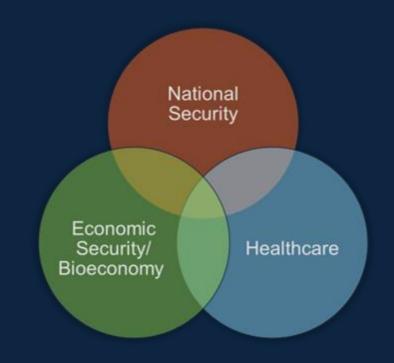


# Geopolitics and the Global Biopharmaceutical Supply Chain

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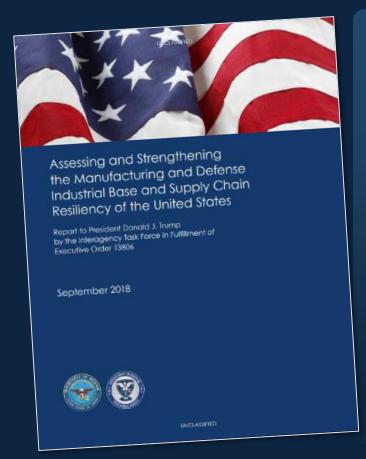
Executive Director, Global Health Security & Biotechnology 16 February 2023



25<sup>th</sup> International Generic and Biosimilar Medicines Association (IGBA) Annual Conference

## Biopharma Has Been Undervalued as a Strategic Component of the National Security Industrial Base

Report assessing the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States (Executive Order 13806)



#### **Sections Covered in the Report:**

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

### **Industrial Sectors Engaged:**

- Aircraft
- Electronics
- Ground Systems
- Munitions and Missiles
- Machine Tools
- Radar and Electronic Warfare
- Macro Forces
- Workforce
- Space



## MITRE's Data-Driven, Evidence-Based Analyses of the Biopharma/Biotechnology Industrial Base



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.'

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

#### Context

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

#### Vision

MITRE

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:

- Protection of the United States population from future pandemics and other biological threats (naturally occurring, accidental, and intentional), as aligned with core global health security principles:
- Development of supply chain resilience that absorbs supply and demand shocks and scales to meet national needs; and
- Leadership of the bioeconomy to meet domestic needs as well as global export requirements both during crises and intercrisis.



Three Lenses of Biopharma Industrial Policy

#### 10-Point Action Plan

MITRE, a non-profit public interest organization, operating federally funded research and development centers in sur of USG missions, proposes the following 10-point action plan.6 This plan was developed with guidance from leadin experts with decades of public and private sector experin this mission and ecosystem. These actions are aligned multiple policy priorities of the Biden-Harris Administratio 8,9 As the biological threat landscape evolves in frequence and intensity, MITRE also recognizes the need for conti across administrations in executing against the needs of t mission space. Several action items proposed here may be significantly advanced in a three-to-six-month timefram offering near-term wins that can be built upon for longer gains. We note that the USG leader who presides over th action plan should have expertise in each discipline pert to the product development lifecycle, in addition to the broader biopharmaceutical ecosystem.<sup>9</sup>

RE-ENVISIONING PREPAREDNESS

#### Collaborating Across Sectors to Build a Biopharma Industrial Base

MITRE | Global Health Security

In an evolving threat landscape, MITRE's public service mission and trusted relationship with government has never been more important than it is today. The nation will continue to grapple with the threat of biological events such as COVID-19, and MITRE stands ready to partner across sectors to mitigate the consequences of such events to the American people.

MITRE has extensively engaged leaders from industry, academia, and government to develop sustainable solutions for building a biopharma industrial base. This industrial base, fins industrial base, fins industrial base, on ad supply of medical countermeasures, essential medicines, and critical medical supplies, which MITRE understands as vital to national, economic, and health security interests.

In bringing interdisciplinary, systems thinking to the complex challenges facing government in securing and sustaining a biopharma industrial base, MITRE serves as a uniquely qualified partner to government. Our experts offer decades of experience related to the persistent challenges facing government and industry in the strengthening and sustainment of this industrial base.

In crisis or "peacetime," we lead with a driving sense of urgency to help government develop innovative business models, establish strong partnerships, and implement evidence-based recommendations to see world safer from health threats. the next threat.

Dr. Jay Schnitzer, Chief Medical and Technology Officer

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The loss of life and

livelihood caused by

COVID-19 brought

in stark relief the

devastating nature of

novel pathogens and

the critical importance

of being prepared for

MITRE

https://www.mitre.org/publications/technical-papers/building-a-sustainable-biopreparedness-industrial-base

https://www.mitre.org/news/press-releases/mitre-proposes-10-point-plan-to-sustain-a-biopharma-industrial-base

https://www.mitre.org/sites/default/files/2021-10/Global-Health-Security-Fact-Sheet.pdf



## U.S. needs a biopharma industrial base strategy and implementation plan to drive government action and accountability to meet policy objectives



Protect the United States
population from future
biological threats (naturally
occurring, accidental and
intentional), as aligned with core
global health security principles



Provide supply chain resilience that absorbs supply and demand shocks and scales to meet national needs



Maintain United States
leadership of the bioeconomy
to meet domestic needs as well
as global export requirements
during both crises and peacetime

### **Supporting Elements**









Finance Acc

## MITRE's Proposed Courses of Action Provide a Roadmap Aligned with U.S. Government Policy Priorities

U.S.G. must effectively execute national policy and legislation to establish and sustain a bioindustrial base fit for mission in a complex, dynamic threat domain.

### **Initial initiatives:**

- Clarify government roles and accountabilities related to the bioindustrial base and bioeconomy
- Develop a national bioindustrial base strategy with objectives and accountability
- Establish a strategic implementation plan with clear roles across industry and government
- Effectively finance, staff and assess in a manner fit for mission; incorporate implementation into the budget requests





5G

Digital Silk Road

Digital Currency

**Strategic Influence** 

Alternative Futures

MITRE created a whole-of-nation, whole-of-government analysis framework

that brings together a suite of tools to develop solutions to issues of strategic competition and national resilience

BioPharma Industrial Base

Natural Resource Exploitation