

Testimony of
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before the
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“Safeguarding Pharmaceutical Supply Chains in a Global Economy”
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Chairwoman Eshoo, Ranking Member Burgess, Members of the Subcommittee. I want to thank you for the invitation to testify before you today on “Safeguarding Pharmaceutical Supply Chains in a Global Economy.” This is a critical issue for U.S. economic and national security interests and directly affects every one of our citizens.

My name is Michael Wessel and I am appearing before you today as a Commissioner on the U.S.-China Economic and Security Review Commission (Commission), where I have served since its creation in 2001. Although my comments are informed by my service on the Commission and our work on this issue, my remarks today represent my views, and not those of the Commission or any individual Commissioner.

The Commission was created by Congress in 2001 in conjunction with the debate about the grant of Permanent Normal Trade Relations (PNTR) to China, paving the way for its accession to the World Trade Organization. The Commission was tasked with monitoring, investigating and submitting to Congress an Annual Report on the national security implications of the bilateral trade and economic relationship between the United States and the People’s Republic of China, and to provide recommendations, where appropriate, to Congress for legislative and administrative action.

The grant of PNTR ended the annual debate about whether to extend most favored nation status to China. But as it passed PNTR, Congress created the Commission because it did not want to forego the annual review of our relationship with China. Since its creation, the Commission’s mandate has been extended and altered as the U.S.-China relationship evolved.

The Commission is a somewhat unique body: We report to and support Congress. Each of the four Congressional leaders appoint three members to the Commission for two-year terms. In seven of the last ten years, we have issued unanimous reports. In the three years where it was not unanimous, there was only one dissenting vote. In many ways, the evolving challenges and opportunities posed by the relationship with China have united us in our analysis.

The Commission held a hearing related to the subject of today’s hearing in July of this year. Former Senator Jim Talent and I co-chaired the hearing which was entitled “Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products.” Our hearings have supported our annual reports that are submitted to Congress. Our annual report will be issued on November 14, 2019, and will include a section covering our work on this issue.

The growing U.S. reliance on pharmaceuticals and ingredients from China has been the subject of other work of the Commission in the past. In 2014, the Commission held a hearing entitled “China’s Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products.” In addition to hearings and briefings, our staff provides updates on a variety of topics on an ongoing basis and periodically prepares staff reports. This work has been supplemented by contracted research projects. A list of relevant papers is attached to my testimony.

Chairwoman Eshoo, your September 10 op-ed in the *Washington Post* with Congressman Schiff, was spot on. As you indicated, the problem demands action and bipartisan solutions. The U.S.-China Commission is unanimous in identifying the threats and the need for action and we look forward to working with you and your colleagues to produce workable solutions to protect our country’s interests.

This issue is of critical importance for a number of reasons. First, of course, is the fact that pharmaceuticals are often lifesaving and life sustaining. From long-term treatments for conditions such as diabetes and high blood pressure, to critical interventions, vaccines and other products, pharmaceuticals touch American’s lives every day. Today, we are talking about pharmaceuticals, but the same issues arise with regard to dietary supplements which the majority of Americans ingest daily. The safety of medical devices, too, is affected by a number of these issues.

New treatments are being developed every day to address long-term challenges such as Alzheimer’s, heart conditions, and pandemics. Global cooperation on health care challenges is critical. But, as with so many other issues involving China, there are rising questions about whether such global cooperation is based on shared goals and aspirations or could lead to lopsided gains advancing China’s interests at the expense of the United States and other nations.

The bioeconomy is of increasing importance for U.S. economic competitiveness and national security. It is an economic engine driving growth and opportunity and is an increasingly important source of jobs. As the White House Summit on America’s Bioeconomy earlier this month identified, biotechnology now represents \$388 billion, or 2 percent of U.S. GDP,¹ and is growing every day.

China has focused on the importance of this sector for some time and its policies are designed to advance its capabilities. With over 1.4 billion people, its health care challenges are huge. Simply meeting those needs requires significant resources. Rather than rely on the innovation and capabilities of established global players, China has, as it has in many other sectors, decided that it wants to develop its own capabilities: A Chinese biotech sector with unique Chinese characteristics.

The Chinese government's priorities are publicly identified in multiple high-level industrial policy documents. The Made in China 2025 program, China's 13th Five-Year Plan, and other plans identify biotechnology as a priority sector.

It is critical to focus on China as part of today's hearing because of its growing importance in global pharmaceutical supply chains. In the pharmaceutical sector, increasingly, all roads lead to China. Those roads are rocky, sometimes treacherous and, all-too-often, unsafe. China is the world's largest supplier of active pharmaceutical ingredients (APIs). The drugs our citizens consume are increasingly dependent on the APIs China supplies either directly or indirectly, as those APIs are often the primary ingredients in drugs supplied by India and other nations. India is a significant supplier of generic medicines to the United States, but a significant portion of the APIs used in its medicines is sourced from China. Many other countries also increasingly source from China.

As noted, China's industrial policies are contributing to this problem as the country's predatory practices, subsidies and regulatory system spur the growth of its industry—all-too-often at the detriment of foreign producers. China has supported its chemical and pharmaceutical sector, driving out of many U.S. lines of production, or out of business altogether. As you will hear from the second panel, America has lost the capacity to produce many vital drugs and APIs used by patients every day.

Access to China's health care market has been restricted, prompting some global companies to increase their investments there to try and access the market. This has led to further erosion of productive capabilities here in the United States, as well as the migration of research and development to China. As with many other industries, China often gains critical intellectual property through both licit and illicit means. As examples, this year, Pfizer opened up a global headquarters for its Pfizer Upjohn generic division in Shanghai.² Thermo Fisher Scientific announced in August that it will set up a new production base in China.³ These and other investments by U.S. companies need to be assessed for their impact on our country's interests.

China is luring top U.S. researchers to work for its companies as they set up outposts here in the United States.⁴ At the same time, China's Thousand Talents program seeks to entice key U.S. researchers and experts to go to China to advance the country's domestic capabilities. China's government has an integrated and expansive program to meet the goals of the Chinese Communist Party's plans.

It is also important to note that while Chinese foreign direct investment in the United States has declined this year, the pace of Chinese investment in our biotechnology sector has remained steady. Biotechnology is one of the top sectors for Chinese venture capital investment in the United States, as China seeks to harvest opportunities and, often, capitalize on intellectual property advances here.

As Acting Deputy Assistant Director of the Defense Health Agency told our Commission at our hearing, “the national security risks of increased Chinese dominance of the global API market cannot be overstated.”⁵ Our ability to meet the needs of our warfighters could be constrained by China, in the event of conflict. Or, as with China’s decision to threaten the supply of rare earths to Japan several years ago, China could weaponize its position in the supply chains to our disadvantage and peril.

The risk to our people is due not only to the loss of productive capacity, which can take significant time to regain, but also from the threats attributable to insufficient regulation and oversight of China’s producers. These risks are real as shown by the deaths of our citizens from tainted heparin to blood pressure medicines tainted with rocket fuel. China lacks the regulatory infrastructure, resources and, it appears, commitment to regulate its industry which creates a clear and present danger.

The number of chemical firms making inputs that are used in medicines and the fact that China’s regulatory regime and infrastructure is still developing fosters many risks. But, the problem of corruption also impacts the safety of the sector’s products. In 2007, the former head of China’s State and Food and Drug Administration was executed for accepting bribes from drug companies that resulted in the approval of hundreds of untested drugs. Since then, several scandals have occurred, including the vaccine scare in 2018 resulting from Chinese health regulators uncovering that two companies falsified data to obtain approval for faulty DPT vaccines that affected 400,000 injections.⁶

Questions have been raised about the ability to address safety violations in China, potentially because of the potential to create drug shortages in the U.S. In her testimony at the Commission’s recent hearing, Katherine Eban, said:

According to the FDA’s own data, which I obtained, from 2013 to 2018, out of 864 inspections in China that FDA investigators recommended as Official Action Indicated, FDA officials downgraded 78 of those. By contrast, in the same time period, out of 11,642 inspections that FDA investigators conducted in the U.S. and recommended as Official Action Indicated, only one inspection was downgraded in that time. This reflects the FDA’s willingness to give foreign plants, particularly in China, an opportunity to reform without sanctions.⁷

Some positive steps have been taken, as Chinese consumers have faced tainted drugs and vaccines and have demanded action. For example, in 2016, the China Food and Drug Administration investigated more than 1,622 drug clinical trial programs and cancelled 80 percent of those drug applications after it found evidence of fraudulent data reporting and submissions of incomplete data, among other problems.⁸

But China’s regulatory system is still deficient, and the problem is exacerbated by the growing size of the domestic industry with thousands of producers across the country.

My colleague on this panel from the U.S. Food and Drug Administration (FDA) will testify to what that organization knows about production in China of certain components of the drugs our citizens utilize. All our citizens rely, as does the Department of Defense, on FDA's capabilities.

I am deeply troubled by how much we simply don't know about China's pharmaceutical sector—from APIs to chemical intermediaries to finished drug forms. The risks are large and growing.

Confidence in the safety and quality of Chinese production facilities is limited. FDA inspectors often have a difficult time gaining access to the facilities, due to a variety of factors. In the past, FDA inspectors had trouble simply gaining visas to get into China. When the Government Accountability Office (GAO) last evaluated FDA's foreign drug inspection program as part of its report to this Committee, GAO found that 45 percent (243 of 535) of the establishments in China may never have been inspected.⁹ This is based on the number of facilities, not necessarily their output and, therefore, the impact of the resulting production on our people may be even greater.

At the same time, the productive capacity of our own industry here in the U.S. is declining. As more and more production is outsourced, we have seen the hollowing out of our own capacity. Clearly this results in riskier supply chains. But it has also diminished our ability to reclaim production as the size of our skilled workforce diminishes as well. A review of Trade Adjustment Assistance petitions between April 2011 and May of this year shows 12,463 lost jobs attributable to changed trade conditions. Not all of these are attributable to jobs lost to China, but a substantial portion surely are, based on trade flows. Every lost job represents a shattered personal life and, potentially, a shuttered facility impacting an entire community.

Let me turn to some recommendations to safeguard our pharmaceutical supply chains, specifically with regard to APIs and drugs produced in China. The Commission's soon-to-be-released Annual Report addresses this issue as well as other concerns in the biotech and pharmaceutical sector.

First, we need to draw attention to this issue, ensuring that we have a fact-based assessment of the risks. Madame Chair, the op-ed you co-authored with Congressman Schiff—coupled with today's hearing—should be a wakeup call, spotlighting the need for greater focus on this issue.

As part of the assessment, I would suggest that earlier report this Committee requested from the GAO be updated, with a deeper dive into the ability of the FDA to gain access to Chinese facilities that supply APIs or finished drug forms directly, or indirectly, to the United States. Chinese APIs are a principal ingredient in the drugs sent here from other suppliers, and we cannot simply rely on the authorities in other countries to protect the interests of our people. FDA's ability to inspect must be timely, unfettered and independent.

We must also identify critical medicines which, if supplies are limited or quality is imperiled, will have significant adverse impacts on our people. We must pay particular attention to the

requirement of our warfighters in the field or battleground, and seek to, at a minimum, develop multiple supply sources and, in my view, domestic sources, of supply.

I believe consumers, have a right to know to know where the medicines they ingest, and give to their families, come from. Labelling to provide consumers with the country-of-origin of active ingredients should be considered.

In addition, we should look at expanding the role of private insurers in assessing the integrity of products they are insuring. If insurers know that their liabilities could be increased due to inadequate attention to the safety of inputs that are used by manufacturers or distributors they insure, they are likely to require greater scrutiny of suppliers. This could supplement the work of government inspectors.

I appreciate the invitation to appear before you today and look forward to working with you.

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Additional Resources

(available on the Commission's website: www.uscc.gov)

- “China’s Biotechnology Development: The Role of U.S. and Other Foreign Engagement,” Gryphon Scientific and Rhodium Group (prepared for the U.S.-China Economic and Security Review Commission), February 14, 2019.
- Sean O’Connor, “Fentanyl Flows from China: An Update Since 2017,” *U.S.-China Economic and Security Review Commission*, November 26, 2018.
- Matt Snyder and Bart Carfagno, “Chinese Product Safety: A Persistent Challenge to U.S. Regulators and Importers,” *U.S.-China Economic and Security Review Commission*, March 23, 2017.
- Sean O’Connor, “Fentanyl: China’s Deadly Export to the United States,” *U.S.-China Economic and Security Review Commission*, February 1, 2017.
- Sean O’Connor, “Meth Precursor Chemicals from China: Implications for the United States,” *U.S.-China Economic and Security Review Commission*, July 18, 2016.
- U.S.-China Economic and Security Review Commission, Chapter 1, Section 3, “China’s Health Care Industry, Drug Safety, and Market Access for U.S. Medical Goods and Services,” in *2014 Annual Report to Congress*
- “Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients,” *NSD Bio Group, LLC* (prepared for the U.S.-China Economic and Security Review Commission), March 1, 2010.

¹ White House Office of Science and Technology Policy, Summary of the 2019 White House Summit on America’s Bioeconomy, October 7, 2019.

² Ten Jing Xuan, “Pfizer Upjohn Becomes First Multinational Drug Company to Open HQ in China,” *CX Tech*, May 30, 2019.

³ Xinhua, “Thermo Fisher Scientific to Set Up Production Base in China,” August 23, 2019.

⁴ Preetika Rana, “China Biotech Lure Industry Talent in the U.S.,” *Wall Street Journal*, June 16, 2019.

⁵ U.S.-China Economic and Security Review Commission, *Hearing on Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products*, testimony of Christopher Priest, July 31, 2019.

⁶ Javier C. Hernandez, “In China, Vaccine Scandal Infuriates Parents and Tests Government,” *New York Times*, July 23, 2018.

⁷ U.S.-China Economic and Security Review Commission, *Hearing on Exploring Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products*, testimony of Katherine Eban, July 31, 2019.

⁸ Sing Man, “Chinese Clinical Trials Data 80 Percent Fabricated: Government,” *Radio Free Asia*, September 27, 2016.

⁹ Government Accountability Office, Report to the Committee on Energy and Commerce, “Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices,” December 2016, 45.