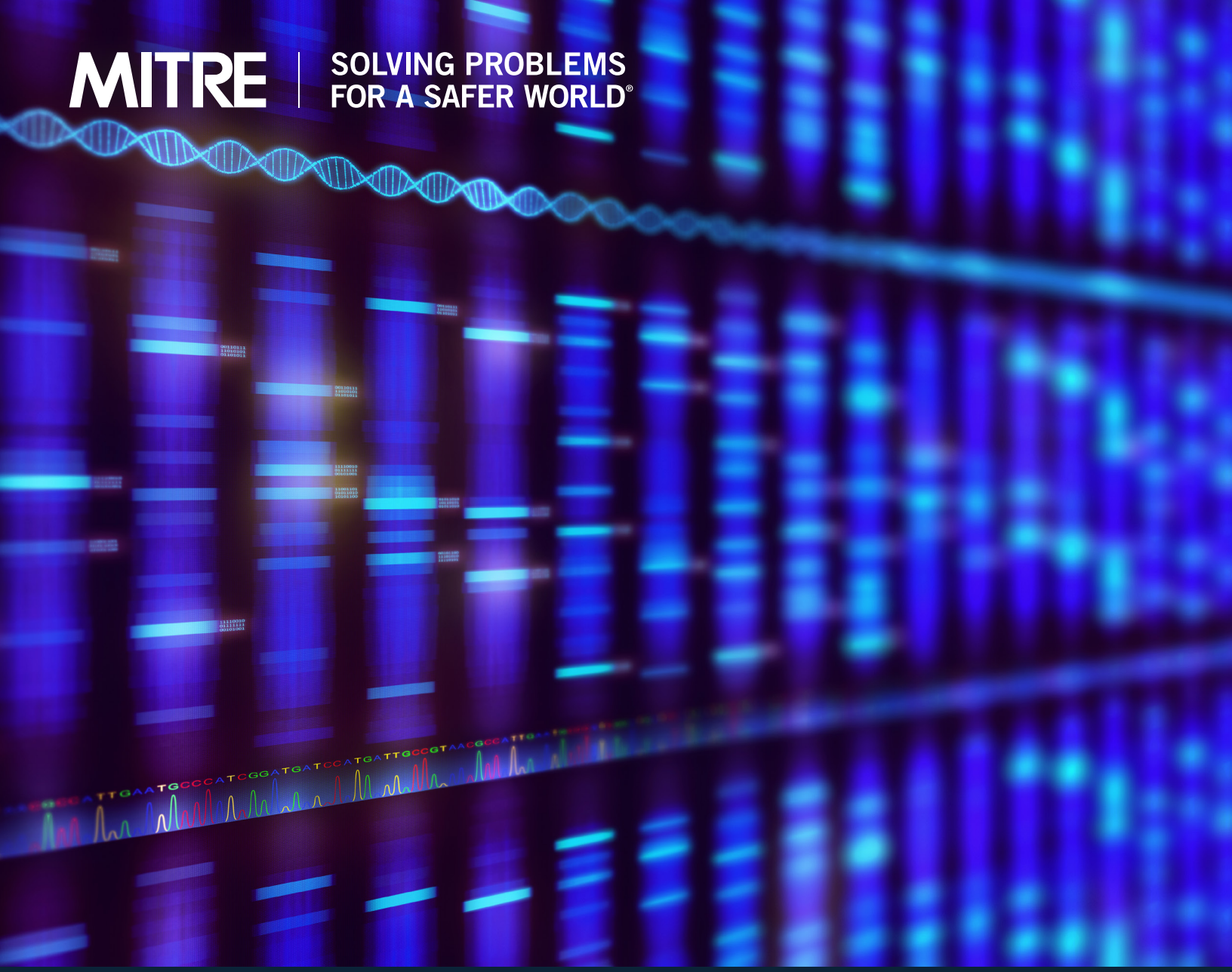
MITRE | SOLVING PROBLEMS FOR A SAFER WORLD®



# A CRITICAL NATIONAL ASSET TO US STANDING IN THE STRATEGIC POWER COMPETITION—THE BIOPREPAREDNESS INDUSTRIAL BASE

A MITRE-Funded Study in the *Great Power Competition Initiative*

The USG finds itself at a critical inflection point in the way in which it invests in and interfaces with the biopharmaceutical sector, a highly advanced industry with implications for national, economic, and health security. A team of MITRE experts undertook a rapid 6-month study to identify the systems-level factors, which affect USG access to critical emerging biotechnologies and biopharmaceutical products.

**Defining the Path Forward**

US access to critical medical technologies and products is interlinked with national, economic, and health security interests; however, the USG is currently not positioned to address the myriad of competitive threats and complex challenges that threaten our biopharma industrial base. The sustainment of this industrial base is needed now more than ever as the nation will continue to grapple with biological events like COVID-19 and strategic competition by foreign adversaries. To ensure the stability of this industrial base during crisis and intercrisis, MITRE recommends a system of courses of action (COAs), which together provide federal government a comprehensive roadmap for addressing these high consequence challenges. The COAs fall into four categories: (1) Improve Government Effectiveness, (2) Invest in Capability and Capacity, (3) Manage Risks, and (4) Engage the Ecosystem.

These COAs were developed through a rigorous mixed methods analysis that found that, overarchingly, the USG can anticipate foreign adversaries, in particular China, to strategically compete and challenge US preeminence in the biopharmaceutical sector through familiar market tactics. In the commercial market for a critical emerging biotechnology, such as mRNA, strategic competition presents risks to security interests given the growth, applicability, and potential of the technology to address US needs in crisis and intercrisis.

## THE COAs FALL INTO FOUR CATEGORIES: (1) IMPROVE GOVERNMENT EFFECTIVENESS, (2) INVEST IN CAPABILITY AND CAPACITY, (3) MANAGE RISKS, AND (4) ENGAGE THE ECOSYSTEM.

**Improve Government Effectiveness**

Sustaining the biopharma industrial base will require the government to work as a whole to identify an industrial base strategy, and address the policy, authorities and accountabilities which will enable execution of the strategy. However, we found the USG lacks biopharma industrial base policy and strategy, which places the US at a strategic disadvantage relative to China, who has articulated in numerous long-term strategies (e.g., Made in China 2025) their priorities in nationally developing this sector. In contrast, the existing governance structures for issues pertaining to the bioeconomy, biodefense, and global health security policy in the US remains a fragmented and complex environment, limiting a cohesive whole-of-government, whole-of-nation approach to this sector.

The USG needs to resolve the complexity of existing policy, authorities, and accountabilities to properly develop, execute, and manage a biopharma industrial base capability. This includes developing a clear strategy to sustain and secure the biopharma industrial base, with following goals in mind: protecting the US population from future biological threats, developing supply chain resilience to absorb shocks, and maintaining US leadership in the bioeconomy to meet domestic and global needs.

**Invest in Capability and Capacity**

The USG needs to create the environment for domestic capacity investment and sustainment through government and private sector financing mechanisms and incentives, including investing in workforce growth and supply chain resilience. The mRNA platform is poised for growth, and both internal and strategic competition, which presents risks and opportunities to a national industrial base. China is investing in mRNA capabilities through state-led investments, and joint-ventures (JVs) between Chinese and western biopharma companies. This follows a historical pattern in biotechnology, which in plain terms, can be viewed as US innovating and China industrializing biotechnology. At the same time, US commercial pipelines are investing in R&D of more profitable products (e.g., cancer vaccines), further increasing risk to long-term access to lower margin medical countermeasures.

Sustaining a domestic industrial base capability will require leveraging innovative financing and contracting methods across complex biopharma supply chains to encourage the development and production of critical products at the scale and agility needed for a bioresponse.

We note that investing in capacity requires investing in the specialized workforce and other elements essential to a thriving biopharma industrial base. Finally, a key capacity consideration is ensuring that the second and third order impacts of government investment do not hinder industry, and that policy levers such as the Defense Production Act (DPA) are leveraged appropriately.

**Manage Risks**

USG need to actively monitor and manage the risks in the biopharma industrial base. This includes developing the metrics and measures to monitor industrial base strength and related trends. MITRE developed a prototype industry heatmap to track the status of US industry vs. strategic competitors.

AS THE NATION WILL CONTINUE TO FACE THE THREAT OF BIOLOGICAL EVENTS, THE SUSTAINMENT OF THIS INDUSTRIAL BASE IS NEEDED NOW MORE THAN EVER AS THE NATION WILL CONTINUE TO GRAPPLE WITH BIOLOGICAL EVENTS LIKE COVID-19, WITH THE ADDED CHALLENGE OF STRATEGIC COMPETITION.

The USG currently lacks this type of monitoring capability so agencies cannot act on the actionable insights it may provide.

The USG also needs to invest in a Test and Evaluate (T&E) capability that will work with industry to test the capability and capacity of industry to respond to health security threats and inform future policy and investments. A T&E capability will ensure industry capacity needed to respond to crisis, but also provide a mechanism for government and industry to regularly work together to identify industrial base concerns and opportunities. Together with industrial base monitoring, this will help systematically advance the USG capabilities needed to meet our biosecurity needs and retain global competitiveness.

**Engage the Ecosystem**

The USG needs to more deliberately interface with industry across the product lifecycle from R&D to clinical trials to the production phases of the lifecycle. In addition, as reccomended in several prior government documents (e.g., EO 14017), government should establish a forum to engage with industry on industrial base capacity issues. Biopharma industry engagements from the USG have suffered from short-term budgetary support to fund partnership structures as well as an overall

transactional approach to industry engagement. Building a sustainable industrial base partnership across the biopharma ecosystem necessitates a shift from a short-term to a consistent, concerted interface between government and industry.

**Conclusion**

Our findings broadly demonstrate that the USG is unprepared to deal with threats to critical biotechnologies and medical products, without appreciating an industrial base lens to this problem-space. Each set of actions must be viewed as interdependent upon one another such that alone they may help progress USG forward in building a biopharma industrial base, but in concert with each other, they systematically sustain, update, and coordinate the requirements of an industrial base.

*We expand upon the findings and recommendations from this study in the MITRE-authored white paper titled 'Building a Sustainable Biopreparedness Industrial Base.'*

***MITRE's Mission***

*MITRE's mission-driven teams are dedicated to solving problems for a safer world. Through our public-private partnerships and federally funded R&D centers, we work across government and in partnership with industry to tackle challenges to the safety, stability, and well-being of our nation.*

MITRE | SOLVING PROBLEMS FOR A SAFER WORLD®