

## **Beyond PPE: The Health and National Security Threats Posed by the United States' Reliance on China for Medical and Pharmaceutical Manufacturing**

*By Danyale C. Kellogg*

*On Dec. 17, after two months of dialysis using heparin produced by Baxter, Bonnie Hubley was rushed into intensive care. She had developed diarrhea, vomiting and eventually severe pain in her chest and abdomen. She deteriorated rapidly and by Dec. 19 was unconscious and on a breathing tube. Stunned doctors at the Toledo, Ohio, hospital told Leroy there was no hope. "She was gone," he says. So with "Christmas carols playing in the background," he says, "we said our goodbyes, and my wife of 48 years drifted away."<sup>1</sup>*

The above excerpt appeared in a 2008 *Time* article chronicling the mysterious deaths of several dozen patients across the world. Upon first reading, you may think that the woman, Bonnie Hubley, suffered from some acute illness which struck fast and hard before killing her. In reality, she suffered for years from polycystic kidney disease, a disease which causes large cysts to grow inside the kidneys, often leading to failure. However, dialysis and other treatment may relieve symptoms for several years. If the patient doesn't have other diseases, they are usually a good candidate for organ transplant, allowing them to live a relatively normal life.<sup>2</sup> While this inherited disease is painful and life-threatening, many Americans live with it for years, thanks to dialysis. Yet, for Bonnie Hubley and 80 other Americans in 2008, contaminated heparin, a popular anticoagulant, entered the United States' drug supply, causing their deaths as well as 785 severe injuries in other patients.<sup>3</sup> While 81 deaths isn't very many in the grand scheme, and thousands are injured severely in this country every single day, perhaps the most disturbing part of this story is that these people died while seeking routine care because companies in China adulterated heparin and sold it to US distributors as if it were legitimate.

This occurred because the main supplier of heparin in the United States, Baxter Healthcare Corporation, sourced its raw materials (animal mucosal tissues which are almost exclusively sourced from pig intestines) from a company which operated in mainland China. The country saw a major shortage of pigs resulting from a 2006 outbreak of blue-ear disease (a highly virulent respiratory virus), leading to the company, Scientific Protein Laboratories, to adulterate the active pharmaceutical ingredient later supplied to Baxter with oversulfated chondroitin sulfate.<sup>4</sup> Though the FDA still has been unable to pinpoint where exactly the adulteration happened in the supply chain, the results were disastrous regardless. Dozens of Americans, including children, seeking routine therapies such as dialysis were seriously harmed or killed as a result of this adulteration. The FDA was forced to recall batches of heparin from Baxter and other suppliers and the safety of drugs in the US and Australia, Denmark, France, Germany,

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<sup>1</sup> Bill Powell, "Heparin's Deadly Side Effects," Heparin's Deadly Side Effects, November 13, 2008, accessed August 11, 2020,

<https://web.archive.org/web/20081121194220/http://www.time.com/time/magazine/article/0,9171,1858870,00.html>)

<sup>2</sup> "Polycystic Kidney Disease," Mount Sinai Health Library, accessed August 11, 2020,

<https://www.mountsinai.org/health-library/diseases-conditions/polycystic-kidney-disease>)

<sup>3</sup> Clifford S. Mintz and John Liu, "China's Heparin Revisited: What Went Wrong and Has Anything Changed?" *Journal of Commercial Biotechnology* 19, no. 1 (2013): [PAGE], doi:10.5912/jcb579)

<sup>4</sup> Rosemary Gibson and Janardan Prasad Singh, *China Rx: Exposing the Risks of America's Dependence on China for Medicine* (Amherst, NY: Prometheus Books, 2018), p.24-26)

Italy, Japan, Sweden, and Switzerland was called into question as reports emerged of the ramifications of heparin adulteration.<sup>5</sup> While this did receive Congressional attention, relatively little was done, despite the fact that it was clear the FDA had little handle on the situation.<sup>6</sup> This problem has gone largely unaddressed since and, right now, as we learn more about the devastating impacts of COVID-19, doctors have begun to prescribe anticoagulants to patients as a precaution due to high rates of blood clotting.<sup>7</sup> Clearly the U.S. reliance on China for medical equipment and pharmaceutical manufacturing extends well beyond PPE and is a critical threat to the national and health security of the United States that must be addressed immediately.

The FDA estimates that 40% of finished pharmaceutical products and 80% of active ingredients used by U.S. patients are manufactured abroad, primarily from China and India.<sup>8</sup> The risk of this is two-fold; 1) it is inherently dangerous for the United States to rely so heavily on any single other country for its drug supply and 2) as the 2008 heparin story demonstrated, we cannot guarantee the safety of Chinese pharmaceutical products. As the figure below shows, the U.S. is dependent on China for some common drugs, further increasing the risk of shortages in certain situations.

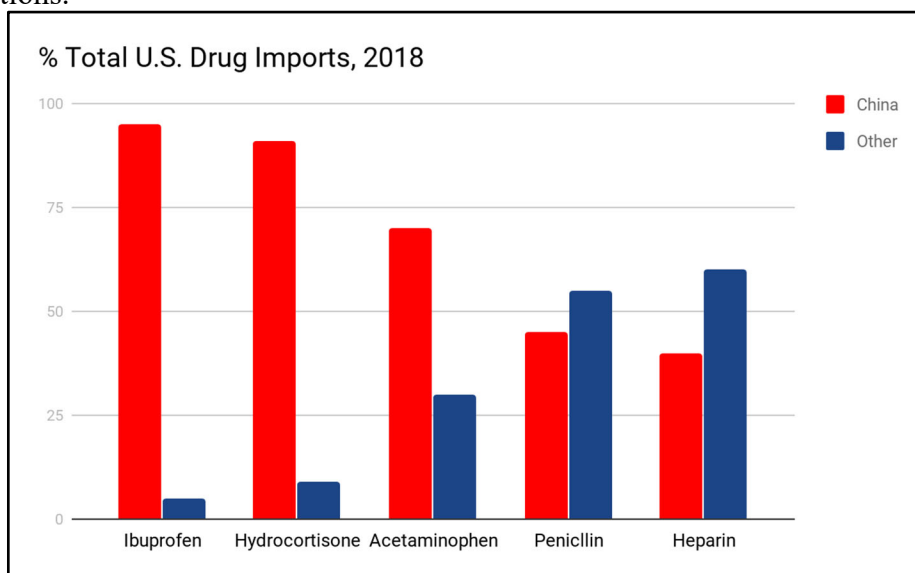


Figure 1. Percentages of total U.S. drug imports for selected drugs in 2018.<sup>6</sup>

It is not at all difficult to imagine scenarios in which this could become dangerous. For starters, China could use drug and medical equipment supply disruption as a means of coercion against the U.S., potentially increasing the morbidity of otherwise treatable conditions. Furthermore, given that both the Departments of Defense and Veterans Affairs are inundated

<sup>5</sup> Matt Mulkey, "Heparin: A Wake-Up Call on Risks to the US Drug Supply," The Pew Charitable Trusts (Pew Research, May 16, 2012), <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2012/05/16/heparin-a-wakeup-call-on-risks-to-the-us-drug-supply>, p.4-5)

<sup>6</sup> Gibson, Rosemary, and Janardan Prasad Singh. *China RX: Exposing the Risks of America's Dependence on China for Medicine*. S.I.: PROMETHEUS, 2020.

This graph I created originally appeared in a policy brief I co-authored at SCONA65.

<sup>7</sup> Jecko Thachil, "The Versatile Heparin in COVID-19," *Journal of Thrombosis and Haemostasis* 18, no. 5 (2020): [PAGE], doi:10.1111/jth.14821)

<sup>8</sup> Mulkey, p. 3.

with these drugs, the risk to the warfighter is very much real and immediate. Therefore, the risks to the general public and our most essential personnel are too big to continue ignoring this issue.

One could make the argument that this is simply capitalism at work and that the invisible hand has played its role. U.S. companies simply did not adapt to market demands at a time when Americans were, rightfully so, concerned about soaring healthcare prices. However, as Gibson and Singh write:

In the 1980s, four US companies made the active ingredients in aspirin. Monsanto was the largest aspirin maker in the world and had a plant in St. Louis Missouri. The other three companies were Dow Chemical in Midland, Michigan; Norwich-Eaton in Norwich, New York; and Sterling Drug in Trenton, New Jersey. The last aspirin manufacturer in the United States was French company Rhodia. It bought the Monsanto plant but had to close it in 2002 when Chinese companies sold bulk aspirin in the United States at artificially low prices.<sup>9</sup>

Gibson and Singh point to one of the most concerning parts of this crisis- China wanted this to happen, and there was very little U.S. companies could do to counteract it. How can a domestic manufacturer compete when the Chinese are willing to sell at artificially low prices and Americans, rightfully concerned about the rising costs of healthcare, prefer to buy cheap? They could not then and they cannot now, but this does not mean we can continue to ignore this issue. We must work to end U.S. dependence on China for drugs and other vital medical supplies.

But what can policymakers do to achieve this decoupling of the U.S. and China, particularly when American consumers have demonstrated time and time again that buying cheap rather than buying American remains a priority? Furthermore, many, including Uri Friedman of *The Atlantic*, might view stances such as mine as hawkish and unnecessarily hardline.<sup>10</sup> However, the truth is that the dangers posed by this problem pre-date COVID-19 and have very real implications for U.S. health and national security that must be addressed. At the same time, the U.S. should be careful not to seek isolationist or protectionist solutions to this problem as such “solutions” could actually do much more harm than good. As such, there are two key ways that the United States can address this problem: 1) encouraging and incentivizing American manufacturers to resume and increase production of pharmaceuticals domestically, and 2) diversifying our suppliers of these goods, paying particular attention to our allies in Europe and East Asia.

Presently, the United States has virtually no industrial base left to produce generic drugs, which account for 90% of the medications Americans consume annually. As was discussed earlier, Chinese manufacturers made sure to stamp out domestic competition in the United States by introducing their products at artificially low prices. Furthermore, thanks to drug labeling standards, consumers and providers alike oftentimes do not know that a drug has either been entirely manufactured in China or was made with Chinese ingredients prior to re-labeling and distribution through a non-Chinese company.<sup>11</sup> As such, American-made medications are often

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<sup>9</sup> Gibson and Singh. P 34-35.

<sup>10</sup> Uri Friedman, “China Hawks Are Calling the Coronavirus a 'Wake-Up Call',” *The Atlantic* (Atlantic Media Company, March 16, 2020), <https://www.theatlantic.com/politics/archive/2020/03/coronavirus-crisis-china-trump-trade-economy/607747/>

<sup>11</sup> Gibson and Singh.

much more expensive than their imported counterparts, which could be mitigated by expanding the domestic production capacity for these goods.<sup>7</sup> Other potential trading partners that can export drugs in similar quantities to the U.S. do not provide a viable alternative. India, for example, relies on China for 80% of API and chemical intermediates essential for the production of its own pharmaceuticals.<sup>8</sup> The U.S. entertained the idea of turning to allies, such as Canada, for prescription drug imports in 2019, though such proposals were limited in scope and fizzled out.<sup>9</sup> It is time for the federal government, as it has done in the previous century during wartime, to divert defense resources to funding collaborations between government, academia, and industry to boost efficiency and capability in the medical sector. Furthermore, as it is also dangerous to be too self-sufficient, coordinating with allies in Europe or, even more likely, in East Asia to boost their exports will help mitigate potential damages to American consumers while diversifying our supply line. We cannot rip the bandaid off overnight, but we need to attack this problem aggressively as it is simply too important to wait any longer.

The time to address this problem is not now; it was a decade or more ago. The most basic functions of American citizens are left vulnerable to disruption because we cannot guarantee the safety of the medications used in this country, despite thousands of federal rules and regulations governing every part of the drug-production process. In a time when COVID-19 has made it abundantly clear that the United States is not prepared to effectively handle the impacts of the pandemic at home, let alone lead the world through this crisis, we have to start securing our healthcare system and medical manufacturing for the future.

The American people have a lot of questions about the future of healthcare in this country that are complex and often at the center of the partisan divide in this country. What should not be complex or partisan is acknowledging how gross of a vulnerability the United States' dependence on China for medical equipment and pharmaceuticals is. A sick population, particularly one which cannot count on the safety of its drug supply, is not a secure one. There will be more pandemics, more spillovers, more antigenic shifts and, most likely, more superbugs that require scientists to stretch the bounds of modern medicine. Even right now, we are heading into cold and flu season as the COVID-19 pandemic continues on, resurging in some portions of the United States. If we have experienced drug shortages while just battling COVID-19, what can we expect when we have to also deal with influenza? What will this look like when the next killer flu pandemic, which we are due for, rolls around?<sup>12</sup> The short answer is that it will likely be devastating.

Finally, it needs to be said that the debates we in the International Relations community like to have about whether or not we should pursue restraint in foreign policy, if we are in a new era of great power competition, if we really are in a new kind of cold war with China, etc. are of questionable importance if we cannot get the basics right in protecting the U.S. population from the internal dangers of depending on China for drugs. Disease does not care about troop counts, international borders, democracy, economics, who sells us our drugs or anything else other than reproducing and spreading to new hosts. It will take some extreme measures in order to get the United States to a point where its pharmaceutical supply is secure, but we have spent more on

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<sup>12</sup> "The next Flu Pandemic: A Matter of 'when', Not 'if'," Eastern and Mediterranean Region, accessed August 11, 2020, <http://www.emro.who.int/pandemic-epidemic-diseases/news/the-next-flu-pandemic-a-matter-of-when-not-if.html>)

less in the name of national security. Our adversaries certainly will not forget the images of the *USS Theodore Roosevelt* in port in Guam as her crew underwent quarantine and the ship herself decontamination following an outbreak of COVID-19 onboard. For two months earlier this year, there was no U.S. aircraft carrier in the western Pacific because disease got the better of us.<sup>13</sup> We can debate the efficacy of our global military presence at length, but, ultimately, what we did was broadcast to the world that we can be brought to our knees at home and abroad by disease in an incredibly short period of time. These dangers are too real and disruptions in the pharmaceutical supply line will only make it worse. We must act now to prevent further disaster in coming years.

*Danyale C. Kellogg is an MIA student at the Bush School on the national security and diplomacy track with concentrations in East Asia and pandemics and biosecurity. She is also a Global Health Graduate Certificate student at the Texas A&M School of Public Health, a graduate research assistant, and a Women in Defense HORIZONS Scholar in addition to representing the Bush School in Student One Health Association in the College of Veterinary Medicine. She has interned with DoD, DHS, the US Congress, and several other organizations. Her research interests include biodefense and health security broadly, US military preparedness for naturally-occurring and man-made infectious disease outbreaks, and US interests in East Asia, particularly on the Korean Peninsula. She previously earned a BA in history from Southwestern University in Georgetown, TX.*

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<sup>13</sup> Gregory Koblentz, "Will COVID-19 Inspire Bioterrorism or Biological Warfare?" Schar School of Policy and Government, August 10, 2020, accessed August 11, 2020, <https://schar.gmu.edu/news-and-events/latest-news/will-covid-19-inspire-bioterrorism-or-biological-warfare>)