Prescription America

How To Protect Americans from a Dangerous Dependence on China for Their Medicines

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THE SELECT COMMITTEE ON THE STRATEGIC COMPETITION BETWEEN THE UNITED STATES AND THE CHINESE COMMUNIST PARTY



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Executive Summary

It is 2040, and China controls the world's most advanced medicines. You walk into a pharmacy to refill the cancer therapy that has kept you alive for years—only to learn that supplies have been frozen after China halted shipments due to a disruption in diplomatic relations. What rare earths are to the current era of geopolitical competition, innovative medicines could become in the next—unless the United States acts decisively.

Biotechnology underpins U.S. economic strength, national security, and scientific leadership. Like artificial intelligence and advanced semiconductors, it will shape the nation's competitiveness for decades to come. The Chinese Communist Party (CCP) has made the sector a priority and is rapidly building the capacity to challenge U.S. dominance. The United States must act now to protect and strengthen its biotechnology ecosystem or risk being overtaken.

The stakes are especially clear in biopharmaceuticals, where companies are developing the next lifesaving medicines. China has progressed from manufacturing generics to generating novel drug candidates, and Western pharmaceutical companies and venture capital (VC) firms are increasingly turning to Chinese biotechnology companies to replenish their pipelines. Through licensing and investment, American capital is helping build the competitors Beijing aims to place at the center of global drug innovation.

The House Select Committee on the Strategic Competition Between the United States and the Chinese Communist Party (Select Committee) set out to examine how this shift is occurring. This Select Committee report draws in part on interviews with dozens of biotechnology executives, pharmaceutical companies, investors, researchers, clinical trial professionals, and government officials. The report identifies a reinforcing cycle: China's health system offers patients fewer accessible standard-of-care treatment options, ostensibly pushing patients toward experimental clinical trials;[1] Chinese researchers then generate early human data quickly through clinical trials with less regulatory oversight; Chinese firms use that early human data to accelerate novel therapies and fast follow American discoveries; Western investors and pharmaceutical companies supply capital and commercialization expertise; and weaknesses in the American clinical research system further reward development in China. Meanwhile, American patients and taxpayers foot the bill through purchase of medicines covered by Medicare, Medicaid, and private insurance—at the world's highest prices. The result is a trajectory that threatens to hollow out the ecosystem that has produced the lifesaving medicines that Americans depend on—even as American patients subsidize its erosion.

Time and first-in-human data drive drug development. Drug development consumes years of a treatment's patent-protected commercial life. Early human studies provide initial evidence about safety, dosing, and potential therapeutic

activity, guiding investors on whether to double down on investment or cut their losses. Because most drug candidates entering clinical trials ultimately fail, companies that obtain credible human data sooner gain an edge in attracting financing, securing licensing agreements, and advancing treatments toward the market.

China has built two pathways for obtaining this data. Its formal regulatory pathway has become faster and more closely aligned with international standards. Alongside it, fast and cheap investigator-initiated trials (IITs) allow individual researchers to test experimental therapies through hospital-based approvals without the same national regulatory review required for formal drug trials. These trials can produce valuable data. But there are serious weaknesses in oversight, informed consent, and transparency in these IITs that have implications for patient safety, including patient deaths that remained undisclosed for months or years. Recent Chinese reforms acknowledge the need for stronger controls; whether they will close these gaps remains uncertain. Where protections fail, patients bear the risks while companies outsource their bioethical standards to less regulated Chinese researchers.

American capital is financing the CCP's biotechnology ambitions, helping turn China's advantages into global competitiveness. Licensing agreements between U.S. pharmaceutical companies and Chinese biotechnology firms provide the latter with financing, while co-development partnerships help them acquire the regulatory, operational, and commercial expertise needed to compete internationally. U.S. VC firms are establishing new companies around Chinese assets and moving further upstream into Chinese laboratories and early research. These relationships do more than purchase individual drug prospects: they help build Chinese infrastructure and the expertise of future competitors. American capital finances the development, and revenues from American patients help reward the success. The United States is financing its own displacement.

The U.S. regulatory system is compounding the problem. Executives interviewed by the Select Committee describe burdensome and uncertain Food and Drug Administration (FDA) requirements and fragmented clinical trial startup processes that delay first-in-human clinical trials in the United States. Meanwhile, the FDA conducts far fewer clinical trial inspections in China than in the United States (about 4% of total volume) and generally does not inspect the early IITs that help attract investment and inform subsequent development.[2] Chinese-generated clinical trial data can then be used to support applications to the FDA for entry into the American clinical development system. The FDA has also been blocked at times from conducting inspections at high-risk sites at People's Liberation Army (PLA) hospitals, which exist to enhance the readiness and capabilities of the PLA. The FDA also does not conduct inspections in Xinjiang, where the U.S. government has determined that China is committing an ongoing genocide. Despite this, the FDA continues to accept clinical trial data from these locations. All of this creates an opportunity for regulatory arbitrage: companies obtain early

data under weaker scrutiny in China while companies developing treatments here bear the full costs of the U.S. system. Accepting early data generated under weaker safeguards also threatens the quality and reliability of evidence used to support trials in U.S. patients, ultimately risking patient safety.

China's speed also gives its companies an advantage in developing "fast follower" therapies built on discoveries first advanced by American innovators. Once an American company discloses its research or patent application, a Chinese competitor can develop a lightly altered version of the molecule around the same validated target and use faster clinical trials to obtain human data ahead of the originator, enabling it to license the follower to U.S. pharmaceutical companies or VC firms. Fast following is common throughout the industry and can produce better treatments. But the growth in its scale and speed in China represents a sea change and is diverting investment from the American companies doing costly foundational work. China's fast follower drugs have reportedly grown from 220 in 2015 to 3,352 in 2025.[3] Separately, ongoing lawsuits and personal accounts provided to the Select Committee credibly allege that some competing Chinese technologies were built using stolen trade secrets.[4]

These issues are addressed in greater detail in the findings of this report:

- Finding 1: China is Executing a Highly Coordinated, State-sponsored Industrial Policy to Dominate the Global Biotechnology Sector
- Finding 2: China's Fast Clinical Trial System is Accelerated by Weak Ethical Safeguards
- Finding 3: U.S. Companies are Fueling China's Strategy
- Finding 4: Challenges in the U.S. Regulatory and Clinical Research Ecosystem Encourage Drug Development in China
- Finding 5: Chinese Government Representatives have blocked the FDA from conducting certain inspections at PLA hospitals where major U.S. companies run clinical trials
- Finding 6: China's Innovation is Feeding Off of Fast Followers and Alleged Theft

The consequences of this competition extend beyond medicine. Biopharmaceutical success sustains scientific talent, investment, research infrastructure, and technologies that support gene editing, agricultural biotechnology, biomanufacturing, and other dual-use frontier applications. As early development moves abroad, clinical experience and investment will follow. Losing leadership in medicines risks weakening the foundations of American biotechnology itself.

The U.S. must respond with a comprehensive set of measures to protect American leadership and the U.S. biotech ecosystem from China's aggressive intentions, and to make the United States a more competitive place to develop new treatments.

Based on its findings, the Select Committee makes the following 12 policy recommendations:

- Stop subsidizing the CCP's strategy to dominate biotechnology and pharmaceuticals
- Restrict FDA acceptance of Chinese clinical trial data
- Ban FDA acceptance of clinical trial data from PLA hospitals and clinical trial sites in Xinjiang
- Modernize the U.S. clinical trial system
- Ensure strong support for foundational biomedical research
- Pressure the International Council for Harmonisation (ICH) to exclude China's membership
- Explore centralized Institutional Review Boards (IRB)
- Explore monetary incentives for companies that conduct early-stage clinical trials in the United States
- Explore surcharges or penalties for Investigational New Drug (IND) applications for therapies that were developed from early-stage clinical trials in China
- Study patent disclosure vulnerabilities affecting American biotechnology innovators
- Ensure the FDA and its clinical reviewers are adequately staffed
- Establish a White House Biotechnology Coordinator

Restrictions can buy time, but the United States must use that time to remove unnecessary barriers while upholding strong patient protections. It is far easier to protect an existing strategic sector than to rebuild one after it has been lost. Dependence on China for future medicines would create a profound national vulnerability. The U.S. still has time to act—if it acts now.

Background

Global Shift in Biopharmaceutical Innovation

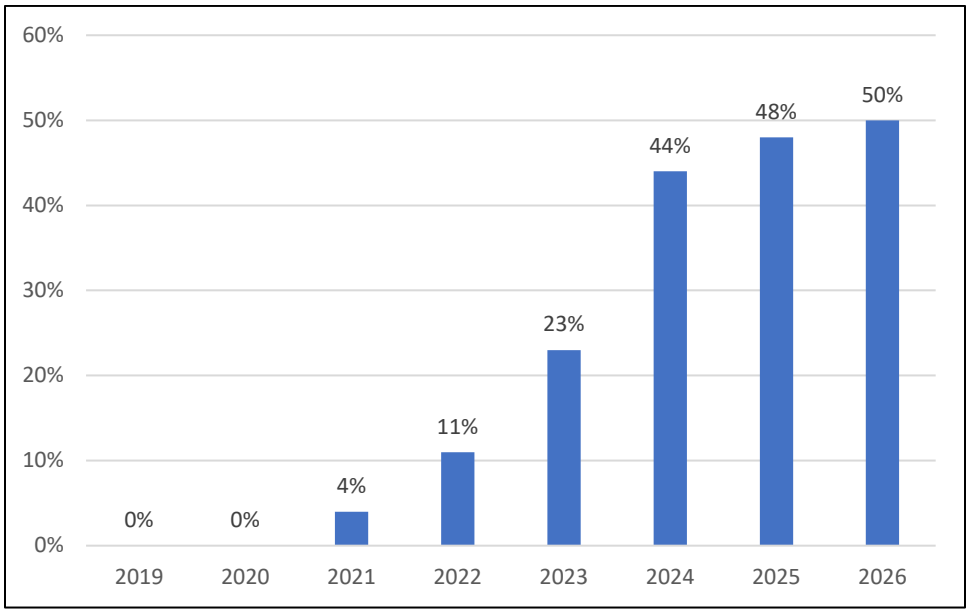
The life cycle of a drug begins in a science lab with a promising molecule, continues through multiple phases of clinical trials to test it for safety and efficacy, and ultimately leads to a market launch for innovative drugs. The patents for innovative drugs eventually expire, and generic versions come to market, offering cheaper and more accessible treatments.

The U.S. has been the world leader in pharmaceutical innovation—the early phase of this life cycle—for decades because of our reinforcing ecosystem of basic-research funding, robust capital markets, world-class scientific talent and research labs, strong intellectual property (IP) protections, a regulatory environment that ensures ethical and scientifically rigorous clinical trials, and a pricing environment in the U.S. that rewards the enormous cost and risk of drug development.

For years, as the U.S. established itself as the global source of newer, advanced therapies, China has been known for manufacturing the key inputs to cheap and generic drugs due to its labor and manufacturing cost advantages or for producing copycat or fast follower drugs. Over the past five years, however, the biopharmaceutical competitive landscape has shifted ***dramatically***. Chinese biotechnology companies are now developing novel drugs in high-value areas, including treatments for cancer, immune system disorders, and diabetes. China's increasing biopharmaceutical innovation is evident in the growing number of Chinese biotechnology firms licensing the right to their innovative drug prospects to large American and European pharmaceutical companies for millions, if not billions, of dollars in upfront payments, milestone fees, and royalties on sales.

In 2025 alone, ***48%*** of all large pharmaceutical global licensing deals with upfront payment of $50 million or more were inked with Chinese companies, up from ***0% in 2020*** and 4% in 2021, as shown in the figure below.[5] In the first quarter of 2026, the cross-border out-licensing activities of Chinese biotech firms were reported to have reached a record transaction value of $60 billion—a 73% jump from the same period a year earlier and nearly half of the total $135.7 billion worth of agreements signed in 2025.[6] Out-licensing is when a pharmaceutical or biotech company grants another company the rights to develop, manufacture, market, or otherwise commercialize its drug, technology, or IP—usually in exchange for fees, milestone payments, and/or royalties.

Figure 1: Percent of Large Pharma Licensing Deals of $50 Million or More Upfront Done with Chinese Counterparties, 2019 to 2026[7]



Source: DealForma, through June 13, 2026.

This trend is set to continue, as U.S. pharmaceutical companies are facing what are known as "patent cliffs." The key patents of many U.S. drug companies are set to expire on billion-dollar-plus "blockbuster" drugs generating approximately $230 billion in annual sales between this year and 2030.[8] This means U.S. drug companies are on the hunt for new money-making drug prospects to offset that lost revenue, and they are increasingly looking to China's biotechnology companies. Due to numerous factors, this often comes at the expense of U.S. biotechnology companies. By 2040, Chinese drugs are projected to account for 35% of U.S. FDA approvals, up from only 5% now.[9]

These deals are indicative of a massive and rapid shift in the global biopharmaceutical ecosystem, driven by the CCP's highly coordinated strategy to take over the supply chain of new medicines. The Select Committee spoke with dozens of leaders from the biopharmaceutical sector, including from biotechnology and pharmaceutical companies, industry associations, VC firms, clinical trial sites, research institutions, and government agencies to understand how this shift occurred and why it matters.

Developing Drugs in the U.S. is a Costly, Time-Consuming, and Risky Venture

The U.S. drug development process, while producing groundbreaking medicines, is extraordinarily expensive, slow, and high-risk. Drug prospects go through a lengthy, multiyear development and clinical trial review process to identify, develop, and finally commercialize a new medicine. Industry research has found

that, from laboratory discovery to FDA approval, a drug takes at least 10 years, with the clinical trial phase accounting for about six to eight years of this time.[10]

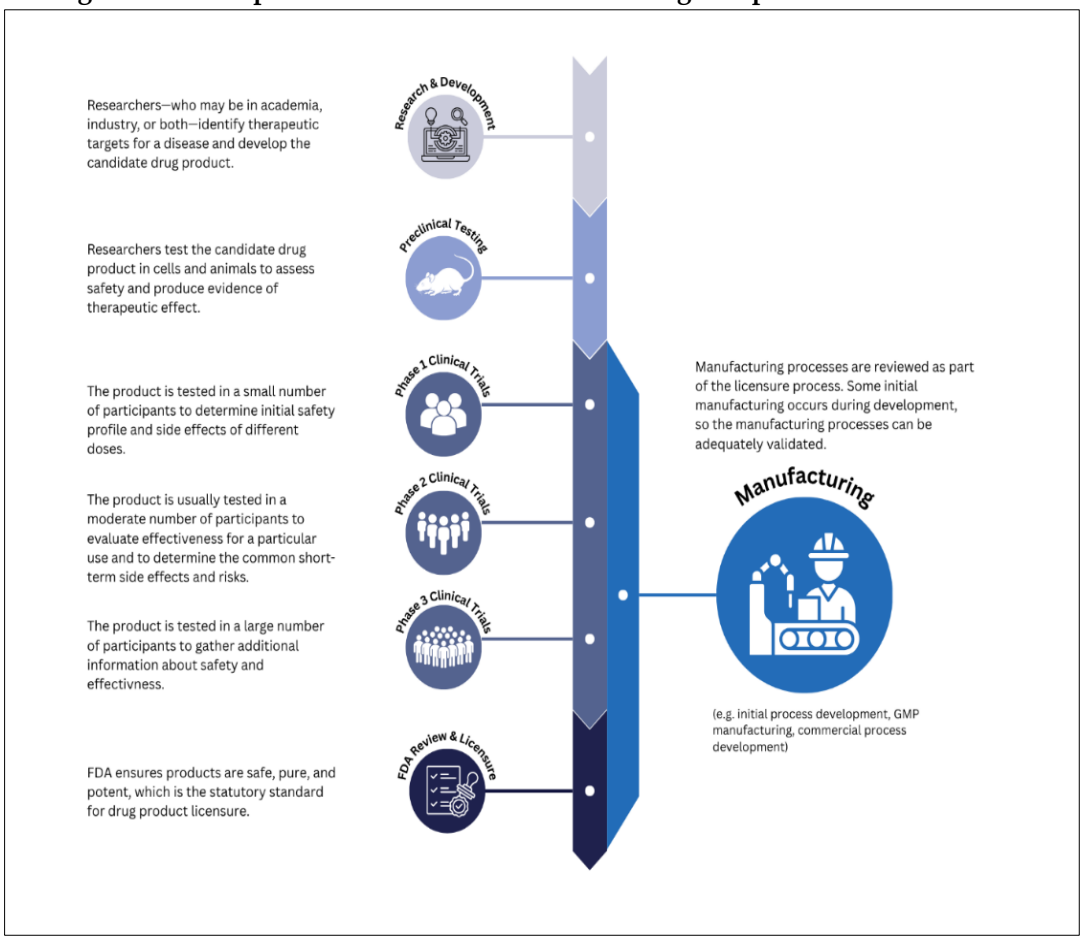
The risk of failure is high: Some analysts estimate that only roughly 7 to 8% of drug development candidates entering Phase I human clinical trials receive FDA approval.[11]

The drug development process begins with foundational research in a university lab or another research institutions as researchers hunt for novel drug targets and groundbreaking therapies. This is largely funded by grants from government agencies, foundations, and nonprofits. At this stage of early discovery, researchers are identifying therapeutic targets, filing for patents to protect their IP, and testing the concept in laboratory settings.

The most promising early discoveries are licensed to existing companies or spun off to become the core assets of new companies (biotech companies) formed to further develop these potential therapies or platform technologies, readying them for sale to a larger company or eventual commercialization.

From the lab, potential therapies are typically tested in animals and go through three phases of human clinical trials with increasingly large numbers of participants to gather information about safety and effectiveness before they are reviewed by the FDA for final approval.[12] Under federal law, a new drug must be shown to be safe and effective for its intended use before it can be marketed in the U.S.[13] The graphic below depicts the general phases of this process.

Figure 2: Development and Review Process for Drug Prospect[14]



Each phase of this process can take one to two years (or more) and requires that the researcher or company testing a drug candidate work with the FDA through its Investigational New Drug (IND) application to gain approval to conduct clinical trials in the United States.[15]

Clinical trials in the U.S. also generally must be approved by independent Institutional Review Boards (IRB) at each clinical trial site. IRBs operate separately from the FDA and exist to ensure that the study is conducted ethically, including that enrolled patients provide informed consent.

This process is enormously expensive, and biotech companies typically rely on outside funders, such as grant organizations or VC firms, to enable the preparation of data for submission to the FDA, as well as early stages of clinical trials. A large, well-funded biotech company may be able to shepherd its most promising assets through FDA approval and commercialization. Many biotech companies, however, are acquired by, or license their top drug prospects to, deep-pocketed pharmaceutical companies that can fund global Phase III clinical trials and obtain market approval from the FDA.

In written testimony to the Select Committee, biotech VC executive Francisco Gimenez of 8VC stated: "When you incorporate a low success rate of ~10%, the fully loaded cost of each successful drug is somewhere between $1 and $3 billion. To put it plainly: making a new drug is equivalent to building a skyscraper in Manhattan, where 90% of those skyscrapers explode at some stage of construction."[16]

Time to First-in-Human Data is the Currency of the Industry

The currency of drug development is time and human data. According to many U.S. biotech executives and VCs, the most critical step for a biotech firm is getting its new drug into humans as quickly as possible. The early efficacy data are what the industry runs on because most drugs fail.[17] Since bringing a drug to market costs billions of dollars, early data on the safety and efficacy of drug prospects tell investors whether to pivot or double down.

Patents add to the pressure. A patent application becomes public 18 months after it is filed, and the patent expires 20 years after filing. Because it takes roughly 8 to 12 years from patent filing to drug approval, companies have an ever-shrinking window to recoup their investment. Every day spent in development is a day of patent-protected revenue lost, so the faster a drug reaches market, the more the company earns.

Speed in this space is where China is creating an advantage.

Findings

Finding 1: China is Executing a Highly Coordinated, State-sponsored Industrial Policy to Dominate the Global Biotechnology Sector

The CCP is executing a highly coordinated, state-sponsored industrial policy to dominate the global biotechnology sector. The policy origins can be traced back decades through its five-year plans and other industrial policy initiatives. China's "Made in China 2025" initiative targeted biopharmaceuticals as a priority sector, and China has since gradually intensified and expanded its aims through successive five-year plans to target self-sufficiency and eventually global dominance. [18] The CCP views biotechnology as a key to future economic development and comprehensive national power.

Most recently, in its 15th Five-Year Plan, the CCP called for PRC global leadership in biotechnology innovation, building a self-sufficient biotech ecosystem, and achieving breakthroughs in frontier biotechnologies like pharmaceutical innovation and brain science. [19] The plan also outlines ambitious goals to lead significant portions of global drug innovation by 2030, announcing its intentions to directly compete with existing U.S. and other multinational pharmaceutical companies, including:

- Biopharmaceutical R&D and application will consistently rank among the best in the world.
- China-developed first-in-class drugs will make up at least 25% of the global total.
- The number of new drugs undergoing first-in-human clinical trials and the number of innovative drugs launched rank among the top in the world.
- Pharmaceutical enterprises will generate a combined 3.5 trillion yuan (about $522 billion USD) in revenue, with at least five blockbuster drugs generating $1 billion in sales.
- 20% annual growth in the innovative drugs sector. [20]

To achieve these aims, China has directed massive central and local subsidies into its biotechnology infrastructure; [21] established sprawling biotechnology innovation parks; [22] used talent programs to repatriate Chinese scientists trained and educated in the United States into its domestic biotech system; [23] and made significant reforms to its clinical trial system under the National Medical Products Administration (NMPA) to better align it with international standards, including joining the ICH [24] as a regulatory member in 2017. [25]

Finding 2: China's Fast Clinical Trial System is Accelerated by Weak Ethical Safeguards

China has created an environment where first-in-human data for promising drug prospects—the currency of the biotech industry—can be obtained more quickly and cheaply than anywhere else in the world, and where compromised ethics and risky science are a feature, not a bug.

China created an unregulated pathway for first-in-human data

In 2015, China began making significant reforms to the way that it conducts early-stage human clinical trials. It moved aggressively to shorten the timeline for testing novel therapeutics in human patients, ultimately transforming itself from one of the slowest drug development systems to one of the fastest in the world. In the U.S., moving from ideation to dosing the first human patient takes 24 to 36 months, according to Jacob Becraft, CEO of Strand Therapeutics, who testified before the Select Committee.[26]

China has created dual paths for conducting human clinical trials. The first pathway is a formal clinical trial IND process governed by China's NMPA, which is aligned with ICH standards, and is used to generate clinical trial data to support drug registration and commercialization in China or elsewhere around the globe. Like trials overseen by the FDA, these trials require a formal IND application and technical review by NMPA's Center for Drug Evaluation. In 2018 China introduced an "implied approval" system for IND applications and updated in it 2025 so eligible clinical trials can begin within 30 days if no objections are raised.[27] This replaced China's prior open-ended approval system, which was known for long delays.[28]

The second pathway is China's investigator-initiated trial (IIT) system—a fast, decentralized clinical trial option to generate first-in-human data. IITs can be quickly initiated by doctors or researchers on site at hospitals, with approval from a hospital's ethics committee (akin to an IRB in the Western world), without having to obtain national regulatory approval or adhere to the same stringent Good Clinical Practice[29] and perhaps also Good Manufacturing Practice standards required for formal Phase I trials conducted under regulatory agencies like the NMPA or FDA.[30] While Good Clinical Practice is technically required, there is questionable oversight of these trials to ensure compliance with those standards. Chinese IITs are not designed to be an alternative to INDs in China or in the U.S. IITs are used to provide early safety and proof-of-concept efficacy data for new molecules or biologics that can de-risk investments, inform dose selection, and generate data that can support IND submission packages for therapies seeking commercialization.

China's speedy patient enrollment is enabled by weak ethical safeguards

A critical factor adding to China's clinical trial speed is its ability to enroll patients quickly—reportedly two to five times faster than patients are enrolled into trials in the U.S.[31] This is due in part to the large, treatment-naïve potential patient populations that are concentrated around large hospitals in China where clinical trials are conducted.[32] The speed of China's patient enrollment is also helped along by its lack of ethical safeguards surrounding individual patient rights and informed consent, making it easier to quickly enroll patients, according to some U.S. biotech executives who have worked in China.[33]

Industry trade publication articles dating back to 2007 and 2010 touting clinical trial opportunities in China forecast this issue, but framed it as a cultural benefit that would enhance the speed of patient enrollment:

- "…within the Chinese culture (more so than in the West), physicians are highly respected and trusted. As a result, patients are more likely to enroll in a trial if their physician recommends it..."[34]
- "Most Chinese subjects enroll in a clinical trial when they see a doctor or they are hospitalized. If the investigator finds the patient meets inclusion criteria, they try to *persuade* (emphasis added) them to participate in the study after the patient is given some general information about it. However, the patient has the right to refuse the investigator's offer. One study estimates that in the United States, 66% of subjects enroll independently of their doctor. In China, almost 90% to 100% of subjects are offered enrollment by their doctor."[35]

This patient-trust model presents concerns given the rise in IITs in China where a physician recruiting a patient could also be the same person who designed the trial and stands to benefit most from enrollment numbers, which could present conflicts of interest. For instance, China's National Cancer Hospital in Beijing conducts more than 100 clinical trials at any given time—about 60% of them initiated by investigators, according to public reporting.[36] Similarly, in large industry-sponsored trials, principal investigators are selected in part for their patient populations and their ability to recruit a sufficient number of clinical trial volunteers who meet the inclusion criteria.

While China has laws requiring informed consent in clinical trials, Chinese researchers have documented significant issues with obtaining informed consent in practice. For example, a 2023 review of research on informed consent in Chinese cancer clinical trials found that:

- 91.2% of surveyed participants mistook clinical trials for the standard-of-care treatment;
- 55.9% of surveyed participants said their doctors did not offer any alternatives besides treatment in a clinical trial and 41.2% were unsure whether they had been offered alternative treatments;

- More than 70% of surveyed participants in cancer drug trials believed that treatment regimens studied in the trial were proven to be the best;
- 80% of surveyed participants mistakenly believed that drugs in clinical trials would not cause severe side effects;
- Undue influence was observed in clinical trials and investigators were prone to tendentious explanations of trials, including understating potential toxic effects and overstating efficacy of trial protocols.[37]

A 2025 study involving a literature review and two rounds of expert consultation with researchers, ethics committee members, regulatory officials, clinical trial sponsors, and contract research organizations (CRO) identified significant gaps in the protection of clinical trial participants in China, including:

- 81.25% of experts consulted agreed that investigators exhibit a deficiency in awareness and competence around informed consent obligations, often not affording it the requisite attention;
- 93.75% of experts consulted agreed that there is a lack of legal norms governing the precise execution of comprehensive informed consent for clinical trial human subjects;
- 87.5% of experts consulted agreed that a fortified oversight regime for the actual informed consent process is essential.[38]

A 2025 study that sampled 287 clinical researchers from China's Clinical Trial Registry found persistent ethical challenges in Chinese clinical trials stemming from personal ethical limitations and structurally weak oversight systems.[39] Selected quotes from clinical researchers cited in this study are in Figure 3 below.[40]

Figure 3: Ethical Observations from Chinese Clinical Trial Researchers

"After ethical approval, no one really comes to oversee it. How you performed in the clinical trial or whether you obtained informed consent…No one cares."

"The research cycle is short and the time is tight … which makes some researchers can't wait to start clinical studies until ethical approval is obtained."

"Ethical violations mainly occur during the informed consent process. Some physicians lack objectivity when presenting information. They often overemphasize incentives such as free medication and patient subsidies, while failing to clearly explain the nature of the study."

"To reduce the impact of the unethical behavior, some departments or hospitals tend to downplay the wrongdoing. Some hospitals even pay for the misconduct and try to cover it up."

China is now among the cheapest and fastest places in the world to develop new medicines

Between China's streamlined IND pathway, unregulated IITs, and speedy enrollment, developing medicine in China is now materially faster and cheaper than in the United States. According to some U.S. biotech executives, China's streamlined clinical trial pathways and cheaper labor and input costs have led to China being able to generate human clinical data two to five times faster and 30% to 50% cheaper than in the United States.[41] The head of a large U.S. pharmaceutical firm told the Select Committee that it can be up to *eight* times cheaper to run certain trials in China than the in United States.[42] This is due in part to China providing large direct subsidies at the central and local levels to lower the cost of drug development, including financial support for clinical trial sites, tax breaks, and research funding.[43] The cost of medical care for patients in clinical trials—for which trial sponsors are generally responsible—is also significantly lower in China.[44]

Chinese biotechnology firms are the greatest beneficiaries of this system, although U.S. and other multinational firms are also increasingly going to China to conduct their clinical trials. In 2024, according to one analysis, 14.3% of clinical trials in China were conducted by multinational firms. While still a relatively small percentage of trials conducted in China, the percentage has been growing at a compounding annual rate of 7% since 2019 and the trend is expected to continue, according to a China-based life sciences market analyst.[45]

These data do not tell the whole story, however, as many of the drugs tested by Chinese biotech firms in early-stage trials in China are now being licensed to U.S. or multinational pharmaceutical companies or Western VC firms. Furthermore, several U.S. biotech company and VC executives told the Select Committee that U.S. companies are increasingly being strongly encouraged by their boards and investors to move their early-stage drug development to China to compete due to cost and speed advantages in China.[46]

In 2021, China's global share of Phase I trials surpassed that of the U.S. for the first time.[47] In 2024, according to the World Health Organization's International Clinical Trials Registry, China registered over 7,100 clinical drug trials across all phases, compared to about 6,000 in the U.S,[48] or about 39% of global trials. China's lead in clinical trials may be even greater as the number of IITs is not formally tracked.

To assess the impact of IITs, various researchers have attempted to capture the number of IITs in specific therapeutic areas. While they differ in methodology and timeframes, these studies show that IITs in China are an increasingly dominant modality for innovative drug development in China. For example, one research study found that 1,033 IITs were conducted to test cell and gene therapies between 2015 and 2023, and that the annual number grew 11-fold between 2015 and 2023.[49]

Another study examining cell therapy clinical trials in China—the majority of which target cancer—found that 90% of clinical trials conducted from 2005 to 2024, or 2,519 trials, were IITs.[50]

High-risk Chinese IITs compromise patient safety for innovation

IITs are the rocket fuel of China's biotech innovation ecosystem. Cutting-edge biotech companies are now flocking to China to get the type of early data needed to entice investments from U.S. VC firms or pharmaceutical companies necessary to get their drugs to market. With little scrutiny, IITs also allow biotech companies to test cutting-edge therapies to see whether their medicines are promising—or to quickly fail, return to the lab to iterate, and start up a new trial with the modified prospect. One U.S. biotech executive described this to the Select Committee as "N of 1 permutation testing," or serial single-patient trials where the patient is the experimental unit for engineering iteration.[51] In some cases, this means that trial patients are essentially guinea pigs subject to experimental testing.

Media reporting about the use of IITs to develop cutting-edge cell therapies quoted Lu Han, CEO of Imviva Biotech (formerly known as Bioheng Therapeutics), as saying that IITs can help a company "fail fast."[52] Han's company is using IITs to develop off-the-shelf cell therapies, where cells from a donor are manufactured in advance and are prone to immune rejection responses from patients. "If you really want to crack this code of immune rejection, you might need a little more than just one or two trials – maybe 10 or even more," Han said.[53] Absent from the calculation are the patients who are the subjects of these failed trials and whether they understand the risks of these highly experimental tests.

While IITs can and do produce high-quality science, the quality and safety of an IIT depend entirely on the individual investigator and local ethics officials. Recent investigative reporting by U.S. publications exposed the dark side of these types of high-risk experiments: three separate, tragic deaths of patients in China—two of them children—enrolled in experimental therapy IITs.[54] The three cases differed in disease, therapy, and company, but each was marked by risky science, limited regulatory oversight, and serious ethical questions. And, in each case, the fatalities stayed hidden for months or years.

Media reporting indicates that HuidaGene, which sponsored the trial in which a young boy died from a severe immune response to an experimental CRISPR gene editing therapy for Duchenne muscular dystrophy, was already known for conducting questionable IITs for gene editing therapies.[55] One U.S. biotech executive told STAT in late 2024, "They are shoving as much Cas into the clinic as they can without much thought," using Cas as a shorthand for CRISPR-Cas9.[56] CRISPR is a gene-editing technology whose development earned the 2020 Nobel Prize in Chemistry, allowing scientists to make targeted changes to DNA. STAT's reporting on this case indicates that the problem in the trial was not CRISPR itself, but how the therapy was delivered.[57] Applying gene editing to diseases like

Duchenne is high-risk because delivering editing tools to muscle tissue requires high doses of viral vectors, which can trigger dangerous immune reactions.[58] Such risks demand careful dose escalation and independent safety oversight—safeguards STAT reported were absent in HuidaGene's IIT trial.[59]

China has recently instituted new guidelines for clinical research in certain new biomedical technology areas (gene therapy, cell and cell-derivative therapies, tissue and organ therapies, microbial therapies, brain-computer interfaces) through State Council Order No. 818.[60] Among other things, the regulation stipulates:

- non-clinical research, including laboratory studies and animal experiments, must be completed and must demonstrate safety and efficacy before human clinical research begins;
- clinical research can only be conducted at institutions that are class III grade A medical institutions, the highest tier in China's hospital classification system;
- informed consent requirements and prohibitions on charging patients for research;
- clinical research must be independently approved by an academic committee and an ethics committee;
- the research plan must be filed with China's National Health Commission, which has the authority to suspend or terminate the research if risks emerge.

While increased regulatory scrutiny is desperately needed in China's biotech ecosystem, it remains to be seen how effective the guidelines will be in reining in risky IITs for novel medicines. Several of these elements were already in place for the recently reported clinical trial death of a 6-year-old girl: the trial occurred at Xinhua Hospital, a top-tier Chinese hospital, and a primate study was conducted, but the ethics committee reportedly approved the trial without reviewing the final study results.[61] The new guidelines also highlight the glaring scientific and ethical gaps that have existed previously—such as absence of required animal testing before humans—which Chinese biotech companies have ostensibly leveraged to drive their innovation forward.

Finding 3: U.S. Companies are Fueling China's Strategy

U.S. pharmaceutical companies and VC firms are fueling China's global biotechnology leadership ambitions through multibillion-dollar licensing and co-development deals. United States capital flowing to Chinese biotechnology companies through licensing agreements, equity investments, and other co-development strategies is fueling China's strategy, aiding it in its rapid ascent up the pharmaceutical value chain.

U.S. pharmaceutical companies are increasingly signing deals with Chinese biotech companies to license and co-develop Chinese-origin drug prospects

Cross-border out-licensing deals between United States and European pharmaceutical firms and Chinese biotechnology firms continue to increase as a share of licensing activity and deal value. In the first half of 2026, large global pharmaceutical companies completed 10 China-origin licensing deals with at least $50 million upfront, totaling $4.4 billion in upfront cash and equity—already nearing the 2025 full-year total of $5.1 billion.[62] Globally, China-origin assets represented 42% of big pharma deals with $50 million-plus upfront, with 68% of all upfront dollars in licensing deals going to Chinese companies—almost double the 36% share that went to Chinese biotech companies in 2025.[63] The top five licensing deals in total deal value all involved a Chinese out-licensor.[64] Table 1 below shows recent licensing and co-development deals by U.S. companies for Chinese assets.

Table 1: Select U.S. Licensing Deals for Chinese Assets, by Company[65]

Company	Date	Licensor	Asset & Target	Upfront*/Total	Structure
BMS	May 2026	Hengrui	13 early-stage programs	$600M / $15.2B	Co-development, platform
	Dec 2025	Harbour BioMed	Antibody discovery programs	$90M / $1.1 B	Co-development, platform
	Dec 2023	SystImmune	Iza-bren, EGFR×HER3 bispecific ADC	$800M / $8.4B	Co-development & licensing
Pfizer	May 2026	Innovent	12 early-stage and de novo oncology programs	$650M / $10.5B	Co-development & licensing
	May 2025	3SBio	SSGJ-707, PD-1×VEGF bispecific	$1.25B / $6.05B	Single asset license + $100M equity
Merck	Sep 2026	SciBrunch	SPR2015, KRAS G12D inhibitor	$400M / $2.13B	Single asset license
	Mar 2025	Hengrui	HRS-5346, oral Lp(a) inhibitor	$200M / $1.97B	Single asset license
	Dec 2024	Hansoh	HS-10535, oral GLP-1	$112M / ~$2.0B	Single asset license
	Nov 2024	LaNova	LM-299, PD-1×VEGF bispecific	$588M / ~$3.3B	Single asset license
	2021 2022 2023	Kelun-Biotech	Sac-TMT, TROP2 ADC, + other ADCs	~$257M / ~$11.8B	Series of Multi-asset licenses
Eli Lilly	May 2026	Haisco	Up to 5 undisclosed programs	$87M / ~$3.05B	Co-development & licensing, discovery, platform
	Mar 2026	Insilico Medicine	AI-discovered programs	$115M / $2.75B	Collaborative AI research, discovery
	Feb 2026	Innovent	Oncology & immunology programs	$350M / $8.85B	Co-development & licensing, platform
AbbVie	Jan 2026	RemeGen	RC148, PD-1×VEGF bispecific	$650M / $5.6B	Single asset
Summit	Dec 2022	Akeso	Ivonescimab, PD-1×VEGF bispecific	$500M / $5.0B	Single asset

Notes: Some of the upfront numbers include near-term payments. The totals include the upfront payment and "biobucks," which include development, regulatory and commercial milestones that are rarely paid in full.

U.S. companies are not just buying the rights to Chinese biotech innovation. Public reporting about recent deals by large U.S. pharmaceutical companies including Eli Lilly (Lilly),[66] Pfizer,[67] and Bristol Myers Squibb (BMS),[68] have moved beyond licensing and into co-development. BMS, for example, announced a partnership worth up to $15.2 billion with Chinese biotech firm Hengrui Pharma, involving co-development of early-stage molecules from each company's pipeline and the apparent transfer of IP and know-how from BMS to Hengrui.[69] According to BMS'

press release, the deals include "four oncology/hematology assets from Hengrui, four immunology assets from BMS, and five innovative assets to be jointly discovered and developed by both companies, leveraging Hengrui's discovery engine and platform technologies across several innovative modalities." [70] Hengrui also "has the option to co-develop select assets and the potential to conduct certain commercialization activities globally with BMS."[71] As one reporter described, the deal enables Hengrui to gain access to "some of the fruits of BMS' drug discovery engine, plus its partners' global R&D regulatory and commercial capabilities."[72]

The CCP's goal is not for its biotech firms to be the innovation farm systems that license drugs to U.S. pharma companies or to achieve dominance of early-stage medical trials. Its goal is to grow global pharmaceutical companies that can actively compete with and eventually displace U.S. and other multinational companies—as the CCP made clear in its most recent five-year plan.

Chinese biotechnology executives have been clear about their intentions in partnering with U.S. companies. For example, Zhu Yi, the chairman of Chinese pharma company Sichuan Biokin Pharmaceutical, who partnered with BMS in a 2023 licensing and co-development deal, said in 2025: *"Partnering with a multinational [pharmaceutical company] lets us learn first-hand how global operations work. It's like having a personal tutor showing you, day by day, how to build a global business…we mirrored that and learnt by doing."*[73]

Similarly, Innovent CEO Michael Yu, who inked a co-development deal with Pfizer in May 2026, has spoken of his plan to develop Innovent into a global premier biopharmaceutical company by 2030, with the help of U.S. companies like Pfizer, as reported by Fierce Biotech and detailed below in Figure 4.[74]

Figure 4: Pfizer's Partnership with Innovent: Developing a Global Competitor

In May 2026, Pfizer and Innovent Biologics, a Chinese biotech company, entered a strategic global licensing and collaboration partnership for the research and development of 12 promising cancer medicines—eight from Innovent's pipeline and four to be proposed by Pfizer. The deal could be worth up to $10.5 billion, including a $650 million upfront payment to Innovent with another $9.85 billion in payments linked to development, regulatory, and commercial milestone payments, licensing, co-development, and co-commercialization of the drug prospects.

In reporting by Fierce Biotech, Innovent CEO Michael Yu was clear about how deals like this one with Pfizer are fueling his ambition to make Innovent a global pharma company.

"The deals Innovent has signed so far 'not only bring substantial financial returns to the company, but more importantly, integrate global resources to accelerate the realization of our pipeline's value and help us build the core capabilities needed for our journey to becoming a truly global biopharmaceutical company,' Yu said during Innovent's 2025 full-year earnings call in March [2026]. 'We are confident to propose our Vision 2030: evolving from a leading biopharmaceutical company in China into a global premier biopharmaceutical company,' he said."

"Pfizer initially resisted the co-development, co-commercialization structure, Yu recalled. Leveraging interest from other parties, Innovent threatened to walk away."

"Market reality determines that a company with first-tier ambition must aim for the Western market.… For now, Innovent's global capabilities, including clinical development, regulatory affairs and manufacturing, are not robust enough to get a novel drug across the FDA by itself, the CEO acknowledged. On the commercial side, Innovent is no better than a biotech startup when it comes to reimbursement negotiations, placement on hospitals' drug formularies, medical affairs, as well as distribution and marketing pathways in the U.S., he added. 'That's why we have to find a company that is willing to take this journey together with us,' Yu said."

U.S. VCs are forming new companies to license and develop Chinese biotech drug prospects

U.S. VC firms have also rushed in to boost Chinese biotech. Chinese capital is limited, so funding from American VC investors is critical to helping Chinese biotech firms develop their assets. One common model is where VCs form new companies—called NewCos—with Chinese biotech companies to license, develop, and manage the latter's promising drug prospects. Initially, the trend started with NewCos being established around mature, late-stage drug prospects with clinical proof-of-concept from China. As demand for those increased amid the flood of licensing deals with large pharmaceutical firms, the model has evolved with many VCs now forming companies around early-stage prospects, such as those in Phase I trials or even in preclinical phases.[75]

According to public reporting, some VC firms are now actively courting Chinese scientists and biotech companies by "moving upstream, embedding themselves in labs and courting scientists before they publish their research" in an effort to identify potential drug prospects before they reach the market.[76] In some cases, the goal of these partnerships is to eventually sell the drug prospects developed by these NewCos to large pharmaceutical firms.

For example, U.S. VC firm RA Capital is a major investor in the Chinese biotech sector. According to public reporting, it partnered with BioBay, a state-backed, government-owned Chinese organization, to invite 60 scientists from across China to meet with them in a series of roadshows. At these roadshows, scientists could be offered funding support or help in designing a strategy, building a team, or conducting overseas operations.[77] RA Capital has also launched an initiative to help its U.S. portfolio companies navigate early-stage clinical trials in China, advertising its services as "Chinese clinical trial expertise in a box," and to help them identify Chinese biotech companies to partner with.[78]

Table 2 below describes significant U.S. VC-funded deals based around Chinese assets.

Table 2: Select U.S. VC-backed NewCos Built Around Licensed Chinese Biotech Assets

Date	NewCo (lead VCs)	Licensor	Asset & Target	Upfront*/Total
May 2024	Kailera (Bain Capital LS, Atlas, RTW)	Hengrui	3 GLP-1-based obesity drugs incl. ribupatide	$110M + ~19.9% equity / ~$6.0B
Jan 2025	Verdiva (General Atlantic, RTW)	Sciwind	GLP-1 obesity portfolio, incl. ecnoglutide	$70M / ~$2.5B
Feb 2026	Solstice Oncology (RA Capital; Canaan, Forbion participating)	Harbour BioMed	Porustobart (HBM4003), Fc-enhanced CTLA-4 antibody, MSS colon cancer	$55M cash + >$50M equity / ~$1.1–1.2B
Sep 2025	Braveheart (OrbiMed, Forbion)	Hengrui	HRS-1893, cardiac myosin inhibitor, oHCM	$65M (half equity) / ~$1.1B
Aug 2023	Aiolos (Atlas, Bain Capital LS, Forbion, Sofinnova)	Hengrui	SHR-1905, TSLP antibody, asthma	~$25M / >$1B
Jan 2025	Windward (OrbiMed, Novo Holdings, Blue Owl)	Kelun + Harbour BioMed	WIN378, long-acting TSLP antibody	$45M (cash + equity) / ~$1.0B
Sep 2025	Kalexo (Aditum Bio)	Mabwell	2MW7141, dual-target siRNA, dyslipidemia	$12M + equity / $1.0B
Nov 2024	Ouro (Monograph, GSK)	Keymed	CM336, BCMA×CD3 T-cell engager, autoimmune	$16M + 15% equity / ~$626M
Jan 2025	Prolium (RTW)	InnoCare + Keymed	ICP-B02, CD20×CD3 T-cell engager	$17.5M + equity / $520M
Jan 2025	Timberlyne (Abingworth, Bain Capital LS, Venrock HCP)	Keymed	CM313, CD38 antibody, autoimmune	$30M + ~26% equity / ~$368M

Notes: Some of the upfront numbers include near-term payments. The totals include the upfront payment and "biobucks," which include development, regulatory, and commercial milestones that are rarely paid in full. Windward is a Swiss company and Verdiva is UK-headquartered, but both are largely backed by U.S. investors.

Licensing deals threaten to hollow out the U.S. biotech ecosystem

More than a dozen U.S. biotech executives and industry experts expressed concern to the Select Committee that U.S. pharmaceutical and VC deals with Chinese biotech companies threaten to hollow out the U.S. biotech ecosystem, as billions of dollars are invested in China instead of the U.S.[79]

U.S. pharmaceutical and VC executives who are heavily invested in China have told the Select Committee that China licensing deals are not detracting from the U.S. biotech system, and that the state of the U.S. ecosystem is strong. They pointed to the historic level of mergers and acquisitions (M&A) involving U.S. biotech firms as a marker of the health of the sector. According to data provided to the Select Committee by one VC firm, there was a record $118 billion worth of disclosed public and private acquisitions of U.S. biotech companies in 2025—a major reported increase over cumulative deals worth $40.1 billion in 2024, $99.7 billion in 2023, $45.4 billion in 2022, and $51.2 billion in 2021.[80] In 2026, there were reportedly 36 M&A transactions of at least $1 billion as of July 6, 2026—on track to surpass 2025 activity, according to this same data set.

Other U.S. biotech insiders disputed that high levels of M&A activity were a clear marker of health for the U.S. biotech sector, arguing instead that it was more representative of pharmaceutical firms looking for drug prospects in the face of looming patent cliffs and U.S. biotech companies being forced to sell their companies due to a lack of available VC funding with which to develop their own assets. One biotech VC argued that M&A activity is a lagging indicator that largely reflects venture investments made years earlier and says little about whether early-stage drug development can get funded today. The M&A data also include the acquisitions of U.S.-based VC-backed NewCos that were formed around Chinese biotech assets. For example, two of the NewCos highlighted in the table above—Aiolos and Ouro—were acquired by large pharmaceutical companies for more than $1 billion.[81]

In fact, fewer U.S. biotech companies are getting funded. Biopharma venture rounds are running at roughly 470 VC funding deals a year in 2026, versus 803 in 2021 and 564 in 2022, according to industry analysis.[82] VC dollars available remain about 27% below the 2021 peak, although funding is on an upswing since 2023.[83] As U.S. venture investors increasingly source early-stage assets from China, early-stage U.S. biotech companies face a more difficult funding environment. Even early-stage U.S. biotech companies are increasingly engaging Chinese companies to evaluate whether purchasing Chinese innovation is more efficient than developing their own early-stage assets, according to public reporting,[84] an ominous sign of growing U.S. dependency on China for future drug innovation.

A June 2026 report by Cure, a healthcare research and innovation company, rated the U.S. and Chinese biotech industries on 35 metrics across six areas.[85] China had clear leads on clinical development and supply chain metrics. U.S. strengths included capital and commercialization metrics, such as venture funding, regulatory credibility and the business-development ecosystem. The scorecard found that the two countries were tied on scientific discovery with the U.S. leading in research quality and novelty, while China leads on volume. Essentially, China supplies fast, cheap clinical assets, and U.S. companies and VCs bring the capital and commercial reach to take them global. Surveyed experts did not expect the fragile U.S. leads to last beyond the next 10 years. According to the National

Security Commission on Emerging Biotechnology ("the Biotech Commission"), the window is even smaller: the U.S. has only a three-year window to secure its lead or risk ceding it to China.[86] These deals are especially insidious as they are steadily eroding the American biotech ecosystem's advantages by sending U.S. capital to China, bolstering its scientific discovery and clinical development engines, as licensing and co-development deals risk transferring our commercialization know-how.

On October 16, 2026, the Chinese government proposed adding five innovative biopharmaceutical technologies to its export control list to block foreign acquisitions of proprietary cell and gene therapy and small interfering RNA (siRNA) and pathogen gain-of-function platforms.[87] It also proposed restricting transfers of technologies for discovering and validating entirely novel drug targets in those same two fields.[88] Notably, however, these proposed restrictions explicitly exclude the out-licensing deals between U.S. companies and Chinese biotech companies, among other things.[89] The restrictions and allowances the CCP believes are necessary to support its strategy of global pharmaceutical domination should be a clear wake-up call to American companies. The CCP is controlling foreign access to future medicines and innovation platforms, while leaving open the licensing channel that today brings in foreign capital and access to the American market.

The Select Committee recognizes that China will continue to advance its biotech capabilities regardless of U.S. companies' investments. In this critical competition for the frontier of biotechnology capabilities, however, U.S. capital would be better invested in the U.S. biotech ecosystem instead of building up the capabilities of our chief foreign adversary. Furthermore, actively cultivating global competitors fostered by the CCP's strategy to dominate pharmaceutical innovation undermines U.S. national interests.

Finding 4: Challenges in the U.S. Regulatory and Clinical Research Ecosystem Encourage Drug Development in China

U.S. companies are incentivized to run their clinical trials in China instead of the United States due to FDA's burdensome IND process, uneven FDA inspection oversight in China, and the lack of any additional statutory or regulatory guardrails for clinical trial data from China or drug molecules originating in China despite the uneven regulatory playing field. The high cost and complexity of the U.S. clinical research ecosystem also contribute to making early-phase trials more attractive in China. In effect, Chinese biotech companies are winning a game of regulatory arbitrage where U.S. biotech companies which seek to innovate and develop their drugs in the United States are the losers.

FDA's burdensome IND process is driving U.S. firms to China

Numerous U.S. biotech, VC, and pharmaceutical executives have told the Select Committee that FDA's Phase I IND process is overly burdensome and filled with duplicative and uncertain requirements. Jacob Becraft, founder and CEO of Strand Therapeutics, stated on a podcast that his company's first application to FDA for an IND was 22,000 pages long, took 18 months to put together, and cost $25 million due to the testing and data required.[90]

In a recent essay, FDA leaders acknowledged that the Phase I IND process can take up to two years in the U.S. compared to nine months in China,[91] noting that FDA's process is outdated for today's complex and voluminous drug development ecosystem and the influx of novel cell and gene therapies.[92] According to the FDA, because the FDA provides no specific guidance for Phase I trials, sponsors often over-submit data due to uncertainty about IND expectations. They also note that additional meetings between FDA and trial sponsors—beyond the current practice of a single, non-binding pre-IND meeting—would help sponsors prepare stronger IND submissions.[93]

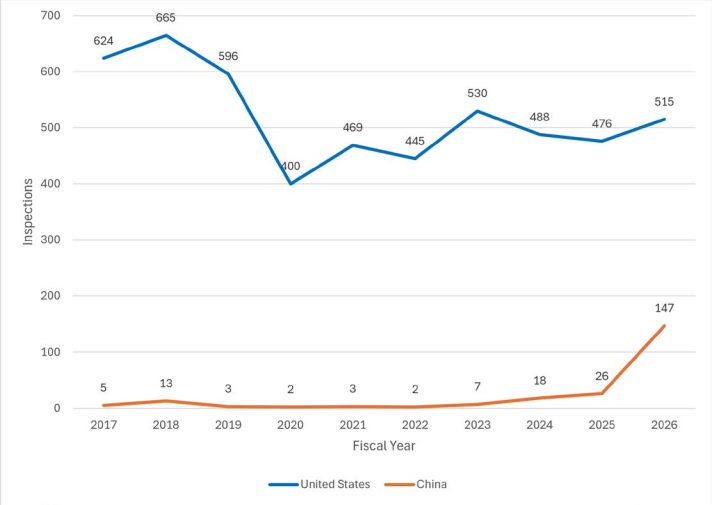
The FDA has launched initiatives to address some of these challenges, but in the meantime, companies running clinical trials in China have an enormous advantage in the race for first-in-human data.

FDA conducts far fewer clinical trial inspections in China than in the United States

The FDA conducts inspections of clinical investigators at Chinese clinical trial sites at a much lower rate than sites in the United States. FDA conducts inspections of clinical investigators under its bioresearch monitoring program for multiple reasons, including to verify that the trial was conducted as designed, that informed consent was properly obtained, and that the data submitted to the FDA accurately reflect what happened at the site, among other things. According to clinical investigators and ethics professionals at a top U.S. medical research institution, knowing that they could face a clinical trial inspection pushes clinical trial sites to maintain high ethical and scientific standards.[94]

Between 2017 and 2026, according to FDA data, the FDA conducted 6,752 global inspections of clinical investigators and sponsor investigators at clinical trial sites.[95] During this period, it conducted 5,208 of those inspections in the United States and only 226 in China, or about 4% as many inspections in China as in the United States, as seen in Figure 5 below.[96]

Figure 5: FDA Inspections of Clinical Trials: US vs. China (2017-2026)



The data show an uptick in FDA inspections conducted at Chinese clinical trial sites since 2024, with a sharp rise in FY 2026. Over the full period, however, they remain far fewer than in the U.S.[97]

The FDA conducts clinical trial inspections for Phase I, II, and III trials, but does not typically inspect IITs in China, according to FDA officials.[98] Phase I and II clinical trial inspections are targeted at generic drug development, where the purpose is to validate bioavailability or bioequivalence. The FDA typically does not conduct clinical trial inspections for innovative new drugs before Phase III,[99] according to FDA officials, when the purpose is to validate safety and efficacy of a drug after a New Drug Application or Biologics License Application has been filed.[100] The FDA said that it does not have statutory authority to inspect every clinical study conducted outside the United States that does not proceed under an IND. Its inspection program is focused on studies submitted to the Agency, particularly those designated as pivotal in support of a pending marketing application, because those are the studies that directly determine whether a medical product is approved for American patients. This means that the unregulated fast and cheap early-stage IITs in China (and the data they generate) used to entice investment from U.S. companies and that could be used to advance later-stage drug trials in the United States are almost never inspected by the FDA.

Without the credible threat of clinical trial inspections at sites in China, the FDA is essentially holding clinical trials conducted in the United States to a higher standard than those conducted in China.

FDA has no China-specific guardrails or reviews

Despite the uneven regulatory and inspection playing fields allowing for risky and opaque trials to run in China, the FDA does not treat Chinese clinical trial data any differently than data from clinical trials held in the U.S. or elsewhere in the world.[101]

For drugs to be approved in the U.S., FDA requires an adequate and well-controlled clinical investigation to support a marketing application—a requirement that is often met by large, global Phase III trials. However, Chinese biotech companies can run faster, cheaper, and in some cases less ethical early human clinical trials in China, and then "skip the line" ahead of U.S. companies running clinical trials in the United States. They do this by using that data in part to support an IND for study in the U.S. at a later stage in development (e.g., Phase II or III). Once approved, an IND enables a company to begin the next stage of clinical trial in the U.S. Although FDA says it will only accept foreign data that meet Good Clinical Practice and informed-consent standards, some U.S. biotech companies argue that differences in development timelines and oversight still create a structural advantage for companies starting their programs in China.

In July 2026, FDA officials told the Select Committee that the FDA has received and approved only a small number of marketing applications where the early phase studies were conducted largely in China: for example, two out of 28 applications to date in 2026.[102] However, given the growing number of biotech firms leveraging the Chinese clinical trial system for drug development, the Select Committee expects this number will likely increase in the future.

Additionally, Chinese biotech companies and China-origin molecules currently face no China-specific restriction on accessing FDA's expedited development programs, including Fast Track and Breakthrough Therapy designation, so long as they meet the programs' statutory and regulatory criteria.

Hurdles at clinical trial sites extend timelines in the United States

Even after an IND is in effect, clinical trial sponsors in the United States often contend with a fragmented site-activation process that is beyond the FDA's purview, including duplicative IRB reviews across sites, contract and budget negotiations with individual institutions, and other site-specific requirements.[103] Estimates indicate that the average time from site identification to the first patient starting the trial is about six to eight months at each site—or about 30% of the total pre-trial timeline.[104]

Finding 5: Chinese Government Representatives have blocked the FDA from conducting certain inspections at PLA hospitals where major U.S. companies run clinical trials

The FDA cannot freely inspect some high-risk clinical trial locations where major U.S. companies have run clinical trials. Specifically, the FDA has been blocked from conducting certain inspections at People's Liberation Army (PLA) hospitals. The FDA also does not conduct clinical trial inspections in Xinjiang (where the U.S. government has determined that China is committing an ongoing genocide).[105] Some U.S. pharmaceutical companies have decided to cease the initiation of new clinical trials in these locations in response to Select Committee letters and investigations, dating back to August 2024.[106]

FDA has been impeded from conducting inspections at PLA and Xinjiang sites

The FDA has been blocked or impeded from conducting inspections at hospitals in Xinjiang and at PLA sites due to actions of the Chinese government, Chinese government-associated researchers, and the U.S. government's own precautions. As discussed previously, the FDA conducts relatively few clinical trial inspections in China, and its direct visibility into these high-risk sites is almost non-existent.

The Select Committee analyzed FDA site-level clinical investigator inspection data from 2009 to 2025 and found that FDA has not conducted any inspections at clinical trial sites in Xinjiang[107] during this period.[108] FDA officials told the Select Committee that they cannot send staff to Xinjiang to inspect clinical trial sites because the State Department's U.S. Embassy in China will not allow it.[109] State Department officials said that the U.S. China Mission travel policy does not forbid official travel to Xinjiang Uyghur Autonomous Region (XUAR), but it is on a case-by-case approval basis, and inspection activities must be reported to the local CCP Foreign Affairs Office, which may or may not give permission for the inspection to occur.[110] Thus, while there is no policy that explicitly forbids FDA inspections in the region, there are significant limitations.

The FDA has experienced more direct impediments from representatives of the Chinese government at PLA sites. In one particularly egregious example of nefarious Chinese behavior to prevent clinical trial inspections, the FDA was blocked twice from conducting an inspection at the 5th PLA Medical Center in Beijing in 2021 and 2024.[111] The latter attempted inspection targeted the same clinical investigator, who used administrative roadblocks to obstruct an FDA inspection and try to coerce the U.S. government.

Specifically, in 2021, according to FDA officials, the FDA attempted to inspect a clinical trial at the 5th PLA Medical Center run by clinical investigator Jianming Xu, M.D., head of gastrointestinal oncology.[112] Before he would allow the FDA to carry out the inspection, Dr. Xu first required the FDA investigator to submit a long list of materials in order to access the hospital, including an official site application, a

Chinese and English-language curriculum vitae (CV), and most alarming: a form that attempted to coerce the inspector into declaring a formal recognition of China's "One China Principle," which is the CCP's frequently-used, ham-fisted attempt to distort history and subjugate Taiwan as a province of China.[113] In an Orwellian display of the CCP'S insecurity, the coercive document was apparently entitled the "Visitor's Attitude Towards China" document. Beyond being an appalling affront to the notion of patient safety, this is explicitly at odds with the U.S. government's long-held official "One China Policy."[114] The FDA investigator rightly declined to provide this information. After significant back and forth with the investigator without resolution, the FDA categorized the operation as a "refusal" by the investigator to allow inspection.

In 2024, Dr. Xu was again targeted for inspection. When the FDA pre-announced the inspection in March 2024, Dr. Xu replied to FDA with the same requirements as in 2021 and was told that the FDA could not comply with these requirements and would cancel the upcoming inspection.[115] The FDA's Office of Inspections and Investigations (OII) informed colleagues at the FDA Center for Drug Evaluation and Research (CDER) that it would not be able to verify the data and prepared to call it a refusal, as before. CDER asked OII to hold off on finalizing the refusal while the review division negotiated with the clinical trial sponsor over the ensuing months. Several months later, the hospital agreed to allow access to the facility with more limited requirements (including removal of the "Visitor Attitude Towards China" document). The FDA was eventually able to complete the inspection in January 2025—its first completed clinical trial inspection at a PLA hospital since 2018, and only its sixth since 2009.[116]

The FDA was only able to complete an inspection of Dr. Xu's trial in 2025 after an extensive negotiation involving the clinical trial sponsor, according to information provided by the FDA.[117] Of note, the 5th PLA Medical Center is historically connected to the PLA's Academy of Military Medical Sciences (AMMS), an organization on the Department of Commerce's Bureau of Industry and Security (BIS) Entity List,[118] as it was established through a merger of the former 302nd and 307th hospitals, the latter of which was the affiliated hospital of AMMS.[119] On June 29, 2026, Select Committee Chairman John Moolenaar sent letters to five companies—AbbVie, BMS, Eli Lilly, Merck, and Pfizer—requesting information about their clinical trials at sites in Xinjiang and at PLA hospitals and associated due diligence processes.[120] All five of these companies have conducted clinical trials at the 5th PLA Medical Center (or its predecessor 302nd and 307th hospitals), where FDA was effectively denied access.[121]

This behavior by a Chinese government representative at a PLA site is antithetical to the fundamental principles of ICH Good Clinical Practice and to basic tenets of science, safety, and trust. Yet this is just one further example of China's continued disregard of international norms and practices, politicization of routine scientific and safety activity, and its willingness to shield the insidious activities that occur

behind its Great Firewall while projecting a false, shameless image of liberal openness and leadership.

In July 2026, FDA officials told the Select Committee that China is the only country in the world where clinical trial inspections have been refused, and that FDA inspectors have also been refused twice by other hospitals in China for medical device inspections.[122] In September 2026, the FDA acknowledged in a public essay written by its senior officials that "for some foreign inspections of clinical trial sites, the FDA has been denied access or has been told that inspection would require the agency to sign agreements that restrict the scope or conduct of the inspection or attest to geopolitical principles unrelated to the inspection with clinical trial sponsors."[123]

In this same essay, the FDA stated that "…it is being more systematic about communicating to sponsors and the public when trial sites and relevant personnel and documents have not been available for inspection, or where inspections were conditioned on agreements the FDA cannot execute."[124] Such communication is critical as regulatory inspections are a core component of U.S. pharmaceutical companies' clinical trial quality frameworks, and facilities that cannot be inspected by the FDA should lose credibility. Also, in instances where FDA inspectors are unable to conduct an inspection, the data will not be used to support approval of a new drug or biologics license application, according to the FDA, which creates risk for the clinical trial sponsor.[125]

The FDA routinely accepts clinical trial data from trials that are conducted overseas. For clinical data to be accepted, however, the FDA must be able to validate that data submitted were collected in accordance with Good Clinical Practice, and that it is applicable to the U.S. population and medical practice, for them to be used in support of regulatory decision-making, including through the use of onsite inspections.[126] Despite this requirement for all countries in the world, the Chinese government and its researchers have at times flouted those rules, such as in the instances described above. Refusal of access or obstruction of even one FDA inspection is indicative of a problem. Multiple impediments are indicative of systemic failure, and more importantly, are an indictment of the Chinese clinical trial system. Furthermore, it places American companies conducting clinical trials at home—which are subject to the same strict rules around site inspections—at a significant compliance disadvantage.

Yet the FDA continues to accept clinical trial data from PLA sites and hospitals in Xinjiang to advance applications despite its inability to freely inspect these locations.[127] As of October 2026, the FDA said it is developing agency-wide policies regarding the acceptability of data from these sites.[128]

Major U.S. companies have run hundreds of clinical trials at risky sites in Xinjiang and at PLA Hospitals

Major U.S. pharmaceutical companies have run hundreds of clinical trials at high-risk locations in Xinjiang and at PLA hospitals that present ethical and national security concerns.

In XUAR,[129] there have been numerous credible investigations documenting forced medical testing, procedures, medications, and biodata collections on Uyghurs and other oppressed minorities in Xinjiang, with linkages to hospitals in the region.[130] This medical oppression has taken place within a broader environment of deliberate and systematic state-imposed forced labor specifically targeting the Uyghur people and other minorities in the region—abuses which led to passage of the Uyghur Forced Labor Prevention Act (UFLPA) in December 2021.[131] The UFLPA does not address the conduct of clinical trials in the region, but it clearly establishes the ethical risks of operating there. While not part of a supply chain for physical goods, clinical trials are a critical part of the drug discovery pipeline—an intellectual supply chain, where human clinical trial subjects are a foundational input. Given what is known about human rights abuses and oppression in Xinjiang, it is indisputable that conducting clinical trials there presents ethical risk.

On October 29, 2026, the Department of Homeland Security added BGI Genomics Co., Ltd., MGI Tech Co., Ltd., and Shenzhen BGI Technology Co., Ltd. to the UFLPA Entity List. DHS found reasonable cause to believe that all three supported genetic testing associated with Xinjiang government programs oppressing and exploiting Uyghurs and other persecuted populations. DHS separately identified BGI Group's testing of human genetic material originating in Xinjiang.[132] These findings continue to raise questions about how much BGI and others are using American pharmaceutical companies for CCP political ends. Merck announced a genomics research collaboration with BGI in 2011, while Pfizer, Merck, and Eli Lilly established a cancer research consortium that subsequently collaborated with BGI.[133] A 2012 corporate disclosure filed with the Securities and Exchange Commission also identified Johnson & Johnson, Amgen, and Celgene as organizations working with BGI.[134] Available public records do not establish that these pharmaceutical manufacturers currently maintain contracts with the three newly designated entities. In February 2019, Natera entered a ten-year licensing and development agreement with BGI Genomics. The agreement covered genetic testing technology, and the companies announced the commercial launch of a jointly branded oncology assay in China in June 2021.[135]

Cutting-edge, innovative medicines are also being tested through clinical trials at PLA military hospitals—including many conducted by U.S. pharmaceutical

companies. As a general matter, clinical trials involve collaborative research activities with doctors, nurses, and other officials at the trial sites and produce sensitive and proprietary data. Conducting this research at PLA hospitals puts the cutting-edge biotechnology intellectual property and trade secrets of American companies at potential risk of being transferred to the Chinese military. As evidence of these vulnerabilities, the Commerce Department has listed the PLA's AMMS on its BIS Entity List, due to recognition that biotechnology research can be used to support Chinese military end uses, including development of potential dual-use technologies.[136]

Some U.S. companies that conduct clinical trials at PLA hospitals have argued that these hospitals function just like civilian hospitals. These companies, however, fail to recognize the dual-purpose nature of these hospitals and their roles in enhancing the readiness and capabilities of the PLA. Even civilian clinical trials held at these hospitals can indirectly benefit the PLA, as revenue, credibility, and expertise gained through clinical trials at the hospitals can then be used to support military medicine and research. The examples below highlight just a few of the research and operational activities of PLA hospitals, at each of which one or more of the companies that received investigative letters from the Select Committee have conducted clinical trials.[137]

- Southwest Hospital, the First Affiliated Hospital of Army Medical University (formerly known as the Third Military Medical University), has described its primary responsibility as "preparing for and fighting a war" (备战打仗主责主业).[138] The hospital deployed a mobile high-altitude MRI system to support troops,[139] and conducted collaborative research on war-trauma simulation software to improve battlefield care,[140] and into the effects of nitrogen mustard, a chemical agent.[141]
- The Seventh Medical Center of the PLA General Hospital's research projects, across more than twenty departments, are heavily aligned with battlefield needs, according to a 2024 PLA Daily article.[142] Its leaders have said that military hospitals exist for war and that research "should not deviate from the battlefield" (军队医院姓军为战，科研攻关的方向不能偏离战场).[143] The center has also worked with AMMS's Institute of Military Cognition and Brain Sciences on military-relevant studies, including brain-structure comparisons between pilots and non-pilots and brain responses to acute stress.[144]
- Tangdu Hospital, the Second Affiliated Hospital of the Air Force Medical University (formerly the Fourth Military Medical University), performed western China's first fully invasive brain-computer interface implant,[145] in line with high-priority PLA-aligned brain-interface and "cognitive warfare" research,[146] provides frontline training and medical support to PLA troops in remote border areas,[147] and its researchers conducted

electric-brain-stimulation studies to increase soldiers' ability to focus on military tasks.[148]

- The General Hospital of the Northern Theater Command in Shenyang conducts military medical research and training, including a 2022 deployment to a PLA Rocket Force unit to practice casualty assessment, concealment, and evacuation under simulated combat conditions.[149] It has also developed tools like frostbite-risk models to reduce troop attrition in winter combat scenarios,[150] and studied combined blast and cold-weather injuries using advanced combat trauma modeling.[151]

Some U.S. companies have stopped running new clinical trials in Xinjiang and PLA sites

BMS, Lilly, Merck, and Pfizer have all told the Select Committee that they do not currently plan to initiate new clinical trials at PLA sites or in Xinjiang. AbbVie has also committed to the Select Committee that it will not initiate new clinical trials at PLA sites.

BMS, Lilly, Merck, and Pfizer are not initiating new clinical trials at PLA sites or in Xinjiang

In July 2026, BMS informed the Select Committee that it has no plans to initiate any new clinical trials in Xinjiang or at PLA hospitals.[152] According to BMS, the company had been examining the issue before the Select Committee's inquiry, as part of an internal review of its global clinical trial operations, and the inquiry helped inform the timing of its decision.[153]

Lilly has now implemented an enhanced site review process in China which requires all potential sites in China to undergo additional evaluation of potential risks.[154] This updated process refines the review of issues such as site staff qualifications, hospital-system records management, Good Clinical Practice conformance, informed consent, and other operational considerations relevant to conducting clinical research in China.[155] Consequently, in October 2026, Lilly told the Select Committee that the company does not anticipate initiating new clinical trials at PLA-affiliated institutions or sites in Xinjiang going forward based on the use of this process.[156]

In October 2026, Merck told the Select Committee that, "in the current environment," the company will not initiate new clinical trials in Xinjiang or at PLA hospitals, stating that it appreciates the important issues flagged by the Select Committee.[157] Specific to PLA sites, Merck stated that it has not selected any new PLA hospitals for clinical trials since March 2025.[158] Company officials said that contract negotiations had become increasingly difficult with PLA sites due to language around requirements for regulatory inspections, and the company does not intend to initiate new trials at these sites.[159] The Select Committee notes that the challenges faced by Merck in such contract negotiations are indicative of the

issues experienced by the FDA when it attempted to conduct inspections at the 5th PLA Medical Center.

According to Pfizer officials, the company made the decision in October 2024 to no longer conduct new sponsored interventional clinical trials at PLA sites and in Xinjiang due to the company's evaluation of an "evolving landscape" of risks—including concerns that PLA hospitals could end up on export control lists.[160] Of note, this decision came shortly after an August 2024 letter from Chairman Moolenaar and then-Ranking Member Raja Krishnamoorthi to the FDA raising concerns about U.S. companies conducting clinical trials at PLA sites and in Xinjiang, which highlighted one of Pfizer's clinical trials at the 307 Hospital of the PLA (now the 5th PLA Medical Center)—and the hospital's connections to AMMS.[161]

AbbVie is not initiating new clinical trials at PLA sites

AbbVie has also decided not to initiate new interventional clinical trials at PLA sites. In an August 7, 2026, letter to Chairman Moolenaar, AbbVie's legal representatives stated that the company has not selected a site affiliated with the PLA for any new interventional clinical trials since Chairman Moolenaar's August 2024 letter to the FDA concerning trials at PLA sites.[162]

Unlike the other companies, AbbVie did not decide to cease initiating new clinical trials at sites in Xinjiang. AbbVie cited its duty to provide potentially lifesaving treatment to patients there, most of whom company officials stated are oncology patients in a critical state of disease.[163] AbbVie officials told the Select Committee that the company is comfortable that its oversight processes at hospitals in Xinjiang are sufficient to ensure clinical trials there are compliant with Good Clinical Practice—regardless of what is occurring in the broader region.[164]

All five companies indicated that they screen clinical trial locations against various government entity and sanctions lists, such as the BIS Military End User and Entity Lists, or the UFLPA Entity List.[165] However, Xinjiang and PLA hospitals are not currently covered by these lists.[166]

<u>Pharma companies reticent to discuss Chinese clinical trial risks despite some applying enhanced scrutiny to sites in China</u>

All five companies subject to the Select Committee investigation have global quality frameworks and procedures intended to ensure the quality and ethics of clinical trials, aligned with ICH Good Clinical Practice guidelines. These frameworks outline procedures for trial planning, site and investigator selection, ethics and regulatory review, site staff training, site activation, and obtaining informed consent.

The companies also described quality control systems at sites in China, which generally include on-site monitoring to verify adherence to procedures, training,

informed consent, and data completeness; central data monitoring across trial sites; risk-based audits at selected sites; and regulatory inspections by FDA, NMPA, or other authorities.

While each company stated that its global standards apply uniformly in every country, several acknowledged that meeting these standards in China sometimes requires additional effort, including to adhere to local laws. Some companies reported instituting enhanced oversight measures for trials in China, including 100% source data verification and review, more frequent site monitoring, and enhanced oversight of monitoring activities.[167] However, none of the companies have provided the Select Committee with documentation of internal risk assessments from clinical trial sites in China more broadly, or from Xinjiang- and PLA-affiliated sites specifically. Officials from most of the companies were reticent to identify any specific concerns or risks associated with clinical trials in China.[168]

Only one company acknowledged general, China-specific risks that drove its enhanced scrutiny, citing factors such as geopolitical instability, a rapidly evolving healthcare system, and variations in data and documentation practices across trial sites. Another company noted that higher enrollment rates at certain sites in China necessitated more frequent monitoring to support data review and trial oversight. A different company's official said that, although their company had not identified Good Clinical Practice issues in China beyond those seen in other regions, its monitoring practices are intended to identify problems early and address them promptly.

One company did describe a 2021 audit at a site in Xinjiang. The auditor observed that several signatures on informed consent forms were unclear, suggesting that some participants were not bilingual and may not have understood the consent materials.[169] The company reported that it subsequently addressed the observation through a documented corrective and preventive action plan, retrained its clinical research associates in China, and confirmed through subsequent monitoring that
participants requiring language assistance were consented in accordance with Good Clinical Practice requirements. While the Select Committee recognizes that Good Clinical Practice lapses can occur globally and this is only one example, the incident reflects the committee's concerns regarding informed consent and patient protections in the region.

The Select Committee has requested examples of site monitoring reports and audit findings from trials conducted in Xinjiang and PLA hospitals, as well as data on protocol deviations and Good Clinical Practice noncompliance in China, to better understand how quality controls have been applied at higher-risk sites and what companies have observed at the sites through their efforts. As of the publication of this report, none of the companies have provided this documentation.

Finding 6: China's Innovation is Feeding Off of Fast Followers and Alleged Theft

While Chinese biotech companies are now developing novel medicines, many of the therapies they are licensing to U.S. pharmaceutical and VC firms are "fast followers" and, in some cases, are alleged to be built upon trade secret theft.

China's clinical trial system has supercharged Chinese biotech companies' ability to produce "fast follower" therapies built on U.S. innovation. According to one publicly reported analysis, China's follower drugs have grown from 220 in 2015 to 3,352 in 2025.[170]

A fast follower is a company that does not originate a drug target or mechanism but moves quickly to develop its own version once another company has validated it. Chinese biotech companies have long been known for fast following. Fast following is a common phenomenon in the biotech sector, where an originator develops a therapy, but a newcomer may be able to patent augmented versions with better outcomes such as fewer side effects, reduced dosage frequency, or different delivery mechanisms (e.g., oral dose over injection). The difference now is that Chinese IITs are enabling companies to exploit the transparency of the U.S. patent system—which requires American patent filers to publicly reveal their drug's composition within 18 months of patent issuance—to develop fast followers on a scale not seen before, according to U.S. pharmaceutical and biotech executives.[171]

The phenomenon has become so pervasive that small American biotech innovators are increasingly deciding not to publish their data in scientific journals and delaying patent applications as long as possible in order to prevent disclosure of their IP.[172] Eli Lilly, the largest pharmaceutical company in the world, has also stopped disclosing certain information about its early-stage pipeline to protect competitively sensitive information, according to the company.[173]

The head of a large U.S. pharmaceutical company that has licensed drugs from Chinese biotech companies described to the Select Committee the two primary strategies he has observed Chinese biotechnology companies using.[174] The U.S. biotech innovation model focuses on target discovery first: researchers identify a biological target driving a disease, spend years and considerable money validating it and engineering a molecule that acts on it, then patent the molecule and its uses. The target itself cannot be patented, which means the arduous and expensive work of validating it can be leveraged by anyone.

- In the first Chinese strategy, the Chinese biotech companies hijack the innovator's target validation work. In the U.S., patent applications become public 18 months after filing, usually before the originator in the U.S. is able to get its molecule into a clinical trial; a Chinese company can read

the filing, design a molecule around the claims, and use China's faster and cheaper early-stage trials to reach first-in-human data ahead of the innovator.

- The second Chinese strategy inverts discovery. Chinese companies are reported to be stacking existing tools—AI-assisted molecule design, combinatorial chemistry, published Western molecular structures—to generate dozens of candidate molecules, then looking for targets or indications those candidates might fit. As he described, promising candidates then get taken into IITs—without any initial clinical rationale—and the molecules that produce a signal in humans can then get licensed to VC firms or global pharmaceutical companies.

Biotech industry experts told the Select Committee that fast following in the pharmaceutical industry is not new and is common in the United States as well.[175] A critical difference, however, is that Chinese biotech companies can leverage the structural advantages in their clinical trial system to quickly test many versions of re-engineered molecules, in some cases beating the original U.S. biotech innovator to the critical metric of first-in-human data.

One biotech company CEO said that Chinese fast following of U.S. biotechnology innovation is now happening on a scale that is "destabilizing" to the U.S. biotech industry. Leaders of VC and pharmaceutical firms that have licensed some of these Chinese "fast followers" argue that the Chinese molecule adaptations are innovative and sometimes better than the U.S. molecules they are built upon. They also argue that it is good for U.S. patients to have competing molecules because it could lead to better drugs. In the short term, this may be true. But several U.S. biotechnology executives expressed concern to the Select Committee that widescale licensing of the Chinese fast followers will "cannibalize" and "disincentivize" biotech innovation in the U.S. In such situations, biotech innovators spend years of their lives discovering new targets or developing technology platforms, only to then watch U.S. VCs and pharmaceutical companies license the Chinese followers of their innovation.

The line between "fast following" and IP and trade secret theft has also been blurred in the cases of some of the Chinese-origin molecules licensed by U.S. companies. In one case, Beam Therapeutics, a precision genetic medicine company, has sued both a Chinese biotech and a U.S. biotech, alleging that a former employee stole trade secrets and used them to establish a competing company in China, which subsequently licensed its technology to newly created U.S. biotech Serapha Bio, backed by U.S. biotech VC firms.[176] In a second case, Revolution Medicines alleges that a third-party contract research, development, and manufacturing organization misappropriated trade secrets related to its pancreatic cancer therapy.[177] Revolution further contends that the misappropriated technology was used to create a "substantially equivalent"

therapy, ERAS-0015, which was subsequently licensed by Chinese biotech Joyo Pharmatech to U.S. biotech Erasca.[178]

Aside from these public allegations, the Select Committee has heard directly from other U.S. biotechnology founders with similar stories of former PRC-national employees who stole trade secrets and then returned to China to start competing companies.[179] The Biotech Commission also cited concerns it had received from U.S. biotechnology founders and investors about "unabated IP theft, copycat activity, and artificially low prices that allow Chinese companies to undercut their competitors."[180]

Conclusion: The U.S. is Ceding the Future of Innovative Medicines to China

The United States, through outbound capital flows to Chinese biotech, is gradually ceding the innovation high ground to China and hollowing out its own ecosystem. As early-stage trials increasingly move abroad, the infrastructure and capital follow. U.S. trial sites thin out while Chinese sites gain experience with every cutting-edge study they run, compounding China's advantage. Over time, America will come to rely on China not just to test new drugs but to discover them, and Chinese companies will increasingly decide which drugs get developed at all.

American taxpayers and patients are unwittingly underwriting this Chinese innovation. Molecules are developed and tested in China are done so with eventual commercialization in the United States in mind. Chinese patients pay among the world's lowest prices for drugs, while U.S. patients (through Medicare, Medicaid, and U.S. private insurance) account for roughly 70% of global pharma profits.[181] Without the U.S. patient, Chinese biotech companies would have an ever-decreasing market in which to sell profitably. It is untenable for American patients to bear the world's highest drug prices while surrendering the United States' high-tech innovation and funding the advancements of our chief foreign adversary—China. When U.S. patients demand prices equivalent to what Chinese patients pay, which market will be able to sustain the profits of the sector?

The stakes go well beyond medicine. Biopharma is the most profitable segment of biotech, and its profits, generated overwhelmingly in the U.S. market, fund the basic science, VC, and talent that spill over into gene editing, agricultural biotech, biomanufacturing, and other future disruptive biotechnologies. The Biotech Commission calls this a flywheel, warning that "surrendering this cycle to China would facilitate the decline of U.S. biotechnology leadership and provide unrivaled advantages to a foreign adversary."[182]

When U.S. capital funds early-stage drug research and scientists in China, it is not just buying individual drugs; it is financing the underlying technologies that will define the biotech frontier and handing that frontier to China. Cede biopharmaceutical innovation to China, and the rest of the frontier goes with it.

Keeping the innovative drug pipeline, and the clinical trial infrastructure behind it, in the United States is an economic, health, and national security imperative.

Policy Recommendations

Winning the biopharmaceutical competition with China will require a comprehensive set of measures that are designed both to strengthen the U.S. biotech ecosystem and to protect against China's aggressive intentions. Of note, the Biotech Commission has developed a commendable and comprehensive set of recommendations that the Select Committee supports. This report does not attempt to capture all areas of agreement or retread the same ground. Rather, it highlights select policy recommendations that the Select Committee believes to be critical in addressing the concerns laid out in this report.

Policy Recommendation 1: Stop subsidizing the CCP's strategy to dominate biotechnology and pharmaceuticals

The United States should take a whole-of-government approach to end the significant flows of U.S. capital that support pharmaceutical development, clinical research capabilities, and related technologies, including licensing transactions, with China.

Congress should pass the bipartisan, bicameral Biotech Investment National Security Act (H.R. 9102) to codify biotechnology into the existing U.S. outbound investment regulatory framework and provide a specific legal mandate for outbound investment restrictions to cover the licensing of Chinese molecules. The Treasury Department's proposed rule to implement the Comprehensive Outbound Investment National Security Act of 2025 (COINS) proposes using existing authorities to significantly restrict outbound U.S. investment into China's pharmaceutical and biotech ecosystem.[183] The proposed rule, if implemented, would make substantial progress in preventing the offshoring to China of our drug discovery and innovation. The Treasury Department should take a maximalist approach as the regulatory process progresses and include pharmaceutical and VC licensing deals as prohibited transactions. The necessary objective is to preserve the American biotechnology ecosystem and prevent U.S. capital from building Chinese biotechnology firms into global pharmaceutical competitors, as they have publicly stated they aspired to become. This requires looking beyond transaction-level issues or Chinese military affiliations alone and assessing the broader risks of allowing the biotech ecosystem to be offshored to a significant foreign adversary.

Supporters of U.S.-China licensing deals argue that they provide American companies with promising treatments and benefit American patients. But licensing and co-development divert capital from American innovators and help Chinese firms acquire the capital and capabilities to displace them. These transactions must be evaluated for their cumulative effect on American innovation

and long-term dependence, rather than solely for the next drug they add to a company's pipeline.

Critics also argue that restrictions would move transactions to Europe, Japan, or elsewhere, referred to as "Euro-washing." Some substitution is possible, which makes coordination with allies and effective anti-circumvention rules essential. It does not justify leaving American capital unrestricted. The U.S. government cannot guarantee that foreign investors will not finance China's biotechnology ambitions, but it can decide whether American investors should do so. Furthermore, the primary market for these therapies is patients in the United States, who account for 70 percent of global pharmaceutical profits with medicines paid for by U.S. patients and the U.S. government (including through Medicare and Medicaid). Thus, Washington should use the power of its market to ensure that transactions routed through intermediaries remain subject to applicable U.S. restrictions.

Policy Recommendation 2: Restrict FDA acceptance of Chinese clinical trial data

Congress should establish restrictions on FDA acceptance of Chinese clinical trial data (except for adverse event and other safety reporting data), with particular scrutiny of early-stage IITs conducted outside China's formal drug regulatory pathway. Acceptance should depend on independently verifiable evidence of informed consent, appropriate ethical review, complete safety reporting, and unimpeded FDA inspection of clinical trial sites in China. Congress should establish a presumption against reliance on data from pathways where these protections cannot be reliably verified, with narrowly defined exceptions.

FDA already requires Good Clinical Practice for foreign studies submitted outside an IND, including independent ethical review and informed consent. The question is whether compliance can be established in practice. Paper assurances should not substitute for verifiable protections and credible oversight.

The prospect of a useful treatment does not excuse the conditions under which its supporting data were obtained. Nor should companies gain a regulatory advantage by conducting early experimentation under weaker scrutiny and then bringing the results into the U.S. development system. Restrictions should be implemented prospectively with clear transition rules to avoid unnecessary disruption of ongoing patient care. They must also preserve reporting of adverse events and other safety information, even when data are ineligible to support an application.

In 2026, to address this issue, Chairman Moolenaar and Rep. Andy Harris, Chair of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee of the House Appropriations Committee, secured language in the report to accompany the relevant appropriations bill (H.R. 8646) "to prohibit FDA from accepting, reviewing, or considering any covered clinical

data generated by a clinical investigation site located in [China]…in support of an investigational new drug application [in the United States]."[184]

Policy Recommendation 3: Ban FDA acceptance of clinical trial data from PLA hospitals and clinical trial sites in Xinjiang

Congress should prohibit the FDA's acceptance of clinical trial data generated at PLA-operated or controlled hospitals and at clinical trial sites in Xinjiang to support INDs or applications for marketing approval. The prohibition should apply regardless of the sponsor's nationality or whether the data reach the FDA through a subsequent licensing agreement. Implementing requirements should compel sponsors to disclose the institutions and locations where their supporting clinical data were generated.

Military-controlled sites in China present national security and independent-oversight concerns. Research in Xinjiang raises heightened concerns about coercion and whether voluntary, informed participation can be credibly established in the context of the region's documented repression of ethnic minorities. Access to the American pharmaceutical market should not reward research conducted in settings where those risks cannot be adequately addressed.

In 2026, the report accompanying the Departments of Labor, Health, and Human Services, and Education, and Related Agencies Appropriations Bill (H.R. 9260) introduced several new provisions to apply increased scrutiny of new medicines with clinical data derived from Xinjiang or PLA hospitals.[185]

Policy Recommendation 4: Modernize the U.S. clinical trial system

Congress and the Executive Branch should work together to accelerate efforts to make early-stage clinical development in the United States faster, more predictable, and less costly. Priorities should include clear, phase-appropriate IND requirements, earlier and more frequent engagement between FDA and sponsors, and parallel preparation of regulatory submissions and clinical trial sites. Reform should also address contracting, budgeting, and site-activation delays that occur outside FDA. Success should be measured by the time and cost required to begin a safe, scientifically sound trial.

The FDA under the Trump Administration has rightly acknowledged these challenges and introduced an Expedited IND Pilot (Operation TrialBlazer) emphasizing clearer requirements, iterative scientific support, and rolling submission of application components, as well as IRB and site activation reforms. This initiative is a strong first step in the right direction. Going forward, these efforts should be supported and evaluated for whether they meaningfully shorten development timelines without compromising patient protections. If they are successful, the FDA must move quickly from a pilot program to full

implementation. Congress should ensure that FDA has the staffing and scientific expertise needed to deliver timely, consistent reviews.

Congress and FDA should also evaluate an Australian-style Clinical Trial Notification pathway for eligible early-stage trials, allowing studies to proceed after qualified independent scientific and ethical review, institutional authorization, and notification to FDA, rather than a separate FDA pretrial evaluation. Australia's model assigns assessment of trial design, safety, and ethical acceptability to Human Research Ethics Committees while retaining Good Clinical Practice requirements and regulatory inspections. This approach has been widely held up by industry as a positive template to learn from. The U.S. should establish clear eligibility criteria, retain FDA review for higher-risk products, and measure whether this approach reduces time to first-in-human data without compromising patient protections.

Some argue that the United States needs only to go faster, without restricting its support for China's biotechnology ecosystem. Faster development is essential, but it does not address theft of trade secrets, transfers of commercial capabilities, or financing that strengthens strategic competitors. Domestic policy reform and protective measures must advance together, with protective measures buying time for critical reforms to yield results.

Policy Recommendation 5: Ensure strong support for foundational biomedical research

Congress and the Administration should sustain strong support for foundational biomedical research, consistent with the Administration's emphasis on Gold Standard Science, transparency, and responsible stewardship of taxpayer dollars. Funding should prioritize scientific merit, reproducibility, and research that strengthens American capabilities, while reducing unnecessary administrative burdens and safeguarding against conflicts of interest and illicit foreign diversion. Preserving the discoveries and scientific talent that underpin future treatments is essential to maintaining U.S. biotechnology leadership over China.

Policy Recommendation 6: Pressure the ICH to exclude China's membership

The FDA, through its membership on the ICH management committee, should seek temporary suspension of China's ICH membership until China demonstrates that its IIT clinical testing pathway is subject to effective, enforceable protections articulated in ICH's Good Clinical Practice principles. Participation in an international standards-setting body should carry meaningful obligations to implement the standards it promotes. Good Clinical Practice implementation is part of ICH's regulatory membership criteria, yet China has decided to craft a parallel clinical trial pathway not required to meet ICH standards.

The objective should be verifiable compliance across the relevant research pathways. China should demonstrate independent ethical review, meaningful informed consent, timely registration and reporting, disclosure of serious adverse events, and effective oversight of experimental therapies. Announced reforms and formal commitments are insufficient without evidence of implementation. The United States should press for a transparent assessment and concrete corrective actions, rather than allow membership to serve as a blanket assurance of credibility.

Policy Recommendation 7: Explore centralized IRBs

Congress and the Administration should expand and strengthen single-IRB review for multisite clinical trials, building on existing federal requirements. The revised Common Rule and NIH policy already require a single IRB of record for most federally funded domestic multisite research.[186] FDA proposed extending that requirement to FDA-regulated multisite research in 2022, subject to limited exceptions, and HHS has made finalizing it a priority under Operation TrialBlazer.[187] The rule would close the gap that still allows each site in a privately funded multi-site trial to review the same protocol independently.[188] The priority should be making coordinated review work consistently and eliminating unnecessary duplication across the clinical research system, including local "shadow" reviews that recreate the burden single-IRB review is meant to remove.

Implementation should rely on standardized reliance agreements, clear divisions of responsibility between the reviewing IRB and participating sites, and predictable review timelines, while preserving attention to state and tribal law, local patient populations, and site capabilities. Because contracting and site activation often account for more startup time than ethical review, single-IRB review must be paired with reforms in those areas.

Policy Recommendation 8: Explore monetary incentives for companies that conduct early-stage clinical trials in the U.S.

Congress should examine targeted financial incentives to make early-stage clinical trials in the United States more competitive. Options could include refundable tax credits, competitive grants, or milestone-based support for eligible domestic trial expenses, particularly for small biotechnology companies advancing promising therapies. Assistance should be tied to research conducted here and structured to help companies obtain the human data needed to attract further private investment.

Incentives should be limited, measurable, and designed to support additional domestic research rather than subsidize activity that would occur anyway. Evaluation should examine whether they increase trial activity, shorten development timelines, and preserve clinical capabilities in the United States. Companies respond to the economics of drug development. If Washington wants

more trials conducted here, it must address those economics alongside meaningful regulatory reform.

Policy Recommendation 9: Explore surcharges or penalties for IND applications for therapies that were developed from early-stage clinical trials in China

Congress and the Administration should examine surcharges or other financial disincentives for companies that conduct or finance early-stage clinical trials in China and subsequently seek to use those data for U.S. regulatory development. Measures should address indirect arrangements, including trials conducted through affiliates or Chinese partners and later acquired through licensing. The use of unethical or unreliable data must never be allowed merely because someone paid a surcharge.

Congress should also examine whether changes to federal reimbursement policy or IND application review priority could discourage reliance on Chinese-origin drug development and strengthen incentives to develop medicines in the United States. American taxpayers should not be an unquestioned source of financial returns for an innovation ecosystem that threatens to displace our own. The study should assess options for prospective reimbursement adjustments or other payment disincentives, including what statutory authority would be required.

Measures should focus on influencing future investment and development decisions while avoiding unnecessary disruption of existing care. Paired with domestic incentives and clinical trial reform, these policies should make developing medicines in the United States more attractive and reduce the rewards for shifting innovation to China.

Policy Recommendation 10: Study patent disclosure vulnerabilities affecting American biotechnology innovators

Congress should direct the U.S. Patent and Trademark Office (USPTO), working with relevant agencies and biotechnology stakeholders, to study whether current patent disclosure rules expose American innovators to risks when Chinese firms can rapidly translate disclosed discoveries into competing therapies. The study should examine how faster clinical development in China lets competitors obtain human data before the American companies whose foundational research they build upon, and whether narrow changes to biotechnology disclosure rules could help address this imbalance.

Potential reforms should be evaluated for their effects on patent rights, scientific exchange, investment, and international patent protection. The study should distinguish lawful competition based on public disclosures from patent infringement and trade-secret theft. The objective should be to preserve incentives for costly American discovery while identifying ways to prevent the transparency

of our patent system from becoming a systematic advantage for competitors operating under a faster, less rigorously overseen development system.

Policy Recommendation 11: Ensure the FDA and its clinical reviewers are adequately staffed

Congress and the Administration should ensure that the FDA has sufficient clinical reviewers and specialized scientific expertise to provide timely, rigorous, and predictable reviews. Staffing should reflect the volume and complexity of applications, particularly for emerging therapies such as cell and gene treatments. Retaining experienced reviewers and recruiting experts in new technologies are essential to sustaining an efficient American drug development system.

Regulatory reform cannot deliver its intended benefits without the personnel needed to implement it. Clearer requirements and streamlined processes must be matched by FDA's capacity to engage with sponsors, resolve scientific questions, and review submissions promptly. Adequate staffing should support measurable improvements in review timeliness and consistency while preserving rigorous patient protections.

Policy Recommendation 12: Establish a White House Biotechnology Coordinator

Congress should establish a National Biotechnology Coordination Office in the Executive Office of the President with a Director, appointed by the President, who will coordinate interagency actions on biotechnology competition and regulation, as recommended by the bipartisan Biotech Commission.[189]

According to the Commission, "federal departments and agencies perform a wide range of activities that advance biotechnology, such as conducting research and regulating biotechnology products. While valuable, these efforts are fragmented and lack a common understanding of how the federal government should advance biotechnology to meet national goals. There is an urgent need for lasting coordination that would connect federal agencies, provide a long-term strategy, and de-duplicate redundant investments."[190]

[1] Xingyue Zhu & Yang Chen, *Bridging the New Drug Access Gap Between China and the United States and Its Related Policies*, 14 Frontiers Pharmacology art. 1296737 (2024), https://doi.org/10.3389/fphar.2023.1296737.
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[100] *Id.*

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[109] Oral Briefing by FDA Officials to Sel. Comm. Staff (Jul. 31, 2026).

[110] E-mail from a U.S. Dep't of State official to Select Comm. on the CCP staff (Sep. 3, 2026) (on file with the Select Committee).

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[124] *Id.*
[125] Oral Briefing by FDA Officials to Sel. Comm. Staff (Jul. 31, 2026).
[126] U.S. Food & Drug Admin., *Good Clinical Practices Are Not Optional: The FDA's Commitment to Human Subject Protections and Gold Standard Science in an Era of Global Clinical Research*, FDA Voices (Sep. 3, 2026), https://www.fda.gov/news-events/fda-voices/good-clinical-practices-are-not-optional-fdas-commitment-human-subject-protections-and-gold-standard.
[127] According to the FDA, if it is unable to validate that data submitted was collected in accordance with Good Clinical Practice, including in sites where the FDA's ability to perform in-person inspections is constrained or denied, FDA regulations allow the agency to refuse to accept such evidence in support of a marketing application.
[128] Documentation on file with the Select Committee.
[129] According to a search of The U.S. National Institutes of Health (NIH) clinical trial repository (clinicaltrials.gov) on October 19, 572 clinical trials have included clinical trial sites in Xinjiang since 2009, which most certainly far undercounts the actual numbers since Chinese clinical trials are not required to be registered on the site and IITs are not formally tracked.
[130] Human Rights Watch, *China: Minority Region Collects DNA from Millions*, (Dec. 13, 2017), https://www.hrw.org/news/2017/12/13/china-minority-region-collects-dna-millions; Emile Dirks and James Leibold, *Genomic Surveillance: Inside China's DNA Dragnet*, Australian Strategic Policy Institute, Policy Brief Report No. 34/2020, (Jun. 2020), https://www.aspi.org.au/report/genomic-surveillance/; Dake Kang et al., *China Cuts Uighur Births with IUDs, Abortion, Sterilization*, Associated Press (Jun. 29, 2020), republished by *PBS NewsHour*, https://www.pbs.org/newshour/world/ap-report-china-stifling-uighur-births-with-iuds-abortion-sterilization; Office of the United Nations High Commissioner for Human Rights, *OHCHR Assessment of Human Rights Concerns in the Xinjiang Uyghur Autonomous Region, People's Republic of China* (Aug. 31, 2022), https://www.ohchr.org/sites/default/files/documents/countries/2022-08-31/22-08-31-final-assesment.pdf; U.S. Department of State, *2023 Country Reports on Human Rights Practices: China*, (accessed Oct. 29, 2026) https://www.state.gov/report/custom/cffccc34d2/.
[131] Uyghur Forced Labor Prevention Act, Public Law 117-78, 135 Stat. 1525 (2021), https://www.congress.gov/bill/117th-congress/senate-bill/65/text.
[132] Uyghur Forced Labor Prevention Act Entity List Update, 91 Fed. Reg. 68,159, 68,161–62 (Oct. 29, 2026), https://www. govinfo.gov/content/pkg/FR-2026-10-29/html/2026-22094.htm. The Forced Labor Enforcement Task Force determined that BGI Genomics, MGI Tech, and Shenzhen BGI Technology satisfied the statutory listing criterion under section 2(d)(2)(B)(ii). It also designated BGI Genomics and Shenzhen BGI Technology under section 2(d)(2)(B)(v). The notice identifies the specific government findings for each entity, including the provision of genetic testing capacity and testing of genetic material sourced from Xinjiang. The House Select Committee publicly acknowledged the announcement on October 28, 2026. *See* House Select Comm. on the Strategic Competition Between the U.S. and the Chinese Communist Party, DHS Bans Imports From Three Chinese Genomic Companies Because of Their Ties to Forced Labor (Oct. 28, 2026).
[133] *Merck and BGI Establish Strategic Collaboration Focused on Biomarkers and Genomic Technologies*, Merck & Co., (Sep. 12, 2011). Merck announced a strategic relationship involving genomic sequencing, biomarker discovery, and pharmaceutical research. The announcement contemplated contributions of expertise, samples, and research materials. It does not establish that the relationship continues in 2026; *Lilly, Merck, and Pfizer Join Forces to Accelerate Research and Improve Treatment of Lung and Gastric Cancers in Asia*, Pfizer Inc. (Feb. 23, 2010). The three companies established the Asian Cancer Research Group as an independent research organization. See also BGI Americas, Collaborative Projects (describing BGI's collaboration with that consortium). These records establish a relationship through the consortium.

[134] Complete Genomics, Inc., Schedule 14D-9C, Complete Employee FAQ, Item 2 (filed Sept. 17, 2012), https://www.sec.gov/Archives/edgar/data/1361103/000119312512394168/d412925dsc14d9c.htm. In describing BGI during its proposed acquisition of Complete Genomics, the filing identified Pfizer, Johnson & Johnson, Amgen, and Celgene among organizations working with BGI. This statement is a historical corporate representation submitted to the SEC.

[135] Natera, Inc., Quarterly Report (Form 10-Q), at 19–20 (Nov. 5, 2026), https://www.sec.gov/Archives/edgar/data/1604821/000162828026071145/ntra-20260930.htm. Natera reports that the February 2019 agreement with BGI Genomics expires in February 2029. The company identifies oncology assay interpretation as its single remaining performance obligation, with $20 million of transaction consideration allocated and prepaid by BGI Genomics. During the nine months ending September 30, 2026, Natera recognized $600,000 against deferred royalties and reported $16.3 million in related deferred revenue; *Natera and BGI Genomics Announce Commercial Launch of the BGI/Natera Signatera Assay in China* Natera, Inc., (Jun. 24, 2021). https://www.natera.com/company/news/natera-and-bgi-genomics-announce-commercial-launch-of-the-bgi-natera-signatera-assay-in-china-2/. The companies announced the launch of an oncology assay for biopharmaceutical customers and clinicians throughout China. The announcement does not identify Xinjiang government programs as customers or establish any involvement by Natera in coercive testing.

[136] "Supplement No. 4 to Part 744: Entity List," *Electronic Code of Federal Regulations*, Title 15, Subtitle B, Chapter VII, Subchapter C, Part 744, U.S. Department of Commerce, Bureau of Industry and Security, (Accessed May 7, 2026) https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-C/part-744/appendix-Supplement%20No.%204%20to%20Part%20744.

[137]All five companies conducted clinical trials at least at one of the listed sites.

[138] *Army Medical University Southwest Hospital: "Combat-Type" Disciplinary Clusters Drive Talent Growth* [陆军军医大学西南医院："**打仗型**"**学科群**牵引人才成长], Ministry of Nat'l Def. of the People's Republic of China (Oct. 7, 2023), http://www.mod.gov.cn/gfbw/gffw/ws/16256621.html.

[139] *Id*.

[140] Xin Hu et al., *Creation and Application of War Trauma Treatment Simulation Software for First Aid on the Battlefield Based on Undeformed High-Resolution Sectional Anatomical Image (Chinese Visible Human Dataset)*, 22 BMC Med. Educ. art. 498 (2022), https://doi.org/10.1186/s12909-022-03566-6.

[141] Haoyue Deng et al., *Targeting TRPV1-Mediated Autophagy Attenuates Nitrogen Mustard-Induced Dermal Toxicity*, 6 Signal Transduction & Targeted Therapy art. 31 (2021), https://doi.org/10.1038/s41392-020-00389-z.

[142] Fu Lingyan & Kang Zizhan, *Quan Lingyu Jishu Chuangxin Duijie Zhanchang Fuwu Zhanxun* [All-Field Technological Innovation Alignment for Battlefield Service and Training], Jiefangjun Bao [PLA Daily] (Apr. 28, 2024), http://www.mod.gov.cn/gfbw/gffw/16304343.html.

[143] *Id*.

[144] Chuanya Qiu et al., *Brain Structural Plasticity in Visual and Sensorimotor Areas of Airline Pilots: A Voxel-Based Morphometric Study*, 411 Behav. Brain Rsch. art. 113377 (2021), https://doi.org/10.1016/j.bbr.2021.113377; Ying Zhu et al., *Endogenous Cortisol-Related Alterations of Right Anterior Insula Functional Connectivity Under Acute Stress*, 274 J. Affective Disorders 231 (2020), https://doi.org/10.1016/j.jad.2020.05.085.

[145] Wang Bao, Zhang Ruili & Ruan Banhui, *Tangdu Yiyuan "Quan Qinru Shi Naoji Jiekou Shoushu," Youwang Rang Sizhi Tanhuan Huanzhe Yong "Yinian" Chongqi Xin Shenghuo* [Tangdu Hospital's "Fully Invasive Brain-Computer Interface Surgery" Offers Hope for Quadriplegic Patients to Restart Life with "Thought"], Sanqin Dushi Bao [Sanqin Metropolis Daily] (Sep. 18, 2026), https://www.sanqin.com/2026-09/18/content_20122228.html.

[146] Elsa B. Kania, *Minds at War: China's Pursuit of Military Advantage Through Cognitive Science and Biotechnology*, Prism, no. 3 (2019), at 82, https://ndupress.ndu.edu/Portals/68/Documents/prism/prism_8-3/prism_8-3_Kania_82-101.pdf.

[147] *A Letter of Condolences to All Medical Staff at the University* [**致全校医**务工作者的慰问信], Air Force Med. Univ. (Fourth Mil. Med. Univ.) (Aug. 19, 2026), https://www.fmmu.edu.cn/news/info/1214/175873.htm.

[148] Hongliang Lu et al., *Improvement on Attention Networks Among Military Personnel: The Right IFG and tDCS Matter*, 46 Hum. Brain Mapping art. e70365 (Sep. 27, 2025), https://doi.org/10.1002/hbm.70365.

[149] Wang Yu & Lou Yang, *Beibu Zhanqu Zong Yiyuan Zoujin "Dongfeng Kuaidi" Yanxunchang, Chuilian Lianhe Weiqin Baozhang Nengli* [The Northern Theater General Hospital Visits the "Dongfeng Express" Training Ground to Hone Joint Medical Support Capabilities], Guofangbu Wang [Ministry of Nat'l Def. Website] (Mar. 7, 2022), http://www.mod.gov.cn/gfbw/gffw/ws/16042949.html.
[150] Sitong Wang et al., *Construction and Validation of a Risk Prediction Model for Soldiers with Frostbite in Northeast China: A Cross-Sectional Study*, 24 BMC Pub. Health art. 2493 (2024), https://doi.org/10.1186/s12889-024-19959-9.
[151] Gong Tiantian et al., *Pathophysiological Effects of Cold Environment on Gastrointestinal Blast Combined Injury in Beagle Dogs*, 46 Lab'y Animal & Compar. Med. 507 (2026), https://doi.org/10.12300/j.issn.1674-5817.2025.179.
[152] Oral Briefing by BMS Officials to Sel. Comm. Staff (Sep. 2, 2026) (documentation on file with the Select Committee).
[153] BMS is continuing trials that were already ongoing at these locations to minimize impacts on patients.
[154] Oral Briefing by Lilly Officials to Sel. Comm. Staff (Aug. 28, 2026) (documentation on file with the Select Committee); WilmerHale, Letter to the Hon. John Moolenaar (Oct. 9, 2026) (documentation on file with the Select Committee).
[155] Potential sites in China are also reviewed by Lilly's internal ethics and compliance and trade and sanctions functions under this process; *Id.*
[156] Lilly intends to continue trials that are ongoing in line with the protocol for each trial, in large part to avoid discontinuing care for patients who are benefitting medically from Lilly's medicines. Documentation on file with the Select Committee.
[157] Documentation on file with the Select Committee.
[158] Gibson Dunn LLP, Letter to the Hon. John Moolenaar (Oct. 5, 2026) (documentation on file with the Select Committee).
[159] Oral Briefing by Merck Officials to Sel. Comm. Staff (Oct. 20, 2026) (documentation on file with the Select Committee).
[160] Oral Briefing by Pfizer Officials to Sel. Comm. Staff (Sept. 3, 2026) (documentation on file with the Select Committee).
[161] Letter from John Moolenaar, Chairman, Select Comm. on the CCP, et al., to Robert Califf, Comm'r, U.S. Food & Drug Admin., at 2 (Aug. 19, 2024), https://chinaselectcommittee.house.gov/sites/evo-subsites/selectcommitteeontheccp.house.gov/files/evo-media-document/8.19.24%20FDA%20Letter%20on%20PLA%20Trials.pdf.
[162] Kirkland & Ellis LLP, Letter to the Hon. John Moolenaar (Aug. 7, 2026). AbbVie officials told Select Committee staff that the company allowed sites that were already selected to continue, and thus, a clinical trial at PLA General Hospital that began in February 2025 and was cited in the Chairman's letter, was allowed to proceed because the site was selected in May 2024. Oral Briefing by AbbVie Officials to Sel. Comm. Staff (Sep. 14, 2026) (documentation on file with the Select Committee).
[163] Oral Briefing by AbbVie Officials to Sel. Comm. Staff (Sep. 14, 2026) (documentation on file with the Select Committee).
[164] *Id.*
[165] Documentation on file with the Select Committee.
[166] In January 2025, Chairman Moolenaar and then-Ranking Member Krishnamoorthi sent a letter to the Department of Commerce requesting that Bureau of Industry and Security (BIS), as part of its rulemaking efforts to expand export controls, update its definition of "Military End User" to state that 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. Letter from John Moolenaar, Chairman, House Select Comm. on the CCP, et al., to Gina Raimondo, Sec'y, U.S. Dep't of Com. (Jan. 9, 2025), https://chinaselectcommittee.house.gov/sites/evo-subsites/selectcommitteeontheccp.house.gov/files/evo-media-document/1.9.24%20Letter%20to%20BIS%20on%20Clinical%20Trials.pdf.
[167] Source data verification is the process of comparing data entered in a case report form or electronic data with the original source records, such as lab reports and medical charts. Source data review is a

review of all source documents to assess data collection methods, trial conduct, protocol adherence, and safety standards. ICH Good Clinical Practice standards allow for risk-based monitoring.
[168] Several companies discussed assessing and mitigating risks at each site individually but did not provide details about the types of the risks they observed in China that required mitigation.
[169] Uyghurs primarily live in Xinjiang Uyghur Autonomous Region, which is situated in the northwestern corner of the People's Republic of China. Uyghur is a language spoken natively by 11 million people worldwide and is an official language of Xinjiang Uyghur Autonomous Region (XUAR), https://celcar.indiana.edu/materials/language-portal/uyghur.html.
[170] Cheng, *U.S. Biotechs Are Keeping More Secrets to Beat Copycats in China*.
[171] Documentation on file with the Select Committee.
[172] Documentation on file with the Select Committee.
[173] Documentation on file with the Select Committee. Drew Armstrong, *Post-Hoc: The World's Biggest Drugmaker Gets More Secretive*, Endpoints News (May 29, 2026), https://endpoints.news/post-hoc-lilly-gets-more-secretive-and-hides-phase-1-pipeline/.
[174] Documentation on file with the Select Committee.
[175] Documentation on file with the Select Committee.
[176] Darren Incorvaia, *Beam Therapeutics Sues Base Editing Rival, Claims Former Scientist Stole Secrets*, Fierce Biotech (Sep. 30, 2026), https://www.fiercebiotech.com/biotech/beam-therapeutics-sues-base-editing-rival-claims-former-scientist-stole-secrets.
[177] Max Bayer, *Revolution Medicines Threatens to Sue Erasca in Showdown over Closely Watched RAS Drugs*, Endpoints News (Apr. 27, 2026), https://endpoints.news/revolution-medicines-threatens-to-sue-erasca-over-patent-efficacy-claims/.
[178] *Id.*
[179] Documentation on file with the Select Committee.
[180] *The Future of U.S.-China Biotech Competition*, at 11.
[181] Dana Goldman & Darius Lakdawalla, *The Global Burden of Medical Innovation* (USC Schaeffer Ctr. for Health Pol'y & Econ. White Paper (Jan. 13, 2018), https://schaeffer.usc.edu/research/global-burden-of-medical-innovation/; Emily Rappleye, *White House: US Taxpayers Are Subsidizing International Drug Prices*, Becker's Hosp. Rev. (Feb. 19, 2020), https://www.beckershospitalreview.com/finance/white-house-us-taxpayers-are-subsidizing-international-drug-prices/.
[182] *The Future of U.S.-China Biotechnology Competition*, at 6.
[183] Press Release, U.S. Dep't of the Treasury, Treasury Issues Proposed Rule to Implement Comprehensive Outbound Investment National Security Act (Oct. 22, 2026), https://home.treasury.gov/news/press-releases/sb0667/.
[184] H.R. Rep. No. 119-632 (2026).
[185] H.R. Rep. No. 119-696 (2026).
[186] 45 C.F.R. § 46.114(b); NIH, *Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research*, NOT-OD-16-094 (Jun. 21, 2016).
[187] Institutional Review Boards; Cooperative Research, 87 Fed. Reg. 58752 (proposed Sep. 28, 2022) (to be codified at 21 C.F.R. pt. 56); U.S. Dep't of Health & Hum. Servs., *Operation TrialBlazer: HHS Roadmap to Maintaining U.S. Leadership in Early Clinical Research and Development*, at 12 (Jun. 22, 2026), https://www.hhs.gov/sites/default/files/operation-trialblazer.pdf.
[188] *Id.*
[189] Nat'l Sec. Comm'n on Emerging Biotechnology, Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity, rec. 1.1a (2025), https://www.biotech.senate.gov/wp-content/uploads/2026/07/NSCEB-Full-Report-%E2%80%93-Single-Pg-%E2%80%93-July-2026.pdf.
[190] *Id.*