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The BIOSECURE Act: Key implications for U.S. Biotechnology, National security, and Federal funding

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Abstract

The BIOSECURE Act is aimed at ensuring that U.S. taxpayer money isn't going to fund biotech-aligned companies that can threaten national security. Specifically, the legislation prohibits federal contracting with companies tied to "foreign adversaries." The legislation is a continuation of an earlier version that clearly targeted few key Chinese biotech firms. The law has laid out the process through which companies can be designated or exempted with an appeal process also provided. While the law does not name specific biotechnology companies of concern, the focus remains on some of Chinese entities. There will be pressure on U.S. companies to do reshoring of their manufacturing capabilities and adopt a China plus one strategy. The legislation also provides an opportunity for contract manufacturers/CDMOs including those from India, to make inroads in the U.S. market. Companies need strong cross-functional coordination and flexible strategies to maintain market access and resilience.

Conclusion: In the post-BIOSECURE environment, firms must comply with the Act's restrictions while also identifying and taking advantage of new opportunities it creates.

Keywords: BIOSECURE Act; Biotechnology; CDMO; 1260H List; NDAA; WuXi; Biotechnology companies of concern (BCOC)

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1. Introduction

The BIOSECURE Act, which was passed as an amendment to the U.S. National Defense Authorization Act (NDAA) in December 2025, has been a long time coming. The BIOSECURE Act, or H.R. 8333, was a Bill initially introduced during the 118th U.S. Congress that aimed to halt U.S. federal funding to organizations working with businesses flagged as "companies of concern," and to organizations associated with a U.S. foreign adversary, a move which was expected to focus on Chinese biotech firms. The Bill had designated five Chinese firms, essentially Contract Research, Development, and Manufacturing organizations (CRDMOs) in its initial version as "biotechnology companies of concern" (BCOC). A BOCC, considered as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). These 05 companies were WuXi AppTec; WuXi Biologics; BGI (formerly known as the Beijing Genomics Institute); MGI (a subsidiary of BGI); and Complete Genomics. WuXi and BGI had m`aintained their opposition to the Bill when it was first put up in 2024. WuXi has previously called it "a pre-emptive and unjustified designation", while BGI said the Bill contains "falsehoods and baseless allegations." (1) Besides making life difficult for U.S. drug companies and academic labs that relied on supplies and services from these Chinese companies, the Bill threatened academic collaborations on plant, cancer, and other genomes. (2) The Bill which did get bipartisan support, couldn't make its way into the NDAA legislation (a Bill widely considered "must-pass" legislation) in December 2024 and as a result, it did not become law at that point in time.

After a year in the shadows, the controversial BIOSECURE Act made a return following an endorsement of a revised iteration by both chambers of U.S. Congress. The revised version of BIOSECURE Act (2.0), made its way into the NDAA legislation in the Fiscal Year (FY) 2026, with U.S. President having signed on 18 December 2025 the NDAA into law, enacting a wide range of statutory directives that will shape U.S. defense, trade, and national security policy in the years ahead. Section 851 of the NDAA for FY 2026 formally codifies the BIOSECURE Act, which imposes federal procurement, contracting, and funding restrictions on a government-wide basis on certain types of dealings with BCOC. (3)

2. BIOSECURE Act and its provisions

The BIOSECURE Act prohibits federal agencies from:

- Procuring or obtaining biotechnology equipment or services from BCOC; 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 (BCOC)" as per the Act includes:

- Entities that manufacture, distribute, provide or procure biotechnology equipment or services that are listed on the Department of Defense (DoD) list of "Chinese military companies," known as the 1260H List; and
- Biotechnology entities the Office of Management and Budget (OMB), in consultation with other federal agencies, determines are/is
  - Controlled by or operating for the government of a "foreign adversary" (China, Iran, North Korea, and Russia)
  - Involved in making or providing biotechnology equipment or services
  - Poses a risk to U.S. national security together with any of the subsidiary, affiliate of such entities/companies.

The Act also has very broad definitions of "biotechnology equipment or service." The definition of equipment encompasses any machine, device, or subcomponent, including software that is "designed for use in the research, development, production, or analysis of biological materials." (4) However, the enacted version has removed the specific mention of mass spectrometry technologies and polymerase chain reaction (PCR) machines, which was included in earlier versions of the Bill. The definition of 'services' is similarly broad. The BCOCs would be identified primarily through the DoD 1260H List, and will be compiled and maintained and reviewed periodically by the OMB, rather than being named directly in the statute. The Federal Acquisition Regulation Council has one year to revise the Federal Acquisition Regulation (FAR) to implement the BIOSECURE Act's provisions. The Act provides a five-year unwinding period for contracts and agreements entered into before the Act's effective date. Contracts entered into after the Act's effective date, do not qualify for the unwinding period. The restrictions for DoD 1260H List entities will take effect 60 days after the FAR is updated, and the restrictions for entities designated through the review process will take effect 180 days after the FAR implementation. The Act applies only to federal procurement contracts - those subject to the FAR.

Critically, the Act does not require OMB to notify a company prior to the DOD making the designation. Rather, a company will receive notice that it is being designated and placed on the BCOC list. Moreover, the criteria for listing will only be provided "to the extent consistent with national security and law enforcement interests." BCOC, once listed will have an opportunity, within 90 days of receipt of designation notice, to contest designation by submitting information and arguments opposing the listing. The company may be removed from the list in the case that mitigation steps are possible.

The Act has safe harbour provision for biotechnology equipment or services that were formerly but no longer provided or produced by a BCOC. This safe harbour seems intended to allow a BCOC to sell their ownership of a product or service to another company without prohibitions applying to the new owner. (5)

Agency heads may waive the Act's prohibitions on a case-by-case basis, but only with the approval of OMB acting "in coordination with the Secretary of Defense." Waivers must be reported to the U.S Congress within 30 days of being granted. The waiver may last for up to a year with an additional "one time" extension of 180 days allowed if an agency head determines it is "in the national security interests of the U.S. (6)

The prohibitions under the Act do not apply to intelligence activities and health care services provided to U.S. federal employees, members of the armed services, and government contractors who are stationed in a foreign country or on official foreign travel. (7)

3. Impact of BIOSECURE Act

Controversy has continually surrounded the BIOSECURE Act, despite it going through several rounds of iterations. Concerns have been raised about the impact it would have on the R&D and manufacturing of medicines, given the heavy reliance on Chinese companies in the supply chain. The enacted legislation has a narrower reach (than the initially proposed version) at least for now. Some of the critics suggest that the legislation doesn't go far enough in either protecting health security of Americans or safeguarding the U.S. biotech industry. All said and done, the impact due to the key changes which have been listed below, won't be felt immediately. Prohibitions on working with BCOCs would likely go into effect on new grants sometime in 2028, and the prohibitions on contracts already in effect would likely have until 2033 to redirect their work. (2)

3.1 Sourcing Challenges for U.S. Pharma

In a 2024 survey of small and emerging U.S. biotech firms, the Biotechnology Innovation Organization (BIO) found that approximately 65% of U.S. biotech companies engage with China-based CRDMOs in some capacity. (8) WuXi Biologics, WuXi AppTec, and WuXi STA together accounted for roughly 33% of the top ten global CDMO revenues in 2023, underscoring their dominant position in the industry. A number of prominent U.S.-based pharmaceutical and biotechnology companies—including AbbVie, Amicus Therapeutics, Bristol Myers Squibb, Cabaletta Bio, Eli Lilly, Iovance Biotherapeutics, Johnson & Johnson, Merck & Co., Mylan, Pfizer, Regeneron Pharmaceuticals, REGENXBIO, Vertex Pharmaceuticals, and Vir Biotechnology—rely on Chinese CDMOs for product development and manufacturing. WuXi AppTec and WuXi Biologics are deeply embeded in the supply chains of major pharmaceutical companies be it Eli Lilly's

tirzepatide (marketed as Mounjaro for type 2 diabetes and Zepbound for obesity), or Pfizer's COVID-19 treatment product Paxlovid (co-packaged nirmatrelvir and ritonavir), or for products from AbbVie, Merck etc. (9)

Despite the emergence of new domestic manufacturing capabilities in the U.S., a potential shift away from China-based supply chains could result in higher drug costs. Impact would also be felt by start-ups indirectly linked through supply chains. Transitioning to new manufacturers or reshoring production would likely entail temporary production disruptions and increased labour and operational expenses. While existing contracts may continue for several more years, the long-term implications of such a shift are substantial.

Notably, WuXi AppTec and Complete Genomics have currently not been included on the U.S. DOD Section 1260H list, a significant development given their central role in the global pharmaceutical ecosystem. However, with nearly 120 U.S. biopharmaceutical drugs currently under development in partnership with Chinese CDMOs, the potential designation of these companies/entities, under Section 1260H could have far-reaching consequences, including higher drug prices in the U.S., drug shortages, and prolonged development timelines across the industry. (10)

3.2 Other CRDMOs likely to benefit from market disruption

Analysts estimate that a select group of CDMOs outside China—including those based in the U.S., Southeast Asia, India, and Europe—are well positioned to benefit from an anticipated shift in sourcing, driven by the need to control development and manufacturing costs. For these providers, heightened scrutiny of drug pricing in the U.S, particularly following the enactment of the Inflation Reduction Act, represents a meaningful tailwind.

Beyond technological expertise, key factors in the selection of outsourcing partners include cost competitiveness, quality assurance, and proximity to end user markets. In addition, the CRO/CDMO selection process is highly rigorous and can take six to twelve months, depending on the complexity of the operations involved. That said, pharmaceutical companies face a more constrained set of options when seeking CDMOs with capabilities in specialized modalities such as gene-modified cell therapies, genome editing, and plasma-derived products. In these areas, limited supplier availability may result in premium pricing and more favourable contractual terms for CDMOs. By contrast, for more established modalities—including monoclonal antibodies, peptides, recombinant proteins, and small-molecule drugs—clients benefit from a broader pool of CDMOs, enabling selection based on capacity, technical expertise, and operational fit.

3.3 Need for reassessment of partnerships

The U.S. is currently evaluating measures to encourage the reshoring of pharmaceutical and biotechnology manufacturing, including potential tax incentives, loan guarantees, and grant programs. Pharmaceutical and biotechnology companies that receive U.S. federal funding or enter into contracts with U.S. federal agencies should consider winding down business relationships with entities designated as BCOC. Beyond partnership restrictions, the BIOSECURE Act also requires the government to examine the potential misuse by foreign parties of sensitive multi-omic health data belonging to U.S companies. (11) Also, concerned firms need to revisit their internal quality systems to align with global standards, for e.g., U.S FDA has modernized its Quality Management System Regulation (QMSR), harmonizing its medical device current good manufacturing practices (CGMP) with global standards by incorporating ISO 13485:2016, which will be effective from February 2026 (12)

Affected U.S. companies should begin assessing risks to their supply chains, manufacturing capacity, and research and development pipelines in the event that a business partner is designated BCOC (7) Similarly, U.S. universities and research institutions that receive federal funding will need to conduct comparable reviews of their research partners and collaborators to ensure compliance and mitigate potential disruptions. Companies that do not meet any of the exceptions or waivers may wish to re-examine their funding sources for impacted CDMOs and CROs to ensure those contracts are not funded by federal loans, grants or contracts.

3.4 A Boost for Indian Pharma and Biotech Industry

The Act has created a favourable environment in which Indian pharmaceutical and CRDMO players - including Divi's Laboratories, Laurus Labs, Neuland Laboratories, Syngene, Suven, and Piramal Pharma that stand to benefit. As per Boston Consulting Group report, Indian CDMO market share of $ 3-3.5 billion out of a global market valued at $140 billion plus in 2024, is expected to expand to $22-25 billion by 2035. Indian CDMO market Benefiting from cost competitiveness and government incentives such as the Production-Linked Incentive (PLI) scheme, Indian CDMOs are well positioned to capture increased demand from U.S. pharmaceutical companies seeking alternative partners. Some Indian CDMOs have witnessed a 50% year-on-year increase in Requests for Proposals (RFPs) in 2024, as global pharmaceutical companies look to diversify supply chains beyond China. (13)While customers are actively evaluating Indian capabilities through due diligence, pilot engagements, and exploratory collaborations, the impact on financial performance is likely to materialize gradually, given the long development and commercialization cycles characteristic of the pharmaceutical and biotechnology sectors. Early indicators are encouraging, and meaningful financial gains are expected to emerge over the next 12 to 24 months as initial inquiries and pilot projects translate into commercial agreements.

3.5 Advantage for manufacturers engaged in the Medicaid Drug Rebate Program

The BIOSECURE Act contains a safe harbour for drug manufacturers taking part in the Medicaid Drug Rebate Program. Such manufacturers would remain compliant with program requirements if deemed to have been eligible to enter into a master agreement with the Secretary of Veterans Affairs, aside from its use of biotechnology equipment or services produced or provided by BCOC.

3.6 Hinder collaboration on cutting edge science

Some critics argue that the BIOSECURE Act, even in its current form, could impede collaboration at the frontiers of science and technology. This includes initiatives such as international cancer genomics programs aimed at developing global databases of genomic and clinical cancer data. As Michael Snyder, a genomics expert at Stanford University, has noted, "It's just going to build more barriers, which is the antithesis of science."

3.7 Retribution from China

The passage of the BIOSECURE Act is likely to prompt a response from the Chinese government if Chinese companies are designated under the Section 1260H list. WuXi alone, for example, has a substantial footprint in the United States, operating 12 facilities and employing nearly 2,000 people. In December 2024, WuXi AppTec announced that it has entered into a definitive agreement to sell the U.S and UK based operations of WuXi Advanced Therapies (ATU), its cell and gene therapy unit, to Altaris, LLC, a healthcare investment firm headquartered in New York, U.S. All other WuXi AppTec operations remain unchanged. (14) In case the Chinese firms are forced to give up their operations in the U.S. due to them featuring in the infamous 1260H List, then a potential response from the Chinese government could range from the imposition of retaliatory export controls targeting U.S. biotech firms to the use of expansive national security laws to exert pressure on U.S. businesses and their employees operating in China. Companies with operations or commercial ties to China—particularly in the pharmaceutical and biotechnology sectors should be prepared for heightened regulatory and geopolitical risk, if at all such a scenario unfolds.

4. Conclusion

Overall, the BIOSECURE Act aims to safeguard sensitive genomic data from falling into the hands of U.S. foreign adversaries. It seeks to reduce China's influence in the U.S. biotechnology supply chain. The stakes include data privacy, potential supply chain disruptions, and the possibility of shifting manufacturing dependence on other countries. Existing and prospective government contractors and federal grant recipients in the biotechnology sector should proactively map their supply chains, develop vendor transition plans where necessary, and update procurement and sub-recipient policies. The BIOSECURE Act is also expected to create significant opportunities for CDMO players, including those from India. However, growing concerns of U.S. dependency on offshore suppliers may also result in a shift towards U.S. companies selecting domestic CDMOs. Companies will have to have well-coordinated cross-functional oversight and flexible operational strategies for ensuring continued market access and resilience. Successfully navigating the Act's prohibitions in a post-BIOSECURE landscape will be critical, but equally important will be recognizing and capitalizing on the opportunities the Act presents and encashing it.

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