May 7, 2025

Department of Commerce
Bureau of Industry and Security, Office of Strategic Industries and Economic Security
1401 Constitution Avenue NW
Washington DC 20230

# Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Docket Number: 250414-0065

The Open Markets Institute is a nonprofit based in Washington, D.C. that works to combat harmful concentrations of market power across the U.S. and global economy. We welcome the opportunity to respond to the Request for Public Comments by the Department of Commerce Bureau of Industry and Security to inform the Office of Strategic Industries and Economic Security investigation of imports of pharmaceutical and pharmaceutical ingredients.

The Open Markets Institute's response to this Request for Public Comments draws from the findings of our forthcoming report on the subject of American dependence on Chinese supplies of active pharmaceutical ingredients. In particular, we are responding to the following topics of interest: (iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients; (iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks; and (vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies.

The Open Markets Institute applauds the Department of Commerce for its ongoing efforts to investigate the risks to critical pharmaceutical supply chains. We are eager to continue supporting this work. Any questions about our research into pharmaceutical supply chains can be addressed to Audrey Stienon, Industrial Policy Program Manager (stienon@openmarketsinstitute.org).

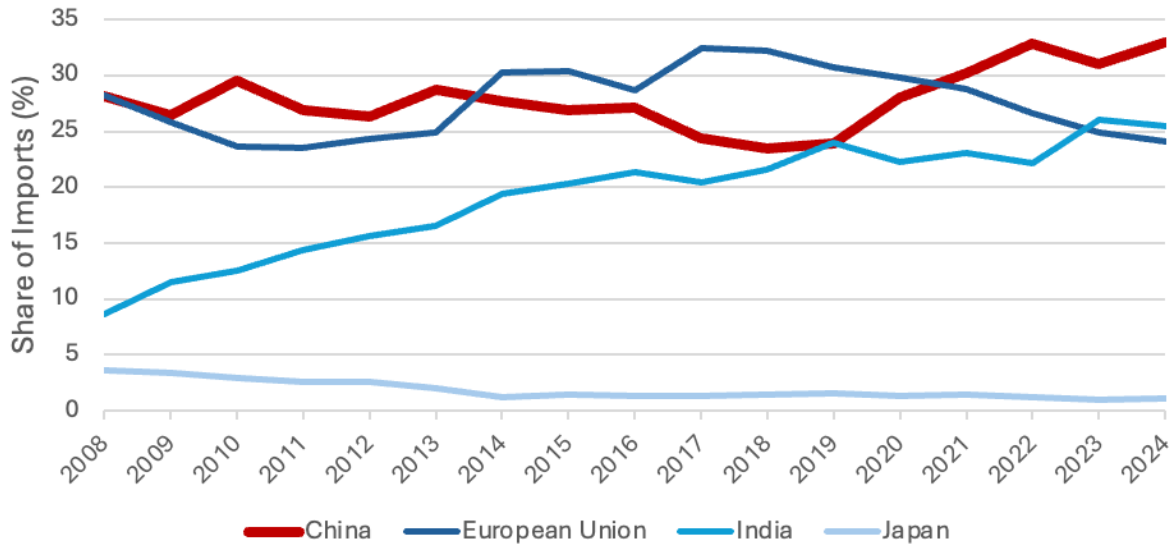
## (iii) Role of foreign (Chinese) supply chains in meeting U.S. demand for pharmaceutical ingredients

**American dependence on China for pharmaceutical manufacturing is concerning, especially for the basic inputs—or active pharmaceutical ingredients (API)—that underpin all other pharmaceutical drug production.** Although the Food and Drug Administration (FDA) estimates that only 13 percent of the API that the U.S. imports come from China, this figure masks the fact that China produces a far higher share of specific APIs, especially the chemical APIs critical to the

production of generic drugs, which make up 91 percent of the prescriptions filled in the U.S.[1] Furthermore, China also supplies API to countries, like India, that manufacture the majority of the drugs exported to the U.S.; 70 percent of Indian API comes from China.[2]

**The U.S. has been increasing its dependence on China for pharmaceutical products since the 2020 pandemic.** The share of American pharmaceutical imports remained steady for over a decade, but between 2019 and 2024, the share of imports from China rose by 10 percentage points (Figure 1). This is part of a larger trend in which the U.S. has increased its imports of medical products from China. Between 2020 and 2022, the value of American imports of pharmaceuticals and other related products—including blood, organic cultures, organs, and banadages—increased by 485 percent. [3]

**Figure 1: U.S. Imports of Pharmaceutical Products from China, by Weight (2008-2024)**



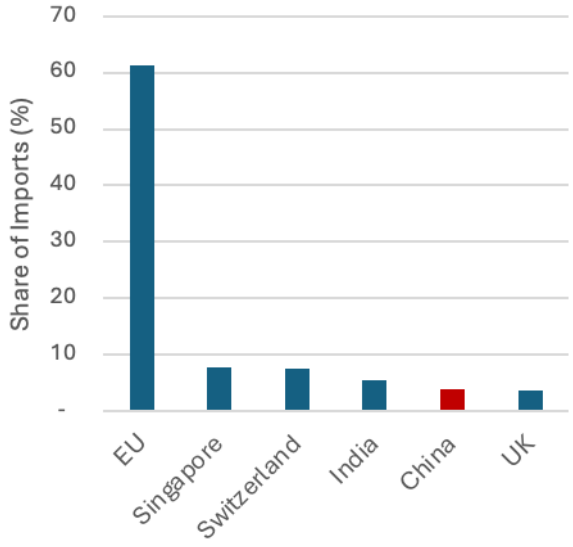

**Source**: US Census Bureau, NAICS Code 3254

**China is among the largest suppliers to the U.S. of pharmaceutical products, including products ranging from API all the way to finished drugs.** Although China supplies only 3.7 percent of American pharmaceuticals import as measured by the dollar value of imports (Figure 2), China supplies 23 percent of pharmaceutical imports when measured by weight (Figure 3). This matters because over 90 percent of American pharmaceutical drug consumption is of generic drugs, which are considerably cheaper than branded drugs—and which thus constitute a

[1] Hahn, "FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order"; U.S. Food and Drug Administration (FDA), "Office of Generic Drugs 2022 Annual Report"; Raghavendran and Christian, "Geographic Concentration of Pharmaceutical Manufacturing."
[2] Chatterjee, "Indian Pharma Threatened by COVID-19 Shutdowns in China."
[3] Graham, "The US Is Relying More on China for Pharmaceuticals — and Vice Versa."

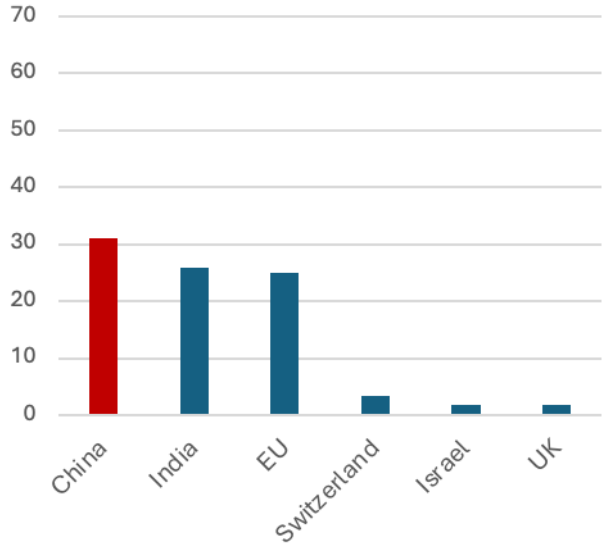
significantly smaller share of pharmaceutical import value.[4] The fact that China and India are the largest suppliers of imported pharmaceuticals, by weight, reflects the fact that these two countries supply the majority of the drugs consumed in the U.S.[5]

**Figure 2: Source of U.S. Pharmaceutical Imports, by Value (2023)**




**Source**: U.S. Census Bureau, NAICS Code 3254

**Figure 3: Source of U.S. Pharmaceutical Imports, by Weight (2023)**

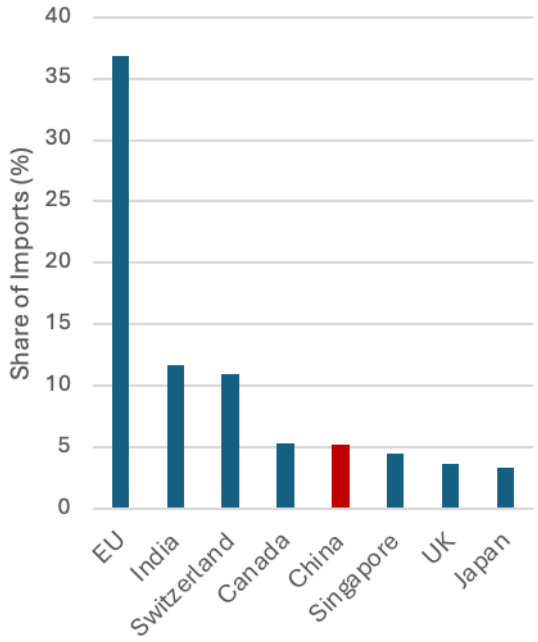



**Source**: U.S. Census Bureau, NAICS Code 3254

**Calculating Chinese contributions to American API consumption is much more challenging.** The U.S. government does not collect trade data specifically about APIs, meaning that information about API imports embedded in other imported pharmaceutical product data. China supplies about 5 percent of U.S. imports (by value) of the chemicals used in pharmaceutical manufacturing—most of which are used as chemical APIs (Figure 4). This already suggests that the U.S. imports a higher share of APIs from China than it does pharmaceuticals. Meanwhile, certain organic chemicals can also be used as APIs. Although it is again impossible to know the share of these chemicals that are used as APIs, for a quarter of the organic chemicals imported by the U.S., 60 percent come from China (Figure 5). Furthermore, an estimated 80 percent of the intermediates (raw materials, chemical compounds) used as building blocks for API globally come from China.[6]

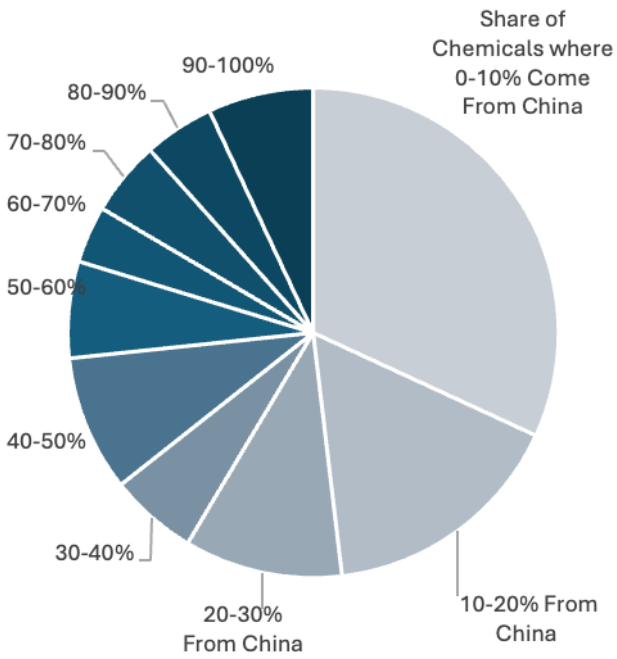
[4] U.S. Food and Drug Administration (FDA), "Office of Generic Drugs 2022 Annual Report"; Association for Accessible Medicines (AAM), "The U.S. Generic & Biosimilar Medicines Savings Report."
[5] Ferry, "Surge in Pharmaceutical Imports Threatens U.S. National Security as India/China Dominance Grows."
[6] DCAT Value Chain Insights, "Global API Market: Crunching the Numbers."

**Figure 4: Source of U.S. Pharmaceutical Chemical Imports, by Value (2023)**




**Source**: US Census Bureau, NAICS Code 325412

**Figure 5: Share of Imported Organic Chemicals Produced in China**

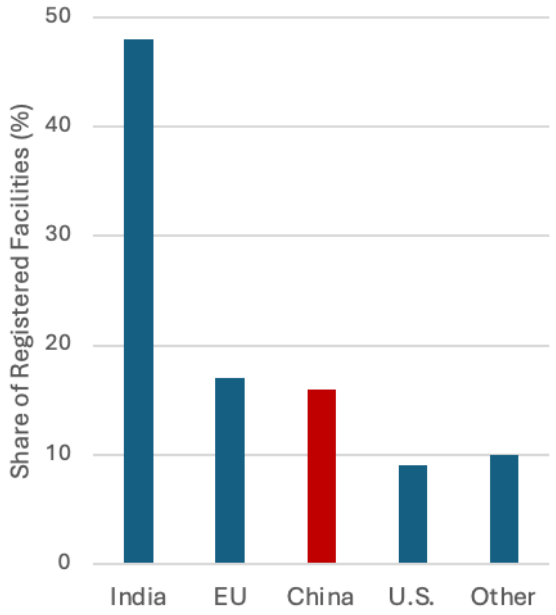



**Source**: U.S. Census Bureau, HS Code 29

**Another way of estimating American dependence on Chinese API is by looking at the share of API manufacturers registered with the FDA are located in China.** 16 percent of API manufacturing facilities—and 13 percent of API manufacturers for generic drugs—were located in China (Figure 6, Figure 7).[7] Although this confirms the disproportionate clout that China has in API markets, these figures do not tell us about how much each of these factories produce. Therefore, the actual share of API produced in China could be higher or lower depending on the productive capabilities of facilities in China relative to those in India or other trade partners.

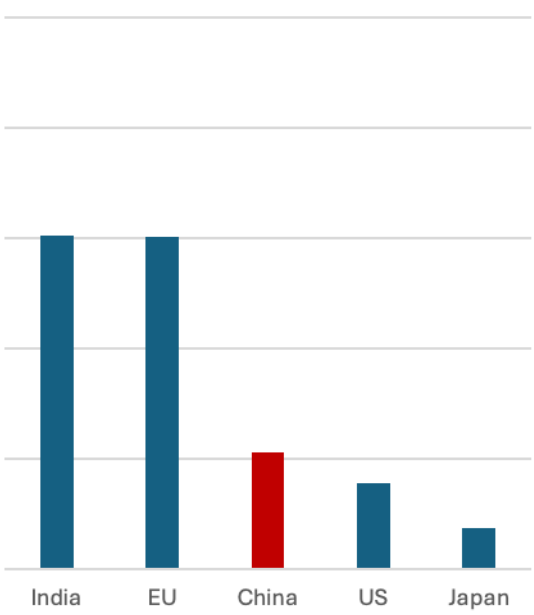
[7] Duman, "Global Manufacturing Capacity for Active Pharmaceutical Ingredients Remains Concentrated."

**Figure 6: Location of API Manufacturing Facilities Registered with the FDA (2023)**




**Source**: Duman, "Global Manufacturing Capacity for Active Pharmaceutical Ingredients Remains Concentrated"

**Figure 7**: **Location of API Manufacturing Facilities for Generic Medicines Registered with the FDA (2021)**

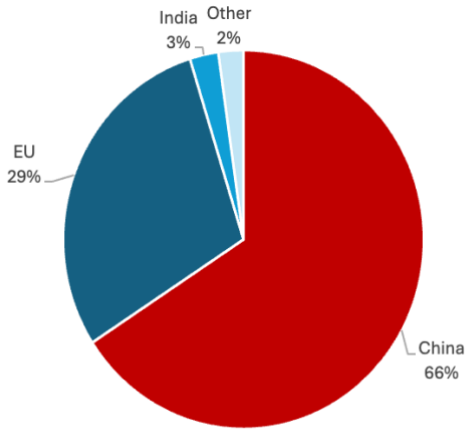



**Source**: Clarivate Analytics' Cortellis Generics Intelligence Database[8]
**Note**: EU consists of data from Italy, Spain, Germany, and France

**Chinese API is a key component of several drugs that are critical to public health and national security.** During the pandemic, the Food and Drug Administration (FDA) identified 20 essential drugs that solely sourced their API or finished products from China.[9] Two years later, an analysis of the Defense Logistics Agency's essential medicines list found that 46 of the drugs listed were supplied by China—with seven of these drugs solely sourced from China.[10] Finally, in 2023, the Department of Defense (DOD) reported that 5 percent of their procured drugs used Chinese API, and classified these drugs as facing "very high risk."[11]

[8] Socal, Crane, and Anderson, "Global Production of Active Pharmaceutical Ingredients for US Generic Drugs Experiencing Shortages."
[9] Hahn, "Coronavirus (COVID-19) Supply Chain Update."
[10] U.S. Department of Defense, "Report on the Department of Defense Pharmaceutical Supply Chain Risks."
[11] U.S. Department of Defense.

**Figure 8: 2023 US Imports of Antibiotics and Antibiotic API, by Weight (kg)**




**Source**: US Census Bureau, HS Code 2947

**Chinese producers are also essential in antibiotics supply chains.** China produces 71 percent of the antibiotic ingredients exported globally, and 97 percent of the ingredients used in antibiotics destined for sale in the U.S.[12] In 2023, China supplied 65 percent of American imports of antibiotics goods, including API and final products (Figure 8). Both penicillin and cephalosporin use API that are single sourced from China. [13]

**An additional concern is that the other countries that supply pharmaceutical products to the U.S. are similarly dependent on Chinese API.** India, for example, sourced an estimated 70 percent of its API from China in 2023.[15] Indian imports of Chinese API has been rising for decades, driven by the fact that Chinese production, subsidized by the Chinese government, is 35-40 percent cheaper than in India.[16] The early production stages of certain drugs—like vaccines and HIV/AIDS medicines, 60 percent of which are supplied to the U.S. by India—takes place outside of India.[17] Meanwhile, Europe, another critical source of pharmaceuticals for the U.S. imports an estimated 90 percent of its generic APIs, and 79 percent of its APIs for antibiotics from China.[18]

**Table 1: Pharmaceutical Exporters' Dependence on Chinese API (2021)**

| | **Share of U.S. Imports, by weight** | **Share of API Sourced from China** |
|---|---|---|
| **China** | 30% | - |
| **India** | 23% | 70% |
| **European Union** | 29% | 45% |
| **Source**: U.S. Census; Indian Department of Pharmaceuticals; Patricia Van Arnum[14] | | |

[12] Boston Consulting Group, "Understanding the Antibiotic Manufacturing Ecosystem."
[13] Boston Consulting Group.
[14] Department of Pharmaceuticals, "Survey for Novel/Innovative and Cost-Effective Technologies for Route of Synthesis to Decease the Cost of Production of APIs Which Are Currently Being Imported to Reduce Import Dependency"; Arnum, "The EU's API Supply Chain Under Focus."
[15] Department of Pharmaceuticals, "Survey for Novel/Innovative and Cost-Effective Technologies for Route of Synthesis to Decease the Cost of Production of APIs Which Are Currently Being Imported to Reduce Import Dependency."
[16] Joseph and Ramaa, "Reducing Import Dependence on APIs in the Indian Pharmaceuticals Sector."
[17] Cherian et al., "India's Road to Independence in Manufacturing Active Pharmaceutical Ingredients."
[18] White House, "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth"; Bayerlein, "The EU's Open Strategic Autonomy in the Field of Pharmaceuticals."

**(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks**

As much as high dependence on any company or country or company is dangerous, these levels of dependence on China—and thus on the Chinese government and regulatory landscape—pose their own set of unique risks.

## Risks from Industry Consolidation and Single Points of Failure

**Not only are pharmaceutical companies reliant on China as a source of API, but their extreme emphasis on keeping costs low means that they often are overwhelmingly reliant on single companies or factories within China.**

**This risk is being exacerbated by the fact that the Chinese government's campaign of regulatory reform has repeatedly resulted in widespread factory closures and industry consolidation.** For example, stricter environmental regulations from 2016 caused nearly 150 factories producing APIs to shut down within two years. This drove up the price of a number of different APIs, and prompted American pharmaceutical companies to start stockpiling the ingredients whose supply was suddenly threatened.[19] Many small manufacturers, faced with the increasing price of regulatory compliance, have been open to mergers.[20] This has also raised the risk of price gouging. For example, in 2018, the monopolist producing one API, chlorphenamine, raised the price of this ingredient 57 times before the Chinese government intervened to bring prices back down. [21]

**This consolidation is extremely risky since it creates potential points of failure in companies' supply chains.** For example, in 2019, an explosion at the Chenjiagang Chemical Industry Plant, which was contracted to serve the Lonza Group, a Swiss pharmaceutical multinational that controlled 35 percent of the market for biologic drugs, caused major disruptions to the company's entire supply chain, and shortages for consumers.[22]

**Environmental risks should also be a growing concern for the world's pharmaceutical companies**. Most Chinese API production is concentrated in coastal provinces—like Zhejiang,

[19] Jain, "How China Is Impacting the Global API Market"; Mukherjee, "Shut Chinese Companies Hit Desi Pharma Players"; Zainzinger, "Chinese Plant Closures Disrupt Supply Chains."
[20] Jermini, "The New Frontier for Western CDMOs?"
[21] Jain, "How China Is Impacting the Global API Market."
[22] Palmer, "Lonza Plagued by Supply Problems after China Plant Explosion | Fierce Pharma."

Jiangsu, and Shandong—that are among the regions of the world most vulnerable to the effects of climate change.[23]

## Quality and Transparency Risks

**For decades, drug supply shocks due to quality failures in Chinese factories has been among the most visible forms of evidence about the risk of over-dependence on China for API.** In one notable case from 2006, a Chinese manufacturer used a synthetic alternative for an ingredient that Baxter International used to produce heparin, a blood thinner. [24] This contamination led to 81 deaths and 700 allergic reactions in the U.S., prompting the FDA to suspend the sale of Baxter heparin, which constituted about half of American supply of that drug. [25] This incident prompted the FDA to establish its first outpost in China in order to increase its oversight over Chinese manufacturers.[26]

**Supply chain failures caused by quality failures have persisted, even as China has improved its domestic quality standards, underscoring the challenges of enforcing regulation over such a fragmented industry.** In 2018, the FDA had to recall several generic versions of valsartan, a drug used to treat hypertension, after they found that the API supplied by the Chinese company Zhejiang Huahai Pharmaceutical, which supplied close to half of the American valsartan market, was contaminated with a known carcinogenic material.[27] Two years later, the Chinese factory that was the sole supplier of API used in Bevacizumab, a cancer drug, substituted this API with a synthetic, untested chemical, resulting in adverse reactions among American cancer patients. [28] China ranks with India as the country that receives the most warning letters from the FDA over quality concerns.[29]

**In the past five years, these quality risks have grown because the FDA has faced growing barriers to inspecting Chinese API production facilities.** The FDA suspended most of its inspections of foreign facilities during the pandemic, but the agency faced particular difficulties in resuming normal activity levels in China relative to in other countries; FDA inspection rates in China did not return to pre-pandemic levels until 2024.[30] In large part, this was the product of Chinese officials denying American inspectors visas to enter the country—a move that was seen

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[23] Cross Dependency Initiative (XDI), "XDI Gross Domestic Climate Risk"; Grumiller, Grohs, and Reiner, "Increasing Resilience and Security of Supply Production Post-COVID-19: From Global to Regional Value Chains? Case Studies on Medical and Pharmaceutical Products."
[24] Harris, "U.S. Identifies Tainted Heparin in 11 Countries"; Vilanova, Tovar, and Mourão, "Imminent Risk of a Global Shortage of Heparin Caused by the African Swine Fever Afflicting the Chinese Pig Herd."
[25] Associated Press, "Families Tell Lawmakers of Heparin Death."
[26] Perrone, "FDA Will Open Inspection Office in China This Year."
[27] FDA, "FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of an Impurity."
[28] Public-Private Analytic Exchange Program, "Threats to Pharmaceutical Supply Chains."
[29] U.S. House Committee on Energy and Commerce, "E&C Republicans Press FDA Over Inadequate Inspection of Drug Manufacturing in India and China."
[30] FDA, "Foreign and Domestic Inspections."

as a retaliation against American visa restrictions on Chinese nationals. [31] Meanwhile, the FDA inspectors who remained in China reported an increase in the rate at which they were denied entry into Chinese facilities. [32] Inspectors have also voiced concern that China's tightening anti-espionage laws could eventually lead to their being arrested for doing their jobs on behalf of the U.S. or another foreign government.[33]

**These conditions have made American consumers increasingly dependent on Chinese regulators to guarantee the quality of American drug supply**. Unfortunately, Chinese regulatory systems often do not allow for the high levels of transparency needed for companies and consumers to monitor supply chain risks. For example, small Chinese API manufacturers can export through state-owned trading companies, which do not pass on critical information about the origin of the API that they sell. [34] Similarly, Chinese free trade zones do not require country-of-origin determinations for the goods that pass through them.[35] This raises concerns that Chinese ports, as well as ports that are part of the Belt and Road Initiative, are facilitating the sale of counterfeit drugs. Italy, for example, has determined that between 2014 and 2016, China and Hong Kong were the source of an inflow counterfeit pharmaceutical products.[36]

## (vii) potential for export restrictions by foreign nationals (China), including the ability of foreign nations to weaponize their control over pharmaceutical supplies

**Among the most pressing risks facing the U.S. is that the Chinese government could chose to restrict exports of API as part of a broader geopolitical dispute.**

**Chinese officials have indicated that they would considered leveraging their control over pharmaceutical supply chains in future disputes with the United States and its allies.** In 2020, Chinese economist and central banker Li Daokui suggested that China should use its status as the largest exporter of vitamins and antibiotics to counter Western sanctions on semiconductors. According to Li, "We are at the mercy of others when it comes to computer chips, but we are the world's largest exporter of raw materials for vitamins and antibiotics. Should we reduce the exports [in the trade war], the medical systems of some western countries will not run well."[37]

**The U.S. does not have readily available alternative sources of supply for critical pharmaceutical ingredients.** According to the American Chemistry Council, no or few alternatives exist for valuable inputs in the chemical manufacturing process needed for

[31] Perrone and Forster, "FDA Has Massive Backlog of Factory Inspections as Staffers Leave for Private Sector Jobs."
[32] Alim, Barnes, and Johnston, "Pharma Groups Warn of Supply Crunch over China Spying Law."
[33] Alim, Barnes, and Johnston.
[34] Nagur, Kumar, and Puranik, "Active Pharmaceutical Ingredients (API) Supply Chain in Europe, United States, India, China and Canada."
[35] Chow, "Three Major Problems Threatening Multi-National Pharmaceutical Companies Doing Business in China."
[36] Bandini, "Belt and Road Initiative and Its Effects on Intellectual Property."
[37] Collins and Erickson, "Economic Statecraft."

pharmaceuticals.[38] As the U.S. China Economic Security Commission noted: "if China were to block or slow supplies of common, essential drugs, such as those to treat hypertension, high cholesterol, pain, stroke, cardiac disease, infections, pain and so on, morbidity and mortality would skyrocket worldwide – in effect, cause a policy-induced pandemic."[39]

[38] American Chemistry Council, "ACC Oral Hearing Testimony."
[39] Chatterjee, "Indian Pharma Threatened by COVID-19 Shutdowns in China."

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