CAPITOL STREET

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House Pushes to Ban China Trial Data for INDs

Ban Unlikely to Pass in 2026; Issue May Resurface in PDUFA Negotiations in 2027

Relevant Companies

Our Take & Next Up

China's competitive risk is gaining legislative attention as lawmakers focus on the FDA, but the House clinical trial restrictions are unlikely to pass in 2026. On April 29, the House Appropriations Cmte (Chair Cole, R-OK) advanced the FY27 Agriculture-FDA spending bill that included a non-binding report banning the use of foreign clinical trial data for INDs. The bill directs the FDA to reject clinical trial data generated in China, Russia, Iran, or North Korea for Investigational New Drug (IND) applications.

Separately per *BIOSECURE,* we expect to see guidance and an updated 1260H list in the coming weeks. Guidance for industry stakeholders on *BIOSECURE* implementation is expected to be released within the next month, followed by an update to the DoD's 1260H list of Chinese military-linked companies that are barred from US federal funding and contracting. See our recent *BIOSECURE* analysis here.

Key Points

The national security clinical trial language would have to pass the full House and Senate for implementation: a tall order in an election year. We note that the report language is a signal that Chinese competition and biosecurity are ongoing concerns in Congress. The next vehicle for China reforms (on the FDA side) is (a) budget bills 2H26 and (b) PDUFA reauthorization in mid-2027. The user fee reauthorization discussions are likely to consider this ban (or similar restrictions on the use of Chinese data) that could be paired with ways to accelerate the IND process for US trials (another major FDA reform issue that we have projected as happening here).

Lawmakers are proposing to ban FDA's acceptance of Chinese, Russian and North Korean clinical data to support IND applications. Foreign adversaries named include China, Russia, Iran, or North Korea. New Drug Application (NDAs) and Biologic License Application (BLA) filings are not addressed in the House Appropriations Committee report on the FY27 Agriculture-FDA spending bill from April 29 (here). The provision includes a one-year implementation period, signaling that lawmakers expect both FDA and industry to adapt. The report is rooted in national security concerns.

Any ban could force companies to shift away from leveraging Chinese companies as early development platforms. Lawmakers are noticing the rapid development speed that is accessible in China ("concerned that FDA allows this data, which can be gathered 3–5 times faster in China"), and the incentives for pharma and biotech companies to conduct early clinical trials in China.

The bill is unlikely to pass in 2026; PDUFA is the next major vehicle to watch. We note that a committee report doesn't have the force of law, so this is limited to headline risk for now. The next major legislative vehicle is PDUFA discussions in early 2027. FDA is finishing their commitment letter for PDUFA and will send that to committees by early next year. We expect several policy riders to be discussed in mid-2027 including a possible China data ban, IND trial reform, and AI reforms.

Even without legislative intervention, the FDA has continued to scrutinize Chinese data. The FDA currently allows foreign trial data (assuming it meets certain standards), but maintains a tougher stance on China and does not approve drugs based on trials conducted solely within the country. In June 2025, the FDA also announced an immediate review of new clinical trials exporting Americans' cells to China and other hostile countries to prevent China and other "countries of concern" from accessing genomic data. As a reminder, this was a part of the administration's larger effort in 2025 to prevent China and other "countries of concern" from accessing sensitive information (see similar DOJ rule here).

Biosecurity risk from China is still a key legislative issue – per Rick Scott (R-FL) letter – going into the midterms. In March 2026, Senator Rick Scott (R-FL) sent a letter to senior officials at HHS, NIH, and FDA calling for a review of Chinese Communist Party (CCP) involvement in U.S. clinical trials and drug approvals, citing national security and patient safety concerns. The letter specifically flagged China-linked companies conducting IND-stage clinical work and raised concerns about data security, manufacturing oversight, and foreign access to clinical trial information.

On *BIOSECURE*, which passed in 2025, OMB is set to release guidance within a month with HHS, DoD, and Department of Commerce input. Guidance for industry stakeholders is expected to be released within the next month by the White House's Office of Management and Budget (OMB) in consultation with relevant agencies. Following the release of the guidance, the DoD is expected to update its 1260H list, which identifies Chinese military-linked companies operating in the U.S. Companies placed on the DoD's 1260H list have limited due process protections, while companies on the new list of biotechnology companies of concern will be able to challenge their designation, per *BIOSECURE*. As a reminder, the Trump administration in February briefly added Chinese companies, including WuXi Apptec, Alibaba and Baidu, to the Pentagon's now-withdrawn "1260H" risk list. See our past *BIOSECURE* analysis here.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

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