

Testimony of Rosemary Gibson
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Before the Senate Committee on Small Business and Entrepreneurship
The Coronavirus and America's Small Business Supply Chain
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Thank you, Chairman Rubio, Senator Cardin, and Committee Members for the opportunity to testify today. 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 am not paid by any industry or government entity for this work. It is conducted solely in the public interest.

My remarks today emphasize that small businesses are ready to begin immediate production of essential generic medicines for people hospitalized with coronavirus that are in shortage or altogether unavailable.

The \$8.3 billion emergency supplemental package to respond to coronavirus does not address this critical vulnerability in the nation's medicine supply.

1. Small businesses want to help our nation respond to the coronavirus. Small businesses are prepared to start manufacturing within weeks in the United States critical medicines that are unavailable or are being rationed.

The coronavirus outbreak has magnified vulnerability in the nation's supply chain for medical supplies such as masks and other protective gear for health care workers. The \$8.3 billion emergency supplemental package to respond to the coronavirus outbreak passed by Congress and signed by the President is a critical step forward to assure the nation's health security.

The supplemental aid package contains more than \$3 billion for:

- research, development and testing of vaccines to *prevent* people from getting coronavirus; and
- research for drug treatments to *cure* coronavirus.

The package *does not include*:

- *funding to manufacture generic drugs that are being rationed or unavailable* and needed to *care for seriously-ill people hospitalized with coronavirus*, as well as other seriously ill people without coronavirus, to enable them to receive effective treatments and return home healthy.

Members of Congress, the White House, members of the military, veterans, seniors, and hard-working families – will all depend on these essential generic medicines if affected by a severe coronavirus infection.

2. The United States faces an existential threat posed by China's control over the global supply of the ingredients in thousands of essential generic medicines.

China's official news outlet threatened in March 2020, "If China retaliates against the US at this time, in addition to announcing a travel ban on the United States, it will also announce strategic control over medical products and ban exports to the United States. If China announces that its drugs are for domestic use and bans exports, the United States will fall into the hell of a new coronavirus epidemic."

The unleashing of this threat will cause unprecedented deaths and social disorder on a scale never seen before on our country. The civilian and military health care systems will collapse. China can wreak other havoc. Medicines in the hands of an adversary can be weaponized. 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.

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. Coronavirus has brought to the fore U.S. dependence on a single country for its generic medicine supply, and exposed the risks to the nation's health when the dominant global supplier country shuts down production.

The U.S. medicine supply chain is being severely disrupted as production in China has been shut down and transportation and logistics greatly constrained. China has withheld exports of masks and other protective gear. It would be prudent for China to withhold exports of medicines to assure it has enough for its people.

Here is how dependent the United States is on China:

- **90 percent of the medicines used in the United States in hospital intensive care units, emergency rooms, and ambulances, and sold in big box stores and corner drug stores are generic.** Thousands of them are made with chemical compounds and ingredients from China.
- **China makes 9 percent of our generic drugs.** This market share is likely to rapidly increase. The *Financial Times* reported that China is gaining steam in the US generic drug market. China's stated aim is to become the pharmacy to the world, and it is on track to do that.
- **India makes 25 percent of our generic drugs but depends on China for the chemical compounds to make them.** India has recently banned the export of 26 medicinal products because of supply blockages owing to the coronavirus in China, the world's hub of the pharmaceutical chemical industry. *China Rx* predicts that China will eventually overtake India in generic drug production. This is consistent with China's industrial plan which includes the pharmaceutical industry as a target to achieve global dominance.
- **90 percent of the chemical ingredients for generics in the U.S. to care for people with serious coronavirus infections and are hospitalized are sourced from China.** Sedatives, antibiotics, anti-inflammatories, and medicines to raise blood pressure are among the medicines used to care for people with severe coronavirus. China produces 90 percent of the chemical ingredients for these essential medicines.

4. Essential generic drugs to treat severe cases of coronavirus infection are in shortage, being rationed, or unavailable.

While many generic antibiotics and other medicines have been on the FDA drug shortage list and are being rationed, the coronavirus outbreak has exacerbated the situation.

Here are examples of ***generic antibiotics in shortage and being rationed*** that are needed to treat secondary bacterial infections in coronavirus patients.

- Azithromycin is a generic antibiotic to treat severe coronavirus infection in hospitalized patients. Its chemical components are sourced from Hubei Province whose capital, Wuhan, has been the epicenter of the coronavirus outbreak in China. This antibiotic is listed on the FDA shortage list.
- Ciprofloxacin is a generic antibiotic whose chemical precursor (2,4-Dichloro-5-fluorobenzoic acid) is sourced only in China. It is an essential medicine for severe coronavirus infections. This antibiotic was prescribed for anthrax exposure after the 2001 anthrax attacks on Capitol Hill
- Piperacillin/tazobactam is an essential antibiotic medicine for severe coronavirus infection. It is a treatment for sepsis, a life-threatening blood stream infection that kills 27,000 Americans every year. A single factory in China exploded several years ago, causing a global shortage of this antibiotic. The factory was rebuilt and FDA approved product is made there. Three months later, the EU regulator, the European Medicines Agency, found the plant did not meet US/western standards but allowed the product to be sold to avert a shortage.

5. Generic drugs are being rationed in the United States because the manufacturing base in the U.S. and other Western countries is collapsing as China’s generic industry is growing rapidly

Many medicines on the FDA drug shortage list are generic medicines once made by the three largest western generic drug makers: Mylan, Sandoz and Teva.

- Mylan, a U.S.-headquartered generic company, merged with Pfizer. Pfizer announced last year the opening of its global generic headquarters in China.
- Sandoz and Teva announced in early 2019 that they will discontinue production of many medicines. This has occurred as evidenced by many of their generic drugs appearing on the FDA drug shortage list.
- *Western companies cannot compete because there is no free market in generic drug manufacturing and in the production of chemical ingredients.*

6. There is no free market to solve the problem. Chinese cartels and Chinese government subsidies to its domestic manufacturers are driving U.S. and other western generic companies out of the business of generic manufacturing.

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. That is not the full 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.

7. Small businesses with expertise in chemistry and pharmaceutical engineering are ready to produce the most critically needed medicines and their ingredients all in the United States using advanced manufacturing technology that lowers the cost of generic drugs.

Small businesses can play a pivotal role to help assure that the nation's hospitals have the essential generic medicines they need during the coronavirus and any other serious infectious disease outbreak, as well as in normal medical care situations. By using continuous processes in advanced manufacturing, all the ingredients for many drugs can be made fully in the United States.

Innovator pharmaceutical companies have been very slow to use advanced manufacturing technology for new branded pharmaceutical products.

Generic companies have no incentive to invest in this manufacturing technology. Their margins are too thin and risk is too high to move from older, more established batch manufacturing technology. As noted earlier, U.S. and western generic drug makers are stopping production of many generic drugs altogether because of severe pricing pressure from China.

8. Small businesses can help assure the country's ability to meet current needs and be prepared to mitigate the impact of future threats on the nation's health security.

Small businesses can work with the Department of Health and Human Services to identify priority generic drugs, their active pharmaceutical ingredients, and chemical precursors. For example, APIs *fully made in the United States without dependence on other countries* can be manufactured for current use and stockpiled for future use. They have longer periods before expiration than finished drugs. Ready-to-go manufacturing plant capacity can use stockpiled APIs to manufacture finished drugs within weeks. This will assure emergency preparedness and avoid the severe drug shortages that we are facing now.

9. There is precedent for federal investment in manufacturing of medicinal products.

A number of years ago Congress provided funds for flu vaccine manufacturing in the United States. Implementation of congressional intent is performed by the Department of Health and Human Services, Biomedical Advanced Research and Development Authority (BARDA), which executes contracts in a public-private partnership with companies to produce a designated volume of flu vaccines each year.

For domestic production of essential generic drugs and their core components, federal investment for small businesses should be for capital investments to refurbish vacant plants and buy equipment.

The number of finished drugs produced will depend on the complexity of the products selected (which will be determined by the federal government and national health security requirements) and the volume required. One of them could be, for example, enough ciprofloxacin, an essential antibiotic noted above, for the Strategic National Stockpile, the Department of Defense, and the VA.

Once the initial capital investment is made, the cost to actually make the finished drug product can be up to 40% less than current production practices because of much greater efficiency of advanced continuous manufacturing processes as well as direct distribution to government partners.

The sale price of products should include full cost price transparency to the government and be based on manufacturing cost plus a fair rate of return on investment. If products are priced too high, the private market will not purchase the product and the federal investment will have failed to serve the public.

Any federal investment in assuring essential generic drugs should be considered a national security asset that cannot be sold to companies whose governments are strategic competitors to the United States.

This investment will help reinvigorate the U.S. generic manufacturing base and the capacity for the United States to eventually achieve a minimum level of self-sufficiency in the making of essential medicines vital to the nation's health security.

10. Federal investment in small businesses for advanced manufacturing of critical generic drugs is highly likely to attract private investment.

US hospitals are using their procurement dollars to buy essential medicines in shortage made with active ingredients not from China. Civica Rx is a non-profit formed by the Mayo Clinic and 1300 other hospitals representing one-third of licensed hospital beds in the U.S.

Civica Rx 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 finished dose form and other places.

Civica Rx wants to assure all ingredients are sourced in trustworthy countries. Federal investment can spur private investment to expand production capabilities and continue to reduce US dependence on China.

11. Thousands of children with rare diseases in the United States have died in recent years because the generic medicines they need are no longer available. There is no “business case” because the “market” is too small. Small businesses want to fill this vacuum and save these children.

There is an untold tragedy happening in hospitals in the United States. Thousands of children with rare diseases have died in recent years because no one wants to make the “old” generic drugs that would help them live. Small businesses that have approached me want to make these medicines on a non-profit basis so children can live. Using advanced manufacturing, these generic drugs can be made quickly and fully produced in the United States.

Concluding Remarks

The American people are deeply concerned and outraged about U.S. dependence on China for medicines. Investing in small businesses is one part of the solution to eliminate U.S. dependence on China for critical medicines. Federal policy to support entrepreneurship and capital investment to restart industries using innovation in manufacturing will yield high-paying American manufacturing jobs and restore common sense in our medicine supply.