

CAPITOL STREET

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ALERT: BIOSECURE Bill Passes House Committee

Full House Passage Likely This Summer & Final Action 4Q24

Relevant Companies



»» Our Take & Next Up

The full House will take up BIOSECURE in mid-June, as the House Oversight and Accountability Cmte (Chair Comer, R-KY) passed the BIOSECURE Act today 40-1 ([here](#)). Republican leadership's goal is to send BIOSECURE to the floor on June 17, when the House is slated to vote on several other bills related to China. The bill has bipartisan, bicameral support with a clear focus on protecting biometric and genomic data from foreign entities. Committee passage puts the bill on track for full House passage this summer; however, the lack of a clear path in the Senate means that full passage is not likely until December 2024. A Senate bill with very similar text [advanced](#) out of the Committee on Homeland Security and Governmental Affairs (Chair Peters, D-MI) in March. Even without BIOSECURE passage, the pressure is growing on Chinese companies with the White House recently announcing a stiff increase in tariffs for Chinese imports including medical supplies (see [details below](#)). [Other catalysts](#) on our radar (1) Biosecurity Council recommendations (Nov/Dec), (2) Biden EO regulations (Fall) and (3) Agency (NIH, FDA) responses to House Oversight Committee inquiries (Summer).

»» Key Points

The BIOSECURE Act was passed (40-1) by the House Oversight and Accountability committee, with no amendments, moments ago. Markup commentary (and a significant reason for the bipartisan support) was focused on the alleged IP theft by WuXi AppTec and the collection of personal genomic data by China via Chinese biotechs (largely BGI).

Tweaks may be coming, per ranking member commentary. Committee Ranking member Raskin (D-MD) noted that lawmakers will work on any additional alterations to address unintended consequences before a House floor vote.

The BIOSECURE Act provides biopharma some breathing room, with recently added grandfathering language (see our memo [here](#)). The bill 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.

- 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 extend 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.

In more anti-China news, Pres. Biden announced new tariffs on imported Chinese medical products yesterday. The White House announced an increase in tariffs for several Chinese products including steel and aluminum, semiconductors, electric vehicles, batteries, critical minerals, solar cells, ship-to-shore cranes, and medical products. The tariffs are meant to encourage China to “eliminate its unfair trade practices regarding technology transfer, intellectual property” and protect domestic manufacturing.

The tariff rates on medical products are as listed and will largely start in 2024 (rubber products will start in 2026). The anti-China tariff is bipartisan in the race for the White House. Earlier this year, Republican Presidential nominee Donald Trump floated tariffs of 60% or higher on all Chinese goods and 10% across-the-board tariffs on goods from all points of origin.

- Syringes and needles will increase from 0% to 50% in 2024.
- Personal protective equipment (PPE), including certain respirators and face masks, will increase from 0–7.5% to 25% in 2024.
- Rubber medical and surgical gloves tariffs will increase from 7.5% to 25% in 2026.

CATALYSTS ON OUR RADAR

1 -- The National Security Commission on Emerging Biotechnology recommendations are due early December, 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 from House Oversight Committee will also trickle this summer. 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 interested 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 are 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.

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