

Memorandum

The BIOSECURE Act: On the Road to Passage, With Significant Implications for Life Sciences Companies, and Their Owners

June 5, 2024

Federal legislation targeting key Chinese biotechnology service providers is advancing through the U.S. Congress on its way to possible passage later this year. Last month, the U.S. House of Representatives Committee on Oversight and Accountability voted overwhelmingly favorably to report the BIOSECURE Act (H.R. 8333, substituted from H.R. 7085) to the full House. The Senate Committee on Homeland Security and Governmental Affairs had previously voted overwhelmingly in March to report a similar BIOSECURE Act to the full Senate. These votes are a sign of strong, bipartisan support for the bill, which was recently proposed as an amendment to the Servicemember Quality of Life Improvement and National Defense Authorization Act for Fiscal Year 2025.

If enacted, the BIOSECURE Act would prohibit the U.S. government from providing funding or loans to, or otherwise contracting with, entities that use biotechnology equipment or services from a “biotechnology company of concern” in the performance of that contract. The legislation would have far reaching effects for life sciences companies and private equity sponsors who invest in these areas.

The BIOSECURE Act’s Prohibitions

In general, the BIOSECURE Act would prohibit the heads of U.S. executive agencies from entering into or renewing any contract with, or providing loans or granting funds to, any entity that, in the performance of that contract (1) uses a biotechnology equipment or service produced or provided by a biotechnology company of concern or (2) knows or has reason to believe will require use of biotechnology equipment or services produced or provided by a biotechnology company of concern.

Biotechnology Companies of Concern—BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics

The House bill specifically names as targets BGI Genomics Co., LTD (“BGI”), MGI, Complete Genomics, WuXi AppTec and WuXi Biologics and also covers any subsidiary, parent, affiliate, or successor of such entities, so long as they are subject to the administrative governance structure, direction, control, or operate on behalf of the government of a foreign adversary. U.S. lawmakers have explained that these companies are targeted due to the Chinese government’s efforts “to dominate biotechnology as an industry of the future” and its pursuit of “a strategy known as ‘military-civil fusion’”.

The bill's targets include significant Chinese biotech companies. WuXi, for example, has been described as being “heavily embedded in the U.S. medicine chest, making some or all of the main ingredients for multibillion-dollar therapies”¹ WuXi is known to provide a broad portfolio of R&D and manufacturing services including to large pharmaceutical and biotechnology companies, including as a pharmaceutical CRDMO (Contract Research, Development and Manufacturing Organization) and a preclinical testing and clinical research services CTDMO (Contract Testing, Development and Manufacturing Organization). A Biotechnology Innovation Organization survey of 124 biopharma companies found 79% have at least one contract or product with a China-based or owned contract development and manufacturing organization or contract manufacturing organization.²

The proposed legislation calls for the Office of Management and Budget (“OMB”) to develop a broader list of “biotechnology companies of concern” who are subject to the jurisdiction of the government of a “foreign adversary” and pose a risk to U.S. national security. Foreign adversary is defined to include China, Iran, North Korea and Russia, although the greatest practical impact will likely come from the named Chinese companies.

Exceptions and Waiver Provisions

The proposed legislation has raised concerns of major disruptions to an already strained supply chain, with fears of greater pressure on U.S. life sciences companies and subsequently higher costs.³

In apparent recognition of such concerns that have been voiced, the current draft of the House bill provides for several noteworthy exceptions and limitations:

1. **Medicare and Medicaid Carve-out**—By defining “contract” to mean those contracts subject to the Federal Acquisition Regulation, the bill effectively excludes Medicare Part D manufacturer discount agreements and Medicaid national drug rebate agreements.
2. **Grandfathered Contracts**—Contracts that would be otherwise subject to the BIOSECURE Act are exempted until 2032, so long as they were entered into prior to the BIOSECURE Act’s effective date.
3. **Safe Harbor**—Biotechnology equipment and services do not include biotechnology equipment and services that were formerly, but are no longer, produced or provided by a biotechnology company of concern.
4. **Waiver**—Executive agency heads can, with the approval of the Director of the OMB and in consultation with the Secretary of Defense, and with subsequent notification to appropriate congressional committees, waive the bill’s prohibitions to make specific biotechnology exceptions, or for contracts regarding the provision of overseas health care services, subject to certain conditions.

¹ Christina Jewett, *Chinese Company Under Congressional Scrutiny Makes Key U.S. Drugs*, *New York Times* (Apr. 15, 2024), available [here](#).

² *BIO Survey Reveals Dependence on Chinese Biomanufacturing*, *BIO* (May 9, 2024), available [here](#).

³ David Wainer, *U.S.-China Decoupling Poses Supply-Chain Risks for Drug Companies*, *Wall St. J.* (Mar. 23, 2024), available [here](#).

Implications

Life sciences companies should review whether they have any contracts with the entities named above, but also with any entity that could later be named as a biotechnology company of concern. The most important step for life sciences companies to take right now is to review whether they have any contracts with any biotechnology companies of concern. This includes a review of dealings with BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics, and also with any Chinese (or Iranian, North Korean and Russian) biotechnology company that might be at risk of designation as a biotechnology company of concern. While there is still time for the bill to evolve, and for its prohibitions to take effect should it be enacted as currently drafted, the advancement of the BIOSECURE Act through Congress presents a logical opportunity for life sciences companies to review the diversity and strength of their supply chains, and their owners to integrate BIOSECURE Act-related diligence into their investment planning.

For further information regarding this memorandum, please contact one of the following authors:

WASHINGTON, D.C.

Vanessa K. Burrows
+1-202-636-5891
vanessa.burrows@stblaw.com

Abram J. Ellis
+1-202-636-5579
aellis@stblaw.com

NEW YORK CITY

George S. Wang
+1-212-455-2228
gwang@stblaw.com

Daniel S. Levien
+1-212-455-7092
daniel.levien@stblaw.com

Jacob Madden
+1-212-455-3283
jacob.madden@stblaw.com

BELJING

Shuhao Fan
+86-10-5965-2987
shuhao.fan@stblaw.com

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