

**Testimony of Rosemary Gibson, Senior Advisor, The Hastings Center and
Author, “China Rx: Exposing the Risks of America’s Dependence on China for Medicine”
Before the U.S.-China Economic and Security Review Commission
“Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products”
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Thank you for the opportunity to testify at today’s hearing. I am Rosemary Gibson, Senior Advisor at the Hastings Center and author of “China Rx: Exposing the Risks of America’s Dependence on China for Medicine.”

I. Introduction

Millions of Americans are taking prescription drugs made in China and don’t know it and neither do their doctors. These are prescription drugs in the legal supply chain that are distributed to U.S. hospitals, sold in corner drug stores and grocery store pharmacies, and distributed to military hospitals and clinics around the world. These are *not* the counterfeit drugs bought on the internet, or illicit drugs such as illegal versions of fentanyl.

The public and many policymakers have been kept in the dark about U.S. dependence on China for medicine and the health security and national security risks of this dependence. It’s time to turn on the lights. The focus of this testimony is on generic drugs which are 90 percent of the medicines that Americans take.

II. National Health Security at Risk

National health security and national security are threatened by U.S. dependence on China for thousands of ingredients and raw materials to make our medicines. China’s aim is to become the pharmacy to the world, and it is on track to achieve it.

China’s dominance is global. European countries depend on China for medicines. A Dutch Public Television documentary in February 2019 reported the national security risks of the Netherlands’ dependence on China for medicine. A retired Dutch industry official said, “Now we’re afraid that China will do things to deprive us of our medication.”

India’s large generic drug industry may be perceived as a viable alternative supplier. Its generic manufacturers, however, depend on China for 80 percent of the active ingredients and chemical intermediates essential for production. If past performance is indicative of the future, China will eventually overtake India in generic drug production

The centralization of the global supply chain of medicines in a single country, whatever country it may be, makes it vulnerable to interruption, whether by mistake or design.

Meanwhile, as U.S. factories have shut down, causing the loss of tens of thousands of manufacturing jobs to China, the U.S. industrial base and our capacity to make most of our medicines is rapidly collapsing.

1. The U.S. Has Lost Virtually All of Its Industrial Base to Make Generic Antibiotics The nation’s health security is in jeopardy. The U.S. can no longer make penicillin. The last U.S. penicillin fermentation plant closed in 2004. Industry data reveal that Chinese companies formed a cartel, colluded to sell product on the global market at below market price, and drove all U.S. European, and Indian producers out of business. Once they gained dominant global market share, prices increased.

The U.S. can no longer make generic antibiotics. Because the U.S. has allowed the industrial base to wither, the U.S. cannot produce generic antibiotics for children's ear infections, strep throat, pneumonia, urinary tract infections, sexually-transmitted diseases, Lyme disease, superbugs and other infections that are threats to human life. We cannot make the generic antibiotics for anthrax exposure. After the anthrax attacks on Capitol Hill and elsewhere in 2001, the U.S. government turned to a European company to buy 20 million doses of the recommended treatment for anthrax exposure, doxycycline. That company had to buy the chemical starting material from China. What if China were the anthrax attacker?

2. Beyond Antibiotics, the U.S. Industrial Base for Generic Drug Manufacturing Is on the Brink of Collapse. Generic Drugs are 90 Percent of the Medicines Americans Take Beginning in 2007, China turned its attention to encourage its domestic companies to manufacture generic drugs for the U.S. The first was an HIV/AIDS medicine. China's generic industry is thriving as exports to the U.S. grow rapidly. Examples of generic drugs made in China by domestic companies and sold in the United States include: antibiotics, anti-depressants, birth control pills, chemotherapy for cancer treatment for children and adults, medicine for Alzheimer's, HIV/AIDS, diabetes, Parkinson's, and epilepsy, to name a few. If past performance is indicative of future performance, China's generic drug companies will engage in cartel formation and predatory pricing, and drive out U.S. and other western generic companies.

3. If China Shut the Door on Exports of Medicines and Their Key Ingredients and Raw Materials, U.S. Hospitals and Military Hospitals and Clinics Would Cease to Function Within Months, if Not Days A natural disaster, global public health crisis, or adverse foreign government action could disrupt the supply of medicinal ingredients and finished drugs. Surgeries could not be performed at Walter Reed National Military Medical Center (Bethesda Naval Hospital), Johns Hopkins Hospital, George Washington University Hospital, INOVA/Fairfax, every other U.S. hospital, and military hospitals around the world. Children and adults with cancer will suffer without vital medicines. For people on kidney dialysis, treatment would cease, a veritable death sentence.

4. Presently, the pharmaceutical and chemical industry's successful requests to the U.S. Trade Representative not to impose tariffs on medicinal products made in China corroborate that much of the US industrial base, and our self-sufficiency in manufacturing products essential for life, has collapsed.

As documented in *China Rx: Exposing the Risks of America's Dependence on China for Medicine*, within four years of the U.S.-China Trade Relations Act of 2000, the last penicillin fermentation plant in the U.S. closed; China's vitamin C (ascorbic acid) cartel forced the closure of the last U.S. production facility, and the last aspirin (acetylsalicylic acid) manufacturing facility ceased business because of predatory pricing by Chinese firms. Baxter Healthcare switched heparin suppliers from Wisconsin to China, and a lethal contaminant in heparin was later found that killed hundreds of Americans.

Nearly twenty years later in 2018 and 2019, U.S. industry has advocated successfully to keep medicinal products—prescription drugs and their core components—off U.S. tariff lists. The rationale for this position is tariffs would increase drug prices and health spending.

It is unclear whether, or how much, costs will rise absent transparency on the price paid to manufacturers by a handful of companies that buy generic drugs from manufacturers in China in large quantities, and absent the ability to compare this price with the amount consumers, hospitals, the military and the VA pay.

Second, emphasis on monetary price ignores a very high price the U.S. is paying: the loss of trust in medicines by doctors and the public because of substandard, defective, and lethal drugs sold to U.S.

hospitals and consumers. Ninety-five percent of Americans don't trust medicines made in China. A prominent physician said to me, "We are becoming like a developing country with our medicines."

Third, the absence of protection for U.S. generic and pharmaceutical chemical manufacturers from China's medicine cartels and predatory pricing has caused the near collapse of U.S. manufacturing, and remaining capacity faces an imminent existential threat.

Fourth, once China gains even more domination in production of generics, consumers, hospitals, and the government will lose control over the price they pay for medicines. China will be the price setter, and the U.S. will be the price taker.

Fifth, at that point, the FDA will have an even more difficult time than it does now to inspect and regulate the quality of medicines.

These points are discussed in greater detail below and illustrate that protecting China's industry and helping it grow, while causing the collapse of U.S. generic manufacturing, is a mistake of epic proportions to the country's health security and national security that will have serious adverse effects for generations to come.

5. As the U.S. Rapidly Loses Control Over the Production and Supply of Vital Medicines, It Loses Control Over the Price of Medicines Consumers and Hospitals Pay As China gains more control over America's supply of medicines, it could charge American consumers and patients higher prices, or extort concessions from the federal government to keep prices affordable. This is not mere speculation. China's domestic companies formed a vitamin C cartel in the early 2000s and increased prices up to 600 percent, which increased the cost to American consumers and businesses. When U.S. businesses sued the Chinese companies for antitrust violations, the Chinese government asserted in federal court that Chinese law *required* its domestic companies to fix prices and control exports of vitamin C to the United States. This assertion reveals China's clear strategy to control the supply and price of health-related commodities in the United States.

6. Risks of Contaminated and Potentially Lethal Medicines Are Increasing The deaths of 246 Americans who were administered the blood thinner heparin in 2007 and 2008 were reported to be associated with a lethal contaminant that was deliberately placed during the manufacturing process in China for economically motivated reasons. More recently, millions of Americans were sold blood pressure medicines that contained a cancer-causing genotoxic impurity. While many manufacturers have been forced to recall their products, the most troubling was a manufacturer in China whose blood pressure medicine, valsartan, contained per pill more than 200 times the acceptable interim limit for the carcinogen. Even more concerning is the manufacturer knew its product did not meet U.S. standards but sold it anyway to unsuspecting U.S. hospitals and patients. In the case of this company, the FDA banned all products from its facility from entry into the United States.

7. The FDA Cannot Fix the Underlying Cause of These Threats to National Health Security The FDA cannot fix the underlying cause of the proliferation of contaminated and potentially lethal medicines in the legal supply of America's medicines. It cannot fix the penchant of large purchasers of generic drugs to pay manufacturers the cheapest price rather than a price based on value, which includes quality, an uninterrupted supply, and health security.

The current approach of hammering down on manufacturers on price is the root cause of contaminated and lethal drugs in the legitimate supply chain and shortages and unavailability of life-saving medicines. Since the early 2000s, hundreds of medicines at any point in time are in short supply or unavailable

altogether in the United States. In 2015, the FDA banned twenty-nine products from a manufacturing plant in China. But because of concerns about shortages of vital medicines, the FDA exempted fifteen from its ban including products to make chemotherapy for children and adults with cancer, and to treat an AIDS-related cancer.

The FDA can regulate only the medicines that large buyers of generic drugs purchase. It cannot dictate *what* they buy. The FDA is caught in the “regulator’s dilemma” whereby it is in the unenviable position of weighing the relative risks of allowing vital but defective medicines to remain on the market or exacerbating shortages.

8. *More than 10 Percent of Generic Drugs Tested Do Not Meet Quality Standards* A growing number of Americans and their doctors are concerned about the quality and safety of their medicines and rightly so. An online pharmacy Valisure is reportedly the first pharmacy that chemically tests every batch of every medication it sells. At its laboratory located at the Yale Science Park in New Haven, Connecticut, more than 10 percent of the batches of medicines it has tested are rejected for not meeting quality metrics. Reasons for rejection include issues with dosage, dissolution, marketing claims related to dissolution or levels of probable human carcinogens.

9. *Procurement of Medicines from Trustworthy Manufacturers Based on Value, Not Cheap, is the Antidote to Threats to National Health Security* The threats to national health security are driven by the race-to-the-bottom on price paid to generic manufacturers. This price is different from the higher price that consumers pay. This practice is driving production to China, the only country whose government subsidizes its domestic manufacturers. It is building China’s industry while rapidly dismantling U.S. manufacturing.

C. National Security Risks

1. *Medicines Can Be Used as a Strategic and Tactical Weapon Against the United States* Medicines in the hands of an adversary can be weaponized. Supplies can be withheld. Medicines can be made with lethal contaminants or sold without any real medicine in them, rendering them ineffective. These products can be distributed to specific targets. Detection is time-consuming at best, and virtually impossible at worst.

2. *Dependence on China is a Risk to the U.S. Military, Combat Readiness, and Force Protection* The thousands of men and women on U.S. aircraft carriers in the South China Sea are dependent on the adversary for many of their essential medicines. Combat readiness and force protection are at risk with the military vulnerable to disruptions in supply and contaminated and toxic medicines. In 2018, more than 31,000 active duty military personnel, veterans, and their family members were notified they may have been given blood pressure medicines containing a cancer-causing ingredient.

3. *No one in the federal government is responsible for knowing who controls the U.S. supply of medicines.* The federal government lacks a locus of responsibility for conducting ongoing risk assessments to the U.S. supply of medicines. There is no point of accountability to take all means necessary to assure an uninterrupted supply of quality medicines produced by trustworthy manufacturers.

4. *Medicines should be treated as a strategic asset similar to oil and other energy supplies and agricultural commodities such as wheat and corn.* The United States would cease to function within days if supplies of energy and food commodities were disrupted. The same is true of medicines.

Recommendations

Recommendation #1: Require a whole of government review and assessment of the nation’s vulnerabilities in the medicine supply chain and recommendations to strengthen the U.S. industrial base to be able to meet the nation's critical generic drug needs.

A whole of government review and assessment of vulnerabilities in the medicine supply chain and industrial base to manufacture generic medicines and their ingredients is essential and should include the Department of Health and Human Services, Department of Homeland Security, Department of Defense, Department of Veterans Affairs, the National Security Council, and other relevant departments, agencies and other entities.

A framework for consideration that can be drawn upon is the 2018 Department of Defense report, Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States. The effort assessed the status of U.S. manufacturing and the defense industrial base, identified current risks, and identified action steps for risk mitigation.

Similarly, a whole of government review and assessment of the nation’s vulnerabilities in U.S. manufacturing of generic medicines and their ingredients should, inter alia:

- (i) identify finished drugs and essential components necessary for the manufacture of medicines vital for civilian and military use whose supply chains are at risk of safety and quality concerns and disruption;
- (ii) identify the defense, homeland, economic, geopolitical and other contingencies that may disrupt, strain, compromise, or eliminate supply chains of medicines and their essential components that are sufficiently likely to arise and require preparation for their occurrence;
- (iii) assess the resilience and capacity of the manufacturing base and supply chains to support health security and national security needs in the event of the contingencies including an assessment of: the manufacturing capacity of the United States; gaps in domestic manufacturing capabilities including non-existent, extinct, threatened, and single-point-of-failure capabilities; and supply chains with single points of failure and limited resiliency;
- (iv) recommend legislative, regulatory, and policy changes and other actions to avoid, and prepare for, contingencies identified; and
- (v) recommend federal investments to strengthen the U.S. manufacturing base and increase self-sufficiency in the manufacture of priority generic medicines and their ingredients in the interest of the country’s health security and national security.

Recommendation #2: The National Health Security Strategy, the National Security Strategy, and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) strategy should include actions to strengthen the U.S. industrial base to assure an uninterrupted supply of generic medicines and the ingredients to make them. This is vital for the continuity of day-to-day operations of the nation’s hospitals, health care systems, and military hospitals and clinics around the world.

A robust and resilient industrial base capable of manufacturing generic medicines and their essential ingredients should be a national health security and national security priority. Further, it should be the policy of the federal government to reduce the nation’s vulnerability to disruptions in the supply of medicines and their essential ingredients.

Identification of actions in the above strategic plans to strengthen the U.S. industrial base will elevate the importance of domestic capacity to manufacture generic medicines most vital for continuity of operations in the civilian and military health care systems.

Recommendation #3: Manufacturers of generic medicines who sell medicines to the Department of Defense and VA should be required as a condition of receipt of taxpayer dollars to disclose to the Department of Defense and VA whether their products and the active ingredients, chemical intermediates, and raw materials contained in them are sourced from countries that are adversaries or strategic competitors to the United States. This information is vital for the Department of Defense to conduct its mission on behalf of the nation.

Some generic drug manufacturers will not disclose the country-of-origin of medicines to the Department of Defense. Lack of transparency in country-of-origin poses a risk to combat readiness and force protection.

Recommendation #4: The Department of Defense and the VA should have the flexibility to procure medicines based on value and not the cheapest price. Currently, the DoD and VA buy medicines based on price alone. This practice undermines force protection and combat readiness. It also increases the military's dependence on China. Further, American taxpayers will be dismayed to learn that their money is helping China grow its domestic generic industry while enabling the imminent collapse of U.S. generic manufacturing.

The Department of Defense and the VA buy the cheapest medicines to assure prudent use of taxpayer money. This practice exposes the U.S. military to dependence on China and helps build China's industry as U.S. manufacturers face an imminent existential threat. This practice stands in contrast to military procurement of nuclear submarines and aircraft carriers for which outsourcing of manufacturing to China is not an option on grounds of national security. The same rationale should apply to vital medicines such as generic antibiotics.

Combat readiness and force protection will be strengthened by providing the Department of Defense the flexibility to procure medicines based on value (price, quality, reliable supply, and security).

U.S. hospitals are using their procurement dollars to launch the purchase of prescription drugs based on value not just price. Civica Rx is a non-profit formed by the Mayo Clinic and 900 hospitals representing one-third of licensed hospital beds in the U.S. It pays manufacturers a fair, sustainable, and transparent price, not a race-to-the-bottom price. The country-of-origin and manufacturer are transparent to the purchasers. Long-term contracts with manufacturers enable them to invest in their facilities and assure an uninterrupted supply of quality medicines. Civica Rx is procuring life-saving generic antibiotics that will be manufactured in Ohio.

The combined purchasing power of the Department of Defense and the VA, coupled with long-term contracts with manufacturers, could spur production in the United States and deliver quality medicines for the men and women in uniform, their families, and America's veterans.

Recommendation #5: Congress should provide funding for pilot projects to demonstrate the feasibility of commercial-scale advanced manufacturing technology to produce generic drugs and their essential ingredients to meet national health security needs. This funding will enable medicines to be produced much faster, at lower cost, more reliably with real time quality control, and a smaller environmental footprint.

The Defense Advanced Research Projects Agency (DARPA) has supported the development of advanced manufacturing technology to strengthen battlefield medicine in field hospitals and remote areas with disease outbreaks among other applications.

Currently, applications of this technology have successfully demonstrated small-scale production of the active ingredients in a number of essential medicines.

While pharmaceutical companies with new drugs under patent are beginning to adopt advanced manufacturing technology, U.S.-based generic companies are unlikely to invest in innovative manufacturing because it is financially infeasible due to severe price competition from Chinese domestic firms.

Federal investment is needed to show proof-of-concept of commercial-scale domestic production for generic drugs, their active ingredients, and chemical starting materials. This action will create a robust and resilient manufacturing base and secure the nation's health security and national security.

Recommendation #6 The Committee on Foreign Investment in the United States (CFIUS) should review the health security and national security implications of Chinese company ownership of Smithfield Foods, the world's largest pork processor and hog producer. Pig intestines are the "rare earths" of medical care and vital for the day-to-day functioning of U.S. civilian and military hospitals.

The U.S. and the world depend on China for an estimated 80 percent of the pig intestines to make heparin, a blood thinner which is ubiquitous in hospitals. It can be said that pig intestines are the "rare earths" of medical care. Rare earths are essential components for electric vehicles, consumer electronics, other high-tech devices, and the defense industry. In the health care sector, pig intestines are essential components for the functioning of the U.S. medical care system. It takes one pig to make a vial of heparin.

In 2018, African swine flu virus erupted in China and the US Department of Agriculture estimates a nearly 20 percent decline in China's pig population in 2019 from 428 million to 350 million. Twelve years ago, blue ear disease in China decimated its pig population, not as severely as the present situation. Facing a shortage of the authentic ingredient at that time, economically motivated criminals in China's heparin manufacturing industry developed a lethal substitute that mimicked the real one. Product was shipped to the United States and other countries, and the estimate of 246 deaths is a likely underestimate because of the insidiousness of lethal ingredients in medicine and the challenge of linking cause and effect.

In the short term, severe heparin shortages are predicted for the U.S. and other countries. In the medium-term, global demand for heparin will increase because of U.S. and global population growth coupled with the expansion of China's hospital and health care sector. Meanwhile, the land carrying capacity for an increase in the pig population, and the threat of more disease outbreaks, suggest supply will not keep pace with demand.

In 2014, the FDA Science Board, which advises the FDA Commissioner on matters of scientific affairs, discussed heparin supplies and shortages. It was noted that if the U.S. has virtually all the heparin coming from a single country, no government agency can order U.S. pig producers "to put all of their pig guts after slaughter into heparin production" to assure continuity of health care provision in the United States. It was suggested that this concern be elevated to the highest levels of national security.

The Committee on Foreign Investment in the United States (CFIUS) should review the national security implications of Chinese ownership of Smithfield. According to the CFIUS website, its members do not

include the Secretary of the Department of Health and Human Services, who oversees national health security and public health emergencies. This needs to change. Components of medicinal products are essential to the business continuity of the U.S. medical care system.

Conclusion

I want to thank the Commission for holding today's hearing and drawing attention to U.S. dependence on China for medicines and the impact on the nation's health security and national security. Thank you for the opportunity to testify and I look forward to your questions and helping the Commission in any way going forward.