

**Testimony of Rosemary Gibson,  
Author of “China Rx: Exposing the Risks of America’s Dependence on China for Medicine”  
Before the Committee on Energy and Commerce Subcommittee on Health:  
Safeguarding Pharmaceutical Supply Chains in a Global Economy  
October 30, 2019**

Thank you Congresswoman Eshoo and Subcommittee Members for the opportunity to testify today. I am Rosemary Gibson, author of *China Rx: Exposing the Risks of America’s Dependence on China for Medicine*. I am not paid by any industry or government entity for this work. It is conducted solely in the public interest. My focus today is on generic drugs which are 90 percent of the medicines Americans take.

**A. The Chinese Government Has Infiltrated the U.S. Medicine Supply**

**1. The U.S. is Dependent on China for Penicillin and Many Other Life-Saving Antibiotics and Generic Medicines.**

The United States can no longer make penicillin. In 2004, the last U.S. penicillin fermentation plant in Syracuse, New York announced it was closing. The attached graph from the European Fine Chemicals Group, the trade association of pharmaceutical ingredient makers, illustrates how it happened.

Chinese companies formed a cartel and dumped penicillin ingredients on the global market at very low prices beginning in 2004, the same year the New York plant closure was announced. It could not compete with China’s illegal trade practices and its government subsidies. China’s cartel also forced the closure of penicillin fermentation plants in Europe and India. After four years, when China gained a chokehold on global supply, the Chinese cartel increased prices dramatically.

This is China’s playbook: drive U.S. and other manufacturers out of business by selling below manufacturing cost for several years and then raising prices when its domestic companies achieve global dominance.

To be clear, the United States has also lost virtually all of its other antibiotic raw material production capability.

Mothers who give their children generic antibiotics for ear infections; seniors who take generic antibiotics for pneumonia, and patients in the hospital with life-threatening sepsis are likely dependent on the mercy of China to supply core components.

**2. China’s Cartels Subsidized by the Chinese Government -- Not Simply Lower Labor Costs and Weak Environmental Regulations – Are a Main Reason for the Collapse of the U.S. Industrial Base for Manufacturing of Pharmaceutical Raw Material and Other Ingredients.**

A common view is that because China has lower labor costs and weaker regulations governing worker safety and environmental protection, China is a cheaper place to outsource.

There’s more to the story. China’s cartels fueled by government subsidies are undercutting U.S. and other competitors and driving them out of business. U.S. and other generic drug companies and ingredient makers are competing against the Chinese government, a battle they will not win unless and until the U.S. government develops in concert with industry a smart strategy and executes it successfully on behalf of the American people.

### **3. China's Vitamin C Cartel Exposes the Chinese Government's Playbook to Overtake the U.S. Medicine Supply.**

China's intentions are clearly expressed in the Vitamin C anti-trust case pending in U.S. federal court. The Chinese Ministry of Commerce filed its own court brief in support of Chinese firms that formed a cartel and drove out U.S. and other global producers, similar to the penicillin cartel.

The Chinese government wrote in the brief that it requires its domestic companies as a matter of Chinese law to fix prices Americans pay and control the supply and amount of product they send to the U.S. Further, the Chinese government asserted that its domestic companies should be immune from U.S. antitrust laws, thereby undermining the entire U.S. competitive economic system.

This stance is unequivocal evidence of China's strategy: to use the U.S. federal court system to allow Chinese cartels to operate freely in the United States; to disrupt, dominate, and displace U.S. and virtually all other competitors; to undermine America's free market system; and to create perpetual dependence on China for medicines and everything else it sells to the U.S. When it comes to medicines, this is China's approach to achieving its stated goal to become the pharmacy to the world. A decision by the federal appeals court in Manhattan is pending.

### **4. All Roads Lead to China: India is at the Mercy of China for Raw Materials and Chemical Intermediates to Make Active Pharmaceutical Ingredients (APIs) for Generic Drugs for the U.S. and the Rest of the World.**

The Association of Accessible Medicines reports that India is the source of 24.5 percent of generic drugs sold in the U.S. This appears to suggest that we don't need to worry about generics coming from China.

In fact, India is dramatically dependent on China for raw materials and chemical intermediates that are used to make active pharmaceutical ingredients.

A quick Google search will reveal the extent of India's dependence on China. The dependence is recognized by senior Indian government officials as a national security threat to that nation, its military, and its large generic drug industry which would shut down within weeks without Chinese components. Senior government officials in India have not hesitated to talk publicly in the media about the national security risks to their country if China withheld supplies. Even countries such as Italy and Spain are buying raw materials from China.

The *Economic Times* in India published a story about the risks to national security, and the opening line was, "Imagine a situation where a(n Indian) soldier's medical kit is running out of essential drugs on a battle front." This is what prompted me while writing *China Rx* to ask whether the U.S. military is similarly dependent on China—which it is for many medicines whose components are made in China.

So, India, a global powerhouse in generic manufacturing, is at the mercy of China. A deterioration in India's relationship with China could trigger China to withhold supplies of vital components in essential medicines. China can use its economic leverage to extract concessions from India on a host of political, economic, and military matters. The same is true for how China can use its leverage to compel the U.S. government to act in China's interest.

### **5. America's Seniors, Working Families, Veterans, and Taxpayers are Sending an Estimated \$6 Billion to China for Generic Drugs Annually Which Causes Two Public Health Problems: Loss of U.S. Self-Sufficiency for Medicine-Making and the Risk of Increased Illegal Opioids from China in Communities Suffering from Unemployment Due to Shuttered Manufacturing Facilities.**

The Association for Accessible Medicines reports that 8.5% of generic drugs sold in the U.S. are made in China. China's first generic drug, made in China by a Chinese company, was approved for use in the U.S. in 2007. So, in about 10 years, Chinese companies gained an 8.5% market share.

With an 8.5% market share of generic drug spending going to China, a rough back-of-the-envelope calculation prepared quickly for this testimony suggests that America's seniors, veterans, working families, and taxpayers are sending an estimated \$6 billion of our hard earned money to China to grow its generic industry as the U.S. is littered with shuttered, abandoned factories, families unable to make ends meet, and communities ravaged by illegal opioids made in China.<sup>1</sup> Two public health crises are created: dependence on a foreign country for life-saving medicines and a deepening crisis of opioid-related deaths.

Let's take a closer look at the 8.5% of generic drugs made in China. Here are a few of the generic drugs made by Chinese domestic companies and sold here: anti-depressants, HIV/AIDS medicine, birth control pills, chemotherapy for cancer treatment for children and adults, medicines for Alzheimer's, diabetes, epilepsy, Parkinson's, and much more.

The *Financial Times* reported that China is gaining steam in the US generic drug market. If past performance is indicative of future performance, ten years from now China will make 20 percent of our generic drugs, and 10 years later 30 percent. And by the 100<sup>th</sup> anniversary of the 1949 founding of the People's Republic of China, Chinese companies will be the dominant supplier of generic drugs to the United States.

In *China Rx*, I predict that China will overtake India as the largest global generic drug producer because of China's pattern of cartels, subsidies to its domestic companies, and other predatory trade practices that drive out market competition.

This reality should give pause to the prevailing notion in the U.S. that "generic competition lowers prices." This approach is merely shifting production to China whose government will subsidize production until such time that China has a full chokehold on the U.S. generic supply and can raise prices at will. The U.S. will have no alternative but to pay China's monopoly or near-monopoly price.

## **6. Members of Congress, Presidents, the Military, Veterans, Seniors, and Hospital Intensive Care Units Will Soon Have No Alternative but to Use Generic Drugs Made in China by Its Domestic Companies.**

China is ramping up production of generic drugs made in China by domestic companies and selling them in the United States. In the near future, Americans will likely have no alternative but to buy generic drugs made in China by Chinese domestic companies. Chinese companies will undercut U.S. and other western generic manufacturers on price and drive them out of business, just as China's cartel drove out all U.S., European, and Indian penicillin raw material manufacturers.

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<sup>1</sup> The \$6 billion figure is calculated as follows: Generic drug spending is 22% of overall drug spending (Source: Association for Accessible Medicines <https://accessiblemeds.org/resources/blog/2019-generic-drug-and-biosimilars-access-savings-us-report>). Total U.S. drug spending in 2017 was \$333 billion (Source: HHS - CMS <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>). Hence, generic drug spending was \$73 billion (22% of \$333 billion). With 8.5% of generic drugs in the U.S. made in China (October 18 2019 AAM tweet), more than \$6 billion spent by Americans on generic drugs is going to China. (8.5% of \$73 billion in total generic spending = ~ \$6 billion spent on generics made in China. Author welcomes improvements in this rough methodology and data sources.

## **B. China's Infiltration of the U.S. Medicine Supply Poses Devastating Public Health Consequences**

### **1. Doctors and the public are losing trust in generic medicines. There is a crisis of confidence. Americans pay the highest prices in the world for generics, which are plagued by rationing due to shortages and substandard, unsafe products.**

Many Americans remember when thousands of dogs and cats died because of an industrial chemical used in pet food from China. Consequently, many people will no longer purchase dog food made in China and are shocked to learn that thousands of prescription drugs sold in the U.S. are made with ingredients from China. 95% of Americans don't trust medicines made there, according to a poll conducted a number of years ago by the Pew Charitable Trusts. Recently, a prominent physician said privately, "We're becoming like a developing country with our medicines."

The online pharmacy Valisure tests every batch of medicine before it sells them and has found that more than 10 percent of generics it tested did not meet standards.

Other examples of defective and substandard medicinal products include:

- A retired Army colonel described to the U.S.-China Economic and Security Review Commission about chemicals in rocket fuel in his blood pressure medicines from China. "My blood-pressure medications were contaminated with rocket fuel. I imagine active (duty military) people have the same problem. This affects the readiness of our troops."
- For a thyroid medicine, the active ingredient made in China did not contain the proper potency. It may have contained too much or too little medicine.
- For birth control pills, the factory in China making the active ingredient was plagued by data integrity issues that call into question the quality of the product. The FDA banned the product from the U.S.

I appreciate that the FDA has presented an idea that would rate facilities based on their quality management maturity. Pharmaceutical companies could choose to disclose the rating of the facilities where their drugs are manufactured, according to the proposal. This proposal doesn't solve three fundamental problems.

First, consumers aren't interested in the quality manufacturing culture at the factory where their cars, phones, laptops, or medicines are made. They want the bottom line: does the product work as it should and is it safe.

In the case of medicines, consumers do care about -- and want to know -- if their bottle of medicine meets U.S. standards which can come only with independent testing and public reporting of results. Purchasers of medicines for the American public should want the same bottom line as their customers.

Second, ratings systems in the absence of actual product testing have proven to hide latent quality problems that only independent and publicly-reported product testing can uncover. Take the case of a Chinese manufacturer which had eighteen inspections and received a clean bill of health. Ten of these inspections were conducted by the FDA, one inspection was conducted by the European Union's regulatory body (the European Medicines Agency), and other inspections were done by German,

Japanese, and Australian regulatory authorities. The company's quality control system was reported to be "very close to advanced level internationally."

How the company received a clean bill of health for so many years is unclear. Later, the FDA had received sixty-one complaints from the company's commercial customers about products allegedly contaminated with bacteria and lacking the full amount of therapeutic ingredient. Drugs without full potency are especially dangerous for people with cancer, infections, and other life-threatening conditions. They could die, and the disease, not the inadequate drug, would be listed as the cause. FDA banned 29 products from this plant and exempted 15 of them from its ban because of concerns about hospitals having to ration supplies. The exempted products included ingredients for antibiotics and chemotherapy for cancer treatment in children and adults.

Third, this rating system ignores the threat that China poses to the U.S. medicine supply. Even if a Chinese manufacturer received a high-quality rating and was the sole supplier, it would be imprudent to rely solely on a single metric and ignore public health and national security concerns to assess a company's fitness to supply Americans with life-saving medicines.

The present situation is like the FAA and Boeing 737 Max planes. Who was looking out for the passengers and their families? When it comes to medicines, who is looking out for us?

**2. Counting the number of API facilities in China, and not counting the reported antibiotic fermentation plants in China near the Inner Mongolia border and China's chemical intermediate manufacturing facilities, provides a misleading and inaccurate assessment of U.S. dependence on China for medicines.**

Accurate, independent data on the extent of U.S. dependence on China is essential for the United States to assess the threat that China poses to the U.S. medicine supply. FDA data is incomplete by showing simply the number of API manufacturing plants in China.

The lack of accurate data is the reason for the first recommendation (below) for an entity in the federal government within the national security apparatus to collect market intelligence, track and monitor global supply and demand, conduct country and supplier risk assessments, make recommendations for strategy investments to assure public health and national security, and be held accountable for an uninterrupted supply of trustworthy medicines.

Further, by counting only the number of facilities and not knowing what they produce, the volume they produce, and whether they are a sole supplier or fragile supplier – represents incomplete information. Consider the following events that have occurred because of a single manufacturing facility in China:

- A single API facility for heparin used a lethal contaminant, oversulfated chondroitin sulfate, that was associated with the deaths of hundreds of Americans.
- A single chemical plant in China exploded, triggering a global shortage of an essential antibiotic to treat sepsis, a life-threatening condition that causes the deaths of 270,000 Americans.
- A single factory in China produced the active pharmaceutical ingredient for a common blood pressure medicine valsartan that contained a cancer-causing chemical found in rocket fuel, and millions of people in the U.S. and around the world were exposed to a genotoxic impurity.

**3. The U.S. medicine supply is broken. The health care system is having to ration drugs that are limited in availability. Substandard and defective products are being produced and given to**

**patients, with some containing toxins that are a threat to human health. The FDA cannot fix the underlying cause of these extremely serious problems that threaten public health and 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 rationing and shortages 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.

### **C. National Security Risks**

#### **1. China Doesn't Have to Hack the Electric Grid or Fire a Missile to Take America Down: It Can Withhold Antibiotics and Other Essential Medicines.**

Throughout history, food has been used as a weapon of war. During World War II, Germany's Atlantic blockade tried to starve food-import-dependent Britain. Germany could hardly forget Britain's blockade of the German coast in World War I to starve its citizens into submission. Hundreds of thousands of Germans died from starvation

Medicines can be used as a weapon of war against the United States. In the hands of an adversary, they 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.

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.

#### **2. China's Social Credit Score for Foreign and Domestic Businesses in China Threatens the U.S. Medicine Supply.**

China is launching its social credit score for businesses operating in China. I have no doubt that in the event of a global pandemic or geopolitical event, the Chinese government would coerce U.S. and other

companies in China making generic drugs and ingredients to reduce or stop supplies to the United States, turning their backs on the American people, our military, seniors, and veterans.

### **3. A Country That Controls the World's Medicines Controls the World.**

The U.S. would not allow China to be its dominant supplier of oil. Neither should the U.S. allow China to be its drug maker.

#### **Recommendations**

#### **Recommendation #1. Designate a Point of Accountability in the Federal Government in the National Security Apparatus to Assure an Unfettered Supply of Quality Medicines from Trustworthy Sources.**

No entity in the federal government is accountable for knowing who controls our medicine supply. A point of accountability in the federal government within the national security apparatus is needed to conduct the ongoing functions: collect market intelligence, track and monitor global supply and demand, conduct country and supplier risk assessments, make recommendations for strategic investments for domestic production to assure public health and national security, and be held accountable for an uninterrupted supply of trustworthy medicines.

#### **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, public health, 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.

#### **Recommendation #3: A Consumer Reports-type Independent Testing of Generic Drugs and Transparency of Results is Essential to Restore America's Trust.**

A Consumer Reports-type independent testing of every batch of every generic manufacturer's medicine and public reporting of the results in real time will help restore the public's trust in their medicines.

Consumers have access to information about the quality of cars, washing machines, mobile phones and hundreds of other consumer products. But they don't have access to testing information about whether the generic drugs they take, which can be a matter of life and death, sickness or health, meet U.S. standards.

If the federal government wants to quickly incentivize quality medicines and provide assurance to the public, stimulating an independent testing capability is the way to do it. Manufacturers and distributors who are confident of their products will be proud when independent testing reveals their products meet the highest standards. This is a competitive advantage in a global marketplace littered with poor quality and rogue suppliers/manufacturers. If companies are reluctant to be transparent, doctors, patients and consumers will wonder why.

#### **Recommendation #4: Generic drug manufacturers and distributors that sell medicines to the Department of Defense should be required to disclose the country of origin.**

To protect warfighters and assure combat readiness, generic drug manufacturers and distributors that supply the DoD should be required to disclose in their contracts with the DoD the country-of-origin of finished drugs, active pharmaceutical ingredients, chemical intermediates and raw materials, including the identification of medicines and their ingredients made in China.

**Recommendation #5: The Department of Defense should be encouraged to have selected generic drugs independently tested for quality similar to the testing conducted for its food supply.**

The Department of Defense Food Analysis and Diagnostic Laboratory protects active duty military by ensuring food safety, food fitness for consumption, and contractual compliance through microbiological, chemical, and toxicological testing of food and bottled water. Regrettably, but by necessity, the Department should be encouraged to contract for testing of selected generic drugs to protect warfighters and ensure combat readiness.

**Recommendation #6: 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 more than 1,000 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 #7: 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 of generic drugs and their active ingredients using advanced manufacturing technology. This action will help create a robust and resilient manufacturing base and secure the nation's health security and national security.

**Recommendation #8 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.**

China produces a reported 80 percent of the global supply of pig intestines to make heparin, a blood thinner which is ubiquitous in hospitals.

To understand the importance of heparin to the U.S. health care system, 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.

In 2018, African swine flu virus erupted in China and continues to devastate the pig population. 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. At least one company whose headquarters are in Europe has publicly stated that it is carefully allocating heparin because of the anticipated shortage. 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 health 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 Subcommittee for holding today's hearing and drawing attention to U.S. dependence on China for medicines and the impact on the nation's public health and national security. Thank you for the opportunity to testify and I look forward to your questions and helping the Subcommittee in any way.