MAKING MEDICINES IN AMERICA

HOW CONGRESS CAN HELP AMERICA'S AI, BIOPHARMA, AND MANUFACTURING INDUSTRIES MAKE IT HAPPEN



A 25 YEAR PERSPECTIVE ON THE OPPORTUNITIES AND CHALLENGES

MONIQUE K. MANSOURA, PHD MBA

7 MAY 2025

OVERVIEW

WHY

Manufacturing medicines is a national security priority

WHERE

Do we stand?

WHAT

Have we “LEARNED”?
Cautionary Tales

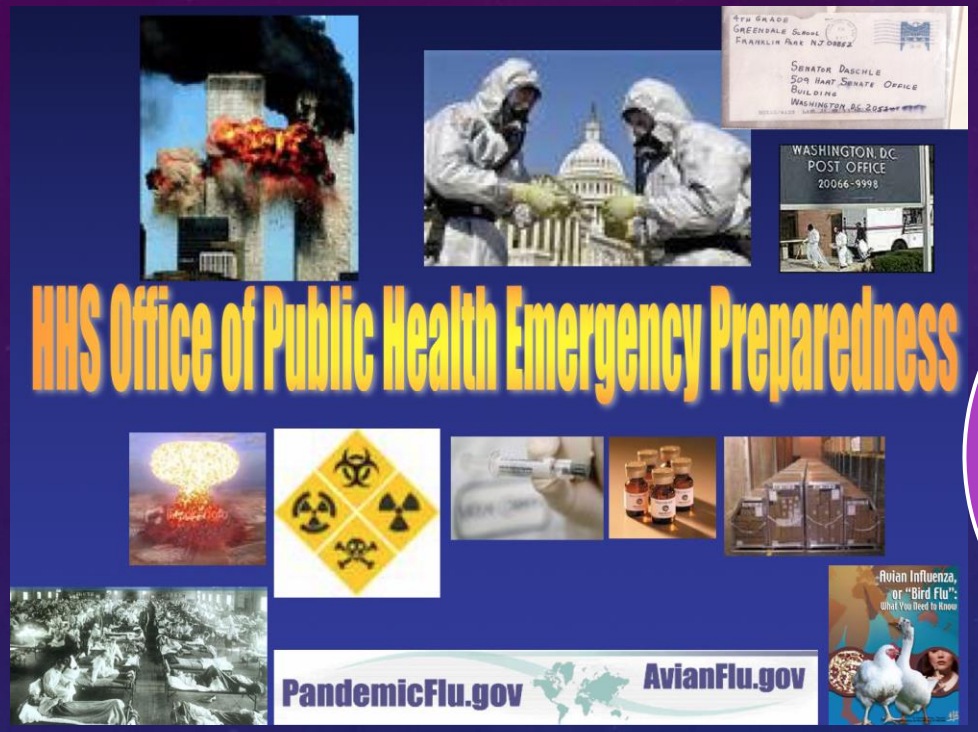
HOW

Do we seize the Opportunities?

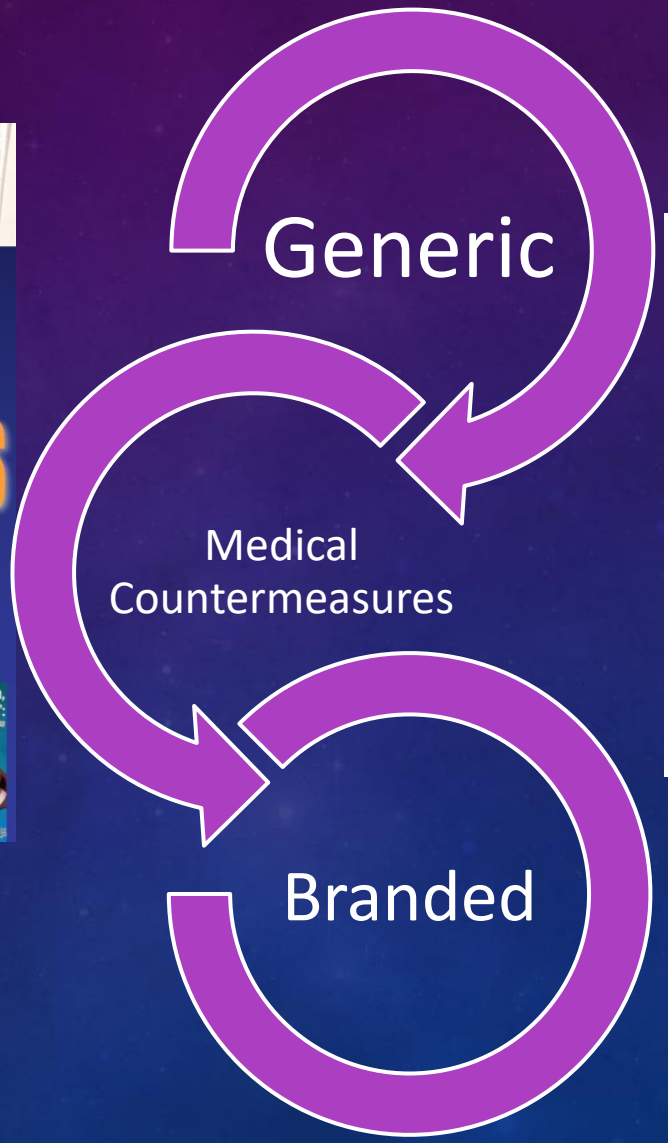
WHEN

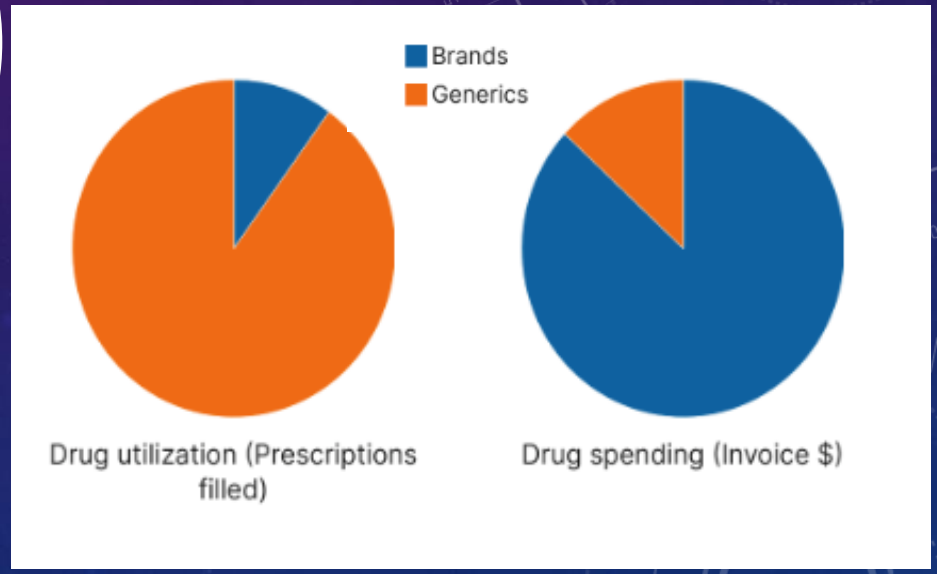
Should we act?

WHY MEDICINES ARE A MATTER OF NATIONAL, ECONOMIC AND HEALTH SECURITY



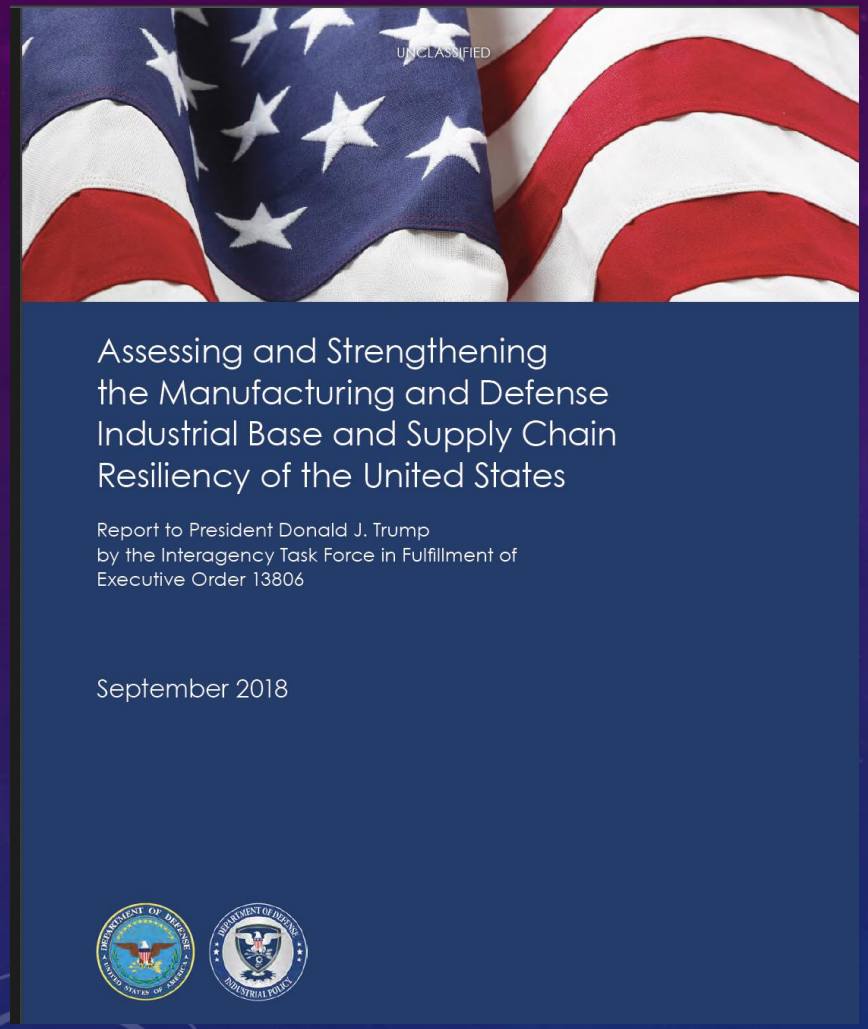
2001 was a wake-up call and positioned the development and manufacturing of medicines into a national security imperative





In 2025 we face development and manufacturing challenges across the broader spectrum of pharmaceuticals – generics and branded

BIOPHARMA HAS BEEN UNDERVALUED AS A STRATEGIC COMPONENT OF THE NATIONAL SECURITY INDUSTRIAL BASE

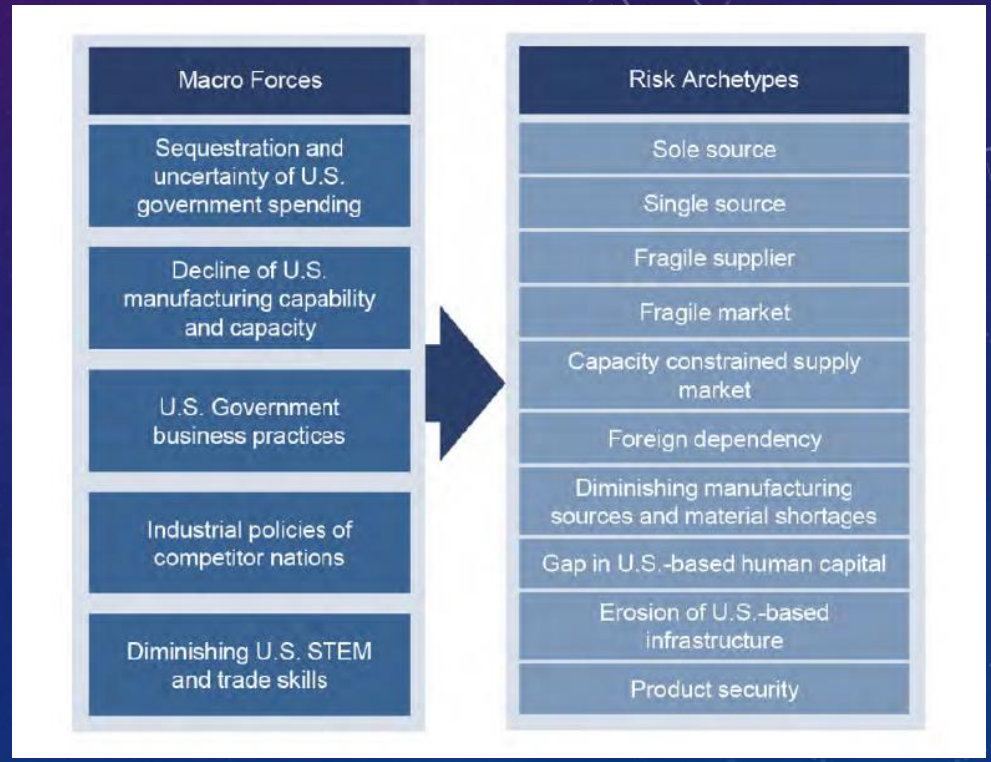


Nine Industrial Sectors in the Report

- Aircraft
- CBRN
- Ground Systems
- Munitions and Missiles
- Nuclear Matter Warheads
- Radar and Electronic Warfare
- Shipbuilding
- Soldier Systems
- Space

Cross-Cutting

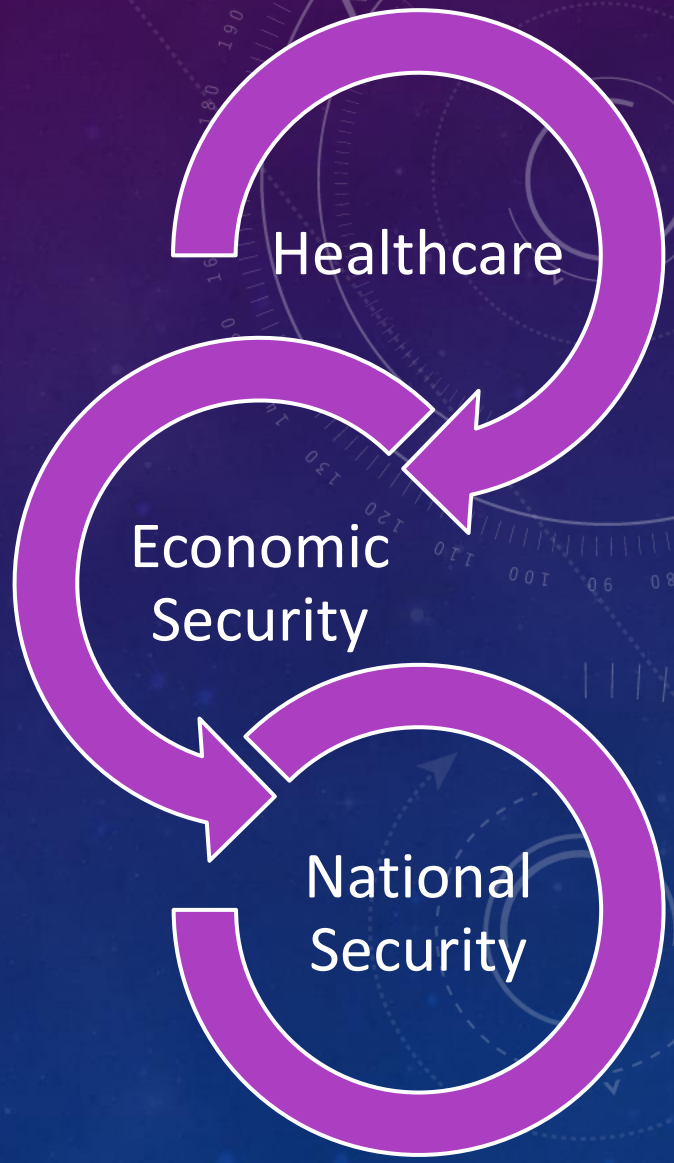
- Cybersecurity for MFG
- Electronics
- Machine Tools & Controls
- Materials
- Organic Base
- Software Engineering
- Workforce



CAUTIONARY TALES – COLLISION OF CULTURES

Health and National Security: A Contemporary Collision of Cultures

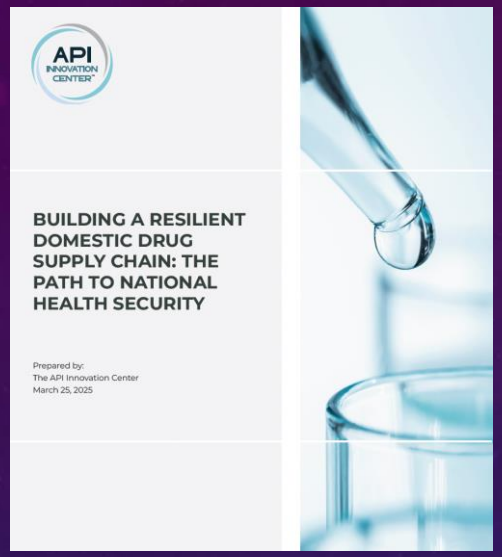
Kenneth W. Bernard



- The health community must temper its tribal convictions and convince powerful defense and foreign affairs communities to embrace relevant health issues in the first tier of policy and budget concerns
- Health professionals and organizations generally have little experience in crafting messages and issues that speak to the critical power players who have foreign policy, intelligence, and defense credentials. But it is not solely their fault. The security sector is not enthusiastic about being told that issues such as pandemics should be considered ‘‘front burner’’ security problems

Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science Volume 11, 2013

FRAGILITY OF THE US MEDICAL SUPPLY CHAINS ARE WELL DOCUMENTED AND INNOVATIVE APPROACHES ARE BEING PROPOSED AND PURSUED

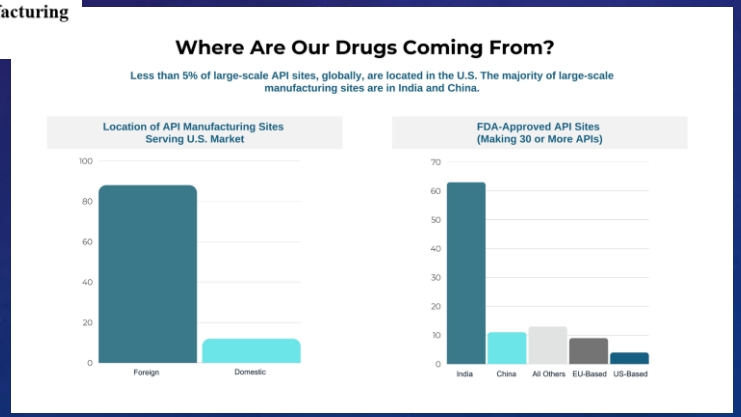




- U.S. overdependence on foreign production for 100's of medicines Americans rely on every day
- 2024 saw a record number of shortages (323)
- 72% of FDA-approved API manufacturing facilities are ex-US
- 11 Drug Shortage lists leads to fragmentation
- Reimbursement policies create a race-to-the-bottom driving prices below market equilibrium
- U.S. drug makers lack incentives - economic, regulatory and market factors
- "There is a high cost of a low price" . . . Tony Sardella







PROPOSED SOLUTIONS

- Enhance Supply Chain Transparency
- Measure and refine
- Invest strategically
- Prioritize and incentive quality
- Stockpiles/buffer inventories
- Leverage technology - advanced manufacturing , AI

PROPOSED BIOSECURE ACT IN 2024 CATALYZES REVELATION OF EXTENSIVE FOREIGN DEPENDENCIES IN THE BIOMANUFACTURING OF PHARMACEUTICALS

BIOSECURE Act Update Offers Biotech Companies Eight Years to Divest Contracts With Firms Of 'Concern'

10 May 2024 | ANALYSIS



by Derrick Gingery

@dgingery | derrick.gingery@citeline.com

Executive Summary

But that clock is already ticking as the House Oversight and Accountability Committee prepares to mark-up the bill and a likely reconciliation effort with the Senate looming.



(Original Signature of Member)

118TH CONGRESS
2D SESSION

H. R. _____

To prohibit contracting with certain biotechnology providers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. WENSTRUP introduced the following bill; which was referred to the Committee on _____

A BILL

To prohibit contracting with certain biotechnology providers, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "BIOSECURE Act".

SEC. 2. PROHIBITION ON CONTRACTING WITH CERTAIN BIOTECHNOLOGY PROVIDERS.

Bio Biotechnology Innovation Organization

Key Elements of the Global Supply Chain

Survey Results

May 6th, 2024

- Survey represented 124 companies
- **79% have at least one contract or product with a Chinese-based or China owned contract manufacturer**
- Millions of patients depend on these medicines
- It would take up to 8 years to switch

H.R. 8333, the BIOSECURE Act (Wenstrup-Krishnamoorthi): Prohibits a federal agency from procuring any biotechnology equipment or service from a biotechnology company of concern. The bill also prohibits a federal agency from contracting, either directly or through a subcontract, with an entity that uses such equipment or service in performance of the contract. The bill places similar prohibitions on federal loan or grant dollars.

BIOTECHNOLOGY'S INFLECTION POINT?

STAT+ | BIOTECH

At JPM, biotech industry expresses excitement — and some anxiety — about therapies from China

Both rival and partner, the country is increasingly at the heart of U.S. drug development



Workers with China's Sinovac Biotech stand on a production line in Beijing. Kevin Frayer/Getty Images



By Allison DeAngelis Jan. 15, 2025

Biotech Startups and Venture Capital Reporter

Chinese Biotech CN



China Drug Deals Were the Talk of the JPMorgan Healthcare Conference

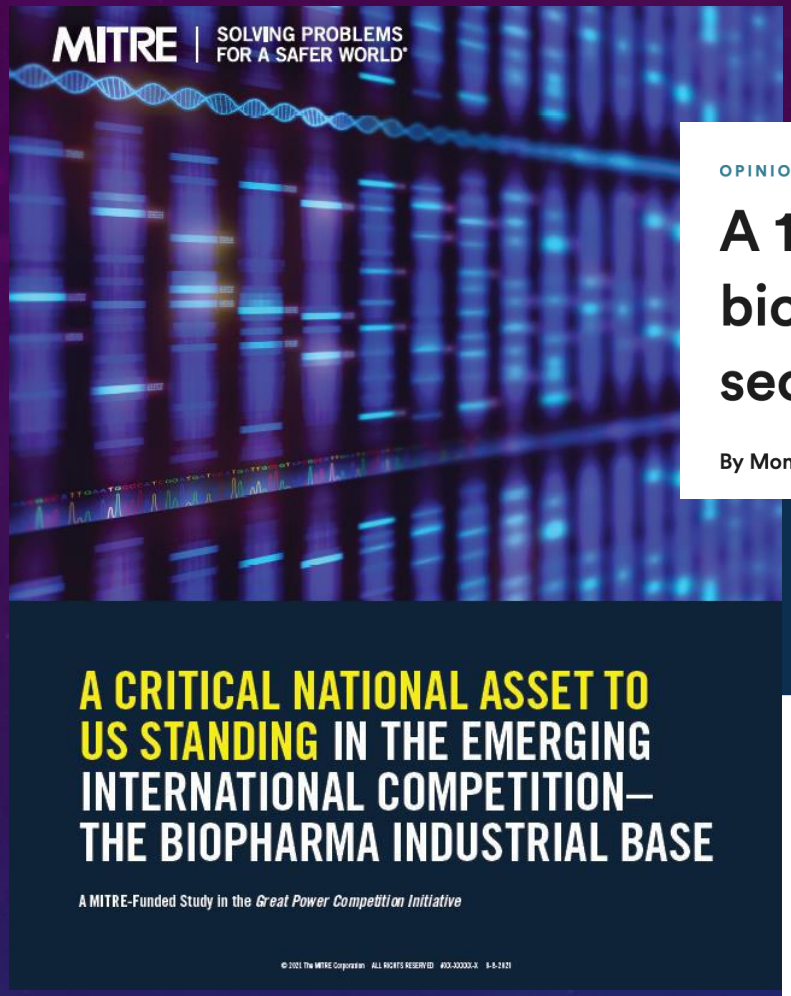


Getty Images

obert Langreth and Gerry Smith

ary 16, 2025 at 6:00 AM EST


Office of the Director of National Intelligence | March 2025
ANNUAL THREAT ASSESSMENT
OF THE U.S. INTELLIGENCE COMMUNITY
China's approach to and role in global biological, medical, and other health-related global priorities present unique challenges to the United States and the world.
The PRC's dominance in pharmaceutical and medical supply production combined with lower quality safety and environmental standards than those of the United States positions Beijing to potentially restrict such exports for leverage over Washington and others in trade or security disputes. The PRC plays an increasingly important role in supplying pharmaceuticals and related medical supplies to the United States, as well as the rest of the world.



OPINIONS+

STAT+

A 10-point plan for sustaining the biopharma industrial base for a more secure nation

By Monique K. Mansoura Sept. 3, 2021

Reprints

10-POINT ACTION PLAN:
SUSTAINING A BIOPHARMA INDUSTRIAL BASE FOR A MORE SECURE NATION

High-impact events, including pandemics, extreme weather events, and trade disputes, put U.S. national security and long-term economic competitiveness at risk.[1]

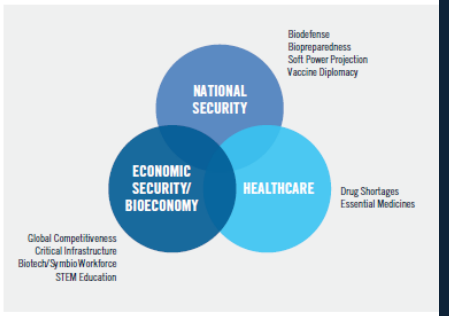
A lack of a sustainable biopharma industrial base, including critical infrastructure and a trained workforce, to ensure adequate supply of medical countermeasures, essential medicines, and medical supplies at sufficient scale and speed, warrants urgent action. We propose this 10-point action plan to mitigate risks from these high-consequence events, while fostering a stronger bioeconomy and a safer world.[2]

Context

Over the past two decades, the U.S. Government (USG) has made strides in bolstering our capacity to respond to biological threats from natural, accidental, or intentional causes.[3] The USG has, for example, instituted new agencies, programs, and funding sources dedicated to the nation's biosecurity.[4] Despite these actions, our preparedness and response to biological threats remain reactive and transactional as opposed to proactive and strategic.[5] This has resulted in several systemic consequences for U.S. security.

Vision

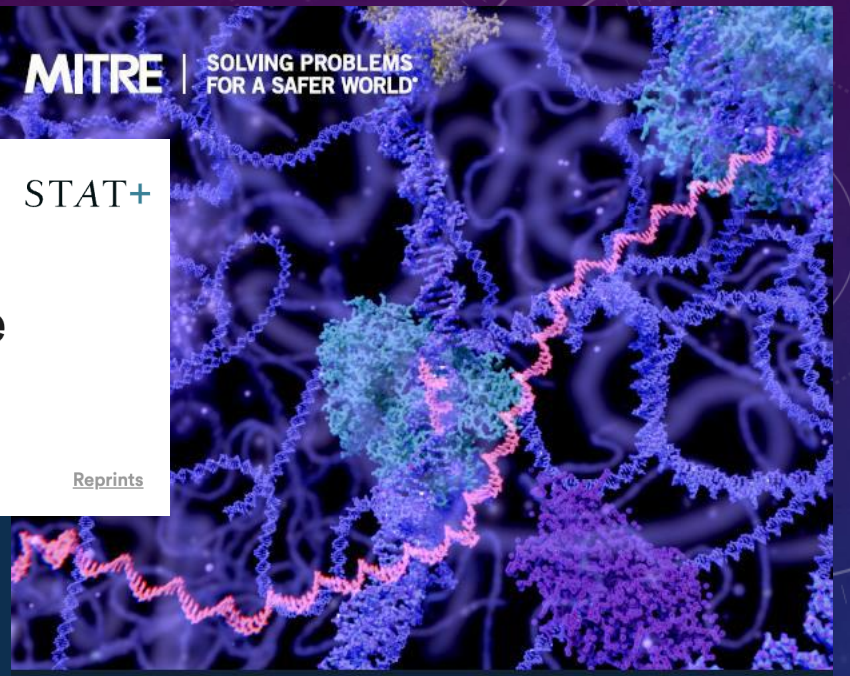
The USG creates industrial policy to sustain a world-class industrial base, responsive to national, economic, and health security needs. We propose three primary objectives by which to accomplish this:



Three Lenses of Biopharma Industrial Policy

10-Point Action Plan

MITRE, a non-profit public interest organization, operating six federally funded research and development centers in support of USG missions, proposes the following 10-point action plan.[6] This plan was developed with guidance from leading experts with decades of public and private sector experience in this mission and ecosystem. These actions are aligned with multiple policy priorities of the Biden-Harris Administration.[7,8,9] As the biological threat landscape evolves in frequency

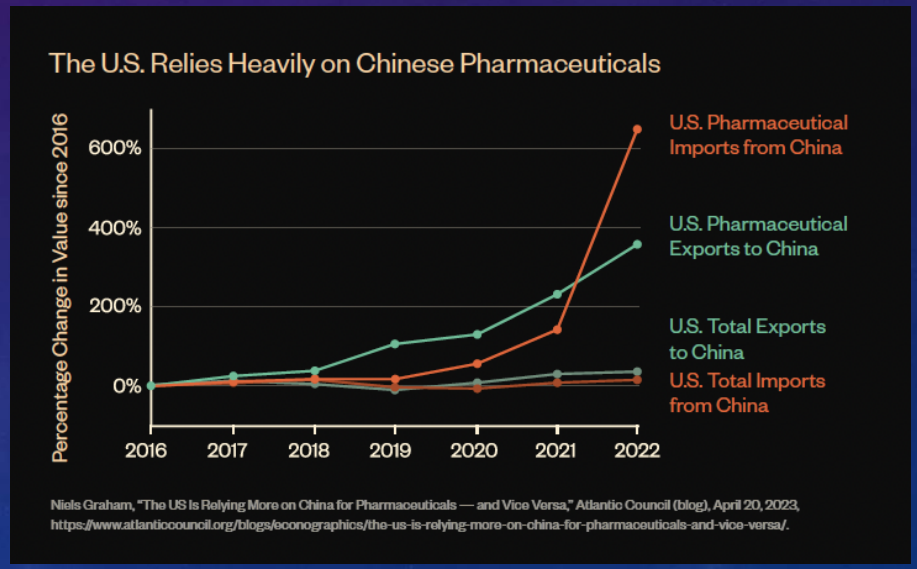




"There is time to act, but no time to wait"

Excerpts from the ACTION PLAN

- Promote Biotechnology Innovation and Out-Innovate our Strategic Competitors
- Use National Security Tools to Protect US innovation and our Industrial Base
- Mobilize the Private sector to get U.S. Products to Scale



From 2016-2021, the market value of Chinese biotechnology firms grew 100-fold, to $300 billion, with market capitalization second only to the U.S. companies, and are on track to catch up quickly

THE WHITE HOUSE EXECUTIVE ORDER ON DOMESTIC PHARMACEUTICAL MANUFACTURING





"My administration will work to make the United States the most competitive nation in the world for the manufacture of safe and effective pharmaceutical products"

President Donald J. Trump
May 5, 2025