

# Publications

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## Return of the BIOSECURE Act: What Life Sciences Companies Need to Know

### Key Takeaways

- **House advances BIOSECURE Act as part of NDAA legislation.** The latest version would bar contractors and federal funding recipients from using certain biotechnology equipment or services linked to foreign adversaries, with a Senate vote expected next week.
- **Proposed restrictions reflect growing national security concerns around biotech.** If enacted, the law would restrict federal dollars from flowing to companies linked to national security risks, prompting new compliance obligations across the life sciences sector.
- **Life sciences companies should begin evaluating supply chain exposure.** Although implementation may take years, early planning will be essential as vendor eligibility, contract terms and subrecipient policies come under new scrutiny.

A key provision targeting foreign biotechnology firms is back on the table. On Oct. 9, 2025, the U.S. Senate adopted an amendment to add a version of the BIOSECURE Act — Section 881, Prohibition on Contracting with Certain Biotechnology Providers — to its version of the FY 2026 National Defense Authorization Act (NDAA), a bill widely considered “must-pass” legislation. Yesterday, the House passed its own modified version of the 2026 NDAA, including the BIOSECURE Act under Section 851. The Senate is expected to vote on the bill sometime next week.

If enacted, the BIOSECURE Act would prospectively bar the use of certain “biotechnology equipment or services” from “biotechnology companies of concern” in the performance of federal procurement contracts, grants and loans. The House is expected to vote on the compromise NDAA this week. Once the FY 2026 NDAA is enacted, we will update this alert with a brief summary of the final BIOSECURE Act requirements included in the legislation. Life sciences companies that work with or receive funding from federal agencies should take note, as the measure could trigger long-term changes in vendor eligibility, contract structures and compliance planning. For additional background, see our May client alert, “Trump EO Promotes Domestic Biopharma.”

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- James W. Kim
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## Why the BIOSECURE Act Matters for Life Sciences Companies

Pharmaceutical manufacturers are required to hold Federal Supply Schedule contracts to facilitate drug price reporting and Medicaid Drug Rebate program payment calculations as a condition of Medicare/Medicaid reimbursement eligibility for certain products, as defined by statute. Medical device manufacturers that sell products to the Department of Veterans Affairs or the Defense Health Agency do so principally in the form of federal contracts.

Although implementation would be phased and could take several years — with certain existing commercial agreements grandfathered for up to five years — contractors and grant recipients in the life sciences and health care sectors should begin assessing their supply chains now, as changes may require substantial implementation time.

## How Companies of Concern Will Be Designated

Companies of concern would be identified primarily through the Department of Defense's (DOD) Section 1260H list of Chinese military companies and a new list to be compiled and maintained by the Office of Management and Budget (OMB), rather than being named directly in the statute.

## What the BIOSECURE Act Would Prohibit in Federal Contracts

The BIOSECURE Act would prohibit federal agencies from:

- Procuring or obtaining biotechnology equipment or services from “biotechnology companies of concern”; and
- Entering into, extending or renewing procurements, grants and loans with entities that contract for or use biotechnology equipment or services in the performance of those federal agreements, including through their supply chain.

“Biotechnology companies of concern” include:

1. Entities that manufacture, distribute, provide or procure biotechnology equipment or services that are listed on the DOD's list of Chinese military companies operating in the U.S.; and
2. Biotechnology entities that the OMB, in consultation with other federal agencies, determines are controlled by a foreign adversary, involved in the manufacture, distribution, provision or procurement of biotechnology equipment or services, and pose a risk to U.S. national security, together with any subsidiary, parent or successor of such entities.

## Timeline, Implementation and Carveouts to Watch

The amendment would take effect 60 days after the subsequent Federal Acquisition Regulation (FAR) revision for entities on the Section 1260H List and 90 days after the FAR revision for companies placed on the new OMB list, following an implementation period that could extend up to three years while OMB and the FAR Council complete their respective tasks.

The OMB Director must publish the initial list of biotechnology companies of concern within one year of the amendment's enactment and update it at least annually, with companies entitled to advance notice and an opportunity to object before being listed.

Notably, this amendment does not apply to U.S. intelligence-associated activities; the acquisition or provision of overseas health care services for foreign-stationed federal government employees and beneficiaries; the acquisition or utilization of legally compiled,

commercially or publicly available human multiomic and genomic data; or certain medical products used directly in response to an official public health emergency.

## **How Life Sciences Companies Can Prepare for the BIOSECURE Act**

Overall, the BIOSECURE Act is intended to prevent sensitive genomic data from falling into the hands of U.S. foreign adversaries. Existing and potential government contractors and federal grant recipients in the biotechnology sector should map out their supply chains, build a vendor transition plan (if applicable), update their procurement and subrecipient policies, and begin preparing for potential new FAR clauses and agency guidance that will flow down BIOSECURE's requirements.

If you have any questions about the BIOSECURE Act or how it may affect your organization, please contact any of the authors of this alert or your regular Polsinelli attorney.