how to provide appropriate support. Additionally, they are working with partners, such as distributors, to design what those programs would look like based on possible scenarios and identify, now, the trigger points for implementing them.

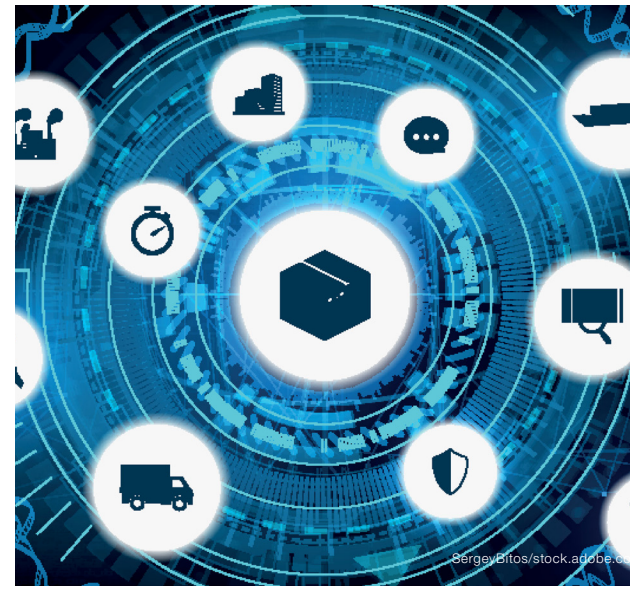
Ultimately, as all stakeholders in the healthcare system continue to battle this global pandemic, throughout its many stages, sustained collaboration—especially between manufacturers and their distribution partners—is essential.

With an understanding of the efforts distributors are taking to protect access and support patients, manufacturers and distributors can navigate whatever unique supply chain challenges may come.

Heather Zenk

Senior Vice President,
Strategic Global Sourcing at AmerisourceBergen

This article first appeared in *Pharmaceutical Executive*, 40 (7), 32-33 (2020).



The Future of Payer Engagement: How Pharma Can Break Through

Interview with Matt Sarnes, PharmD, and Allen Lising

Payers and IDNs representing over 275 million covered lives access a single platform for pertinent product information. Learn how to meet them where they are.

Xcenda's Senior Vice President, Business Development & Strategy, Matt Sarnes, PharmD, and FormularyDecisions' Managing Director Allen Lising share insight on the product information payers and other healthcare decision makers (HCDMs) find most valuable.

Q: How much progress has the healthcare industry made in driving meaningful dialogue on product value between pharmaceutical companies and formulary decision makers?

ALLEN LISING: As the number and complexity of products coming to market continues to increase, payers are asking for product information to guide their formulary planning and budget forecasting earlier in the development process.

Supporting the bi-directional exchange of information between payers and life science organizations is one of the keys to unlocking real value in pharmaceutical-led care by driving value-based reimbursement decisions. When we joined Xcenda last year, the

most exciting aspect of combining the FormularyDecisions technology and payer community with Xcenda's leading global market access and health economics expertise was the opportunity to deliver more information on pipeline and approved products directly to payers, and deliver more actionable insights on payer needs to manufacturers.

Q: Where are you seeing the most activity in terms of information exchange between pharma and payers?

MATT SARNES: Data from FormularyDecisions shows the therapeutic categories most reviewed by HCDMs in 2019 were oncology, neurology, infectious disease, rare diseases and autoimmune disorders. The high activity in these disease areas aligns with product launch activity in these categories, with oncology having 10+ products come to market in 2019.

Interestingly, HCDMs not only reviewed pre-approval product information, but also information on existing products in those same therapeutic categories. Of the almost 23,000 hits on oncology products in 2019, existing oncology product pages accounted for more than two-thirds of the page views. This likely reflects payers' need to understand both the new product and competitive products in that space.

"The top product in terms of reviews by payers in 2019 was actually not an oncology product, but a rare disease product, Zolgensma, with almost 2,000 page views over the year."

The top product in terms of reviews by payers in 2019 was actually not an oncology product, but a rare disease product, Zolgensma, with almost 2,000 page views over the year.

Q: When are HCDMs most likely to review product information?

MS: For the first quarter of 2020, HCDM activity on the platform continues to align around product launches. In fact, five of the top 10 most reviewed products during the quarter launched in either Q4 2019 or Q1 2020. Our data also shows that HCDM activity around a new product or indication starts to increase significantly 4-6 months pre-launch and stays elevated through a five-month post-launch period.

Q: Where/how are payers accessing the information they need on these products?

MS: The use of FormularyDecisions among HCDMs continues to increase. That's on top of the existing base of 2,100 registered users representing 275 million covered lives. In 2019, we saw more than 1,200 logins per month. Session time—the amount of time a payer spends evaluating information, so to speak—also increased by 35% (or almost 30 minutes per session). This indicates that HCDMs are finding the relevant and consolidated information useful.

AL: Our community of payers has expressed the desire for manufacturers to put more information on the platform, especially during the pipeline phase when there is a

dearth of information. When manufacturers add information to the platform, whether clinical trial information in the public domain or an eDossier for payers to request, we see double digit growth in overall product activity by HCDMs on those products.

FormularyDecisions continues to be a valuable centralized resource where HCDMs can conveniently access information when they need it and directly request more information from the more than 500 manufacturers connected to the platform as needed. More than 1,700 new dossier requests came through the platform in 2019. We also see a significant uptick in engagement with PIE webinars and other features that facilitate collaboration.

Q: What does the future look like for this kind of information exchange?

MS: Data from first quarter 2020 showed a greater than 100% spike in user activity in both March and April, with over 2,000 page views in the platform per working day. Even though the world was already on the path to various forms of digital engagement and immediate access to data, the COVID-19 pandemic certainly accelerated both innovation and consumption of technology in the healthcare space. Now that many manufacturers are finding themselves launching products in a virtual world, we'll no doubt continue to see use of the platform grow.

Pharma CEO Leadership During Pandemic

Lisa Henderson

A recent roundtable moderated by Dr. Scott Gottlieb gathered biopharma CEOs to share thoughts and strategies on navigating their companies through the COVID-19 outbreak.

Michael J. Hennessey, Jr., President and CEO of MJH Life Sciences, the parent company of *Pharmaceutical Executive*, convened a closed roundtable of pharmaceutical CEOs in mid-May to discuss the industry's pandemic response and preparations for an as-now uncertain future. The virtual roundtable was moderated by Scott Gottlieb, MD, former FDA commissioner and, more recently, the go-to, non-partisan expert on COVID-19 developments and CNBC Contributor on the topic. Gottlieb received kudos from all the participating leaders as the voice of science and reason, providing the public balanced insights as the pandemic unfolds.

Overall, the gathered leaders, representing various therapeutic areas, revenue-sized companies, and states of commercialization, are optimistic and predict the industry will rise to the myriad pandemic challenges, ultimately transforming public perception and elevating science.

"Incyte has been working on potentially treating COVID-19-associated cytokine storm."

Gottlieb provided a snapshot of where the US was in relation to COVID-19 in mid-May before observing the specific nuances faced by these leaders and asking for their experiences, which included working with the FDA around COVID therapeutics, as well as other therapeutic areas; clinical trial issues such as protocol amendments, trial suspensions, or dwindling recruitment; product launches; patient access to therapies for disease management and outcomes; and longer-term business operations.

Regeneron has been on the front lines of COVID-19 therapeutics development using its VelociSuite technologies to develop a novel cocktail of fully human antibodies that are specifically targeted at the SARS-CoV-2 virus. It jumped into gear to address COVID-19, said CEO Leonard S. Schleifer, MD, PhD, in the early part of January, identifying the most potent and effective virus-neutralizing antibodies and scaling them up using Regeneron technologies (the company's antibody candidate entered clinical trials in June.

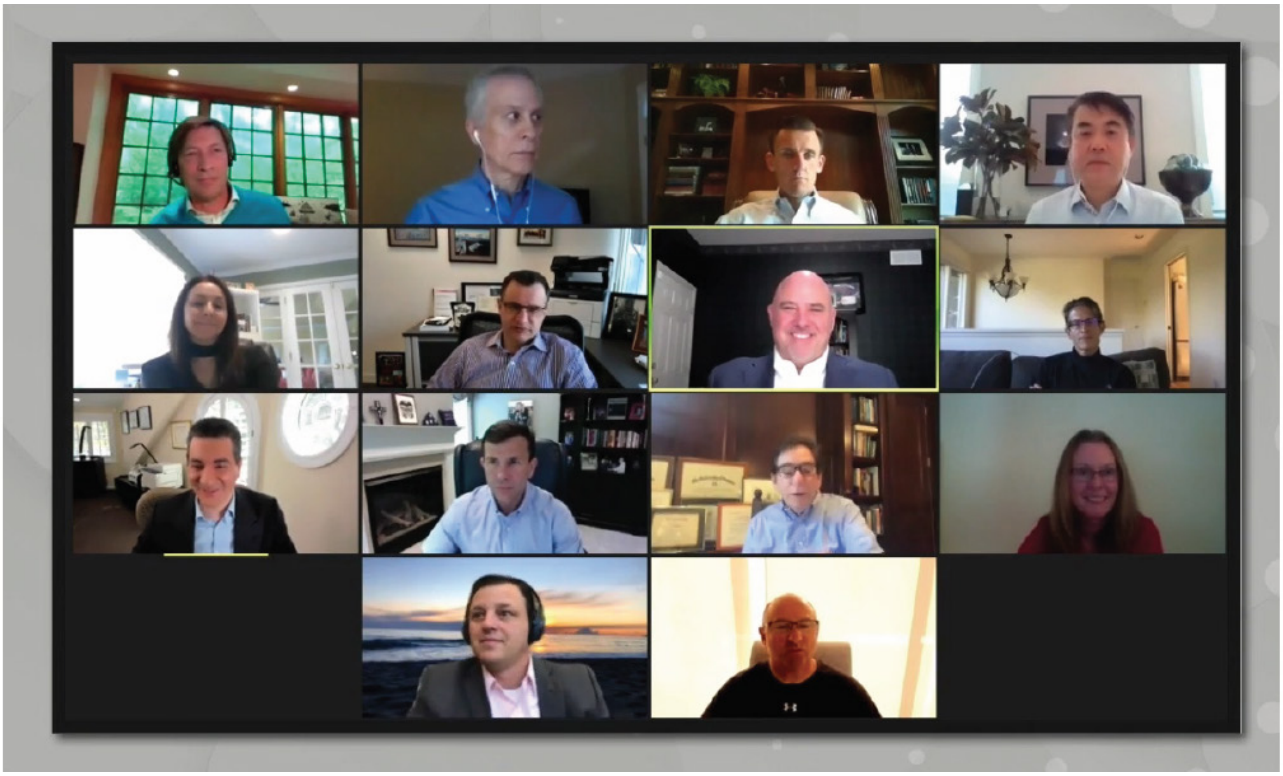
At the other end of the spectrum is Michael Castagna, CEO of MannKind, whose COVID "a-ha" moment was around manufacturing and the company's dry powder capabilities. He asked: "Is there an opportunity for us to take someone else's therapy and replicate that into our inhaled platform and scale that up?"

Clearly, none of the potential treatments can advance without regulatory authority approval. Michael G. Kauffman, MD, PhD, CEO of Karyopharm Therapeutics, described how he and co-founder Sharon Shacham decided to look hard at COVID-19 and test low doses of its anti-myeloma drug, which has both anti-inflammatory and antiviral components. Most striking to Kauffman was the speed with which the company was able to secure a clinical trial protocol "in a disease that we and most other people knew nothing about." Within two weeks, the protocol was turned around by 10 different global regulatory bodies and it opened up for patients in three weeks. "It really tells you what is possible when most obstacles are eliminated," said Kauffman. "And this is tenfold faster than we've ever done in the past."

Incyte has been working on potentially treating COVID-19-associated cytokine storm. President and CEO Hervé Hoppenot said of Incyte's efforts, "Although virology is not our area of focus, we quickly realized that inflammation may play a key role in severe COVID-19 patients and mobilized our teams to initiate trials to hopefully answer some key questions."

Like Kauffman, Hoppenot also witnessed efficiency-RUXCOVID study protocol was written with its large pharma partner, Novartis, over a weekend to submit to the FDA on a Monday morning. "The level

PHARMA CEO LEADERSHIP DURING PANDEMIC



of urgency was very clear," he said. "We quickly decided to move forward with the RUXCOVID study, where we are trying to determine whether treatment with ruxolitinib can prevent the inflammatory cascade that results in serious complications in many patients infected with the virus."

This level of cooperation, collaboration, and speed has not gone unnoticed outside of COVID-19 trials. For example, in oncology, Hoppenot noted Incyte had three reviews ongoing with the FDA's Oncology Division during the early stages of the pandemic, of which two are now approved. Said Hoppenot, "There were all kind of issues including the inability to perform site inspections; it was interesting to see the adaptability of the FDA and the commitment to keep things moving."

Kauffman concurred. "[The oncology division] has moved with our sNDA. They haven't slowed down, which is important for cancer patients." So too with Clay B. Siegall, PhD, president and CEO of Seattle Genetics Inc., which gained two approvals during the early pandemic in breast cancer and bladder cancer. Siegall said, "The FDA has been incredibly collaborative. Rick Pazdur has been innovative and forward-thinking; driving a number of initiatives to rapidly bring important medicines to patients in need."

Liz Barrett, president and CEO of UroGen Pharma, said the pandemic began during the review of its first NDA, and found the FDA was very engaged, and received approval prior to the PDUFA date for its therapy, the first non-surgical treatment for upper tract urothelial cancer. She said, "I think the agency really understood the high unmet need and wanted to get this product to patients as quickly as possible."

FDA has also responded outside of oncology. Steven Lo, president and CEO of Zosano Pharma, whose NDA of its microneedle patch technology with a migraine drug was submitted in December, said: "One of the big questions for us was what's going to happen with the FDA? But our NDA was accepted in March, right on time. We have had productive interactions, and it certainly appears the FDA is humming along quite fine."

Product launch

Of course, amid FDA's approval output during this period, the subsequent product launches will require attention in the pandemic environment.

Tim Whitten is president and CEO of Taiho Oncology, which has a PDUFA date in August, and is preparing to launch its product. "Our sales representative are getting trained virtually. It goes beyond just disease training and product training. We want to understand how our customers want to interact with us. In addition to ensuring our field personnel's adherence to new state rules and requirements in terms of PPE and similar requirements, we're training our employees and our sales reps and MSLs on how to conduct better virtual interactions-everything from logistics to lighting, giving them better cameras-so that when they do have access they're able to have an effective interaction."

"As they say, 'Necessity is the mother of all invention,'" noted Barrett. "As an industry, we have talked about digital for a very long time and we all have digital as part of our plan, both from a commercialization and a development perspective. This is forcing us to accelerate the adoption of digital tools." UroGen was launching its aforementioned approved Jelmyto on the day of the roundtable at the American Urological Association's annual meeting, with its physicians presenting virtually. Barrett shared, "Over the last couple of weeks, we had face-to-face Zoom meetings with physicians. We have shifted our events and meetings to virtual, and we've had willing audiences of physicians and patient groups who all want to engage."

Looking forward, Lo asked the participants what launching products might mean post-pandemic. Zosano, should it receive approval on its PDUFA date in October, is rethinking how to allocate resources. "We have to acknowledge the fact that not every physician is going to be happy to see a sales rep or a medical science liaison walk into their office, and we have to reshuffle some of the targets in terms of the number of people that you would need for a launch in our particular space," said Lo.

Clinical trial concerns

Gottlieb wondered if oncology clinical trials were a special case, as most studies that have been suspended are non-cancer related.

Siegall seemed to think so. "Our trials are still ongoing and enrolling. I think oncology is a special case. Outpatient oncology facilities have largely stayed open," he said. "It gets complicated if you need PET scans or if you need to go to a hospital for a test; that can make a trial more cumbersome. But I think

cancer is unusual in that the clinical trials are still going strong. In different, non-cancer applications, it's bumpier."

John F. Crowley, chairman of the board and CEO of Amicus Therapeutics, spoke to the rare and life-threatening disease aspect, citing its Phase III program in Pompe disease. Crowley shared that Amicus's therapy was being made in China with WuXi Biologics, in a program that required, logistically, getting product patient-by-patient, site-by-site, with about 60 different sites on six continents. "The rare disease community-the patient groups, the individual investigators, the hospitals, the IRBs stepped up beautifully," he said. "In one of our studies, we had to move patients to home infusions. We thought that could take up to six months. We did it in less than three weeks for all those patients."

Oncology-focused biotech Exelixis was executing on nine pivotal trials globally, with plans underway to initiate three additional studies, when the health crisis ensued. Michael M. Morrissey, PhD, the company's president and CEO, said that despite its scalable technology platform and seasoned and sizable staff, "it's been a workout." He described going to a "SWAT team level where we're literally tracking every trial, every patient, every scan, every delivery of drug literally every day."

Exelixis also unblinded a large global pivotal trial with Bristol Myers Squibb, which Morrissey said went well even though it was a huge undertaking to achieve remotely with two different companies on two different coasts. "It reinforces the idea that if everybody's aligned, and there's the right level of leadership and commitment, you can get a lot done under less than optimal circumstances," he noted.

For Whitten, though accrual has slowed, Taiho Oncology didn't consider closing clinical trials. "We have several trials for which we finished enrollment, but still have patients in those trials. We've put much greater scrutiny on ensuring patients and investigators get reminders to come in for scans and bloodwork. And so far, we haven't had one patient who has missed a scan or their bloodwork. It's a balancing act. You don't want to put an undue burden on your investigators by overcommunicating, but we felt it was really important that we maintain quality."

Barrett, peering at the future of clinical trials, noted the likelihood of more virtual activities such as wearables and monitoring patients. She also noted on a recent call about UroGen's ongoing studies-they've shifted from purely traditional studies to real-world evidence (RWE) studies, which she believes will be a continued shift in drug development.

"Exelixis also unblinded a large global pivotal trial with Bristol Myers Squibb, which Morrissey said went well even though it was a huge undertaking to achieve remotely with two different companies on two different coasts."

Gottlieb, too, referenced RWE, and said, "Trends that have been underway for a while in terms of different kinds of evidence generation, different kinds of clinical trial designs, are going to be accelerated in this environment as both companies and regulators realize that we're going to need to do things differently for an extended period of time and maybe in perpetuity as a result of COVID."

ImmunoGenesis was the only startup represented at the roundtable. CEO and President James Barlow, Jr., believes its lead asset provides a superior foundation of PD-1 pathway blockade. The company is trying to raise Series A funding; the pandemic has made it easier to reach investors, Barlow said, and there is clearly still funding available. But Barlow noticed some hesitancy as certain VCs are focused on shoring up existing portfolio companies rather than speculating on new ones.

However, since ImmunoGenesis is trying to get into the clinic rapidly in a very competitive immuno-oncology environment, the choice of vendors for pre-IND activities is important. While working with MD Anderson Cancer Center initially, it was impacted by shutdowns. Barlow said, "Moving forward, I think we need to look at non-academic choices, the Charles Rivers of the world, to make sure that we can keep things moving and keep hitting our timelines."

Patient access

UroGen's Barrett noted pandemic effects on its current Phase IIb study, which has seen a delay in patients coming in for follow-up, due to safety concerns. She predicts a shift of trials from large academic centers into large community practices because patients will be less inclined to enter institutions also treating COVID patients. "Much of the recent literature shows that up to 40% of cancer patients are not going in to see their doctor," said Barrett. "As an industry, we owe it to the patients to help them understand that it is safe and that they need to make these visits because we don't want them to delay treatment."

Access to safe treatment environments for patients is closely coupled with their ability to pay for treatments. For example, patients who can't afford or have inadequate insurance can use Taiho Oncology's patient access program to get their drug for free from the company. Said Whitten, "Once the pandemic hit, for every three patients that are getting our drug and we're getting reimbursed, we have one that's getting that drug free. That's increasing and I think it'll continue to go up because our drug is for metastatic gastric cancer and metastatic colorectal cancer, which tends to affect seniors. And if you're on Medicare, relying on Social Security, it doesn't matter if you have a copay of $300 or $3,000, you can't afford that drug. We're very fortunate we can help meet the increasing need and ensure those patients have access to their drug."

Similarly, for Zosano Pharma, Lo explained: "Most of us have set aside resources for copay assistance. We always want to take care of patients. I think it's fair to say, in this environment, we have to make sure we don't underestimate the amount of patients who could become or are uninsured, or who

would need more copay assistance or help. That is true in the migraine space, and it's caused us to rethink our financial models around patient resources."

Incyte's Hoppenot believes the pandemic has put a "magnifier on the dysfunction of the healthcare system" in the US as it pertains to patient access to doctors, tests, and treatments. "It was very clear, very early on that access to doctors and access to tests were prevented by the copay organization used by insurers," he said. "They are penalizing people for seeing their physicians. They are penalizing people for getting prescription drugs, for getting a test. [The pandemic] started at the beginning of the year when many people are still in the deductible phase of their plan. I think this had an impact on the speed at which this disease was treated and diagnosed compared to other countries. This issue of access needs to be addressed."

Leadership matters

For many of the leaders, ensuring employee safety and maintaining communication during and after the pandemic is key. Crowley created a taskforce of 100 (of its 600) employees to "Help me to reimagine what Amicus looks like on the other side of this. We call it our R3 project - rediscover, reimagine, and reinvent Amicus." The project includes questions about how, when, and where do the employees work? It could be that some jobs will be five days a week in the office, others entirely at home, or a hybrid. "I think when we're together, let's not be running from meeting to meeting," said Crowley.

Siegall thinks coming out of COVID-19 that his company's commercial staff will be more remote, and thus the amount of real estate needed will be less. Conversely, Seattle Genetics owns and operates one manufacturing center in the US, and is going to build a second. "We are going to bring in more manufacturing that we can control," said Siegall.

Castagna noted that the pandemic has been an opportunity to lead employees through tough times. "We haven't furloughed or laid off anybody and actually hired 13 people over the last two months," Castagna said of MannKind.

Taiho Oncology has also onboarded about 20 people during the COVID-19 pandemic; Whitten is happy to see people that are willing to join the company amid the difficulties of determining culture fit in a virtual environment.

"Our motto is PACT. *P* for people, and that includes employees and patients, *A* for accountability, *C* for collaboration, *T* for trust," explained Whitten. "How we make decisions will not change from those operating principles. What will change is how we implement and operationalize some of those decisions."

"While lessons applied internally will have great impact, the expert learnings and achieves may herald a new beginning for the biopharmaceutical industry."

Industry's finest hour

While lessons applied internally will have great impact, the external learnings and achievements may herald a new beginning for the biopharmaceutical industry.

With Hoppenot, the focus is on his experience with Novartis in the decision to move forward with the RUXCOVID trial. "It was a new way of thinking; one that focused on quickly finding solutions to problems in a highly collaborative manner," he said.

Kauffman's similar lightning-speed experience getting into trials led him to observe that, hopefully, "we'll be able to at least not go back to six-to-nine months to start-up and begin enrolling on a protocol, especially for patients with severe illnesses like cancers."

Gottlieb shared, "This once-in-a-generation pathogen has put a spotlight on the life sciences industry like nothing really has in modern times. And everyone's really looking to the industry for hope and for a way out here, and it's ultimately going to be something definitive with our technology that quells this epidemic and gives us a definitive end to it."

Barrett added, "I hope we will take this opportunity to ensure we don't revert back to the negative public sentiment of our industry prior to this pandemic. We need to take advantage of educating the typical consumer about our industry and the benefit we bring to human health."

Crowley said, "Just like physicians and nurses have taken an oath to heal the sick, we as innovators in this business have taken an oath to make the best medicines and to ensure access as broadly as possible. And I think by the actions that we've shown and hopefully will continue to show, this will be our finest hour."

Schleifer concluded, "This is an existential moment for the industry. I think we will rise to the occasion. I am excited about the number of different companies trying incredibly novel approaches for vaccines, the number of companies who are trying different therapeutics. We have to do it scientifically, and we have to do it in an affordable, successful way. If we do, we'll change industry and, frankly, we'll change society for a long time."

Lisa Henderson

Lisa Henderson is the editorial director of *Pharmaceutical Executive*.

This article first appeared in *Pharmaceutical Executive* 40(7), 18-22 (2020).


We’re still optimistic about the future of healthcare
Discover inspiring stories, illuminating insights, and actionable guidance on the issues that matter most to healthcare
Visit us at amerisourcebergen.com/insights
AmerisourceBergen®

Selecting the Right Message: Tips and Solutions for Pharma Manufacturers

An interview with Jay Dombi

In the era of COVID-19, the influence and reach of product messaging are more crucial than ever.

The COVID-19 pandemic has greatly affected how product messages are shared and how appropriate audiences are targeted, especially for pharmaceutical manufacturers. Whether it be in person, digital, or paper, when it comes to getting messages to the right audience, a new normal requires a new approach, according to Jay Dombi, Vice President of Specialty and Branded Strategic Planning at AmerisourceBergen.

Pharmaceutical Executive spoke with Dombi to discuss challenges, strategies, and solutions for reaching the right audience for product messaging in the era of COVID-19, and beyond.

PHARM EXEC: **What are some of the biggest challenges that pharma manufacturers are facing right now when it comes to getting their product messaging in front of an audience that can influence uptake?**

DOMBI: Without a doubt, COVID-19 is impacting all of us. With that said, it's particularly impacting manufacturers' ability to reach customers. Social distancing means limited or no face-to-face product

marketing and education opportunities that would typically happen in person with prescribers and key opinion leaders, which are the ones driving uptake of new and existing medications. This is further compounded by fewer new prescriptions as patient office visits have declined. And for their part, patients are experiencing the highest unemployment rates we've seen in years.

According to the nonpartisan Kaiser Family Foundation, an estimated 27 million Americans have lost coverage during the pandemic (1). Many of these Americans are on multiple medications for chronic illnesses, and that means they may be looking for lower-cost prescription alternatives. This is exactly the type of information that many pharma manufacturers would love to get into the hands of providers, but they're just unable to right now.

PHARM EXEC: Who are some potentially overlooked influencers? Why is it important for manufacturers to message and market to pharmacists?

DOMBI: Potentially overlooked influencers include the pharmacists and the pharmacy staff. For years, pharmacists have been consistently ranked near the top of the most trusted healthcare providers (2). Despite this, many pharma manufacturers still don't think that pharmacists play a significant role in prescriptions besides filling them.

Whether it's acting as health coaches, wellness guides, and even financial advisers, pharmacists and their staff have considerable influence on patients. Hence, manufacturers need to avoid thinking pharmacists don't have a role in patient decision making.

It's important to note that titles don't really tell the full story when it comes to influence on patients. Since the tech is the one frequently doing the ordering, filling, and working with patients, what a pharmacy technician sees in a marketing message is almost as important as what the pharmacist sees.

Additionally, pharmacists play an ever-expanding role in medication adherence. According to a 2019 NCPA Digest study, 91% of independent pharmacies offer some sort of medication adherence program, and 39% of pharmacists have a collaborative drug therapy agreement with a physician, which gives them the additional flexibility to help patients identify alternative therapies (3).

Further, as the role of pharmacists continues to expand—which is certainly only being accelerated by COVID-19—some states are allowing pharmacists to suggest alternative therapies without a doctor's consent. For example, the state of Texas now allows pharmacists to choose the appropriate biosimilar for a patient when receiving a script that is written as a chemical similar to a generic (4).

As more physicians and health systems adopt electronic prescribing and electronic health record (EHR) systems, more scripts are reaching pharmacists as chemical names; this gives more choice to the pharmacists. As more biosimilars, authorized generics, and other similar products are launched, this provides pharmacists more choices to help patients find financial alternatives, the products that work best for them, and so forth.

What does this ultimately mean for manufacturers? As pharmacists have a growing

SPONSORED CONTENT

Case Studies: The Power of Multichannel Marketing

role in advising patients by helping them find lower-cost alternatives and pointing patients toward manufacturer-sponsored adherence programs, it is critical for manufacturers to get their messaging to pharmacists.

PHARM EXEC: What are some innovative methods and programs savvy manufacturers have deployed to reach the right audiences?

DOMBI: In the past, these programs likely focused on getting an army of sales folks out face to face with doctors—maybe even trying to speak with a pharmacist at retail or within a health system. This was difficult prior to the COVID-19 pandemic, given the limited time a lot of these folks normally have, but now it's somewhat impossible.

Some manufacturers have started focusing on how to get their message to the audience within their workflow in an unobtrusive way. This can take a number of different forms—everything from the tried-and-true paper insert in a shipping tote to digital interventions such as targeted banner ads or product icons in ordering platforms and dispensing systems.

The key here is leveraging the data available to understand who the right audience is, as well as how they prefer to consume information to make it as impactful as possible—whether that be through digital, paper, or a combination of the two.

PHARM EXEC: Can you share any examples of success with these programs?

DOMBI: Here's an example of how to take what we know about the role of pharmacists and turn it into an actionable solution.

At AmerisourceBergen, we recognize that while pharmacists play a key role in helping patients solve financial barriers, they also have limited time to focus on product selection. That's why based on pharmacists' feedback, we created a program called the Brand Catalog Program (BRx Catalog). This is a program that includes a select list of products that offer pharmacies and patients potential savings and additional economic value. The primary goal here is to enable pharmacists to easily identify cost savings opportunities where multiple product choices are available within a therapeutic class and where both pharmacists and patients could benefit from cost savings.

Because we understand that pharmacists have limited time, AmerisourceBergen purposefully incorporated some key features into the BRx Catalog. For visual impact, products included in the program are identified with a special bright icon in the ordering platform. For ease of use, there's also functionality to access patient co-pay assistance programs and to easily see pricing versus competitive products.

The program, which leverages the multichannel tools from our Custom Connect® suite of marketing services for manufacturers, is specifically designed to educate pharmacists without disrupting their workflow. It empowers them during patient affordability and brand

alternative discussions. As a result, patients, pharmacists, and physicians can make an informed decision together.

Over the last two years, we've observed consistently excellent results with the BRx Catalog. For example, at the start of the program, we ran a diabetes pilot program that resulted in the pilot stores dispensing 20% more commercial volume at the three-month mark and retaining more retail patients on the specific therapy at both the three- and six-month mark. In addition, we've continued to grow and expand the program and, today, have over 7000 participating locations.

PHARM EXEC: Why is there added value in promotional programs coming from a distributor?

DOMBI: It's a combination of a few things. The first is AmerisourceBergen's deep customer relationships and customer experience insights that enable us to craft the right type of message for the right channel and customer. The second is our understanding of pharmacy workflows—we can ensure a message gets delivered in the right place at the right time, be it in their totes, on an ordering screen, etc.

A final point of value can be found in our unmatched access to omni-channel marketing opportunities and data via our Custom Connect suite of marketing services—including our digital ordering platform and daily customer deliveries—that, in collaboration with a pharma manufactures creative agency, can help them improve the reach and impact of their targeted communications.

It is important to note that we're not here to displace the manufacturer's creative partner. Those partners bring a lot of great work, thought partnership, and leadership to their relationships with manufacturers. Instead, we're here to help enhance that messaging and ensure it gets to the right audience.

PHARM EXEC: What tips can you share with manufacturers that want to leverage targeted marketing programs today?

DOMBI: Be open to new ideas and approaches; a new normal requires a new approach. Further, selecting the right message is more important than ever now, as customers are struggling to balance financial stability with delivering care in their communities.

Also, don't overlook pharmacists. They have an increasingly critical and expanding role in healthcare today. Another important tip is to follow the data and listen to it. There are certainly lot of "My gut says this," moments, but the data can tell you a different story that must be prioritized over sticking to the way things have always been done.

Important questions to ask include: Who's buying your product? Who isn't buying the product? Why is the current message not swaying a customer? Is it the wrong message, or is it just the wrong medium or channel for delivering that message?

SPONSORED CONTENT

How does the BRx Catalog work?

AmerisourceBergen's Custom Connect and BRx Catalog solutions reach customers through their own channels of engagement and their own preferred consumption methods. These solutions can truly educate pharmacies and other healthcare providers on how a pharma manufacturer's product or support programs can impact affordability or shift their market share for the better, reaching the patients that really need it.

References

1. R. Garfield, et al. "Eligibility for ACA Health Coverage Following Job Loss," Kaiser Family Foundation, May 13, 2020, Available at https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss

2. C. Blank, "Pharmacists: A Profession People Trust," Drug Topics, January 8, 2019, Available at https://www.drugtopics.com/view/pharmacists-profession-people-trust

3. National Community Pharmacists Association Digest and Cardinal Health, "2019 NCPA Digest," Available at http://www.ncpa.co/pdf/digest/2019/2019-digest.pdf

4. R. Cauchi, "State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars," National Conference of State Legislatures, May 3, 2019, Available at https://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx

Jay Dombi

Jay Dombi is the Vice President of Specialty and Branded Strategic Planning at AmerisourceBergen.