

US Dependence on China for Medicines

Rosemary Gibson

Author, *China Rx: Exposing the Risks of America's*

Dependence on China for Medicine

Senior Advisor, The Hastings Center

@Rosemary100

ROSEMARY
GIBSON

CHINA

Rx

JANARDAN
PRASAD
SINGH

**EXPOSING THE RISKS
OF AMERICA'S DEPENDENCE
ON CHINA FOR MEDICINE**

4 Points

How dependent is U.S. on China for medicines?

What is FDA not telling us?

How did we become so dependent? It's more than lower costs!

Risks: interruptions in supply + quality problems



Topics: [Facilities](#) | [Outsourcing](#) | [Regulatory](#)

Dangers aside, drugmakers can't live without Chinese APIs

September 3, 2012 | By [Eric Palmer](#)

SHARE

Email

3

Tweet

4

Share

0

Like

When it comes Chinese-made APIs, Western drugmakers are between a rock and a hard place. They know Chinese oversight of bulk APIs is insufficient to snuff out substandard producers, but since China produces more APIs than any other country, they can't live without them.

"If China for some reason decided to stop exporting APIs, within three months all our pharmacies would be empty," Guy Villax, CEO of Hovione, tells *Reuters*. The Portuguese API supplier has factories in [China](#), as well as the U.S. and Ireland.

After 80 U.S. patient deaths were tied to tainted Chinese [heparin](#) in 2008, Chinese authorities pledged to crack down on [API](#) suppliers. But a *Reuters* investigation finds that while China is doing more, the fact that many Chinese APIs are substandard or counterfeit is an open secret. "Illegal ingredients in bulk are a big problem, but nobody talks about it," Villax says.

US-China Economic and Security Review Commission Hearing July 31, 2019

“The national security risks of increased Chinese dominance of the global active pharmaceutical ingredient (API) market cannot be overstated.”

Pharmaceuticals to protect servicemembers from nuclear, biological and chemical threats are also sourced in China.



National Security Risks of
Dependence on China

Christopher Priest
Defense Health Agency

Testimony: House Energy and Commerce Health Subcommittee

- ▶ Testimony of Michael Wessel, Member of the U.S.-China Economic and Security Review Commission, to the House Energy and Commerce Health Subcommittee, October 30, 2019
- ▶ “China is the world’s largest supplier of active pharmaceutical ingredients (APIs).”

United States Senate

WASHINGTON, DC 20510

December 5, 2019

The Honorable Mark T. Esper
Secretary of Defense
United States Department of Defense
1000 Defense Pentagon
Washington, D.C., 20301

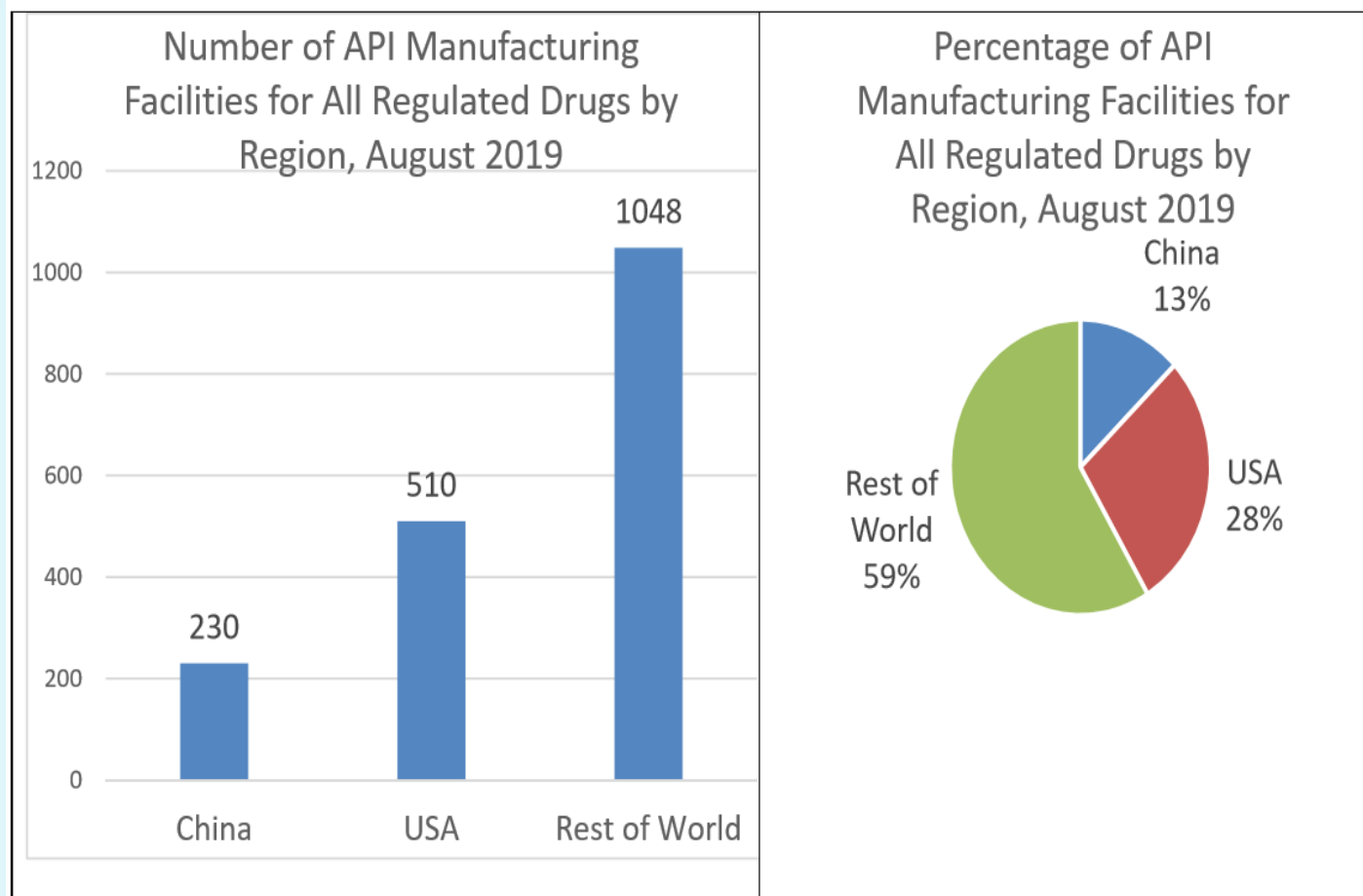
Dear Secretary Esper:

We write to request information regarding the national security risks posed by the role of foreign manufacturing in the pharmaceutical products supply chain. Millions of Americans, including servicemembers, rely on drugs to stay healthy—yet the United States imports a significant portion of these drugs' components from China.¹

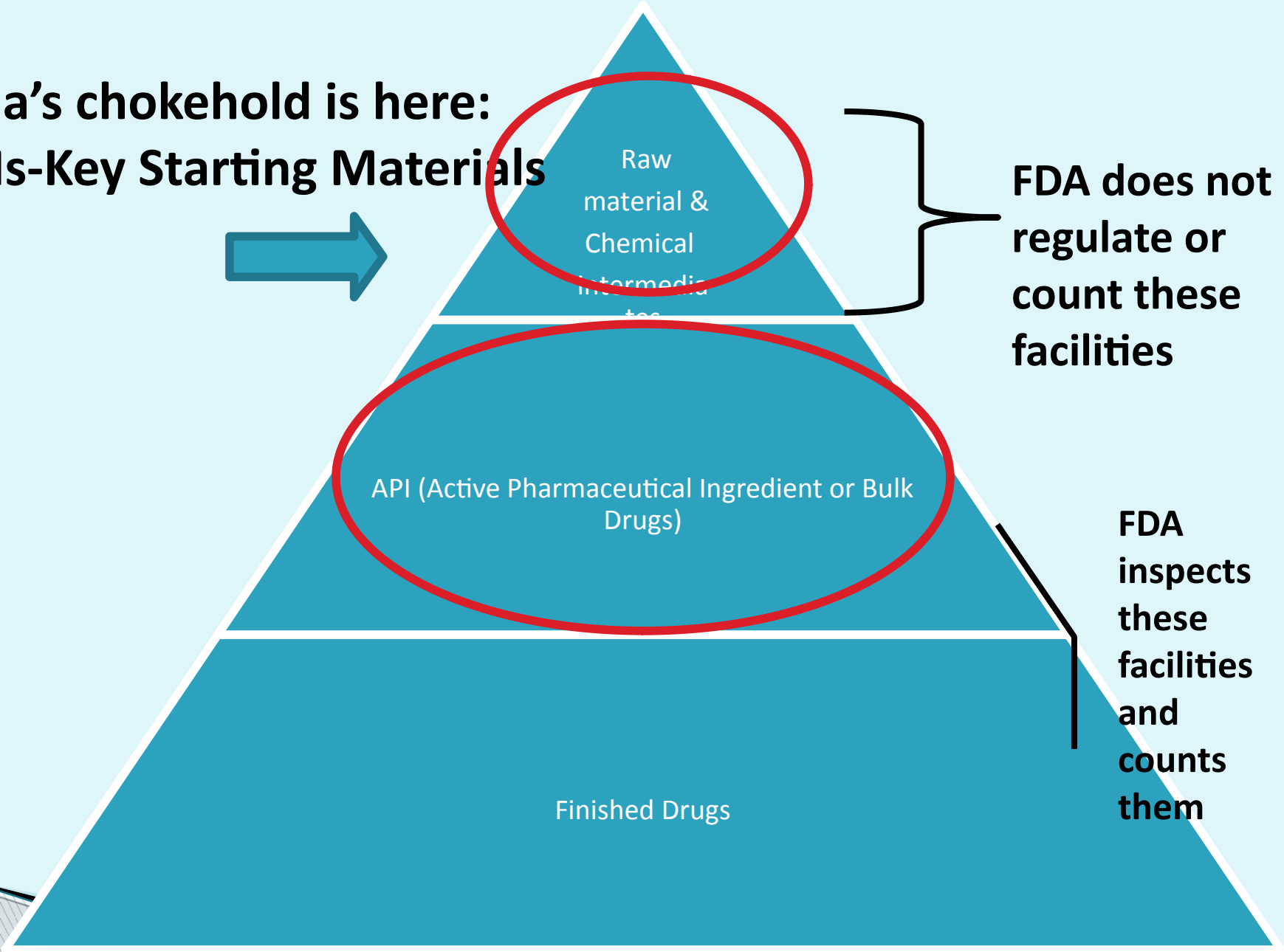
In light of a recent report from the U.S.-China Economic and Security Review Commission (Commission) highlighting the nation's "growing reliance" on drug products made in China, it is critical that DoD, along with other key federal agencies, address the dangers posed by U.S. reliance on foreign drug makers.²

What is FDA NOT telling us?

FDA Testimony House E&C Health Subcommittee 10/30/19: Appears as If US Not Too Dependent on China



**China's chokehold is here:
KSMs-Key Starting Materials**



FDA does not regulate or count these facilities

FDA inspects these facilities and counts them

Raw material & Chemical Intermediates

API (Active Pharmaceutical Ingredient or Bulk Drugs)

Finished Drugs

Key Starting Materials: KSMs?

There are thousands of key starting materials for drugs

They include chemical molecules, raw material from antibiotic fermentation plants and from pigs (for heparin)

Companies' sources are "a closely guarded secret."

Regrettable Statements

US Chamber of Commerce:
U.S. manufacturers already
meet 70% of current
pharmaceutical demand.
(Reuters, May 4, 2020)

Understating dependence and
associated risks is a grave
disservice to our country

U.S. Chamber of Commerce

BUSINESS NEWS MAY 4, 2020 / 1:09 AM / 8 DAYS AGO

Trump administration pushing to rip global supply chains from China: officials

Humeyra Pamuk, Andrea Shalal 7 MIN READ  

WASHINGTON (Reuters) - The Trump administration is “turbocharging” an initiative to remove global industrial supply chains from China as it weighs new tariffs to punish Beijing for its handling of the coronavirus outbreak, according to officials familiar with U.S. planning.

Reuters, May 4, 2020

What DO we know about the sourcing of Key Starting
Materials? (KSMs)

India Depends on China for 69% of Raw Materials/Chemicals to Make Generic Drugs

India's generic industry depends on China for 69% of the raw material and chemical intermediates to make Active Pharmaceutical Ingredients (India Directorate of Commercial Intelligence and Statistics)

Facts: From the Front Lines of Pharma Manufacturing

“Not dependent on China... means one can have several sources for materials – some can be outside of China and some may come from China. If China were to cut supply to the US, you would still be able to operate your supply chain. Right now even that is difficult to do.”

Ph.D. Chemist in Branded
Pharma Manufacturing

From The Editor | May 6, 2020

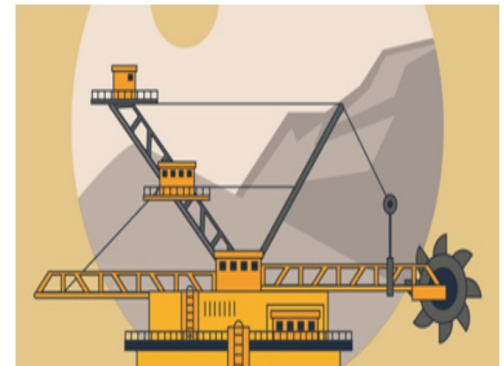


The Raw Materials Of A Supply-Chain Revolution

By Louis Garguilo, Chief Editor, Outsourced Pharma

You say you want a revolution.

What will it take exactly? How would you diversify China-dependent supply chains so you can procure more materials, and develop and manufacture more API and products outside of that



Outsourced Pharma
May 6, 2020

China Owns Global Raw Materials Market



Europe/World in same situation as U.S.

“Now you can say that China owns the raw materials market worldwide.” Former Dutch pharma industry leader

Chris Oldenhof, former EU industry leader

Dutch Public TV Documentary
Updated: March 2020

Dominance is Global



“Now we’re afraid that China will do things to deprive us of our medication.” Former Dutch pharma industry leader

Chris Oldenhof, former EU industry leader

Dutch Public TV Documentary
Feb 2019

2. How We Got Here

Case Study:

Closure of Last U.S. Penicillin Plant

The U.S. can no longer make penicillin

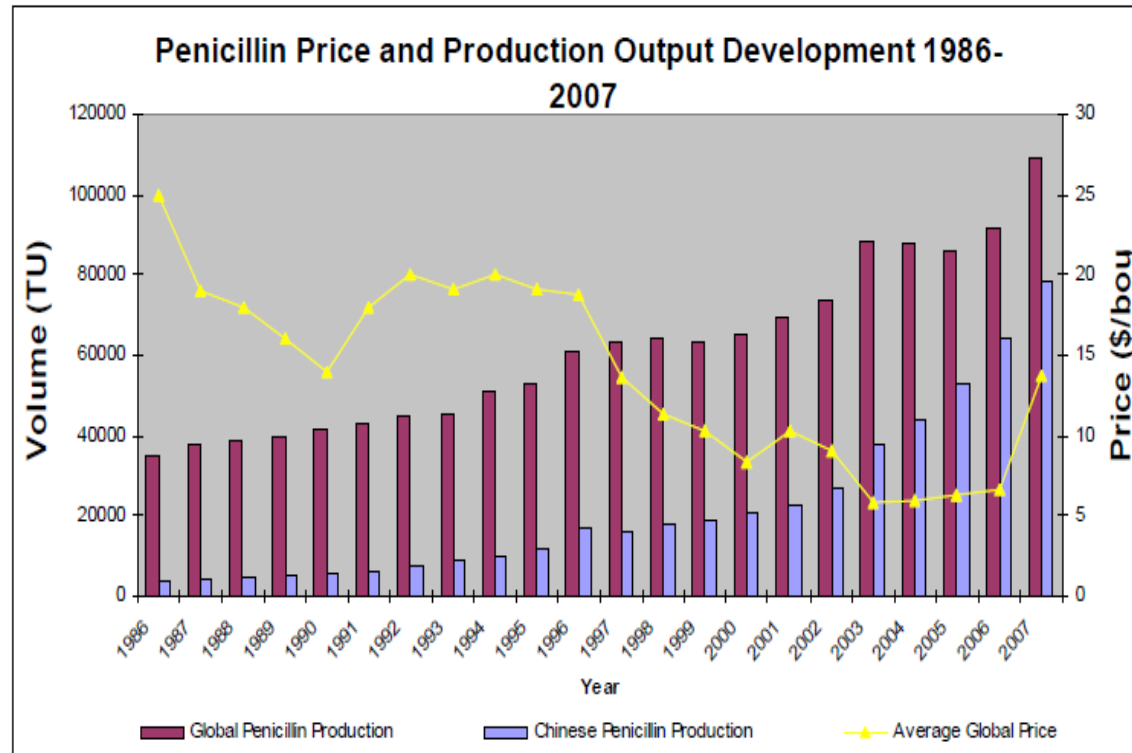
The last U.S. penicillin plant closed in 2004.

Why? China's penicillin cartel.

China's cartels fix prices and control supply + government subsidies, currency manipulation, etc.



Penicillin Market Price vs. Global Market Share of Chinese Penicillin: Chinese market share vs. annual price average



Chinese inroad: After several years of having put extreme downward pressure on prices (through dumping via India) a sharp price increase starts after a critically dominant world market share has been obtained by China.

Last US Penicillin Industrial Capability

- ▶ The last penicillin plant was a Bristol Myers Squibb capability that once made 70% of raw material (fermentation)
- ▶ Closure = demolishing 50 buildings = loss of industrial base/security (Syracuse.com)



US-China Economic and Security Review Commission Hearing 7/31/19

“[My blood-pressure medications] were contaminated with rocket fuel. I imagine active people have the same problem. This affects the readiness of our troops.”

Dr. Larry Wortzel, retired army colonel.



Medicines Made in China with
Rocket Fuel

Dr. Larry Wortzel Commission
Member

Thank you

Gibsonr@thehastingscenter.org

@Rosemary100