RICK SCOTT
FLORIDA

United States Senate

ARMED SERVICES
BUDGET
FOREIGN RELATIONS
HOMELAND SECURITY
SPECIAL COMMITTEE ON AGING
CHAIRMAN

March 19, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Martin Makary, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Jay Bhattacharya, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Secretary Kennedy, Director Bhattacharya, and Commissioner Makary:

I write to express serious concerns regarding the participation of Chinese Communist Party (CCP)-linked entities in the United States clinical trial and drug approval process, and to request immediate action to ensure that national security considerations are fully integrated into the review of such applications.

For years, the CCP has engaged in systematic efforts to acquire American intellectual property, including through economic espionage and the exploitation of research collaborations. These actions have imposed high economic costs and created substantial national security risks. The biotechnology sector – particularly advanced therapeutics such as cell and gene therapies – represents a strategic domain in which protecting American innovation and sensitive health data is paramount. The stakes could not be higher: the U.S. bioscience industry employed nearly 2.3 million Americans and generated more than $3.2 trillion in economic output in 2023, while indirectly supporting nearly 8 million additional jobs. Communist China's IP theft and espionage directly threaten this powerful engine of national prosperity.

I have been made aware that Bioheng, also known as Imviva, a China-based company reportedly financed by CCP-linked sources[1], has received authorization to proceed under an Investigational New Drug (IND) application and has been granted Regenerative Medicine Advanced Therapy (RMAT) designation and priority review. The decision to extend expedited regulatory benefits to a CCP-linked entity warrants careful scrutiny.

[1] https://www.bioheng.com/news_Detail_1/10.html

According to publicly available information, the company proposes to collect donor cells in China, engineer CAR-T cancer therapies in China, and administer those therapies to American patients through U.S.-based clinical trials[2], and transmit related clinical and patient data abroad. In the context of cell and gene therapies, this model raises not only data security concerns, but also patient safety risks related to chain-of-identity, chain-of-custody, manufacturing quality control, and the ability of U.S. regulators to conduct effective oversight and enforcement when critical processing occurs outside U.S. jurisdiction. Given the CCP's legal authority to access data held by Chinese companies[3] and longstanding concerns about intellectual property protection and state-sponsored economic espionage, this model presents significant risks that must be addressed.

This case appears to reflect broader vulnerabilities in the current oversight framework. Federal law enforcement agencies have repeatedly documented Chinese state-sponsored trade secret theft and economic espionage, including in the biomedical sector.[4] National Institutes of Health (NIH)-funded researchers have faced prosecution for failing to disclose foreign affiliations[5], and federal agencies have taken steps in recent years to strengthen disclosure and transparency requirements. Despite these efforts, it remains unclear whether national security risks are being consistently and rigorously evaluated in connection with IND approvals, expedited designations, and clinical trial authorizations involving entities linked to foreign adversaries.

As the world's largest public funder of biomedical research, the NIH has a responsibility to safeguard taxpayer-funded innovation. As the federal regulator responsible for approving and overseeing clinical trials and therapeutics, the Food and Drug Administration must ensure that safety, efficacy, and national security considerations are fully integrated into its decision-making. The Department of Health and Human Services plays a central role in coordinating these responsibilities.

Accordingly, I request that your agencies take the following actions:

1. Immediately review all pending and recently approved clinical trial applications involving entities with financial backing from, ownership by, or significant operational ties to Chinese state-controlled entities, the CCP, or the People's

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[2] https://www.globenewswire.com/news-release/2025/12/22/3209226/0/en/Imviva-Biotech-Announces-First-Patient-Dosed-in-Phase-1b-2-TENACITY-01-Trial-of-CTD402-CAR-T-Cell-Therapy.html
[3] https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/FINAL_NCSC_SOF_Bulletin_PRC_Laws.pdf
[4] https://www.justice.gov/archives/opa/pr/hospital-researcher-sentenced-prison-conspiring-steal-trade-secrets-and-sell-china
[5] https://www.gao.gov/products/gao-21-523t

Liberation Army, and pause approvals where appropriate pending a comprehensive national security review.

2. Reevaluate expedited designations, including RMAT and priority review status, granted to entities with such ties, including Bioheng/Imviva.
3. Establish and implement mandatory national security screening protocols for IND applications and clinical trial proposals that involve:
    a. Foreign manufacturing or processing of therapeutic products;
    b. Collection, storage, or transmission of patient data outside the United States;
    c. Sponsorship by entities based in, or substantially controlled by, countries designated as foreign adversaries; or
    d. Use of technologies or methodologies that may have been derived from misappropriated intellectual property.
4. Require comprehensive disclosure and independent verification of all foreign funding sources, partnerships, data-sharing agreements, and manufacturing arrangements for any clinical trial conducted on U.S. soil or involving U.S. patients.
5. Prohibit the transmission of identifiable U.S. patient data to entities based in or controlled by countries designated as foreign adversaries, absent explicit statutory authorization and robust safeguards.
6. Coordinate with the Department of Justice, the Federal Bureau of Investigation, and the intelligence community to identify researchers, institutions, and companies with undisclosed ties to Chinese state entities and take appropriate enforcement action where warranted.
7. Conduct a comprehensive audit of all active clinical trials involving Chinese entities or researchers with potential CCP ties to assess national security and patient safety risks.

This matter extends beyond routine regulatory review. It involves protecting American patients receiving advanced therapies, safeguarding sensitive health data, and preserving U.S. leadership in biotechnology. The CCP has publicly articulated a strategy of "military-civil fusion," which seeks to integrate civilian research advances into military capabilities. That context must inform our evaluation of foreign participation in strategically sensitive sectors.

The United States must remain open to legitimate scientific collaboration, but openness cannot come at the expense of national security or patient protection. A failure to account for these risks undermines both.

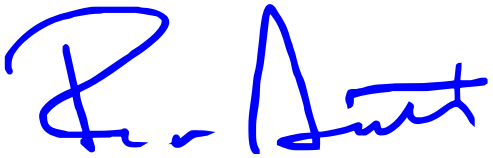
I request a detailed written response within 60 days outlining:

- The steps being taken with respect to the Bioheng/Imviva approval;
- Any broader policy changes being implemented to address similar risks;

- A timeline for the requested audit of existing trials; and
- The specific national security screening protocols currently in place or under development for foreign-linked entities.

Thank you for your prompt attention to this important matter. I look forward to your response.

Sincerely,



Rick Scott
United States Senator