



Insight

The BIOSECURE Act: Considerations Before Passage

JOHN WALKER | JUNE 5, 2024

Executive Summary

- In May, the House Committee on Oversight and Accountability reported the BIOSECURE Act, a bill intended to protect Americans' genetic data from Chinese data mining, with a bipartisan vote of approval.
- Specifically, the bill would prohibit federal agencies from procuring biotech equipment or services from "biotech companies of concern," as well as from contracting with an entity that uses said equipment or services; it would also place similar prohibitions on federal loan and grant dollars.
- While the bill's protections may be needed, it would significantly restrict U.S. access to critical drugs; as such, Congress should first prioritize strengthening U.S. domestic pharmaceutical and active pharmaceutical ingredient manufacturing to prevent exacerbating critical-drug shortages and a future reliance on undependable international drug exports.

Introduction

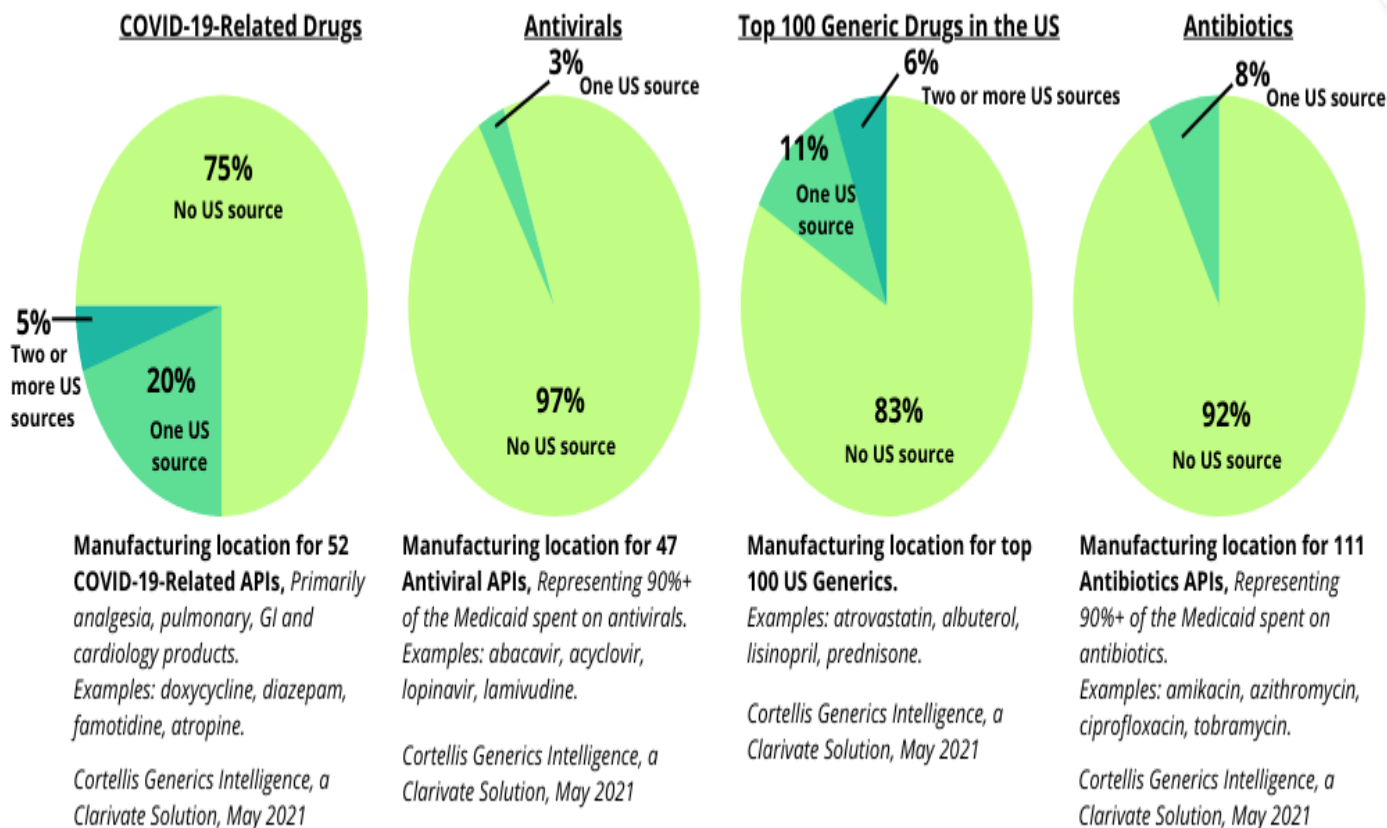
Recently, the House Committee on Oversight and Accountability reported the BIOSECURE Act, a bill intended to protect Americans' genetic data from Chinese data mining, with a bipartisan vote of approval. The Senate Homeland Security and Governmental Affairs Committee also reported a similar bill with overwhelming bipartisan support in March.

Specifically, the BIOSECURE Act would prohibit federal agencies from procuring biotech equipment or services from "biotech companies of concern" as well as from contracting, either directly or through a subcontract, with an entity that uses said equipment or services. It would also place similar prohibitions on federal loan and grant dollars. With China's introduction of anti-espionage laws, it is likely that the United States has a greater need for updated data and national security protections. While the bill's protections may be needed, they would significantly restrict the United States' access to critical drugs. As such, Congress should first prioritize strengthening U.S. domestic pharmaceutical and active pharmaceutical ingredient manufacturing to prevent exacerbating critical-drug shortages and a future reliance on undependable international drug exports.

U.S. Pharmaceutical Production

Roughly 83 percent of the top 100 prescribed generic medications are imported, with antibiotics and antivirals being the most import dependent.^[1] Furthermore, according to data collected by the American Society of Health-System Pharmacists, there are 323 active pharmaceutical shortages in the United States, the highest active pharmaceutical shortage on record.^[2]

Figure 1: Sources of API Manufacturing, Select Product Areas



Source: R. Sardella, "The US Active Pharmaceutical Ingredient Infrastructure: The Current State and Considerations to Increase US Healthcare Security," Olin Business School, Washington University (St. Louis, MO), August 2021.

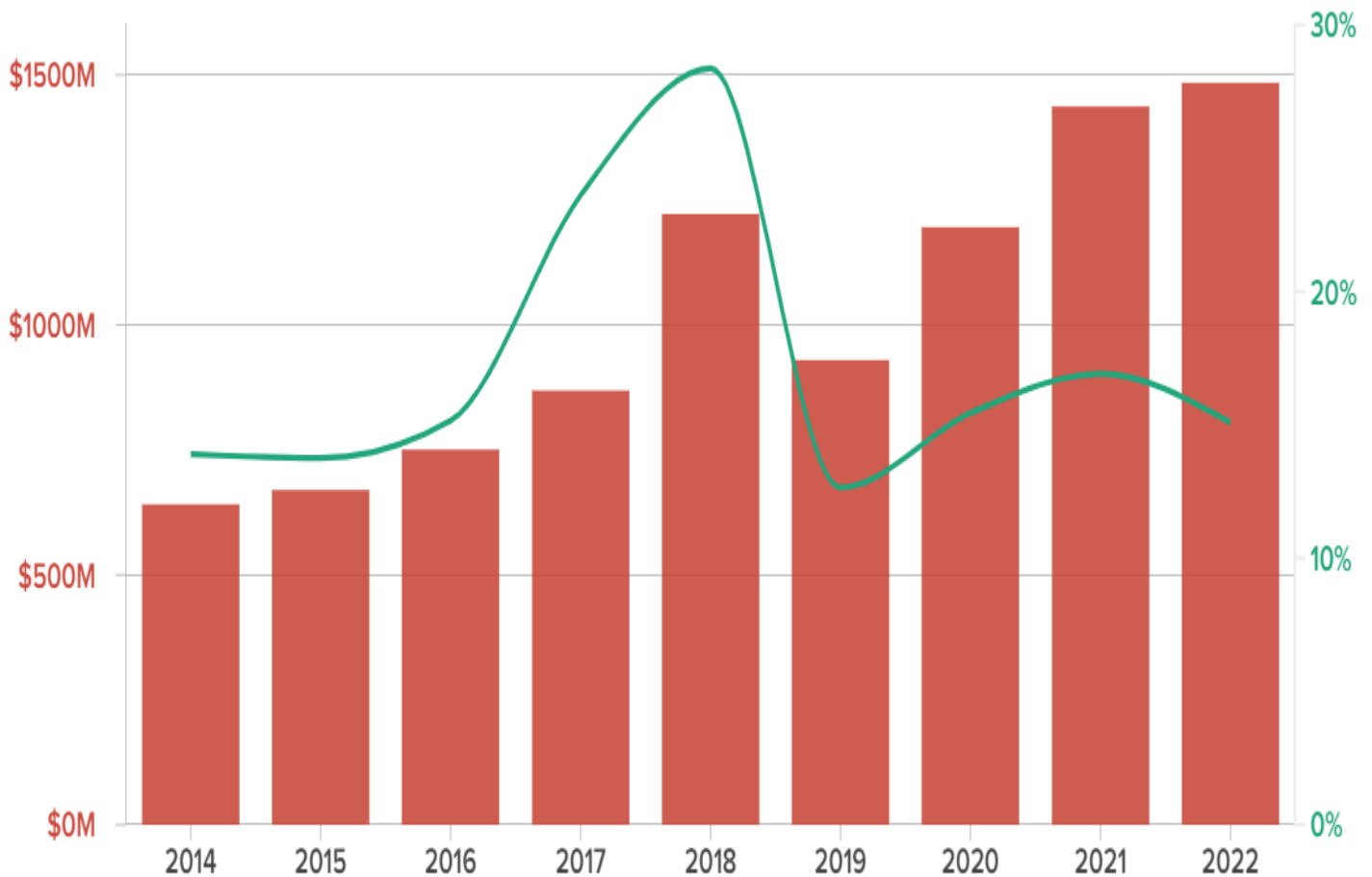
[3] China was the leading source of U.S. pharmaceutical imports (by weight), accounting for approximately 418 million pounds or 23 percent of total pharma imports. The following year, the United States spent roughly \$196 billion on pharma imports, with China and India accounting for 95 percent of ibuprofen imports, 91 percent of hydrocortisone imports, 70 percent of acetaminophen imports, and roughly 45 percent of penicillin imports.

Another pivotal component of the pharmaceutical manufacturing chain is what are known as active pharmaceutical ingredients, or APIs. APIs are the primary, biologically active components of medicine that make it effective as a treatment. Without a strong and steady API supply chain, pharmaceutical manufacturers would experience bottlenecks at all levels, causing mass pharmaceutical shortages.[4] This is particularly troubling when placed in context of where these APIs are primarily produced. As of 2021, of the 349 sites globally that produce 10 APIs or more, only 15 sites are based in the United States. Even more troubling, of the 103 sites globally that produce 30 or more APIs, only four operate in the United States. In comparison, China has more than double the number of production facilities capable of producing 30 or more APIs, while India has 15 times the number of 30+ API facilities. Estimates of API imports also paint a similar picture. A previous American Action Forum insight found that China provided roughly 17.8 percent of U.S. API imports in 2019.[5] This study aligns closely with similar research conducted by the Atlantic Council that found imports of Chinese

APIs held at an average of 17 percent over the past decade.

US Imports of Active Pharmaceutical Ingredients from China

Import Value (LHS) vs Portion of Global Imports (RHS)



Source: Author's Calculations, US Census Bureau

Author defined active pharmaceutical ingredients (API) to include 10-digit harmonized tariff system (HTS) Chapter 29 (Organic Chemicals) codes that had an end-use classification of pharmaceuticals (40100).

This data shows a clear pattern. While the United States is not at the mercy of China's pharmaceutical manufacturing, with only a fifth of its APIs and pharmaceuticals originating from the country, its domestic API and pharmaceutical manufacturing is significantly lacking. Before legislators move to decouple the United States from Chinese pharmaceutical manufacturing, it's imperative that lawmakers first prioritize strengthening domestic production, reducing legitimate barriers to entry, and resolving critically low pharmaceutical shortages.

Undependable Drugs and a Shaky Supply

A decoupling from China would most likely necessitate a significantly greater reliance on Indian pharmaceutical manufacturers. While India is a substantial and trusted source of generic products, a recent

enforcement action should give us pause about over-reliance on Indian manufacturers. In July 2023, the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research Office (CDER) sent a warning letter to Intas Pharmaceuticals, an Indian-based, multinational pharmaceutical manufacturing company with roughly \$2.8 billion in annual revenue. In the letter, CDER cited Intas for several "significant violations" of Current Good Manufacturing Practice (or CGMP, a regulation system of minimum requirements for assuring proper design, monitoring, and control of drug manufacturing processes and facilities) stating that the firm's quality control unit "failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity."^[6] This letter came as a follow-up to a surprise inspection of Intas' facilities where the FDA found an analyst had destroyed documents "by pouring acetic acid in a trash bin containing analytical balance strips" and that Intas' management showed an "egregious pattern" of shortfalls, demonstrating the firm's inability to carry out "basic responsibilities."

Based on recent market approximations, Intas covers roughly 3 percent of the Indian pharmaceutical manufacturing market and is India's 10th largest pharmaceutical manufacturer. While primarily a generic manufacturer, in the past several years Intas has become the primary U.S. supplier of two lifesaving injectable cancer drugs, methotrexate and cisplatin. It should come as no surprise, then, that following the plant's temporary closure, U.S. supplies of cisplatin and methotrexate dropped to critical levels. A recent National Comprehensive Cancer Network (NCCN) study found that by May of 2023, 70 percent of all academic cancer centers reported shortages of cisplatin.^[7] Furthermore, because of the complicated requirements involved with the production of a sterile and injectable form of cisplatin, domestic and foreign manufacturers alike struggled to cover the new demands. As a ripple effect, the new high demand for cisplatin replacements also created a shortage of carboplatin (a similar chemotherapy drug), of which NCCN found 93 percent of academic cancer centers reported a shortage. Methotrexate, "one of the major chemotherapeutic choices for various types of cancer," remains in relatively short supply.^[8]

These three cancer drugs are not simply palliative medications. Having a consistent and regular supply of any of these drugs is the difference between dying from cancer and living to be cancer free. Hence, during prolonged shortages, medical professionals are expected to ration and triage^[9] treatment options, prioritizing patients with the highest survival chances and the young.^[10] According to studies conducted by the American Cancer Society Cancer Action Network,^[11] "one-in-ten of those in active treatment have been impacted by recent drug shortages, with Medicaid enrollees most likely to be impacted (22%)." It is thus critical that legislators understand the risks and potential effects of endangering the United States' supply of lifesaving drugs as they weigh the merit of the BIOSECURE Act

The data above indicates that India is not ready to undertake the increased manufacturing requirements of a possible U.S. decoupling from Chinese pharmaceutical manufacturing. Furthermore, even if Indian pharmaceutical markets rise to a level considered ideal by the FDA, relying on a single nation for a majority of the country's necessary and lifesaving medications poses a greater national and economic security threat than retaining a diverse pharmaceutical supply chain.

Conclusion

As Congress continues to weigh the threat that Chinese-based pharmaceutical manufacturing presents to U.S. national security, it's imperative that lawmakers understand the implications of decoupling. First, the United States does not have the current domestic supply chain or infrastructure necessary to support a decoupling from China. Second, the United States is currently in a record-high pharmaceutical shortage that is forcing doctors to triage patients. Third, India, the second-largest producer of U.S. pharmaceuticals and APIs, does not have the

current capability to make up for the lapse created from decoupling. Fourth, relying on a single nation (India) for a majority of the country's necessary and lifesaving medications poses a much greater national and economic security threat than retaining a diverse pharmaceutical supply chain. While the bill's protections may be needed, Congress should look before it leaps and first strengthen domestic pharmaceutical and API production to prevent long-term damage to the critical domestic drug supply.

[1] <https://apicenter.org/news-updates/white-paper>

[2] Drug Shortages Statistics – ASHP

[3] The US API Manufacturing Base: Generics – DCAT Value Chain Insights (dcatvci.org)

[4] Addressing U.S. Drug Shortages and Drug Recalls – AAF (americanactionforum.org)

[5] <https://www.americanactionforum.org/insight/u-s-dependence-on-chinese-pharmaceuticals-overstated/>

[6] <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/intas-pharmaceuticals-limited-652067-07282023>

[7] <https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortage-Survey.pdf>

[8] <https://www.ncbi.nlm.nih.gov/books/NBK556114/#:~:text=In%20today's%20world%2C%20methotrexate%20is,many%20>

[9] <https://abcnews.go.com/Health/cancer-drug-shortage-forcing-doctors-decide-patients-treatment/story?id=99753886>

[10] <https://www.nytimes.com/2023/06/26/health/cancer-drugs-shortage.html>

[11] <https://www.fightcancer.org/policy-resources/survivor-views-one-ten-impacted-recent-drug-shortages>