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Assessing and Reducing Risks to the Pharmaceutical Supply Chain: The Security of Onshore Manufacturing

Introduction

Supply chain security is a serious concern today. In the pharmaceutical industry, where products enable patient wellbeing and even save lives, the stakes are particularly high. The concern is even greater for medications on the US Food and Drug Administration's lists of essential medicines[1] and drug shortages[2] where the need is critical and there are often few suppliers.

The risks to global supply chains are diverse and ongoing, with tariffs presenting an added form of disruption. It has been estimated that across industries, supply chain disruptions that last a month or longer can be expected to occur every 3.7 years.[3] With such disruptions, patients may lose access to critical medications. The American Society of Health-System Pharmacists (ASHP) already lists more than 230 drugs on its shortages list.[4]

Given this situation, companies in the pharmaceutical industry are assessing the structure, strengths, and weakness of their supply chains, and the potential for disruptions. In doing so, more and more are choosing to onshore drug development manufacturing as a significant way to reduce risk and increase supply chain security. Indeed, pharmaceutical companies have announced a combined $158 billion in U.S. manufacturing spending in response to the current tariff threat.[5]

Contract Development and Manufacturing Organizations (CDMO), likewise, are preparing for more domestic capacity. Halo Pharma, a Noramco Group CDMO, announced in 2025 a $25 million investment for a new high-speed, state-of-the art sterile injectable line at its New Jersey facility to address constraints in parenteral manufacturing capacity, in part because of the demand for vaccines and GLP-1 medications.

Threats to Globalized Supply Chains

While the disruptions caused by the Covid-19 pandemic brought concerns about globalized supply chains into focus, supply chain risks derive from many causes and sources, such as tariffs, broader geopolitics, shipping disruptions, and future pandemics.

Tariffs and Trade Disputes

Tariffs, which are taxes on imported goods, present a significant concern for the pharmaceutical industry by greatly increasing the cost not only of imported finished products, but also of starting materials, active pharmaceutical ingredients (API), reagents, solvents, and consumables like filters and personal protective equipment (PPE) that are sourced internationally.

For branded pharmaceuticals, instituting manufacturing within the United States may be a wise strategy in the face of tariffs. Tariff exposure for branded drugs weighs heavily on the API country of origin and the API is generally the primary driver of the cost of a finished dosage form. Domestic API production averts tariff exposure. Involving a reliable CDMO with the appropriate capabilities enables domestic production without the need to build new manufacturing facilities or assets, limiting tariff exposure

For generic drugs, which comprise the vast majority of the US volume, tariffs are unlikely to provide a significant enough incentive for onshoring manufacturing. The profit margins on generic medications are already low. The time, capital, and regulatory impact of setting up a new domestic supply as well as the fully loaded cost of domestic manufacturing would likely result in more significant price increases to generic drugs. Additionally, there is currently a lack of API capacity for the volume of generic drugs in the United States.

Broader Geopolitical Risks

Geopolitical risks to the supply chain are also more evident than ever. When European countries imposed sanctions on Russia following its 2022 invasion of Ukraine, Russia cut off natural gas supplies, leading to soaring energy prices that harmed European industries.

Political and trade tensions between the United States and China, over concerns that range from human rights to intellectual property protection, have been high for some time. The proposed BioSecure Act, which would prohibit US federal agencies from contracting with companies that obtain biotechnology products from specific Chinese companies, threatens to bring these concerns to the pharmaceutical industry.

Trade tensions could escalate into much bigger geopolitical threats. If China were to invade Taiwan, the effects could be wide ranging, with the potential for major destabilization in Southeast Asia and possibly bigger concerns for the global supply chain, which is highly interconnected between Asia Pacific and the United States.

Future Pandemics

The global Covid-19 pandemic gave the world a hard lesson in supply chain security, as isolation measures led much of the world's business operations to shutter or significantly slow down. Even when manufacturing restarted, getting necessary inputs was often impossible, with many borders closed and container ships piling up in ports. The entire country of India—the world's largest supplier of generic pharmaceuticals—locked down completely for 21 days. India then banned the export of 26 drugs, including antibiotics such as erythromycin, clindamycin, and metronidazole.[6] Strict pandemic rules severely restricted economic activity in China, a major source country for APIs, until the end of 2022, long after business had been largely normalized in most of the world.

While the disruptions of the recent pandemic have been largely resolved, the risks have not. In a globalized world affected by climate change, future pandemics are all but a certainty. Global health authorities are closely monitoring avian influenza, for example, for potential human-to-human transmission.

Shipping Disruptions

Shipping disruptions are another significant supply chain risk. When the Ever Given container ship became stuck sideways in the Suez Canal in March 2021, this major worldwide trade route was completely blocked off, freezing nearly $10 billion in trade a day.[7] The delays were felt in industries worldwide, while the costs of shipping through longer, alternative routes added up.

It's not just accidents that cause shipping problems. Modern day piracy and terror attacks in the Red Sea have caused some shipping companies to avoid this key route,[8] leading to delays, logistical issues, and price increases.[9]

A Globalized Pharmaceutical Supply Chain and Drug Shortages

More than a decade ago, pharmaceutical companies began increasing their offshoring of manufacturing, particularly of generic small-molecule APIs. Generic drug production has gone offshore because wholesalers and pharmacy benefit managers (PBMs) have captured a large portion of the profit margin of this sector, leaving manufacturers to adapt by finding more cost-effective sources of APIs. Today, approximately 80% of APIs sold in the United States are made abroad, with roughly 65% made in India, 4% in China, and 5% in Europe.[10] Nearly 60% of generic sterile injectables are manufactured outside the United States.[10]

This reliance on offshore manufacturing is an important risk factor for US pharmaceutical supply. Offshoring pharmaceutical manufacturing also comes with increased concerns about product quality, particularly given the US FDA's limited resources for conducting inspections abroad.

Drug Shortages

Meanwhile, the US has faced serious shortages of critical drugs for years. Drug shortages have been on the rise over the past several decades and are lasting longer.[11] The US FDA currently lists more than 100 drugs on its drug shortage database[2] while the ASHP lists more than 240.[4] The problem of shortages is particularly acute in hospitals

and oncology treatment centers, which rely heavily on injectable drugs. Indeed, injectables make up a disproportionate share of drugs on the shortages lists, accounting for 50% of the total,[12] even though about two-thirds of prescribed drugs are oral solid dosage forms.

Concerns about drug shortages prompted the creation of an FDA list of essential medicines in 2020.[13] That effort was followed by a 100-day review of risks in the supply chain of pharmaceuticals and APIs and an examination of policy recommendations to address those risks.[14]

The report from that 100-day review by several US government agencies indicated that a key strategy to improve the resilience of the supply chain is to expand onshore production of pharmaceuticals.[15]

Tariff Effect

Any tariffs on pharmaceutical products, or the materials or consumables needed to manufacture them, will likely exacerbate these drug shortages. In the US generics market, manufacturers already have extremely low margins. For oral solid drugs, price pressure comes from unregulated PBMs and wholesalers. For generic injectable medications, prices are controlled through hospital group purchasing organization (GPO) contracts and the Medicare 340B Drug Pricing Program. Because of price pressures, generic APIs are generally sourced internationally, creating high tariff exposure. If tariffs cause manufacturers' costs to exceed their slim margins, generic medications risk being withdrawn from the market. In the case of generic injectables, some of which are essential medicines (see below), the result may be new shortages. Many injectables, including generic drugs, are consistently on drug shortage lists.

The Security of a US Pharmaceutical Supply Chain

In the face of the serious threats to globalized supply chains, many pharmaceutical companies are adopting a strategy that aligns with the recommendation of the US government report on supply chain risks: bringing manufacturing back onshore.

These companies realize that by working with CDMOs located within the United States, they can enjoy the peace of mind of increased supply chain security. Worries about shipping disruptions and geopolitics are gone. Tariff concerns are mitigated. The complexity of the supply chain is reduced. Logistics are simpler.

Partnering with CDMOs in the United States also eliminates concerns about interference from autocratic foreign governments, ensuring that innovator companies maintain control over their intellectual property for their drugs, formulations, and drug delivery, as well as for advanced manufacturing technologies.

Companies that work with onshore CDMOs also often find that they experience additional benefits in the arena of quality. They gain the trust of working with US companies that share their quality mindset, combined with the easy logistics of conducting in-person quality audits on the same continent.

An Integrated US Supply Chain for the Full Product Life Cycle: Halo Pharma, Purisys, and Noramco

As pharmaceutical companies move to secure their supply chains through onshore drug development and manufacturing, they need to find a US-based CDMO for APIs and finished dosage forms that can provide the right technical capabilities and robust quality systems. They also need a flexible partner they can trust. To meet those needs, companies can turn to the Noramco Group.

This integrated group of providers, which includes the CDMOs Purisys and Halo Pharma, and the bulk API supplier Noramco, can safely and expertly take a molecule from clinical-stage API manufacturing through drug product formulation and commercial-scale manufacturing of finished dosage forms, including analytical services, all in the United States.

Purisys, in Georgia, has more than 40 years of experience in custom API synthesis and clinical and commercial production for emerging biotechs through large pharmaceutical companies. Purisys provides an API-based CDMO offering that links route selection, process development services, analytical support, and manufacturing into one integrated process.

Halo Pharma, in Whippany, New Jersey, provides drug product formulation and commercial manufacturing for diverse dosage forms—especially complex, difficult-to-manufacture therapeutics. Halo's $25 million investment in a high-speed sterile injectables line in New Jersey will meet the growing demand for domestic sterile manufacturing for small-molecule through large-molecule applications, including biologics, vaccines, and peptides. This new capacity is especially critical given the current capacity shortage for parenteral manufacturing—the fastest growing and most

profitable segment of life sciences market—due to growth in vaccines and GLP-1 medications.

In addition, Halo's experience in complex oral solid dosage forms, topicals, and oral liquids, particularly for controlled substances, is unmatched in the CDMO space. Halo also provides commercial manufacturing, packaging, and analytical services.

Working with these coordinated CDMOs, which can handle different stages of drug development and commercialization, has the added benefits of streamlining and simplifying project management, logistics, and technology transfer.

Purisys and Halo Pharma provide additional supply chain security through an advanced sourcing strategy, with redundancy of suppliers. And companies that need API sourcing can rely on a secure, high-quality supply from Noramco, located in Delaware. Noramco can also provide production of new chemical entities (NCEs) and custom, branded APIs. Noramco also has access to essential manufacturing solvents and reagents from the domestic US petrochemical industry, minimizing the need to import supplies from Europe or Asia that may be subject to tariffs.

And while Purisys and Halo Pharma excel at ensuring quality through their scientific, manufacturing, and regulatory know-how, they also strive to be the best partner. The teams are collaborative and responsive, working with customers to find effective and scalable solutions to their pharmaceutical development and manufacturing challenges. Unlike many larger CDMOs, Purisys and Halo Pharma can easily accommodate changes at any point in a product's life cycle.

Summary: Achieving Supply Chain Security with US Development and Manufacturing

As pharmaceutical companies assess the vulnerabilities of their supply chains, they are increasingly choosing to carry out product development and manufacturing onshore. In doing so, they not only mitigate the risks of tariff costs and shipping disruptions but also increase protections for product quality and intellectual property.

The Noramco Group is the perfect partner for companies seeking the security of US drug development, manufacturing, and supply. Through the integrated CDMO operations, along with dedicated API sourcing, the Noramco Group can manage molecules through the full drug development life cycle, with coordinated management that simplifies technology transfer and streamlines operations through different phases of development. The peace of mind gained through this controlled, onshore operation is strengthened by the robust quality systems and technical expertise of the Purisys and Halo Pharma teams.

Indeed, given the threats to globalized supply chains, and the advantages and security of conducting drug development and manufacturing in the United States with a trusted partner, onshoring pharmaceutical operations is fast becoming a best practice for pharmaceutical companies across the continent.

Secure Your Supply Chain with US Drug Development and Manufacturing

Contact the Noramco Group today to find out more about how we can provide the quality, capabilities, and service you need as you ensure your pharmaceutical supply chain security through onshore drug development and manufacturing.

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