SESSION
05

The Rise of New Modalities: A Game Changer in Drug Development

May 8 (Thu), 13:00~17:00 / Rm. 401

More detail ▲

The rise of new modalities is creating a major turning point across the pharmaceutical and biotech industries, going beyond the traditional framework of drug development.Innovative treatment approaches such as CAR-T, mRNA, gene and cell therapies, and antibody-drug conjugates (ADCs) are rapidly advancing, moving past the conventional focus on small molecules and biologics.This session brings together leaders from global pharmaceutical companies, law firms, investment firms, and promising domestic biotech ventures to explore the core concepts and latest trends in new modalities. The discussion will delve into how these approaches are expanding the paradigm of drug development, and examine the challenges and opportunities faced during the research, development (R&D), and commercialization stages.

Featured Speakers

01 Speaker

Friedemann Janus, SVP
Head of Business Development & Licensing, Co.Lab, Regional and Divestitures, Bayer

* Senior Vice President responsible for Regional Business Development, Licensing, Open Innovation, and Divestments within Bayer's Pharmaceuticals Division
* Spearheads Bayer's innovation strategy, including the establishment of Bayer Co.Lab in Berlin to support life science startups

Koji Yashiro, Director
Business Development and Licensing, MSD

02 Speaker

* As the Director of Business Development and Licensing at MSD Asia Pacific, he leads search and evaluation efforts focused on early-stage assets in Japan and Korea.

Biosecure Act Article

By | **Sean Kim_Partner, Ice Miller LLP**

Date & Time : S6. May 8(Thu) 2025, 09:30~11:40
S7. May 8(Thu) 2025, 13:30~16:00

Venue : COEX Rm. 307

Coordinating : Dongguk University College of Pharmacy, Ice Miller LLP, U.S. Embassy & Consulate in the Republic of Korea

*The content of this article represents the author's opinion and may differ from the official views of the BIO KOREA Organizing Committee.

BIOSECURE Act article

As a life sciences company doing business in the United States, it is important to not only be aware of the latest trends in the industry, but also any potential (and actual) developments in the law that may impact the business. With the recent emergence of China as a noteworthy contender in the biotech space, the proposed BIOSECURE Act (H.R. 7085) received a lot of attention last year. This proposed legislation sought to place restrictions on companies that contracted with a "biotechnology company of concern," or used such biotechnology equipment or services. The bill explicitly identified five Chinese "biotechnology companies of concern"[1]: "Beijing Genome Institute (BGI), MGI Tech Solutions (MGI), Complete Genomics, WuXi AppTec, and WuXi Biologics, and any subsidiary, parent affiliate or successor of such entities." If passed, the Act would prohibit U.S. federal funding (for example, loans, grants, and contracts) in connection with obtaining or procuring biotechnology equipment or services produced or provided by a "biotechnology company of concern."

The Proposed Legislation and its Amendments

Introduced in January 2024 by bipartisan members of the United States House of Representatives, Rep. Raja Krishnamoorthi (D-IL.) and Rep. Mike Gallagher (R-WI.), of the House Select Committee on the Strategic Competition between the United States and the Chinese Communist Party (House Select Committee on the CCP),[2] the proposed legislation sought to accomplish two main objectives: to prevent entities receiving federal funding from utilizing biotechnology equipment and services from companies linked to foreign adversaries, including those in the People's Republic of China (PRC), and to protect U.S. genetic data from being accessed by the Chinese Communist Party (CCP)[3].

The proposed legislation's definition of "biotechnology companies of concern" include any entity that: (1) is "subject to the jurisdiction, direction, control, or operates on behalf of the government of a foreign adversary," (i.e., PRC, Cuba, North Korea, Russia, and Iran)[4]; (2) is "involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service"; and (3) "pos[es] a risk to the U.S. national security..."[5]

The definition of "biotechnology equipment or services" was broad, including any machine, equipment, software, data storage, consulting services, support services, or disease detection that involves "research, development, production or analysis" related to "biological materials."[6]

With China's emergence as a strong contender in the biotech space, both as a service provider and potential partner, the potential effect from the passage of such a bill would have affected not only those companies that fall under the definition of a "biotechnology company of concern," but also ones that do business (or want to do business) with such companies, as the U.S. government is a strong source of funding in the industry, including through government contracts and grants.

The proposed legislation for the BIOSECURE Act passed the House of Representatives through a 306-81 vote on September 9, 2024, but has not yet passed the U.S. Senate, which is necessary for the bill to be presented to the President for signature.

Despite bipartisan support, the BIOSECURE Act faced opposition, including from both Senator Rand Paul (R-KY) and Representative Jim McGovern (D-MA), who voiced concerns about its extensive restrictions on "biotechnology equipment and service." They worried that the Act would severely disrupt existing supply chains and potentially cause drug shortages, as industry surveys indicated an insufficient number of non-Chinese Contract Development and Manufacturing Organizations (CDMOs) capable of replacing the services currently provided by the designated companies of concern.[7] These concerns persisted even after the proposed Act was amended (H.R. 8333) to provide an approximately eight-year "grandfathering" transition period for severing ties with the affected PRC firms.

The bill was further amended to clarify that "biotechnology equipment or services" would not include those that "were formerly, but no longer, produced or provided by biotechnology companies of concern"[8] and that it would only govern federal contracts under the Federal Acquisition Regulation. Other criticisms focused on the Act's inadequate notification requirements for companies of concern and insufficient due process provisions for appealing their designations.

S. 3558, the Senate's version of the BIOSECURE Act that failed to progress, did not include the grandfathering period but clarified that the Act would not apply to existing arrangements with named biotechnology companies of concern that were in effect as of the legislation's effective date. Unlike the House version, S. 3558 did not specify which types of federal contracts would fall under its purview.

The bill was not presented for a vote at the Senate before the new Congressional term began in 2025, and with the new Republican-led Congress and Trump administration, its future is unclear.

Outlook and Potential Impact

Nonetheless, the amended House version of the BIOSECURE Act (H.R. 8333) (or another similar bill) may resurface in 2025 or beyond, with two main factors supporting its potential revival. First, the legislation enjoys relatively strong bipartisan support in a Republican-controlled Congress. Second, it could align with the broader policy agenda, including measures to protect U.S. domestic jobs and manufacturing. This development indicates a shift in governmental approach to international collaboration and national security within the life sciences sector.

Companies in the life sciences are monitoring this bill and assessing the potential risk/s of either continuing to do business with Chinese biotech companies and/or potentially serving as an alternative source. For example, some companies in the life sciences industry appear to be exploring alternatives to PRC firms, possibly in preparation for potential regulatory changes and to address geopolitical risks in their operations. If enacted, the ultimate impact and scope of the BIOSECURE Act will depend on multiple factors: Congress' final drafting of the legislation, federal agencies' interpretation and implementation of its provisions, and the private sector's response to the new regulatory framework.

Ultimately, the bill's passage (or a similar bill's passage) will depend in part on the new Congress and Trump administration's agenda and priorities, including with the relationship between U.S. and China, national security concerns, US-manufacturing, and issues impacting the biotech/life sciences. We are continuing to monitor developments to this bill and/or potential alternative proposals by Congress or the new Trump administration.

1 https://www.congress.gov/118/bills/hr8333/BILLS-118hr8333rfs.pdf
2 https://www.congress.gov/bill/118th-congress/house-bill/8333
3 Clause 2(b) of the bill.
4 10 U.S.C. 4872(d) (2024).
5 https://www.congress.gov/118/bills/hr8333/BILLS-118hr8333rfs.pdf page 9
6 Section 1(k)(2)(C) of H.R. 8333.
7 https://health-isac.org/wp-content/uploads/11.4.24_WP_ImpactsoftheBIOSECUREActontheGlobalBioTechIndustry.pdf (bottom of page 5-6)
8 Section (c)(3)(A) of H.R.8333.