Congress of the United States
House of Representatives
SELECT COMMITTEE ON CHINA

August 20, 2026

The Honorable Kyle A. Diamantas, J.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Diamantas,

We write today to urge action to address the serious risks of clinical trial data generated in China given the stakes for patients in the United States and around the world. The Food and Drug Administration (FDA) has long been the global gold standard for drug safety, ethics, and informed consent, and we want to work with you to ensure this standard is never diluted by unverifiable data.

China operates one of the most restrictive media and information environments on earth.[1] Its censorship machinery is designed not to inform the public, but to protect the interests and image of the Chinese Communist Party (CCP). We have seen this in Xinjiang and Tibet—where the CCP has perpetrated grave human rights abuses—and across numerous areas of policy. Biomedical research is no exception. Basic transparency, something we rightly expect in the United States, is often absent in China.

We note with grave concern recent reporting that has exposed three separate, tragic deaths of patients—two of them children—enrolled in experimental gene-editing investigator-initiated trials (IITs) in China. In one case, the sponsoring company halted all public updates about the treatment for more than a year and only acknowledged the death after persistent inquiries.[2] In another, researchers concealed a child's death and went on to publish scientific findings without disclosing the fatal outcome.[3] In the third case, the patient died in March 2026, yet in early August 2026 the FDA reportedly cleared the therapy to begin clinical trials in the United States —without the company ever having publicly reported the death.[4]

These events are heartbreaking, and they underscore a fundamental truth: we do not know what is happening inside China's clinical research and testing system. As we see from these recent

[1] https://freedomhouse.org/country/china/freedom-net/2025
[2] https://www.statnews.com/2026/08/05/china-clinical-trial-fatality-safety-questions-investigator-led-studies/
[3] https://www.science.org/content/article/exclusive-death-girl-chinese-gene-editing-trial-was-never-made-public
[4] https://endpoints.news/exclusive-third-death-revealed-in-chinas-popular-but-opaque-trials

cases, if not for aggrieved families taking great personal risks to speak with media, or the tireless work of independent journalists, the world may never have learned the truth. The affected families almost certainly will never see justice. And the breadth and scope of unreported fatalities and serious adverse events in China's clinical trials remain unknown.

This matters for the FDA because American pharmaceutical companies are increasingly incorporating China-generated clinical trial data into submissions for U.S. drug development or acquiring or licensing therapies from Chinese companies based on tests run in China. Just as the United States does not accept goods manufactured with forced labor under the Uyghur Forced Labor Prevention Act (UFLPA), we should not accept clinical data that exposes patients to risks and harms that would never be permitted under FDA oversight. In short, the offshoring of early-stage clinical trials to China risks rewarding a system that has shown it is willing to treat children's deaths as an acceptable cost of faster, cheaper research.

In recent years, biotechnology firms, investors, and pharmaceutical companies have flocked to China for the same reasons manufacturers have for decades: lower costs and quicker speeds enabled by weaker regulation and questionable ethics. China now conducts thousands of clinical trials annually, but the American public has almost no visibility into how these trials are run,[5] how data are collected, or whether adverse events are fully disclosed. As more stories like these come to light, it is becoming clear that accepting Chinese clinical data poses real risks for patients.

The United States must lead with integrity. We cannot allow our regulatory system to become dependent on data produced in opaque, high-risk environments. In that vein, we respectfully urge the FDA to take the following steps:

1. **Decline acceptance of China-generated clinical trial data** for U.S. Investigational New Drug (IND) applications, New Drug Applications (NDA), or Biologics License Applications (BLA) unless the FDA has conducted an in-person audit of the trial site within the last twelve months prior to application submission. This would protect the integrity of the U.S. regulatory system and patients in China who currently have no advocate.
2. **Conduct a comprehensive risk assessment** examining the extent to which U.S. drug development and marketing approvals rely on data from Chinese IITs and Clinical Trial Applications (CTA), with special attention to high-risk modalities like gene editing—and publish the results for public review.

American families deserve confidence that the treatments approved in our country are supported by data produced with rigor, ethics, and accountability. We cannot outsource that responsibility to a CCP-controlled system that does not share our standards or our values.

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[5] For example, according to GAO, FDA conducted only 46 inspections of clinical trial sites in China from fiscal year 2012 through March 1, 2023. GAO-24-106383, CLINICAL RESEARCH: FDA Should Evaluate Its Efforts to Recruit and Retain Its Inspection Workforce.

Thank you for your attention to this matter. We look forward to working with you as the FDA evaluates the appropriate safeguards to protect American patients and preserve the integrity of our regulatory system.

Sincerely,

JOHN MOOLENAAR
Chairman
House Select Committee on China

BEN CLINE
Member of Congress