Securing America's Medicines and Supply

Steps to Bolster Our Supply Chain

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Background:

Coherus is a biotechnology and cancer care company focused on developing, licensing, and commercializing high-quality biosimilar and biologic products. Our first marketed product, UDENYCA® (pegfilgrastim-cbqv), a biosimilar referencing Neulasta® (pegfilgrastim), was developed in our labs in Camarillo, California.

Most recently, we have initiated agreements abroad to bring additional cancer treatment technologies here for the benefit of the American patient. Coherus is an American-made company that employs more than 300 team members in the U.S. We're committed to investing in high tech manufacturing in the U.S. - with sites in Maryland, Colorado, and our offices in California.

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Introduction:

The U.S. needs U.S.-based capacity to reduce vulnerability in our supply of medicines as a matter of national security and patient safety. For nearly two decades, the U.S. has fallen ill to companies who were lured abroad with tax incentives and labor laws that encouraged them to build manufacturing facilities elsewhere. The COVID-19 crisis has further brought this issue to light.

We know that the 2020 pandemic and overreliance on ex-US sources led to drug shortages across the country. Indeed, drug shortages are increasing again due to supply chain vulnerabilities – as indicated in numerous press reports and the new creation of hospital alliances and partnerships focused on developing critical supplies.

According to a story in the New York Times, "Chinese pharmaceutical companies have supplied more than 90 percent of U.S. antibiotics, vitamin C, ibuprofen and hydrocortisone, as well as 70 percent of acetaminophen and 40 to 45 percent of heparin in recent years, according to Yanzhong Huang, a senior fellow for global health at the Council on Foreign Relations."[1]

Several government officials are raising the need to address U.S. supply chain vulnerabilities. As they weigh policy solutions, they must thoughtfully craft effective incentives and policies that not only encourage the return of companies that have taken advantage of foreign tax breaks and low wages, but also—and more importantly—invest in American companies that have already created domestic jobs and manufacturing. Companies like Coherus are already in position to provide immediate resources to shore up the security of our supply chain for American patients. We are already seeing movement in government to shore up our supply chain and expand our capabilities

As the federal government officials launch national supply chain integrity month, we believe more needs to be done now to fix the U.S. medical supply chain.

We Cannot Wait to Act: A Tale of Three Disasters

The following case studies highlight real-world examples of how safeguarding the supply chain with robust, U.S.-grown industry is essential for ensuring the resilience of the American health care system, safeguarding and expanding patient access to life-saving medicines, and fostering free-market competition.

1 Case Study: COVID-19- Pandemic

More than any one event, the global COVID-19 pandemic has irrevocably altered the way nations, including the U.S., contemplate public health crises and the cascading effects of quarantines, shut-downs, and disruptions to both commerce and the global supply chain. To this end, on August 6, 2020, President Donald Trump issued Executive Order 13944, proclaiming it "critical that we reduce our dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize our Nation's Public Health Industrial Base to respond to these threats."[2] Senate Finance Committee Chairman Chuck Grassley concurred, stating that "[i]t's now clear that supply chain diversification and increased domestic manufacturing of medical products is critical to preserving our country's ability to respond to major public health crises[.]"[3] Upon being sworn into office, President Biden also committed to examining the U.S. supply chain and addressing vulnerabilities.

The shutdowns and quarantines arising from complications due to COVID-19 reveal the weaknesses in the U.S. drug supply chain which have existed since the dawn of globalization. Such a system works imperfectly even in normal times. A global pandemic for which each nation formulates its own responses, procedures, standards, as well as rates of success, creates an unacceptable level of risk and uncertainty as applied to the drug supply chain. We must take the time to learn from the COVID-19 response efforts and ensure this breakdown in supply does not occur again.

2 Case Study: Genzyme – Sole Source Concerns

The story of Genzyme's Allston Landing plant is another cautionary tale that underscores the ongoing need for a multi-sourced biologics market.[4] Allston Landing, located just outside of Boston, MA, is a manufacturing facility which in 2004 was the sole producer of 3 biological products, all with orphan designations. In 2009, after an FDA Warning Letter and subsequent consent decree and fine, Genzyme began to fall behind in production, unable to meet patient demand. The crisis lasted well into 2010, with patients suffering from rare disorders unable to access Genzyme's products – the chain was broken, and patients suffered as a result. Genzyme, now a subsidiary of Sanofi, has since reorganized its organizational structure, but the damage was done, and important lessons were learned. As seen by this case study, diversity and security must be a top consideration when looking at the supply chain as a whole.

3 Case Study: Hurricane Katrina – Natural Disasters

Viral pandemics are only one of the myriad crisis events which could potentially cause disruption to supply chain integrity. Hurricane Katrina,[5] which devastated the north gulf coast in August 2005, notably affected and disrupted the operations of 3 of the top 10 ports (in terms of cargo tonnage) in the US, all within the state of Louisiana. The port of New Orleans, for example, completely ceased operations from August 28 – September 12, taking approximately 6 months thereafter to become fully operational.[6] As a result of these closures, several critical drugs and medical products went into shortage.

The risks inherent to a global pharmaceutical supply chain – or, indeed, any other global supply chain – cannot be understated. It was not the first time nor the last time such disruptions occurred. Without suitable and comprehensive domestic supply chains, disasters at home and abroad will continue to impact patients by depriving them of access to their needed medicines.

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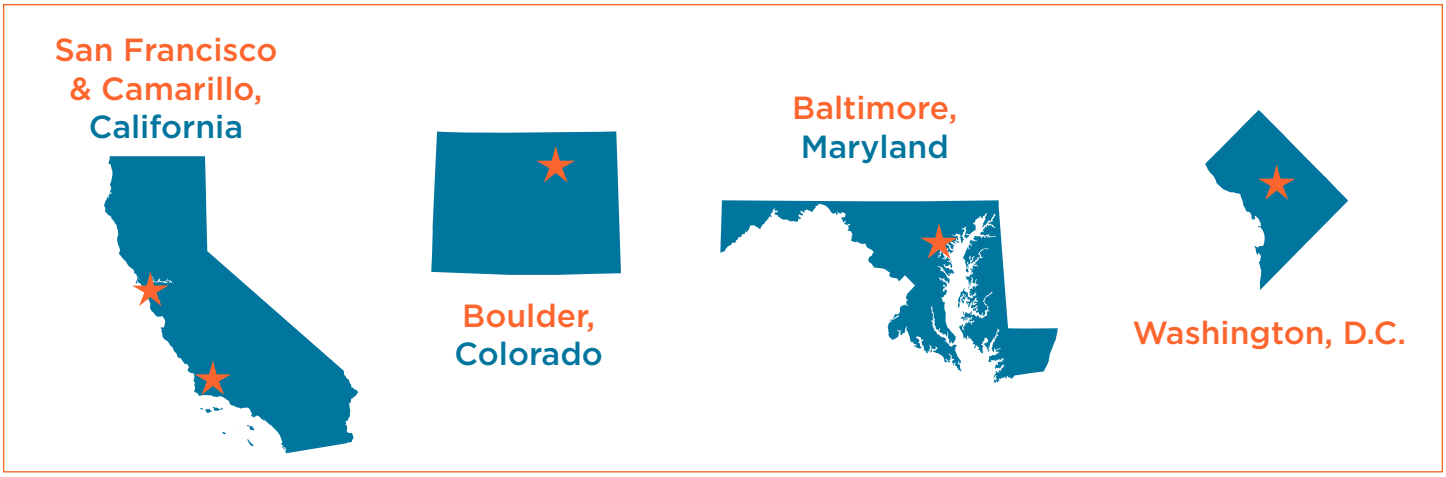

Coherus: An American-Made Success Story

While much remains to be done to reduce the U.S.'s reliance on manufacturing overseas, a handful of companies are doing their part to help. Coherus is a great example of one of these companies. Coherus is a biotechnology and cancer care company focused on developing, licensing, and commercializing high-quality biosimilar and biologic products. Since its founding, Coherus has invested all of our manufacturing operations inside the U.S. because of our commitment to provide high-quality jobs and contribute to the U.S. tax base. We developed our first marketed product, UDENYCA® (pegfilgrastim-cbqv), a biosimilar referencing Neulasta® (pegfilgrastim), in our labs in Camarillo, California. Most recently, we have initiated agreements abroad to bring additional cancer treatment technologies here for the benefit of American patients, the government, and taxpayers.

"Our focus is with U.S. products. We strongly believe in the U.S. manufacturing and made in America. This is our positioning. We will absolutely insist on U.S. manufacturing for any products we are to in-license or develop – we want to manufacture post-tech transfers in the United States."

– Denny Lanfear, CEO

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Coherus employs over 300 team members in the U.S., comprising all aspects of Research and Development, Product Development, and Marketing and Sales, as well as our headquarters in California. In 2014, Coherus formed a strategic collaboration with KBI Biopharma and introduced the first clinical and commercial biosimilars to their Boulder, Colorado site. Ongoing UDENYCA production at the site contributes to highly skilled and highly desirable biotechnology jobs. Coherus also partnered on a drug product manufacturing contract with Emergent BioSolutions in Baltimore, Maryland, supporting more jobs in an underserved area.

"We need to do everything we can to deliver high quality health care, but right now drug shortages are hurting patients, pharmacists, and physicians alike."

- Tina Smith, U.S. Senator

While we will broaden our capabilities as we grow, our focus on Made in America will remain a top priority and enable us to offer supply surety and quality medicines to the U.S. population. However, we need the support of the American government to create policies and incentives that make it possible for companies, like Coherus, to exist. The reality is being a Made in America company, unfortunately, comes with additional costs and regulatory barriers. The time is now to create an environment that promotes American-made pharmaceuticals and medical products.

"It's now clear that supply chain diversification and increased domestic manufacturing of medical products is critical to preserving our country's ability to respond to major public health crises."

- Chuck Grassley, U.S. Senator

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Steps the Biden-Harris Administration and Congress Can Take to Promote American-made Polices

The Biden-Harris Administration and Congress must do all they can to support and encourage U.S. pharmaceutical production capabilities before the next health care crisis hits. A domestic supply chain is far more difficult to disrupt than a global supply chain. Simply put, when active and inactive ingredients can be shipped on trucks instead of airplanes or ships, and likewise finished products can mostly be distributed by the same means of transportation, then even global pandemics can do little to offset the effectiveness in the manufacturing and distribution process. The Biden-Harris Administration and Congress should:

1. **Ensure American-made PRODUCTION for the SNS:** Reinforce and expand the strategic national stockpile to spur additional domestic medicines and supplies

2. **Encourage American-made MANUFACTURING:** Encourage a comprehensive review of trade and tax law changes to ensure policies that strengthen more manufacturing and production here at home

3. **Expand American-made INVESTMENTS:** Maintain and expand U.S. government loan, grant, direct investment, and purchase agreement programs for important medical infrastructure

4. **Enhance American-made FORMULARIES:** Promote opportunities within Medicare, the Veterans Administration, and the Department of Defense to recognize and support U.S.-made pharmaceutical products and supplies

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1 Ensure American-made PRODUCTION for the SNS:

Reinforce and expand the strategic national stockpile, to spur additional domestic medicines

COVID-19 has shown us that now more than ever is the time to evaluate the operations and content of the strategic national stockpile. The needs of the stockpile have changed vastly since its original creation as a tool against bioterrorism. One of the biggest lessons learned was the stockpile was not developed to respond to a large national event.[7] As a result, many states and providers were left looking for additional response tools during the start of COVID-19. In preparation for the next health care crisis, the Biden-Harris Administration and Congress should look for ways to encourage the development of needed products within the U.S. and expand the definitions of what is critical to the stockpile. What is seen as critical constantly changes for patients and the U.S. The SNS should have more flexibility in making this adaptation.

The strategic stockpile policy should also incent and encourage pharmaceutical, diagnostic, medical device and personal protective equipment production here in the U.S. This policy would not only have an immediate impact on supply chain security and American jobs, but also bolster American suppliers of raw materials and ingredients. Additionally, this would offer certainty to companies that dedicate additional dollars to be American-made.

2 Encourage American-made MANUFACTURING:

Encourage a comprehensive review of trade and tax law changes to ensure policies that strengthen more manufacturing and production here at home

Incentivizing companies to develop, stay or return to the U.S. begins with making it economically feasible and viable for companies to do so. Previous policies have been enacted to encourage manufacturing including research and experimentation tax credits, but more is needed to reassure companies that it is viable for them to return or stay within the U.S.[8]Additionally, these incentives cannot be for quick or limited periods, as it takes time to produce new products or to “move lines” home. In order to ensure that global manufacturers working within a global economy decide to operate and manufacture domestically, it must be affordable to do so, relative to the rest of the world. This is crucial not only for ensuring that the medicines American patients count on for survival are made at home, but also for growing American jobs which employ American workers who pay American taxes.

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3 Expand American-made INVESTMENTS:

Maintain and expand U.S. government loan, grant, direct investment, and purchase agreement programs for important medical infrastructure

Through Congressional and Executive Action, the federal government can provide direct incentives to those companies willing to take on the challenge of rebuilding our domestic supply chain, and reimagining our domestic manufacturing capacity, particularly in the pharmaceutical space. Agencies including the National Institutes of Health (NIH), Biomedical Advanced Research Development Authority (BARDA), the Strategic National Stockpile (SNS) and the U.S. International Development Finance Corporation (DFC) play an important role in developing unique partnerships that benefit the supply chain.

We have seen several recent examples that are a step in the right direction, including BARDA's announcement of $812 million awarded to the PHLow-led partnership with CivicaRx, AMPAC Fine Chemicals, and the Medicines for All Institute at Virginia Commonwealth University. This award aims to provide immediate, U.S.-based capacity to produce the active pharmaceutical ingredients (APIs) and the chemical compounds for those ingredients to make critical medicines to help alleviate or prevent drug shortages, particularly during the COVID-19 pandemic.

Continued public-private partnerships will enable robust dialogue and collaboration, insights into challenges, and brainstorming solutions. A strong supply chain equipped with redundancies and backstops can make all the difference.

4 Enhance American-made FORMULARIES:

Promote opportunities within Medicare, the Veterans Administration, and the Department of Defense to recognize and support U.S.-made pharmaceutical products and supplies

Government payers can play a significant role in encouraging the utilization of American-made pharmaceuticals, and they should explore opportunities to promote these products. If there is an American-made pharmaceutical product available, it should be preferred and paid for differently so that jobs and U.S. tax dollars are not sent overseas unnecessarily. An incentive or formulary preference or step-through pathway should be enacted not only during public health emergencies, but also as a permanent change in law. The utilization of an American-made formulary within Medicare, the Veterans Administration and the Department of Defense would help to bolster American-made products and business, while ensuring supply chain security.

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Recent Legislative and Administrative Actions

The Biden-Harris Administration and Congress have an essential role to play in supporting the American supply chain and businesses that have committed to investing in the U.S.

Highlighted below are recent initiatives, legislative proposals and Executive Orders that have been explored and, in some instances, implemented to address supply chain vulnerabilities in the U.S.

Executive Orders & Initiatives

As a result of COVID-19 and several natural disasters, the Trump and Biden-Harris Administrations initiated Executive Orders that direct the government to setup American-made buyer arrangements, along with an examination of the current U.S. supply chain.

- President Biden's Executive Order 14001
  "A Sustainable Public Health Supply Chain" - directs agencies to increase the threshold and price preferences for domestic goods, review agency waivers of Buy American requirements and report on the implementation of current Made in America laws. Additionally, the order establishes a new Director of Made in America policies within the Office of Management and Budget (OMB).

- President Biden's Executive Order 14017
  "America's Supply Chains" - launches a comprehensive review of U.S. supply chains and directs federal Departments and Agencies to identify ways to secure U.S. supply chains against a wide range of risks and vulnerabilities.

- President Trump's Executive Order 13944
  "Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States" - directs the federal government to buy certain drugs only from American factories.

During campaign season, President Biden suggested the notion of creating a research project agency known as the Advanced Research Projects Agency for Health (ARPA-H). The goal of the research agency would be to focus on and solve medical issues that private companies have not addressed due to a lack of incentives. This agency would be housed within the Department of Health and Human Services and potentially have a budget of up to $50 billion. Most recently, on April 9, the Biden Administration requested $6.5 billion to launch the ARPA-H within the National Institutes of Health (NIH). With an initial focus on cancer and other diseases such as diabetes and Alzheimer's, this major investment in federal research and development will help to drive transformational innovation in health research and speed application and implementation of health breakthroughs while bolstering America's innovation and supply.

Congressional Proposals and Actions

Several legislative proposals from Congress have demonstrated a bipartisan, bicameral appetite for developing and implementing policies that support American manufacturing. These policy proposals broadly fall under two categories;

1. Proposals that would bolster national preparedness and response infrastructure to strengthen the country's response to both the current public health emergency and those of the future;

2. Proposals that would reform trade and tax laws to encourage American manufacturing and American jobs;

The first category consists of proposals that would strengthen the security and resilience of the American supply chain and to ensure that the U.S. is better prepared for the next public health crisis.

- The Office of Manufacturing and Industrial Innovation Policy Act (H.R. 2279), introduced by Rep. Marcy Kaptur (D-OH) on March 29. This bill would establish the Office of Manufacturing and Industrial Innovation Policy. This office will provide manufacturing and industrial perspective and advice to the President.

- U.S. Senator Tom Cotton recently published a report regarding the importance to a U.S. supply chain in which he suggests:
  - Expand the Strategic National Stockpile so that it contains sufficient medical supplies and equipment to last at least six months during a crisis
  - Retain or reshore enough domestic medical-equipment manufacturing so that production can be increased to meet crisis-level demand within six months

> *"Medicine and medical devices are strategic national resources as surely as food, oil, and weapons. U.S. policy should finally treat them accordingly..."*
>
> - Tom Cotton, U.S. Senator

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- Safely Back to School and Back to Work Act (S. 4322), introduced last Congress by Senator Lamar Alexander (R-TN), would direct the Biomedical Advanced Research and Development Authority (BARDA) to support domestic manufacturing and domestic supply chains to increase surge capacity and capabilities for public health emergencies. The bill would appropriate billions of dollars to improve and sustain state medical stockpiles, and would improve the Strategic National Stockpile (SNS) by increasing coordination between the government and private sector entities that make up the domestic supply chain.

- In 2019, Senator Tina Smith (D-MN) introduced the Mitigating Emergency Drug Shortages (MEDS) Act (S.2723), legislation that would address national security risks of drug shortages and require the Department of Health and Human Services and the Department of Homeland Security to conduct a risk assessment of national security threats associated with the lack of adequate domestic capacity and capability for the manufacturing and distribution of critical drugs, their APIs, and associated medical devices used for preparation or administration.

- Another proposal from last Congress by Senators Bob Menendez (D-NJ) and Marsha Blackburn (R-TN), the Securing America's Medicine Cabinet (SAM-C) Act (S. 4342; see also H.R. 6708), would expand the FDA's Emerging Technology Program and establish a designation for advanced manufacturing technologies that address drug shortages or maintain supplies of critical medicines for public health emergencies to expedite the development and implementation of such manufacturing methods.

- Further, the Prescription for American Drug Independence Act of 2020 (H.R. 6670), introduced by Representative Anna Eshoo (D-CA) would promote coordination between the National Academies of Sciences, Engineering, and Medicine to engage experts on drug supply issues and analyze the impact of U.S. dependence on foreign drug manufacturing.

The second category consists of proposals that would reform trade and tax laws to encourage domestic manufacturing.

- The America LEADS Act (S. 4629), sponsored last Congress by Senator Bob Menendez (D-NJ), is a significant and sweeping bill that would make comprehensive investments in American competitiveness, American workers, and the American economy. The bill recognizes the imperative to reinvigorate domestic industries and invest in research and development (R&D), domestic manufacturing, and the American workforce. It also would establish an interagency Critical Technologies Program to coordinate initiatives to advance critical technologies through R&D and domestic production. Moreover, the bill also would invest billions to expand domestic manufacturing programs and partnerships.

- The MADE in America Act of 2020, introduced last Congress by Representative Buddy Carter (R-GA), would support FDA review and inspection of manufacturing practices, require HHS to develop a report on barriers to domestic manufacturing of APIs, drugs, and devices, and establish certain tax credits for qualified production activity expenditures in distressed regions to create American jobs in areas with high poverty rates.

Conclusion

We applaud those in the government who have begun to incent American-made medicines and supply of medical products, but more must be done. COVID-19 and recent natural disasters have shown us that we cannot wait to foster American manufacturing of critical pharmaceutical products, devices, and personal protective equipment.

These American-made policies will benefit our American patients, our American government, and our American taxpayers.

The time is now to work with allied groups to ensure the safety, security, and reliability of our medical supply chain.

Endnotes

1. Coronavirus Spurs U.S. Efforts to End China's Chokehold on Drugs, available here

2. President Donald J. Trump, Executive Order 13944, Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (6 August 2020)

3. Senator Chuck Grassley (R-IA), Grassley Statement on Trump Executive Order on Domestic Drug Manufacturing (6 August 2020), available here.

4. See generally, Life Science Leader, "How Genzyme Got Its Manufacturing Mojo Back" (2 June 2014), available here.

5. See generally, e.g., National Weather Service, Hurricane Katrina – August 2005 (last updated November 2016), available here.

6. See Congressional Research Service, CRS Report for Congress, Hurricane Katrina: Shipping Disruptions (13 September 2005), available here.

7. The Strategic National Stockpile and COVID-19: Rethinking the Stockpile (last visited 26 February 2021), available here.

8. GAO: Pharmaceutical Industry's Use of the Reseafch Tax Credit, available here.