Protecting Americans Against Biological Threats

Ensuring Biosafety and Biosecurity to Prevent Bioincidents

By Paul Friedrichs, J. Stephen Morrison, Sophia Hirshfield, and Michaela Simoneau

This is the second in a series of briefs about making the United States safer against rising biological threats.

KEY TAKEAWAYS

1. As the risk of deliberate, accidental, and naturally occurring biological events grows, the United States should prepare to detect and respond to these events, as well as proactively prevent them whenever possible.
2. Russia and North Korea have bioweapons; other state and non-state actors are seeking to develop them. Authorizing and funding modernized programs to prevent bioweapons development and employment is imperative to keep the United States secure.
3. The acceleration of AI and new biotechnologies, uncertain federal leadership on biosafety and biosecurity, and the rise of new high-containment laboratories increase the imperative for legislative action to improve domestic biosafety and biosecurity.
4. U.S. capabilities have never met the true need and have regressed significantly in 2025; Americans today face greater risks from biological threats than at any time in this century.

BACKGROUND & CONTEXT

Non-state and state actors can develop bioweapons much more easily than in the past (biosecurity). Proliferating labs raise the risk of biological accidents (biosafety).

President Trump's 2018 National Biodefense Strategy identified multiple vulnerabilities and recommended actions to manage the risk of biological incidents and bolster U.S. national security. The April 2025 Department of State assessment of compliance with the Biological Weapons Convention (BWC) noted that Russia and North Korea unquestionably have such programs. Since then, the risk of deliberate biological threats has grown, fueled by advances in AI and the rapid expansion of computational capacity and biotechnological tools. The United States has eliminated the Office of the Director of National Intelligence (ODNI) team responsible for monitoring these programs. International action has been hampered by the BWC's weakness.

The risk of accidental biological threats has grown due to the proliferation of domestic and global labs researching highly contagious pathogens. The United States has distributed oversight of labs doing this kind of work across multiple departments and agencies.

In 2025, the United States eliminated or reduced funding for multiple civilian and military programs that mitigate Americans' risk from biological threats, increasing vulnerability.

LEGISLATIVE OR POLICY IMPLICATIONS

There is a path forward to protect Americans—with bipartisan congressional action, the Trump administration could be the first administration to successfully deliver comprehensive biodefense to ensure the United States has a healthy population that will sustain a robust economy, which in turn funds U.S. national security. Congress can enhance U.S. preparedness for and resilience against future biological threats by authorizing and appropriating funds for departments and agencies with jurisdiction over biosafety and biosecurity through the National Defense Authorization Act (NDAA), the Pandemic and All-Hazards Preparedness Act (PAHPA), and the Department of State Policy Provisions Act, and several bills derived from the National Security Commission on Emerging Biotechnology (NSCEB) recommendations.

The president's new National Security Strategy and the recently published America First Global Health Strategy and America's AI Action Plan are relevant. The president has not yet directed updates to the National Biodefense Strategy.

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CHALLENGES & RISKS

AI and New Technology Raise the Risk of Deliberate and Accidental Bioincidents: As the cost of gene synthesis plummets, state and non-state actors who seek to achieve a military or economic advantage over the United States will more easily misuse these technologies in novel ways that put Americans and others at higher risk of harm. The Trump administration has eliminated the requirement for private companies that sell synthetic DNA to track purchasers. Steps to reduce risk, such as the screening of DNA synthesis orders, have been insufficiently resourced and implemented.

High-Containment Labs Raise the Threat: Human error remains the leading cause of unintentional lab accidents in the United States. Following the recent pandemic, many countries are building new research facilities, but they lack an experienced workforce and oversight mechanisms. The International Organization of Standardization (ISO)'s bio-risk management standard ISO 35001 establishes helpful standards for biosafety and biosecurity, as does recent guidance from the World Health Organization (WHO). Yet there is insufficient effort at the international level to build capacity in high-containment labs around the world to implement these standards.

No One Is In Charge: There is no single U.S. entity responsible for oversight of laboratories conducting biological research. The U.S. Department of Agriculture, U.S. Department of Health and Human Services, Environmental Protection Agency, and other federal departments and agencies have varied responsibilities for setting or monitoring compliance with policies on biosafety and biosecurity. There is no established mechanism for integrating these efforts across the U.S. government and with industry and global partners outside government.

RECOMMENDATIONS

- **Bioweapons:** Reestablish the ODNI bio unit to resume monitoring the development of bioweapons and fund the Department of Defense to protect the United States from them.
- **Commerce:** As recommended by the NSCEB, establish and resource an empowered, unitary **entity** within the Department of Commerce mandated to advance safe, secure, and responsible biotechnology innovation. That entity should develop systems to monitor compliance, report biosafety or biosecurity incidents, and interrupt irresponsible research; conduct applied research on biosafety and biosecurity; provide training and education to biosafety and biosecurity professionals; promulgate standards (e.g., ISO 35001) for field and laboratory biosafety and biosecurity; and provide other oversight and enforcement capabilities and technical assistance to any labs working with pathogens of pandemic potential that may infect humans or other species of interest (e.g., commercial cattle and wheat).
- **OSTP Guardrails:** Require the White House Office of Science and Technology Policy (OSTP) to work with frontier labs and other private sector entities to establish and implement safety and security practices to guide the responsible convergence of AI technologies and synthetic biology, including confidence-building measures to monitor for BWC compliance and prevent bioterrorism. Identify and implement new mechanisms, such as domestic purchase preferences and tax incentives, to encourage private sector investment, training, and best practices in biosafety and biosecurity. Require all institutions subject to U.S. laws, regulations, or funding agreements to buy synthetic DNA from companies that screen their orders and customers. These measures, in combination, will greatly raise the probability that AI, synthetic biology, and other evolving biotechnologies will reach their potential to bring optimal benefits to Americans.
- **Diplomatic Leadership:** Sustain technical coordination with international partners, including NATO, the G7, and the United Nations, especially the World Organization for Animal Health, the Food and Agriculture Organization, the Pan American Health Organization, and the WHO, to reduce vulnerabilities to accidental, deliberate, and naturally occurring biological threats outside of U.S. borders. Prioritize strengthening the enforcement of the BWC. Accelerate biosafety and biosecurity cooperation in bilateral discussions, especially with China, by including these issues on the agenda if Presidents Xi and Trump meet in Beijing in April 2026, and in the United States late in the year for the G20 summit.
- **Grantmaking Practices:** Require biosafety and biosecurity resourcing in terms and conditions for grants awarded in infectious diseases with epidemic or pandemic potential.
- **Trade Agreements:** Mandate that all trade agreements that involve the importation of products into the United States that could lead to a biological incident in humans, animals, or plants must include provisions for the exporting nation to mandate commensurate biosafety and biosecurity standards.

For more information, contact: **Chloe Himmel** at 202.775.3186 or **chimmel@csis.org**.

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