CAPITOL STREET

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ALERT: New BIOSECURE Bill Positive for Biopharma

8-Year Delay for Named Companies, 5-Year Delay for New Co's

Relevant Companies

Our Take & Next Up

We think the recently updated BIOSECURE draft is positive for biopharma and could pass 4Q, with a scheduled House markup Weds, May 15. The updated text released yesterday provides an 8-year implementation delay for WuXi and others named in the bill, and a 5-year delay for new companies. We believe the changes reflect drug shortage manufacturing concerns (particularly for biologics). Anti-China sentiment persists, with a recent ban on TikTok, and we could see BIOSECURE passage at the end of the year in the context of a must-pass defense authorization bill. A House Oversight markup next week makes potential House passage this summer, but with no clear path forward in the Senate this Spring, we are unlikely to see full passage until December 2024.

Key Points

Why a 8-year delay? The bill addresses unintended biologic and brand drug shortages. The old language would have caused delays in the drug supply chain, leading to shortages of brand name drugs (i.e. different from the current generic shortages that Senate Finance and others are seeking to fix at the end of the year). Biologics are difficult to manufacture. A recent BIO survey found that 79% of companies have "at least one contract or product with a China-based or China-owned CDMO/CMO, and they'll need up to eight years to switch manufacturing partners". The 8-year delay in implementation in the new text matches the timeline provided by BIO members.

An updated version that BIO applauds contains the following key changes.

- A delay in the China biotech ban to January 2032 for companies working with named Chinese biotechs: BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics.
- A 5-year delay to allow for contract changes for any future entities that will be named.
- Any companies that are listed on the ban will *not* be made public until the final determination by the OMB.

- We see no government reimbursement penalties (e.g., Medicare/Medicaid reimbursement ban)
- There is a new definition of what constitutes a contract (anything subject to the Federal Acquisition Regulation). Medicare contracting may fall under this definition, but the impact on reimbursement (penalties) remains unclear.
- 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.

As a reminder, the bill prohibits federal agencies (and for U.S. companies contracted with the government or receiving grants) from working with certain Chinese biotech companies.

- Chinese companies named in the ban include BGI, MGI, Complete Genomics, WuXi AppTec, and any subsidiary, parent affiliate, or successor of such entities.
- This 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

The House Committee on Oversight and Accountability (Chair Comer, R-KY) is scheduled to mark-up the BIOSECURE Act on Weds May 15. House drafters have been able to bypass the House E&C Committee with the language of the bill as the bill focuses on government contracting which falls under the House Oversight committee jurisdiction and takes a more national security approach rather than a biopharmaceutical regulation or reimbursement focus.

- The bill has bipartisan support in both chambers and there has been no significant hardline industry opposition to the bill. The latest co-sponsor is Rep. Eshoo (D-CA) whose district has a significant biotech presence. The Senate Committee on Homeland Security and Governmental Affairs (Chair Peters, D-MI) passed BIOSECURE nearly unanimously on March 6 (here).

The House and Senate updated versions are similar. The Senate Homeland Security Committee amended its bill to let companies appeal when they're placed on the list of biotechnology companies of concern. Similarly, the new House text allows for a notice and review process for any new companies added to the list. Other companies that could be named include those that allegedly have ties to the Chinese military in an April letter from the House's Select Committee on the Chinese Communist Party. Companies named in the letter include MGI Group and Complete Genomics, Innomics and STOmics, Origincell, Vazyme Biotech, and Axbio.

OTHER CATALYSTS

The National Security Commission on Emerging Biotechnology recommendations are still 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).

Executive order guidances on genomics & personal data security 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.

NIH & FDA response letters from House Oversight Committee. 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 others topics.

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