

Testimony before the Select Committee on Strategic Competition Between the United States and the Chinese Communist Party

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Chairman Moolenaar, Ranking Member Khanna, and distinguished members of the Committee: I am grateful for the opportunity to testify before you today regarding the importance of competing with the rapidly expanding Chinese biomedical innovation ecosystem.

I am the CEO and Co-Founder of Strand Therapeutics, a clinical-stage biotechnology company based in Boston, MA, with a pipeline of breakthrough RNA therapeutics for cancers and autoimmune diseases. Since founding Strand, I have personally witnessed the impacts of Chinese competitors on our biotech industry's ability to discover and advance medicines for patients with these serious conditions. Beyond my role as a founder, I also serve on the Board of Directors for the Biotechnology Innovation Organization, where I interact with biotechnology and pharmaceutical leaders from across the nation, through which I have also seen how China is impacting the development of our medicines¹. I am grateful to the Committee for its focus here today on the ways in which Chinese firms and the Chinese government have attempted to undercut American innovators.

The challenge before us centers heavily on the supply chains that biomedical discovery – and commercialization – depend on, not just for the materials that go into our medicines, but the data that drives decision-making. Investment in therapeutics, and the scientists who make them, depends on data. Data may come “preclinically” in the form of animal studies, or more importantly, “clinically,” where we test the safety and efficacy of drugs in humans through clinical trials. China is rapidly usurping our command of both of these sources of data.

The result is an increasing reliance, not only on Chinese manufacturers for basic ingredients, but Chinese innovators for early in-human results. This is a very precarious position for our nation, as the country that commands the infrastructure to produce this “first-in-human” (FIH) data most efficiently, is where much of the upstream and downstream development of drugs will be anchored.

Thus, biotechnology and medical innovation *is* national security: Full-stack development, testing, and manufacturing of novel therapeutics happening solely in China means it is not

¹ The views and opinions I express below are solely my own and do not necessarily reflect the views of Strand Therapeutics, BIO Inc., or any of their affiliates.

happening here at home. In strategic competition, the house always wins if the underlying infrastructure favors one side. The risk of this foreseeable future lies in our looming dependency on China for key drugs that everyday Americans need today, as well as the drugs of tomorrow. Fortunately, this future is not inevitable. We can and must work to secure our nation's ability to invent, produce, and distribute the therapeutics keeping hundreds of millions of Americans healthy, without having to turn to Chinese competitors at each step of the process.

The Importance of First-in-Human Data:

The defining competitiveness metric in 21st-century biotechnology is no longer who can discover a therapeutic candidate first. It is the time and cost required to move from ideation to dosing the first human patient with a novel therapeutic, while preserving safety. Today in the United States, that timeline typically ranges from 24–36 months. During that period, promising candidates remain in regulatory and manufacturing limbo, capital is held back pending early human validation, and innovators increasingly look overseas for faster pathways to early clinical readouts. Competitors who are able to move through this process faster not only get the advantage of being first, but also benefit from the lower overall cost of development.

China has moved aggressively to compress this metric, decentralizing early clinical initiation and investing in geographically dispersed clinical trial infrastructure. China is positioning itself to become the place where early clinical proof is generated, and therefore where capital, partnerships, and manufacturing capacity concentrate. In turn, Chinese firms have attracted exponential amounts of large partnerships, reducing cash-flow to American innovators². Furthermore, in 2025, China also surpassed the U.S. in overall clinical trial activity, largely driven by the number of early-phase trials that are conducted there³.

First-in-Human (FIH) clinical data has become a driver of where entire biotechnology ecosystems concentrate, and where the absence of that capability can create significant economic and strategic fallout. Innovation ecosystems tend to influence where production happens and biotechnology companies will increasingly cluster around the locations where human clinical data can be generated most efficiently. Such readouts increase the likelihood of programs succeeding, thus driving investment, growing companies that draw talent, leading to more innovations, and necessitating better biomanufacturing capacity and regulatory expertise. The cycle repeats, pulling more investment, partnerships, and talent away from American innovators. All the while, our existing clinical trial infrastructure atrophies as China's grows stronger and more experienced, producing more FIH readouts.

² [JPM Q2 Biopharma Report](#). Share of global big pharma deals has increased to 38% YTD in 2025, compared to 3% in 2022; a nearly 1200% increase in just 3 years.

³ [China surpasses US for annual number of clinical trials](#). In early 2025, China surpassed the U.S. in Clinical Trial Activity.

The national security implications of this layer migrating overseas are straightforward. As early clinical validation layers of biotechnology shift to adversarial nations, the United States is actively losing leverage across not only upstream manufacturing of key pharmaceutical ingredients, but also downstream pricing, distribution, and industrial control. As investment into these pillars goes overseas, domestic counterparts are weakened. The resulting situation hands China growing unilateral control over an industry that saves millions of American lives every year.

This is the same structural logic that created strategic vulnerability in hard manufacturing and critical mineral supply chains. It is not the warehouse that matters, it is control of the input that enables all downstream value creation. In biotechnology, early human validation has become that input.

Beyond that, keeping FIH trials in America becomes an economic imperative. The U.S. accounts for roughly half of global pharmaceutical spending through public programs and private insurance. If discovery and early development move abroad, we risk locking in a massive trade imbalance: foreign countries develop the drugs, and Americans pay the bills.

The Bottleneck from Preclinical Readiness to FIH Dosing

Our existing system makes it too slow and expensive to obtain FIH readouts relative to global competitors. Even when an early study is small, single-site, and based on a modality with existing precedent, it is often cheaper and faster to initiate that trial overseas (often in China). The effect is that the United States has built a discovery engine capable of generating increasingly sophisticated therapeutic candidates, but our infrastructure to bring that candidate to patients has not scaled in parallel.

The reason why trials in China (and Australia) are quicker and easier comes down to one simple factor: **decentralization** (and, in China's case, cheaper labor and input costs). In the U.S., when a sponsor seeks to initiate a trial in humans (even a single site FIH trial), they almost always have to submit an investigational new drug (IND) application with the FDA. This process is incredibly laborious, time-consuming, and resource-intensive, for both companies and the agency. In Australia and China, their regulatory agencies delegate the approval of these early phase trials to local institutional review boards (IRBs) without compromising safety and while retaining approval and review rights for trials with less proven modalities and larger cohort sizes, such as later-phase safety and efficacy trials. In Australia this is known as a "Clinical Trial Notification" (CTN) scheme which allows trials with therapeutics of precedented modalities to move into trials simply by sending documents to the federal regulatory body, and moving into discussions with the IRB. The federal government still retains a "Clinical Trial Application" (CTA) scheme for early trials of very novel therapeutics with unknown safety profiles, and larger, later-stage trials.

This greatly accelerates the speed of getting clinical trials set up while still ensuring the legitimacy and safety of trial sponsors. I personally know of many biotechnology founders who have faced decisions of quality vs speed when facing the financial realities in the board room of initiating trials abroad.

As therapeutics become more personalized and AI-assisted design accelerates iteration, this mismatch becomes more pronounced. Personalization implies smaller batches, tighter logistics, and more rapid design-to-test cycles. Operating in China or Australia means that regulatory affairs aren't a major rate-limiting factor, whereas operating in the U.S. will be an increasingly costly decision. This rising cost is being factored into countless decisions that drive where new companies incorporate, where biomedical manufacturing sites are built, and where later stage trials are run. In turn, fewer and fewer companies are innovating *and* translating their discoveries here at home. Beyond the economic and industrial effects of this shift, this will mean fewer Americans will have access to innovative clinical trials, especially those in rural parts of the country. Already, millions of Americans are unable to access clinical research sites because of distance⁴, a problem that will only be exacerbated if more trials shift overseas.

Integrating Manufacturing and Clinical Trials

Another major constraint lies in the relationship between manufacturing and clinical testing. China has invested heavily in biomanufacturing capacity in order to enhance the efficiency of developing precision (and personalized) therapeutics. Here in the U.S., biologic production batches, even for FIH trials, must be manufactured in *full* "GMP" sites, analyzed, transported, and then delivered to the patient at the clinical site. In many cases, the company, manufacturing facilities, and clinical trial sites operate as separate institutions with independent processes and timelines, thus adding another layer of time and cost that drives innovators and drug development overseas. Integrating early manufacturing capabilities directly with clinical trial infrastructure could significantly reduce these delays.

Clinic-integrated or clinically-aligned (geographically co-located) manufacturing facilities can allow therapeutic candidates to move rapidly from production to patient dosing. This integration would enable faster iteration, support accelerating trials of platform therapeutics, and allow multiple early-stage programs to run simultaneously. Importantly, early manufacturing decisions also shape downstream production geography. Where early-stage production occurs, scaled manufacturing often follows as capacity scales "out". Ensuring that early development infrastructure remains in the United States therefore strengthens the broader domestic bioindustrial supply chain.

⁴ Shriver SP, Sahar L, Douangchai Wills VL, Adams DV, Fleury ME. Assessing populations with access to National Cancer Institute-funded sites using local distance-based service areas. *Journal of Clinical and Translational Science*. 2025;9(1):e218. doi:[10.1017/cts.2025.10148](https://doi.org/10.1017/cts.2025.10148)

This infrastructure is particularly important as biotechnology shifts toward more personalized and modular therapeutic modalities such as cell therapies, genetic medicines, AI-designed proteins and small molecules, and other emerging platforms that increasingly rely on smaller manufacturing runs and rapid iteration between design and testing. These therapies do not fit neatly into traditional pharmaceutical manufacturing models built around centralized facilities producing large volumes of a single product. Instead, they require development environments capable of producing small, specialized batches and delivering them to patients quickly. When early manufacturing and clinical systems are tightly integrated, companies can test more programs, iterate faster between design cycles, and generate the early human data needed to guide further development.

The competitive implications of this integration are significant given the importance of manufacturing capacity to the aforementioned cyclical relationship between FIH data, investment, manufacturing capacity, etc. Because early-stage manufacturing and clinical testing is consistently slower here at home, companies have been (and will continue to be) moving their research and development programs – as well as their manufacturing partners – to China. Conversely, strengthening the integration between early manufacturing and clinical infrastructure in the United States would help anchor the earliest stages of therapeutic development domestically, ensuring the initial validation of new biological technologies occurs within American clinical systems, reinforcing our broader innovation ecosystem and maintaining the industrial base necessary for long-term leadership in biotechnology.

Shifting Biodata Strategies to Account for Breadth and Depth

For most of modern biomedicine, depth of evidence has been the central aim: large, later-phase trials providing a “pivotal” readout on a single therapeutic. Such a system is still necessary for safety-focused regulatory approval and marketing to patients. But the AI-enabled era in which we are living introduces a second strategic objective: breadth. Countries that can generate structured, diverse, and multi-modal FIH data across many programs simultaneously gain a powerful advantage. It is not enough to generate high-quality data on one or a few programs. These data enable faster iteration for platform/personalized therapeutics and allow AI tools to identify patterns in human biology that would otherwise remain invisible.

The clearest way to illustrate this is to understand the subsetting problem in biotechnology. For many large trials, some patients respond differently than others. The same drug causes different patients to have different responses because the underlying biology is different. These “subsets” of patients represent areas where depth (i.e. more patients on the same drug) does little to improve outcomes. Generating 1000 data points for 1 intervention is valuable for validating the efficacy and safety against biology we know. But 10 data points across 100 drugs can help us run more specific trials for those different “subsets” of patients, before the larger trial ever begins.

Although the U.S. retains leadership in the large, late-stage trials (such as the 1000 patients on 1 drug), China is rapidly catching up, while handily outpacing us in the depth component.

The total number of data points may be similar, but the informational value is not. While large American firms are able to reinforce the finding on candidates they have developed or acquired, smaller American biotechs and spin-outs face Chinese competitors that are able to obtain much richer data across multiple variations of a drug, faster and cheaper. Meanwhile, these companies are also competing with large domestic pharmaceutical companies that have the incumbent advantage of capital and regulatory expertise to outpace or acquire start-ups before they can obtain FIH data. While my company, Strand Therapeutics, has succeeded in this space, many similar companies have not, to the detriment of our innovation ecosystem and the options eventually afforded to patients.

In the long run, the country that can safely generate both breadth and depth of early human data will host the ecosystem amenable to rising firms and innovators creating more competitive markets, with more therapeutic options and trials for patients, optimized for the future of AI-guided biomedical discovery. The country winning that race right now is China.

Reinforcing the Competitiveness of American Biotechnology

The U.S. continues to hold the lead in biomedical discovery, entrepreneurship, and clinical excellence; we must not ignore that this lead is rapidly dwindling. The decisive competitive question before us is whether we can translate those discoveries into early human validation faster and at a greater scale than Chinese competitors. The CCP has recognized that the critical infrastructure in biotechnology is not just manufacturing capacity or laboratory research, it is the system that connects discovery to early clinical data. As such, they have invested heavily in reducing the regulatory and logistical burdens to obtaining that FIH data, drawing a great deal of partnership investment, talent, and clinical trial activity to date.

If this shift continues, the consequences will extend far beyond individual clinical trials. Over time, this dynamic could relocate the center of gravity of the biotechnology ecosystem to cities like Shanghai and Beijing instead of Boston or San Francisco. However, we can reverse this trajectory. Doing so requires focusing on the key bottlenecks that currently slow American innovators in the transition from preclinical data to FIH dosing.

Three strategic priorities are particularly important:

Recommendation 1: Create a Phase-Appropriate Pathway for Defined Early FIH Trials

The U.S. must modernize the pathway for initiating defined early-phase clinical trials. Many FIH studies are small trials with 1-4 clinical sites designed primarily to evaluate safety and biological activity among patients for whom no other standard of care exists. Establishing more flexible

initiation pathways for these studies while maintaining FDA oversight and safety standards would reduce unnecessary delays and allow innovators to rapidly obtain early clinical signals.

It will be essential to explore legislative and regulatory mechanisms to create such opportunities for accelerated FIH trials. This shift would not need to alter the regulatory mechanisms of larger later stage trials but create accelerated initiatory pathways such as those seen under the CTN scheme in Australia.

Recommendation 2: Align Early Manufacturing and Clinical Systems for Speed and Breadth

Early-stage manufacturing infrastructure must be better aligned with clinical trial systems. As emerging therapies increasingly rely on smaller manufacturing batches and rapid design-to-test cycles, closer integration between manufacturing and clinical environments will become essential. Hospital-integrated or clinically aligned manufacturing capabilities can reduce logistical delays, enable faster iteration between therapeutic designs, and ensure that early validation of new technologies occurs within American clinical systems. Given the success of pilot small-scale manufacturing collaborations between American biotechnology companies and hospitals, reducing financial barriers through capital support from the U.S. government would be an efficient and effective mechanism to expand this model.

Recommendation 3: Establish Standing Coordination Architecture for FIH Data Acceleration

The U.S. must align regulators, funders, clinical systems, and innovators around a shared objective: **compressing the timeline from therapeutic discovery to first-in-human dosing**. The prior examples of such coordination from Operation Warp Speed during the COVID-19 pandemic demonstrated that when regulatory engagement, manufacturing preparation, and clinical planning occur in parallel rather than sequentially, development timelines can be dramatically reduced while maintaining rigorous safety standards. Aligning key stakeholders around this metric is the primary way in which we can counteract the central decision making authority of the CCP and state-affiliated biotechnology entities to ensure America remains the most competitive and preferable location to discover, test, and manufacture new medicines.

Conclusion

In conclusion, biotechnology is increasingly becoming a strategic industry that will shape economic growth, public health, and national security in the decades ahead. In the end, the entire modern competitive dynamic can be summed up in two words: **human data**. This data will be the determining factor of where the orbit of biomedical innovation will be centered upon for decades to come. The defining competitive metric in this industry is no longer simply who discovers a promising therapeutic candidate first. It is who can move from discovery to validated human data most quickly and effectively.

FIH data is the input that drives the biotechnology ecosystem, attracting investment, enabling partnerships, building manufacturing capacity, and accelerating the next generation of innovation. The country that generates this data most efficiently will shape where biotechnology companies form, where scientific talent concentrates, and where future therapeutic breakthroughs occur.

Today, the United States remains the global leader in discovery science. But if early clinical validation increasingly occurs overseas, the downstream consequences will gradually shift the biotechnology ecosystem away from American innovators. If the infrastructure required to generate early human clinical data predominantly exists elsewhere, competition may feel rigged from the start for American biotechnology companies, leading to a decreased ability to access early stage investment capital. This outcome is not inevitable. By modernizing early-phase clinical pathways, integrating manufacturing with clinical infrastructure, and aligning stakeholders around faster generation of first-in-human data, the United States can secure the infrastructure required to maintain leadership in biotechnology.

Doing so will ensure that the medicines of the future are not only discovered in America, but also developed, validated, manufactured, and first commercialized here at home.