

Proposed BIOSECURE Act Targets Chinese Biotech Firms – Could Disrupt Life Sciences Supply Chains in the Federal Sector

By John O'Loughlin and Christina Carone

The U.S. House of Representatives and the U.S. Senate are advancing a new bill – the BIOSECURE Act (H.R. 8333ⁱ and S. 3558ⁱⁱ) – that would (i) prohibit the U.S. Government from contracting with “biotechnology companies of concern”ⁱⁱⁱ and (ii) prohibit U.S. life sciences companies with federal government contracts or that receive federal funding from collaborating with such designated companies. The BIOSECURE Act attempts to counter perceived national security threats posed by Chinese biotechnology companies who could exploit information about American citizens through joint research and utilization of biotechnology equipment or services.

House and Senate committees have voted favorably on the bill with overwhelming bipartisan support. As of this writing, however, the bill has not been debated on the floor of either chamber. Some observers anticipated that the BIOSECURE Act would be rolled into the proposed Fiscal Year 2025 National Defense Authorization Act (NDAA) which has passed in the House, but so far that has not happened. The BIOSECURE Act nevertheless could become law as a standalone bill or as part of the NDAA or another bill, including appropriations bills needed to fund the government in the next fiscal year, which begins October 1.

The BIOSECURE Act would prohibit federal executive agencies from directly procuring or obtaining any biotechnology equipment or services produced or provided by a “biotechnology company of concern.” Both the House and Senate versions of the bill list WuXi AppTec, MGI, Beijing Genomics Institute (BGI), and Complete Genomics as biotechnology companies of concern. The amended House bill also lists WuXi Biologics.

The sponsors of the bills claim that these companies collect, test and store genomic data of Americans.^{iv} The Chinese Communist Party’s (CCP) national security laws require all Chinese firms to share any requested data, including genomic data obtained by Chinese biotechnology companies. The sponsors allege that BGI has collected DNA from millions of people and used that data without consent on genomic projects performed by the Chinese military. Lawmakers have requested that MGI and Complete Genomics, a subsidiary of MGI, be labelled as “Chinese Military Companies” due to their strong ties to the CCP.

In addition to the named companies, the law would allow the U.S. government to expand the restrictions to other companies. A “biotechnology company of concern” is a biotechnology company that “is subject to the jurisdiction, control, or operates on behalf” of a foreign adversary’s government – a seemingly broad definition. For a company to receive such a designation, however, the bill also would require the U.S. government to determine that such a company poses a threat to national security based on that company (1) engaging in joint research with, being supported by, or being affiliated with a foreign adversary’s military, internal security forces, or intelligence agencies; (2) providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or (3) obtaining human multiomic data via the biotechnology equipment or services without express and informed consent. As a result, the law would not encompass all biotechnology companies solely because they have operations in China.

The bill includes a provision for the U.S. Office of Management and Budget (OMB) to publish a list of entities that constitute “biotechnology companies of concern” in consultation with the Secretary of Defense, the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of National Intelligence, the Secretary of Homeland Security, the Secretary of State, and the National Cyber Director. Any subsidiaries, parents, affiliates or successors of a designated entity would be included in the designation. The BIOSECURE Act requires that companies designated as a biotechnology company of concern receive notice of such designation, which identifies the criteria relied upon for the basis of the designation, provides information on the opposition process and potential mitigating factors, and describes procedures governing the review and possible issuance of the designation.

In addition to prohibiting the U.S. government from contracting with the designated companies, the BIOSECURE Act would prohibit federal executive agencies from contracting with companies that use biotechnology equipment or services produced or provided by a biotechnology company of concern in the performance of the contract. The potential reach of this provision could be significant. Although the House version of the bill would not prohibit Medicare or Medicaid reimbursement for prescription drugs or medical devices supplied by companies that had collaborated with the proscribed companies, the House bill seemingly would prohibit the sale of such drugs or devices to the Department of Defense or the Department of Veterans Affairs. Moreover, the bill could affect companies with federal grants and loans that have other ties to the designated companies, like licensing agreements or joint ventures.

The BIOSECURE Act is another effort by the U.S. Government to restrict transactions involving certain Chinese companies to address perceived national security threats. For example, Section 889 of the 2019 National Defense Authorization Act prohibits the federal government, government contractors, and federal grant and loan recipients from procuring or using certain “covered telecommunication equipment or services” that are produced by Huawei, ZTE, Hytera, Hikvision, and Dahua and their affiliates. Government contractors are required to certify annually to the U.S. Government whether the supplies or services they offer include covered telecommunications equipment or services. This required government contractors to review their systems and, in many cases, replace them with components from other suppliers.^v

Revised Bill Provides for Exceptions and Limitations

On May 15, 2024, the House Committee on Oversight and Accountability voted 40-1 to approve an amended version of H.R. 8333 (formerly H.R. 7085). The Senate Committee on Homeland Security and Governmental Affairs voted 11-1 and approved its version of the bill (S. 3558) on March 6, 2024. H.R. 8333 includes the following exceptions and limitations:

- **Safe Harbor for Certain Biotechnology Equipment and Services:** The revised House bill includes a safe harbor for biotechnology equipment and services that were previously, but are no longer, produced or provided by a biotechnology company of concern.

- **Grandfathered Contracts:** The House bill grandfathers until 2032 contracts that were executed prior to the BIOSECURE Act's effective date. The effective date is defined as 60 days after the issuance of regulations for BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics. For other biotechnology companies of concern, the effective date would be 180 days after the regulations are issued. The regulations have to be issued within one year after guidance is issued, and guidance must be issued no later than 120 days after the enactment of the Act. These provisions would allow time for U.S. life sciences companies to transition away from utilizing equipment and services provided by biotechnology companies of concern.
- **Medicare and Medicaid Carve-out:** The revised House bill excludes Medicare Part D manufacturer discount agreements and Medicaid national drug rebate agreements from the definition of "contracts" by defining "contracts" as those contracts subject to the Federal Acquisition Regulations (FAR), which do not apply to these Medicare and Medicaid drug programs. If this provision is adopted, the law would not prohibit Medicare or Medicaid reimbursement for prescription drugs or medical devices supplied by companies that had collaborated with the proscribed companies. As drafted, however, the law would prohibit the sale of such drugs or devices to the Department of Defense or the Department of Veterans Affairs. It also is not clear at this stage if biopharmaceutical companies that in-license technology from the listed companies would have difficulty obtaining Medicare and Medicaid coverage approval, as the current text does not address this issue.
- **Executive Agency Waiver:** The revised House bill allows the heads of federal executive agencies to waive the bill's prohibitions to make certain biotechnology exceptions, subject to certain conditions.

The Senate version of the bill currently includes an uncapped grandfathering clause, but does not include the safe harbor or list WuXi Biologics as a biotechnology company of concern. These differences must be reconciled before the bill becomes final.

Considerations for Life Sciences Companies

The U.S. industry trade group Biotechnology Innovation Organization (BIO) has publicly supported the bill but also raised concerns that an abrupt decoupling from the designated biotechnology companies of concern could harm patients by interfering with drug access.^{vi} The proposed law provides incentives for life sciences companies with federal government contracts or that receive federal funding to consider moving away from using biotechnology goods and services from firms with significant connections to the Chinese government. The law eventually could expand to include biotech companies with connections to other adversaries, including Russia.

Publically and privately owned biotechnology companies that are not designated as "biotechnology countries of concern" are in a position to displace the designated companies if the law is enacted. In fact, some drug companies have already made public statements about transitioning away from the listed companies. The market potential for other companies is significant. In 2023, WuXi AppTec counted 65% of its 26.1 billion yuan (\$3.6 billion) revenue from customers in the U.S.^{vii} WuXi Biologics reported approximately 47% of its 17 billion yuan (\$2.4 billion) revenue last year from North America.

Although the proposed restrictions potentially will not take effect until 2032 for pre-existing contracts, biopharmaceutical and biotechnology companies should begin evaluating their supply chains to identify potential touch points with the listed biotechnology companies of concern or other biotechnology companies with significant connections to the Chinese government or other U.S. adversaries. Life sciences companies should review their existing relationships with defined biotechnology companies of concern and monitor possible U.S. government actions to expand the list of biotechnology companies of concern. Biotech companies also should confirm that existing contracts with companies of concern address termination rights and technology transfer, and amend such contracts to include such provisions if needed.

We will continue to monitor developments with the BIOSECURE Act.

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If you have questions concerning the contents of this alert, or would like more information, please speak to your regular contact at Weil or to the authors:

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- ⁱ H.R. 8333, BIOSECURE Act, Amendment in the Nature of a Substitute, available at: <https://oversight.house.gov/wp-content/uploads/2024/05/BILLS-118-HR8333-C001108-Amdt-4.pdf>.
- ⁱⁱ S. 3558, Amendment in the Nature of a Substitute Proposed by Peters, available at: https://www.hsgac.senate.gov/wp-content/uploads/S.-3558_Peters-Modified-ANS_DAV24358.pdf.
- ⁱⁱⁱ A “biotechnology company of concern” means BGI, MGI, Complete Genomics, WuXi, AppTec, and any subsidiary, parent affiliate, or successor of such entities; and any entity that (i) is subject to the jurisdiction, direction, control, or operates on behalf of the government of a foreign adversary; (ii) is to any extent involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service; and (iii) poses a risk to the national security of the United States based on (1) engaging in joint research with, being supported by, or being affiliated with a foreign adversary’s military, internal security forces, or intelligence agencies; (2) providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or (3) obtaining human multiomic data via the biotechnology equipment or services without express and informed consent. See S. 3558, Section 2(f)(2).
- ^{iv} <https://democrats-selectcommitteeontheccp.house.gov/media/press-releases/krishnamoorthi-wenstrup-introduce-bipartisan-biosecure-act-safeguard-american>.
<https://selectcommitteeontheccp.house.gov/media/press-releases/gallagher-presses-doj-us-trade-group-bio-lobbying-behalf-chinese-military>.
<https://selectcommitteeontheccp.house.gov/media/letters/letter-dod-hidden-bgi-subsiary-innomics-operating-us-call-pentagon-list-chinese>.
- ^v In November 2022, the U.S. Federal Communications Commission issued an order that effectively excluded equipment from the five Chinese companies not just from federal procurement but to the entire U.S. market by prohibiting the authorization of equipment through the FCC’s certification process. <https://www.fcc.gov/document/fcc-bans-authorizations-devices-pose-national-security-threat>.
- ^{vi} <https://www.fiercepharma.com/pharma/biotech-trade-group-pledges-support-biosecure-act-plans-boot-member-wuxi-apptec>.
- ^{vii} <https://www.bloomberg.com/news/articles/2024-03-18/wuxi-apptec-s-us-sales-rise-as-congress-weighs-a-federal-ban>.