

# CAPITOL STREET

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## BIOSECURE Unlikely in 2025

### Additional Policy & Artificial Intelligence Concerns

Relevant Companies



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## »» Our Take & Next Up

**We believe additional regulations are likely forthcoming in 2025, despite BIOSECURE being unlikely to move this year.** We view (1) biosecurity policies (2) export controls for the synthetic biology industry could have ripple effects throughout biotech, manufacturing, technology sectors. We expect the National Security Commission on Emerging Biotechnology's policy recommendations to be released on April 10 ([here](#)). We believe that recommendations will likely address a range of concerns including how to promote a domestic supply chain, how to protect US IP and other sensitive information, and how to prevent potential misuse of synthetic bio. Federal regulators may be considering additional export controls on top of what was announced in January (our analysis ([here](#)) to address supply chain and IP vulnerability concerns.

## »» Key Points

**Synthetic DNA tech is being advanced further alongside artificial intelligence (AI).** The synthetic biology industry is attempting to draw attention to the potential for synbio in therapeutics, biofuel, technology, among other uses. AI enables the capability in early ideas and design phases and reduces the development burden. A key concern is the global supply chain and the challenge of companies with Chinese-based manufacturing leading the market.

**A biosecurity protocol framework is being utilized but not a requirement for manufacturers and developers.** Office of Science and Technology Policy (OSTP) lays out a framework for nucleic acid synthesis screening [here](#). We note this is a Biden-era rule.

**Legislation has been introduced in prior Congress' but we see other priorities being top of mind.** *Securing Gene Synthesis Act* (introduced in 2023 by Sen. Markey (D-MA) and Rep. Eshoo (D-CA)) [requires](#) HHS to issue regulations to prevent the misuse of de novo gene synthesis products (i.e., manufactured gene products), including screening protocols. Entities that receive federal funds may only purchase such products from providers that comply with the screening protocols.

**Is BIOSECURE dead? Likely, yes.** The National Security Commission on Emerging Biotechnology (Chair Sen. Young, R-ID) is scheduled to release a policy report on April 10 ([here](#)). Comprised of members of Congress --

Sens. Padilla (D-CA), Reps. Bice (R-OK) & Ro Khanna (D-CA) and industry experts, the National Security Commission on Emerging Biotechnology is unpacking 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).

**Additional tariff/trade controls are likely on the horizon for research and biopharma industry.** We will likely see trade/tariff policy instituted as a part of the administration's protectionist stance. We also note biotech & research sector concerns of Chinese IP theft and incursion. As a reminder, in January 2025, the US Commerce Dept Bureau of Industry and Security imposed export controls on biotechnology equipment and related technologies due to national security and data concerns. See our analysis ([here](#)).

**China remains under a 20% tariff and has retaliated by banning Illumina (ILMN).** China is able to utilize BGI for its purposes. China accounts for 7% of Illumina sales. Despite the announcement of tariffs we have not heard China complain too loudly (yet).

**An observation: AI staffers are becoming present in many Congressional offices – healthcare and non-healthcare.** Where it's a visiting fellow or a temporary or permanent staffer, artificial intelligence is clearly a priority for most members to keep a finger on the pulse as additional legislation/oversight and private market developments take place.

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

202.250.3741 | [www.capitol-street.com](http://www.capitol-street.com)

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

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