AMERICANS for RESPONSIBLE INNOVATION

Biosecurity Modernization and Innovation Act of 2025

The Problem

Gene synthesis is vital to scientific progress, enabling new therapies and diagnostics. But as this technology has become more accessible, it has also created significant security risks: approximately 100,000 people worldwide can now successfully engineer pandemic viruses, and this number could grow dramatically with advances in AI. In the wrong hands, gene synthesis could be used to build and release pathogens that cause a pandemic worse than Covid-19.

Currently, companies selling synthetic DNA are not required to screen orders for hazardous sequences. Emily Leproust, the CEO of Twist Bioscience, says, "the vast majority of DNA synthesis companies are good actors, but there are some companies that are not good actors."

Recent red-teaming studies have demonstrated that several companies in the United States will ship fragments of Select Agent viruses to residential addresses without asking any due diligence questions. Leading companies and trade associations, including the International Gene Synthesis Consortium, have long called for policies to close this gap and level the playing field across the industry.

Key Political Developments

This bill represents the legislative culmination of bipartisan efforts to secure the bioeconomy:

Eshoo/Markey Bill

The *Securing Gene Synthesis Act* first proposed mandatory screening standards.

Brownley Letter

A bipartisan congressional letter signed by 5 Republicans and 5 Democrats and led by Rep. Julia Brownley urged the White House to implement mandatory gene synthesis screening standards.

Executive Action

This bill builds on the momentum of a Biden-era Executive Order regarding AI and a Trump Executive Order focused on improving the safety and security of biological research.

Policy Agendas

Gene synthesis screening has been included in key policy frameworks, including the National Security Commission on Emerging Biotechnology's final report, OMB/OSTP FY27 R&D priorities budget memo, AI Action Plan, and America First Agenda.

International Progress

The European Commission included gene synthesis screening in a must-pass biotechnology bill and the UK Government has publicly stated that they will consider mandatory screening in the coming months.

What the Bill Does

1. Mandates security screening for industry:

In line with the request for legislation embedded in the Trump Administration's May EO, the bill requires the Secretary of Commerce to issue regulations within one year mandating that all "covered providers" implement security protocols.

Who is covered?

"Covered providers" are defined as persons who synthesize and sell nucleic acids, or produce and sell synthesis equipment (including benchtop synthesizers).

Screening requirements:

- Screen all orders for "sequences of concern" (to be maintained and updated by the Secretary).
- Verify the identity and legitimacy of all customers.
- Implement privacy-preserving mechanisms to detect "split orders" (parts of a pathogen ordered separately across different providers as a disguise).

2. Enforces compliance via funding and penalties:

The legislation moves beyond voluntary guidelines by establishing strict enforcement mechanisms:

Conformity assessment:

Establishes a system for auditing providers, including "red-teaming" (adversarial testing) to ensure protocols actually work.

Civil penalties:

Violating providers face statutory damages of up to **$500,000 for individuals** and **$750,000 for entities**.

Federal funding "hook":

Any entity receiving Federal funds is prohibited from purchasing gene synthesis products from non-compliant providers.

3. Streamlines federal oversight:

Recognizing that current biosecurity authority is fragmented, as recommended by the NSCEB, the bill directs the Office of Science and Technology Policy (OSTP) to:

Assess and consolidate:

Conduct a 90-day assessment of all federal biosecurity authorities to identify redundancies and gaps.

Implementation plan:

Develop a plan to consolidate oversight, potentially under a single government entity, to make governance more effective and efficient.

4. Promotes innovation (the "sandbox"):

To ensure security doesn't stifle progress, the bill creates a "Biotechnology Governance Sandbox."

Safe testing:

A secure environment for providers and researchers to test new biosecurity tools and governance strategies without fear of immediate regulatory penalty.

Rapid updates:

The Secretary must update regulations at least every two years to keep pace with technological advances.