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Deglobalization of APIs and Pharmaceutical Manufacturing:

Addressing a Significant National Security Risk

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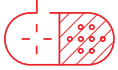

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Introduction

The global COVID-19 pandemic has shined a spotlight on a significant national security risk that has been festering for quite some time: Our nation's reliance on China and India for our pharmaceutical drugs. Although some people have been sounding the alarm for months or years, it is only recently that the momentum has begun to build to address this risk.

Why is this a problem? Because millions of Americans depend on pharmaceutical medications to get and stay healthy. For many people the availability of a safe and reliable supply of medications is literally a matter of life and death. Even when medications are manufactured here in this hemisphere, in most cases the active ingredients (i.e. the raw materials that enable the finished product to produce the desired effects) and/or other inputs are sourced from somewhere else.

As Rosemary Gibson, a senior advisor on health care issues at the bioethics-focused Hastings Center explains, "Medicines can be used as a weapon of war against the United States. Supplies can be withheld. Even without the specter of the weaponization of medicines, there are other problems associated with reliance on China and India as well. These include geopolitics, the lack of transparency around quality issues, the impact of harmful environmental practices and more.

Background

How Pharmaceuticals are Made

Pharmaceutical manufacturing involves two main stages. In stage one the active ingredients, known as the Active Pharmaceutical Ingredients (APIs), are produced. This is a very sophisticated chemical/biochemical process. In stage two these APIs are mixed with non-active ingredients known as excipients to produce the final blend. This is then turned into a consumable form, such as a capsule, tablet, liquid, cream, ointment or injectable product. Stage one and stage two are usually completed by two different companies, often in two different hemispheres.

API Markets

API manufacturing has been slowly moving to China since China opened up under Den Xiao Ping in the 1970s. Prior to that, the production of medicines for the U.S. population (both APIs and the end products) was primarily domestically based. Until the mid-1990s, the U.S., Europe and Japan produced 90% of the world's APIs. But this is no longer the case today.

What is driving this shift? To a large degree it is costs.

In October 2019, Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA), spoke to Congress. She said, "The number of Chinese facilities producing APIs for the U.S. market has increased over the past decade, as part of a massive movement of pharmaceutical production offshore. This movement is being driven by the pharmaceutical industry's desire for cost savings and less stringent environmental regulations."

In many ways China's policies create unfair and difficult conditions for foreign manufacturers to compete against. From currency manipulations and state-sponsored subsidies to lax or nonexistent environmental damage controls and low wages, China has made producing APIs there extremely cost-effective.

Some pertinent facts about the API market:

- **The global API market is huge—$182.2 billion in 2019—and projected to grow to $245.2 billion by 2024.**
- **Only 28% of API manufacturing currently takes place in the U.S.**
- **31% of API manufacturing takes place in China and India combined.**
- **China has over 40% of worldwide API market share. ,**
- **India relies on China for about 70% of its supply of APIs.**
- **In 2019 India imported 665,000 tons of active ingredients from China .**
- **It is estimated that the U.S. relies on China and India for 75 to 80% of its supply of APIs.**

Background

Pharmaceutical Markets

The global market for pharmaceutical drugs, of course, is even bigger than the API market that it encompasses: It is estimated that by 2023 it will reach the $1.5 trillion mark.

Currently, 8.3% of the manufactured pharmaceutical drugs are exported out of the United States and Canada, while Asia accounts for 9.5% of exports, and 80.7% is exported from elsewhere in (Europe) the Western Hemisphere . While at one time the United States was at the forefront of drug manufacturing, this clearly is no longer the case.

As Senator Chris Coons (Democrat—Delaware) has explained, "The U.S. ignored the decline of domestic medical manufacturing and waited too long to seriously invest in the federal office designed to prepare for pandemics."

The situation is even more dire when one considers that the lion's share of many common/essential medications needed by US citizens are imported from China :

- **All Antibiotics – 97%**
- **Ibuprofen – 95%**
- **Hydrocortisone – 91%**
- **Acetaminophen – 70%**
- **Penicillin – 40 to 45%**
- **Heparin (used to prevent blood clots) – 40%**
- **It is estimated that the U.S. relies on China and India for 75 to 80% of its supply of APIs.**

China has exclusive manufacturing agreements for drugs for anaesthesia, cancer and HIV/AIDS, along with many other medicines used in hospitals and at home. According to Rosemary Gibson, co-author of "ChinaRX: Exposing the Risks of America's Dependence on China for Medicine," it's "all part of a plan that China laid out in its 2025 initiative to become the pharmacy to the world."

"Without action," states Senator Marsha Blackburn (Republican—Tennessee), "U.S. dependence on China for medications puts American lives at risk."

Risks of Reliance on China and India

Reliance on China and India for APIs and/or pharmaceutical medications poses many risks to the United States and, in some cases, to the world. Many see this "single point of failure" (or, technically, double points of failure) in our pharmaceutical supply chain as a disaster waiting to happen. The following provides a discussion of the major threats...

Geopolitics and the Potential Weaponization of Medications

The potential weaponization of medications is the most serious risk.

The Chinese or Indian government can, at any point in time and with absolutely no warning, decide to simply stop medical exports altogether. One or both of these governments can stop exports to specified countries. Or they can vastly increase the cost of exported medications.

China and India, of course, are aware of this. Speaking at a National People's Conference in China, Li Daokui, a professor of economics at Tsinghua University, said, "We are at the mercy of others when it comes to computer chips, but we are the world's largest exporter of raw materials for vitamins and antibiotics. Should we reduce the exports, the medical systems of some western countries will not run well."

In March 2020, at the beginning of the coronavirus pandemic, India chose to restrict the export of many common medicines and pharmaceutical ingredients, in order to ensure the supply for their domestic market. This, of course, had an impact on all of the countries that would normally import these medicines from them.

More recently, tensions between China and India have provided another illustration of how geopolitics can impact pharmaceutical production. Movement from China to India of key chemicals used to produce APIs were delayed at ports and airports due to a decision by Indian customs authorities to closely scrutinize these imports. This supply chain delay has been painful, as India is dependent on China for key raw materials used to manufacture a variety of vital pharmaceuticals, including Remdesevir and Favipiravir, which are used to treat COVID-19; antibiotics; and other cardiovascular, respiratory and diabetes medicines.

Against this backdrop, the U.S. has been engaged in a trade war with China since 2018, when President Trump began setting tariffs that he hoped would force China to change its trade practices. This trade war has had negative economic impacts on both the U.S. and China. What is to stop China from "upping the ante" and placing an embargo on vital APIs or medications?

Also, worth considering is the geopolitical situation in Asia. China is using the power it has in manufacturing to impose its will on neighboring countries. The recent military clashes with India , the power grab in Hong Kong and China's maritime claims in the South China Sea (which the US opposes) are all examples of China flexing its muscles.

Given the imbalance in the production of APIs, there can be dangerous repercussions in a case of war or epidemic. In the past China and India have both stopped containers at the border. Many of these containers have contained essential, active pharmaceuticals that are vital to U.S. national security. This security can be compromised if the Chinese and Indian governments start restricting API supply to the U.S.

Quality and Safety Issues Stemming from Lax Oversight

There are serious deficiencies in the health and safety standards in Chinas' pharmaceutical sector. In its 2019 report to Congress, the U.S.-China Economic and Security Review Commission specifically identified a number of risks stemming from China's lax oversight of pharmaceutical production. These include:

- Inadequate regulation by the Chinese government
- Fraudulent tactics of many Chinese manufacturers
- Inability of the U.S. Food and Drug Administration (FDA) to adequately inspect Chinese manufacturing facilities and guarantee the safety of these imports.

There have already been numerous drug safety scandals related to contaminated medicines or APIs from China. Some notable recent examples include:

- Contaminated baclofen from China was flagged in 2015. Baclofen is an API used as a central nervous system depressant. The manufacturer confirmed that, due to the low level of controls in the manufacturing process, the API could be contaminated with particulates. Importers were warned by the FDA not to use baclofen from this manufacturer, as it was not suitable for injectables and could pose serious safety risks for patients.

- Contaminated crude heparin sourced by a number of Chinese ingredient makers is suspected to have caused more than 80 deaths in the U.S. in 2008.

- In 2018 an unannounced inspection found evidence of forged data related to the manufacturing of 113,000 rabies vaccines. The manufacturers, Changsheng and the Wuhan Institute of Biological Products, had their licenses to produce vaccines revoked and recalls were initiated.

- In 2018, there was an FDA recall of a number of blood pressure medications made in China that were contaminated with N-nitroso dimethylamine (NDMA), a cancer-causing toxin.

- There are bound to be more such drug safety scandals in the future.

Lack of Transparency in Pharmaceutical Labeling

There are many ingredients that go into a pharmaceutical product. In addition to the active ingredients (i.e. the APIs) there are also inactive ingredients, known as excipients, such as oils and stabilizers. For medicines made in capsule form there is also the capsule itself. Each of these inputs, of course, might also have sub-ingredients.

Surprisingly, the U.S. does not require drug companies to disclose the country of origin of their APIs on their product labels. Consequently, many consumers may not know that their "made in the U.S." medication contains APIs and possibly other ingredients made elsewhere.

In 2017, Benjamin Shobert, Founder and Managing Director of Rubicon Strategy Group and Senior Associate of the National Bureau of Asian Research, expressed concern about this issue. Testifying before the U.S.-China Economic and Security Review Commission he spoke of the risks related to "transparency as to where APIs are manufactured in China, and robust regulatory mechanisms...to ensure that quality, safety and efficacy standards are upheld."

Exactly who is currently overseeing the quality, safety and efficacy of these vital inputs into the pharmaceutical manufacturing process?

Most U.S. consumers assume that the Food and Drug Administration (FDA) is responsible for the safety of all aspects of pharmaceutical medicines. The FDA, however, may not be as on top of things as consumers assume.

During testimony before the Senate Committee on Finance in June 2020, Doug Throckmorton, Deputy Director for Regulatory Programs at the FDA's Center for Drug Evaluation and Research, spoke about the FDA's lack of information about the earlier stages of the pharmaceutical supply chain. Referring to the APIs and the chemicals used to produce them, he stated, "We know substantially less about the sources of those products than we do about API and...we know less about API and its manufacturing and distribution than we do about finished dosage forms."

Chinese Acquisition of Western Intellectual Property

- As FBI Director James Comey has said, "Chinese hackers target the intellectual property of U.S. companies in China every day."

- Given that fact, it should not come as a surprise that there is currently a significant problem with Chinese companies acquiring Western companies for intellectual property (IP) enhancement. Often the American employees of those companies are instructed to train their Chinese counterparts. After they do so, they are fired. Chinese scientists get the know-how and knowledge to be able to build the technology in China, while jobs in the U.S. get eliminated.

Key examples of unethical Intellectual Property practices are:

- The case of Massachusetts-based American Superconductor (AMSC), whose Intellectual Property was stolen by Sinovel, a Chinese company. Chinese cyber criminals are trying to steal Coronavirus vaccine secrets; they have targeted biomedical research for years.

- The Justice Department charged a government-owned Chinese company, Fujian Jinhua Integrated Circuit Co., and co-conspirators, with stealing trade secrets from the U.S. semiconductor company Micron Technology.

- The company Kings Nower Seed, a subsidiary of the Chinese conglomerate Beijing Dabeinong Technology Group Co., was accused of acquiring corn seed and shipping it to China so scientists could attempt to reproduce the seeds' genetic traits.

- Another example is the GSK and Renopharma case. Five Chinese scientists, two of whom have worked for GSK, have been indicted by the US attorney's office with conspiracy to steal trade secrets, conspiracy to commit wire fraud, conspiracy to commit money laundering, theft of trade secrets, and wire fraud to benefit a pharma startup in China.

- A Chinese scientist, Weiqiang Zhang, was sentenced to 121 months in a U.S. federal prison for conspiring to steal samples of a variety of rice seeds from Ventria Bioscience, a Kansas biopharmaceutical research company. ,

- In 2014, federal prosecutors investigated a case where an IP theft occurred in the white Oreo cream cookie filling, which uses the chemical titanium dioxide (TiO_2) to achieve its brilliant white color. In the pharmaceutical industry, titanium dioxide is used in most sunscreens to block UVA and UVB rays, similar to zinc oxide. It is also commonly used as pigment for pharmaceutical products such as gelatin capsules, tablet coatings and syrups.

Drug-Resistant Infections Fueled by Harmful Environmental Practices

In the U.S. and other Western countries, strict regulations ensure that waste products from pharmaceutical manufacturing are not simply discharged directly into the environment. This, however, is not the case in China and India. Today the pollution from antibiotics manufacturing facilities in these countries is one of the three primary factors fueling the global rise of antimicrobial drug resistance and multi-drug-resistant infections. (The other two significant factors are misuse and/or overuse in both human medicine and farming).

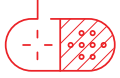
India has been referred to as the "Antimicrobial resistance capital of the world." This is driven, in part, by waste from the pharmaceutical sector.

To examine the extent of this problem, the investigative agency Ecostorm tested 34 antibiotics production sites in India. Of these, 16 were found to be harboring bacteria resistant to antibiotics.

Waste from antibiotic manufacturing migrates into the ground and/or water, where it goes into the livestock-rearing and human food chains. This, in turn, perpetuates the spread of multi-drug-resistant infections. As Ecostorm reports, "The substantial quantities of antibiotics released from polluting factories, which frequently combine with runoff from farms and human waste in water bodies and sewage treatment plants, provide a perfect breeding ground for drug-resistant bacteria."

Antimicrobial resistance poses a significant health problem. According to the Centers for Disease Control (CDC), each year antibiotic-resistant bacteria and fungi cause an estimated 2,868,700 or more infections in the U.S. alone, resulting in at least 35,900 deaths.

Our continued reliance on pharmaceuticals made in countries that have lax manufacturing practices contributes to this problem. Ironically, as Ecostorm points out, the antibiotics made by these polluting manufacturers are sold directly to hospitals. This means that the public health services that are spending billions to treat people and fight the "superbug" infections are also indirectly channeling vast sums of money to the very companies that are contributing to this problem in the first place.



Recommendations for Policy Makers

There is an urgent need to decrease the reliance of the U.S. supply of medications on countries such as China and India. For all the reasons presented in this paper, doing so is a national security issue.

As economist and White House trade advisor Peter Navarro has shared, "This is not about China or India or any one country. It's about America losing its pharmaceutical supply chains to the sweat shops, pollution havens, and tax havens around the world that cheat America out of its pharmaceutical independence."

The solution: Deglobalize the production of APIs and pharmaceuticals. Incentivize moving manufacturing back to the U.S. and other countries in the Western Hemisphere. Reinvent these manufacturing processes to be more efficient and ecologically friendly. Ensure a secure supply of vital APIs and medications for our citizens.

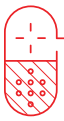
The U.S. must diversify and introduce redundancy into its supply chains. Moving manufacturing closer to home will make it possible for the FDA to provide the necessary oversight to ensure the safety, quality and efficacy of the pharmaceuticals upon which so many depend.

Some specific recommendations as to how to do this follow...

Enact Legislation

Senators Marsha Blackburn and Bob Menendez (Democrat—New Jersey) have introduced a bipartisan bill entitled the "Securing America's Medicine Cabinet Act of 2020" (S. 3432). According to Senator Blackburn, this bill aims to "bring drug manufacturing back to the United States, where ingredients and processes can be more easily verified."

The Securing America's Medicine Cabinet Act would expand the FDA's Emerging Technology Program. This Program is meant to encourage the adoption of innovative approaches to product design and pharmaceutical manufacturing. The Act would authorize $100 million to develop centers of



excellence for advanced pharmaceutical manufacturing to help with both development and manufacturing. Plus, it would also create a unit within the FDA which would, among other things, prioritize addressing critical drug shortages and bringing pharmaceutical manufacturing jobs to the U.S.

This bill is an excellent start. The Act should be further extended to include the creation of a list of certified producers of APIs that are manufactured in friendly countries in the Western Hemisphere. Included on that list should be capsule manufacturers and finished dosage form manufacturers (including manufacturers of generic drugs) from approved countries.

Other legislative priorities include:

Reduce imports of Chinese APIs. This could be accomplished via specific restrictions on what is allowed into the U.S. or by increasing tariffs on these materials.

Require transparency in pharmaceutical labeling. Compel pharmaceutical manufacturers to include the source of the APIs and raw materials they use. This will introduce traceability to medications.

Encouraging buyers to "buy local." Hospitals, pharmaceutical distributors and other buyers can be required or encouraged to source pharmaceuticals from friendly countries in the Western Hemisphere. Manufacturers can be required or encouraged to do this for the APIs they use. This effort could be aided by the list of certified API producers mentioned above.

Encourage the Adoption of New Technologies

Manufacturers should be encouraged to utilize new technologies that increase efficiencies while reducing the environmental footprint. "Continuous Manufacturing" is an excellent example of this. With Continuous Manufacturing the finished dosage form is produced as a continuous stream, as opposed to traditional batch manufacturing, which has breaks or stops between different steps of the process.

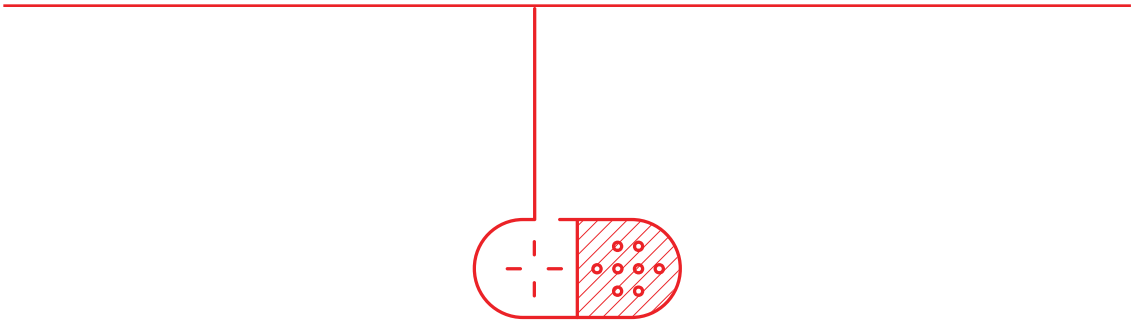
Another innovation that can be put into widespread use is Quality by Design (QbD) . The well-designed operational reliability created when processes are designed with quality in mind mitigates the regulatory risk and lowers the cost of manufacturing. This allows the developer to gain greater understanding and control over the process and allows regulatory agencies and the API manufacturers to achieve better—and safer—performance.

Provide Incentives for “Local” Production

To decrease reliance on China and India, the proper incentives need to be put into place. The goal should be to bring manufacturing to the U.S. and to friendly, low-wage countries in the Western Hemisphere such as Mexico, Colombia, Peru, and Ecuador and even to U.S. territories such as Puerto Rico.

API and final dosage forms manufacturers from U.S. FDA-approved manufacturing countries should be able to get tax incentives and/ or subsidized loans to develop new production facilities in the Western Hemisphere.

The recent announcement of a $765 million loan to help Kodak shift into drug production is an excellent example of this. In a unique use of the Defense Production Act, Kodak has received this loan from the U.S. International Development Finance Corporation. Kodak plans to use its long history in chemical and advanced materials to produce APIs used in a variety of generic drugs. Kodak’s planned focus on generic drugs is not surprise, as single-compound generics are truly the “low hanging fruit” here.



Conclusion

Deglobalizing the supply chain for APIs and pharmaceuticals is an urgent need. As Senator Coons has pointed out, "If we have another global pandemic that leads the world to close borders and leads supply chains to shatter or to break down, we are distinctly vulnerable because we are now so dependent upon globally-integrated supply chains." Undeniably, the vulnerability exists whether or not there is another global pandemic, and regardless of how long it takes before the current global pandemic stops wreaking havoc in the world.

As a matter of national security, manufacturing must be brought back to the U.S. and other friendly countries in the Western Hemisphere. This is the only way to ensure the quality, consistency, safety, availability and reliability of our pharmaceutical supply and the supply chains upon which it depends.

Moving manufacturing closer to home would allow for greater oversight of ethical employee practices and appropriate environmental controls. It would drastically reduce the number of adulterated APIs in the market. It would solidify supply chains and reduce cycle times. And it would create jobs in the regions that host the new manufacturing sites.

The U.S. should not undertake this deglobalization alone. Other governments should also institute similar incentives to bring manufacturing close to their countries as well. In fact, Japan is already doing this. The ultimate goal is to have API and pharmaceutical manufacturing take place in multiple places around the world, to reduce the inherent risks for people everywhere.

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About the Author

JONATHAN GILINSKI

Known for his ability to successfully develop and grow businesses, Jonathan Gilinski is the Executive Director of CapsCanada® a Lyfe Group company. In this role he promotes excellence in the execution of all aspects of hard capsule manufacturing, from capsule formulation and materials to product design, customization options and efficient manufacturing processes. Jonathan's business acumen and ethos, as well as his strong focus on regulatory compliance and quality assurance, are recognized worldwide.

Regularly quoted as a subject-matter expert in customized encapsulation and medicinal cannabis innovation, Jonathan is a sought-after speaker at key industry conferences and events. As a trusted media source for delivering valuable industry insight and commentary, he has been featured in Entrepreneur, The Huffington Post, CNBC, Money, Success and more.

Jonathan developed FLAVORCAPS®, a patented line of flavored capsules specifically to optimize product appeal for kids with autism and other pediatric applications. The innovations that Jonathan has brought to the nutritional supplements industry include new health and wellness product formulations and manufacturing technologies.

As a philanthropist, Jonathan has focused on community-strengthening initiatives in education and nutrition, groundbreaking cancer and medicinal cannabis research, and development aimed at finding cures for children suffering from severe encephalopathies.

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