

# ENSURING THE SAFETY AND CONTINUITY OF THE DRUG SUPPLY CHAIN

America's innovative biopharmaceutical companies are committed to ensuring the safety and continuity of the drug supply chain. Biopharmaceutical companies work closely with the Food and Drug Administration (FDA), supply chain partners, health care providers and others to prevent and mitigate potential shortages of prescription medicines. While it is important to note that, historically, serious drug shortages have more frequently involved generic drugs, PhRMA members are sensitive to the potential for manufacturing and supply disruptions across the industry.<sup>1</sup>

Unexpected circumstances do arise, and the makers of innovative medicines have not been immune from shortages. As a matter of course, PhRMA members typically have comprehensive, adaptable business continuity plans that include protective levels of inventory in their supply chains and plans for additional or alternate manufacturing sites. These measures have helped prevent any major disruptions in the supply chain for innovative medicines during the COVID-19 pandemic. An overview of some of the approaches employed by innovative biopharmaceutical companies to ensure safety and continuity in the supply chain include:

- Developing and maintaining robust inventory management systems
- Maintaining stock reserves
- Making significant and sustained investment in the design and maintenance of manufacturing facilities and their quality systems
- Robust data collection and reporting, and documenting compliance with FDA requirements
- Long-term facility planning to ensure geographic diversity across the drug supply chain

One reason manufacturers have been able to respond so quickly to the current public health crisis is the years of investments made in developing and securing the biopharmaceutical supply chain.

## SETTING UP A PHARMACEUTICAL MANUFACTURING SUPPLY CHAIN IS A COMPLEX AND LENGTHY PROCESS

Ensuring a safe, stable and secure supply chain requires a significant investment in time and resources to make sure that patients receive safe and effective medicines when they need them. Manufacturers begin setting up the manufacturing supply chain for a medicine years before that medicine is even approved for use by patients. In fact, building a new manufacturing facility alone can take five years or longer before it is registered and operational and can cost as much as \$2 billion.

As the research and development process progresses and researchers get closer to a potential successful treatment, companies must build the capacity to safely and efficiently manufacture sufficient quantities of that medicine for patients needing treatment, as well as develop plans for getting those medicines to patients. Beyond building new manufacturing capacity, this also includes contracting with various suppliers to ensure high-quality, reliable sourcing of a large number of input materials, ensuring the availability of the highly skilled labor force with the ability to manufacture the medicine and building and maintaining the critical quality control and testing systems needed to protect patients.

These manufacturing systems developed over long periods of time are not only incredibly complex, but also critical to avoiding any major or long-term disruptions in the supply chain that may impact access to medicines for Americans and patients around the world.

# GEOGRAPHIC DIVERSITY IS KEY TO THE STABILITY OF THE MANUFACTURING SUPPLY CHAIN

Biopharmaceutical companies do everything they can to make sure the manufacturing of medicines is uninterrupted so that there is enough supply to meet demand. One strategy for maintaining a stable, operational supply chain is geographic diversity.

Geographic diversification of the supply chain is particularly beneficial during pandemics as it provides flexibility to companies when they need it most. If an entire pharmaceutical supply chain is dependent upon one geographic area and that area experiences a natural or national disaster or pandemic, there could be significant infrastructure and supply disruptions with global implications. Take, for example, Hurricane Maria in 2017. Approximately 50 pharmaceutical manufacturing facilities were in Puerto Rico at the time of the hurricane, and their capacity was impacted by the disaster. Because of robust supply chains and close coordination with FDA, the industry was quickly able to shift manufacturing to facilities in other areas and prevent long-term drug shortages.

Biopharmaceutical companies often need to be able to make adjustments in the sourcing of their materials and shift manufacturing to different facilities in the case of an emergency that may result in disruptions, like Hurricane Maria. Building a new facility takes significant time and resources, so it is not a feasible solution in an emergency situation. Instead, companies typically build in redundancies and business continuity plans when setting up supply chains to mitigate any potential disruptions that may occur. Companies take into account the locations of each facility and have extensive measures in place to manage the various elements of the manufacturing process, including ensuring sufficient access to skilled workers, specialized equipment and materials.

Over decades, biopharmaceutical manufacturers have carefully built these robust global supply chains to ensure patients in the United States and around the world have ongoing access to medicines. Biopharmaceutical companies invest significantly in the design and ongoing maintenance and modernization of manufacturing facilities and their quality systems, and these efforts have been successful in avoiding any major disruptions during the COVID-19 pandemic.

In these unprecedented times, it is understandable that there are concerns regarding the continuity of the pharmaceutical supply chain and a desire for the United States to not be overly reliant on any countries that might pose a national security risk when it comes to pharmaceutical manufacturing. Discussions about ways to increase manufacturing in the United States are important to growing jobs and our economy, but policymakers must take a long-term, holistic look at global pharmaceutical manufacturing supply chains before jumping to rash proposals that may cause significant disruptions to the U.S. medicine supply.

<sup>1</sup>Scott Gottlieb, M.D., and Janet Woodcock, M.D., "FDA is Advancing New Efforts to Address Drug Shortages" November 19, 2018, available at <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm626108.htm>

