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GROWING STAKES: THE BIOECONOMY

AND AMERICAN NATIONAL SECURITY

Thursday, March 7, 2024

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 9:02 a.m., in Room HVC-210, The Capitol Visitor Center, Hon. Mike Gallagher [chairman of the committee] presiding.

Chairman Gallagher. The Select Committee will come to order.

I want to thank our witnesses for their patience. We are not in our normal room, because the State of the Union has kicked us out of our normal room, and as a Select Committee, you know, we kind of just rotate to different rooms. We're like a pirate ship that occasionally lands in different ports. So this is our latest stop, and I'm sure members will continue to filter in. We were also originally supposed to do this hearing in Boston. Weather intervened. Even our smartest citizens with fancy technology companies can't figure out how to control the weather in Boston, but we await that day. But this is a -- we had an incredible visit and learned a lot, and this hearing is very important.

Biotechnology, unlike other areas of technology, it's not just a supply-chain battle, or a national security battle, or an economic security battle. It's also a moral and ethical battle, because as the sector advances at an astronomic pace, the country who wins the race will be able to set the ethical standards around how these technologies are used.

We've already seen how China is going to use advanced biotechnology for things like forced DNA collection, genetic surveillance, the genetic enhancement of soldiers for the PLA. Genetically tailored weapons are already a trending topic in PLA military circles.

So we, i.e., America and the free world, need to be there first so we can set the rules of the road responsibly. Otherwise, the Chinese Communist Party is going to do it, and we are going to live in a less free, less moral world.

So I would submit we need to act quickly. The CCP has made domination in biotech and genetic sciences a \$9 billion national priority. It's executing a plan to build a DNA database on every man, woman, and child on the planet. The database includes

Americans whose DNA they're collecting with large cyber hacks, corporate acquisitions, and other methods, to include the collection of DNA from 8 million pregnant women globally.

Unfortunately, American capital technology and know-how is flowing to the Chinese Communist Party and helping them advance in these areas. This needs to stop. American companies need to take off the golden blindfolds and recognize that there's no such thing as a truly private business in China.

The CCP requires every company to aid the military upon request and mandates that most Chinese companies of significance hire party members to ensure companies closely follow the party line. And biotech is no different. This is well established. Beijing Genomics, the company building the CCP's DNA bank, for example, is also conducting joint research with the PLA in identifying genetic susceptibilities of Uyghur Muslims to diseases. The Pentagon has designated it a Chinese military company, and commerce sanctioned it for involvement in abusive DNA collection and analysis schemes to repress its citizens in Xinjiang.

WuXi AppTec, another supposedly private company, operates one of the genetic testing technology application demonstration centers established in coordination with the PLA. Every bit of value flowing to Chinese biotech or genetic science companies will be used to strengthen the CCP and the PLA. We must assume that. We must operate accordingly, and we must cut off this flow of support.

These are the basic principles at stake. American taxpayers and American businesses cannot be complicit in a genocide or other human rights abuses, and we cannot afford to keep funding our own destruction.

And with that, I recognize the ranking member for his opening statement.

Mr. Krishnamoorthi. Thank you, Mr. Chair. And thank you all for being here

today.

This hearing, as you know, as the chairman mentioned, was supposed to be in Boston. But I want to just thank Congressmen Auchincloss and Moulton for hosting us for just a fascinating day to learn about biotech, and we look forward to more conversations about this issue.

There are two sides to biotech: on the one hand, boundless possibilities and, on the other hand, existential risks. Our job is to make sure those possibilities from curing diseases through new medicines, to eradicating hunger through new crops happens here in America, and that those risks, including the CCP's efforts to use biotech to potentially harm Americans, are addressed.

With that in mind, I think it's only fitting to show this side by side of Steve Rogers before and after the U.S. military used advanced biotech to turn him into Captain America.

In all seriousness, the CCP is conducting human experiments to develop soldiers -- I'm not kidding. They're developing experiments to make human soldiers have biologically-enhanced capabilities today. By some reports, it's even researching mind-reading software to ensure CCP officials remain loyal to the party. You can't make this stuff up. And the CCP is not content to simply experiment on its own soldiers or read the minds of its own officials. They are collecting large quantities of genetic data from Americans. This is because of companies like BGI Group, which sequenced DNA right here in America.

This committee has already begun to take action by introducing the BIOSECURE Act, a bill to ensure foreign adversary biotech companies do not gain access to U.S. taxpayer dollars.

Now, however, we need to do even more. First, we need to draw a line in the

sand and ensure biotech innovation reflects our values. This means holding bad actors accountable and imposing outbound investment controls on CCP-affiliated biotech firms. The administration just took groundbreaking action on this very issue in its recent executive order creating data privacy guardrails to stop Americans' genetic information from flowing to foreign countries of concern. The CCP cannot be allowed to impose its values on the very genetic fabric of humankind.

Second, we need to invest in innovation and the talent that makes it possible. We must prioritize investment in STEM education and uphold our status as a welcoming haven for immigrants. A great number of students arrive here for education, obtain their green cards, and then consequently, or subsequently, establish their lives here in America. That is, indeed, the story of my own father who came to this country as a student, obtained his green card, and then taught engineering to thousands of students for 40 years at Bradley University in Peoria, Illinois, which is currently represented by Darin LaHood.

Mr. LaHood. Well represented.

Mr. Krishnamoorthi. Well represented.

Consider the untapped potential for innovation if other promising students who sought to remain in America, but were unable to secure green cards, were actually allowed to stay. Let us embrace talent wholeheartedly and leverage it to the fullest.

Third, let's keep outcompeting the CCP. That means we must not only invest in people, but also work in close collaboration with allies and partners to discover and manufacture biotechnologies. This means investing in research. It means funding basic science, advanced science, and every type of science in between.

Let's imagine a world where a blind child's vision can be restored, or cancer can be cured. It is possible here in America. After all, remember the MRNA vaccines that

saved us during the pandemic? That happened here in America, not in China. Just like we did with MRNA vaccines, let's make it happen here in America.

In closing, the competition with the CCP and biotech is make or break. If we win, it will propel our Nation light years ahead and improve the lives of countless Americans.

But if we lose, we face a bleak future of superhuman soldiers and designer babies. So we must and we will win.

Thank you. And I yield back.

Chairman Gallagher. I thank the ranking member.

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

There being none, we are fortunate to be joined this morning by three experts in the field of biotechnology. We have Dr. Jason Kelly, Dr. Tara O'Toole, and Dr. Charles Clancy, a lot of doctors on this panel.

Dr. Kelly is the cofounder and CEO of Ginkgo Bioworks, a synthetic biology company headquartered in Boston, Massachusetts, that the committee visited recently on its trip to Boston. Thank you for your hospitality.

Dr. O'Toole was the executive vice president at In-Q-Tel and now serves as senior fellow where her work centers on advances in biotechnology and biological sciences.

And Dr. Clancy is a senior vice president at the MITRE Corporation and heads MITRE Labs.

Welcome and thank you for being here this morning.

If you could stand please, stand and raise your right hand, I'll now swear you in.

Do you swear or affirm, under penalty of perjury, that the testimony you're about to give is true and correct, to the best of your knowledge, information, and belief, so help you God?

You may be seated.

Let the record show that the witnesses have answered in the affirmative.

By the way, a lot of people have asked me why we do that because it doesn't happen on other committees. I don't know. It's old school, and I like it, okay? And we're dealing with important issues, so that's why we do it. And, you know, I'm not going to be a chairman for much longer. I get to do what I want. So thank you.

Dr. Kelly, you're recognized for your opening remarks.

STATEMENTS OF DR. JASON KELLY, CO-FOUNDER, CEO, GINGKO BIOWORKS; HON. TARA O'TOOLE, SENIOR FELLOW, FORMER EXECUTIVE VICE PRESIDENT, IN-Q-TEL; AND DR. CHARLES CLANCY, CHIEF TECHNOLOGY OFFICER, MITRE.

STATEMENT OF DR. JASON KELLY

Mr. <u>Kelly.</u> Thank you, Chairman Gallagher and Ranking Member Krishnamoorthi. It's an honor to get to speak to all of you today, and it was great to see some of you in Boston a couple of weeks ago.

I'm Jason Kelly. I am speaking today as the cofounder and CEO of Ginkgo
Bioworks. We're about a 1,200-person public biotechnology company in Boston. I also
sit as the chair of the National Security Commission on Emerging Biotechnology in my
personal capacity. I just want to highlight today I'm speaking in my role as CEO, so it
doesn't represent the views of the National Security Commission what I say today
necessarily.

So I know I see a lot of folks from the biotech industry will be listening in today, and, I think, the industry in general, I think it's surprising to them to be put into a conversation around national security. And I think it is important for the industry to recognize that the United States Government and the CCP are in an era of strategic competition, and that's going to include emerging technologies like AI, and it's going to include emerging technologies like AI, and it is going to include emerging technologies like biotechnology. So us putting our heads in the sand about that is not a good idea.

Now, I would say no one wants to have increased tensions. I think even the people on this committee are not looking to have increased tensions. So I think one of

the ways you can actually help diffuse it is to be clear about where we are being competitive, and also clear about where we might be able to do strategic cooperation with the CCP.

So, I want to highlight today a little bit of both, and in particular, though, some of the areas of strategic competition I think are relevant in the biotechnology industry.

The three areas I'll speak to are, first, supply chain; second, the application of AI to DNA; and then, finally, biosecurity. So supply chain is kind of the easy one, so, you know, this involves us having access to critical supplies when we need them, particularly in a conflict or a crisis.

I would highlight COVID was a little bit of a test run for this, and you might remember, we got a little worried for a minute there about our supplies of, for example, active pharmaceutical ingredients like antibiotics.

Now, these are 80-year-old technologies, but, boy, you really want one when you need one. And much like semiconductors, the U.S., over the last 50 years, has lost the manufacturing base for these critical chemicals, largely manufacturing now done in China and, to a lesser extent, India.

There's been a lot of discussion around Wu-Xi. Representative Gallagher brought it up today. I think it's worth noting that this is a conversation not about these drug manufacturing that we've lost already, which is small molecules, but rather biologics. And biologics are drugs that are made with DNA, DNA at the bottom. So a cell has been engineered. The original biologic was actually human insulin. We took the human gene for insulin, moved it into bacteria. You grow the bacteria in the tank, and you produce insulin. That's a biologic drug.

So this is a manufacturing technology we have not lost in the United States. In fact, in 2018 -- and I'll give you the shift in this. But in 2018, 35 percent of the world's

biologics were made in the United States, 33 percent in the EU, and 7 percent in China. If you fast-forward to 2022, the share for the U.S., or really for North America, had fallen from 35 to 30 percent, EU had stayed about the same, and China had more than doubled from 7 percent to 15 percent.

So I think you are starting to see and I think there's a question about what type of manufacturing base we want to maintain in the United States when it comes to biologics. As we've seen with semis, and as I think we will see if we try to do the chemical stuff, it's a heck of a lot easier to keep it than to lose it and try and bring it back. So we can speak more about that in the questions if of interest, but that's supply chain.

Next up, emerging technology area of AI and biology. I'm going to take a minute and sort of nerd out on this because I think it's worth the committee understanding it.

So my key point in AI is I believe the application of AI to DNA, to biotechnology could be more disruptive than the application of AI to human language, which is mostly what you all have been looking at lately. And the reason for that is these neural networks that have been built to speak English were, in no way, designed for human language, okay? They're an algorithm, right? And I won't get into the details, but it's basically like a bunch of circles connected by lines that's meant to mimic a human brain. And it's got a bunch of weights in it, these numbers. Oh, there's billions of weights, but nothing about it at any point did the programmers at open AI say, This should look this way because English looks this way.

What they did was they trained it. They gave it lots of human sentences, and they'd give it a sentence with 10 words. They'd leave off the 10th word. They'd ask it to predict it. If it did a good job, they'd leave the model alone. If it did a bad job predicting the 10th word, they'd change the weights. And then they'd do it again. They would leave out the second word and the fifth word, and they'd do that for billions

of sentences, and I swear, it learns to speak English.

The key here is this is general. All you needed was lots of sentences. And the reason I'm mentioning this is we have lots of sentences written in DNA code. It's all the genes that are out in nature, okay? These are, you know, often about 1,000 letters long. They're read end-to-end like a paragraph, and you can leave out pieces, feed it into an Al model, and just like you asked it to predict a word, you can ask it to predict the missing piece of DNA. And just like it learns English, it learns DNA.

And the key thing to keep in mind here is we all speak English. So we're asking these neural nets to compete with us on our terrain where we're good. We're good. You know, we wrote -- we invented law. We invented contracts. And so it's no surprise when you deploy this technology, it's like a high school working at a law firm, okay? Right? It's not as good as us with all our training.

But we're not able to write DNA. We don't read and write DNA as humans. So these neural nets with the right amount of data -- and I think this is key, and we can discuss this in the questions -- will ultimately be superhuman long before they're superhuman in the domain of law or English language, because humans are so bad at writing and designing DNA. Does that make sense?

And the reason this should matter to you is if you look at your biotech drugs, 50 percent of them are written in DNA. You might have heard about Lilly's Zepbound, this new weight loss drug, and Lilly is now the first half trillion dollar biopharma company; right? That's 120 letters of DNA long, and so your ability to write and design that. In the agriculture space, GM crops, you know, insecticide resistance, that's 3,500 letters of DNA long, that particular design; okay?

So these are going to be enormously powerful, and I was glad the committee got to hear about Biofab1 up in Boston.

Chairman <u>Gallagher.</u> Yeah, we're out of time.

Mr. <u>Kelly.</u> Yep.

[The statement of Mr. Kelly follows:]

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Chairman Gallagher. I know it's not fair because 5 minutes --

Mr. Kelly. No problem.

Chairman Gallagher. We will get into it in the Q&A though.

Mr. Kelly. Yep.

Chairman Gallagher. Now that you've totally freaked all of us out.

Mr. Kelly. You got it.

Chairman <u>Gallagher.</u> Yeah.

Dr. O'Toole, you're recognized for 5 minutes.

STATEMENT OF HON. TARA O'TOOLE

Dr. O'Toole. Thank you, Mr. Chairman, Ranking Member Krishnamoorthi, and distinguished members of the panel. I appreciate the opportunity to come before you today to talk about this important topic.

I'm going to make four points.

First, biology will be the dominant science of the 21st century, and biotechnologies will transform most industries in many aspects of human lives. Global economic competitiveness will increasingly depend on a nation's bioeconomy; that is, its ability to develop and use biotechnologies to produce food and energy, improve human health, manufacture essential products, and ensure supply chains.

Second, China has explicitly vowed to dominate the biorevolution, and is aggressively pursuing a comprehensive and ambitious strategy to accomplish this. The CCP sees biotechnologies as essential to its economic future, integral to its ambition to surpass the power and influence of the United States, and necessary to solve some of its most urgent problems, notably, in healthcare and in food security.

China's biotech strategy includes using civilian military fusion funding schemes, building extensive infrastructure for biotech R&D, amassing huge biodata collections, and establishing multiple programs to entice scientists from abroad to work in China, as well as growing its own domestic pipeline.

China is also making extraordinary process in building a very innovative and sophisticated pharmaceutical industry. We have seen significant improvements in the quantity and quality of Chinese bioscience and biotech over the past decade. This is not simply the result of China stealing knowledge and technologies developed in the West,

which they have certainly done, but is a reflection of the importance the CCP places on excelling in biotechnology.

Third, the U.S. bioeconomy is the world's largest, but the U.S. cannot assume that its current competitive position will hold. Not only is China making a credible bid to own the biorevolution, other countries also recognize the value of biotechnologies and are investing accordingly. Moreover, the rapid rate of discovery in the life sciences means that unexpected breakout technologies could suddenly disrupt the competitive landscape as Al is doing today.

To maintain its lead in biotech and to outcompete China, the U.S. should apply to the bioeconomy key lessons from historical support from defense-related technologies. Since World War II, government support for R&D enabled American industry to leverage the intellectual property generated by defense R&D in the physical sciences to achieve global military superiority, and also allow U.S. industry to dominate related commercial technology. The Federal Government's investments in an array of translational infrastructure, facilities, programs, and projects, were essential to converting physical science insights into operational technologies and usable projects.

The United States need an analogous approach for biotechnology. Such an approach would include more government support for biotech infrastructure within the context of mission-driven collaborations with the private sector. And in my written testimony, I've offered several examples of such infrastructure.

Finally, three successive presidential administrations have endorsed the importance of building a strong U.S. bioeconomy, and Congress has declared biotechnology to be a sector strategically critical to national security. What is required is a clear vision of what the Nation needs to achieve via biotechnologies and how the government and the private sector can work together to maintain U.S. economic

competitiveness and protect U.S. power in this age of biology.

Thank you.

[The statement of Dr. O'Toole follows:]

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Chairman Gallagher. Thank you, Dr. O'Toole.

Dr. Clancy, you are recognized for 5 minutes.

STATEMENT OF CHARLES CLANCY

Mr. <u>Clancy.</u> Chairman Gallagher, Ranking Member Krishnamoorthi, and committee members. My name is Charles Clancy. I'm a senior vice president and chief technology officer at MITRE, a nonprofit research institute that operates R&D centers on behalf of the U.S. Government. It's my pleasure to address this committee.

Over the past 10 years, the U.S. has led the world in biotech research, development, commercialization, but has outsourced much of the biomanufacturing and a myriad of related bioservices to places like China. This is a common pattern across most U.S. technology sectors, such as semiconductors. As we reexamine our global trade relationships and supply chains, this outsourcing creates significant risk.

Additionally, not content to simply manufacture, China has invested heavily in its own R&D, and has caught up to the U.S. with major ongoing state-directed investments positioning them to take the lead.

2 years ago, MITRE published a set of recommendations for congressional action to maintain U.S. leadership in advanced biotechnology, and they are included as an attachment in my written testimony. In the interests of time, I will focus on a subset of the recommendations in my remarks here, focused on how we can secure the bioeconomy and take steps to mitigate increased risks, with a particular focus on complementing some of the remarks of my fellow panelists.

In the telecommunications area, the U.S. technology strategy to compete with

China focuses on decentralization. Our O-brand strategy takes the notion of a monolithic cell tower and breaks it into functional building blocks. By standardizing the interfaces, we can diversify our supply chains, enable new market entrants, and take advantage of network innovation.

The same approach has applicability across many technology areas, including biology. At MITRE, we're leading an initiative to build what we're calling a Bionet, which is a software and programming layer for biologic research, development, and production. With standardized interfaces and data formats, we can interoperate at scale to advance the U.S. bioeconomy and that of our allies. Efforts like this are key to accelerating the pace of U.S. innovation, particularly as we contemplate sanctions that would slow China's pace.

While automation in internet working enables entirely new innovation pathways for biology, it amplifies existing and creates new cybersecurity risks. Currently, biology is not represented directly among our established critical infrastructure sectors. And minimally, biomanufacturing should be added as an officially designated critical manufacturing sector. This would provide a Federal touchpoint for the relatively new Bio-ISAC.

However, in the biology domain, security risks certainly are broader than just the bioindustrial cybersecurity. A public-private partnership should be launched to provide more operational support to the cyber biosecurity continuum, and this partnership could support a wide range of biosecurity biosafety activities on behalf of the industry and the U.S. Government.

As we make investments in R&D to support growing the bio economy, a final area of concern is research security. Today research security varies considerably across universities, startups, and companies, creating considerable risks that China fast follows

our R&D by stealing the intellectual property right out from underneath us.

At universities, executing restricted research, such as projects subject to CY or ITAR, work is limited to U.S. citizens and permanent residents, and IT systems must adhere to certain cybersecurity standards. However, most research conducted in critical emerging technologies, to include biology, is designated fundamental research and exempted from these requirements. NSPM-33 is in the process of implementation and mandates security for federally-funded work in critical and emerging technologies. It has new requirements for reporting information on foreign national participation and research projects. However, it remains unclear how this information will be used at scale beyond simply the deterrent value of reporting.

The Department of Justice should establish a clearinghouse to work with funding agencies, universities, and laboratories to perform personnel screening based on these disclosures and help enhance the current visa screening processes.

Additionally, NSPM-33 proposes enhanced cybersecurity protections. At a minimum, research organizations receiving Federal funding for critical and emerging technologies should be required to implement network-based threat monitoring, Zero Trust endpoints, data loss detection and prevention tools, and multifactor authentication. These are consistent with requirements of NSPM-33, but many are still waiting on the final rules expected later this year to understand the implications for the cost of implementation.

Science funding agencies, such as NSF, could provide capacity building grants to help organizations with upfront implementation costs. Additionally, NSF should move expeditiously to establish the proposed research security ISAC to help provide a focal point for threat intelligence and information sharing.

I will also note that the appropriations that we've seen coming out this year

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involve 8 to 10 percent cuts to many of our Federal science agencies, and I have a concern

that some of the nascent research security efforts won't get off the ground as a result of

some of these budget actions.

In closing, we're sitting at an inflection point where biology offers huge potential

to fundamentally transform society for the better, but we're in a globally competitive

environment, and we need to align policies and resources, plug security holes to be

successful in the long term.

Thank you.

[The statement of Mr. Clancy follows:]

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Chairman Gallagher. Thank you.

My first question is for all the witnesses.

Last month, I received a curious letter from the then-CEO of the Biotechnology Industry Association, or Organization, and this is, as I understand it, the world's largest trade association for biotechnology companies. In this letter the CEO says that our committee's bipartisan effort to restrict the flow of U.S. taxpayer dollars to PRC firms affiliated with the People's Liberation Army, or human rights abuses, is, quote, "misguided." And then it goes on to say that Congress has no role in identifying entities that pose a threat to the national security of the United States.

Now, it's shocking I have to ask this question, but it's clear that industry still needs an education.

Dr. Kelly, yes or no, should U.S. taxpayer dollars go to PRC biotech companies that commit human rights violations and work with the Chinese military?

Mr. Kelly. Commit human rights violations, no.

Chairman Gallagher. No.

Same question, Dr. O'Toole?

Dr. O'Toole. No.

Chairman Gallagher. No.

Same question?

Mr. Clancy. No.

Chairman <u>Gallagher.</u> I hope BIO hears the witnesses' answers and publicly retracts the embarrassing letter. Where BIO had an opportunity to work with the committee to protect U.S. national security, it chose instead to defend companies, some of whom are implicated in the CCP's ongoing genocide.

I also want to highlight that this bill just yesterday that we've supported passed out of the Senate Committee on Homeland Security and Government Affairs with overwhelming bipartisan support. And I want to thank Senator Hagerty and Senator Peters for their leadership and support in the Senate for this important effort.

Moving on, Dr. Kelly, you publicly raised the alarm about PRC biotech firm BGI's global collection of genetic data. Your company sits at the forefront of biological data and AI as you were talking about before. How valuable is the genetic data that BGI and other PRC biotech companies are collecting? And how could that pose a risk to U.S. national security?

Mr. <u>Kelly.</u> Yeah. So maybe I'll give a little bit of context on what I see happening with BGI in the area of biosecurity in particular.

I think there's two big buckets. There's the sort of human genomic data, which has a lot to unpack there. Maybe we could have a longer discussion about that. But I'm actually more concerned about sort of collection and monitoring of nonhuman genomic data like viruses.

So if you look at what happened with COVID in this country, I think there's two big lessons to me.

First, the U.S. is significantly exposed to the risk of infectious disease, right? We had over a million deaths. We had over \$10 trillion of economic impact from a virus, okay? So we know we have that risk. That's number one.

Second, our inability to know the origin of that, you know, the source of the virus to me is the largest intelligence failure since 9/11, right? This should be thought of -- we need to move to a footing where we're thinking of infectious disease, given the risk to this country. It is public health, but it is also national security. And so, it needs to be taken more seriously. And I think -- I see some changes in that area, but I think the U.S.

Government could do more.

We do do a program, Gingko does, with the CDC, so it's on the public health side where we monitor inbound flights from more than 100 countries to international airports here in the United States. When the plane lands, we collect the wastewater from the plane, and we look at the DNA that's in there to look for viruses.

And so, we did this actually during the COVID waves, and we caught, for example, BA.2, if you remember those sort of different variants, the first 40 days before it showed up in hospitals, we got the sequence at an airport.

Okay. Just to give you a sense of context, I grew up in Florida, right? We're familiar with hurricanes down in Florida. We know about hurricanes when they're starting to form off the coast of Africa, right, not -- we don't get told about them when they hit the coast of Florida. Our current approach to biosecurity is we find out about it when a lot of people show up sick in a hospital, okay? That is the hurricane has hit the coast, okay? So the idea with biosecurity is to have radar stations here in the U.S., sure, actually, importantly, internationally. So we run in a similar program at Delhi Airport, we run it in Rwanda, where we're also collecting, again, this sequence data. So you start to get a picture of how are viruses moving around the planet.

And I want to just mention BGI. Washington Post had an article in September of last year, an investigative report about BGI building out in more than 20 countries these types of genomic sequencing centers under the banner of COVID testing, including in countries like Israel, our close allies. So --

Chairman <u>Gallagher</u>. Could I have this -- in the time I have remaining, is the appropriate analogy sort of what Huawei did for telecom in showing up in these countries, massively subsidize, you know, everything in a box?

Mr. Kelly. Very much so, yes, state paid for facilities. And once they're in, it's

hard for us to get in. So I do think this is similar situation.

Chairman <u>Gallagher.</u> But presumably, you have better technology than BGI?

Mr. <u>Kelly.</u> I certainly think so, and we're working with Illumina, which is the leading genomics company here in the U.S., in terms of the technological deployment alongside the work that we're doing in the airport.

Chairman <u>Gallagher.</u> Thank you. My time has expired.

I recognize the ranking member.

Mr. Krishnamoorthi. Thank you, Mr. Chair.

Now I would like to talk a little bit about brain chips and mind control technology. Two weeks ago, Elon Musk's company, Neuralink, said it successfully installed an implant in a person's brain to allow them to, quote, "control a phone or a computer just by thinking." It would look something like this. This is a picture from WIRED Magazine's article about Neuralink.

And so, Dr. Kelly, this is a technology that, obviously, could do some good. It could help paralyzed people, for instance, regain basic functions, right?

Mr. Kelly. That's correct.

Mr. <u>Krishnamoorthi.</u> But it turns out Musk isn't the only one researching this particular brain biotech. Two years ago, scientists at China's Comprehensive National Science Center claimed to have developed, quote, "mind-reading artificial intelligence" that, quote, "measures the loyalty of CCP members by measuring brainwaves and facial expressions."

This type of technology could allow the CCP to supercharge its surveillance state, right, Dr. Clancy?

Mr. Clancy. Sure.

Mr. Krishnamoorthi. In fact, in 2021, the PLA's Academy of Military Medical

Sciences was added to the Commerce Department's entity list because, quote, "it supports Chinese military end uses, including purported brain control weaponry." This is truly frightening stuff.

Let me just turn to another topic, and I want to go back to BGI since Dr. Kelly and Chair Gallagher talked about it. As everyone knows, BGI group is a PRC biotech company that's at the forefront of human genome collection and experimentation. In fact, BGI is in charge of China's National Gene Bank, the largest genomic database in the world, approved and funded by the CCP.

And this is a picture from the National Gene Bank in China. And as you can tell, here's a BGI machine that's being utilized there.

In 2021, Reuters reported that BGI had a prenatal test called NIFTY. It's called NIFTY. And it took genetic data from 8 million women from over 50 countries.

Further, BGI worked with the PLA to single out Tibetan and Uyghur minorities to identify links between their genes and their characteristics.

So, Dr. O'Toole, BGI claims to the world that, quote, "none of BGI is, in any way, controlled by or linked to the Chinese government or the military." But this Reuters article clearly says the opposite. So why don't you tell us, you know, what is actually going on here?

Dr. <u>O'Toole.</u> Well, I think we have to assume that every Chinese company is linked to the CCP, and possibly to the PLA if they're doing research relevant to the military.

I will say that BGI is very smart. And we ought to be the ones with the biggest gene bank in the world, and we ought to be the ones with the biggest genome collection in the world, and we're not, and shame on us. They are out in front of us in many ways. I understand the proclivity to talk about military applications, and obviously, those are

very important. But what they are doing is outpacing the United States in collecting the world's biggest genome library.

Mr. Krishnamoorthi. Well, I think --

Dr. O'Toole. And you have to understand -- I'm sorry --

Mr. Krishnamoorthi. Go ahead.

Dr. O'Toole. -- one sentence. You have to understand that the larger your genomic library, the more effectively you're going to be able to speak DNA. So that's what they're doing. And the applications to humans are important, but the applications to materials, to food crops, et cetera, are going to be even more important economically and particularly in the --

Mr. <u>Krishnamoorthi.</u> Well, let me jump in, Doctor, because here's the thing, I agree with you. But BGI, if it developed these tests in conjunction with the PLA, should not be receiving taxpayer funding from us.

Dr. <u>O'Toole.</u> Certainly.

Mr. Krishnamoorthi. And that is what the --

Dr. O'Toole. Certainly.

Mr. Krishnamoorthi. And I assume you agree with me on that?

Dr. O'Toole. I do.

Mr. <u>Krishnamoorthi.</u> Let me turn to the flip side of this issue, which is that we actually sell biotech equipment into China. One of these companies is called Ande, which was developed at MIT and funded by U.S. Government research.

Here's the Ande machine. It actually sequences DNA, and it's been sold to

Chinese police forces, including this one in Sichuan, which as you can see on this visual is
the machine here. And it's in the trunk of this vehicle used by the Chinese police here.

I think Chinese -- I think U.S. companies need to stop selling these machines to

Chinese police forces that are targeting minorities. In any case, the U.S. Government needs to establish and enforce stronger export controls to make sure our biotech equipment isn't aiding CCP authoritarianism.

What do you think, Dr. Kelly?

Mr. Kelly. I think it is critical to make sure our technology is not being misused. I do think there's a -- just like we're talking here about what could be sold into our economy, I do think we want to think about winning standards, wars, and getting our technology to be the basis globally. But, you know, like, I think what we did with the internet was great, right? We established open internet standards. We pushed them globally, and ultimately China -- you know, we would have loved to sell to them, and they blocked us because they didn't like the openness of the standard. We should do that same thing when it comes to these gene banks. We should have the biggest one. It should be pushing our ethics in there. If they don't want to use it, they don't have to use it, right? But if they do, we'd love to have them, but they have to follow our rules. And that's what we did with the web, and I think we could do that again here with DNA.

Mr. <u>Krishnamoorthi.</u> But we shouldn't have allow sales to Chinese military -- police forces?

Mr. <u>Kelly.</u> Absolutely. We should be concerned about any military or police applications that don't match our ethics when it comes to our technology, absolutely.

Mr. Krishnamoorthi. Thank you.

Chairman Gallagher. Mr. Wittman.

Mr. <u>Wittman.</u> Thank you, Mr. Chairman. I would like to thank our witnesses for joining us today.

Chairman and Ranking Member, I appreciate you bringing up what we need to do to stop funding these efforts in China to protect our technology, but I think these things

fall in two buckets. Obviously, I believe as we go forward, the most valuable commodity in the years to come is not going to be currency. It will be data. And the question is how do we make sure that we maintain that standard that the dollar is today in the realm of data? How do we make sure that we have the biggest database? How do we make sure that we, from that standpoint, then, can influence some of these things that happen around the world? How can we make sure that the technology surrounding the human genome, the technology surrounding DNA is used for good purposes, is not used for evil?

In my previous life, I worked extensively in molecular biology, developed gene sequencing with Cepheid and others to do rapid detection of things that can harm human beings. We used it for good. The challenge is going to be not just for what China is doing, but for other forces of evil around the world to say, Wow, we could use this for not so good purposes.

So the question is twofold. We talk about what can we do to protect what we do? How can we do things that really move things in the direction of good? But second of all, how do we make sure that we grow our capability and capacity in these fields so that we have the mass to be able to exert influence for forces of good and counter the forces of evil?

Dr. Kelly?

Mr. <u>Kelly.</u> Yeah, this is an absolutely excellent question, and I think it's particularly pertinent, as I was mentioning -- and Dr. O'Toole mentioned this as well -- these data assets are what train these AI models. There has not been the ChatGBT moment yet for these DNA models. I think it's in the next 2 years. It is imperative that we get there first.

And to answer your question, as you know from being in the field, data is expensive to generate in biology. So I actually think the most important thing we can do

is invest in infrastructure. Things like automation is a place where the U.S. is leading. Obviously, we had the commission have the chance to come and visit the foundries at Gingko which is our automated labs. We're building a new one called BioFAB1. It's like a 250,000 -- think of it as almost like a data center for generating biological data. That line of work -- and there are also public versions of these types of BioFabs -- I think is it, because if we don't have the largest data asset, we don't have the leverage to define the rules of the road.

Mr. Wittman. Very good.

Dr. O'Toole?

Dr. O'Toole. Well, we control the standards for data by building the best, biggest, most accessible, and useful biological databases. And to do that in America's very fragmented and frothy environment, we're going to need the help of government to get everybody on the same page basically. I think we can do this, but I think we have to start immediately because China is moving, and we're moving, but we're not moving fast enough, and we're not using the might of the United States to build that absolutely irresistible database that everyone is going to have to have access to, and which we can control via standards, et cetera, et cetera.

Mr. Wittman. Thank you.

Dr. Clancy?

Mr. <u>Clancy.</u> I'd suggest that NIST's bio standards program is dramatically underresourced, and that would be something that congressional action could help with, is really put the emphasis on NIST to build out those standards for data, for interoperability, and that can then be the platform that could help enable all of the things you're talking about.

Mr. Wittman. Very good.

With that, Mr. Chairman, I yield back. Thank you.

Chairman Gallagher. Mr. Moulton.

Mr. <u>Moulton.</u> One of my concerns is that this is essentially a winner-take-all situation where if one company gets all the data -- in the same way, that there might be competing search engines, but everyone by default just goes to Google because that seems to be the best, and so, you might have good principled reasons to go to a U.S. firm like Gingko, but if a Chinese firm is better because they have better data, they're better at designing DNA, then most people in the world are going to go there. Is that correct?

Mr. <u>Kelly.</u> Very much correct, in my opinion.

Mr. <u>Moulton.</u> Dr. Clancy, tell us a little bit more about the various types of data that we need to amass to make sure that we are truly leading the world.

Mr. <u>Clancy.</u> Yeah. And I'll reinforce that I think BGI and Wu-Xi are successful because they offer a superior product in many cases. So we definitely need to step up and be able to compete and replace them with domestic capabilities.

In terms of the types of data, I mean, certainly we've talked a lot about -- a lot of people think about human DNA when they think about this space. But as some of the other panelists mentioned, you've got a wide range of other types of data, including -- I mean, agriculture is a huge market as well. I mean, that's arguably a bigger opportunity for China is to really figure out how to supercharge their agriculture industry as well.

So those are some other areas that I think would be important to focus on from a data perspective.

Mr. <u>Moulton</u>. And as we know, China is leaning into this heavily. And the ranking member mentioned an article from 2021 describing how BGI Group has used its prenatal test to amass genetic data of millions of pregnant women worldwide.

I would like to enter that into record and would also like to enter into the record

another Reuters report showing that BGI used a PLA supercomputer to run analyses on the genes of Uyghurs and Tibetans.

Without -- enter that into record, without objection.

Mr. Wittman. [Presiding.] Sure.

[The information follows:]

****** COMMITTEE INSERT ******

Mr. <u>Moulton.</u> Tell me, Dr. Kelly, when you think about where this is all headed -- you've talk a lot about how to design DNA. Talk about how there might be other national security implications for biomanufacturing. What's the sort of next generation of biotech, and how it could be supplied to national security?

Mr. <u>Kelly.</u> Yeah. And maybe I'll touch on agriculture actually, because I think people often think of biotechnology as largely impacting, you know, the States that are, you know, building our pharmaceutical industry. But I actually think for our farmland in this country, biotechnology is an enormous opportunity.

So if you as a technologist looked at a plant, okay? You plant a seed. You add air, water, and sunlight -- and this is the truth -- if things start self-assembling out of the ground, CO2 is used to build the physical objects. It makes solar panels and the leaves. It starts harvesting energy and then manufacturing things. And one of the things it manufactures is corn, which we eat. But really you should think of that as hectors and hectors of manufacturing infrastructure if you could reprogram those plants to make other things.

And, Representative Moulton, to answer your question, biology's ability to place atoms in the right place when it's building things is superior to Taiwan's semiconductor. So in terms of what could this manufacture, the most advanced things that drive a lot of our strategy here, like, if you look at what is powerful in the world, it's often the smallest things, the things that we can truly design precisely, I think biology is the manufacturing technology of the next 50 years, but we need to build out these tools of design.

Mr. Moulton. So biotech could be manufacturing semiconductors?

Mr. <u>Kelly.</u> If you look out 50 years, absolutely, yeah. It places atoms in three dimensions atomically precise. We don't really do that well right now with lithography,

right? So I think that's the direction you should be thinking. You should think of it like atomic scale manufacturing because that's what it is.

Mr. <u>Moulton.</u> Dr. O'Toole, why should Americans care about this? Why should -- what should we recognize about how it does or can affect our lives?

Dr. O'Toole. We've been talking about the dark side of biology today, but I think biology is going to be the key to making good lives for America. I think virtually anything that can be made biologically will be made biologically because as Jason said, it's extremely efficient. And as far as we can tell so far, biomanufacturing of virtually anything is a lot greener than any alternative processes, and it's going to be much more energy efficient.

So I think biotechnology is going to cause extraordinary advances in biomedicine which we're already seeing. I think it's going to allow us to make materials with new properties that we can't even dream of. We're going to go way beyond Velcro. Virtually anything nature can do, biotechnology can do.

I think it's going to make possible food security for the world, which is going to be a huge problem because of increasing demand, climate change, loss of water, et cetera, et cetera, and I think it is the only solution to supply-chain vulnerabilities. We have to be able to biomanufacture the stuff we need.

Mr. Moulton. Thank you very much.

Dr. O'Toole. So I think it's going to change the world.

Mr. Moulton. Thank you.

Chairman Gallagher. Mr. Luetkemeyer.

Mr. <u>Johnson.</u> Mr. Chairman, I would ask unanimous consent to strike Dr. Kelly's reference to corn and insert soybeans.

Chairman Gallagher. Without objection.

Mr. Johnson. I'll withdraw.

Chairman <u>Gallagher.</u> Noted. We have gone overboard on the bipartisanship of this committee.

Mr. Luetkemeyer.

Mr. <u>Luetkemeyer.</u> Thank you, Mr. Chairman.

And welcome to our guests this morning. Interesting we have a Clancy, an O'Toole, and a Kelly here this morning, which are very strong Irish names. My wife is half Irish, so I kind of note those kind of things, but welcome.

You know, I take a little bit different tact on some of the questions here, because it's a fascinating discussion, but I also want to go into how dependent are we with our biotechnology research with our universities and educational facilities?

Dr. Clancy, do you want to answer that?

Mr. <u>Clancy.</u> Yeah. I think our universities are extremely active in driving the innovation ecosystem that we have today in biology.

Mr. <u>Luetkemeyer.</u> So that begs the question then. How involved are the Chinese with those universities? Because we see them donating to universities through direct salaries to professors, which means they're on the take, as far as I'm concerned, endowments to these universities. How concerned should we be about that?

Mr. <u>Clancy.</u> Very concerned. I think the administrations recognize that, right? NSPM-33, which sort of came out at the tail end of the Trump administration, is focused on fundamentally changing the equation there with new reporting requirements, fundamentally barring people that are a part of these Thousand Talents Programs from being able to participate in certain types of research. We've created a set of policies that will give us the sensors we need, but in my opening statement, my concern is that we haven't put the analytics back end on it to really understand the techniques and

procedures that the Chinese are using at scale, because they can -- researchers will hop from one university to another to find the lab where they can get in and get access to the research. And if we were able to cross-correlate activity across research institutions, we could be able to detect and stop that kind of activity.

Mr. <u>Luetkemeyer.</u> In December, Chairman McCaul released the report on ways to improve and strengthen U.S. export controls. One finding found that the Bureau of Industry & Security is using a licensing regime that allows companies on the entity list to still access U.S. technology without a license or under a presumption of denial.

To my knowledge, BIS does not have to report licensing decisions to Congress. Is that accurate? Are you guys aware of what that is?

You don't. Okay. Very good. Well, our concern is that they don't do this, and we need to find a way to make sure that this Bureau of Industry & Security does do the licensing correctly and then report it to Congress. So that's the point on that one.

Dr. O'Toole, you talked about public-private partnerships as a way to sort of go forward with some biological research here. Would you like to define how the relationship could work, where the line should be drawn with how much involvement the public side -- the government side should be, versus the freedom to be able to do the right thing with regards to the private sector?

Dr. <u>O'Toole.</u> Certainly. So we invest in small startup companies within innovative technologies that we think will be useful to U.S. national security agencies. And we have nine agencies as IQT's customers today.

Much of the innovative biotech coming out of the United States is actually happening at the small companies, both for biomed and for other applications of biotech. Large corporations also have a role to play, and it is certainly clear that in this country, at least, the private sector is going to have to be key to building any biotech infrastructure

or products that we want to have. But because the country is so big, because there is so much going on, we really need the government to play a strategic role in saying these are the priorities the country must pursue right now. These are the things we need industry to help us accomplish. And I think with that kind of guidance, as happened after World War II, industry will go to work. They don't need a detailed minute-by-minute blueprint. If they know the government wants this, the government will pay for the products if we can actually invent them, and the government will support the creation of markets for those private sector products, I think we'll be fine.

That's what we did after World War II with the physical sciences, but we have to do it now with the biological sciences. For the most part, the government has only funded basic research in biology, and we haven't translated it into products.

Mr. <u>Luetkemeyer.</u> Okay. I've just got a limited amount of time here. Just one quick question, though, before I give up my time here.

You guys are talking about an enhanced DNA database, and I'm assuming that it's DNA as a result of all the different kinds of things that grow out there, including humans, but not specific to a particular human because, otherwise, now we're getting into some privacy issues. I'm going to make sure we draw a line here and make sure we know where we're at.

Would somebody like to just comment briefly on that?

Mr. Kelly. I would be happy to.

Yeah, I think you're 100 percent right to bring that up. In fact, I think you have enormous privacy issues around human genomic data. And the thing that just -- the flag -- I know we're proud of ourselves, but most of the species on the planet are not humans. So the books that are out there to train all those AI models, most of them aren't written in humans, so yeah.

Mr. Luetkemeyer. Thank you very much.

Chairman Gallagher. Ms. Brown.

Ms. <u>Brown.</u> Thank you, Mr. Chairman.

I am proud to represent one of the greatest hubs of biotechnology innovation in Ohio's 11th Congressional district. Our expertise, experience, and influence are known around the world, thanks to institutions like the Cleveland Clinic Foundation and Case Western Reserve University, which provides education and training to the next generation of biotech leaders.

All across the country, American innovators are combating challenges in the medical field, leading to remarkable breakthroughs in medicine, from the COVID-19 vaccine to new treatments for breast cancer and Alzheimer's to over-the-counter birth control which has just made it onto pharmacy shelves for the first time in history.

Now, as exciting as this innovation is, we must remain cautious about three concerns:

First, efforts by the Chinese Communist Party to unfairly steal American technology or promote harmful biotech weapons.

Second, the COVID-19 pandemic exposed shortcomings in our global supply chains, which is why I introduced the bipartisan Critical Supply Chains Commission Act to examine and identify gaps in our supply chain and reduce our reliance on any outside nation to provide the critical materials we need.

And third, the rising use of artificial intelligence poses great risk with its advanced and widespread abilities which we must make sure does not get out of hand.

So Dr. Kelly, can you speak to how AI is changing the field of biotechnology and what impact it has on competition between the U.S. and the CCP?

Mr. Kelly. Yeah, absolutely. So I think you're right to highlight this. I think it's

the most important thing coming up that I believe could be truly disruptive in this area, for some of the comments I made earlier around how poorly we write DNA, but how well these models could write DNA.

I'd highlight, you know, you talked about misuse of this technology around biological weapons. I actually think -- again, framing how we want to manage strategic competition in certain areas I actually think helps ultimately reduce tensions by us understanding the game here, the playing field.

There's areas where I think we could cooperate, and I think biological weapons -- the U.S. and China are both signatories to the Biological Weapons Convention. I think as countries that have other forms of, you know, substantial weapons in the form of nuclear weapons, it doesn't behoove us to enter a world where biological weapons are prevalent. And I actually think this is a key point.

As the technology becomes more democratized, in part, due to AI, I think both us, both the U.S. Government and the CCP, have an interest in it not being weaponized in the reduction of the ability for, you know, nonstate actors and others to be able to develop biological weapons in the form of viruses.

So I actually think, interestingly, this might be one of the places where we do want to make sure there's a global monitoring regime and we're quite careful about it, and maybe it's an opportunity for strategic cooperation.

Ms. Brown. Thank you.

The Biden administration has been leading the way on advancing biotechnology for the greater good while safeguarding the U.S. against foreign threats. The Advanced Research Projects Agency for Health, or ARPA-H, is the President's signature initiative to invest billions in American biotechnology with returns for generations to come.

President Biden also initiated the amazing Cancer Moonshot Program to cut the

cancer death rate in half over the next 25 years. As we know, people who look like me, Black and Brown folk, are disproportionately impacted by cancer. The administration's effort and commitment to this cause is, quite literally, saving lives.

In September of 2022, President Biden released his executive order on advancing biotechnology and biomanufacturing innovations for a sustainable, safe, and secure American bioeconomy.

Dr. Clancy, please talk about how President Biden's executive order advances our strategic interests in this space, and how Congress can support him even further.

Mr. <u>Clancy.</u> Sure. I think that the executive order really got the ball rolling on a wide range of initiatives, and certainly, some of the biomedical opportunities with ARPA-H and the Cancer Moonshot, I think, are tremendous. I mean, I think the idea is that as this technology continues to mature, we'll be in a position to use it to fundamentally cure cancer, right, be able to do very targeted therapies. And so the opportunity, from a biomedical perspective, is tremendous.

I do want to point out, though, that there's a whole bunch of nonbiomedical applications of the technology that we've been talking about as well that also have significant opportunity for the United States and our bioeconomy more broadly, from agriculture to new materials to lots of other things as well.

So I want to make sure that as we think about this, we don't -- but certainly the biomedical part is important, but there's a much bigger opportunity as well.

Ms. <u>Brown.</u> Thank you, Mr. Chairman. I yield the remaining balance of my time.

Chairman Gallagher. Thank you.

Mr. Newhouse.

Mr. Newhouse. Thank you, Mr. Chairman. Thank you to all of our three guests

this morning. I appreciate your testimonies on this fascinating, fascinating subject.

You all mentioned that biotechnology translates into nearly all aspects of our lives, including the field of agriculture and energy. I've been a farmer all my life. My family are farmers. We're fourth or fifth generation.

I also represent the Hanford Nuclear Site, as well as the Pacific Northwest National Laboratory, so I really find these two topics of ag and energy particularly important and just would like to go into that a little bit deeper, if I may.

Right now, there's, I think, more than a dozen Federal entities, including agriculture and energy, tasked with the biotechnology funding as well as oversight processes. Some experts, including some Members of Congress, including my colleague, Mr. Auchincloss, have called for the creation of a bioeconomy initiative coordination office. So I would like to ask a little bit about this, the status for interagency biotech coordination.

I know the CHIPS Act -- CHIPS and Science Act and some recent executive actions have attempted to address this interagency issue. DOE currently leads the interagency group with 13 Federal agencies. So several questions along these lines, if I could.

RPTR KERR

EDTR SECKMAN

[10:03 A.M.]

Mr. Newhouse. Is the status quo sufficient to meet the emerging demands of our bioeconomy? What role should CFIUS play in this process? Should it have expanded authorities, do you think? What actions should the Departments of Agriculture and Energy execute? Which funding mechanisms or accounts are critical in addressing this challenge? And, maybe more importantly, should a coordinated office be created? And could you please focus on the role of data genetic editing and biomass resources?

So all in 3 minutes.

Mr. <u>Kelly.</u> Maybe I'll comment on this one regulatory. And then if you want to speak to the CFIUS. Did you ask Tara? I'm sorry.

Dr. O'Toole. Do you care?

Mr. <u>Newhouse.</u> All three. No, go ahead. Why don't we start with ladies first. Since the chairman is old school, so am I.

Dr. <u>O'Toole.</u> Thank you.

Wow. Okay. Reorganizing the Federal Government. The current arrangement is not sufficient. There are some real strengths in the current organization, particularly in the Department of Energy and its long-term focus on bioenergy and biomanufacturing.

And I am a veteran of newly created organizations, specifically DHS and, back in the day, DOE. And I would try to avoid creating new organizations if at all possible. So I would leave DOE intact.

I think USDA needs a real big push towards investing in innovation. I think we'll get more bang for the buck investing in biological technology for agriculture than just about anything else.

Mr. Newhouse. I agree.

Dr. O'Toole. So you're going to have to rebuild R&D in USDA in my opinion.

Mr. <u>Newhouse.</u> Okay.

Dr. O'Toole. I do think there's great value in having an overall office for coordination partly because it allows -- it sends a message to the agencies that this is important, and somebody is going to be looking over your shoulder and coordinating.

And this is a very broad range of activities we're talking about. So some node that other people, particularly the private sector, can plug into I think would be very important.

Mr. Newhouse. Very good.

Dr. O'Toole. And I'll stop there.

Mr. Newhouse. Yes. Thank you. Less than a minute to go.

Mr. <u>Kelly.</u> I have one quick, small thing. I spent a lot of time interacting with ag biotech companies, startup companies. Ninety percent of our startups are in the pharmaceutical space in biotechnology, and maybe less than 5 percent are in agriculture. And the reason is we, back in the '80s, when biotechnology first got started, we were rightfully concerned about was the technology dangerous and understanding how to regulate it.

And we roughly created similar regulatory regimes for a therapeutic drug intended to perturb a human body, fix a disease, and any genetic change you make to a plant.

Okay.

And so, as a consequence, the value of a drug is up here. So the risk of the

timeline of that regulatory justifies venture investment. The value of a lot of these changes to plants is down here, but the risk and regulatory is equal to pharma. So it gets no funding, which is why we have no startup ecosystem around our cropland and our great ag research universities that are producing just as much great research as you're seeing out of medical research institutes, but the regulatory needs to be updated. It is tied to a 1980s view of biotechnology, and there has not really been, in my view, substantial incidence like there has been in pharma that would justify why you have that level of scrutiny.

Mr. <u>Newhouse</u>. And yet we have tremendous potential there.

Mr. <u>Kelly.</u> Truly. I mean, the research in agriculture goes faster because it's easier to work, you know, in a plant than a human, right. But we just cannot commercialize it due to the regulatory.

Mr. Newhouse. Okay. Thank you very much.

Chairman Gallagher. Mr. Auchincloss.

Mr. <u>Auchincloss.</u> I appreciate you calling the hearing, Mr. Chair, and also for bringing the field hearings to Massachusetts to discuss the life science of ecosystem.

This is the century of biology, and the life science's leadership that the United States needs can't be one in this century through gamesmanship or protectionist, prohibitions, or industrial policy. It's got to be earned through the cultivation of a dynamic ecosystem.

And I think that we can cultivate that dynamic ecosystem through congressional policy that never actually uses the word "biology" or "bioeconomy" or the prefix "bio," period. It's a very complicated industry, but a lot of the things we have to do to get it right are pretty simple.

One, we've got to protect intellectual property. Bayh-Dole has been one of the

most successful laws of the last 50 years. We've got to make sure that we cultivate that tech transfer from universities to the private sector that has enabled such innovation.

We need to get high-skilled immigration right. In my home State of

Massachusetts, when I look at some of the most successful biotechs across

pharmaceutical, agriculture, et cetera, energy, so often it's an immigrant at the helm who had the vision, who executed, who's created jobs, discovered cures.

And adjusting schedule A in the Labor Department would be a good first step that I think could get bipartisan support even in the heated politics of immigration.

And then, finally, basic research funding. We should aim for 6 percent R&D national intensity, meaning the aggregate of private sector and public sector R&D should hit 6 percent of our gross domestic product. Right now we're barely scraping 3 percent. After World War II, it was closer to 6 percent.

If we look at our peers, Korea, Israel, in particular, they're steamrolling us. Their 5, 6, 7 percent of their GDP is going to R&D, and we are way back in the dust. And that's something that we can do, again, on a bipartisan basis. Department of Energy, National Institutes of Health, National Science Foundation, these are bipartisan agencies that have strong support across the aisle, and we should be funding them much more generously.

Let me now speak to some specifics. First, for you, Dr. Clancy, I appreciate that Dr. Newhouse talked about the standardization letter or, excuse me, the coordination letter that we previously sent in a bipartisan way. We have a followup letter to that about standardization, also bipartisan.

I'd like to enter this into the record.

Chairman Gallagher. Without objection.

[The information follows:]

****** COMMITTEE INSERT ******

Mr. <u>Auchincloss.</u> Dr. Clancy, could you just quickly speak to the benefits of standardizing terminology and measures across the bioeconomy, and particularly for manufacturing? And if you could do that in maybe 30 seconds.

Mr. <u>Clancy.</u> I'll just say that, over the last 10 years, those areas like synthetic biology have grown considerably. They're still artisanal in nature, right, and the more we can standardize the vocabulary, the data formats, the more we can move it from being this artisanal thing that only a few people know how to do to something we can do at scale.

Mr. <u>Auchincloss.</u> So it's not like a pinch of salt. It's like we need some teaspoons and tablespoons.

Mr. <u>Clancy.</u> Exactly.

Mr. Auchincloss. Got it.

And this is a very detailed letter that we sent, again, with Republican and

Democratic support that offered some guidance to NIST on how to do that, and we had a

lot of consultation from experts.

Second, for you, Dr. O'Toole, in your testimony, I think you circled around this.

You talked about the human genome project having a tremendous return on investment.

And I get a sense of what you're suggesting the next moon shot project could be, but could you just state what you think?

If the government was going to say we're going to do one thing to be kind of biotech infrastructure as a public -- for public partnership with private sector innovation, what might that be?

Dr. <u>O'Toole.</u> Well, I'll cheat and give you three things. We have to improve biomanufacturing. We have to get in the game. We're not there yet.

Secondly, we have to build our databases, as was discussed.

The third thing we should do is something flashy, something that will attract the next generation of talent bio. We could do a plant genome project. We could sequence all of the furry mammals in North America. It doesn't matter what we sequence.

As Jason was saying, we need this data, but we should do it in a way that attracts public attention as well as moves the field forward.

Mr. Auchincloss. A bat signal.

Dr. O'Toole. Exactly.

Mr. <u>Auchincloss.</u> For talented people to organize and galvanize.

Dr. O'Toole. Bats would be good, actually.

Mr. <u>Auchincloss</u>. There we go.

And then, Dr. Kelly, close us out. You're the chair of the National Security Commission on Emerging Biotech. In your preliminary report, you talked about updating the coordinated framework. You've already spoken a little bit about the disparity between ag and pharmaceutical regulation.

Are there any other updates in the coordinated framework you think we should be looking at?

Mr. <u>Kelly.</u> Yes. And, again, I'll speak in my personal capacity. That's a big one. And then I think just generally like tightening up on who's responsible for what is the biggest thing, right. Like, a lot of these things follow where you've got multiple agencies reviewing the same thing.

And, just to add to Dr. O'Toole's comment, yeah, national parks genome project is what I would like to see.

Mr. Auchincloss. National park. I like that idea.

When you talked to the agencies about this as part of your work as chair of that committee, what is the level of prickliness that you get when you talk about tightening things up? Are they open to it, or are they like, "No, back off"?

Mr. <u>Kelly.</u> A bit prickly.

Mr. <u>Auchincloss.</u> Okay. I yield back.

Mr. <u>Kelly.</u> We could use support there.

Chairman Gallagher. Medium-high prickly.

Mr. LaHood.

Mr. <u>LaHood.</u> Thank you, Mr. Chairman.

I want to thank all three of our witnesses today for your valuable testimony here today.

I was one that got to participate in the Boston field hearing, and I want to thank the chairman and Mr. Auchincloss and Seth Moulton for helping to put it together.

Great academic experts there, industry leaders, VCs, and really highlighted the thriving ecosystem of innovation in Boston.

And, without question, the United States is the global leader in biotechnology innovation and research.

At the same time, however, it's no secret that this industry relies heavily on international supply chains, especially from China. And I'm concerned and it was highlighted by our visit there on the dependence and how this could be exploited by an adversary, obviously like the CCP, causing damaging bottlenecks within U.S. biotech supply chains.

Obviously, we saw that, and it was highlighted during COVID in a number of different fields. And so it's paramount, given U.S.'s national security interest, that we diversify our supply chains through international cooperation with our trading partners

and by investing in domestic production.

And, during the visit to Boston, I had the opportunity to visit with Jake Becraft.

He's the CEO and cofounder of Strand Therapeutics, a biotech company that researches and develops state-of-the-art new therapies with mRN technology.

Jake actually grew up in my district in Illinois, and his family still resides near Peoria. But Jake and his team have really -- have this wonderful company, but they recently launched a new initiative called Peoria Bio-Made, which partners with local community school and healthcare workers to create a hub for manufacturing biologics, viral vectors, and nucleic acids and other input products required to manufacture treatments.

The vision of this initiative is to develop production capacity, attract biomedical companies to central Illinois, and create a viable alternative to our reliance on international supply chains in the biopharmaceutical industry.

My district, like many others across the Midwest, has a storied history of manufacturing and innovation and presents a great opportunity for reskilling and training workers for these and new emerging industries.

Dr. Kelly, I'm going to start with you. In terms of the strategic vulnerability of our reliance on China, I'm wondering if you could comment on that.

And then, secondarily, as we look at closing the skills gap here, we could see over 2 million unfilled manufacturing jobs by 2030 in the U.S., particularly in new and emerging sectors like biotechnology. So how can the U.S. better address the skills gap in biomanufacturing? And also talk about the strategic vulnerability and our reliance on China.

Mr. <u>Kelly.</u> Yes. I mentioned earlier that percent of biologics moving into China. I think one answer here also is no problem if a Chinese manufacturer built a site in the

U.S., right. So I think that's a little bit different than like communication technology where there might be some chance to spy or something. We'd love to have it, you know. So I think, you know, that's an answer to some of this is have them build here.

I think community colleges. I'm seeing increasing numbers of programs like affiliated next to a biomanufacturing plant. I think that could work extremely well. That's the level of training you need for these things.

And the last point I'll make, I was down in Illinois -- sorry, Indiana, touring a Lilly plant, and these new drugs, these obesity drugs that are going to have hundreds of millions of customers for them are changing the story around manufacturing of these biologics and proving how valuable it can be if you have these things that affect everybody.

You know, make muscle tone last longer, longevity. If we want to access those truly, like, major health changes and wellness, we will need manufacturing at a hundred or a thousand times our current scale.

So it's an enormous opportunity for all of these areas. In terms of build-out, if these types of drugs end up being successful and under the direction of pharma industry and moves in the future, you might see a hundred or a thousand times more manufacturing.

Mr. <u>LaHood.</u> Excellent.

I may just ask the other two to comment on how do we diversify away from China in this field, particularly on manufacturing, if you want to comment.

Mr. <u>Clancy.</u> I'll just note the tech hub you mentioned is a great example of what we're trying to do as a Nation with the CHIPS and Science put into motion. This notion of play space innovation. We have the EDA tech hubs. We have NSF engines.

And I would just say that continued support for the CHIPS and Science from an

appropriations perspective would be very helpful in making sure that we are creating these regional centers of excellence, to include in biology.

Mr. <u>LaHood.</u> Dr. O'Toole, anything to add?

Dr. O'Toole. I would only add that we have to pay attention to getting young people excited about these opportunities. In my experience, they don't know about them. They don't see science as a route forward for them because they're not going to go get a Ph.D. And we need to think seriously about how we recruit and then train young people for this new dawn that is happening.

Mr. <u>LaHood.</u> Thank you. I yield back.

Chairman Gallagher. Ms. Sherrill.

Ms. Sherrill. Thank you.

I'd like to point out how incredibly important this is to me because I am a Member of Congress from New Jersey, and as we speak, Bruce Springsteen tickets are on sale.

But I am here. I am here.

So it's wonderful to have all of you here today, and I really appreciate your time.

Dr. Kelly, you discussed how generative AI could transform the bioeconomy and significantly accelerate our pace of biotech and pharma R&D. It's an incredible opportunity for the American economy and one for my home State of New Jersey, which generates about 20 percent of its GDP from biopharmaceutical and medical technology companies.

So can you discuss how biotech companies are currently using AI to expand their innovation and competitiveness? And what barriers currently exist to greater usage of AI by U.S. companies?

Mr. <u>Kelly.</u> Yes. So you now see a number of companies using it in the area of protein design. So a lot of these therapeutics are proteins. And I would say the

barriers are largely around aggregating data in the biology space.

So the reason we had that ChatGPT moment here in the U.S. is we had a Big Data asset called Common Crawl, which now I understand, OpenAI is getting sued over this now, but it was a big scrape of the entire internet.

And the reason we have the image model is because we had something called ImageNet, which was an open, available training set of images and what was in the image.

Well, there's been some early success in protein design for AI because the government has a database called the Protein Data Bank, which has all the structures, the shapes of all these proteins. So that means, if you know the gene and you know the shape, you can build a model that predicts the shape.

We don't have many other PDBs. And so I think there's a coordinating role the government can play to pull data.

Let's take safety data. Why don't all the bio pharma companies share all the safety data they've had on failed drugs so that we put that into a big pool dataset, and we start to have AI models that could also predict the safety in advance of a clinical trial by having that data.

That is not a data asset today. It's all siloed in these companies.

Ms. <u>Sherrill.</u> So there is a sense that, because of their lack of some of the privacy concerns we have here that the Chinese Communist Party has access to quite a bit more data, as you're talking about. To what extent is the CCP prioritizing the development of generative AI for its bioeconomy? And how advanced are their models compared to those used by the American firms? And how successful have Chinese firms been at integrating AI into their R&D process?

Dr. O'Toole. China is all over AI and bio, and they've created 17 AI bio hubs

specifically to facilitate the integration of these two emerging technologies.

They have ordered their large internet companies, who are very good at AI, to pay attention to health and start using their expertise to help biotech companies develop new drugs and so forth.

I would also say that it isn't just or even mostly privacy concerns that inhibit the aggregation of data, which we must do to get databases big enough to apply AI to. It's mostly proprietary concerns. It's "I don't want to share with you. I'm going to get rich on this myself."

The different healthcare systems think that they own their own clinical data and want to use it to good effect but also for profit, and they don't want to share it with other health systems.

We need to start modeling different ways of collecting and sharing data for different purposes. There's a number of models out there that wouldn't damage privacy. It wouldn't damage proprietary concerns. But we need government to sponsor them and figure out which works in what situation.

Ms. Sherrill. And, with our concerns about the theft of IP from the Chinese Communist Party and yet our desire to come together throughout the world to bring this information together to create better outcomes for humanity, how are we tackling those prompts? How much integration is there in the work we do with China and some of the research? And where are the areas where we find that it actually behooves us to sort of segregate that?

You know what; we'll go to Dr. Clancy. We haven't heard from you.

Mr. Clancy. All right.

No, I think, as Dr. Kelly was mentioning earlier, it's best to think where we need to compete versus where we can then strategically cooperate, right. And so I think there is

a whole range of things in the biosecurity space where, obviously, we don't want to share information with others. There's a whole set of other things, I'd say, in the biomedical space where there's a lot of opportunity to share, right, for the common good.

Now, I think certainly some trust has eroded with China over things like global pandemics, which is something that ordinarily you'd think everyone would want to collaborate around. So it sort of begs the question of what the opportunity really is in terms of any sort of cooperation with China in the biospace.

Ms. Sherrill. So, yeah, that's kind of depressing.

So do we have any sense of the way forward for any sort of work with China? Or is it just really a bridge too far at this point or in the moment?

Dr. <u>O'Toole.</u> No, I think there's a way forward. BGI was founded out of a desire some graduate students, Chinese graduate students in America took to participate in the human genome project. So I think collaborative endeavors like that are a possibility.

And I think the research community, which is very used to collaborating internationally might be a place to start. There is also evidence from COVID that even pharma can cooperate on sharing precompetitive data. So I think there are opportunities out there.

Chairman Gallagher. The gentlelady's time has expired.

Ms. Sherrill. Thank you. I yield back.

Chairman Gallagher. Ms. Hinson.

Ms. Hinson. Thank you, Mr. Chair. Good morning.

Agriculture is a massive economic driver in my home State of Iowa. So, when I hear about the little jabs from my colleague from the north about soybeans and corn, and we have hogs that outnumber people seven to one, and all of these things combined to be a great economic opportunity for us in Iowa when it comes to advancement in

America's bioeconomy.

There is just so much of an implication here for our national security interest when it comes to food security, and while we still are the leader here in the United States for agricultural-based bioeconomy, our stature there is being challenged, as we've already discussed today.

Chinese investors contributed over \$14.4 billion to their bioeconomy here. U.S. private sector only about 10.4 billion. So there is a significant gap there in investment.

And my first question is for you, Dr. O'Toole. We know that the U.S.-led human genome project was really instrumental in laying the groundwork for countless health innovations that we, as humans, used today. But, in your written testimony, you talk about that next frontier really being sequencing plants. Genetic sequencing right now only available for about 10 percent of cultivated food crop.

So what would you say are some of the implications for agricultural competitiveness with the PRC if they are the first to be able to sequence these things?

Dr. O'Toole. I think it would put U.S. agriculture in a very poor position as a competitor. I think we need a plant genome project for historical food crops, of which there are about 700. I think we'd learn a lot about which genes would increase yield. I think we'd learn a lot about how to make plants less thirsty.

I think we could help Jason succeed in making all plants capable of fixing nitrogen, which would mean we could do without fertilizers, which are synthesized using high pressure and high energy and contribute to greenhouse gases. I think we'd be able to grow crops places we cannot do so today, and I think it would be critical to get through climate change.

Ms. <u>Hinson.</u> Well, Norman Borlaug is from my district, so we take that very, very seriously in terms of food security and the research that goes along with it.

We actually hosted a roundtable discussion in my district with the chairman and ranking member to talk about the innovation that's happened in seed technology and why that is a vulnerability. And the Chinese want to steal it, right, because they know we are making those leaps in terms of drought-resistant, hardier, pest-resistant crops and that technology, and we've invested billions of dollars, obviously, as an industry.

So, Dr. Kelly, you touched on this actually a couple minutes ago, but in terms of the plant research and some of the regulatory barriers that exist there, we know it takes years and billions of dollars of investment.

So, given the importance here of the future of the global bioeconomy, can you elaborate a little bit on the regulatory barriers that companies like yours might face?

What can we do to get the government out of the way so that we can really super charge this?

Mr. <u>Kelly.</u> Yes. And I'll say one of the best days of my life was touring in Ankeny, Iowa. The genomics sequencing facility of Bayer-Monsanto is incredible technology, truly.

Yeah, I think one of the big challenges is -- so Dr. O'Toole mentioned a project that we're working on with Bayer to engineer microbes to produce fertilizer for crops.

Ms. <u>Hinson.</u> On the seeds, right?

Mr. Kelly. Yeah, put it on the seed.

So soybeans are magic. They have little microbes in their roots that self-fertilizer the crop. But, you know, corn, wheat, rice, they don't have this. And it's a, you know, \$70 billion ton. So we have to engineer those microbes.

Well, the old regulations around transferring microbes across State lines that are engineered, each microbe you send is a separate regulatory process. Well, that made sense back in the '80s when it was very difficult to make a change to a microbe. Now

we make tens or hundreds of thousands of designs weekly, right.

So you've been a real leader in helping to update that. I actually want to say thank you for that. And so I'm hopeful we'll see motion in that area.

Ms. <u>Hinson.</u> So we need to move forward with that and rapidly to keep up with you, right? That's what we've got to do.

Mr. Kelly. Yes, with U.S. companies.

Ms. <u>Hinson.</u> And then my last question, and I think anyone can answer this, but we're very concerned, obviously, about the exploitation of this data. And we know that they're not hypothetical what the PRC is doing with weaponizing these things.

So what would you say are the risks of them exploiting -- whether it's plant genomics or human genomics, what are the risks really with the PRC exploiting that and weaponizing it against the United States?

Mr. <u>Clancy</u>. I think, specific to plants, I'd say the CCP's biggest goal is to just satisfy their own food security needs more so than trying to weaponize it against the U.S. So I would be more concerned about them exploiting the data to create their own line of crops that are better, faster, cheaper than ours and out-competing us in the global agricultural market.

Ms. <u>Hinson.</u> Putting lowa farmers out of business. Not a good thing.

Thank you so much. I appreciate it.

I yield back.

Chairman <u>Gallagher.</u> We very much enjoyed that trip to lowa. The rumors are true. There's a lot of cornfields there, the very field of dreams in my memory. So thank you for your hospitality.

Mr. Torres.

Mr. Torres. Thank you, Mr. Chair.

Biotechnology is revolutionary. It has the potential to revolutionize the production of food and fuel, medicine, and materials. It has the potential to cure disease and combat climate change.

The bioeconomy could have the benefit of a new industrial revolution, a bio-industrial revolution without the cost of environmental degradation. Although biotechnology could be every bit as transformative as AI, it seems to command far less attention from both policymakers and the public.

And so, Dr. Kelly, why do you think that is? What is the public and what is Congress missing about the magnitude of the biotech moment?

Mr. <u>Kelly.</u> That's a great question. We take biology for granted is the challenge, right. So we're so familiar with it, right, that we don't think of it as technologists. And so I think what we're taking for granted is how quickly the technology is moving to improve it.

And I mentioned in my opening statement, sir, I actually think the application of AI models in biology will be more disruptive than they are in human language. And so, actually, it's turning out that AI is one of the things that's opening people's eyes to what's happening in biotechnology.

Mr. <u>Torres.</u> So, back in 2019, China arrested and imprisoned a scientist for genetically editing babies. How should the United States think about the bioethics of gene editing? And how do we prevent gene editing from becoming a 21st century version of eugenics?

It seems to me that we, as a society, should permit gene editing for the purpose of preventing disease but probably should prohibit gene editing for the purpose of changing traits and producing designer babies. Is that the right place to draw the line?

Dr. O'Toole, I don't know if you --

Dr. O'Toole. I think that's going to be a really hard line to draw, honestly. I think there are some bright lines we could draw today, but what I would recommend firstly is we have to get started. Every time we talk about biotechnology, people talk about the ethical and legal and social implications of it, and then we do nothing because it's hard.

I think convening a group of people, including so-called ordinary citizens, to think through specific cases of how to use biotechnology or how to not use biotechnology would be a good place to start.

We're going to have to have a very public and a long-term conversation about these technologies, and we're going to be much better off if we get started earlier.

Mr. <u>Torres.</u> So with biotechnology comes the need for biosecurity. There are pathogens that are highly transmissible but are not highly lethal. There are pathogens that are highly lethal but not highly transmissible. You know, one could imagine a world where the combination of AI and biotech enables anyone anywhere to manufacture the, quote, perfect pathogen that is both highly lethal and highly transmissible.

I mean, how do we prevent that nightmare from becoming a reality? And is that nightmare even preventable?

Dr. O'Toole. Might I answer that?

Mr. <u>Torres.</u> Oh, please.

Dr. O'Toole. I do not think that is a credible near-term nightmare, and I am getting increasingly worried that doomsday fears of AI and biotechnology is going to get in the way of productive use of those two very powerful technologies.

I think we have to be very careful when we speculate about the bad things that could happen. We certainly need biosecurity, as you say, but we have to focus on what we can do today and not think in terms of all possible speculative futures.

Mr. Torres. Absolutely.

Mr. <u>Kelly.</u> I'd maybe just add, yeah, the ChatGPT moment has not happened yet for AI models built on top of DNA. The biggest risk to the United States is that it doesn't happen here first. So I think that's number one. We've got to win that.

Mr. <u>Torres.</u> And having a project of our time, right?

Mr. <u>Kelly.</u> Yeah, but then I think we need to think of biosecurity like cybersecurity. The idea will be you will have distributive threat, and so you need persistent monitoring just like we monitor -- we monitor our phones more than we monitor ourselves for viruses.

Mr. <u>Torres.</u> Ms. O'Toole, you described China as a genuine challenge to U.S. preeminence. The United States developed three effective COVID vaccines at an astonishing speed. China, essentially, developed none.

How do you reconcile China's abject failure to develop an effective COVID vaccine with the notion of China as a challenge to U.S. pharmaceutical preeminence?

Dr. <u>O'Toole.</u> I'm really surprised they didn't develop their own vaccine, to tell you the truth. They used old methods. They didn't know how to use the mRNA techniques.

China is not anywhere near where U.S. pharma is today, but if you look at their progress over the last 10 years, it is really astounding. And they are saying, and they are moving in the direction of, you know, beating us. That's what they want to do, and they need to do it not just for their geopolitical ambitions. But they have the second biggest pharma market in the world. Their people are really sick. They really need medicines, and China needs to build its own pharmaceutical industry, and they're using all means at their disposal to do that and making very clear progress very fast. They're learning from us.

Chairman Gallagher. Ms. Steel.

Mrs. Steel. Thank you, Mr. Chairman.

Thank you to all our witnesses for sharing your testimony today.

And, Dr. Clancy, I agree with you that we must protect intellectual property, especially with critical, emerging technologies. Many of these technologies are being developed in my State of California.

As a member of the Ways and Means Committee, I have been fighting hard to allow U.S. companies to expense their R&D. I've also been leading efforts to ensure that our tax system will allow companies to keep and move IP back to the United States.

Dr. Clancy, you mentioned that you must reconsider our globalized trade relationship with supply chains. I agree. This committee's recent economic reporting included my bill, the Medical Supply Chain Resilience Act, which would allow the U.S. to secure our medical supply chains and reduce our reliance on the CCP by empowering the USTR to negotiate trade agreements for medical goods and services between the United States and the key allies.

Do you believe bipartisan approaches like this can help protect biomanufacturing and allow these industries to grow in the United States as we move to reshape our trade relationships?

Mr. <u>Clancy.</u> Most certainly. And I think one of the most important parts of that is working with our allies. If the U.S. tries to build a U.S. bioeconomy only to satisfy the U.S.'s needs, then it won't be able to scale or compete with what China is doing with their network through Belt and Road and other activities.

So I think whenever we're contemplating trying to build a competitive economic -- a durable competitive economic advantage over China, we need to not think of it just as the U.S. domestic production to satisfy the U.S. market. It has to be, how do

we take advantage of ally European production, and how do we become not only the domestic production for the U.S. but also for the rest of the world?

I think we see that in semiconductors. We see that certainly in biotech. And so it's a common formula that really we need to make sure that we're engaged with our allies and partners globally.

Mrs. <u>Steel.</u> I think I'm going to go just a little on the side, but, you know, those United States' protectionism right now, they try to work with our allies. But, at the same time, we are guarding our allies' work with others. Such as like rare mineral earth like from Malaysia, 95 percent goes to China. And then we are actually stopping. Those allies became like they are in so big debt. So we really have to work with allies, our most important part.

You know, right now the administration has been pushing for these allies that, you know, not to work with, you know, other countries but just work with us. But we are not really opening up ourselves in this country. That's really causing a lot of problem that I think.

So we really have to do little step by step working with these allies for any like, you know, CHIP industries or pharmaceutical industries and other industries. We really have to open ourselves up.

So, Dr. O'Toole, according to report prepared for the U.S. China Economic Security Review Commission, a handful of Chinese companies with critical laboratory improvement amendments, certifications enabling Chinese companies to direct access to American medical and health data.

That being the case, what questions can we ask CMS, as agency in charge of issuing CLIA certificates and enforcing regulatory compliance to ensure it does not green light bad actors to access sensitive data?

Dr. O'Toole. So this goes back to the need for much more robust biosecurity in guarding data. And certainly human data, in particular human clinical data, is of particular concern not just for privacy reasons, but it's very valuable for creating drugs that you could make a lot of money off of, among other things.

So I think we definitely need to help CMS and demand that CMS increase their -- it's a combination of bio and cybersecurity. We need a lot of digital data. We're going to definitely create these Big Data banks. And, alongside that, in parallel, we have to develop cybersecurity provisions for these data caches that we really didn't think of as national security assets until recently.

Mrs. <u>Steel.</u> My time is up. And I yield back.

Chairman Gallagher. Thank you.

Mr. Moolenaar.

Mr. Moolenaar. Thank you, Mr. Chairman.

And thank all of you for being here with us.

I wondered if you could comment on the agreement between the United States and the PRC on cooperation and science and technology, the STA. It's set to the expire at the end of this month. I'm concerned that the PRC has previously leveraged the STA to advance its military objectives and will continue to do so.

Do you believe the State Department should, once again, extend the STA?

Should there be negotiations and amendments to that? Or should we withdraw from that entirely?

Mr. <u>Clancy.</u> I guess I think everything that's happened over the last 5 years would make it very hard to move forward with it in its current format.

I also will observe that the U.S. has a range of S&T collaborations that the State

Department executes with governments all over the world, but they often don't get much

energy put behind them. The State Department doesn't own the S&T dollars. So they're signing the agreement, but then it's up to other agencies to actually follow through with some of the joint collaborative programs.

And so I think we've already seen many of the programs under that agreement atrophy over the last 5 years, as our position with China has changed. I think it certainly makes sense to re-examine, if we were to continue a treaty like that, how we would orient it.

Mr. Moolenaar. Thank you.

Dr. O'Toole, you're an expert in biosecurity. I wanted to focus on the HHS Biomedical Advance Research and Development Authority, BARDA, and the role that they may play in working with companies to onshore pharmaceutical manufacturing.

You had mentioned that the government needs to play a strategic role. I wondered if you could talk a little bit about any role you think BARDA might play with U.S. companies who are trying to onshore, you know, aspects of their business and how BARDA might play a role in that.

Dr. O'Toole. Yeah, I think BARDA could play a very important role. They are fluent in biotechnologies for biomedical purposes. They have a very good notion of what's key to our supply chain needs. They are well-known by the biotech community, and they have access to innovative companies in the U.S. ecosystem.

So they would have -- they would occupy a unique position in coordinating trying to onshore companies for specific purposes or in general.

Mr. Moolenaar. Okay. Thank you.

Dr. Clancy, your organization partners with different companies across America on research for our country. Do any of the companies ever enter into agreements with -- you know, licensing agreements or partnerships with CCP-affiliated companies?

Mr. <u>Clancy.</u> I'd say that would not be common among the partners that we're working with. But I think, in general, we see a lot of sort of predatory investments from the CCP in the U.S. innovation ecosystem.

So the Bayh-Dole Act, which was referenced earlier, is a critical piece of our tech transfer and IP innovation engine moving R&D from universities into startups and into companies. And, certainly, the PRC also recognizes that as a weakness. So they are able to target early-stage companies with investment and get access to the IP after it's sort of left the enclave of the university environment.

So I think it's something that we need to pay a lot of attention to and make sure that there is an awareness of the risks of that, the safeguards to prevent it, and sufficient capital available in the U.S. such that you don't have to look to the PRC for investment.

Mr. Moolenaar. Okay, thank you.

And, Dr. Kelly, I wondered if you could talk -- you know, it seems like there's an issue of trust involved when it comes to, you know, innovation and biotechnology. You know, I remembered that, you know, big debate on GMO. You know, this whole area and food.

How do you address some of the issues of trust and sort of a public relations issue for some of these technologies?

Mr. <u>Kelly.</u> Yeah, actually, I think that framing is quite perfect. There was a large debate back around GMO labeling in this country maybe now almost 10 years ago almost. At the time, actually, Ginkgo was a much smaller company. I wrote a New York Times editorial because we kind of had nothing to lose where I said, you know, "We're a GMO company. I think we should label GMOs."

Because the average scientist -- oh, by the way, I got hate mail from a Nobel laureate as soon as it hit the New York Times.

The scientific view is we just need to educate people more. If we just teach, you know, they will just learn that there has never been a negative case of anything from a GM crop. We've just got to educate them.

And what people are saying when they want something labeled is not that they need to be educated. They're saying, "I don't trust the people in charge of this technology to act in my interest." It's a trust problem. And what do -- "Hey, will you label this so I can make a decision on my own?" And you turn around and you say, "No." How does that do for trust, right?

And so what ended up happening is, after the labeling, nothing, you know, right.

The sales of these products has gone up. You go in the store now and almost everything says it's made as a project of genetic engineering, right.

And so that footing -- and I think the industry has learned this over time, that we need to build trust in the motives of the people deploying the technology is absolutely the most important thing. It's far more surprisingly important than educating.

And the last point I will make. People trust things that they can do themselves.

Like we teach literacy in this country, right. We teach you to read and write. We teach computer literacy so that you can not just use your phone but write software, participate.

We need to teach bio literacy. We need people to be able to participate.

So those folks, the brilliant people, you know, in farming communities and things like that can actually innovate and develop their own crops with genetic engineering.

They should be bio literate, and I think it's a big opportunity in this country.

Mr. Moolenaar. Okay. Thank all of you.

Chairman Gallagher. I believe the ranking member had a followup question.

Mr. Krishnamoorthi. Yes.

So, Dr. Kelly, you raised a fascinating idea of these plant structures, you know,

manufacturing various items of importance to us and performing other useful roles as well.

Okay. What is the research right now with regard to plant structures absorbing more carbon from the atmosphere than they are currently and the role of plants with regard to fighting climate change?

Can we engineer that at this point? And what's the science and status of research on that?

Mr. <u>Kelly.</u> That's a great question.

Yes, there's actually a company called Living Carbon. They are doing a genetic engineered poplar tree that grows faster exclusively for this purpose, right, to capture carbon more quickly.

I think, in the near years, if you think about taking carbon out of the atmosphere, one of the best things we have at our disposal is plants, truly. And so I do think that is a big opportunity. There is not much of a market, right. The market -- the problem is who is buying carbon, and that's a whole can of worms.

But I do think there is a real opportunity for leadership in setting the standards that would allow for not carbon trading like, "Oh, I'm moving this around. I didn't cut this forest down. But carbon removal." I think the government could lead in setting those standards and has started to recently.

Mr. <u>Krishnamoorthi.</u> But this is feasible? This is not science fiction?

Mr. <u>Kelly.</u> A hundred percent feasible. Yeah, it's going through regulatory approval right now, actually.

Mr. Krishnamoorthi. Wow. Okay. Well, we solved climate change.

Chairman <u>Gallagher.</u> Done. Another great success. What can't the select committee do at this point?

Mr. <u>Clancy.</u> There could be a market for poplar tree, like building materials. So that's the important part.

Chairman <u>Gallagher.</u> Just a quick -- the last question and my magic wand question. If I give you a magic wand and you could do one thing with it, what is that one thing?

I know that's unfair. We'll go reverse. Dr. Clancy first.

Mr. <u>Clancy.</u> I guess I would say go back to the biomanufacturing topic. I think we have significant capacity in the U.S. around ethanol production, and so we think that we have this sort of at-scale bio production capability, but it really is designed to satisfy a narrow set of use cases.

And, if we really want to broaden the set of use cases we're applying biotech to at scale, we need to fundamentally expand our biomanufacturing capacity.

Chairman Gallagher. Okay. Dr. O'Toole.

Dr. O'Toole. Data is the oil of the biotechnology industry, and we have to build big databases that are secure, that are accessible, and that include all kinds of data available to U.S. industry and researchers.

Chairman Gallagher. Thank you.

Dr. Kelly.

Mr. <u>Kelly.</u> We need to treat biosecurity as a national security and intelligence problem in addition to a public health problem and be monitoring globally for viruses genomically so that we don't get surprised again like we did a few years ago.

Chairman Gallagher. Thank you. I appreciate that.

Your written and spoken testimony was excellent, substantive. You've given us a lot to think about and a lot of ideas for future legislative action. So, sincerely, thank you for your time. Thank you for being flexible in light of the fact that we had to cancel the

field hearing. I know that's very annoying, but we're Congress. We cancel all the time, okay.

With that, questions for the record are due one week from today.

And, without objection, the committee hearing is adjourned.

[Whereupon, at 10:50 a.m., the committee was adjourned.]