

CAPITOL STREET

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BIOSECURE Omitted from Senate NDAA Manager's Amendment

Final Passage Likely to Slip to 2025

Relevant Companies



»» Our Take & Next Up

Momentum on the BIOSECURE Act appears stalled once again after being left off the Senate Armed Services Committee manager's amendment of the FY25 National Defense Authorization Act (NDAA).

While the final passage of BIOSECURE remains possible before year-end, NDAA was viewed as the likeliest legislative vehicle. This update – which took place late last eve -- in and of itself doesn't mean that BIOSECURE cannot be included, it's just one step backwards. BIOSECURE recently passed the House (see our memo [here](#)), but the companion bill in the Senate (passed in Homeland Security in [March](#)) remains stalled (see our memo [here](#)). See major components of the bill & upcoming catalysts below.

»» Key Points

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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