Congress of the United States
House of Representatives
Washington, DC 20515

August 19, 2024

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver
Spring, MD 20339

Dear Commissioner Califf,

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. As a key regulatory body interfacing with the biopharmaceutical ecosystem, the U.S. Food and Drug Administration (FDA) should play an active role in ensuring the United States remains ahead of the PRC in biotechnology, and that America's biopharmaceutical industry benefits American innovators and American patients.

For over a decade, it appears that U.S. biopharmaceutical companies conducted clinical trials with China's military organizations, and specifically with medical centers and hospitals affiliated with the People's Liberation Army's (PLA), to determine the safety and effectiveness of new drug candidates prior to approval. As a general matter, such trials produce sensitive and proprietary data. While it is the clinical trial sponsors such as biotechnology companies that design clinical trials and enroll patients around the world in these trials, it is the FDA that has the essential role in determining whether products tested in patients around the world should be approved for American patients.

In addition to U.S. biopharmaceutical entities working with the PLA, we are also concerned that U.S. biopharmaceutical companies have conducted clinical trials with hospital infrastructure located in the Xinjiang Uyghur Autonomous Region (XUAR), where the Chinese Communist Party (CCP) is engaged in genocide of the Uyghur population. Given the historical suppression and medical discrimination against ethnic minorities in this region, there are significant ethical concerns around conducting clinical trials in the XUAR.

These collaborative research activities raise serious concerns that critical Intellectual Property (IP) is at risk of being transferred to the PLA or being co-opted under the People's Republic of China's (PRC) National Security Law. Conversely, there are also concerns with the trustworthiness of clinical trial data produced overseas from PLA institutions. The FDA has previously declined to approve oncology treatments based on clinical trial data solely produced from clinical trial sites in China, suggesting the FDA should also impose similar scrutiny to clinical trial work done in cooperation with the PLA.

According to publicly available data on the clinicaltrials.gov website, over the last ten years, major U.S. biopharmaceutical companies have conducted hundreds of clinical trials in China that included at least one entity with PLA in the name as a research trial partner. Even today, one major U.S. biopharmaceutical entity is actively recruiting patients for an advanced Alzheimer drug trial and is partnered with the PLA's General Hospital and Medical School (中国人民解放军总医院 中国人民解放军医学院) and the PLA's Air Force Medical University (中国人民解放军空军军医大学).[1] Previously, another U.S. biopharmaceutical entity used the 307 Hospital of the PLA (307 医院) as the setting for a cancer therapeutic clinical trial.[2] The 307 Hospital of the PLA is directly operated by the PLA's Academy of Military Medical Sciences (AMMS),[3] an entity on the U.S. Department of Commerce's Entity List which precludes U.S. companies from transferring technology to AMMS due to the threat it poses to U.S. national security.[4] The transfer of early-stage clinical trial data, including the chemical composition of the therapeutic itself, involves incredibly sensitive data.

In addition to work with the PLA, there are also U.S. biopharmaceutical trials listed on clinicaltrials.gov that were conducted with hospitals located in the XUAR, where credible investigative reports have shown that ethnic minorities in the region are repeatedly forced by the CCP to surrender their body autonomy.[5] As we know, there is simply no ability for firms to conduct due diligence to ensure that clinical trials done in XUAR are voluntary. Given this, we believe that U.S. biopharmaceutical entities could be unintentionally profiting from the data derived from clinical trials during which the CCP forced victim patients to participate.

Although the FDA primarily makes determinations on whether responsible parties are complying with requirements for submitting information to clinicaltrials.gov and meeting FDA regulatory guidelines, FDA regulations specifically grant the Commissioner the authority to request and analyze data from clinical trials conducted domestically and outside of the United

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[1] Clinicaltrials.gov. "A Study of Donanemab (LY3002813) in Participants With Early Symptomatic Alzheimer's Disease (TRAILBLAZER-ALZ 5)" https://clinicaltrials.gov/study/NCT05508789. Accessed June 20, 2024

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

[3]解放军第 307 医院, https://web.archive.org/web/20140812223145/http://www.81.cn/zghjy/node_63848.htm

[4]86 FR 71557, https://www.federalregister.gov/documents/2021/12/17/2021-27406/addition-of-certain-entities-to-the-entity-list-and-revision-of-an-entry-on-the-entity-list.

[5]"Uyghur Women are China's Victims – and Resistance," *Foreign Policy,* March 12, 2021, https://foreignpolicy.com/2021/03/12/uyghur-women-are-chinas-victims-and-resistance/#:~:text=%E2%80%9CTheir%20bodily%20autonomy%20has%20been,is%20being%20detained%20in%20Xinjiang.

States.[6] As such, data from U.S. biopharmaceutical companies who conducted clinical trials at institutions affiliated with the PLA or other organizations in the XUAR are likely already in FDA's possession. We therefore request a timely response to the following questions:

1. Has the FDA reviewed clinical trials involving the PLA or PLA facilities or conducted on-site inspections of PLA facilities?

2. Has the FDA ever been denied access to foreign clinical trial sites in the PRC, including but not limited to trial sites located on facilities affiliated with or owned by the PLA?

3. How many PLA-owned, operated, or affiliated facilities has the FDA reviewed for clinical trial work?

4. What is FDA's estimated average cost for adjudicating a clinical trial conducted in the PRC?

5. What is the earliest date for which the FDA received clinical trial data that included PLA organizations?

6. Given FDA's regulations for ensuring that clinical trials are conducted according to ethical and safety standards, has the FDA ever notified any U.S. biopharmaceutical organization that it has conducted studies with the PLA or in the XUAR? If so, please provide the number of notices and time periods when they were issued, and if companies were responsive.

7. What metrics does FDA use when assessing IP and technology transfer risks? Within those metrics, how are the risks calculated when research studies identify collaborations with the PLA or involve PLA-owned facilities as the setting for the research?

The United States needs the FDA to take on a greater role in protecting U.S. national security interests. With this data, it is clear that the FDA should play a greater role in analyzing U.S. biopharma entities clinical trial operations in the PRC.

We request that you provide these answers to the Select Committee no later than October 1, 2024.

Sincerely,

[6] U.S. FDA. "Step 4: FDA Drug Review." Accessed July 20, 2024. https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review#:~:text=Directions%20for%20use-,FDA%20Review,whether%20to%20approve%20the%20drug.

John Moolenaar
Chairman, Select Committee on the CCP

Raja Krishnamoorthi
Ranking Member, Select Committee on the CCP

Anna Eshoo
Ranking Member, Health Subcommittee, Energy and Commerce

Neal Dunn
Member of Congress