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COVID-19 is Reshaping the Pharma Supply Chain

(Source: An article by Rick Mullen for Chemical & Engineering News)

While the COVID-19 pandemic has not seriously impeded the production and shipment of pharmaceuticals in the first quarter of 2020, the future will be critical as chemical deliveries slow down and inventories of backup supplies dwindle. The onslaught of the pandemic has alerted regulators and world leaders to the extent which China dominates the world's supply of active pharmaceutical ingredients and the raw materials used to manufacture them. An ongoing industry effort in the U.S. and Europe to rebalance the pharmaceutical chemical supply chain is likely to be energized by government initiatives to ensure domestic production of drugs.

In the beginning of February, many chemical plants across China were closed for a one-week extension of the Chinese New Year holiday, followed by a longer shuttering of facilities due to quarantine. By the end of February, a significant break in the pharmaceutical supply chain was imminent as the virus spread across the Northern Hemisphere.

Yet, as of April, the chain remains largely functional and intact. Chinese suppliers are back in operation, and US and European API producers continue to operate without serious impediment. Manufacturers generally keep emergency stocks of ingredients on hand, and most claim they are not yet threatened by a slowdown in deliveries of raw materials.

Roger Laforce, a Switzerland-based industry consultant, credits Western producers with making strides in recent years to secure themselves against volatility in supply from Asia, and China in particular. "The coronavirus accelerates this, I think, and will have a long-term effect on how supply chain management will be run," Laforce said.

But there is no doubt that China will continue to control a large swath of the global pharmaceutical supply chain for years to come, posing a potentially significant risk. Industry watchers warn that the full impact of the COVID-19 pandemic will not be known for months, possibly going into 2021.

A pandemic should not have been a surprise to anyone. Scientific and government bodies, not to mention science fiction writers and filmmakers, have been raising the alarm for years. Nor should anyone be surprised to learn that pharmaceutical chemical manufacturing—and the production of finished dose generic drugs—has steadily moved to China and India as Western drug companies and contract development and manufacturing organizations (CDMOs) sought to cut costs and wash their hands of the highly polluting chemicals used to make drugs.

According to the FDA, the US remains home to the most API manufacturing plants worldwide, with the European Union a close second. Each account for just over a quarter of the world's FDA-registered facilities. China and India combined account for 31%.

But a factory count is a poor gauge of actual production volume. It is hard to determine with any precision the volume of API that China is actually producing, or the volume of APIs manufactured in

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In Brief...

- **IQVIA** Vice President of Industry Relations, *Doug Long*, in a *Drug Store News* webinar, outlined the ways COVID-19 has impacted the U.S. pharmaceutical market. Long sized up several industry trends amid COVID, including a slowdown in mergers and alliances like Aurobindo and Sandoz, and the Mylan-Upjohn merger. He also predicted that pharmaceutical reform has "fallen by the wayside" and predicted it will not occur until COVID and the next election cycle are past. In terms of traditional and specialty pharmaceuticals, that specialty pharmaceuticals will continue to grow from about 48% of the invoice price basis to 50% of the market in about a year or two. Telehealth has had a ten-tear growth in on month, healthcare provider visits are coming back but telehealth will continue.
- **McKesson Corporation** has reported its 4th quarter revenues of US$58.5 billion, a 12% increase year-over-year, and full year revenues were US$231.1 billion, up 8%, driven by growth in McKesson's **U.S. Pharmaceutical and Specialty Solutions** segment. McKesson CEO, *Brian Tyler*, said, "McKesson delivered a strong finish to fiscal 2020, reflecting continued momentum in the business and meaningful progress in our transformation towards becoming a more focused organization as we look to capture future growth opportunities. During fiscal 2020, we achieved adjusted operating profit growth in all three operating segments, generated $3.9 billion of free cash flow, and successfully completed the exit of our investment in Change Healthcare."
- **Cardinal Health** reported its third-quarter revenue at US$39.2 billion, an increase of 11% from the same period last year. For the pharmaceutical segment, third-quarter revenue was US$35.1 billion, a 12% increase year-over-year, which was attributed to growth from pharmaceutical distribution

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Gilead Partners with Generic Firms In Plans for Supplying *Remdesivir*

(Sources: An article by Sandra Levy for Drug Store News and an article by Beth Snyder Bulik for FiercePharma)

Gilead has reached a deal with five generic firms – Cipla, Ferozsons Laboratories, Hetero Labs, Jubilant Lifescience and Mylan to further expand the supply of *remdesivir*. The agreements follow on the heels of the U.S. Food and Drug Administration granting emergency authorization for the drug in the United States as a treatment for hospitalized patients with severe COVID-19 symptoms.The generic companies will manufacture *remdesivir* for distribution in 127 countries.

Under the licensing agreements, the companies have a right to receive a technology transfer of the Gilead manufacturing process for *remdesivir* to enable them to scale up production more quickly and efficiently. The licensees also set their own prices for

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COVID (cont.)...

China that is entering the U.S. market, either directly or indirectly by incorporation into finished dosages manufactured in China or other parts of the world. The problem is that there is a shocking lack of awareness of the risks associated with having the bulk of pharmaceutical manufacturing taking place outside of a country. At the end of the day, there needs to be capabilities within a country regarding medical supply. Countries need to start looking at medication on the same level of strategic importance as weapons.

That awareness is quickly emerging. In the US, White House economic adviser Peter Navarro proposed a "Buy American" executive order last month. Meanwhile, the Protecting Our Pharmaceutical Supply Chain from China Act, introduced by Senator Tom Cotton (R-AR) and Representative Mike Gallagher (R-WI), calls for a cessation of purchases of APIs and finished drugs from China by 2022.

Among the more temperate proposals, the Strengthening America's Supply Chain and National Security Act, a bipartisan bill spearheaded by Senator Marco Rubio (R-FL) and introduced in March, would require drug companies to provide the FDA with more information on their API supply. The Coronavirus Aid, Relief, and Economic Security Act, signed by President Donald J. Trump in March, aims to coordinate industry and government efforts to mitigate drug and supply shortages.

Andrew Badrot, CEO of C2 Pharma, a Luxembourg-based API supplier that outsources manufacturing, sees the US government's coronavirus response as a turning point in efforts to realign the pharmaceutical supply chain. "In the context of what is happening between the United States and China and Europe, I think nobody has any doubt about China's ability today to bring the world to its knees should they stop supply of medical devices or raw materials or intermediates for the pharmaceutical industry," he said.

Industry executives acknowledge the irony that the very companies that spent the past 20 years outsourcing the supply of chemicals and APIs to China are now asking for support to bring it back. But they dismiss the criticism, responding that capitalist industries must compete globally on price. Their request for support, they say, aims to establish a more level, competitive playing field.

Gilead (cont.)...

the generic product that they produce.

The licenses will be royalty-free until the World Health Organization declares the end of the Public Health Emergency of International Concern regarding COVID-19 or until a pharmaceutical product other than *remdesivir* or a vaccine is approved to treat or prevent COVID-19, whichever comes first.

The world is waiting for Gilead Sciences to set a price tag for *remdesivir*. To complicate the issue is the fact that the world is full of its own ideas.

Patient advocates and some researchers are clamoring for US$1 per day but an influential U.S. cost watchdog says US$4,450 per patient is warranted, provided it can save lives. Investors will want the higher end. Between those two extremes is a minefield of tone-deaf accusations, accessibility blame and reputation hits.

Gilead's choice will affect its own reputation and bottom line, set a tone for follow-up meds and either help polish up the pharma industry's image or create a new flashpoint for criticism. So how "affordable" is defined is paramount.

Gilead Chairman and CEO Daniel O'Day promised in an open letter in late March that Gilead would "ensure affordability and access so that *remdesivir* is available to patients with the greatest need."

The recently passed coronavirus CARES Act demands that drug prices must be "fair and reasonable." How do you define affordable, or fair or reasonable? Gilead said in a first-quarter securities filing that it spent US$50 million on remdesivir in Q1, but by year's end it could shell out US$1 billion or more. What constitutes a fair payback depends on whom you ask.

Watchdog group Public Citizen maintains US$1 per day is fair. It points to a cost-recovery model developed by the University of Liverpool which calculated that the cost of manufacturing *remdesivir* at scale would be US$.93 per dose, leaving the remainder as, in its view, "a reasonable profit to Gilead." Industry analysts figure a higher price is reasonable, although maybe not as high as the Institute for Clinical and Economic Review's calculated estimate of up to US$4,500.

Drug pricing is an age-old dilemma within the industry and one in which Gilead hasn't always fared well. In 2013, the company garnered widespread criticism for its US$84,000 price tag for groundbreaking hepatitis C treatment *Sovaldi*—followed up by its combo pill *Harvoni*, priced at US$94,500.

The company has already pledged to donate its current supply of *remdesivir*, or about 1.5 million doses, in addition to setting up more general COVID-19 help with a US$20 million fund that donates to not-for-profit groups affected by the pandemic. One thing for certain is that there is no way Gilead will satisfy everyone, whatever it chooses. Likewise, Gilead has pledged donations to to the U.S. to 940,000 doses by June, up from 607,000.

As of Tuesday morning, the global case count had neared 4.83 million, and more than 319,000 people had died, according to Johns Hopkins University.

In Brief (cont.)...

customers and specialty solutions customers. Cardinal said this growth included an acceleration in overall pharmaceutical sales in March, due to the COVID-19 pandemic.

- The Chinese city of Wuhan is implementing a "10-day battle" to test its over 11 million citizens following the report of 6 new cases of the virus. A city-wide nucleic acid testing will occur prioritizing people living in older compounds, densely packed residential buildings, or people originally from outside of Wuhan who are more likely to travel between different places. The plan to meet the huge volume demand of testing kits is still unclear. The directive came after Wuhan reported a new cluster of infections.
- The Trump administration is considering a four-year, US$354 million contract with **Phlow Corporation** to build a generic medicine and active pharmaceutical ingredients (API) plant in Richmond, Virginia, and supply COVID-19 treatments produced there. The deal, awarded by the **Biomedical Advanced Research and Development Authority** (BARDA), has the potential for an expansion to a 10-year deal, and a total of US$812 million. The grant represents the Trump administration's war on foreign drug supply as the novel coronavirus continues to expose fragilities in the global manufacturing industry.

(Sources: Company Press Releases, Drug Store News, FiercePharma, and Scrip)