

SECTION 3: GROWING U.S. RELIANCE ON CHINA'S BIOTECH AND PHARMACEUTICAL PRODUCTS

Key Findings

- China is the world's largest producer of active pharmaceutical ingredients (APIs). The United States is heavily dependent on drugs that are either sourced from China or include APIs sourced from China. This is especially true for generic drugs, which comprise most prescriptions filled in the United States. Drug companies are not required to list the API country of origin on their product labels; therefore, U.S. consumers may be unknowingly accepting risks associated with drugs originating from China.
- The Chinese government has designated biotechnology as a priority industry as a part of its 13th Five-Year Plan and the Made in China 2025 initiative. The development of China's pharmaceutical industry follows a pattern seen in some of its other industries, such as chemicals and telecommunications, where state support promotes domestic companies at the expense of foreign competitors.
- China's pharmaceutical industry is not effectively regulated by the Chinese government. China's regulatory apparatus is inadequately resourced to oversee thousands of Chinese drug manufacturers, even if Beijing made such oversight a greater priority. This has resulted in significant drug safety scandals.
- The U.S. Food and Drug Administration (FDA) struggles to guarantee the safety of drugs imported from China because of the small number of FDA inspectors in country, the large number of producers, the limited cooperation from Beijing, and the fraudulent tactics of many Chinese manufacturers. Because of U.S. dependency on China as a source of many critical drugs, banning certain imports due to contamination risks creating drug shortages in the United States.
- As a result of U.S. dependence on Chinese supply and the lack of effective health and safety regulation of Chinese producers, the American public, including its armed forces, are at risk of exposure to contaminated and dangerous medicines. Should Beijing opt to use U.S. dependence on China as an economic weapon and cut supplies of critical drugs, it would have a serious effect on the health of U.S. consumers.
- Lack of data integrity in China presents challenges for U.S. and Chinese health regulators. In 2016, the China Food and Drug Administration investigated 1,622 drug clinical trial pro-

grams and canceled 80 percent of these drug applications after it found evidence of fraudulent data reporting and submissions of incomplete data, among other problems.

- China places great emphasis on genomic and other health-related data to enhance its biotech industry. Domestically, China established national and regional centers focused on big data in health and medicine. Investment and collaborations in the U.S. biotech sector give Chinese companies access to large volumes of U.S. medical and genomic data, but U.S. companies do not get reciprocal access.
- Foreign firms continue to face obstacles in China's health market. These obstacles include drug regulatory approval delays, drug pricing limitations, reimbursement controls, and intellectual property (IP) theft. U.S. companies must also compete with Chinese drug companies that introduce generic products or counterfeit drugs to the Chinese market shortly after a foreign patented drug is introduced.
- China is the largest source of fentanyl, a powerful synthetic opioid, in the United States. Although the Chinese government made multiple commitments to curtail the flow of illicit fentanyl to the United States, it has failed to carry out those commitments.

Recommendations

The Commission recommends:

- Congress hold hearings assessing the productive capacity of the U.S. pharmaceutical industry, U.S. dependence on Chinese pharmaceuticals and active pharmaceutical ingredients (APIs), and the ability of the U.S. Food and Drug Administration (FDA) to guarantee the safety of such imports from China, with a view toward enacting legislation that would:
 - Require the FDA to compile a list of all brand name and generic drugs and corresponding APIs that: (1) are not produced in the United States; (2) are deemed critical to the health and safety of U.S. consumers; and (3) are exclusively produced—or utilize APIs and ingredients produced—in China.
 - Require Medicare, Medicaid, the U.S. Department of Veterans Affairs, the U.S. Department of Defense, and other federally funded health systems to purchase their pharmaceuticals only from U.S. production facilities or from facilities that have been certified by the FDA to be in compliance with U.S. health and safety standards and that actively monitor, test, and assure the quality of the APIs and other components used in their drugs, unless the FDA finds the specific drug is unavailable in sufficient quantities from other sources.
 - Require the FDA, within six months, to investigate and certify to Congress whether the Chinese pharmaceutical industry is being regulated for safety, either by Chinese authorities or the FDA, to substantially the same degree as U.S. drug manufacturers and, if the FDA cannot so certify, forward to Congress a plan for protecting the American people from unsafe or contaminated drugs manufactured in China.

- Congress direct the U.S. Government Accountability Office to update its 2016 report, *Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices*. The updated report should focus on the U.S. Food and Drug Administration's ability to conduct inspections of Chinese drug manufacturing facilities.
- Congress consider legislation requiring generic drug manufacturers that sell medicines to the U.S. Department of Defense and U.S. Department of Veteran Affairs to disclose which essential drugs are at risk of shortage or supply disruption because the relevant products, active pharmaceutical ingredients, chemical intermediates, and raw materials contained in them are sourced from China.
- Congress enact legislation requiring drug companies to list active pharmaceutical ingredients and their countries of origin on labels of imported and domestically produced finished drug products.
- Congress enact legislation creating a risk-based system making importers of active pharmaceutical ingredients (APIs) and finished products liable for any health risks incurred by consumers in the event the product is proven unsafe due to contamination, mislabeling, or other defects. Special attention should be paid to finished drug products imported from China or containing APIs sourced from China.

Introduction

China is a global source of critical generic drugs and pharmaceutical ingredients, as well as health-related products like dietary supplements, biotechnology products, and medical devices. It is also the main source of APIs globally. Even India—the world's leading supplier of generic drugs—relies on China for 80 percent of its APIs.¹ The United States sources 80 percent of its APIs from overseas,² and a substantial portion of U.S. generic drug imports come either directly from China or from third countries like India that use APIs sourced from China.³ Drug companies are not required to list the API country of origin on their product labels; therefore, U.S. consumers may be unknowingly accepting risks associated with drugs originating from China.

China's government has invested significant resources into the development of biotechnology products and genomics research, but has not allocated the same resources toward developing necessary regulatory oversight. As a part of this effort, the Chinese government and affiliated companies and institutions have used licit and illicit means to accumulate personal and medical data on millions of U.S. persons in the process. China's government also encourages investments—including mergers and acquisitions, as well as venture capital (VC) investments—in U.S. biotech and health firms, leading to technology transfer that has enabled the rapid development of China's domestic industry.

U.S. health and biotech firms in China, meanwhile, continue to face regulatory and other market barriers that limit their ability to compete with Chinese firms. The Chinese government has taken steps in recent years to streamline regulatory procedures and allow

foreign medical products to enter the market more quickly. However, concerns remain over China's commitment to protecting IP rights and its continued favoritism of domestic providers of health products.

This section explores China's role in global health industries and the risks and opportunities posed for U.S. public health and national security. It also examines the activities of Chinese health and biotech firms in the United States and the ability of U.S. health and biotech firms to operate in China. Finally, the section discusses U.S.-China global health cooperation and analyzes remaining challenges in the relationship that have the potential to impede further cooperation. The section draws from the Commission's hearing on "Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products," consultations with global health, pharmaceutical, and biotech industry experts, and open source research and analysis.

Definition of Key Terms

This section uses several key terms in the pharmaceutical production process. Pharmaceutical products can generally be broken down into:

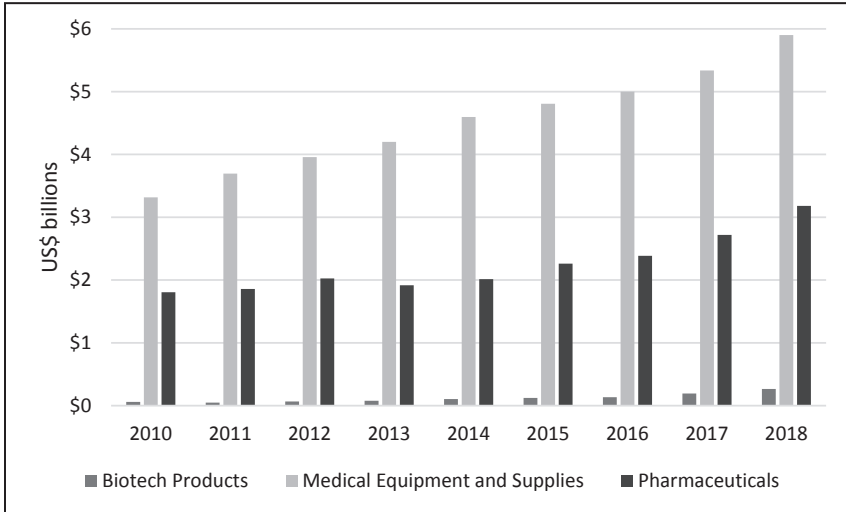
- **APIs:** The FDA defines an active ingredient as "any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals."⁴
- **Finished dosage forms:** Finished dosage forms (FDF) are pills, capsules, and other finished products ready for sale and use. Finished dosage drug facilities produce drugs in their finished forms (e.g., tablets or capsules). The finished dosage of a drug usually contains some kind of API and inactive ingredients. Finished dosage forms can be brand name or generic drugs.
- **Biologics:** Biologics (also referred to as biological drugs or biopharmaceuticals) are products created using living organisms and can range from vaccines and tissues used in transplants to cell and gene therapies. Biologics are produced using biotechnology.
- **Biosimilars:** According to the FDA, biosimilars are biological products that are "highly similar to and have no clinically meaningful differences from" a biologic that has already been approved by health regulators.⁵

U.S. Reliance on Chinese Pharmaceutical and Medical Products

China's share of U.S.-bound exports of biotech products, medical equipment and supplies, and pharmaceuticals has been on a steady increase (see Figure 1). In 2018, U.S. imports of Chinese biotech products were \$266 million, up from \$194 million in 2017.⁶ U.S. imports of Chinese medical equipment have also increased significantly over the past decade. In 2018, for example, they increased to \$5.9

billion, up 78 percent since 2010.⁷ U.S. imports of pharmaceuticals directly from China increased to \$3.1 billion in 2018, up 17 percent year-on-year, and 76 percent since 2010.⁸

Figure 1: U.S. Imports of Health Products from China, 2010–2018



Source: U.S. Census Bureau, USA Trade Online, June 17, 2019. <https://ustrade.census.gov/data/Perspective60/View/dispvie.aspx>; U.S. Census Bureau, U.S. Trade with China in Advanced Technology Products, December 2018. <https://census.gov/foreign-trade/statistics/product/atp/2018/12/ctryatp/atp5700.htm>.

According to the FDA, in fiscal year 2018, 13.4 percent of all U.S. drug imports, by import line,* originated directly from China.† This makes China the second-largest exporter of drugs and biologics to the United States behind Canada.‡ However, the FDA acknowledges these figures understate U.S. dependence on Chinese pharmaceuticals because China is also the primary supplier of APIs for producers located in other countries.⁹ Given China's dominance of the global market for APIs, it is highly likely that most generic drugs imported into the United States contain active ingredients sourced from China.

China as a Global Source of Generic Drugs and APIs

China's pharmaceutical industry consists of more than 4,000 drug manufacturers, which in 2017 recorded revenues of \$127.8 bil-

*Import lines are products listed as separate items on entry documentation that an importer submits to U.S. Customs and Border Protection. U.S. Customs and Border Protection transmits this information to the FDA for those products that are FDA regulated. Federal Register, *Submission of Food and Drug Administration Import Data in the Automated Commercial Environment*, July 1, 2016. <https://www.federalregister.gov/documents/2016/07/01/2016-15684/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment>.

†According to the FDA, approximately 83 percent of drug imports from China are FDF drugs, 7.5 percent are APIs sourced directly from China, and 10 percent are animal drugs and medicated animal feed. See U.S.-China Economic and Security Review Commission, *Hearing on Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products*, written testimony of Mark Abdo, July 31, 2019, 1.

‡In fiscal year 2018, 19.4 percent of all imported drugs to the United States, by import line, came from Canada. U.S. Food and Drug Administration, interview with Commission staff, October 3, 2019.

lion.¹⁰ Its national pharmaceutical market is the second-largest in the world by domestic health expenditures (behind only the United States), and is expected to expand to \$145–\$175 billion by 2022.¹¹ Unlike the United States, which produces costly, high-value compounds, China’s pharmaceutical industry primarily produces inexpensive generic drugs and pharmaceutical ingredients.¹²

Government subsidies, a robust chemical industry, IP theft, lax environmental protections, and regulations favoring domestic companies contributed to China’s emergence as the world’s largest producer of APIs. In 2008, the Chinese government designated pharmaceutical production as a “high-value-added industry” and bolstered the industry through subsidies and export tax rebates to encourage pharmaceutical companies to export their products.¹³ In 2017, China earmarked approximately \$13.2 billion for pharmaceutical research and development (R&D), and its investment in this area is expected to reach \$29.2 billion by 2021.¹⁴

China’s drug industry is built on the foundations of its robust chemical industry—which accounts for 40 percent of global chemical industry revenue—the world’s largest.¹⁵ China’s chemical companies have the capacity to produce a range of products, from fertilizer to drug ingredients, with relatively little regulatory oversight.¹⁶ Lack of robust environmental and labor protections, coupled with poor enforcement of IP laws, have also fueled the growth of China’s pharmaceutical industry.¹⁷

With the growth of China’s chemical industry and its subsequent dominance in API manufacturing, the world is becoming increasingly dependent on China as the single source for life-saving drugs. The U.S. generic drug industry can no longer produce certain critical medicines such as penicillin and doxycycline, and the APIs needed to make these antibiotics are sourced from China.¹⁸ The vastness of the global medicine supply chain and the lack of sourcing transparency for key drug ingredients can obscure early indicators of supply chain problems.¹⁹

Rosemary Gibson, senior advisor at the Hastings Center and author of *China RX*, noted in her testimony before the Commission that the United States is losing its ability to produce generic drugs because Chinese drug companies dumped low-price products into the global market, which in turn pushed U.S., European, and Indian producers out of the generic drug manufacturing business.²⁰ According to Ms. Gibson, China is seeking to disrupt, dominate, and displace U.S. pharmaceutical and other medical companies, and in doing so limit the United States’ ability to produce its own medicines, including critical antibiotics such as penicillin and even generic aspirin.²¹ She believes the United States could see its generic drug industry made uncompetitive within five to ten years due to the Chinese government’s policies (including subsidies and export incentives) that allow Chinese pharmaceutical firms to undercut prices and drive U.S. firms out of business.²²

Dependency on China Creates Supply Chain Disruption Risks

Approximately 40 percent of the generic drugs sold in the United States have just one manufacturer each, and a supply chain disruption could cause a serious drug shortage.²³ The American Medical

Association has called on the federal government to address the potential for critical drug shortages as a national security concern and offer incentives to boost domestic production of these drugs.*²⁴ The American Medical Association suggests mitigating drug shortages would require drug manufacturers to increase transparency in the global pharmaceutical supply chain by sharing information about the location of drug production sites and the causes and duration of drug shortages.²⁵ The American Medical Association also called on the U.S. government to include important drug production sites in critical infrastructure planning.²⁶

U.S. dependence on drugs from China—or drugs that use APIs from China—raises the likelihood of drug shortages should the Chinese supply be disrupted. For example, in 2017 an explosion at a Chinese factory producing APIs for the antibiotic piperacillin/tazobactam, a drug given to patients with severe infections, led to a global shortage.²⁷ Occurrences of adulteration or supply disruption not only highlight the risks of relying on China as the only source of important pharmaceutical ingredients, but also raise concerns that these drugs and other medical products could lead to adverse health impacts in the United States and elsewhere around the world. U.S. policymakers have also expressed strong concern about the impact of substandard health products on U.S. public health, and the national security implications of relying on China as a “single supplier for such lifesaving goods.”²⁸

In the past decade, U.S. consumers have been exposed to adulterated drug products made by Chinese manufacturers who employ dangerous manufacturing practices to save on cost. Last year, the FDA announced that a probable carcinogen once used in the production of rocket fuel was found in valsartan²⁹ and two other blood pressure medicines used in 30 countries by millions of people, including in the United States.^{†30} The companies selling the contaminated medicine sourced APIs from one of China’s leading generic drug companies, Zhejiang Huahai Pharmaceutical Co., where employees ignored signs that the company’s manufacturing practice resulted in contaminated product.³¹ (For more information, see Addendum I, “FDA Letter to Zhejiang Huahai Pharmaceutical.”)

U.S. Armed Forces Vulnerable to Drug Shortages

China’s dominance as a global API producer and the United States’ growing reliance on Chinese pharmaceutical products puts U.S. consumers—including active service members and veterans—at risk if China cuts off drug supplies or hikes the cost of a given medicine during heightened geopolitical tensions. Christopher Priest, principal deputy to the deputy assistant director of healthcare operations of the Defense Health Agency, stated, “The national security risks of increased Chinese dominance of the global API market cannot be overstated ... Should China decide to limit or restrict the delivery of APIs to the U.S. it would have a debilitating effect on U.S. domestic

*U.S. drug production involves a broad array of international players, including top international generic drug companies such as Fresenius Kabi, Apotex, and Cipla.

†As of September 2019, 140 lawsuits have been filed against Zhejiang Huahai Pharmaceutical Co., other drug manufacturers whose products were recalled, and pharmacies that filled prescriptions for valsartan. See Anna Edney et al., “Carcinogens Have Infiltrated the Generic Drug Supply in the U.S.,” *Bloomberg*, September 12, 2019.

production and could result in severe shortages of pharmaceuticals for both domestic and military uses.”³² Many of these products may be critical to life-saving or disease management regimens.

Supply shortages could significantly delay the delivery of critical medicines to the battlefield. Mr. Priest emphasized the importance of bolstering U.S. domestic manufacturing capability to provide an alternate source for critical medicines. U.S. dependence on drugs that contain APIs sourced from China can affect the availability of remedies needed to respond to a public health crisis, including incidents involving a chemical, biological, or radiological/nuclear threat.³³ For example, in 2001 the U.S. government purchased 20 million doses of doxycycline, an antibiotic used to treat individuals exposed to anthrax, from a European manufacturer that sourced the API in its drug product from China.³⁴

The Department of Defense (DOD) is responsible for purchasing pharmaceuticals and medical devices used by U.S. military hospitals both in the United States and overseas. All pharmaceuticals purchased for use in military hospitals are required to be manufactured in countries that have signed on to the Trade Agreements Act (TAA)* of 1979, to which China is not a signatory.³⁵

Although China is a non-TAA country—and is not eligible to directly receive U.S. government contracts—in the absence of other suppliers, drugs and ingredients from China may receive exemptions. The U.S. Defense Logistics Agency, which operates under DOD, estimates 25 percent of pharmaceutical ingredients used in U.S. military hospitals originate from China, even if the drugs themselves are manufactured elsewhere.³⁶ This occurs because companies in TAA signatory countries like India rely on APIs from China. In some cases, pharmaceutical companies with DOD contracts may even be manufacturing products in China, despite the company being headquartered in a TAA signatory country.† DOD contracts require that pharmaceutical suppliers disclose where they manufacture their drugs and where they source their APIs. However, since there is no national registry for API sources, Defense Logistics Agency has no means to independently determine the origin of APIs.³⁷

Mr. Priest expressed concern about supply chain disruptions and the potential for drug shortages as a result of China’s control over critical APIs.³⁸ Of the approximately 6,800 drugs DOD purchases annually, 147 are sourced from non-TAA countries.³⁹ According to Mr. Priest, the Trump Administration is in the process of identifying which of these drugs are most vulnerable to risks associated with the U.S. reliance on Chinese drug and medical products.⁴⁰

*The TAA requires products used by the U.S. government to be manufactured in the United States or in a designated country with which the United States has a free trade agreement or special trade-related arrangement. The U.S. government is able to source non-TAA-compliant products when TAA-compliant products are not available.

†The TAA requires the end product being delivered to the U.S. government to be “substantially transformed” in the United States or a “designated country identified in the Federal Acquisition Regulation (FAR).” Therefore, the location where a finished drug product is manufactured, rather than the origin of the drug’s APIs, determines whether a drug product is TAA compliant. U.S.-China Economic and Security Review Commission, *Hearing on Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products*, oral testimony of Christopher Priest, July 31, 2019, 21.

Illicit Fentanyl Flows from China

According to the U.S. Department of Justice, China is the largest source of illicit fentanyl and fentanyl-like substances in the United States.⁴¹ Fentanyl is a synthetic painkiller about 50 times more potent than heroin and 100 times stronger than morphine.⁴² Fentanyl has legitimate medical uses,⁴³ but has also become one of the most frequently abused drugs. Synthetic-opioid-related deaths in the United States rose from approximately 3,000 in 2013 to more than 30,000 in 2018, and fentanyl is now the cause of twice as many deaths as heroin.⁴⁴

As a result of ongoing U.S.-China counternarcotic negotiations, the Chinese government implemented new comprehensive measures to control “all fentanyl-like substances” in May 2019.* In September 2019, the Chinese government released a statement on fentanyl, saying that it has broadly defined “fentanyl-like substances” in order to prevent drug producers from creating new fentanyl substances not covered by the ban.⁴⁵ The statement claims that the ban has been a success thus far: “Thanks to earnest implementation of various measures, significant progress has been achieved. China’s law enforcement authorities have obtained information about 91 key enterprises and 234 key individuals involved with fentanyl-like substances across the county, and put all of them under strict supervision.”⁴⁶

The Chinese government’s decision to control all fentanyl-type substances is an important step in U.S.-China counternarcotic efforts. However, concerns remain about the Chinese government’s willingness and commitment to effectively curtail the flow of illicit fentanyl to the United States.⁴⁷ Although the Chinese government made multiple promises to the United States to address the fentanyl problem, three troubling trends speak to its failure to carry through on those commitments:

- First is a recent resurgence in fentanyl flows into the United States. In fiscal year 2019 through August, the U.S. Customs and Border Protection Office of Field Operations seized 2,350 pounds of fentanyl, a 32 percent increase over seizures in fiscal year 2018.⁴⁸
- Second is the Chinese government’s failure to arrest individuals indicted for illicit fentanyl production and trafficking. Between 2017 and 2018, the U.S. Justice Department indicted eight individuals from China for crimes related to fentanyl production, trafficking, and financing.⁴⁹ As of September 2019, all of the individuals charged remain free.⁵⁰

*According to a Chinese government announcement: “Fentanyl-type substance” means a substance having one or more of the following chemical structures compared to fentanyl: (1) the use of other acyl groups in place of propionyl groups; (2) the use of any substituted or unsubstituted monocyclic aromatic groups; a group replacing a phenyl group directly bonded to a nitrogen atom; and a substituent such as an alkyl group, an alkenyl group, an alkoxy group, an ester group, an ether group, a hydroxyl group, a halogen group, a halogenated alkyl group, an amino group, and a nitro group; (3) the use of any other group (except hydrogen atoms) instead of phenethyl. See *People’s Daily*, “Three Departments Make Joint Announcement: Regulations on Fentanyl-Type Substances to Go Into Effect May 1st,” (三部门发布公告5月1日起对芬太尼类物质实施整类列管(权威发布)) April 2, 2019. Translation: http://paper.people.com.cn/rmrb/html/2019-04/02/nw.D110000renmrb_20190402_4-02.htm.

Illicit Fentanyl Flows from China—*Continued*

- Third, the Chinese government continues to provide value-added tax (VAT) rebates and other incentives to chemical producers, including fentanyl manufacturers.⁵¹ As of September 2019, China's State Administration of Taxation's website shows fentanyl receives a 10 percent VAT rebate and several other fentanyl-related products receive a 13 percent VAT rebate.⁵²

U.S. Government Oversight of Health Imports from China

Both Chinese and U.S. health regulators face challenges in inspecting Chinese drug manufacturing facilities for quality and adherence to manufacturing standards. The sheer size of China's pharmaceutical industry, further enlarged by the integration of China's pharmaceutical and chemical industries, impacts regulatory capacity. Corruption and fraud persist in China's drug industry due to poor regulatory oversight, leading to the production of adulterated and ineffective medicine. These regulatory issues have directly impacted the health of consumers.

In bilateral forums, such as the now discontinued U.S.-China Strategic and Economic Dialogue (S&ED),* China has acknowledged the need to work toward improving the quality of its generic drug and API exports. During the sixth meeting of the S&ED in 2014, the United States and China agreed to "advance the shared goal of ensuring access to safe and high-quality medicines for patients and protect supply chain integrity ... and to fight against illegal actions to manufacture, distribute, and export counterfeit and substandard active pharmaceutical ingredients."⁵³ Although China has committed to better oversight of its drug industry, poor manufacturing practices, corruption, and product contamination persist five years later.

Chinese Health Regulators Struggle with Oversight

As China's pharmaceutical industry expanded rapidly over the years, its regulatory framework struggled to maintain strong oversight. Understaffing and retention issues have impacted the ability of China's Food and Drug Administration (renamed China's National Medical Products Administration in 2018), the government entity responsible for oversight of food and drug imports and products, to regulate effectively. Furthermore, the fragmented nature of China's regulatory framework itself has caused difficulties with intergovernmental coordination and created unclear jurisdictions for oversight responsibilities.⁵⁴

Corruption, fraud, poor product quality, or contamination have occurred due to weak oversight capacity. In her testimony before the Commission, Katherine Eban, investigative journalist and author of *Bottle of Lies: The Inside Story of the Generic Drug Boom*, cited data that show Chinese drug manufacturers received more

*The S&ED, established during the Obama Administration, was a bilateral forum for the United States and China to discuss issues within U.S.-China relations. The dialogue was held annually from 2009 to 2016.

warning letters* from the FDA over the past decade than any other country.⁵⁵

One of the most notorious scandals occurred in 2007, when the former head of China's then State Food and Drug Administration, Zheng Xiaoyu, confessed to accepting bribes from drug companies to approve hundreds of untested medicines.⁵⁶ A number of food and drug quality scandals have arisen since then, including a vaccine scare in 2018 after health regulators discovered that Changsheng Biotechnology Co. and a separate company in Wuhan falsified data to obtain approval for a diphtheria, pertussis, and tetanus (DPT) vaccine, affecting over 250,000 dosages and 400,000 injections, respectively.⁵⁷ The incident stirred up public distrust in China toward Chinese drugs, especially after faulty vaccines led to the hospitalization of hundreds of children and some deaths in China in 2010 and 2013.⁵⁸

The Chinese government has made efforts to crack down on corruption and consolidate its food and drug regulatory regime to improve drug quality and bolster China's image as a global producer of pharmaceuticals. In 2016, China's Food and Drug Administration investigated 1,622 clinical trial programs of drugs that were pending production approval and canceled 80 percent of these drug applications after it found evidence of fraudulent data reporting and submissions of incomplete data, among other issues.⁵⁹ The following year, Chinese courts determined that penalties should be strengthened for researchers who submit faulty data to obtain drug approvals, which could include the death penalty for instances where a drug causes harm to consumers.⁶⁰ The Chinese government is increasing oversight of its pharmaceutical industry by requiring generic drugs approved for production prior to 2008 to be evaluated for quality and revoking licenses or denying government tendering for products that fail to pass the evaluation. This effort could close smaller manufacturers that produce low-quality drugs out of the market.⁶¹

In 2018, the 13th National People's Congress approved a plan to form the State Market Regulatory Administration in order to strengthen China's regulatory system. The restructuring involved consolidating China's Food and Drug Administration; the General Administration of Quality Supervision, Inspection and Quarantine; the State Administration of Industry and Commerce; and subdivisions of other agencies into one ministry called the State Administration of Market Regulations.⁶²

FDA Faces Impeded Access in China

The FDA is the primary U.S. government agency tasked with ensuring commercial pharmaceutical and health products meet U.S. health and safety standards. The FDA maintains one field office (with 16 FDA officials) in Beijing to train local Chinese regulators

*The FDA issues a warning letter to manufacturers when they have "significantly violated FDA regulations." The letter documents the nature of the violation, which can include but is not limited to "poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use." A company that is issued a warning letter must respond with how it will remedy the issue and provide a timeline for next steps. The FDA then verifies whether the corrections were made. See U.S. Food and Drug Administration, "About Warning and Close-Out Letters," <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters>.

and share information with Chinese counterparts.* FDA officials have had difficulty securing visas for new inspectors deploying to China and have also faced obstacles conducting unannounced factory inspections, which are routine in the United States.⁶³

In 2016, a U.S. Government Accountability Office (GAO) investigation found the FDA may have never inspected approximately 1,000 overseas drug manufacturing facilities, 243 of which were located in China.⁶⁴ The GAO report states these facilities lacked an inspection history due to FDA data management issues, and the FDA was in the process of inspecting all facilities in its catalog with no prior inspection history.⁶⁵ The GAO report also states,

*FDA does not know whether or for how long these establishments have or may have supplied drugs to the U.S. market, and has little other information about them. While the agency has made progress in reducing this knowledge gap, it is important to note that the overall number of foreign establishments with no surveillance inspection history ... remains large.*⁶⁶

Since 2015, there have been 87 cases involving Chinese firms that have either refused FDA inspections or caused a delay in inspections.⁶⁷ Denial of inspection by a foreign facility may cause the FDA to deem a drug product adulterated and place the drug on import alert, which “allows FDA to refuse admission of future shipments of an imported drug product.”⁶⁸ There are currently 51 Chinese companies that export to the United States medical devices, dietary supplements, and drug products placed on import alert due to inspection refusal or poor manufacturing practices.[†]

Beginning in 2012, the FDA established a team responsible for reporting on and assessing drug shortages for high-risk pharmaceutical and medical products.⁶⁹ By ensuring potential shortages are detected and addressed immediately, the FDA has additional time to work with manufacturers and other stakeholders to identify ways to maintain treatment options and prevent a shortage.⁷⁰ As of October 2019, the FDA has determined 113 drugs were in shortage in the United States.⁷¹ There is insufficient information to determine which of these 113 drugs are sourced from China either in their finished form or as active ingredients. The risks of these shortages have been exacerbated by a growing reliance on China as the source of U.S. generic pharmaceuticals.

FDA Inspection Regime

The FDA follows the same protocols for domestic and overseas inspections, including drug preapproval review processes, premarket inspections, and surveillance inspections.

Drug preapproval review process and premarket inspections: The FDA can examine the process and technology used to manufacture generic and/or brand name drugs before the drug is

*In the past, the FDA also had offices in Shanghai and Guangzhou; however, these offices closed in 2014. U.S. Food and Drug Administration, interview with Commission staff, July 22, 2019.

†For a full list of companies, see U.S. Department of Health and Human Services, *Import Alert* 99–32, September 30, 2019. https://www.accessdata.fda.gov/cms_ia/importalert_521.html.

FDA Inspection Regime—Continued

approved and introduced to the market. This preapproval review process allows the FDA to assess the quality of the manufacturing process as well as the quality of the product itself.⁷²

The FDA can also conduct premarket inspections, which involves assessing whether a drug manufacturing facility is in compliance with regulations.⁷³ The FDA additionally requires drug producers to provide notification of changes to their manufacturing process or facilities before or after the drug is introduced to the market.⁷⁴ After market introduction, the FDA tests selected finished drug products and APIs to ensure the “potency, quality, and consistency of generic medicines meets the standards established for the specific drug.”⁷⁵

Current Good Manufacturing Practice (CGMP) surveillance inspections: FDA officials conduct surveillance inspections of foreign drug manufacturing facilities using a risk-based site selection model that maximizes resources by prioritizing inspections of sites that “pose the greatest potential risk for problems that could harm patients.”⁷⁶ Sites that produce inactive ingredients or drugs only for clinical trials are not prioritized unless deemed necessary. If a quality issue is suspected, there are a number of ways the FDA can respond, including: making an unannounced visit to the facility for further inspection, placing companies on import alert, seizing products from warehouses or facilities, or testing imports at points of entry, among other actions.⁷⁷

According to Ms. Eban, the FDA and other regulators have struggled to properly inspect the manufacturing and export of Chinese pharmaceutical and medical products brought to the United States.⁷⁸ Around 90 percent of U.S. dietary supplement products, for example, are imported from China.⁷⁹ However, because its jurisdiction does not extend to pre-inspection of dietary supplements, the FDA does not approve their safety before they enter the U.S. market, potentially exposing U.S. consumers to products that are unsafe or do not contain the proper ingredients.*

In her book, Ms. Eban documents FDA officials in China frustrated by pharmaceutical companies’ efforts to manipulate or obscure their operations.⁸⁰ Chinese pharmaceutical firms sometimes invest in “show” factories, or factories that are open to inspectors but are not the true source of the company’s products.⁸¹

The FDA has the authority to inspect Chinese pharmaceutical facilities and withhold import licenses from Chinese companies that do not comply with U.S. regulatory standards. However, Ms. Eban’s research demonstrates that when the FDA does find safety violations in Chinese plants, it sometimes does not sanction them for fear of creating drug shortages in the United States.⁸² For example,

*The FDA regulates dietary supplements under a different set of regulations than those covering drug products. Firms are responsible for evaluating the safety and labeling of their dietary supplement products before they reach the market, but the FDA is responsible “for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.” See U.S. Food and Drug Administration, *Dietary Supplements*, August 16, 2019. <https://www.fda.gov/media/104838/download>.

Ms. Eban reports that in May 2017, an FDA inspector determined that Chinese drug manufacturer Zhejiang Hisun was hiding the results from pretests of its drug samples.⁸³ The FDA initially restricted imports of 30 Zhejiang Hisun products, but lifted the restriction on half of the drugs because those particular drugs, used in cancer treatments, were in short supply in the United States.⁸⁴

China's Pharmaceutical and Biotech Activities in the United States

China maintains a comprehensive, long-term strategy to become a leader in biotechnology, seeking to create globally competitive domestic biotech firms and incentivize biotechnology manufacturing, design, and operations to move to China. The Chinese government designated biotechnology as a Strategic Emerging Industry in 2010, and prioritizes state support for this industry in state plans such as Made in China 2025 and the Precision Medicine Initiative.⁸⁵ As part of the goals set out in the Made in China 2025 plan, the Chinese government identified the kinds of medicines and technology it aims to develop (e.g., new vaccines and antibody drugs), and plans to increase the domestic market share for biopharmaceutical core components to 70 percent by 2020.⁸⁶ Through the Precision Medicine Initiative, the Chinese government is investing \$9.3 billion in various genome sequencing and clinical data acquisition projects over a 15-year period.⁸⁷

In biotechnology as in other high-tech industries, the Chinese government wants to move away from reliance on foreign companies and imports for both economic and national security reasons. Although the United States is currently the world's leading developer of biotech products, China is an increasingly important player in this space. According to a Gryphon Scientific report prepared for the Commission in 2019, China's biologics market revenue in 2016 was between \$4.7 billion and \$6.2 billion, while its agricultural biotech market revenue was around \$8.1 billion, compared to U.S. biologics and agricultural biotech markets at \$118 billion and \$110 billion, respectively.⁸⁸ China's government prioritized biotechnology as a Strategic Emerging Industry for two overlapping reasons. First, there is a high demand for biopharmaceuticals in the Chinese health market because noncommunicable diseases are a major public health concern with roughly 85 percent of deaths linked to noncommunicable diseases such as cancer, cardiovascular diseases, and respiratory diseases.⁸⁹ Second, biotechnology is a high-tech, high-value industry, with potentially significant long-term economic benefits.

China's biotechnology development is focused on three areas: (1) creating biopharmaceuticals to treat chronic diseases; (2) implementing contract research and manufacturing; and (3) conducting DNA sequencing.⁹⁰ A number of biologics used in China are imported, and Chinese companies aim to increase domestic market share.⁹¹ Many of these drugs are not innovative, but rather are biosimilars.⁹² Drug companies in China often rely on contracted research organizations* to navigate China's regulatory framework and provide preclinical

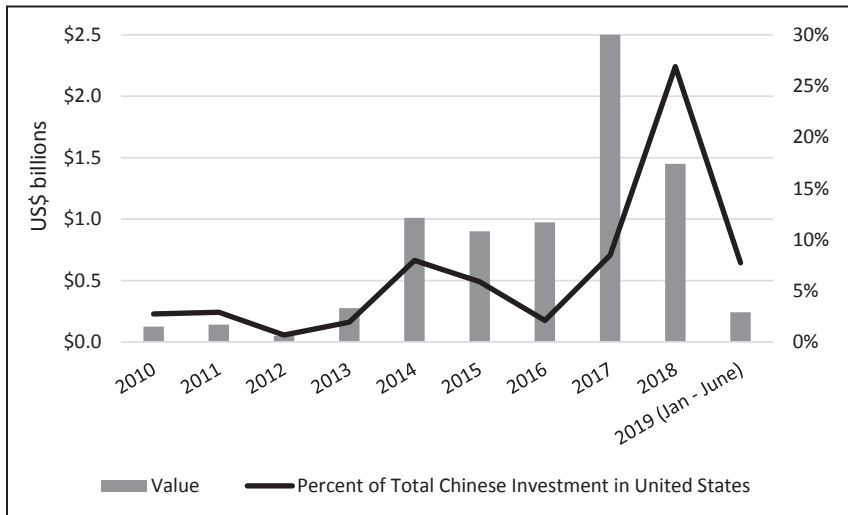
*A contract research organization is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

and clinical drug testing services for drug candidates.⁹³ According to research by Gryphon Scientific, of the 1,100 contracted research organizations worldwide in 2017, 400 were based in China.⁹⁴ Several key DNA sequencing companies are also based in China, including BGI, the third-largest DNA sequencing company in the world, ranking behind U.S. companies Illumina and Thermo Fisher.⁹⁵

Chinese Investment Flows to U.S. Health and Biotech Industries

Chinese investment and trade ties in U.S. medical and biotech industries have increased steadily in recent years. According to the economic consultancy Rhodium Group, Chinese foreign direct investment (FDI) flows to U.S. health and biotech industries increased from \$125 million in 2010—2.7 percent of China’s total investments in the United States that year—to \$2.5 billion in 2017, 8.5 percent of total Chinese investment in the United States (see Figure 2).⁹⁶ In 2018, Chinese investments in U.S. health and biotech industries totaled \$1.45 billion, 27 percent of China’s total investments in the United States.⁹⁷

Figure 2: Chinese FDI in U.S. Health, Pharmaceuticals, and Biotechnology Industry, 2010–H1 2019



Source: Rhodium Group, “China Investment Monitor,” August 16, 2019.

The U.S. Committee on Foreign Investment in the United States (CFIUS) has been stepping up its scrutiny of Chinese investments, especially in high-tech sectors. In 2019, for example, CFIUS forced the Chinese tech firm iCarbonX to divest from its 2017 stake in U.S. health firm PatientsLikeMe after security concerns were raised about the deal.⁹⁸ In an effort to avoid CFIUS scrutiny, Chinese investors in U.S. health, pharmaceuticals, and biotechnology companies are increasingly routing their investments through VC funds.⁹⁹ Health, pharmaceutical, and biotech were the industries Chinese VC investors targeted most frequently in 2018, along with infor-

mation and communications technology firms.¹⁰⁰ The enactment of the Foreign Investment Risk Review Modernization Act (FIRRMA) in 2018 expanded the authority of CFIUS to review VC investments that may threaten U.S. national security interests.*¹⁰¹ The possibility of increased CFIUS scrutiny of VC investments has prompted a drop in the overall Chinese VC investments in the United States.¹⁰² In the first nine months of 2019, Chinese VC investment fell to approximately \$4 billion, a \$5 billion decrease from the same period in 2017.¹⁰³ This fall notwithstanding, health, pharmaceuticals, and biotechnology received the highest level of Chinese VC investment in the United States the first half of 2019 (about \$330 million).¹⁰⁴ These sectors also saw the highest number of transactions involving Chinese investor participation.

Chinese Biotech Firms' Collaboration with U.S. Companies and Universities

Decades-long collaboration with U.S. firms and research institutions has been critical to China's biotech development. Chinese investments and research partnerships with U.S. institutions not only provide Chinese biotechnology companies with technologies crucial to advancement in the field, but also allow them to amass large collections of clinical and genetic data on U.S. residents.¹⁰⁵ These partnerships are typically focused on developing expertise in cancer therapeutics or precision medicine.¹⁰⁶

Gryphon Scientific's research shows six of the top ten ranking U.S. research institutions† have established "at least one life science biotechnology partnership with Chinese institutes."¹⁰⁷ Chinese biotech companies access U.S. assets through a variety of channels, including investment, corporate and academic partnerships, and recruitment of U.S.-trained researchers. In his testimony, Mark Kazmierczak, expert at Gryphon Scientific, noted that some Chinese biotechnology firms have opened R&D facilities and incubators in strategic biotech hubs such as Boston, San Francisco, and North Carolina's Research Triangle region, which gives these companies access to "advanced technology and expertise [and] a well-educated workforce."¹⁰⁸

Chinese Companies' Access to U.S. Healthcare Data Raises Concerns

The acquisition of U.S. personal and health data by the Chinese government and companies presents national security risks. China's access to U.S. health data provides China with the tools to exploit Americans' personal health records and displace U.S. leadership in biotechnology and other fields. Protecting U.S. health data is a serious concern, particularly due to the Chinese government-linked

*The U.S. Department of the Treasury published proposed regulations to implement FIRRMA on September 17, 2019. The final regulations will become effective no later than February 13, 2020. U.S. Department of the Treasury, *The Committee on Foreign Investment in the United States (CFIUS)*. <https://home.treasury.gov/policy-issues/international/the-committee-on-foreign-investment-in-the-united-states-cfius>; U.S. Department of the Treasury Office of Public Affairs, *Fact Sheet: Proposed CFIUS Regulations to Implement FIRRMA*, September 17, 2019. <https://home.treasury.gov/system/files/206/Proposed-FIRRMA-Regulations-FACT-SHEET.pdf>.

†The top U.S. research institutions with at least one biotechnology partnership with a Chinese institution are: Harvard University, Massachusetts Institute of Technology, University of California Berkeley, University of Michigan, University of California at Los Angeles, and Yale University.

cyberespionage and hacking campaigns aimed at obtaining sensitive U.S. personally identifiable information, including personal health data and clinical trial data. The 2015 hacking of Anthem Inc. by Chinese nationals serves as an example: the cyberattack on the health insurance giant allowed hackers to gain access to up to 80 million patient records, not simply personally identifiable information.¹⁰⁹

The Chinese government and companies also carry out a vast personal and health data collection through legal means. Chinese biotech companies gain access to U.S. healthcare and genomic data through investments and partnerships with health companies and research institutes. For example, the *Wall Street Journal* reported in June 2019 that Twist Bioscience Corp., a synthetic DNA manufacturer that had received \$5 million in funding from DOD, partnered with a Chinese company and planned to expand its manufacturing in China.¹¹⁰ Policymakers expressed concern that the potential partnership could lead to the transfer of valuable IP and data on synthetic DNA production.¹¹¹ By acquiring large datasets of health information, Chinese companies can make their drug discovery and clinical trials more reliable and cost efficient, putting them at an advantage against U.S. health and biotech firms.¹¹²

In his testimony before the Commission, Benjamin Shobert, director of strategy for health business strategy at Microsoft, argued asymmetric data-sharing policies between the United States and China weaken the U.S. competitive advantage in medicine innovation and artificial intelligence.¹¹³ Investment and collaborations in the U.S. biotech sector give Chinese companies access to large volumes of U.S. medical and genomic data, but U.S. companies do not get reciprocal access.¹¹⁴ Mr. Shobert believes “protocols specific to de-identification and bilateral cross-border data sharing [are needed] ... to ensure the pace of progress in healthcare continues to accelerate.”¹¹⁵ The Chinese government is also formulating policies to support the acquisition and use of large healthcare genomic and other personal health data sets.¹¹⁶

The Chinese government places great emphasis on collecting domestic genomic and other health-related data for purposes beyond developing its biotechnology sector. In many cases, the Chinese government has taken data from its citizens without informed consent* in order to enhance surveillance of targeted groups. For example, in 2016 local authorities in Xinjiang began implementing a program called “Physicals for All,” which involved conducting free annual health exams for residents with the stated purpose of improving healthcare services and creating digital health records for participants.¹¹⁷ Although official documents describing this health program did not state DNA would be collected, health authorities collected DNA samples from approximately 36 million people in

*The “Personal Information Security Specification,” China’s law on personal data governance, took effect in May 2018, and provides guidelines for consent and the collection and use of personal data, including biometric data. The law’s consent principle states that compliance requires “obtain[ing] authorized consent from the PI [personal information] subject after expressly providing the PI subject with information including the purpose, method, scope, and rules of the processing.” Despite the drafting and adoption of guidelines for consumer data collection and use, misuse of data by Chinese law enforcement and government entities remains a concern. Mingli Shi et al., “Translation: China’s Personal Information Security Specification,” *New America*, February 8, 2019; Human Rights Watch, “China: Big Data Fuels Crackdown in Minority Region,” August 25, 2017.

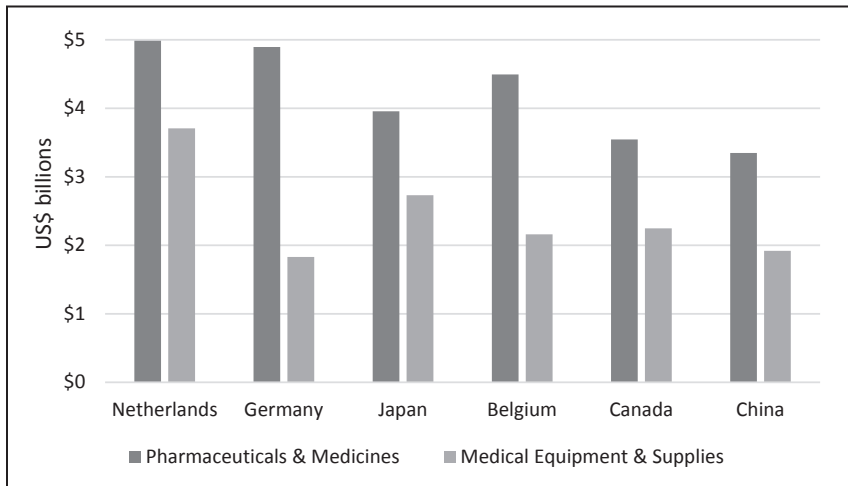
2016–2017.¹¹⁸ Despite Chinese media reports stating the program was voluntary, members of the Uyghur community claimed police and local officials coerced them into participating in these medical checkups, and they were not aware of how their biometric data would be used or even able to access the results of their medical tests.¹¹⁹

U.S.-made equipment and research conducted by U.S. scientists have been used to advance the Chinese government's mass biometric data collection campaign and bolster surveillance and control of vulnerable populations, including the Uyghur community.¹²⁰ In 2017, human rights activists discovered that Xinjiang law enforcement used genetic sequencing equipment manufactured by U.S.-based company Thermo Fisher to collect biometric data from Uyghurs.¹²¹ The *New York Times* reported that a visiting scholar from China working on a research project at Yale University accessed DNA samples that were later used to enhance China's Ministry of Public Security's ability to sort DNA samples based on ethnicity.¹²² These DNA samples were used by authorities with the purpose of identifying and tracking individuals.¹²³

U.S. Companies' Access to Health Industries and Market Opportunities in China

China is the world's second-largest market for pharmaceuticals and the fourth-largest for medical equipment in terms of domestic sales.¹²⁴ U.S. exports of pharmaceuticals to China reached approximately \$3.3 billion in 2018 (see Figure 3).¹²⁵ As China's health and medicine demand has grown, U.S. exports of biotech products, medical equipment and supplies, and pharmaceuticals have also increased (see Figure 4). However, the vast potential of China's healthcare market remains out of reach for U.S. and other foreign companies.

Figure 3: Major Destinations of U.S. Pharmaceutical and Medical Equipment Exports, 2018

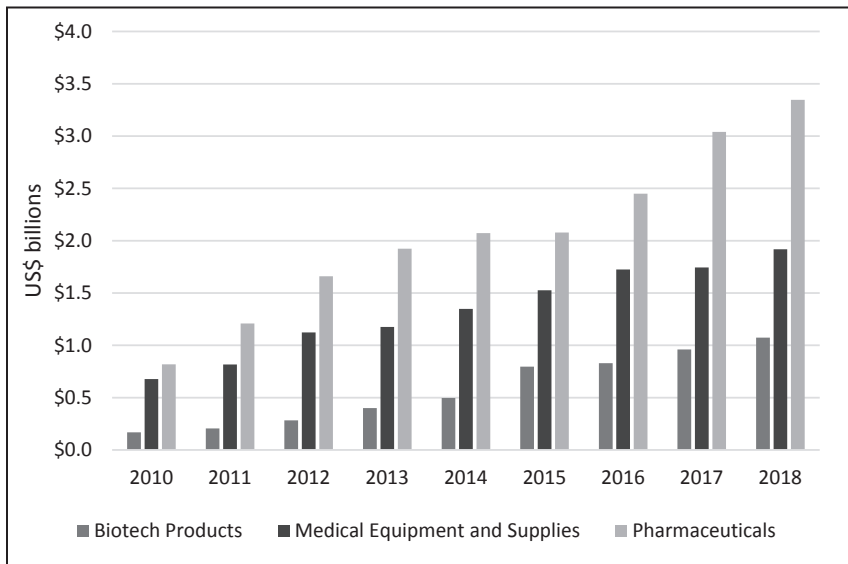


Source: U.S. Census Bureau, *USA Trade Online*, September 17, 2019.

In 2018, China made up only 5 percent of the United States' global biotech exports, 7.1 percent of medical equipment exports, and 6.7 percent of pharmaceuticals exports.¹²⁶ Government policies favoring domestic producers give China's generic drug manufacturers a competitive edge over foreign drug companies.¹²⁷ As a result, U.S. drug companies struggle to gain a large market share in China.¹²⁸ However, the United States is a leading source among Chinese imports of medical products, especially at the higher end of the market. U.S. exports of biotech products* reached \$1.1 billion in 2018, an increase of 11.4 percent year-on-year.¹²⁹

U.S. medical equipment and supply exports to China in 2018, meanwhile, increased 10 percent year-on-year to \$1.9 billion, while U.S. pharmaceutical exports to China increased 10.1 percent year-on-year in 2018 to \$3.3 billion (see Figure 4).¹³⁰

Figure 4: U.S. Exports of Health Products to China, 2010–2018



Source: U.S. Census Bureau, USA Trade Online, June 17, 2019; U.S. Census Bureau, U.S. Trade with China in Advanced Technology Products, December 2018.

The Chinese government is making substantial investments to expand the country's health infrastructure, which could create new opportunities for foreign health and pharmaceutical providers. It is also providing incentives for multinational corporations to operate in China.[†] The reforms aim to achieve nearly universal health insur-

*Biotechnology product exports include products with medical and industrial applications in genetics for the creation of new drugs, hormones, and other items for agricultural and human use.

[†]Pfizer opened a global headquarters for Pfizer Upjohn, one of its divisions, in Shanghai in 2019, making it the first multinational drug company with a main office in China (the headquarters of Pfizer, the parent company, remain in the United States). Thermo Fisher, a leading U.S. biotechnology company, is also setting up a new production base in China. See Teng Jing Xuan, "Pfizer Upjohn Becomes First Multinational Drug Company to Open HQ in China," *CX Tech*, May 30, 2019; *Xinhua*, "U.S. Leading Biotech Provider to Set Up Production Base in China," August 22, 2019. http://www.xinhuanet.com/english/2019-08/22/c_133829967.htm.

ance coverage,* promote more equal access to public health services, and lower costs for innovative drugs.¹³¹ As part of these efforts, the Chinese government has taken several steps to ease the approval processes for foreign firms looking to get their drugs to market in China, which has reduced the time it takes for foreign medicines to become accessible to Chinese patients.

According to Yanzhong Huang, senior fellow for global health at the Council on Foreign Relations, key reform efforts undertaken in recent years include:

- *Updating the national reimbursement drug list:* In 2017, the Chinese government updated the list of pharmaceuticals eligible for government reimbursement to include more innovative foreign medicines. The national reimbursement drug list was introduced in 2004 and last updated in 2009. The 2017 update increased the number of medicines (excluding traditional Chinese medicine) eligible for reimbursement in China by 11 percent to 1,297 drugs.¹³² It was supplemented by a new Essential Drug List, a shorter compendium of generic drugs to be sold by local clinics at government-controlled prices.¹³³ Prior to the national reimbursement drug list being updated, 1,164 medications (excluding traditional Chinese medicine) could be reimbursed.¹³⁴ The list was further updated in August 2019, with 47 new medications added to the list and 150 medications removed due to being determined of low clinical value of inferior to other products from the list.¹³⁵ China has laid out plans to require bi-annual updates to the reimbursement list.¹³⁶
- *Establishing a drug price negotiation mechanism:* The system, introduced nationally in 2017, allows Chinese patients to access over 50 medicines—including cancer drugs and other innovative medicines manufactured overseas—at dramatically reduced prices.¹³⁷ The negotiations are led by an arm of the Chinese government, which negotiates with pharmaceutical companies for lower prices and in return includes the drugs on the national reimbursement drug list so more patients can afford them.¹³⁸ The price negotiation mechanism has helped to reduce drug prices by more than 75 percent for those patients covered by the plan; however, only 44,600 people had benefited from the policy by the end of 2018.¹³⁹
- *Joining the International Council on Harmonization:* In 2017, China joined the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), an international organization tasked with bringing together global regulatory authorities to ensure efficient and effective procedures for developing and registering new medicines.¹⁴⁰ In 2018, China became an ICH management committee member, signaling Beijing's desire to harmonize its drug and medical equipment approval processes to match that of other large pharmaceutical markets around the world.¹⁴¹

*Although a significant portion of China's population has health insurance, out-of-pocket costs for medical care remain high and access to critical drugs and hospital treatment limited, especially for patients living in rural areas. See World Bank and World Health Organization, "Healthy China: Deeping Health Reform in China," 2019, 40–42. <https://openknowledge.worldbank.org/bitstream/handle/10986/31458/9781464812637.pdf?deliveryName=DM11894>.

- *Accepting foreign clinical trial data:* In October 2017, Chinese regulators began accepting overseas clinical trial data when evaluating and approving new imported innovative drugs and medical devices for use in China.¹⁴² Previously, medicines and health equipment were required to undergo clinical testing in China before Beijing would approve the product for use, slowing the approval process for foreign drugs seeking to enter the Chinese market.¹⁴³ This change contributed to the approval of 30 innovative foreign drugs through the first nine months of 2018, up from just three approvals for foreign drugs in all of 2016.¹⁴⁴

Regulatory Challenges and Market Barriers Remain

While the Chinese government is changing regulations to allow for more innovative drugs to enter its market, barriers remain for foreign drug companies in China. IP transfer, both legal and illegal, has become a regular cost of doing business in China's pharmaceutical and medical industries. There have been notable cases of Chinese pharmaceutical companies conspiring to steal foreign medical firms' IP. In 2018, two former scientists at the pharmaceutical firm GlaxoSmithKline pleaded guilty to stealing the company's biopharmaceutical data and research to benefit a rival Chinese pharmaceutical company.¹⁴⁵ In its 2018 midyear report on cyberintrusion trends, the cybersecurity firm CrowdStrike also noted they had observed an uptick in Chinese cyberintrusion attempts against foreign pharmaceutical firms.¹⁴⁶

In addition, Beijing has proposed several new policies that, if implemented, would undermine U.S. pharmaceutical companies' IP rights. Most notably, China has proposed measures that would expand and enhance patent protections only for foreign drug firms that go to market concurrently in China and another country (e.g., the United States, Japan, and the EU). If the proposal is implemented, companies must submit applications for market approval of new products in China and a second country; otherwise, they will not qualify for patent term extension.¹⁴⁷ This law would apply to those drug companies that experienced a delay in the drug approval process; a patent term extension of up to five years would be granted to these companies under the condition that the patent term could not exceed 14 years after the drug is approved.¹⁴⁸

Finally, asymmetric data access policies between the United States and China negatively impact U.S. competitiveness in medicine and biotech. U.S. researchers and companies do not have the ability to work with Chinese data assets in the same way their Chinese counterparts do in the United States. The Chinese government restricts cross-border data sharing through regulations including its 2017 cybersecurity law, which requires companies that are designated "critical information infrastructure" to store certain data on servers in China.¹⁴⁹ The data must be assessed before being transferred overseas, and the government can deny transfers if deemed a threat to national security or public interest. The United States does not prioritize curating health data sets or protecting health data.¹⁵⁰ In addition, to date the United States has not enacted laws that outline trade protocols for big data and health data sharing.¹⁵¹

U.S.-China Global Health Cooperation

Over the past 50 years, China has participated in international health initiatives and infrastructure development in several small but growing areas. In the past, most Chinese assistance took the form of building health infrastructure in foreign countries using Chinese firms and workers.¹⁵² Some of China's global health projects, and particularly hospital construction, are tied to the Belt and Road Initiative (BRI).¹⁵³ In the last two decades, however, China has worked more closely with the United States to address global health crises.¹⁵⁴

Important examples of U.S.-China global health collaboration include developing a coordinated response to the HIV pandemic in the early 2000s, and establishing a research partnership between the U.S. National Institutes of Health and China's National Science Foundation in 2010.¹⁵⁵ The U.S. and Chinese governments continue to work together on medical research and projects in developing countries (primarily in Africa and Asia). The FDA and U.S. Centers for Disease Control collaborate with their counterparts in China to prevent and detect infectious diseases and build more robust regulatory systems for food and drug safety.¹⁵⁶ However, issues such as China's treatment of healthcare data as a national security tool can limit opportunities for information sharing and make bilateral cooperation with the United States more difficult.

According to Jennifer Bouey, Tang Chair in China policy studies at the RAND Corporation, the Chinese government is seeking to expand its role in overseas health markets for three reasons. First, Beijing wants to ensure that pandemics and health-related mass migration do not spread into China and threaten the health and security of the Chinese people.¹⁵⁷ Second, Beijing wants to protect its investments in countries hosting BRI projects. If BRI host countries experience a public health crisis, it could endanger the Chinese nationals living and working in the country and threaten the economic viability of the investment.¹⁵⁸ Finally, Beijing wants to play a larger role in international governance and sees global health issues as one area where it can assert itself as a major player.¹⁵⁹

As development aid from the United States and other high-income countries plateaued in recent years,¹⁶⁰ multilateral organizations are looking to China as a new funder for health initiatives.¹⁶¹ In 2017, China and the World Health Organization (WHO) signed a memorandum of understanding to partner on health projects vis-à-vis BRI, naming the partnership the "Health Silk Road."¹⁶² In 2018, WHO's director general lauded China for the BRI and global health investments, calling China "a model for universal health coverage, a bulwark against health emergencies, and a reminder that transformations can be far-reaching."¹⁶³

Implications for the United States

Nurtured by subsidies and protected from foreign competition, China's pharmaceutical companies have emerged as preeminent manufacturers of pharmaceuticals and their ingredients. This presents a direct threat to U.S. economic competitiveness and national security in a number of ways. First, China's lax regulations put every U.S. consumer taking medicine imported from China, or made with

Chinese APIs, at risk. Over the past decade, the U.S. market has been rocked by high-profile recalls of Chinese drug products, such as the FDA's recall of contaminated heparin, a blood thinner commonly used in U.S. hospitals, which has been linked to 246 deaths in the United States.¹⁶⁴ The 2018 valsartan recall serves as another cautionary tale with global implications, considering the widespread use of the drug.¹⁶⁵ As China's health market continues to grow, bolstering Chinese regulatory capacity will become ever more critical in order to address poor manufacturing practices and the production and export of illicit drugs.

Second, U.S. dependence on drugs from China exacerbates the risk of drug shortages, especially because the Chinese government has not effectively regulated the high volume of drugs, APIs, and other medical products the country produces. U.S. reliance on China for critical drug products presents a dilemma for U.S. health regulators, who have to weigh the consequences of a shortage against the ramifications of allowing U.S. consumers to use a substandard product. For example, in 2015 the FDA banned imports of 29 pharmaceutical products from a manufacturer in China after it received 61 complaints about impurities in the company's products.¹⁶⁶ However, 14 of those pharmaceutical products were exempted from the import ban due to concerns about drug shortages.¹⁶⁷ Although DOD maintains stockpiles of some drugs critical for national security, these drugs only include finished pharmaceuticals, not the ingredients needed to make them. If China were to cut off its supply of drugs or APIs to the United States, it could lead to a public health crisis.¹⁶⁸

Finally, although China's large, rapidly aging population is an attractive market for U.S. health companies, market barriers continue to deny U.S. products a level playing field.¹⁶⁹ Meanwhile, China's biotechnology sector has reaped tremendous benefits from collaboration with U.S. firms and research institutions by accessing U.S. technology and biometric data. U.S. companies' ability to use Chinese biometric data is restricted by China's stringent data regulations. In other words, Chinese companies profit from collaboration while U.S. companies do not get reciprocal advantages. There are risks that data on U.S. patients and drug trials could fall into the hands of the Chinese state or companies that will seek to exploit it for economic or strategic gains. There is a dark side to China's advancements in cutting-edge biotechnology. In Xinjiang and other parts of China, the Chinese government is using U.S. technology and biometric research not only for economic gain, but also to monitor and control Uyghurs and other Turkic Muslim minorities without their consent.

Addendum I: FDA Letter to Zhejiang Huahai Pharmaceutical**Via UPS****Warning Letter: 320-19-04****Return Receipt Requested**

November 29, 2018

Mr. Jun Du
Executive Vice President
Zhejiang Huahai Pharmaceutical Co., Ltd.
Coastal Industrial Zone, Chuannan No. 1 Branch No. 9
Donghai Fifth Avenue, Linhai, Taizhou Zhejiang 317016
CHINA

Dear Mr. Du:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Zhejiang Huahai Pharmaceutical Co., Ltd., located at Coastal Industrial Zone, Chuannan No. 1 Branch No. 9, Donghai Fifth Avenue, Linhai, Taizhou Zhejiang, from July 23 to August 3, 2018.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your August 26, 2018, response in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific deviations including, but not limited to, the following.

1. Failure of your quality unit to ensure that quality-related complaints are investigated and resolved.*Valsartan API*

Your firm received a complaint from a customer on June 6, 2018, after an unknown peak was detected during residual solvents testing for valsartan API manufactured at your facility. The unknown peak was identified as the probable human carcinogen N-nitrosodimethylamine (NDMA). Your investigation (DCE-18001) determined that the presence of NDMA was caused by the convergence of three process-related factors, one factor being the use of the solvent (b)(4). Your investigation concluded that only one valsartan manufacturing process (referred to as the (b)(4) process in your investigation) was impacted by the presence of NDMA.

However, FDA analyses of samples of your API, and finished drug product manufactured with your API, identified NDMA in multiple batches manufactured with a different process, namely the (b)(4) process, which did not use the solvent (b)(4). These data demonstrate that your investigation was inadequate and failed to resolve the control and presence of NDMA in valsartan API distributed to customers. Your investigation also failed:

- To include other factors that may have contributed to the presence of NDMA. For example, your investigation lacked a comprehensive evaluation of all raw materials used during manufacturing, including (b)(4).
- To assess factors that could put your API at risk for NDMA cross-contamination, including batch blending, solvent recovery and re-use, shared production lines, and cleaning procedures.
- To evaluate the potential for other mutagenic impurities to form in your products.

Our investigators also noted other examples of your firm's inadequate investigation of unknown peaks observed in chromatograms. For example, valsartan intermediates (b)(4) and (b)(4) failed testing for an unknown impurity (specification $\leq$ (b)(4)%) with results of (b)(4)% for both batches. Your action plan indicated that the impurity would be identified as part of the investigation; however, you failed to do this. In addition, no root cause was determined for the presence of the unknown impurity. You stated that you reprocessed the batches and released them for further production.

Addendum I: FDA Letter to Zhejiang Huahai Pharmaceutical—*Continued*

Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA. For example, you told our investigators you were aware of a peak that eluted after the (b)(4) peak in valsartan API residual solvent chromatograms where the presence of NDMA was suspected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further. Additionally, residual solvent chromatograms for valsartan API validation batches manufactured using your (b)(4) process, with (b)(4) in 2012 ((b)(4), and (b)(4)) show at least one unidentified peak eluting after the (b)(4) peak in the area where the presence of NDMA was suspected to elute.

Your response also states that you were not the only firm to identify NDMA in valsartan API. In your case, FDA analyses of samples identified amounts of NDMA in valsartan API manufactured at your firm that were significantly higher than the NDMA levels in valsartan API manufactured by other firms. FDA has grave concerns about the potential presence of mutagenic impurities in all intermediates and API manufactured at your facility, both because of the data indicating the presence of impurities in API manufactured by multiple processes, and because of the significant inadequacies in your investigation.

In response to this letter:

- Submit risk assessments for all APIs and intermediates manufactured at your facility for the potential presence of mutagenic impurities.
- Provide an update on investigations and CAPA plans initiated to address the presence of NDMA and other potential mutagenic impurities in all APIs manufactured at your firm.
- Provide a thorough, independent assessment of your overall system for investigating deviations, discrepancies, out-of-specification (OOS) results, complaints, and other failures. In addition, provide a retrospective review of all distributed batches within expiry to determine if your firm released batches that did not conform to established specifications or appropriate manufacturing standards.
- Provide test results for all (b)(4) and intermediates for the presence of NDMA, N-Nitrosodiethylamine (NDEA), and other potentially mutagenic impurities.

(b)(4) API

Your firm received a customer complaint on September 13, 2016, concerning (b)(4) API batches ((b)(4) and (b)(4)) that exceeded the specification for (b)(4) ($\leq$ (b)(4) ppm). (b)(4) has been classified as a probable human carcinogen. Your customer's test results conflicted with your (b)(4) test results, which showed the two batches meeting the specification upon release. Your complaint investigation (CC-16008) identified no clear laboratory error, and no anomalies were detected during the production of the batches. Your investigation failed to evaluate other (b)(4) API batches to determine if the presence of excess (b)(4) was an adverse trend. For example, (b)(4) batches (b)(4), and (b)(4) were OOS for (b)(4) because of production errors; however, they were not discussed in your complaint investigation.

Your response states that (b)(4) API batches (b)(4) and (b)(4) were returned, reprocessed, and released to customers in non-U.S. markets.

Your response also states that in August 2017 you implemented a new (b)(4) test method that uses a (b)(4) LC-MS/MS method, to replace the (b)(4) LC-MS method that was prone to erroneous OOS results. You failed to verify the reliability of the (b)(4) results for all (b)(4) API batches (including (b)(4) batch (b)(4)) originally released using your (b)(4) LC-MS method, which you indicated was inferior to your updated method.

In response to this letter, provide:

- A risk assessment for all (b)(4) API batches manufactured within expiry.
- A revised complaint handling procedure and details of any further controls your facility has implemented to ensure that all complaints are adequately documented and thoroughly investigated.
- Procedures for accepting and reprocessing returned drugs.
- Results of (b)(4) testing of all (b)(4) API batches released to the U.S. market using your updated (b)(4) LC-MS/MS (b)(4) test method.

Addendum I: FDA Letter to Zhejiang Huahai Pharmaceutical—Continued

2. Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API.

In November 2011 you approved a valsartan API process change (PCRC - 11025) that included the use of the solvent (b)(4). Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from (b)(4) degradants, including the primary (b)(4) degradant, (b)(4). According to your ongoing investigation, (b)(4) is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.

You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients.

Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce.

Your response does not describe sufficient corrective actions to ensure that your firm has adequate change management procedures in place: (1) to thoroughly evaluate your API manufacturing processes, including changes to those processes; and (2) to detect any unsafe impurities, including potentially mutagenic impurities. For FDA's current thinking on control of potentially mutagenic impurities, see FDA's guidance document M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk for approaches that FDA considers appropriate for evaluating mutagenic impurities, at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM347725.pdf>.

In response to this letter, provide:

Detailed revised change management procedures describing how your firm will assess and control all impurities, including mutagenic impurities, in API and intermediates manufactured at your facility.

Detailed procedures describing how your firm establishes impurity profiles for products manufactured at your firm. These procedures should contain instructions for comparing at appropriate intervals against the impurity profile in the regulatory submission, or for comparing against historical data, to detect changes to the API resulting from modifications in raw materials, equipment operating parameters, or the production process.

A retrospective analysis of other API and intermediates manufactured at your firm to determine if they were adequately evaluated for anticipated and unanticipated impurities, including potentially mutagenic impurities.

CGMP consultant recommended

Based upon the nature of the deviations we identified at your firm, we strongly recommend engaging a consultant qualified to evaluate your operations and assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

Quality Systems Guidance

Your firm's quality systems are inadequate. For guidance on establishing and following CGMP compliant quality systems, see FDA's guidances: *Q8(R2) Pharmaceutical Development*, at <https://www.fda.gov/downloads/drugs/guidances/ucm073507.pdf>; *Q9 Quality Risk Management*, at <https://www.fda.gov/downloads/Drugs/Guidances/ucm073511.pdf>; and *Q10 Pharmaceutical Quality System*, at <https://www.fda.gov/downloads/drugs/guidances/ucm073517.pdf>.

Addendum I: FDA Letter to Zhejiang Huahai Pharmaceutical—Continued**Additional API CGMP guidance**

FDA considers the expectations outlined in ICH Q7 in determining whether API are manufactured in conformance with CGMP. See FDA's guidance document *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* for guidance regarding CGMP for the manufacture of API, at <https://www.fda.gov/downloads/Drugs/.../Guidances/ucm073497.pdf>.

Conclusion

Deviations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

FDA placed your firm on Import Alert 66-40 on September 28, 2018.

Until you correct all deviations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at Zhejiang Huahai Pharmaceutical Co., Ltd., located at Coastal Industrial Zone, Chuannan No. 1 Branch No. 9, Donghai Fifth Avenue, Linhai, Taizhou Zhejiang, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov or mail your reply to:

Rory K. Geyer
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4235
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Please identify your response with FEI 3003885745.

Sincerely,

/S/

Francis Godwin
Acting Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

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