

## Life Sciences Capital Markets & Securities

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### **The BIOSECURE Act: Proposed New Legislation Could Affect U.S. Companies' Plans to Contract With Chinese Biotechnology Companies**

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The U.S. Senate and the U.S. House of Representatives are both considering legislation that could have a serious impact on the ability of U.S. biotechnology, drug, and medical device companies to do business with biotechnology companies that have connections to the governments of China and three other countries, including the major Chinese service provider WuXi AppTec. While these bills are in the early stage of the legislative process, the market has taken them seriously, with the affected Chinese companies losing almost \$20B in market capitalization around the time of the bills' introductions.

In the House, the BIOSECURE Act (Biosecure Act or the Act) was introduced in January by Rep. Mike Gallagher, R-Wis., Chairman of the House Select Committee on the Strategic Competition between the United States and the Chinese Communist Party (the Select Committee), and Rep. Raja Krishnamoorthi, D-Ill., Ranking Member of the Select Committee. Sens. Mitt Romney, R-Utah, and Roger Marshall, R-Kan., introduced corresponding legislation in the Senate.

The Biosecure Act would prohibit all executive agencies from contracting with or extending loans or grants to any company with current or future commercial arrangements with a "biotechnology company of concern." A "biotechnology company of concern" is a biotechnology company that is headquartered in, or subject to, the jurisdiction of a foreign adversary's government and poses a threat to national security. The Act specifically names four Chinese companies – BGI, MGI, Complete Genomics, and WuXi AppTec – as companies of concern. The Act also provides a process for designating other

companies of concern. In addition to China, the Act includes North Korea, Russia, and Iran as "foreign adversaries."

Specifically, the proposed law would prohibit heads of U.S. executive agencies from:

- Procuring or obtaining any biotechnology equipment or service produced or provided by a company of concern
- Entering into contracts or renewing contracts with any entity that uses biotechnology equipment or services produced or provided by a company of concern or that will require the direct use of biotechnology equipment or services produced or provided by a company of concern
- Expending or obligating loans or grant funds to procure or obtain any biotechnology equipment or services produced or provided by a company of concern

Under the second bullet above, the Act's scope extends to most companies in the U.S. life sciences industry that either are currently government contractors or hope to become one in the future.

The definition of "biotechnology equipment or services" is broad, including any instrument or service in "research, development, production, or analysis" related to "biological materials." It includes software, data storage, diagnosis, consulting services, and support services.

"Biotechnology companies of concern" are defined as any of the following:

1. BGI (the former Beigene Genomics Institute), MGI, Complete Genomics, WuXi AppTec, and any subsidiary, parent, affiliate, or successor of these companies

2. Any entity that:

- i. Is subject to the jurisdiction, direction, or control of, or operates on behalf of, the four named countries
- ii. Is to any extent involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service
- iii. Poses a risk to national security based on (a) engaging in joint research with, being supported by, or being affiliated with the foreign government's military, internal security forces, or intelligence agencies; (b) providing genomic data obtained via biotechnology equipment or services to the foreign government; or (c) obtaining human genomic data via biotechnology equipment or services without express and informed consent"

No later than 120 days after the Act becomes law, the OMB Director, in consultation with the Secretaries of Defense, Health and Human Services, Commerce, Homeland Security, and State; the Attorney General; and the Director of National Intelligence, is to (1) develop a list of additional entities that are "biotechnology companies of concern" and (2) issue "guidance necessary to implement the Act." Any companies named by OMB would become restricted 180 days after OMB issues its guidance.

As for the rationale behind the Biosecure Act, the Act's preamble states that China's military has invested in biotech and AI capabilities and, through control of Chinese businesses, has access to millions of Americans' genetic data. Thus, the Act is intended to stop taxpayer money from funding foreign adversaries' hostile actions and to stop the flow of genomic data of Americans to the Chinese government.

The Act provides for very narrow exceptions. The President can waive the Act's restrictions on a case-by-case basis for up to one year, and OMB may

extend that an additional 180 days. There is also an exception for contracts or transactions to provide health care services outside the U.S., if necessary to support a government program.

The Senate Committee on Homeland Security and Governmental Affairs held a procedural hearing on the Act on Wednesday, March 6. The Committee voted 11-1 to report S. 35581 to the Senate floor. Sen. Gary Peters will present a final draft of the bill to the Senate, along with a favorable committee report. The lone dissenting vote was cast by Sen Rand Paul of Kentucky. Without naming WuXi AppTec, Paul said he worries that one of the companies named in the bill is key to the supply chain of U.S. biotech companies, and he said the committee hasn't studied the potential ramifications of banning that company. No hearing is currently scheduled in the House.

Because the bills have bipartisan support and have been introduced in both chambers of Congress, there is a reasonably good chance the Act will become law. As with most pieces of legislation, it is also likely that the bills will be amended prior to any final passage.

In another recent development, the Biotechnology Innovation Organization ("BIO"), an industry trade group, changed course on the Biosecure Act, announcing in a press release that it now supports the legislation, will work with Congress on it, and that WuXi AppTec had "proactively ended its membership" in BIO.

Most observers believe that the Act would have a significant impact on U.S. life sciences companies if passed. It would be prudent for these companies to evaluate any existing contracts they have with any of the four named companies and with other companies potentially affected by the law, and to carefully consider the wisdom of any new contracts.

### **What companies can do now:**

In light of the Act, companies in the life sciences industry should consider taking the following actions:

**1. Conduct a risk assessment to identify and evaluate the potential impact of the Act on the company's operations, contracts, and international collaborators.**

Understanding the specific provisions and criteria outlined in the Act is crucial for assessing compliance risks. Identify any existing or planned contracts that involve companies listed as "biotechnology companies of concern," and evaluate the broader implications on the company's supply chain, partnerships, and overall business operations.

For public companies, this risk assessment should be done simultaneously with a review of existing risk factor disclosures in public filings to ensure adequate coverage of any risks posed by the Act.

**2. Engage legal and regulatory experts with expertise in national security, biotechnology, and life sciences regulations to interpret the Act's implications for the company.**

Understanding the nuances of the Act, potential interpretations, and industry-specific considerations is key to adequately assessing risk. Engaging experts early on can help companies develop a proactive compliance strategy and prepare for the evolving regulatory requirements.

**3. Strengthen due diligence processes when vetting international service provider contracts.**

With the Act potentially impacting the ability to contract with certain entities, companies should enhance their due diligence practices. This includes verifying the compliance status of potential partners and suppliers, especially those that are international; understanding their connections to countries listed in the Act; and incorporating contractual safeguards to address compliance requirements.

**4. Stay abreast of legislative developments.**

As with all, the regulatory landscape can evolve, and additional guidance or amendments to the Act may occur.

## Contacts

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