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FROM THE SCIENCE LAB TO THE MEDICINE

CABINET: HOW CHINA IS CORNERING

THE MARKET ON OUR MEDICINES

Wednesday, March 18, 2026,

House of Representatives,

Select Committee on the Strategic Competition between

the United States and the Chinese Communist Party,

Washington, D.C.

The committee met, pursuant to call, at 10:02 a.m., in Room 390, Cannon House Office Building, Hon. John Moolenaar [chairman of the committee] presiding.

Chairman Moolenaar. The Select Committee will come to order. Good morning, everyone. China is cornering the market on our medicines from the supply of generic drugs that Americans depend on every day to the cutting edge biotech pipeline that will determine who leads medicine in the years and decades ahead. For most of American history, when a doctor prescribed a medication, it was made in our country or somewhere we trusted. That is no longer true, and it is a problem many Americans are unaware of.

About 90 percent of the prescriptions filled in this country are generic medicines, off-patent drugs for blood pressure, diabetes, infections, blood clots, and other conditions. The ingredients that go into these medicines are called active pharmaceutical ingredients and they are largely produced overseas. The upstream chemical building blocks that feed these ingredients' key starting materials are dominated by one country: China. This didn't happen by market forces. It happened by China's design. Decades of Chinese state subsidies, low environmental standards, and other factors drove western competitors out of the market entirely.

Today, U.S. antibiotics in Tennessee is the only remaining American manufacturer of amoxicillin, which is one of the most commonly prescribed antibiotics in the country. For Heparin, the blood thinner used in surgeries, virtually all global processing occurs in China. According to Washington University in St. Louis, 83 of the top 100 generic drugs used by Americans have no domestic source of key ingredients.

We have seen this playbook before in steel, in solar, and in rare earths. China enters the market with subsidized capacity, prices out competitors, and waits. The difference here is that the product is medicine. If China restricted API exports tomorrow in the same way it has restricted rare earth exports, then American hospitals and pharmacies would begin running short on essential medicines. Our military, our veterans, and our most vulnerable patients would be the first to feel it.

China's also now leveraging its dominance of the low tech base of the pharmaceutical

industry to seize control of its high tech profitable future. China's moving aggressively up the pharmaceutical value chain into the development of innovative new drugs. In 2020, essentially zero percent of the world's large pharmaceutical licensing deals involve Chinese origin molecules. In 2025, that figure was 48 percent.

Chinese biotech firms are now developing novel cancer treatments, diabetes drugs, and biologics, and U.S. pharmaceutical companies facing a wave of patent expirations on the their most profitable drugs are increasingly buying what China is selling. Part of what is driving this is China's clinical trial system. China has transformed itself into the cheapest and fastest place in the world to run early stage human drug trials. However, its combination of deregulation, state subsidies, and lax ethical standards would not be acceptable in the United States.

Studies show that more than 60 percent of patients in Chinese clinical trials were started on treatment before being informed of their diagnosis. China runs trials at PLA military hospitals and in Shenzhen where there has been a documented history of people being coerced into medical studies amid the Chinese Communist Party's genocide targeting Uyghur Muslims and other minorities.

In spite of this forced testing, the Food and Drug Administration currently allows companies to use data from unsuspecting Chinese trial sites -- uninspected Chinese trial sites to advance drug applications in the United States. The result is a feedback loop that hollows out American biotech capacity while building China's. As early stage trials migrate to China, the infrastructure, expertise, and investment follow. The United States is left with fewer trial sites, fewer trained researchers, and a drug pipeline that is increasingly made in China.

The witnesses before us today have direct experience with these two threats to our Nation's medicines. We are going to hear about what the supply chain looks like from the inside, what China's ascent means for the future of American medicine and what Congress can do about it. We have allowed this vulnerability to develop quietly over decades while we focused only on cost and

blinded ourselves to the consequences for national security, the economy, and the health of the American people.

I look forward to hearing from our witnesses, and I now recognize the Ranking Member, Ro Khanna, for his opening statement.

Mr. Khanna. Thank you, Mr. Chairman, and thank you for convening this hearing, which is of bipartisan interest. Thank you to our witnesses for appearing before the committee today. Medicines are not just another traded commodity. They are the foundation of public health. When a geopolitical rival controls the supply of critical medicines, it creates intolerable risks. Over the past two decades, global pharmaceutical supply chains have become concentrated in China, especially the raw materials and chemicals that are used to make medicines. Forty-one percent of key starting materials used in U.S. approved medicines come solely from China. One in 10 critical inputs, China's market share exceeds 99 percent.

The situation with finished pharmaceuticals is similarly dire. The United States relies on China for over 90 percent of antibiotics, imports, including penicillin and streptomycin. We get 99 percent of our prednisone, an anti-inflammatory drug, from China. This kind of concentration creates a dangerous chokepoint. This level of dependence poses risks for drug availability, patient safety, supply chain resilience, and economic security.

Beijing has designated biotechnology and pharmaceuticals as key strategic industries and is investing heavily in medicines of the future. In 2024, China accounted for nearly a quarter of the global pipeline of first-in-class drug candidates. If this trajectory continues and we do not act, the world could face dependence on China not only for raw materials for medicines, but also for new and innovative drugs.

At the same time, we also must acknowledge U.S. policy in shaping these outcomes. The United States cannot address supply chain vulnerabilities if our relationship with China is managed poorly. The unpredictability encourages Beijing to lean even harder on strategic leverage it has

developed across industries.

Now, if we are serious about derisking from China, we have to be serious about rebuilding American strength. Pharmaceutical manufacturing and drug development depend on long-term investment, scientific research, and stable economic policy. This administration's cuts to Federal agencies that support research and regulatory oversight weaken the foundation of American pharmaceutical leadership.

For decades, agencies like the NIH and FDA have helped make the U.S. the global center of pharmaceutical innovation. NIH investments in biomedical research, clinical trials in regulatory science have supported the discovery of life-saving medicines.

From 2000 to 2023, NIH research supported 59 percent of new drug approvals in the U.S. But the Trump administration has led a vicious attacks on the agency. They canceled 5,844 grants, which include clinical trials in cancer research, and Trump has proposed slashing $18 billion, or 40 percent of the NIH budget. Thousands of the career NIH staff have been forced out. The Congressional Budget Office estimates that a 10 percent reduction in NIH funding reduces new drug development by about 4.5 percent. The FDA has lost 20 percent of its staff under Trump, including facility inspection staff and staff who test samples from batches of pharmaceutical ingredients.

The Select Committee has done investigations focused on the safety of drugs coming from China and we rely on FDA inspectors in China to address these concerns. Ultimately, addressing pharmaceutical supply chain vulnerabilities will require serious sustained strategy for reduced dependence, rebuild capacity, and ensure that medicines Americans need are made in secure, resilient, and trusted supply chains not controlled by Beijing. That means strengthening research at home; it means working with allies and partners to diversify supply chains; it means building an economic environment that encourages companies to invest in production and innovation in the United States.

Today's hearing is an important opportunity to understand the scope of these challenges, to

ensure that Beijing does not control the supply chain, and to explore solutions that protect American patients and America's security.

Thank you, Mr. Chairman. I yield back.

Chairman Moolenaar. Thank you.

If any other member wishes to submit a statement for the record, without objection, those statements will be added to the record.

Dr. Jacob Becraft is the CEO and founder of Strand Therapeutics, a company building one of the most advanced programmable genetic medicine platforms in biotechnology. He received his Ph.D. in biological engineering and synthetic biology from MIT. He serves on the board of the Biotechnology Innovation Organization and the Massachusetts Biotechnology Council.

Dr. Francisco Gimenez is partner at the venture capital firm 8VC where he focuses on bio IT investments. Previously he was a resident data scientist at Formation8 and was the founder of Catenus Science, a data science consulting firm. Dr. Gimenez received his Ph.D. in biomedical informatics from Stanford University.

Mr. Patrick Cashman is president of USAntibiotics, the only U.S. manufacturer of amoxicillin-based Augmentin. He leads the team of R&D quality manufacturing regulatory fair supply chain and commercial professionals who operate from the company's world class 394,000 square foot production facility that can produce and fulfill 100 percent of the Nation's demand for these essential life-saving medicines.

And, finally, we are joined by Dr. Marta Wosinska, who is a senior fellow at the Center on Health Policy at the Brookings Institute. She is a healthcare economist with expertise in prescription drugs and pharmaceutical supply chains. Previously she worked in senior roles at the Federal Trade Commission, Department of Health and Human Services, and the FDA.

And with that, I want to welcome all of our witnesses and thank them for being here this morning, and Dr. Becraft, you are now recognized for your opening remarks.

STATEMENTS OF DR. JACOB BECRAFT, CEO AND CO-FOUNDER, STRAND THERAPEUTICS; PATRICK CASHMAN, PRESIDENT, USANTIBIOTICS; DR. FRANCISCO GIMENEZ, PARTNER, 8VC; DR. MARTA E. WOSINSKA, SENIOR FELLOW, ECONOMIC STUDIES, CENTER ON HEALTH POLICY AT BROOKINGS

STATEMENT OF DR. JACOB BECRAFT

Mr. Becraft. Thank you. Chair Moolenaar, Ranking Member Khanna, and distinguished members of the committee, thank you for the opportunity to testify on the importance of competing with the rapidly expanding Chinese biotechnology ecosystem. My name is Jacob Becraft, and I am the CEO and co-founder of Strand Therapeutics, a clinical stage biotechnology company in Boston developing next generation genetic medicines for cancer and autoimmune disease.

Today, Chinese competitors are reshaping the way we make medicines. In the United States -- here in the United States, the pattern we are seeing is all too familiar. Over the past several decades, we allowed critical manufacturing capacity to move overseas because it appeared economically efficient. In hindsight, those decisions created strategic vulnerabilities and supply chain dependencies that we are now rectifying. We cannot afford to make the same mistake with biotechnology.

Rapidly, this expands beyond an issue of health or economics but one of national security. A future where we hand control to China over the discovery, development, and manufacturing of the medicines we rely on is truly not far away. In many ways, it is already here. At the center of this competition is something fundamental to the entire biomedical industry: human clinical data. The defining competitive metric in modern biotechnology is no longer who discovers a promising therapy first. It is who can turn that discovery into first in human clinical data the fastest. The country that generates that early human data most efficiently is the country where the rest of the biotechnology ecosystem will grow. China has recognized that, and sadly, we have not.

Over the past decade, China has aggressively expanded its clinical trial infrastructure and decentralized early phase approvals. As a result, it has become significantly faster and cheaper to obtain early clinical readouts in China than in the United States. In fact, China recently surpassed the U.S. in total clinical trial activity driven largely by early-phase trials.

In turn, American companies look overseas to run trials, and many Americans, especially those in rural areas, are left with fewer options for life-saving therapies here at home. This matters, because early clinical data creates what I describe as a flywheel effect. When a therapy produces early human results, that program becomes derisked. Investors step in, partnerships form, companies grow, and manufacturing capacity expands. Clinical centers gain experience running more clinical trials and the cycle repeats.

While China's system is growing in size and experience, ours is sadly shrinking. If that flywheel continues to spin in Shanghai instead of Boston, San Francisco, or other biotech hubs here in the United States, the center of gravity for the development of most medicines will shift there as well.

But that future is not inevitable and we can fix it. Unfortunately, our current system makes it difficult for American innovators to compete on this metric. Today it often takes 2 to 3 years here in the U.S. to move from a promising discovery to dosing the first human patient in a clinical trial. In China, that timeline is often less than a year. While many American biotech companies spend millions of dollars generating lengthy INDs with thousands of pages of data to initiate a trial here in the U.S., Chinese companies are beating them to clinical trials with similar technologies. This time difference is a painful wrench threatening the future of our domestic biomedical innovation engine.

Two factors drive this delay: regulatory processes and infrastructure coordination. Early trials with only a handful of patients are treated by regulators similarly to large, later-stage trials. At the same time, manufacturing and clinical trial systems often operate separately adding additional time, cost, and even regulatory hurdles that need to be cleared.

As biotechnology moves forward, more platform therapeutic approaches, such as genetic medicines, precision drugs, and novel therapies designed with AI, this model becomes increasingly inefficient.

Fortunately, this challenge is solvable. The U.S. should modernize how early stage clinical trials are initiated. Many first in human studies are small with only a few trial sites for patients with no remaining standard of care. Creating more flexible initiation pathways while maintaining FDA oversight and safety would reduce delays and help innovators generate early clinical signals faster.

Australia is a country that does this well and should be a case study that we should learn from. They use local ethics committees to grant approval for first in human trials while remaining rigorous oversight so that safety is not compromised in the process. Decentralization doesn't mean lowering standards, because no one is more incentivized to protect patients than the hospital's own review boards that oversee the patient's safety.

Secondly, early stage manufacturing infrastructure should be reindustrialized and better aligned with clinical trial sites allowing therapies to move quickly from production to patient dosing. This will reduce logistical delays, enable faster iteration, and ensure early validation of novel therapies occurs within the American clinical setting.

Biotechnology is one of the defining strategic industries of the 21st century. It will shape economic growth, public health, and national security for decades to come. At the center of that competition is a critical question: Where will the next generation of human clinical data be generated?

Thank you for the opportunity to testify today, and I look forward to your questions.

[The statement of Mr. Becraft follows:]

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Chairman Moolenaar. Thank you.

And Dr. Gimenez, you may proceed.

STATEMENT OF DR. FRANCISCO GIMENEZ

Mr. Gimenez. Thank you, Chairman Moolenaar, Ranking Member Khanna, and members of the committee. I am Dr. Francisco Gimenez, a partner at 8VC where I lead our life sciences investment practice. I am here to deliver a warning. China has already disrupted the American biotech industry, and without bold action, we face an existential threat to one of the greatest innovation engines in human history.

In a few weeks, we are going to mark the 50th anniversary of the founding of Genentech, the birth of the modern biotech era and the half century of American exceptionalism in medicine. The scale of what we have built is staggering. In 2023, the U.S. bioscience industry generated over $3.2 trillion in economic output, roughly 7 percent of our private sector GDP. It directly employs 2.3 million Americans and each of those jobs supports nearly four more in the broader economy. That is a footprint of 10 million Americans.

But the true measure goes beyond the balance sheet. Between 1990 and 2015, the pharmaceutical innovation alone was responsible for a full one-third of the increase in American life expectancy, 75 percent improvement in HIV mortality, 60 percent in breast cancer, more than 50 percent in heart disease. These are not abstractions. These are your constituents alive today because of this system. And when COVID-19 struck, it was this same American biotech engine that delivered vaccines and countermeasures at an unprecedented speed to protect America.

To understand why the system is so vulnerable, you need to understand how it works. NIH-funded academic research generates insights into disease biology. Biotech start-ups fueled by

venture capitalists such as myself translates those insights into potential drugs. Pharma companies acquire a license to winners selling them under temporary patent monopolies that fund the next generation of R&D. When patents expire, drugs are genericised, arguably the only consistent deflationary force in American healthcare.

But the cycle is extraordinary fragile. The average drug takes 15 years from conception to approval with a success rate of about 10 percent and a fully loaded cost of 1 to $3 billion. While we were building this engine, China was watching, learning, and planning.

In 2020, essentially zero medicines licensed by global Pharma originated from China. In 2025, that is roughly half. China overtook the United States in clinical trial volume in 2021 and has widened that lead every year since. Cross-border licensing deals from Chinese biotech exploded from $14 billion in 2021 to $138 billion in 2025, a 10X increase in 4 years. This is not an accident. It was a deliberate state-sponsored strategy executed through the made in China 2025 initiative started 10 years ago.

Heavily subsidized Chinese research organizations provided high quality inexpensive labor for biotechs. Their sea turtle policy sent Chinese scientists to train in U.S. institutions and incentivized them to return home with our knowledge in hand. Copycat Chinese biotechs licensed drugs to global pharmaceutical companies at 50 to 80 percent lower costs than we were able to do in the United States. We have effectively trained and funded our own competition.

And they are competing on an unlevel playing field. While they generate data two to five times faster and 30 to 50 percent cheaper, this is due, in part, to running trials in Peoples Liberation Army hospitals in the Shenzhen region where credible informed consent is practically not existent. If this continues, the consequences cascade. Trial sites move abroad weakening our top research institutions. Our biotech private sector will move away, and beyond economics, we lose control over which diseases are prioritized for the American patients. This means we also lose our biosecurity, our ability to rapidly develop countermeasures to pandemics. Imagine facing the next

COVID dependent entirely on what China decides to offer us.

On a global scale, the rise of China is fantastic for patient outcomes and biosciences innovation. My perspective is that we cannot seek to compete by blocking Chinese innovation. Instead, we need to take this moment to introspect on the U.S. system, and make bold measures to improve ourselves to retain our dominance. We need to set moon-shot goals for the U.S. life sciences innovation to not just follow, but continue leading.

My audacious proposal would be to create a system that allows us to take drugs from molecular conception to approval within 5 years. To do so, we would require major rearchitecting of the FDA and our research sector to allow for this level of speed.

Several initiatives could do this. We need to dramatically reduce the overhead for clinical trials and safely cut six to 12 months from early stage pipelines. The FDA has the authority to pilot this today.

We need to stop the sea turtle pipeline and create streamlined immigration paths for top global scientists such that when we train them, we retain them here. We need to modernize our FDA with advanced technologies that can make use of historical data to improve in our private sector companies.

And finally, we need to level the playing field by preventing clinical data from being used for U.S. approvals in sectors where they are not following our same strict rigor in clinical standards.

Members of the committee, the time for complacency is over. We have to protect this crown jewel not just for economic security but for the health and survival of American people. Thank you.

[The statement of Mr. Gimenez follows:]

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Chairman Moolenaar. Thank you.

Mr. Cashman.

STATEMENT OF PATRICK CASHMAN

Mr. Cashman. Chairman Moolenaar, Ranking Member Khanna, and distinguished members of the committee, thank you for convening this hearing. My name is Patrick Cashman and I serve as President of USAntibiotics headquartered in Bristol, Tennessee. We are the last domestic manufacturer of amoxicillin, the most prescribed antibiotic in the United States. We formulate, fill, and finish the drug entirely in America and we have never purchased active pharmaceutical ingredients from China.

The amoxicillin supply chain has three layers: key starting materials, active pharmaceutical ingredients, and finished dosage forms. China dominates the foundational layers. In October 2025, U.S. Pharmacopeia analysis found China is the sole supplier of at least one key starting material for 37 percent of all U.S.-approved medicines. India, often is seen as an alternative, relies on China for about 90 percent of its amoxicillin precursor chemistry. The apparent diversity on pharmacy shelves is largely an illusion. One in three U.S. hospitals experience severe effects from the 2022, 2023 amoxicillin shortage, which resulted from routine supply chain fragility, not foreign interference. A geopolitically motivated restriction as seen recently with critical minerals would be faster and more severe.

The quality gap increases the security risk. A 2025 study from Indiana University and Ohio State University found serious adverse events, including hospitalization, disability, and death were 54 percent higher for generic drugs made in India than those made in the United States. Domestic facilities received unannounced inspections while foreign facilities have historically received up to 12

weeks notice allowing time to conceal issues. A 2023 Pentagon review found the API country of origin was unknown for 22 percent of drugs for servicemembers. We cannot protect a supply chain we cannot see.

Our facility has supplied amoxicillin to American patients for over 40 years. Until 2008, every U.S. amoxicillin prescription was filled from our Bristol plant. A decade of subsidized foreign competition eliminated our market share and forced our previous owners into bankruptcy. In 2021, Jackson Healthcare acquired us as a national security commitment, not a business investment.

Our parent company has invested tens of millions of private dollars to restore domestic production while absorbing losses. We compete with foreign manufacturers who benefit from State subsidies, lax oversight, and prices that sometimes fall below our raw material cost. We accept these disadvantages because the alternative poses a national security risk.

However, our ability to overcome these challenges is not unlimited. If we close permanently, rebuilding from scratch would take a decade assuming capital, regulatory approval, and a skilled workforce are available. None of these are guaranteed.

This committee can take specific actions to help preserve U.S. pharmaceutical manufacturing capacity. First, define domestic pharmaceutical manufacturing as the process of formulating, filling, and finishing drugs from API so that the Federal procurement preferences reward companies that actually manufacture, make medicine in America. Second, direct strategic national stockpile to prioritize domestic manufacturing through multiyear purchasing agreements. Third, signal bipartisan support for the ongoing section 232 investigations into pharmaceutical imports and urge prominent treatment for the upstream supply chain, the KSMs, and the APIs, where China's chokehold is the tightest and the consequences of disruption are the most immediate.

America's most prescribed antibiotic can be made entirely in the United States, and for more than 40 years it was. We have the facility, the expertise, and the production capacity to do it again. My colleagues and I are looking for this committee to help create a policy framework that treats

domestic production of critical medicines as the national security priority it is. Thank you, and I welcome your questions,

[The statement of Mr. Cashman follows:]

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Chairman Moolenaar. Thank you very much.

Dr. Wosinska, the floor is yours.

STATEMENT OF DR. MARTA E. WOSINSKA

Ms. Wosinska. Thank you, Chairman Moolenaar, Ranking Member Khanna, and members of the committee. Thank you for the opportunity to testify. My name is Marta Wosinska and I am a senior fellow at the Brookings Institution. I am testifying today in my personal expert capacity. I am an economist with expertise in prescription drug markets, and I have been studying resilience of generic drug supply chains for about 15 years.

Over these years, I have seen many policy ideas in this space fall short. Many ideas sound good and strong and intuitive, but they often fail to grapple with four key questions. Today I want to use those four questions to frame how we should think about derisking our drug supply chains dependence on China.

Question number one, what problem are we trying to solve? We often hear that about 80 percent of plants that make active ingredients for our drugs are outside the United States. If we treat that as the problem, then unshoring those plants sounds like the obvious fix. But if our concern is China, we must recognize that China controls the chemical precursors those plants need. If China shuts off those chemicals, it won't help that an active ingredient plant sits on U.S. soil. If we want to derisk from China, we need to derisk those chemical inputs.

Question number two, for the solutions to work, what else must happen? Any serious effort to derisk from China will cost money. There is no free lunch. To make progress, Congress must be willing to allocate funding for a more secure chemical and generic manufacturing capacity and to pay more for the products that come from it. At this point, you might reasonably ask aren't we already

spending too much on drugs and you want us to spend more? But please remember I am only talking about generics. Generics account for more than 90 percent of prescriptions but only a small share of drug spending.

A life-saving hospital medicine may earn a generic manufacturer less than a cup of coffee. A 30-day supply of a chronic generic drug sells to pharmacies for less than $1.50. For these generic staples of American healthcare, we must be willing to pay more for supply chains that are not built on cheap Chinese inputs.

Question number three, what is the best use of limited dollars? The scope of our dependence is so broad that we must prioritize which supply chains to secure first recognizing that we must secure more than just the active ingredient and finished dosage form steps we normally call drug manufacturing. If policymakers sprinkle taxpayer dollars across many drug supply chains without clear priorities, they risk spending a lot and changing very little. The smart path is to reserve full end-to-end onshoring for critical drugs for which we are likely to compete with China and with others in a pandemic or a major natural disaster. Think emergency room medicines, antibiotics, and intensive care sedatives.

For the widely used everyday medicines that treat hypertension, high cholesterol, and depression, we should lean on friend shoring. Friend shoring lets us leverage the fact that most of our exposure to China -- most of our exposure to Chinese chemicals is not direct, but runs through India and Europe, countries that supply our market but rely on Chinese inputs. Those countries are also concerned about their own exposure to China, and are working to decrease it benefiting us along the way.

Question number four, how do we avoid unintended consequences? Congress has a critical role here. If tariff policy, procurement rules, and payment reforms sent weak or mixed signals, and purchasers keep paying only for the cheapest version, manufacturers at home and in allied countries will keep leaning on low-cost Chinese inputs. We have already seen firms in allied countries shift

critical manufacturing capacity toward China because buyers would not pay for the derisked production. This is the opposite of what we want.

So as you consider legislation, the question is not only whether a policy sounds tough on China and enhances onshoring, but also whether it enhances friend shoring. Congress can help by locking in clearer long-term signals in statute on tariffs and reliability-based payments so that our policies support our allies efforts to lower their dependence on China, and in doing so, make our own drug supply chains more secure.

If you would like more detail, I refer you to my written testimony which lays out these issues in much more detail. And thank you again for inviting me to participate, and I look forward to your questions.

[The statement of Ms. Wosinska follows:]

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Chairman Moolenaar. Thank you very much, and I will now recognize myself for 5 minutes of questions.

Dr. Becraft and Dr. Gimenez, in the last 5 years, China went from zero to 48 percent of large global pharmaceutical licensing deals. We have seen this trajectory before in other sectors. At what point does the United States lose the ability to reverse course in biotech the way we lost the ability to reverse course in manufacturing sectors?

Mr. Gimenez. I think we lose our ability to do so when we lose this unstructured interplay between all these components. So when the financing environment moves to China, essentially the VCs move to China, that is going to hollow out our ability to have local biotech companies in the United States, and that is going to reduce the amount of clinical trials we have here, and then we are also going to have Pharmas seeking to license drugs from China, so I think from my perspective, and in my vantage point, a lot of the system is managed through financial incentives, and that is going to be when we stop seeing it as valuable to invest in local U.S.-based companies, that is really going to be to me the bellwether that it is over.

Mr. Becraft. To actually build on my colleague's statement there, I actually believe that this movement is very much under way and accelerating. One thing to understand about the biotech industrial base that we have here in the United States as it relates to drug discovery is just how fragile it is, so companies like mine, for instance, we don't make any money. We don't sell any drugs. We are a research and development organization that is 100 percent dependent on investor capital or partner capital to come in to pay for the very large prices of drug development. If you compare that to the manufacturing sector, which took decades to decay and go overseas to China and others, those are industries backed by both revenue, solid assets, real estate, Capex, that took many, many years to decay.

If the financial incentives, as my colleague just mentioned, begin to shift where investors and

partners want to invest into Chinese competitors and licensed Chinese assets, the flywheel is on the order of a few years to completely collapse the ecosystem. Most -- a number of public biotech companies have less than 18 months of cash on hand, and so if you cannot raise money and you cannot sell things, your company will die and that will happen very quickly.

Chairman Moolenaar. Thank you. I would like to address this to all four of you. As you know, in the budget recently signed into law by the President, increased funding for NIH, what can Congress do in the short term in the next 2 years to address clinical trial migration and early stage drug development migration to China in the next 2 years? What can Congress do?

Mr. Gimenez. Very simply, I think the best thing we can possibly do is allow the FDA to get to first in human clinical data as quickly as possible, so that biotech companies can compete with China on clinical trial data.

Mr. Becraft. Between coupling and incentivizing small scale manufacturing, the FDA can also work with companies to find correct regulations for the stage of which a drug is being tested, manufacturing requirements on those drugs, especially for complex new medicines, and in addition, move, like I also laid out in my written testimony, we need to move faster to first in human clinical data. I think that China today is the best at running from idea to dosing a first in human and getting that critical early stage first in human data. They don't aspire to be the greatest country at running first in human clinical data, and I think it is on everyone here on this committee to recognize that.

Mr. Cashman. In the case of generic manufacturing, I don't know if we have a lot to offer in this particular thing, but one thing I would mention that was very favorable is recently the commissioner's voucher program was very instrumental in us bringing some products back to the market quickly, and I think anything that would move products closer to approval quickly, such as a rapid review of data, would be beneficial to the industry.

Ms. Wosinska. I will just, you know, echo here what Patrick Cashman just said in that this is, you know, the drug development piece of it is really for the other witnesses to offer. I have plenty

of recommendations of what Congress could do in the next 2 years on generic drug supply chains, but I think that is a different question.

Chairman Moolenaar. Thank you. And if I could just end by asking you a yes-or-no question. Should Congress require the FDA to inspect and verify foreign trial data before accepting it? And what would that do to the economics of offshoring early trials if so? But yes-or-no question.

Mr. Becraft. Yes. Do you want a response to the other piece of your question?

Chairman Moolenaar. I want to be sensitive to the time, but yes.

Mr. Gimenez. Yes.

Chairman Moolenaar. And then anyone who wants to add to it, but go ahead.

Mr. Becraft. I think one piece about trying to change the economics is understanding two different things, right? So there is the cost to first in human data and how that inflects the value of the given experimental asset, right? And then there is the use of that data in a future trial. The reason first in human data is so important is because it is the most hard to raise money for an idea to test. Changing those economics in terms of, like, making someone redo a phase one trial in the United States does not appreciably solve the problem if it is so radically cheaper to get that data in another country, increase your value, the economics that follow behind that will mostly remain the same.

Mr. Gimenez. So I will answer it, yes, but the second part of your question is a little bit more complex in that I don't think it will necessarily immediately drop -- or better level the playing field with costs, because there is two things we have to think about here: One is data submitted to the FDA for review, and that, of course, will be important, but the other part is that when investors are looking at data, that doesn't necessarily mean it has to be FDA reviewable. Frequently, it just has to be, you know, if you tested a drug in China and it worked on 30 people, an investor will put money behind it. They are happy to put a tremendous amount of money behind that to redo those studies

in the U.S., so it is really the time to information that is really the tricky part here, and so that is why it is just not immediately going to have an effect on cost.

Mr. Cashman. The answer is yes. I think any time, as we see with manufacturing and the FDA needs the resources, adequate resources to do inspections, whether it is for manufacturing or for clinical studies.

Ms. Wosinska. Again, difficult for me to weigh in exactly. Those are really great questions. There is always a lot of consideration, some potential unintended consequences, so I can't really weigh in. I defer to my experts on this topic.

Chairman Moolenaar. Thank you very much, and after I have violated the five-minute rule, I will allow -- I will recognize the ranking member.

Mr. Khanna. Thank you, Mr. Chair.

Mr. Cashman, I found your testimony and your work very interesting. Appreciate what you are doing to try to bring amoxicillin production back to the U.S. My understanding from your testimony is that you don't think tariffs are going to be enough, and the way I understood your testimony is that we are not producing the key starting materials here. We are not producing the APIs here. Their sole source they are being produced in China, so even if we tariff them, we are still dependent on them and we are basically paying them a higher amount because of the tariff, but it is not doing anything to bring the actual production here. Is that an accurate read of your testimony?

Mr. Cashman. Yes, Ranking Member Khanna, that is accurate. In fact, there is so much -- the Chinese Government doesn't look at this as a profitable enterprise. They don't look at it as a business enterprise. I believe they look at it as a strategic asset that they can use to leverage against us, so the cost of production is irrelevant to them. They are going to drive -- they will work to drive anybody out of business if they have to, and that is what they have done in the past and we have seen that in many, many different models across many industries.

Mr. Khanna. So it seems to me while I am a supporter of strategic tariffs to make sure that

China isn't dumping, that certainly they are not dumping steel or the things that we produce, in cases where we have lacked industrial capability, tariffs alone are not going to solve the issue. What we need to do, in my view, is what we have done from the time of Alexander Hamilton, which is actually have an industrial policy in areas that are of critical national security and critical economic security. It seems to me that key starting materials and active pharmaceutical ingredients are one of those areas. How much do you think it would cost the United States if we were to have Federal procurement agreements and help finance production for key starting materials and for the APIs for something like amoxicillin? I mean, it seems to me it wouldn't be that big of an investment that we could bring these industries back on shore.

Mr. Cashman. In the overall scheme of things, Ranking Member Khanna, it would be a very modest investment. When I look at the cost of our medications versus competitors from India and China, we are literally a few cents of dose different from those costs. When we look at the cost of API from China compared to other sources, the difference can be as much as 20 to 40 percent, so it is a significant cost difference. But to have an investment here in the United States to produce API with the, you know, relatively modest investment compared to many things we spend money on.

Mr. Khanna. And that would be the biggest game changer, right? I mean, if we had kind of a chip slack like we did for semiconductors, if we did that for key starting materials and API and if we had Federal procurement for it, like the President in his first term did with Operation Warp Speed where we had Federal procurement for the vaccines. I mean, that kind of policy, in your view, could get a lot of the key starting material and API back into the United States?

Mr. Cashman. Yes, Ranking Member Khanna, I believe that would be very helpful, but we also have to keep in mind that the Chinese will continue to drive prices down, so there needs to be mechanisms to control or restrict the market access of some of those products.

Mr. Khanna. I am all for having restrictive tariffs on them. I just want to make sure we are making stuff too, because if we don't make the stuff, we can tariff it all we want, there is no factory,

there is no production, and it seems to me that the key here is to actually get the production. You said you are about 8 percent of the amoxicillin market, right?

Mr. Cashman. Yes, sir.

Mr. Khanna. And your biggest chokepoint is these materials, correct? Not getting the -- if we had more of the key starting materials and the API here, you would be able to expand dramatically, correct?

Mr. Cashman. Additional key starting materials and API would be helpful for us, yes, of course, but we also are competing with very low-cost drugs coming from India and China and we have to compete with those products.

Mr. Khanna. It seems me a combination of strategic tariffs and smart industrial policies is what we need, and Chair Moolenaar, if there is a desire to have some kind of collaboration on this kind of policy, I would welcome working on that.

Chairman Moolenaar. Okay. Thank you.

And next I will go to Representative Dunn.

Mr. Dunn. Thank you very much, Mr. Chairman.

I want to start with something I know about firsthand not from a briefing, but from 35 years of practice of medicine. When a patient's on the table and you reach for a drug, you need that drug to be there. You need to know where it came from. You need to know that it works, and there is no time for supply chain discussions at that point when somebody's bleeding out.

The clinical reality is exactly what this hearing is about, except the patient on the table is now the United States of America. We have handed the Chinese Communist Party the eastern trade. And I spent much of my career in two institutions, medicine in the Army, institutions that take readiness seriously. You don't wait until a crisis to build a supply chain. You harden it in advance and you know your vulnerabilities and, you know, you never let a strategic adversary control your logistics. On all three counts, I think we have failed in pharmaceuticals in America, and this

committee has an obligation to say so plainly.

Here are some of the facts that we have stumbled upon in the last few years, Mr. Chair. About 90 percent of the drugs Americans take are generics. The active pharmaceutical agreements of those ingredients in those drugs, the molecules actually do the work, if you will, are overwhelmingly manufactured or dependent upon China, and for generic antibiotics roughly 90 percent of API supply originates and/or flows through Chinese manufacturing.

For Heparin, the blood thinner I frequently used over the years, essentially all global processing happens in China, all of it. All of it. That is not a trade policy problem. That is a medical readiness problem and it is a national security problem. In a conflict scenario or even a targeted export restriction, Americans are going to die because of this. I want this committee to understand this hearing's not about the supply chain vulnerabilities. We have already accepted as serious as those are, it is about where China is going next. China is executing a deliberate patient strategy to move up the pharmaceutical value chain, and in 2020 Chinese communists were involved in the virtually zero percent in 2020 of major global drug licensing deals. Today they are involved in nearly half.

In 2014, China ran few of the 2,000 clinical trials; in 2023, they ran over 11,000. As a physician who knows how long it takes to build genuine clinical trial infrastructure, those numbers don't happen by accident. They happen by design. And that is how the CCP is working. And they have done this with rare earth, solar energy, batteries, electric vehicles, all these critical sectors they dominate and they subsidize, and they move up the supply chain until they own the whole stack of the supply chain.

China's goal is not to be a supplier to our Pharma companies. Their goal is to replace our Pharma companies. And based on the trajectory we are on, they are well-positioned to do just exactly that.

As someone who spent his career in both medicine and in military service, I can tell you this

kind of vulnerability does not announce itself until it is too late. We don't find out we have a supply chain problem when everything is fine. We find out when we are in a crisis and the shelves are empty, and I am grateful to you, Mr. Chairman, for holding this committee.

Dr. Wosinska, sorry about that, it is good to see you again. Thank you for your leadership in this space. We met in December. We talked about this very issue. When I read your report, you highlighted that many of the API exposure statistics are incredibly inconsistent with some being -- reporting 8 percent, some 90 percent. So how do we actually know, you know, how exposed we are in terms of API supply?

Ms. Wosinska. Thank you for this question. You are right, it is almost peculiar number on our exposure to China when it comes to API. Some sources will say it is 8 percent and some will say it is 90 percent. I would say it is probably closer to 25 percent, and one reason is -- I mean, it is really important to understand that it varies by therapeutic class. We definitely have significantly higher exposure for antibiotics than for a lot of other drugs, but I think some of this is that those who are looking at these data are either mischaracterizing which part of the supply chain we are talking about. They're thinking about API as anything that precedes it as well, but that is a different vulnerability and different policy solutions that are coming in, so some of that is that. Some of it is misinterpreting India's reliance on China. We can really very easily see how much they import from China. We don't see how much they make in terms of API, so a lot of the mischaracterizations come from that.

What I will say, even 25 percent is very concerning, especially that it is in other settings as well. Like, antibiotics is significantly higher, and what is also really important is that they are moving strongly in that direction. So back to what Congress could do, I wanted to flag something really interesting about tariffs and how tariffs are structured and the fact that India relies increasingly on Chinese inputs, including API, because China is moving into API and really sort of growing the footprint.

The way a tariff works for prescription drugs almost always, it is the finished dosage for manufacturer will pay it based on where the API comes from. So an Indian manufacturer using Chinese API will actually pay the Chinese tariff. One reason why I was really concerned about tariffs on India is that India is trying to derisk their own supply chains, and if we were to impose a tariff on them, we would probably -- you know, they would either not have enough of a margin and they would leave the market or they might want to go for the cheapest and go towards China, and we are basically potentially going to increase our exposure to China by pushing Indian manufacturers there.

Where a tariff is great, and this is where I actually would recommend sending a much stronger signal to manufacturers in India, if you use Chinese API, you will pay a tariff. So putting a tariff on Chinese, taking the existing 10 percent tariff on Chinese manufacturers, which is not very high, increasing it, and then putting this in place in statute would send a much stronger signal to Indian manufacturers not to use Chinese API, so this is an opportunity for Congress to actually be very strategic about tariffs.

Mr. Dunn. We have exceeded my time, Mr. Chairman. I want to thank you for your tolerance, and obviously, we could talk about this all day long. You and I have I think -- yeah, I know you appreciate this given your background.

Chairman Moolenaar. Thank you very much.

Mr. Dunn. I yield back.

Chairman Moolenaar. Thank you.

Representative Brown.

Ms. Brown. Thank you, Mr. Chairman, and thank you to our witnesses for being here today. Today's hearing is about something very real for the people I represent, whether they can reliably and affordably access the medicines they depend on and whether we, as a nation, are building that capacity here at home or outsourcing if abroad.

In Ohio's 11th district, we have some of the best healthcare systems and research institutions

in the country from the Cleveland Clinic and Metro Health to University Hospitals and Case Western Reserve alongside a workforce with a long history in advanced manufacturing.

So when we talk about pharmaceutical supply chains, we are not just talking about global competition. We are talking about whether communities like the ones I represent are positioned to produce, innovate, and deliver the medicines we all rely on. Right now, we know that too much of the upstream supply chain, key ingredients, and materials that go into essential drugs is concentrated in China. And at the same time, China is moving aggressively into drug development and clinical research. Those developments create both short-term vulnerabilities and access to components and long-term risk to American leadership in innovation and production.

For northeast Ohio, this is also about economic opportunity. We have the institutions, the talent, and the infrastructure to be part of the solution, but only if Federal policy is aligned to support domestic manufacturing, strengthen our research ecosystem, and build resilient supply chains with trusted partners. Because at the end of the day, this is about more than competition. It is about health, health security, economic security, and making sure American communities are not lost or left behind.

So, Dr. Wosinska, you have highlighted that our greatest vulnerabilities are often upstream, such as the level of key starting materials, or active ingredients, whether the top targeted actions we should take right now to reduce our dependence on China for essential medicines that patients rely on every day.

Ms. Wosinska. Thank you so much for this question. For essential medicines, the ones that we are likely to compete with China for in a conflict, and frankly, with any other country, I really do think that full onshoring of those medicines including figuring out ways to make the key starting materials here either chemically or using synthetic biology is the way to do this. This is, again, not going to happen on its own. There needs to be funding for this.

And if you think about -- you know, we are thinking about national security and, you know, it

is good to put it in the context of how much DOD spends on, let's say, a fighter jet, it might be close to $100 million per fighter jet. The office of industrial base in ASPR, since I think the last 6 years, their budget was $188 million. They are supposed to be the ones helping to build that infrastructure in the U.S. so we are talking about two or three jets over six years. So. Again, this is a big call to Congress. Chair Moolenaar, this is a way for Congress to step in and, you know, the money needs to come with that.

But that is actually those medicines are actually a very small slice of what we take. If you were to take the ASPR 86 top essential medicines, I would be surprised if they ever even made up 1 percent of the patients that we -- that touched 1 percent of the patients that are in the U.S. We really need to be thinking strategically about what we are going to do about everything else, statins, SSRIs, blood pressure medications. This is where working with allies I think is really critical. In an ideal world we would onshore everything, but again, where is the money coming from? So we need to think about how can we work with India to have them derisk themselves so that we can continue to have those medicines which is, you know, if you think about your constituents, they are probably more likely to be on a statin than end up in an emergency room and need a critical medicine, so we need to be thinking about both.

Ms. Brown. Thank you.

And, Mr. Cashman, from your perspective as a domestic manufacturer, we know the U.S. has the capacity to produce more here, but we are not scaling at the level we need. In a region like mine, northeast Ohio, one that has strong manufacturing base, skilled workforce, and proximity to major healthcare systems, what is the biggest barrier to bringing that production online?

Mr. Cashman. Probably the biggest barrier is getting the right equipment and people trained and prepare to scale up manufacturing quickly. Obviously, once you have demand, we can scale up very quickly at our facility. We have plenty of production space. We have a lot of equipment. Some of that equipment needs to be updated and upgraded so we can produce more

efficiently. And then we need to find good, qualified people and train them to manufacture medications.

RPTR MOLNAR

EDTR ROSEN

[11:00 a.m.]

Ms. Brown. Thank you so much.

And if, Mr. Chairman, you will allow me to close, ultimately this should be about making sure Americans can count on safe, affordable medicines that bring communities like northeast Ohio, to be a part of that building of the future.

If we get this right, we can strengthen our supply chains, support American jobs, and maintain our leadership in innovation, and with that, I look forward to continuing to work with my colleagues on solutions that deliver for both our constituents and our country.

I yield back.

Chairman Moolenaar. Thank you.

Representative Newhouse?

Mr. Newhouse. Thank you, Mr. Chairman and Mr. Ranking Member, for having this important hearing, and also thanks to our guests here for your important testimony. It is a very important topic. It is something that deals with not only our economic security, but also national security issues and the general health and well-being of our American citizens.

So I want to start with Mr. Cashman, if I could. Thank you for coming, Mr. Cashman. Appreciate your testimony.

You talked about the amoxicillin shortage back in 2022 and 2023. So if you could, I would like you to share a little bit more about what you went through during that period, but also help us understand what the Federal Government could be doing to support manufacturers to help prevent shortages, and if they do occur, if shortages do occur, what kinds of things should we be thinking about to help mitigate those impacts?

Mr. Cashman. Thank you, Congressman. Excellent question. In 2022, 2023, we were just

getting back, restarting our facility. So we were starting to ramp up production, scaling up, hiring people, bringing the production back online, and, unfortunately, weren't fully ready to deal with a shortage like that.

We did the best we can, and we ran as hard as we could to do that, and we were able to provide quite a bit of medication to people.

What needs to be done, I think there needs to be additional investment in equipment, in bringing people and training people and bringing people online to train more -- to have higher levels of production.

I think one thing that is very important to consider for this group is that the Federal Government buys a lot of medication, and that can help drive U.S. domestic manufacturing.

The small business set-aside paradox is really something that is very quickly, easily remedied. It requires no appropriations, no regulatory overhaul, no international negotiation. It just requires a narrow clarification that national security considerations can override set-aside classifications when a genuine domestic manufacturer of a critical medication is excluded from competition.

So just getting -- using that demand as a lever to help generate and drive domestic manufacturing can be very helpful to domestic manufacturing.

Mr. Newhouse. Okay. Appreciate that. Thank you.

Ms. Wosinska. Can I chime in on amoxicillin?

Mr. Newhouse. Oh, sure. Just real quickly, sure.

Ms. Wosinska. Just really quickly, so amoxicillin was a really interesting shortage. It was really driven by a demand increase. And this is a great example of us competing with other countries, and us potentially losing because of how our system is structured.

We pay a lot less for generics than other countries do. We pay a lot more for brands, but a lot less for generics. And what was really interesting is that, for manufacturers to shift more of their sales to the United States -- basically they were getting paid more in Europe for these drugs -- but if

they were to sell them here at anything like the prices that they were getting somewhere else, they would have to pay Medicaid inflation rebates.

So we were sort of in this very uncomfortable position, manufacturers were, to a sort of how do you play here when somebody else, outside of the United States, was paying them more?

And I am not talking about China. I am talking about Europe. So you know what, if you look at my testimony, I do, and I have written in the past, that we need to be also thinking about some of the payment mechanisms and potentially making adjustments there.

Mr. Newhouse. Interesting. Thank you.

Dr. Gimenez, in your written testimony, you talked about the fact that your firm does not directly work with Chinese biotech industry. Could you share a little bit more about your decision to not invest in Chinese biotech.

And also, you mentioned that American firms with investments in Chinese biopharmaceuticals are often fearful of testifying or speaking publicly.

What have you heard firsthand from your colleagues in the industry, particularly with those that have invested in China?

Mr. Gimenez. So, despite the fact that we are saying they have great data and it is much cheaper, you have to have boots on the ground in China to be able to do this correctly.

You need to have people who go in, who speak the language, who you trust. You have to be able to diligence their documents, you need to have translators to read Chinese documents, and it is actually a pretty significant investment to be able to go there and truly diligence any kind of products there.

So we have seen this happen with pharmas who set up joint ventures a decade ago, and then we have seen this with emerging life sciences groups who have spent a lot of resources and hired out teams local to China. And that wasn't an investment we were willing to make.

We have been offered and certainly had board-level discussions with our companies to set up

JVs in China. Our concerns there were basically that you are giving up your IP, and you will end up seeing a copycat there.

So from a risk-benefit decision, we decided not to.

Mr. Newhouse. I see.

Mr. Chairman, just trying to follow your lead in going over time. I yield back.

Chairman Moolenaar. Thank you.

Representative Tokuda?

Ms. Tokuda. Thank you, Mr. Chair. You know, I also serve on the Armed Services Committee, and I am very concerned about the military's dependence on Chinese supply chains for critical life-saving pharmaceuticals.

Last year, Dr. Dunn and I, if you were here, we were trying to include in the NDAA a provision that the Department had to develop and implement a plan to derisk battlefield medicines specifically from China. Unfortunately it was dropped in conference, so it did not pass through.

I am going ahead and doing another NDAA amendment this year to specifically ask them to acquire penicillin or amoxicillin, as well as five other key battlefield drugs that we would completely decouple from China, but also to look at stockpiling at least amoxicillin and penicillin, plus 10 additional drugs, some of which could component parts come from China, again, just so that we have it there in our reserves, because I think, Dr. Wosinska, to your point, it is not just an essential list, it is actually the ones that could have the most harm if we were not able to get it, so things like amoxicillin, blood clot -- you know, blood clotting medication, those types of things.

And so I was very disappointed that the military came back actually and said that they could not support, and they would oppose my specific amendment, feeling that they were too small in terms of being a drug purchaser within the Government.

This should be, instead, a whole-of-government approach, and they felt that this was something that was too small for them to do. I am not sure.

Dr. Wosinska, in your opinion, is the military too small of a buyer to make a difference when we are, again, trying to make sure that the drugs that we have in our inventory and in our stockpile are those that have the most life-saving importance?

Ms. Wosinska. So thank you for this question. I think the role of DOD differs somewhat -- I think there is another -- sorry -- the role of DOD differs, I think, and whether they are too large or too small, depends on what you are looking -- what you are considering.

So, for example, I think DOD is in a perfect position to be doing research to understand really where the vulnerabilities are, because they rely on exactly the same supply chains as the civilians.

You know, granted, full disclosure, I am actually a beneficiary of some of the DOD research, and some of my testimony is based on this. But it benefits us broadly. So here it is not -- they aren't too small, they are perfect for this.

They do have tools -- you know, they have incredible sort of flexibility with procurement, and they also have a lot more money. I can't tell you how to think about their role in terms of, you know, could they help build civilian infrastructure that would benefit civilians as well. That is another broader thing.

Where they are limited is as a buyer. They do have only 2 percent of the market. So frequently we will say, If only, you know, DOD and VA were to start signing long-term contracts, it would be transformational.

I think it could be transformational for some small firms, and it could be helpful, but here I actually do agree that they, themselves, as a buyer, are too small. But they do -- you know, in other roles, they have a really important role to play.

Ms. Tokuda. But essentially as a small buyer, they could show the pathway for the rest of the whole-of-government to be able to secure some of these life-saving drugs, as you mentioned.

And if we have a stratified list with top-tier priority drugs that really were necessary to save lives and have the most impact, it could also be a pathway to show how other departments and

agencies should also follow in that decoupling from China.

Ms. Wosinska. That is right, but it would have to be followed by Congress, because to change the incentives for all the other buyers that are not the -- that are not there, you know, getting Medicare to do this, Senate Finance has a proposal for how to get hospitals to be taking this -- you know, to be weighing this kind of resilience much more.

So yes, as a first step, absolutely agree, but Congress really does need to change the incentives outside of VA and DOD for this to really be transformational.

Ms. Tokuda. Thank you. I have just two more quick questions, the second one being, are we maximizing our role in forums like the G7 to create -- create and execute, quite frankly -- a unified pharmaceutical strategy?

Because what we are talking about, to your point being too small, America can't do this by itself, and we have got other allied countries, partners out there, who are trying to also decouple the risk from China.

Do you think that the G7 actually needs a unified strategy and execution plan so we can all work together to be able to decouple this risk?

Ms. Wosinska. So I can't speak to G7 specifically, but I absolutely agree with you that we need to be working with our allies. The example that I gave in my testimony without naming the company, there is a manufacturer in Copenhagen who is shutting down their manufacturing facility for antibiotics.

This is a great opportunity for us to work with Europeans who are a little bit in sort of analysis-paralysis mode themselves. They are far behind sort of where India has been leaning inward. They have actually put money and policies in place.

But those are the kinds of opportunities for us to engage and work with them together. Completely agree.

Ms. Tokuda. Thank you. That is something I have been pushing in this particular forum,

that the G7 and other forums like that need to be more of a tip of a sphere in terms of how collectively we are going to work towards common threats like China.

And I would just end with this rhetorical question that I have asked many times in this committee, whether or not America is ever going to get over its love for buying cheap stuff.

And Ms. Wosinska, you mentioned supply reliability contracts. It is about us paying more, but understanding it is not about cheaper, it is more secure. And I think that is very applicable to the discussion today when we talk about pharmaceuticals and how we derisk and decouple ourselves from China.

We have to get over this cheap obsession and look at what is going to make us more secure as a country and taking care of our people.

Thank you, Mr. Chair. I yield back.

Chairman Moolenaar. Thank you.

Representative LaHood?

Mr. LaHood. Well, thank you, Mr. Chairman. Thanks for having this important hearing today. I want to welcome all of our witnesses today. Thank you for your testimony and the work you do in this space.

Just as a point of personal privilege, I want to welcome Dr. Jake Becraft, who is from Metamora, Illinois, in my district, right outside of Peoria.

We are very proud, Jake, Dr. Becraft, on what you have accomplished at such a young age and your successes and have not forgotten about where you came from. You are still a Metamora Redbird, and we are proud of that, also a graduate of the University of Illinois in Champaign-Urbana. So welcome, glad to have you here today.

As everybody knows, the title of today's hearing -- "From Lab to Medicine Cabinet, How China is Cornering the Market on Our Medicines," is an important topic.

And this committee has been focused on how do we win the strategic competition against

China, and I don't think there is a more important space to do that than when it comes to pharmaceuticals or to medicine. And we have heard a lot about that here today.

China's rapid advancements in biotechnology are increasingly challenging Americans' leadership in developing cutting-edge, life-saving pharmaceuticals. As we know, it takes 10 to 15 years and a minimum of $2 billion to turn a promising idea into a medicine that reaches pharmacy shelves and patients' homes.

With costs for critical trials in China costing up to 30 percent less than the United States, combined with less regulatory hurdles and faster path to recruitment, the U.S. risks losing new investments, while also creating potential health and national security concerns along with supply chain concerns.

It is essential that the United States maintains its position as a global leader in pharmaceutical innovation, and recognizes that China's climb up the value chain could disrupt existing trade dynamics.

Inadvertently, shifting innovation overseas weakens our domestic biotech ecosystem at a time when strategic competition is obviously intensifying. And so, I look forward at this hearing from hearing more from our witnesses on how we can reinforce U.S. leadership in biomedicine innovation while protecting both patients and our long-term economic and national security interests.

Dr. Becraft, as the CEO and co-founder of Strand Therapeutics, you have led the development for the world's first synthetic biology program language for the mRNA.

Your work underscores that life-changing innovation begins in early stage R&D, where clinical trials are often the make-or-break moment for getting new treatments to patients.

Question for you, how is the U.S. currently under-utilizing our clinical infrastructure and decreasing clinical trial availability for patients who need treatments the most?

Mr. Becraft. Thank you, Congressman, and thank you for the introduction -- or the

welcoming as well. I think that, so maybe it is easy to look at it through the perspective of an early-stage, cash-strapped biotechnology company, who, like my colleague here, has said they have made a commitment to not work in China, as a biotechnology company, when you make the commitment to not do the clinical trial in China, you are taking on a number of costs and time overruns, which a lot of times you don't have, right?

It takes longer, and it is much more expensive to run a first-in-human trial here in the United States, partially because of what I said in my opening statements and in my written testimony around the hurdles it takes to run these INDs and the expense and time in which it takes them to run here in the United States.

If we are able to simplify that process, if we are able to shorten it and enable to make it much faster and much cheaper here in the United States through some of the policy pieces I outlined, I believe that we can actually increase the amount of sites in the United States that will actually run clinical trials.

So if we look at it through my or my board's perspective, for instance, when we are running a clinical trial, we know we are in for an IND around $20- to $25 million of expense. That is just regulatory and testing, to get the privilege to ask the FDA in order to run a clinical trial. That is before clinical trial expenses come into the picture.

Once you are in that sort of a spend environment, of course your board, your investors, everyone behind you is going to pressure you. You know, if we are going to bother running the trial here in the United States, if we are going to bother spending that much money, we better go to the best places that we possibly can.

And so you see a clustering of clinical trials at these high-end centers, who are amazing, of course, but we have all of these great hospitals spread throughout the United States, right?

MD Anderson in Houston is incredible, but OSF in central Illinois and in Peoria, is an incredible facility with incredible infrastructure. But no one runs first-in-human trials there, and why?

Because there is a sunk cost fallacy that a lot of companies do. Once you invest all that money to run those trials, you, of course, want to go to the Sloan-Ketterings of the world. Your board wants you to go to the most famous person you can get to in the United States.

If you make that an easier hurdle, if you make it a faster and cheaper amount, you not only open up the capital pools to power that, but you open up the types and places where we will run clinical trials. You create a private market incentive for those clinical trial sites to actually build the infrastructure to run first-in-human clinical trials, and you increase access to brand-new, potentially life-saving medicines to patients across rural America that currently do not have any access, except to get on a plane and spend what could be the last 3 months of their lives in a city they have never been to before just to have the privilege of a shot to extend their life.

And that I think is unacceptable for America.

Mr. LaHood. Well said. Thank you. I yield back.

Chairman Moolenaar. Thank you.

Representative Castor?

Ms. Castor. Well, thank you, Mr. Chairman, for calling this hearing, and thank you to our witnesses for sharing your expertise on how we derisk the U.S. supply chain, the drug supply, build greater resilience from China.

Dr. Wosinska, you were very direct in your recommendations. Thank you very much. You stated the U.S. cannot and should not try to buy its way out of every vulnerability in drug supply -- in the drug supply chain, instead focus on a realistic derisking strategy to reduce the most serious China-related risks to American patients.

And you started your testimony, you gave us four strategic things to think about, and your first was, focusing on the chemical precursors. The reagents, the solvents, they differ across drugs.

Can you summarize for us what good is happening in the U.S. Government right now when it comes to that recommendation, and would you go a little deeper on our recommendations on what

we should focus on?

Ms. Wosinska. So there are some efforts to engage. Again, I mentioned ASPR's budget. They are leaning in, but last I remember, it was $30 million that was appropriated assigned to that effort. So again, it is not -- not enough.

There are efforts, there are domestic manufacturers that are trying to derisk their supply chains fully. We are actually lucky on the antibiotic side. It is somewhat easier to fully derisk it from China because the products -- the API is still made in Europe, so -- I believe Patrick is actually procuring his product from European facilities. So there are great opportunities.

The first steps are actually not chemically synthesized. They are fermented. So we have -- there is a lot of action going on over there.

We are thinking about stockpiling API to buy us time in case of a crisis. There are efforts -- actually, going back to NIH, there are some researchers in Stanford that have developed a way to synthesize, to create, to basically grow API in yeast, so entirely avoiding chemical synthesis.

And now they are licensing it to a number of manufacturers and are working with one of them to actually entirely side-step chemical synthesis.

So there are pockets that are really important, really great, but not at the scale that we would want, and again, this is where we need Congress to step in.

Ms. Castor. And FDA has an indispensable role here as well, and I know at the Energy and Commerce Committee, where I also serve, we were kind of debating the future of the FDA.

They have done critical work in predicting and responding to shortages -- overall shortages in the past, but they have very limited authorities, and access to certain manufacturing data is very opaque.

You previously worked as the director of economics at FDA, and one of the things I look at the current administration that I think is so harmful, when it comes to everything that we want to do and invest in, unfortunately, when you look at FDA, to help better arm them and help address shortages,

is that the administration eliminated over 3,500 positions at the FDA. That is 15 to 20 percent of the overall workforce.

What impact will that have on America's ability to tackle some of these problems?

Ms. Wosinska. So, I am actually not aware of how the -- extent to which the cuts actually affected the staff at the drug shortage team and those that support it.

What I can say, where FDA is very limited, and has been limited for a really long time, is on manufacturing quality oversight. And, you know, something that I would like to clarify, I am concerned about the manufacturing quality of products that are coming from India and -- but when I suggest that we should work with India, I don't necessarily mean that we somehow swipe this under the rug.

I do think that there are other ways that we can pursue that to support FDA. It is not just about giving FDA more staff -- although this is really important, so they can do the inspections -- you know, FDA is sort of like a traffic cop trying to enforce speed limits, and, you know, they can only be in so many places, and they are also visible on the freeway a mile away.

So we need to sort of think differently about how we support FDA in this effort, and I have actually, last October, proposed a solution to this that would shift a lot more accountability towards Indian manufacturers when it comes to manufacturing quality, really supporting FDA and allowing FDA to be much more efficient in the work that they do. And I am happy to share that proposal.

Ms. Castor. Good. I will look forward to that.

Thank you very much. I yield back.

Chairman Moolenaar. Thank you.

Representative Hinson?

Mrs. Hinson. Thank you, Mr. Chairman. Good morning to our witnesses. Thank you so much for being here.

It was just last summer, I think in this very room, we actually had a roundtable where this

committee heard directly from industry professionals about some of the risks to active pharmaceutical ingredients in the Chinese supply chain, and we know that in the broader public health sphere, of course, that China has invested billions of dollars into their own manufacturing capabilities.

They are subsidizing, at government expense, advancing that research, and countering China with our domestic base is not only important to protect American patients, but it is also important to our broader economy.

We have heard about the risks if this all bottoms out and it all goes over there, what that will do to our domestic workforce. So this is about preserving our national security interests, as well as our public health pipeline for every single American.

So, Mr. Gimenez, thank you so much for being here today and kind of giving your perspective on the venture capital and the business side of how this all intersects. And we know that consistent improvement in the coordination across public and private sectors is absolutely critical to making sure that we can maintain a resilient posture in the pharmaceutical manufacturing and biotech space.

So we know not one sector can do it alone. Clearly, we are hearing today about how interconnected they are. So my question to you today is, What does, in your mind, going forward, a successful partnership look like between the private sector and then State, local, Federal partners to make sure that we are not only amplifying production for critical APIs, but also making sure we are not ceding that manufacturing ability as well?

Mr. Gimenez. So with respect to manufacturing, I will kind of cede to my colleagues here who have spent a lot more time thinking directly about that.

That said, the best thing that we can do is strengthen the relationship between the FDA and kind of our research communities right now, as well as our clinical research facilities that are generally funded by government grants.

Mrs. Hinson. And by strengthening the relationship, what is your idea there on how that needs to improve? I mean, you talk about the time, right?

Mr. Gimenez. Yes.

Mrs. Hinson. I heard you mention, let's get to 5 years, which would be great.

Mr. Gimenez. Yes.

Mrs. Hinson. But what else do you think needs to happen to improve that relationship?

Mr. Gimenez. So I think the FDA being much more open to getting to first-in-human clinical data is incredibly important. And so we can follow the examples not just of China, but actually through Australia or CTN programs that allow people to get into clinical data and first-in-human data quickly.

I think we can do that also by, as Jake has alluded to, allowing investigator-initiated trials, which is really the true mechanism that is working within China right now.

Investigator-initiated trials are when clinical research institutions run trials and sponsor those trials as opposed to private companies. And what that does is, it allows a trial sponsor, who is generally going to be a well-trained expert in the field, to run a clinical trial and gather clinical data.

What has happened in China is that is the actual mechanism that people are running these fast trials, and that is not a mechanism that we really fully elaborate on in the United States. It is done, but it is not done to the extent.

And so allowing our NIH and our granting agencies into clinical research facilities, and also giving the FDA the authority to accept data from there and move into fast clinical trials there, is one thing that the government could be doing that would be fantastic.

And then we will take care of the rest. The private sector can fund data.

Mrs. Hinson. And do you think that actually saves money in the long run as well? I mean, if that collaboration is able to happen, not only it is about speed, truly like a warp-speed operation, right, but do you think that will make its way down to the consumer on saving money on these drug

prices as well?

Mr. Gimenez. Oh, absolutely. I think that the best way we have ever seen prices go down is with more competition, and more competition comes from the greater ability for many companies to test these things out and bring drugs to market.

We often cite this $1- to $3 billion to get a drug to approval. If we drop that to 5 years, that number necessarily has to go down, and investment can be much more into many more high-risk activities that would be beneficial to more Americans.

Mrs. Hinson. Yeah. And I see you nodding your head. Do you have anything to add there? Obviously, I mean, driving down prices is one thing, but speed is another, and competition is another. So I think you agree with all those things.

Mr. Becraft. I do, and if I can just say, there is sort of two different pieces of calculus to think about here. One is, of course, the time and the money. When any -- whenever anyone makes an investment, whether it is a company like mine, an investment firm like Francisco's, they are thinking about risk-reward, right?

And if the risk is exorbitantly high because of the time and cost it takes to develop a medicine, then either the reward needs to be exceptionally large, or you need to decrease the risk in another sort of way.

And that is where we get with this high cost and long-time of development. We get a lot of new medications that are being tested that are next logical steps forward instead of radical steps forward, right?

Our goal with drug development should be to keep patients out of the hospital. That is where we will actually find -- or regardless of drug pricing, we will find the highest healthcare savings, writ large, if we keep patients out of the hospital and if we keep people alive.

That is better for patients. It is better for America. If you want to take those radical steps forward, then we need to radically change the calculus of the risk that investors -- both companies

and investment firms -- are making on those drugs, and we can start tackling things as ambitious as aging. Thank you.

Mrs. Hinson. I have a lot of questions about how we can stop the hamstringing of this investment, but I see I am out of time.

So I will yield back, Mr. Chairman. Thank you so much.

Chairman Moolenaar. Thank you.

Representative Moran?

Mr. Moran. Thank you, Mr. Chairman. It is important that the American people hear this testimony today. It is important for them to understand that the Chinese Communist Party plays a crucial role, an adversarial role, and a threat that will infect and impact every American life.

This conversation is about something simple but essential -- the medicines that keep our citizens healthy and the system that produces them. More than 60 percent, as you guys know, of American adults, and nearly 90 percent of seniors, and nearly 25 percent of children fill a prescription at least one time per year.

The United States has historically led that world in medical innovation, and that leadership didn't happen by accident. It grew from the people of our Nation who value scientific inquiry, intellectual property, and respect the dignity of every patient who participates in research.

But the global landscape, as you guys noted today, has changed quickly. China has made biotechnology and pharmaceuticals a national priority, and their goal is clear -- to increase their capabilities to compete with and ultimately surpass American firms.

We can see this just in recent data. Let me give you within example. In 2014, if we go back and look, China conducted about just over 1,800 clinical trials, while the United States led the world with over 7,200 clinical trials.

Less than a decade later, in 2023, China had expanded to over 11,000 clinical trials, surpassing the 7,500 trials conducted in the United States. That is a telling and very significant statistic, many,

many more.

Today, for certain essential generic medicines, China is already the dominant or sometimes the sole producer of key, active pharmaceutical ingredients.

Mr. Chairman, this is why American leadership in new and emerging pharmaceutical technology is critical. Innovation is America's strength, it always has been, and we must ensure that the U.S. continues to spur that for the American people.

Mr. Gimenez, I want to start with you. China under its "Made in China 2025" initiative has aggressively pursued leadership in biopharma- -- pharmaceutical development and manufacturing.

As a result, licensing agreements for early-stage Chinese medicines from grown from below 100 million in 2020, to more than 800 million in 2024.

As China continues to scale its capacity of novel drug development, many view this as a direct challenge to U.S. leadership.

What specific steps should Congress take to ensure that the U.S. remains the global hub for early-stage biopharmaceutical innovation and venture investment, rather than ceding that leadership to China?

Mr. Gimenez. So again, I have an audacious goal, which I think many of my colleagues will, you know, push back on, but I think we have to speed up a process that you can go from molecular discovery through approved drug, while retaining the highest possible standard that the FDA has held, you know, globally.

And everything I suggest is mechanisms to get there. That is going to be faster paths to first-in-human trials. Once you have human proof of concept, the finance community will rally behind and fund these things as quickly as possible. It is very easy to raise money for a company that has a drug that we feel works.

Then it is going to be better systems for the FDA to move more quickly on review. That means both in terms of labor and staffing and training, but it also means in terms of technological

innovation.

The FDA also has probably the largest trove in history of any kind of research material. So if a company fails and it goes under, all of that information disappears into the ether unless somebody kept it in their minds. The FDA holds that.

They have the single greatest set of intellectual property with respect to life sciences and medicine, and so using that and enabling that into companies, I think, is going to be hugely important.

Mr. Moran. Yeah, I think of it a lot like the course of water. If you let water go, it is going to naturally find the easiest path through to its objective. Mr. Becraft mentioned this earlier about the blockades we put up. It just incentivizes companies to go somewhere else or to do something different.

They are going to shift and take the easier path through on research and development to get to the end goal that they need to. So we need to take away those unnecessary blockades. We need to keep safety in place, no question, but we have gone way overboard in doing that.

Let's talk about ethics for a second. In the U.S. clinical trials -- I am going to come to you, Mr. Cashman, on this -- in the U.S., clinical trials operate under strict ethical guidelines.

Patients must give informed and voluntary consent before participating in research. Their dignity and their rights are protected throughout. That commitment is foundational to how we conduct medical research.

But reports indicate that the same safeguards are not always present. In fact, very few times are they present in China's clinical trial system.

Mr. Cashman, given the differences in clinical trial standards and the rapid growth in pharmaceutical-research activity in China, why should these developments create greater urgency for the U.S. and our allies to strengthen pharmaceutical innovation and production at home to make sure that it is safe?

Mr. Cashman. Congressman, I want to make sure I understand your question. I am focused on manufacturing, not clinical trials, and just want to -- just really want to understand what you are asking.

Mr. Moran. Yeah, so China doesn't put near the guidelines around protecting humans through clinical trials as the United States does.

So why is it important then to make sure that we are continuing to lead in that area? Because -- frankly, I can answer the question, it is pretty easy when you throw it up there -- if you do not -- if we do not lead, we are going to cede this to somebody that doesn't care about the ethics of human life, doesn't value human life the way the United States does.

And so that is the point I am trying to make, and I would love for you to make a final comment, and then I am going to yield back to the chairman.

Mr. Cashman. Let me focus on what I know best and that is manufacturing, and I know there is a huge difference in how the FDA views domestic manufacturing facilities compared to international facilities like those in China and India.

We can be inspected at any time. We can be -- the FDA can show up at our doorstep at any moment, and we have to receive them, and we do. We welcome them. We appreciate their input in our facility.

We know in China that they have to give up to 12 days advance notice, which allows those companies to make corrections or hide some things they might not want the FDA to see.

And that is just not a level playing field, and it is not good for the safety and security of the medications that we get from those nations.

Mr. Moran. That is a great way to end our conversation today. We are playing by two different sets of rules. We have two different standards, two different objectives.

We need to support the United States and the development of pharmaceuticals here, and we need to keep China from being the dominant force.

I yield back, Mr. Chairman. Thank you for the time.

Chairman Moolenaar. Representative Stevens?

Ms. Stevens. Hold on. Thank you, Mr. Chairman. I was actually just with some of your tribes. We were talking about a thing in your district that we want to work on. But here is the deal:

I want to know about these cuts to scientific research and the cuts to healthcare, particularly when we are talking about the NIH and competing with China.

You know, we have this bill that I wrote to reinstate the cuts that have gone down to public funding for medical research, cancer trials, and the like.

And how is this impacting the goal of being less dependent on China for the production of our medicines, our pills, that, you know, life-saving meds that we got to take?

Because it strikes me that if we, as the United States of America, are ceding R&D, if we are ceding medical research, particularly with the public valor, that is going to China.

And Dr. Gimenez, I think you wanted to jump in here. I could see you nodding, so I will pass it over to you.

Mr. Gimenez. Yeah. You know, having been a fellow that was funded by the NIH, I am eternally grateful to the NIH, and so I strongly believe in this.

I think that there is many, many parts of this that NIH funding and, broadly, U.S. funding is important for. The NIH funds clinical institutions that run trials. So all the names that we have named today, the major trialist institutions, are basically funded by the U.S. Government.

They are paid for frequently with trials by biotech companies, but those entities exist because of the U.S. Government.

The training that we have for the next generation of scientists, almost entirely funded by our U.S. Government. So when we talk about the Sea Turtle policy, those are post-docs who are also funded by the U.S. Government who are returned back -- who return back to China.

So, you know, in a macabre sense, at least maybe if we shut down our public funding for research, we are kind of shutting down China's too, because we are training them.

But I think that every single innovation that we have ever had in biomedicine has stemmed from our U.S. research institutions, which are basically world class, historical class, and all of that has basically trickled in, either directly or indirectly, into our life sciences and biosciences economy. So that is just innovation and people and institutions.

Ms. Stevens. And what about the brain-drain as well? And, you know, our resident economist here could maybe chime in on that front, because, you know, we are now worried about, okay, if we are not funding the programs, we don't have the talent here.

And in terms of the long-term competitiveness of our biomedical innovation against the Chinese system, you know, are they taking our talent? What is going on with the, you know, current workforce and the next generation?

I don't know if Dr. Marta wants to weigh in on that.

Ms. Wosinska. So I think the workforce, whether on the manufacturing side or on the drug-development side, and science, I think I would need to defer to my colleagues here who really are experts in this.

Ms. Stevens. Okay. So as a healthcare economist, you don't have a comment on the workforce. Okay.

Ms. Wosinska. Yeah, this is not an area that I have studied.

Ms. Stevens. Okay.

Mr. Becraft. I am happy to talk on it as someone who was funded by these exact programs during my Ph.D., and that Ph.D. work did directly lead to the formation of my company, which now employs over 100 scientists in the Boston area.

I think that right now, what I am seeing among my colleagues who did not enter private industry, who stayed in academia, is an incredible pull to other jurisdictions. -- it is not just China,

but even Europe and Canada -- as we cut funding or make it harder to achieve.

Perhaps injecting some unasked-for nuance into it is to examine how the NIH was disbursing money and the issues that existed there that have been highlighted by academics for decades without really having a real solution.

The overhead costs, you know, often exceeding 50 percent that go to some of the academic institutions, I think, needed reined in. Whether or not the approach that we took to rein them in and chop them off immediately was the right one, I can't really say.

In addition that, the NIH, and a lot of Federal funders need to think about what it is we are trying to fund. A lot of funding from those agencies goes to established labs that become mills for writing grants, rather than places of intellectual curiosity. The RO1 NIH, the joke among academics is to do 80 percent of the work before you write the grant --

Ms. Stevens. Yeah.

Mr. Becraft. -- and that way you know you are successful.

So while I think that the cuts have been damaging to our base, I think it would be inappropriate for us to pretend that the funding mechanisms were working correctly as is. Thank you.

Ms. Stevens. That is an important point, and thank you. You know, I know I got to yield back my time, but just for the record, you know, spending time on the Science, Space, and Technology Committee, I have applied for NSF grants in the past, in my previous life before being elected to Congress, and you are spot-on to talk about that as well.

And that is marching orders for us.

With that, Mr. Chairman, I will yield back.

Chairman Moolenaar. Thank you.

Representative Bilirakis?

Mr. Bilirakis. Thank you, Mr. Chairman, I appreciate it. I don't know if you can hear me or

not. No.

Okay. Again, good morning, Mr. Chairman. Thank you very much for holding this very important hearing. I was at E&C, so -- but the issue of Chinese influence on our domestic pharmaceutical supply chain is important for us lawmakers to understand, and we must consider targeted returns to counter this influence. Absolutely true.

I have heard from constituent companies that struggle to stay competitive with Chinese companies due to misaligned incentives in our healthcare ecosystem.

That is why I launched the American-Made Medicines Caucus with Representative Carter and Representative Tenney.

It is important that we pursue policies to incentivize domestic manufacturing, particularly as we face rising affordability concerns in the U.S.

We have also seen safety concerns with many drugs made abroad. American patients should be able to access safe and effective American-made medicines without breaking the bank.

Next year, the Energy and Commerce Committee, which I serve on, has the opportunity to pursue targeted FDA reforms through the prescription, generic drug user fee reauthorizations. As a senior member of the committee, the Healthcare Subcommittee, I look forward to this critical work in the next few months.

So my first question is for Dr. Becraft. You have deep knowledge, sir, of the complex world of drug development. What are your recommendations to Congress to maintain our leadership in the biopharmaceutical space, either through FDA process or CMS reimbursement reforms?

Mr. Becraft. So focus on the pieces I have talked around within my, both written testimony and oral piece. I think that the thing that is the most critical for early-stage discovery is that timeline to first-in-human data, right?

How does either an academic researcher, or an entrepreneur or, you know, a hybrid of both, take an idea and go from, I think this could work, this could change how we treat "X" disease, to,

Now I know that it may work. I have human data in hand. Every animal model, every, you know, mouse, every, you know, cell culture in a dish will never -- at least not in the next 5 to 10 years -- be able to recapitulate the complexity of human disease to a way that it can get us an answer that the investment community will then stand behind it.

And so there is, in my experience, two different major roadblocks to that. There is the regulatory pathway and how we get there, and I have, in my written testimony, laid out ways that I think the FDA could work hand in hand to simplify that process, to decentralize the process, maintain rigorous safety oversight and notification among the Agency, while allowing institutional review boards, or centralized IRBs, as the current director of the FDA has spoken about reform a number of times in the past months, if we are able to decentralize that approval to the first-in-human pathway, that would both massively increase the number of clinical sites that we could do first-in-human trials at and decrease the cost and time to that data.

The second piece of this puzzle is, especially for complex medicines, how and where are we going to manufacture them? I think that both "how" gets to what are the regulations around, you know, what do we need to know? What do we need to assay? What do we need to measure about these medicines to think that they are safe to put into patients as, you know, often a last-ditch effort to save these patients' lives?

I think there is a lot of roundtable incentives that private industry and the FDA could get around to say, What is the correct level of oversight for this GMP -- what is called GMP, which is how these drugs are manufactured -- that sort of oversight for our companies, and to create a more open dialogue so we can all learn together.

A lot of the institutional knowledge around that manufacturing is locked inside of private companies. The FDA is doing their absolute best to keep up with it, but more dialogue, I think, would increase the rate of learning and allow the FDA to more effectively -- and work with companies to figure out what we need to do to make sure that we are putting safe drugs into

patients.

If we incentivize the build-out of that small-scale manufacturing here in the United States, usually geographically located somewhere near where we may be running clinical trials, that also massively increases the logistics, the efficiency of manufacturing to clinical testing, and it serves as a fly-wheel for private industry to continue to invest in the build-out of domestic biomanufacturing.

Once you have a manufacturing process set for that first trial, it is much more in your favor to continue building that out than to outsource, as you get to a later stage and you need to make more drug or more diverse drugs.

Once we start with that seed here for these advanced medications, we will then see that pay dividends into the future. Thank you.

Mr. Bilirakis. Thank you very much. Very valuable information. I appreciate it.

I yield back, Mr. Chairman. I will submit my questions, the rest of my questions for the record.

Chairman Moolenaar. Without objection.

Representative Nunn?

Mr. Nunn. Thank you, Chairman Moolenaar and the China Select for having this conversation today.

Look, I have been on the front lines as a counterintelligence officer, fighting against China for over the last two decades, and I think we all recognize, when China starts to dominate in any sector, whether it is semiconductors, whether it is innovation, critical minerals, it becomes an unfair advantage they gain, particularly when it comes to healthcare and biotech.

So let's be clear. The United States becoming reliant on China for key ingredients of our generic medicines and the infrastructure that drives drug innovation is a loss for everybody.

This panel has been fantastic at highlighting that this is bad for both patients, for physicians, and it is a bipartisan issue that I think we all want to get after solutions for.

I represent a rural district in Iowa with an urban core, and in every town, in every community, we believe that life-saving innovations, championing what helps Iowa across the country is a success story that we are able to drive here at home.

Strengthening U.S. drug innovation and reducing our dependency on China is a direct opportunity to improve healthcare for all Americans. Right now as we noted, China has a dangerous advantage over our essential generic drugs.

For example, about 90 percent of global API supply for generic antibiotics originates, or depends on, Chinese manufacturing.

Ensuring we keep innovation and clinical trials here at home, instead of in China, means having confidence that diabetes patients have access to critical antibiotics, no matter what is happening geopolitically in the world.

And the cancer patients have the opportunity to be first in line for the life-saving drug, not overseas.

Keeping these clinical trial opportunities in our communities improves health outcomes and increases specialized care.

It is not just about our patients either. We have research and capabilities that are strong in America. Every Federal dollar invested in biotech here at home generates more than 150 percent return for local economic activity.

I will highlight in 2025, Federal research dollars supported over 2,000 jobs in Iowa, nearly $485 million in economic activity. This is a win-win-win.

This fight with China isn't only about national security. It is about keeping Americans healthy, keeping innovation in the United States, and keeping jobs in our community.

So with that, I want to talk to the leader of Strand Technologies, Dr. Becraft. You highlighted some of the real challenges that we are trying to get after here and the tragic impacts of cancer on communities across the country.

I will note that diseases like cancer don't impact everyone in the same way, but in my home State of Iowa, Palo Alto County has the second highest rate of cancer in the country.

Equally in my district, Jefferson County has one of the lowest cancer rates in Iowa. It is well below the national average.

This disparity is deeply concerning, but it also gives us reason for hope. It means that we can take real, actionable steps to improve patient outcomes, and I think everyone in this room agrees that no matter where you are, you deserve the opportunity to have access to cutting-edge materials, like the research that you have done that is so encouraging for us.

And a perfect example of that is what the University of Iowa, which conducts more than 200 clinical trials, many of them cancer-related, are supporting not only thousands of jobs, spurring millions in the economy, but they are saving lives, which leads me to my question.

What would it mean if all this went out the door, if all of it was reshored on China, and if our ecosystem sent most of our early-stage clinical development to Beijing instead of right in the heart of America?

Mr. Becraft. So this is -- thank you, Congressman -- this is what has been going on in the biotech sector, and a lot of our -- the rate of increase of early-stage clinical development is increasingly going to China, -- first, with U.S. biotechnology companies going to China to run their early-stage clinical development programs, but now, and as we have seen many time and time again with Chinese economic competition, Chinese domestic competitors now spinning up to run their own trials directly, selling those into America.

Americans by revenue, either from private insurers or from Medicare, Medicaid, and the U.S. Government directly account for roughly 50 percent of global drug revenues.

So as the center of gravity of drug development and drug sales shifts to China, it is the U.S. citizen that is footing the bill for that, either through their taxes or through their private insurance, because in whatever way you model the cash payments, they go out the door.

Not only do I think that we can compete with them by reforming some of our early clinical trials for a district like yours in Iowa, which borders my home State of Illinois, we know that we have incredible clinical resources, incredible clinical centers.

No one runs early-stage, break-in clinical trials at those centers because of the cost and time it takes to run a clinical trial. Often once you are in the hole for $20- to $30 million just to get a clinical trial started, your board, your investors, everyone around the table wants you to go to the most famous institution you can.

If you reformed that, if it was 6 months and $5 million to get that, and you allowed these clinical sites to work more regularly with companies like mine, you would see a greater spread.

And in fact, when Australia reformed their early-stage, first-in-human trials to the clinical trial notification system, that is exactly what we saw. We saw the private sector build centralized IRBs, which allowed a greater spread to more hospital groups, and you would find that, you know, people like my family who grew up in central Illinois, who lives there to this day, if they were to be diagnosed with a cancer that had no standard of care left to have, their options would be to spend the remaining years of their life in a city they had never been to before in order to access a clinical trial, or accept their fate.

And I think that as the richest and most powerful country in the world, America, that is unacceptable.

Mr. Nunn. Dr. Becraft, could not agree more, and just to highlight this as our closing argument, this is already happening. Phase 1 and Phase 2 has already fled to China. Let's not let Phase 3 happen, because the reality is, all of us will be in a harder place.

Thank you very much for your testimony today.

I yield back my time.

Chairman Moolenaar. Thank you very much and I want to give a special thanks to our witnesses today. Appreciate your candor and your insights, and for our members, the questions for

the record are due 1 week from today.

Without objection, the committee hearing is adjourned.

[Whereupon, at 11:57 a.m., the subcommittee was adjourned.]