Setting the Record Straight on Biopharmaceutical Manufacturing Supply Chains

Efforts to ensure a safe, stable and secure supply chain have long been a priority for the branded biopharmaceutical industry. Over decades, biopharmaceutical manufacturers have carefully built robust global supply chains, with an extensive U.S. footprint, to ensure patients in America and around the world have ongoing access to medicines. Any conversations regarding potential changes to these complex supply chains must begin with accurate information.

MYTH	FACT
Changes can quickly be made to supply chains. Moving all manufacturing to the United States would be easy.	**Biopharmaceutical manufacturers must begin setting up the manufacturing supply chain for a medicine years before that medicine is approved for use by patients.** As the R&D 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, obtain the appropriate regulatory approvals for new facilities and plan for how to get those medicines to patients. Building a new biopharmaceutical manufacturing facility can take 5 to 10 years before it is operational and can cost as much as $2 billion – and that's just one piece of the supply chain.
Geographic diversity doesn't really matter when setting up supply chains. It is just an excuse manufacturers use.	The old adage not to put all one's eggs in one basket are wise words to heed for the resiliency of any supply chain. Geographic diversification of the supply chain is beneficial, especially in the time of pandemics and other public health emergencies. If an entire biopharmaceutical supply chain is dependent upon one geographic area and that area experiences a crisis, there could be significant infrastructure and supply disruptions with global implications. **Biopharmaceutical companies are constantly monitoring their supply chains and have the flexibility in place to adjust sourcing of their materials and shift manufacturing to different facilities in case of an emergency that may result in disruptions.**
The biopharmaceutical industry is solely reliant on other countries for its active pharmaceutical ingredients (APIs).	**The biopharmaceutical industry is not reliant on any one country for any aspect of the manufacturing process, including APIs.** According to data released by the FDA in 2019, about 28% of API manufacturing facilities are in the United States, 26% are in the European Union, 18% are in India, 13% are in China, 2% are in Canada and 13% are in the rest of the world. What's more, the total number of biopharmaceutical manufacturing facilities in the United States, including those that produce APIs, has grown by more than 50% in the last five years. Diversification in API sourcing enables manufacturers to better mitigate the impact of natural disasters or other public health emergencies, be more cost-effective, more efficient and to meet the needs of patients around the globe.
There are no controls in place to ensure the safety and quality of APIs manufactured abroad.	**The FDA regulates virtually every stage in the life of a prescription medicine sold in the United States, including closely monitoring any facility that handles APIs.** Biopharmaceutical manufacturers are also required by law to report substantial information to FDA relating to API and sourcing of API, as well as register any facilities used in the manufacturing of APIs. In fact, FDA's Current Good Manufacturing Practice requirements apply to API manufacturers to help ensure their quality. Biopharmaceutical manufacturers also have their own robust quality control systems in place to monitor the entire manufacturing process. For example, manufacturers perform certain tests to ensure that an API meets requirements for its intended use before it is used in a medicine sold in the United States.
The United States is solely reliant on China for API sourcing for critical medicines.	Overly broad claims that the United States is reliant on one country for essential medicines is factually inaccurate. The FDA tracks the location of facilities used to make the APIs for the 370 medicines on the WHO Essential Medicines List. Of these, 221 facilities (21%) are in the United States while 166 facilities (15%) are in China. Looking closer at the data, **FDA determined there are only three medicines on the WHO Essential Medicines list whose API manufacturers are solely based in China – none of which are commonly used.** Two are used to treat Mycobacterium tuberculosis and the other is an antibiotic used to treat two infections whose prevalence has significantly declined globally. What's more, analysis by Avalere Health shows, by dollar amount, the majority (53%) of the $85.6 billion in APIs used in U.S.-consumed medicines are produced here in the United States, compared to 7% from China.