CAPITOL STREET

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BIOSECURE Heats… Then Cools?

Legislative Push Expected in September, Final Passage Could Slip to 2025

Relevant Companies

Our Take & Next Up

Momentum on the BIOSECURE Act slowed over the Summer; however, another legislative push in the House is expected when Congress reconvenes on Sept. 9. House Speaker Mike Johnson (R-LA) is pushing for a floor vote on BIOSECURE as soon as next week to coincide with a so-called "China week" in the House where broader tough-on-China policies are expected to be considered. While the exact timing of a floor vote on BIOSECURE is unclear, it appears likely to pass the lower chamber this month, in our view.

While final passage of some version of BIOSECURE remains possible before year-end, the legislative effort could easily slip into 2025, in our view. A companion BIOSECURE bill in the Senate appears stalled, despite having broad bipartisan support (see our memo here). The FY25 National Defense Authorization Act (NDAA) remains one potential legislative vehicle for BIOSECURE, but NDAA is also expected to be delayed by election-year politics.

A recent Congressional letter to FDA (here) keeps the issue of biosecurity front and center, though we don't expect restrictions on clinical trial practices in China will be added to the BIOSECURE bill. The letter to FDA from the House Select Committee on the CCP focuses on potential security risks associated with clinical trial activity in China by US pharma companies Eli Lilly and Pfizer. FDA officials have indicated they will respond to the inquiry by Oct. 1, while industry stakeholders have insisted safeguards are in place to protect intellectual property.

Key Points

As a reminder, the BIOSECURE Act prohibits federal agencies (and for U.S. companies contracted with the government or receiving grants) from working with certain Chinese biotech companies that present a national security risk. There is flexibility for biopharma with grandfathering language that allows delays to implementation for companies that are already contracted with banned companies (see our memo here).

- Chinese companies named in the ban include BGI, MGI, Complete Genomics, WuXi AppTec, WuXi Biologics and any subsidiary, parent affiliate, or successor of such entities. *These five cannot contest their designation.*

- A list of banned “biotech companies of concern” will be reviewed annually with the Director of the OMB having the power to add and remove companies on the ban list.
- On the extent of the ban, the bill prohibits:
    - procuring or obtaining any biotechnology equipment or service produced or provided by a biotechnology company of concern, or
    - entering into a contract or extending or renewing a contract that the agency knows or has reason to believe will require the use such equipment or service
    - dispensing a federal loan or a grant for such purposes
- Grandfathering of manufacturers: Any existing contracts with named Chinese companies will be grandfathered in and allowed until 2032. Any contracts with new “biotech companies of concern” will also be allowed for a 5-year phase-in period.
- A formal notice of designation and review process is also included. A new company named has 90 days to submit information and their arguments against the decision, and the notice of designation can include mitigating steps that could be taken to rescind the decision.

RECAP: CATALYSTS ON OUR RADAR

1 -- The National Security Commission on Emerging Biotechnology recommendations, expected in early 2025, will likely guide lawmakers’ priorities. Comprised of members of Congress (such as Ro Khanna, D-CA; Todd Young, R-IN; and chaired by Jason Kelly, founder & CEO, Ginkgo Bioworks), the National Security Commission on Emerging Biotechnology will examine the intersection of emerging biotechnology and national security. The Commission’s mandate is to conduct a thorough review of how advancements in biotechnology and related technologies will shape current and future national defense activities, including activities of the Department of Defense (DoD).

2 – Feb. Executive order (EO) guidance on genomics & personal data security are coming this Fall. Recall that Pres. Biden signed an Executive Order on Feb 28 (fact sheet here) focused on preventing genomics and personal data exploitation by foreign countries of concern. Agencies are expected to release guidance within 180 days with HHS directed to “ensure that Federal grants, contracts, and awards are not used to facilitate access to Americans’ sensitive health data by countries of concern, including via companies located in the US.” Some stakeholders believe that the EO is actionable enough in preventing Chinese biotech contracting by federal agencies even if the legislation does not pass this year.

3 -- NIH & FDA response letters to the House Oversight Committee will also trickle in this Fall. House Oversight Committee Chair Comer (R-KY) is further pressuring the agencies to address the potential threat of Chinese biotech via letters.

- The letter sent to the FDA requests a briefing with FDA staff to discuss how the agency communicates quality risks, intellectual property issues, foreign inspection frequency, how FDA trains their investigators assigned to China, among other topics.
- The letter sent to the NIH is much more direct, alleging that the NIH is a target of Chinese espionage efforts with committee interest in how the agency is safeguarding federally funded research and intellectual property. A briefing is requested that will inform how NIH ensures that taxpayer funded research is not transferred to foreign adversaries, efforts taken to protect grants and employees from CCP influence, and NIH’s efforts in advancing STEM research and its outreach to research institutions.
- Leaders of the House Select Committee on the CCP recently sent a letter to FDA on potential security risks associated with clinical trial activity by US pharma companies in China.

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