

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

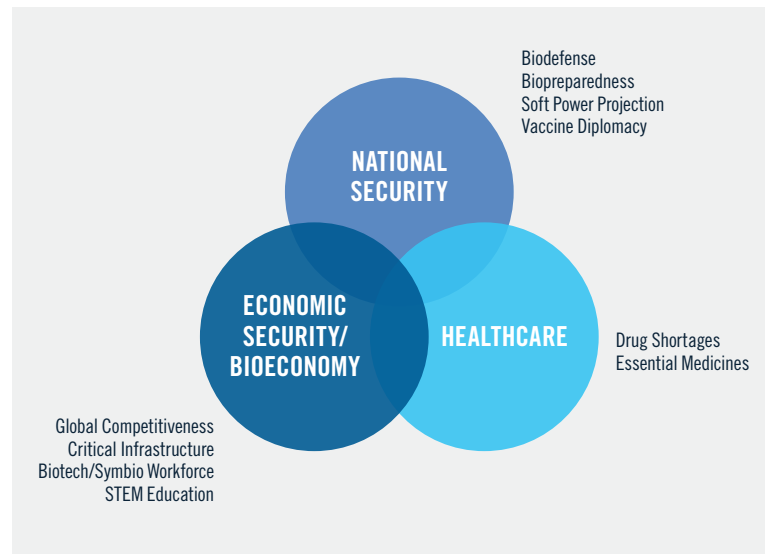
Context

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:

- 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 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 and intensity, MITRE also recognizes the need for continuity across administrations in executing against the needs of this mission space. Several action items proposed here may be significantly advanced in a three-to-six-month timeframe, offering near-term wins that can be built upon for longer-term gains. We note that the USG leader who presides over this action plan should have expertise in each discipline pertaining to the product development lifecycle, in addition to the broader biopharmaceutical ecosystem.¹⁰

10-POINT ACTION PLAN

Creating an Industrial Base for Essential Medicines, Medical Countermeasures, and Critical Medical Supplies to Mitigate National, Economic, and Health Security Risks from Biological Threats

POLICY

We recommend the following policy and strategy actions to achieve a clearly defined biopreparedness capability, including portfolio-based management.

1. Define specific strategic goals of capability and capacity for the biopreparedness mission. For example, one could set a “moonshot” goal akin to that aspired by CEPI and OSTP leadership, i.e., to develop a pandemic vaccine within 100 days.”^{11,12} This goal would create a transparent standard for private sector engagement in medical countermeasure innovation while serving as the foundation for performance-based metrics in industry-government agreements.
2. Establish an integrated portfolio strategy incorporating fundamental principles of industrial base policy (e.g., use systems approach) and assessment as well as sound business cases which address the value of these investments, including elements such as:
 - Creating methodologies to assess the feasibility, costs, and benefits of building resilience through rigorous analysis of trade-offs among options (e.g., capacity building with allies, domestic capacity building, utilizing advanced biomanufacturing/synthetic/biotechnology);
 - Developing clear benchmarks, mission goals, and incentives aligned with commercial partners, for transitions to next-generation products manufacturing; and
 - Optimizing stockpile and surge requirements for the missions.
3. Develop United States Government-led target product profiles (TPPs) by defining the specific requirements and characteristics needed for both medical countermeasures (MCMs) and routine healthcare (consistent with clinical use settings) products along with quantities required for product manufacturing. This will ensure availability of products, in sufficient quantities, when needed, as well as drive innovation across the lifecycle. A requirements-setting exercise for TPPs may help facilitate policy development and investment decisions.

PROGRAM

We recommend the following actions to reform enterprise management, including acquisition and business practices, and asset lifecycle management.

4. Attract, train, and retain a world-class workforce—nimble, risk-taking, adaptable—across the public and private sectors, including biopharmaceutical R&D and biomanufacturing, product lifecycle management, and acquisition/business practices.
5. Promote agile program management and transparent accountability across the ecosystem through metrics, sustained practice for bio-incidents, and enhanced program management across the lifecycle, through actions such as:
 - Developing meaningful metrics for products, portfolios, and personnel that reflect fundamental industrial base principles;
 - Coordinating with multilateral organizations in the development and innovation of medical countermeasures to avoid duplication of effort, accelerate emergency response, and meet global demand;
 - Managing assets aggressively across the lifecycle within the portfolio, offering clear milestones and “go/no go” decisions and ensuring seamless transitions of projects and portfolio decisions through a fully integrated systems approach (e.g., akin to Project Apollo moonshot and the WWII Manhattan Project); and
 - Creating USG capabilities in health economics and outcomes research to support government decision-making in portfolio management.

6. Institutionalize test, evaluation, and safety standards compatible with the speed and scale of MCMs required in a bioresponse, using both existing disease burdens and emerging threats as demonstration projects to validate capabilities.

FINANCING AND INDUSTRIAL BASE ENGAGEMENT

We recommend the following financing and industrial base engagement approach to stabilize and sustain funding to address market failures, secure the nation from high-impact threats, and ensure industrial base objectives are met during a crisis and between crises.

7. Facilitate innovative business models and financing strategies to secure sufficient funding commensurate to the threat environment over an extended period of time (e.g., multi-year funding).
8. Develop a portfolio budgeting approach that provides sufficient flexibilities to meet industrial base mission objectives.
9. Ensure spend plans link financial investments with accountability mechanisms, and are justified, durable, transparent, and aligned with budget.
10. Institute a world-class scientific and national/economic security advisory board. This board, comprised of internationally recognized experts, would offer industry competitive intelligence for the bioeconomy and the government, providing vital information to inform sustained engagement with industry.

1. These events also have downstream effects on food security, while not explicitly mentioned here.
2. Although not a focus of discussion here, these actions must be integrated with other critical functions in the broader system of capabilities for national security (e.g. biosurveillance and public health infrastructure), the bioeconomy (e.g., trade policies), and healthcare (resilient healthcare systems).
3. Alexander, L. (2020). Preparing for the Next Pandemic: A White Paper [Ebook]. Retrieved from <https://www.help.senate.gov/imo/media/doc/Preparing%20for%20the%20Next%20Pandemic.pdf>
4. Ibid.
5. Ayote, K., Gerberding, J., & Morrison, S. (2019). Ending the Cycle of Crisis and Complacency in U.S. Global Health Security: A Report of the CSIS Commission on Strengthening America's Health Security [Ebook]. Washington, DC: Center for Strategic & International Studies. Retrieved from https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/191122_EndingTheCycle_GHSC_WEB_FULL_11.22.pdf
6. We note that we do not address a leadership model by which to execute the recommendations in this action plan, however, this leader should preside over the USG roles in the mission space, with the expertise to oversee critical decisions across the biopharma lifecycle.
7. National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness | The White House. (2021). Retrieved 5 March 2021, from <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/21/national-security-directive-united-states-global-leadership-to-strengthen-the-international-covid-19-response-and-to-advance-global-health-security-and-biological-preparedness/>
8. National Strategy for COVID-19 Response and Pandemic Preparedness (2021). [Ebook]. Retrieved from <https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>
9. Interim National Security Strategic Guidance (2021). [Ebook]. Retrieved from <https://www.whitehouse.gov/wp-content/uploads/2021/03/NSC-1v2.pdf>
10. For the purposes of this action plan; we do not address or recommend a leadership or governance model to execute the action plan, rather we relay the qualities in a leadership structure that we believe are critical to the mission.
11. CEPI. (2021). The Urgency of Now: Turning the Tide Against Epidemic and Pandemic Infectious Diseases [Ebook]. Retrieved from https://cepi.net/wp-content/uploads/2021/03/CEPI_3.5_billion_investment_case_10032021.pdf
12. Borenstein, S. (2021). Science chief wants next pandemic vaccine ready in 100 days. Retrieved 27 July 2021, from <https://www.pbs.org/newshour/health/science-chief-wants-next-pandemic-vaccine-ready-in-100-days>