Congress of the United States
House of Representatives
SELECT COMMITTEE ON THE CHINESE COMMUNIST PARTY

January 9, 2025

The Honorable Gina Raimondo
Secretary
U.S. Department of Commerce
1401 Constitution Ave, NW
Washington, D.C. 20230

Dear Secretary Raimondo,

As you know, the United States is engaged in a fierce competition with the People's Republic of China (PRC) in biotechnology. This competition will not only have implications for our national and economic security, but also for the future of healthcare and the security of American medical data. Accordingly, we believe that your agency should examine imposing an export control requirement for U.S. biopharmaceutical entities seeking to work directly with the People's Liberation Army (PLA) to help ensure U.S. biotechnology does not fall into the hands of the PRC.

The PRC's 14th Five-Year Plan identifies dominance in biotechnology as critical to "strengthen the PRC's science and technological power" and calls to deepen military-civil science and technology collaboration in the sector.[1] PRC military and academic literature further stresses the importance of biotechnology to national power, arguing success on the future battlefield will require "achieving biological dominance," with one former president of the PLA's National Defense University openly discussing biotech's ability to create synthetic pathogens that are "more toxic, more contagious, and more resistant."[2] To this end, the PRC has identified the flow of U.S. IP and data to PLA medical infrastructure as a crucial component of this effort, and further steps are needed to address this issue.

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[1] Center for Security and Emerging Technology. March 12, 2021. "Translation: Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035" https://cset.georgetown.edu/wp-content/uploads/t0284_14th_Five_Year_Plan_EN.pdf

[2] Kania, Elsa and VornDick, Wilson. The James Town Foundation. October 8, 2019. "China's Military Biotech Frontier: CRISPR, Military-Civil Fusion, and the New Revolution in Military Affairs." https://jamestown.org/program/chinas-military-biotech-frontier-crispr-military-civil-fusion-and-the-new-revolution-in-military-affairs/

On July 29, 2024, the Bureau of Industry and Security (BIS) published a notice of proposed rulemaking that would expand export controls, including U.S. persons activities, to military and intelligence end users.[3] We see these proposals as a welcome update in the face of the People's Republic of China's (PRC) ever-changing tactics to circumvent our export controls and leverage U.S. technology for military purposes. We believe this proposed rule is a good first step and an opportunity for BIS to lead on an emerging issue of U.S. technology fueling the People's Liberation Army (PLA) biotechnology ecosystem, in particular, the trend of U.S. biopharmaceutical entities working with PLA medical institutions to conduct clinical trials.

In August, the Select Committee wrote to the Food and Drug Administration (FDA), asking them to examine information suggesting that U.S. biopharmaceutical entities may have worked directly with the PLA over the last decade to conduct hundreds of clinical trials for new drug candidates.[4] As a general matter, such trials produce sensitive and proprietary data that are valuable for both the PLA and PRC companies alike. Some of these trials have even been conducted with entities on the U.S. Department of Commerce's Entity List, including the PLA's Academy of Military Medical Sciences (AAMS).[5]

While the chemical compounds of drugs in development and related IP are not export controlled, BIS's proposed update to toughen military end-user and end-use controls could be strengthened to specifically state that cooperation with PLA medical institutions for the purpose of clinical trials is subject to a licensing requirement. Specifically, we recommend updating the definition of "Military End User" to state medical infrastructure owned or operated by the national armed services of the PRC and other countries as appropriate constitutes a military end-use if a U.S. person is seeking to engage with the institution to conduct a clinical trial.

Adoption of the approach in the proposed rule would be entirely consistent with the approach that the Administration is adopting in other areas of U.S. law and regulation, where the burden would be on U.S. companies to conduct due diligence and prove they are not doing business that would jeopardize U.S. national security or our commitment to human rights.

Furthermore, the burden of such a control would not be heavy; based on previous data on clinical trials over the last decade, we would expect only several dozens of these license applications a year to be submitted to BIS due to the small number of hospitals and institutions that are directly operated by the PLA. Furthermore, we believe the biopharmaceutical industry would seek alternative, non-PLA medical infrastructure in the PRC, for which there is plenty, to conduct these trials if the industry was faced with regulatory restrictions on working with the PLA.

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[3] Federal Register. July 29, 2024. "End-Use and End-User Based Export Controls, Including U.S. Persons Activities Controls: Military and Intelligence End Uses and End Users" https://www.federalregister.gov/documents/2024/07/29/2024-16496/end-use-and-end-user-based-export-controls-including-us-persons-activities-controls-military-and

[4] House Select Committee on the CCP. August 19.2024. "Letter to Commissioner Calif on Clinical Trials with the PLA." https://selectcommitteeontheccp.house.gov/sites/evo-subsites/selectcommitteeontheccp.house.gov/files/evo-media-document/8.19.24%20FDA%20Letter%20on%20PLA%20Trials.pdf

[5] Clinicaltrials.gov. "Axitinib For The Treatment Of Advanced Hepatocellular Carcinoma," https://clinicaltrials.gov/study/NCT01210495. Accessed July 22, 2024.

We would welcome the opportunity to engage with your team to discuss the details of any such rule and share the data we have collected on the nature and scope of U.S. companies' involvement with the PLA for the purpose of clinical trials.

Thank you for your continued work on this important matter and for protecting U.S. national security interests.

Sincerely,

John Moolenaar
Chairman, Select Committee on the CCP

Raja Krishnamoorthi
Ranking Member, Select Committee on the CCP

Neal Dunn
Member of Congress