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Unlocking Patient Access and Product Success in a Digital Healthcare World

(Source: An article by AmerisourceBergen for FiercePharma)

The continued emergence of innovation surrounding pharmaceutical products, coupled with increased adoption of digital solutions designed to expedite patient access to therapies, continues to be a driving force in fueling the accelerated pace of transformation in healthcare.

The COVID-19 pandemic triggered the pivot to virtual care and led to widespread acceptance of digital solutions such as remote monitoring and digital engagement platforms. Even as the world emerges from the grip of the pandemic, it is evident that the digitization of the healthcare industry is here to stay. The question facing the industry now is how can the industry continue to leverage digital innovations?

Healthcare players industry-wide are coming together to make patient experiences simpler, more coordinated, and ultimately, more effective. To achieve that goal, there is an increased focus on expanding patient access to products and clinical trials.

The pandemic has functioned as a catalyst for change within the clinical trial landscape, expediting the broader implementation of the decentralized clinical trial model. As an example, in 2020, AmerisourceBergen's global specialty logistics provider, World Courier, saw its daily volume of direct-to-patient shipment jump by more than five times its pre-pandemic average as the company delivered to 75 countries worldwide. To support the surging growth of decentralized trials in the United States, The Lash Group's team of nurses delivered more in-home visits to safely support the completion of clinical trial protocols, whether it was related to investigational medical product (IMP) preparation or administration, sample collection and process, or biometric screening and monitoring.

By bringing therapies and customized care directly into homes, trial sponsors can improve patient recruitment and retention and, more importantly, expand access to a broader and more diverse range of patients. That is particularly significant given that about 70 percent of potential trial participants live more than two hours away from study centers.

AmerisourceBergen is also leveraging its scale and capabilities, including its research community *AdvanceIQ Network*, to advance efforts to broaden the pool of potential clinical trial participants and extend studies deeper into the community setting. The company recently launched its *Clinical Trial Navigator* platform, which unites oncology practices within the *AdvanceIQ Network* and their patients with trials through digital site selection, patient identification and enrollment tools. By using this solution, companies can enter key protocol criteria to identify relevant

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- Nearly four years after acquiring real estate in Cambridge, Massachusetts, **Sanofi** opened its massive new campus. The facility, which now ranks among Sanofi's largest in the U.S., aims to boost collaboration between its research and development, medical and specialty care business units, among others, the company announced.
- **Pfizer** announced plans to invest US$120 million in its manufacturing facility in Kalamazoo, Michigan to produce its COVID-19 oral drug, *Paxlovid*. The new investment will help expand the active pharmaceutical ingredient and registered starting materials production. Separately, Pfizer plans to exit its 32% stake in **Haleon**, its consumer health joint venture with **GSK**. Pfizer has inked an "orderly marketing agreement" with its big pharma counterpart requiring them to inform each other before making any Haleon share sales. As of April 3rd, Pfizer's stake in Haleon was valued at US$15.8 billion.
- **Takeda** CEO, *Christophe Weber*, warned that a combination of dire factors could lead to lower drug prices. In a letter to shareholders, Weber said "The perfect storm scenario will have an impact on investment in innovation and could accelerate downward pressure on drug pricing." Included in the list of factors are global warming, the worldwide pandemic, economic recession, political instability, supply chain disruptions and the war in Ukraine.
- COVID-19-related restrictions in Shanghai were finally lifted and people were allowed to go out freely on June 1st

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U.S. FDA Lays Out Framework to Tackle Drug Shortages

(Source: An article by Fraiser Kansteiner for FiercePharma)

While the FDA says it has eased or avoided "hundreds of new drug shortages" in the U.S. over the past 10 years, quality problems, global supply chain weaknesses, unexpected demand spikes, market withdrawals, and natural disasters continue to threaten the United States' stock of pharmaceuticals.

To that end, the agency unveiled new draft guidance Thursday to help manufacturers develop risk management plans aimed at circumventing drug shortages. Under this new guidance, manufacturers of certain drugs and drug ingredients would be required to implement risk management plans. For others, the move is simply recommended.

The move follows a 2019 report from the federal Drug Shortages Task Force pushing for the adoption of such plans, plus the Coronavirus Aid, Relief, and Economic Security Act—passed by Congress in 2020—which calls on certain manufacturers to plan ahead to prevent shortages.

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practice sites and their ideal patient populations, and then refine their search by applying advanced filters or adding biomarkers or treatment regimens that patients must have received to qualify for a trial.

As the industry continues to drive toward patient-centricity, companies continue to hone in on predictive analytics to anticipate medication nonadherence, which remains a global health issue. Reports show that as many as 40 to 50 percent of patients with chronic diseases do not take their medications as prescribed by their healthcare provider. While a number of factors contribute to nonadherence, a recent study showed three in ten adults did not take their medications as prescribed because of cost. There is no one-size-fits-all approach, but the use of predictive analytics can help identify which patients are at the highest risk of nonadherence and would benefit from an intervention. Predictive analytics allows healthcare professionals to target the right patients that need additional assistance and direction that can help create a behavior change for a better health outcome while also allowing treating healthcare workers, i.e., nurses, to be more efficient and effective in supporting all patients.

As significant as digital adoption has been, the nursing support—and human touch—is equally important. Nurses are integral in assisting patients manage complex medication regimens or delivery methods by providing in-home or virtual education and training. This provides patients with real-time, personalized support.

U.S. FDA (cont.)...

In its guidance, FDA is mandating risk management plans for medicines used to treat rare diseases, drugs that lack "appropriate alternatives" and medical countermeasures against public health emergencies.

"Makers of sole-source products are also encouraged to consider implementing risk assessment plans, the FDA said, as well as manufacturers of drugs with just one active pharmaceutical ingredient source in their supply chain."

Drug shortages hit a peak in 2011 and dropped to a low point in 2015 and 2016. Unfortunately, "this downward trend did not continue in subsequent years," the FDA said in its guidance. Drug shortages have grown "more persistent" and continue to occur "at roughly the same levels since 2018," the agency explained.

Aside from quality issues, supply chain disruptions and unexpected spikes in demand for certain products have triggered shortages, the agency noted. The agency also remains increasingly concerned about cyberattacks hampering the pharma supply chain.

Drug companies will be given 60 days to submit comments and suggestions on the FDA's guidance.

Over the past two years, supply chain management has been top of mind for the industry—and regulators—as the COVID-19 pandemic cast a spotlight on Europe and the U.S.' fragmented drug ingredient networks compounded by tight demand for raw materials such as those used to make coronavirus vaccines.

As for how the industry itself is looking to tackle disruptions, manufacturing executives from Catalent, Alnylam, Amgen, Sandoz and Bayer sat down virtually with Fierce Pharma earlier this year to share pandemic lessons learned.

Amgen, for its part, said its guiding principles for supply chain resilience over the past two years have been to focus on infrastructure, cybersecurity, digitization, business continuity and inventory.

Another way to mitigate supply chain disruptions would be to simplify across the board, according to Kevin Cook, Sandoz's vice president of supply chain for North America. When manufacturers have a smaller surface area—defined as the sum of all products, processes and networks that make up the supply chain—"you can manage the disruption more effectively," Cook said.

Meanwhile, resource tensions do not seem to be easing at all in 2022. Germany's Merck KGaA warned earlier this month that renewed COVID-19 lockdowns in China and Russia's war in Ukraine have put a further squeeze on global supply chains and prompted a spike in operational costs. To ease potential shortages and price hikes, Merck KGaA says it will rely on higher stockpiles for critical raw materials and actively keep tabs on its supply base. Furthermore, the German-based drugmaker says it will leverage production sites outside of lockdown-affected areas "wherever possible."

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after months of strict lockdown. One pharma executive said that it was bittersweet, with the crowds and traffic returning to pre-lockdown levels, making it seem like nothing had happened. But China's largest commercial city of 25 million was hit hard by the complete standstill for over two months, with the local economy suffering a huge blow. Even the pharma manufacturing industry, one of its most resilient sectors, was reportedly halved in April, the first full month of the lockdown. Data for the month of May is expected to be equally dismal.

- Analysts polled by **Evaluate Pharma** predict that U.S.-based pharma manufacturer **Abbvie** will generate more prescription sales than any company in the industry in 2028, with sales totaling US$65.7 billion, closely followed by **Roche** at US$65 billion, **Johnson & Johnson** at US$62.3 billion, **Merck** at US$59.7 billion and **Pfizer** at US$57.1 billion. This is a big turnaround for some analysts who warned that Abbvie would suffer from the loss of patent rights for its blockbuster drug *Humira*.
- **Gilead Sciences Inc.** announced that *Stacey Ma, Ph.D.* will join the company as Executive Vice President, Pharmaceutical Development and Manufacturing, reporting to Chairman and Chief Executive Officer *Daniel O'Day*. Ma will replace *Dr. Yaiyin Yang,* who will retire after 29 years with the company.
- Oncology trial starts reached record levels in 2021, particularly in rare indications, as disruptions in cancer care brought on by the COVID-19 pandemic began to ease, according to the **IQVIA Institute for Human Data Science**. The return to pace after a disruptive two years is good news. The IQVIA Institute's new report did show that oncologists report more new patients presenting with cancer that had spread due to delays in diagnosis and screenings.

(Sources: Company press releases, Drug Store News, Ednpoint News, Fierce Biotech, FiercePharma, Scrip Intelligence and World Pharma News)