STRENGTHENING BIOSAFETY AND BIOSECURITY STANDARDS: PROTECTING AGAINST FUTURE PANDEMICS

HEARING

BEFORE THE

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OF THE

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C O N T E N T S

WITNESSES

Written opening statements and the written statements of the witnesses are available on the U.S. House of Representatives Document Repository at: docs.house.gov.

INDEX OF DOCUMENTS

Documents are available at: docs.house.gov.

STRENGTHENING BIOSAFETY AND BIOSECURITY STANDARDS: PROTECTING AGAINST FUTURE PANDEMICS

Wednesday, October 18, 2023

HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC
Washington, D.C.

The Subcommittee met, pursuant to notice, at 9:05 a.m., in room 2154, Rayburn House Office Building, Hon. Brad Wenstrup (Chairman of the Subcommittee) presiding.

Present: Representatives Wenstrup, Comer, Malliotakis, Miller-Meeks, Lesko, Cloud, Joyce, Jackson, Ruiz, Dingell, Ross, and Tokuda.

Dr. WENSTRUP. Good morning. The Select Subcommittee on the Coronavirus Pandemic will come to order.

I want to welcome everyone.

I now recognize myself for the purpose of making an opening statement.

And without objection, the Chair may declare a recess at any time.

Today, the Select Subcommittee is holding a hearing to examine our country's biosafety and biosecurity standards. We are not just examining whether they are effective, but whether they are sufficient and whether they can protect us from biological threats, both domestically and abroad, and what actions should be taken if these standards are insufficient or outdated and need to be modernized. The hearing is timely and forward looking. On Monday, the public comment period ended on proposed changes to oversight policies of federally funded, dual-use research of concern and gain-of-function research of concern. I have been told no one knows these proposed changes better than our witness, Dr. Gerry Parker, and we are also honored to have Dr. Yassif here today for her input.

As we move forward, we want to make sure that our standards and capabilities can effectively respond and assess risks related to new research and biotechnologies, including those capable of unleashing new pandemics. In addition to pandemics, we must be prepared for a future public health attack, including the release of a biological weapon. This is necessary to protect American lives,

and because infectious diseases don't recognize borders, lives of those around the world are in jeopardy.

In the earliest stages of the pandemic, scientists and public health authorities raced to understand the novel coronavirus, to understand how it is spread, who is at risk, and, most importantly, its origins. Did it come from a natural spillover transferred from a bad to an intermediate source to human, or was it the result of a laboratory or research related accident? In other words, did it come from a lab, and while there is mounting evidence supporting lab leak theory, especially within certain agencies, we may never know with a 100-percent certainty the origins of COVID–19, especially when transparency is being denied.

However, we do know some things for certain. In early 2018, before COVID–19 emerged, the U.S. State Department had serious biosafety concerns about the Wuhan Institute of Virology. Specifically, they warned that there was a serious shortage of appropriately trained technicians and investigators needed to safely operate the high-contaminant laboratory, concerns that continued through 2019 and into 2020. They also warned that the WIV, Wuhan Institute of Virology, was conducting coronavirus research under inadequate biosafety levels, using reverse genetic engineering techniques to hide their work and creating chimeric coronaviruses to test infectivity to humans. Worse yet, we now know, the American taxpayer was likely paying for it, some of it, and we know, based on emails uncovered by this Subcommittee, that Dr. Fauci himself knew there was gain-of-function research happening in Wuhan, before the pandemic broke out.

We know this wouldn't be the first time that a lab leak occurred. We know that smallpox escaped a laboratory in the U.K. in 1978. We know that the former Soviet Union accidentally released anthrax from the military research facility. We know that two separate lab-related incidents led to the release of SARS from the Chinese Center for Disease Control and Prevention in 2004. Finally, we know that the United States isn't immune to leaks. There have been lab-related accidents involving H1N1, H5N1, smallpox, tuberculosis, and Zika, some as recently as 2016.

These lab leaks can occur for a multitude of reasons. They can occur because of mishandled biological materials, escaped aerosols, laboratory design flaws, or human error, which can be as simple as failing to correctly wear protective equipment or accidentally puncturing a glove. Such an accident could easily have occurred in Fresno County, California, where we know now a Chinese company operated an illegal laboratory where it conducted dangerous experiments involving COVID–19 and other viruses. Inside this lab, authorities found hundreds of mice that had been genetically modified to catch and carry the COVID–19 virus.

Troubling, as we already know, these lab-related incidents, if not contained, can cause predictable, but disastrous consequences. Desiring more laboratory safety and more oversight isn't to chill the scientific community from engaging in research, but to ensure we are taking every precaution necessary to protect the public from escaped pathogens of which we cannot control nor fully understand the consequences until it is too late. It is critically important that these issues be addressed proactively. Scientists that are con-

ducting their work safely and with the proper precautions should not have any concerns about more oversight on bad labs. This oversight should be welcomed. One bad lab gives a good lab a bad name.

In recent years, there have been significant advancements in biotechnology or dual-use technology that makes it far easier to develop and genetically engineer dangerous viruses, advancements that could make a genetically altered virus indistinguishable from a naturally occurring virus. This is one reason increased oversight into the experiments being conducted and the viral holding of labs is vital to preventing another pandemic. There has also been a proliferation of high contaminant labs throughout the world. Left unchecked, this makes it conceivable, if not probable, that another pandemic could occur in the future because of a lab related incident. This is a matter of public health and a matter of national security that requires interagency coordination and international cooperation.

We are holding this hearing today to look at our current standards and circumstances to help prepare for a future pandemic or maybe prevent one, to determine what went wrong and to recommend how to do it better in the future. That is our goal. I look forward to a strong on topic discussion today, and I would now like to recognize Ranking Member Ruiz for the purpose of making an opening statement.

Dr. RUIZ. Thank you, Mr. Chairman. Today's hearing is on a topic of critical importance to our national security and our public health. The fact is we don't know when the next pandemic will strike, and in order for us to truly be prepared, we must devote the time and resources now to strengthening our biosafety and biosecurity so that we can ensure the health security of Americans all across the country. While the path to a bio secure future lies ahead, I hope that during today's hearing, we can identify workable, forward-looking solutions that the minority has long called for to not only bolster pandemic preparedness, but also foster innovation and ensure our country's global competitiveness. At the center of these solutions must be a whole-of-government approach that prioritizes the American people's health and safety.

In the wake of the COVID–19 pandemic, our Nation has taken important steps forward in advancing this approach with targeted investments in pandemic prevention, refined policies to promote biological risk management, and informed recommendations to improve overall biosafety and biosecurity. In fact, last year's Consolidated Appropriations Act included robust funding for the Biomedical Advanced Research and Development Authority to develop countermeasures in response to public health emergencies and biological threats. At the behest of congressional Democrats, the Consolidated Appropriations Act also worked to address public health threats in biomedical research and improve oversight of research involving select agents.

Compounding this work are the National Science Advisory Board for Biosecurity's recommendations to strengthen existing oversight of research that raises biosafety and biosecurity concerns. Released this March after Secretary Becerra tasked the NSABB to evaluate our Nation's biosecurity and biosafety frameworks, these rec-

ommendations demonstrate a sound start for enhanced biosafety and biosecurity standards here in the United States. These are all promising steps forward, and I look forward to discussing them in more detail here today.

However, it is important to note that our work to enhance biosafety and biosecurity cannot and should not end here. Risks to our national security do not end within our borders, and with every step we take to bolster lab safety and security at home, we must do so with an eye toward strengthening biosafety and biosecurity on a global scale as well. That is why I was glad to see President Biden's executive order focused on growing our own, take action to promote biosafety best practices abroad as well. Right now, a patchwork of lab safety standards and guidance may guide nations in their pursuit to bolster their own biosafety and biosecurity. However, we as an international community are without a consistent set of standards that we can all work together toward to reduce the threat of biological incidents.

There is no simple solution to how we can achieve this goal, and every day, emerging technologies further complicate our work. However, if we remain united around our common goal of protecting the health and safety of our communities, fortifying our biodefense, and enhancing pandemic preparedness, I know that we can get there. We have the distinct opportunity right now to make a positive change with constructive policy that improves people's lives and prevents a future disaster. I hope that today's discussion moves us closer to that vision that bolsters biosafety, enhances biosecurity, and, in turn, fortifies our national health security for generations to come. Thank you, Mr. Chairman. I yield back.

Dr. WENSTRUP. Thank you. Our witnesses today are Dr. Gerry Parker. Dr. Parker is the associate dean for Global One Health at the School of Veterinary Medicine & Biomedical Sciences, and director of Pandemic Preparedness and Biosecurity Policy Program at the Scowcroft Institute of International Affairs within the Bush School of Government and Public Service at Texas A&M University. It is quite a business card you have got.

Dr. Parker's service includes more than 26 years on active duty leading military medical research and development programs and organizations. He is a former commander and deputy commander, United States Army Medical Research Institute of Infectious Diseases. After his military career, Dr. Parker held senior executive-level positions at the Department of Homeland Security, Department of Health and Human Services, and the Department of Defense. This includes serving as the Principal Deputy Assistant Secretary for Preparedness and Response at HHS, and Deputy Assistant Secretary of Defense for Chemical and Biological Defense at DOD.

Dr. Parker is a member of several advisory boards, including the Bipartisan Commission for Biodefense. Dr. Parker also temporarily served as senior advisor to the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services from August 2020 to February 2021, during the COVID–19 response.

Dr. Jaime Yassif: Dr. Yassif currently serves as NTI Vice President for Global Biological Policy and Programs, where she oversees

the organization's work to reduce catastrophic biological risks, strengthen biosecurity and pandemic preparedness, and drive progress in advancing global health security. Dr. Yassif previously served as a program officer at Open Philanthropy where she led the biosecurity and pandemic preparedness initiative. Dr. Yassif has also served as a science and technology policy adviser at the U.S. Department of Defense and worked on the global health security agenda at the U.S. Department of Health and Human Services. Dr. Yassif holds a biophysics Ph.D. from UC Berkeley, an M.A. in science and security from the King's College London War Studies Department, and a B.A. in Biology from Swarthmore College.

I want to thank you both for being here today. Obviously, a lot of great expertise with us.

Pursuant to Committee on Oversight and Accountability Rule 9(g), the witnesses will please stand and raise their right hands.

Do you solemnly swear or affirm that the testimony that you are about to give is the truth, the whole truth and nothing but the truth, so help you God?

[A chorus of ayes.]

Dr. WENSTRUP. Thank you. Let the record show that the witnesses answered in the affirmative. The Select Subcommittee certainly appreciates you being here today, and we look forward to your testimony.

Let me remind the witnesses that we have read your written statement, and it will appear in full in the hearing record. Please limit your oral statement to 5 minutes. As a reminder, please press the button on the microphone in front of you so that it is on and Members can hear you. When you begin to speak, the light in front of you will turn green. After 4 minutes the light will turn yellow. When the red light comes on, your 5 minutes has expired, and we would ask you to please wrap up.

And I now recognize Dr. Parker to give an opening statement.

STATEMENT OF GERALD W. PARKER, JR., DVM, PHD
ASSOCIATE DEAN FOR GLOBAL ONE HEALTH
COLLEGE OF VETERINARY MEDICINE &
BIOMEDICAL SCIENCES
TEXAS A&M UNIVERSITY

Dr. PARKER. Chair Wenstrup, Ranking Member Ruiz, and Members of the Select Subcommittee, thank you for the opportunity to testify as you consider biosafety and biosecurity threats to our Nation and the world. My career has spanned from the bench to executive leadership positions in biodefense, health security, and pandemic preparedness, including as a commander of a high-containment lab at Fort Detrick. The views I offer today are my own and not representative of past or current organizational affiliations, employers, or advisory boards.

A high-containment lab consisting of Biosafety Levels 3 and 4 requires the highest level of containment to protect workers and public safety. Within these labs, highly trained workers and scientists are conducting infectious disease research and working with hazardous pathogens that are essential for biodefense, national security, and public health preparedness. These labs require a highly skilled work force and detailed attention to operations and

sustainment. Still, lab accidents happen, and they happen more often than you think. Most are quickly mitigated and contained, but some are more serious.

I am more concerned about the readily available, dual-use technologies and the global expansion of high-containment labs. Lab accidents and misuse are more likely to occur where there is a lack of institutional norms. This is why it is imperative for a modernized, harmonized domestic and international framework to ensure a skilled work force and institutional norms needed to operate these facilities. Because the United States is viewed as a model for biosafety and biosecurity, it will be necessary to make reforms at home to make the biggest difference worldwide. Congress is an essential partner in this mission, which will require funding oversight and, in some cases, legislative authorities.

In my written testimony, I outline the history of U.S. biosafety and biosecurity, which describes how our fragmented oversight framework came to be. Today, my intent is to help the Committee as you look for a path forward. I will discuss five recommendations for your consideration.

First, the single most important thing Congress and the Federal agencies can do is to harmonize biosafety and biosecurity standards and norms domestically and internationally. Congress should direct the Administration to commission a top-to-bottom holistic review of the entire biorisk management framework. The goal will be to harmonize oversight while minimizing unnecessary and unproductive burdens on the research institutions. This is long overdue and is needed to address growing and unproductive compliance challenges caused simply by the fragmentation of the current system. For example, there is no single authority for biosafety or biosecurity oversight at the Federal level, and this actually is increasing risk.

Second, the vast majority of infectious disease research is safe when done in compliance with the existing guidelines, but the exceedingly small subset of especially dangerous research has the potential to trigger an unnatural epidemic or a pandemic. We need to incentivize safer alternatives to reduce or eliminate the need to generate especially dangerous pathogens by the few scientists and institutions engaged in this kind of basic research. Congress should act to ensure that the Administration adopts, implements, and they revise policy to responsibly govern especially dangerous enhanced pathogen research. Third, Congress should authorize and fund an independent biosafety and biosecurity oversight authority, analogous to the FAA's oversight over air transportation. It is imperative that this oversight authority be nimble and able to keep up with the rapidly evolving life science advances.

Fourth, due to the potential for unnatural epidemics or pandemics resulting from accidents or misuse, particularly in countries that lacks strong institutional values and norms, we all should be concerned about the expansion of high-containment labs and readily available to use technologies worldwide. This requires a recommitment to international diplomacy. Congress should direct the State Department to elevate international biosafety and biosecurity harmonization as a diplomatic priority. All member-states must assume their responsibility and accountability for effective oversight. Fifth, as the GAO has repeatedly pointed out, there is

a need for the Administration to develop a national strategy for high-containment labs so we can optimize use, establish a better system for sharing lessons learned, best practices, and increase collaboration.

In conclusion, the U.S. Government must recommit to working with international partners. The goal is to harmonize international standards and norms. This is essential for worker safety and public safety. The public deserves transparency to have confidence that these important systems work. I look forward to answering your questions. Thank you.

Dr. WENSTRUP. I now recognize Dr. Yassif to give an opening statement, please.

STATEMENT OF JAIME YASSIF, PHD
VICE PRESIDENT
GLOBAL BIOLOGICAL POLICY AND PROGRAMS
NUCLEAR THREAT INITIATIVE

Dr. YASSIF. Chairman Wenstrup, Ranking Member Ruiz, and other Members of the Subcommittee, thank you for the opportunity to join today's hearing to share my perspective on strengthening biosafety and biosecurity standards. I serve as Vice President for Global Biological Policy and Programs at NTI, which is a nonprofit, nonpartisan global security organization focused on reducing nuclear and biological threats imperiling humanity.

We are in the midst of a 21st century bioscience and biotechnology revolution. New technologies create tremendous opportunities to benefit society, but these same advances also pose significant risks, namely that the tools of modern bioscience and biotechnology could be deliberately exploited by malicious actors or accidentally misused, which could lead to the next global biological catastrophe.

The world has seen the devastating effects of the COVID pandemic, and the next pandemic could be as damaging or potentially much worse. As discussions continue to swirl about COVID origins, the evidence as to whether it emerged naturally or resulted from an accident is still inconclusive. We cannot say with confidence what the origins of COVID are, but the fact that it is even plausible that so much disruption could have been caused by a possible lab accident is a big blinking red light. It signals the urgent need to strengthen biosafety and biosecurity. To protect the U.S. population here at home and save lives globally, it is in our interest to take an international approach to bolstering biosafety and biosecurity. That is because infectious diseases, no matter their origin, do not respect borders.

Unfortunately, biosafety and biosecurity are very weak globally. For example, according to the Global Health Security Index, only 6 percent of countries have national-level oversight measures for dual-use bioscience research. Furthermore, there is currently no international entity that has its primary mission dedicated to reducing emerging biological risks associated with rapid technology advances.

To address these gaps, I am very pleased that the Biden Administration has taken a number of steps to bolster biosafety and biosecurity, both domestically and internationally. Just last week, the

Administration released updated guidance for DNA synthesis screening, which provides helpful improvements over the original 2010 guidance. Another promising development is a 2023 report from the National Science Advisory Board for Biosecurity. Huge congratulations are due to my colleague, Dr. Gerry Parker, and his colleagues for producing such a forward-leaning set of recommendations for bolstering U.S. Government oversight of dual-use bioscience research. Now, it will fall to the Administration and Congress to find practical, effective ways to implement these recommendations.

Additionally, the White House's 2022 National Biodefense Strategy notes the importance of raising the global bar for biosafety and biosecurity norms and practices. The plan is focused on preventing global biological catastrophe through such efforts and is crucial. The executive order on the American bioeconomy sets up a requirement to launch a biosafety and biosecurity innovation initiative, and it calls for investments in applied biosafety research and biosecurity innovation to reduce biological risks throughout the biotech R&D and biomanufacturing lifecycles.

And yet, even with all the efforts that I have described, most of the work lies ahead. The U.S. Government can take several concrete actions to advance critical biosafety and biosecurity goals going forward: One, make dedicated financial investments to bolstering biosafety and biosecurity, specifically by dedicating 2 to 4 percent of investments in pandemic preparedness research and development to support innovation in biosafety and biosecurity; two, establish an office within the U.S. Government to lead and serve as an innovation hub to build biosecurity and biosafety into life science research, biotechnology, biomanufacturing, and awards; three, establish a legal requirement to screen DNA synthesis orders coupled with incentives to make implementation achievable. The recent guidance from the Biden Administration on DNA synthesis screening is a good first step, but establishing this as a legal requirement will also be important; four, implement key elements of U.S. biosecurity strategy documents. The U.S. Government has set a number of ambitious goals for itself, now is the time to implement these plans; five, and finally, provide political and diplomatic support for the International Biosecurity and Biosafety Initiative for Science or IBBIS. NTI has been working to establish this new independent international organization, which we are planning to launch soon. IBBIS' mission will be to work collaboratively with global partners to strengthen biosecurity norms and develop practical innovative tools to uphold them.

Bolstering biosafety and biosecurity is extremely important work, and it is urgent. If the U.S. Government can achieve the biosafety and biosecurity goals it has set for itself and work with partners in industry and civil society to further advance these goals, it will be a big win for reducing biological risks domestically and around the world. If not, the risk of facing another pandemic on the scale of COVID–19 or larger will grow with even higher stakes as biological threats increase over time.

Chairman Wenstrup, Ranking Member Ruiz, and other Members of the Subcommittee, thank you for inviting me to testify today. I look forward to answering your questions.

Dr. WENSTRUP. Well, thank you both very much. I now recognize myself for questions, and I agree with both of you. To start off, it is important that our focus be forward looking, and as you know, many of our current biosafety and biosecurity policies and regulations, may have been enacted in response to specific events. For instance, the Federal Select Agent Program was effectively created in response to improper orders of plague strains by an unauthorized individual and was subsequently bolstered in response to the 2001 anthrax letter attacks.

I heard both of you saying some of the things Congress can do, and it is appreciated. You talked about investments and investments into what—you have got specifics; I appreciate that as well—and the role of oversight, and role of State Department internationally should be well defined. I think that is something that we can try to do and recommend.

Internationally, I do take concern when I look at an organization like the World Health Organization, which I would like to see it be more independent, aside from the United Nations, which is full of political realm, but may be separate from that and not be under the influence of its members that have a political agenda, and I don't think I need to go into much detail on that. The question is, if we can establish an international organization, what do you recommend as far as how we enforce biosafety and biosecurity? And I am going to ask both of you that question, your opinions on that, as you both have dealt internationally many times.

Dr. PARKER. Yes, I think the question of enforcement is really the hard one, and I guess that is why my recommendation, first and foremost, is focused on recommitment to diplomacy. And there are some actually good efforts already underway and the State Department working with the G7 countries and USDA is part of that, but it is a small effort to try to just encourage collaboration on harmonization of high-containment standards and norms and work with infectious agents, but it just needs to be elevated as a secretarial priority and resourced appropriately.

But I think for those diplomatic negotiations and collaborations, I think some additional ideas will come out of those conversations and through diplomacy about how to better strengthen the World Health Organization so it can be less dependent upon regional offices than member-states within the regional office because the director general does need some support. But there are other ideas, too, that could be considered that I think would come out of those diplomatic conversations.

But first and foremost, member-states, all of us, United States, all member-states of the WHO or the United Nations, we all have a responsibility to make sure that we have the appropriate guidelines, laws, regulations in our own countries. And so how do we encourage all member-states to make sure that they do what they need to do and assume their responsibility and accountability to make sure their institutions have the right norms, ethical values, they are operating high-containment labs, they have to have the appropriate skilled work force, funding, and so forth to do so, so the international community can have better confidence in these labs.

Dr. WENSTRUP. Thank you. Dr. Yassif?

Dr. YASSIF. Thank you. I think the question of how to strengthen global approaches to biosafety and biosecurity through stronger international institutions is really important, and I agree with Gerry that the enforcement part is going to be really challenging. And before we can even envision that possible future, we need to do a lot of groundwork to lay a foundation, have a shared understanding globally of what the rules of the road are, and what are the best practices for biosafety and biosecurity that we would like to see that can meaningfully reduce risks. And I think that is going to take a lot of work. One of the efforts that we are really focused on through IBBIS is to help to build that foundation. We envision that IBBIS will serve as a resource to help countries as well as members in the private sector, in industry and academia and civil society to sort of share and develop best practices, so we can raise the bar both domestically and internationally.

I would say that nations have an enlightened self-interest in advancing biosecurity and biosafety. No one wants to see a lab leak or some sort of catastrophic event from within their borders, and I think that we can enhance that through transparency and accountability of implementing best practices in biosafety and biosecurity. That is why we track those kinds of provisions through our global health security index that I mentioned during my testimony. And I think nations should be accountable to each other for upholding biosafety and biosecurity standards, and by tracking, that we can support that.

And the last thing I will say is, WHO is one place that can carry out this work, the BWC is another piece of it. And they both are international institutions that have credibility internationally, and it will be important to have them at the table to continue to advance this work. But I do think that other complementary institutions, like IBBIS, can support that work, and take on some of the tasks of innovation, and taking risk and developing best practices that may be harder for some of the U.N.-based institutions to do. And I think together, we can really drive progress.

Dr. WENSTRUP. Yes. I mean, I am hoping that maybe here in the United States, we can set the gold standard with high level of expectations and be the example for others. And it just seems to me that if a certain nation is not cooperating, then we point that out to the world, and they no longer are part of the international organization. Just a thought going forward.

I do have a question because we talked a lot about dual-use research and into dual-use, and I am just curious. What positives have come out of dual-use research in the last decade or so, and maybe more specifically, to gain-of-function or creation of chimeras, what positives have come out of that type of research?

Dr. PARKER. Well, by definition, let me just take the dual-use part of that question first. So dual-use, I would say by far that most dual-use is good and bad. And so most of our life science, scientific advances in biotechnology and biomedicine, by far the vast majority of those advancing technologies are improving our way of life, our health, our well-being, our economy, our agriculture. So these are important technologies that we need to continue to innovate and foster. But there is another side to that dual use and that is the bad, and so how do we mitigate the misuse of the potential

of these advancing technologies and somebody who wants to do harm?

Dr. WENSTRUP. But, again, I guess what I am asking specifically, if you look at what has taken place is, one, obviously potential for bioweapon, right? And let's not kid ourselves on that. So what are the positives? If you are advancing research that can lead to a bioweapon, are we advancing research that also can lead to something good? What is that good?

Dr. PARKER. Well, I don't think the intent of most of the life sciences are to develop and advancing technology that is going to be misused. I think our issue is how do we control and mitigate the misuse of it. And almost anything that we have throughout humankind, somebody has figured out how to misuse technology that we develop. And I think you really kind of get into the enhanced dual use, especially dangerous gain-of-function research is what you are really getting at, and what benefits have come out of that research.

And I think we have to be realistic about those benefits, and I think we have to be realistic about what those benefits are. And I can see where there is possibly a need for basic science, knowledge advancement with some of this research. I am not going to negate that that could be useful, but I think we have to be very careful and not exaggerating the benefits of that type of research. And so I am not going to prejudge that somebody may come with a good idea that there may be a need to engage in a dual use, especially dangerous, enhanced pathogen research that might advance our basic science knowledge if it is good for public health too, but that is why we need to have additional oversight of that. And actually, we need to be incentivizing safer alternatives because many believe that safer alternatives can be used for answering the basic science questions for most of these proposed research proposals.

So we need to really incentivize safer alternatives. And if one is justified, I mean, really justified, and the risks are mitigated, and there is verification that there is no safer alternatives, and there is public transparency, then it just needs to be reviewed, and there is nothing wrong with having a review. And so I think a lot of folks don't like the extra review.

Dr. WENSTRUP. Thank you. Dr. Yassif, do you have anything to add to that?

Dr. YASSIF. Yes, I largely agree with my colleague. I think our colleagues in the molecular biology and virology community would share that, for example, gain-of-function research and their view is important for advancing public health and development of medical countermeasures. But I agree that we do have to, on the balance, consider that with downside risks of accidental or deliberate misuse. That is a really serious set of considerations we need to balance in figuring out how to do that as we improve our oversight practices to figure out what kind of research should go forward and what kind of research perhaps should not because the cost-benefit calculation doesn't make sense.

I think that there is more work to be done to figure out how to thread the needle there, and it is a really hard question. So some of the work that the Administration is doing to revise oversight and to revise review processes for funding decisions is going to

have to figure out how to do this well, and I think that is where we really need to focus our efforts at the moment.

Dr. WENSTRUP. Thank you. I appreciate the feedback from both of you. Dr. Ruiz?

Dr. RUIZ. Thank you. Bolstering international biosafety is at the heart of our efforts to prevent future pandemics. And currently, the existing framework for ensuring that research across the globe occurs safely relies on a patchwork of non-enforceable standards and guidance, including the World Health Organization's laboratory biosafety manual. Beyond these international guidance documents, it is incumbent upon each nation to enact its own policies and standards to promote biosafety. Dr. Yassif, what shortcomings exist within this current international biosafety framework?

Dr. YASSIF. Thank you. Yes, the international biosafety framework is primarily, as you have noted, in the form of guidelines and not regulations, and so it is not enforceable. Another challenge is that it is very high level and not necessarily as specific as some of the U.S. biosafety guidelines in particular. I think that there is more work that can be done both in the United States to improve our own biosafety guidelines as well as to improve biosafety guidelines and practices and regulations internationally so that we can really more effectively safeguard this research.

Dr. RUIZ. OK. In the wake of the COVID–19 pandemic, renewed attention has been paid to ensuring that research to advance our understanding of dangerous pathogens is done safely across the globe, including by tightening standards for lab operations. Dr. Yassif, what measures have the United States and other nations taken to bolster lab safety standards, and how can these policies serve as a blueprint for the types of biosafety reforms we would like to see implemented at the international level?

Dr. YASSIF. Sure. So we have a patchwork of biosafety guidelines and regulations here in the United States, includes the recombinant DNA guidelines for recombinant molecular genetics work in labs that work with NIH funding. We have got the Federal Select Agent Program, and then we have got the biosafety in microbiological and biomedical laboratories guidelines, and so this is a patchwork. It is not comprehensive, but it is a lot better than some of the other systems that we see overseas that are considerably weaker.

Some of these features are not perfect, but they could be emulated internationally. So, for example, our system here in United States of biosafety oversight committee review within universities is a really valuable tool that we could replicate overseas. Some of the regulations we have in the United States, like the Federal Select Agent Program, are not perfect and could be made more comprehensive, but it could be the beginning of a blueprint for efforts overseas.

I think one of the challenges, though, is that the sort of personnel training and the resources and the lab infrastructure internationally is not necessarily to the same standard that we have in the U.S. So we would have to make an investment in terms of capacity building, and partnership to really help raise the bar internationally, the level we would like to see. And so we really need to put our money where our mouth is if we really want to drive

progress there, and I think we are also hoping that IBBIS can help with some of this work.

Dr. RUIZ. OK. And so what precautions can be taken to ensure that bolstering lab safety is appropriately balanced with continued scientific advancement, including in the realm of pandemic preparedness? And I will ask you that question too, Dr. Parker. Dr. Yassif?

Dr. YASSIF. Sure. I think we can certainly continue with our work domestically and internationally to invest in pandemic preparedness research and development. That is critical. But as we see the global spread of research into these areas and the global spread of high-containment labs, we have to ensure that it is done in a safe and secure environment. We have to make investments to make sure that the labs, the high-containment labs where this work is being conducted, have appropriate biosafety provisions in place and biosecurity provisions in place. As I have noted in my written and oral testimony, biosafety and biosecurity are very weak globally, so we have a lot of work to do if we are really going to safeguard this work and make sure it is done safely and responsibly.

Dr. RUIZ. Yes. Dr. Parker?

Dr. PARKER. Sure. I think the most important thing to do, I think, internationally is how do we make sure and support institutional norms, even a broader institution, that may host a high-containment lab within their university. It is the institutional norms. I think the guidance and regulations will come. We got to do that, but if we don't have strong institutional norms that understand the need for having a skilled work force that need the funding and resources for operations and maintenance, and sustaining these laboratories are extremely complex. And I am a former commander of a high-containment lab, and I know how complex they are and the detailed attention that you have to do there. And so not all countries share our view of what that means to have strong institutional norms, and that would extend and the need for resources——

Dr. RUIZ. Would a international school of lab safety and biosecurity practices in the United States help with that?

Dr. PARKER. I am sorry. I didn't——

Dr. RUIZ. An international school of biosafety in the U.S. with certain institutions that brings in personnel from other labs to come and get trained here on biosafety, would that be helpful?

Dr. PARKER. That would be helpful, but I also think about it as trainings is necessary, but not sufficient. So educational is important, too, and it is, like, ongoing.

Dr. RUIZ. You also need the equipment.

Dr. PARKER. There is an organization called ABSA International. That is the Professional Society for Biosafety, Scientists and Professionals. And ABSA actually had a great idea several years ago, third-party accreditation for high-containment labs. And that would be analogous——

Dr. RUIZ. What role does gain-of-function research play in pandemic preparedness research, if anything?

Dr. PARKER. Yes. First let's make sure that we are using the right terminology because "gain of function" is a very, very confusing term.

Dr. RUIZ. Yes. Let's clarify.

Dr. PARKER. And, well, it is not codified.

Dr. RUIZ. I said let's clarify.

Dr. PARKER. Oh, clarify it. OK. Clarify it. OK. So gain of function is a common experimental procedure used in biomedical research and biotechnology, so it is fairly common, but there are guidelines. The NIH guidelines are appropriate, but there is then in the vast majority of it, as long as it is done under the appropriate guidelines, can be done safely with appropriate institutional oversight, too, at the laboratory level. But there is this exceedingly small—I think it is exceedingly small—area of gain-of-function research of concern. I actually call it especially dangerous enhanced pathogen research that we have to have more oversight of.

But the first, I would say, the normal research procedures using the relatively safe gain of function, that is just part of our biomedical research enterprise, and it has been important for our biodefense and pandemic preparedness. I don't believe, my opinion, that the especially dangerous enhanced pathogen research has contributed significantly to pandemic preparedness. And remember, I was a previous executive leader at ASPR, and some of those studies came out did not affect any of our vaccine development decisions.

Dr. RUIZ. Got it. Thank you. So beyond building on the guidance and standards promulgated by the WHO and other international institutions, we must also dedicate time and energy to cultivating a shared culture of collaboration on best practices for safe research. As a leader in the global health community, the United States has a key role to play here. So Dr. Yassif, what steps can be taken to promote a culture of shared norms that prioritizes research and lab safety? And also, what role does Congress have in paving the way for stronger international biosafety cultures?

Dr. YASSIF. Thank you. So, I mean, I think we are all in agreement that having stronger norms and best practices for biosafety and biosecurity is critical, and we have to figure out how to do it well. And we see a gap in the international system in terms of the structures in place that aren't really prioritizing this as their top mission, and that is why we are working with international partners to establish IBBIS. We really believe that IBBIS can help contribute to this. We think that IBBIS will play a role in serving as a resource to institutions and countries around the world that are looking to get assistance with having more effective biosecurity provisions and biosafety as well in places where, working alongside organizations like ABSA, so I think that that is critical.

What the U.S. Government can do to support that work is to diplomatically and politically support IBBIS so that we can build more political support in countries around the world to really have IBBIS have a prominent position. I do think that IBBIS, even though it is going to be a non-governmental organization, can help advance U.S. goals on biosafety and biosecurity and raise the bar globally. And so for that reason, I think it is important.

The role of Congress, in particular, I think is funding. There are a lot of initiatives that have been set forth in the various strategy documents that I outlined in my testimony that, I think, are really promising initiatives for supporting research and innovation in biosecurity and biosafety. There are certain things that we know that we need to do, but with rapid advances in science and technology, we have to continue to innovate and stay ahead of the curve. The emerging risks are constantly moving the goalposts, so we need to invest in innovation in biosecurity and biosafety. This will help domestically but also internationally.

Dr. RUIZ. Thank you. And so now that we have turned the page on the darkest days of the pandemic, we have an obligation to enact forward-looking policy solutions to reduce the likelihood of future deadly novel airborne viruses. And I look forward to building on the progress that the Biden Administration and congressional Democrats have made, and do so in a strong bipartisan way to bolster biosafety and prevent future pandemics. And I yield back.

Dr. WENSTRUP. I now recognize Ms. Malliotakis from New York for 5 minutes of question.

Ms. MALLIOTAKIS. Thank you very much, and I appreciate this discussion. I think it is really important to safeguard our future.

The U.S. biosecurity rules don't apply overseas, as has been mentioned here, yet Federal money went to the Wuhan Institute of Virology. And we know now that they had inadequate training. They had subpar conditions. The FBI and Department of Energy testimony here in this Committee as well point to the fact that COVID came from the lab. So my question is really regarding we have no centralized oversight or standards. There is not enough risk assessment. There needs to be a set of standards that are meant to receive U.S. tax dollars, in my opinion. We saw what happened with money going either directly to WIV or through EcoHealth Alliance. So should we stop Federal grants from being sent to foreign subrecipients like it did through EcoHealth, particularly if they don't have biosecurity rules that are comparable to ours?

Dr. PARKER. Is that for me?

Ms. MALLIOTAKIS. Whoever would like to answer.

Dr. PARKER. First, I would just point out, the National Science Advisory Board report of March 2023 actually has a recommendation regarding international funding and the need—essentially, I will summarize it—if international-funded research should comply with the same standards that we have in the United States. That essentially summarizes one of the recommendations in that report.

Ms. MALLIOTAKIS. What is the best way to determine that if they are, if they aren't?

Dr. PARKER. Well, you need to have oversight. I can just give an example. I don't know if this is an example, but what I used to do when I was the commander of a high-containment lab. This is 20 years ago, and we did not fund international research, but we funded domestic research. Most of our research was done intramurally, but we had some extramural contracts. But we would always have a site visit from one of our own biosafety officers, government biosafety officer, to provide a detailed inspection and then further onsite visits later on, but that is just what I did 20 years ago when I was commander at USAMRIID.

Ms. MALLIOTAKIS. And, Doctor, I would like to give you an opportunity to also respond.

Dr. YASSIF. Thank you. I mean, I think the main thing I will say is I do think we should be conducting more effective biosafety and biosecurity pre-funding review to make sure that any grantee, domestically or internationally, is in compliance with our standards. I think that makes sense.

Ms. MALLIOTAKIS. Should we just not allow foreign grant subrecipients? If one entity here in the United States gets a grant, is it appropriate for them to then move that money over to a facility overseas?

Dr. PARKER. Well, subcontracting is pretty normal in Federal acquisitions, whether it be life science research or other lines of research. So subcontracting is fairly common and often needed to get the right expertise to the right location you need to do whatever work may be done. But we need to make sure that whatever Federal acquisition regulation requirements flow down to the subcontractor and the subcontractor is complying with those requirements.

Ms. MALLIOTAKIS. OK. Alright. Thank you very much for your time.

Chairman Comer [presiding]. The Chair now recognizes Mrs. Dingell from Michigan for 5 minutes.

Mrs. DINGELL. Thank you, Mr. Chair. Thank you to the witnesses for what I believe is excellent testimony and balanced, and gives us guidance on how to work together in a very bipartisan way or nonpartisan way, a way that protects research globally to help people. I am going to build on the discussion we are just having that we continually hear, have heard over this hearing, but in other places, is the importance of enhanced biosafety and biosecurity and what they are to the future of pandemic preparedness.

Now, I do want to say to my colleague, it has never been where the original COVID came from. It has not been established that it leaked from the Wuhan laboratory. I think everybody's got their own theories, but I don't want the facts that aren't true to be on the record either, but it is very clear that international labs are not meeting the kind of standards that they should be meeting. And as our witness said, that there is a scientific report out in March that recommends that international standards be the same as our standards.

But it is a fact that bears repeating, we will not be prepared to face the next pandemic if we don't start doing the work now to fortify our biodefense with meaningful biosafety and biosecurity reforms. And to do so effectively, we must take a lessons-learned approach to pandemic preparedness and prevention. So I would like to urge my colleagues on all sides that we must meet the urgency of this moment in the policy issues we are attacking. I will give you an example of something we should be doing. Attempts to reauthorize critical legislation, such as the Pandemic and All-Hazards Preparedness Act, in other words known as PAHPA, currently is falling short of applying the lessons we have learned from the COVID–19 pandemic to improve national health security and biodefense capabilities.

On top of that, we are letting the legislation expire at the end of September, and I wish Republicans unfortunately, no, I don't mean that. That didn't come out right. Republicans have control right now, so we got to work together. I didn't mean that, Ronny, to come out that way, but we are not making the investments needed to actually advance biosafety and biosecurity, two causes that we talked about today and I know that my colleagues care about. In fact, the current Republican PAHPA proposal would reduce funding for state and local public health emergency preparedness grants down to pre-pandemic levels. That is a $50 million cut from current appropriation levels, which would ultimately hamstring the ability of state, local, and territorial public health departments to respond to public health threats, including biological, chemical, nuclear, and radiological events.

So, Dr. Yassif, let me ask you this. What role do state and local public health responses to public health threats, like the ones I just mentioned, play in biosafety and biosecurity at a national level?

Dr. YASSIF. Thank you. If we are really going to have an effective layer defense against pandemic risks to the American public and to the global population, we need to both have stronger biosafety and biosecurity to prevent those events from happening in the first place, but we also have to have effective capabilities to detect and respond quickly. And in addition to Federal capabilities, state and local public health capabilities are critical, and we do have to resource them at the level that is necessary, so they can perform their role.

The COVID pandemic showed that we were woefully underprepared and unprepared to respond, and I am hoping that we can, as you say, learn the lesson from that and build the capacity that we need because when the next pandemic inevitably arises, we need to be ready.

Mrs. DINGELL. I am going to submit questions for the record, too, but yes or no, would you say we are prepared for the next one?

Dr. YASSIF. No.

Mrs. DINGELL. Thank you. Dr. Parker, what policies should Congress consider to fortify our biodefense capabilities from the local all the way to the Federal level?

Dr. PARKER. I think the more that we can emphasize the need to provide the right tools to our local and state colleagues, whether that is public health, emergency management, the private sector, NGO's, all disasters, including pandemics hit multifocal areas around the country at different times and different severity, so the more that we can do to encourage and have our policies emphasize the support, that will support our state and local.

Just as an example, PAHPA, and I am really glad you brought up PAHPA reauthorization. To my view, that is essential, and you might see in my testimony of last June, for that hearing last June, I did talk about the need for supporting. The tools that ASPR needs are really the tools that our state and local community needs. The tools you may be thinking about for CDC are really the tools that need to be at the state and local communities, again, whether that is public health or emergency management. So just that philosophy on supporting the local and state authorities and

citizens is really would be very helpful as we think about policies emanating from Washington, DC.

Mrs. DINGELL. Thank you. I have more questions for the record. I am assuming you would say we are not prepared now, too.

Dr. PARKER. We are not prepared.

Mrs. DINGELL. And I really do want to work with my Republican colleagues because I think this is something we really can agree on, and if we came out of this Committee with just that, it would really be good for our country. Thank you. I yield back, Mr. Chair.

Chairman COMER.[Presiding.] The Chair now recognizes Dr. Miller-Meeks from Iowa for 5 minutes.

Dr. MILLER-MEEKS. Thank you, Chair Comer. And I also thank Chair of this Select Subcommittee, Brad Wenstrup, for holding this hearing, and our witnesses for appearing here. I also want to say thank you very much for your support for local public health and your comments on local public health.

As the former director of the Iowa Department of Public Health, I was one of the very few people in my first year in Congress during the pandemic in 2021 that talked about the COVID funding that was being put across. Only one-half of 1 percent of all of that $1.9 trillion went to noncompetitive grants to local public health. And as we know, the CDC went from the CDC to the CDC&P, the Centers for Disease Control to the Centers for Disease Control & Prevention, and more and more of the funding has gone into other health entities rather than to infectious diseases. And so as this relates to both biodefense and our preparation for the next pandemic, I think it is important.

One of the things I have also talked about repetitively and why I was pleased that this Select Subcommittee was continued into this Congress was one of the rationale in my mind for knowing the origins of COVID–19, and continuing to investigate that and determine that. And I think it is unlikely now, with evidence having been destroyed, we will. But the reason for that is, internationally, all communities, all countries have vested interest in bio lab safety. We know that there was bio lab 4 research being done in a biosafety lab, too, so we have a vested interest in putting out those standards for biosafety labs. No. 2, disclosure. We have requirements for disclosure. They were not followed, and so there is an immediate disclosure, 24 hours, if you think that there is a virus or bacteria that could lead to a pandemic. So we have a vested interest in making sure that that is followed by all countries, and our international community needs to be part of that.

And then three, the ethics of what research is being done, whether or not gain-of-function research should be done. We had a temporary prohibition on funding that in the United States, and then that was waived. But too often I found in medicine that the research goes forward, and then after it is unleashed and there is a problem, then we start looking at the ethics of that. So the ethics of that research should be done concurrently and in parallel, in tandem. So thank you very much for being here and thank you for your testimony.

I am going to skip over some of the things that I was going to talk about because of the research component of this and just going to say Allison Young, author of Pandora's Gamble, highlights many

lab biosafety failures that have largely gone unnoticed, including one in my home state of Iowa. She describes the threat to suspend a USDA National Animal Disease Center's permit to work with dangerous pathogens in Ames, Iowa. And I visited these facilities and they are truly great facilities, but it had a failure to abide by regulations that are meant to prevent releases from wastewater systems.

According to information from a FOIA request, the USDA National Animal Disease Center had three releases of wastewater that were potentially contaminated with select agent pathogens. The Select Agent Pathogen Program by mistake released an unredacted report of the three lab incidents which occurred on June 5, 2019, to April 16, 2020 and May 3, 2020. None of these incidents were reported to the Iowa Department of Natural Resources, even though the incidents were considered as posing a risk to agriculture and public health.

So, Dr. Parker, the former CDC director, Tom Frieden, expressed concerns that the Select Agent Program did not complete any unannounced inspections to see how labs truly operated. Furthermore, the U.S. doesn't have comprehensive regulations, as you both have indicated, on biosafety at laboratories experimenting with infectious organisms, to ensure a safe operation in the United States. You state in your written testimony that you support an independent biorisk management Federal authority and claim that such authority could consolidate the patchwork of current biosafety and biosecurity policies and regulations. I am just going to ask you to further clarify that and whether ASPR would be a good place for that location, given the CDC's failure in this pandemic to take research and then translate that into action or policies or messaging.

Dr. PARKER. Sure. Thank you for the question, and I do believe that it is time to consider an independent biosafety oversight someplace in the Federal Government to consolidate the current patchwork of fragmented guidance and policies. And I am not saying that each one is a bad policy or hasn't been effective, but it is the overall kind of patchwork. It is confusing for research institutions about who is their oversight authority, and for what pathogen, for what funding stream and so forth. So we need some kind of consolidation and also to look for how we can get efficiencies, close any gaps, and really make it easier for the research institutions because it is pretty confusing, and that confusion increases our biosecurity risks.

As far as the organizational home for something like that, I am not sure if ASPR is the right home. You know, remember, I was a Principal Deputy Assistant Secretary at ASPR. You know, actually when the Federal Select Agent Program was first established, I think that that decision had a lot of debate, and it was understood there is really no good place. At least in USDA, it is in APHIS, and APHIS is a regulatory agency, and I think that is something to think about is what is the right regulatory agency that has that culture. But you have to do it in a way that is going to still not stifle scientific innovation, and that is the challenge. How do you improve efficiencies in our current fragmented system and put it in the right regulatory structure without stifling innovation? And that is hard.

Dr. MILLER-MEEKS. Thank you very much. I am sorry, I went over. I yield back.

Chairman COMER. The Chair now recognizes Ms. Ross from North Carolina for 5 minutes.

Ms. ROSS. Thank you very much, and I am pleased that my Republican colleagues are heeding our calls to consider forward-looking policy solutions with today's hearing, and I am also very pleased that there is some consensus about what we should be doing going forward.

In the wake of the COVID–19 pandemic, Democrats have been at the forefront of Congress' work to fortify our Nation's biosafety, biosecurity, and biodefense. Last year, congressional Democrats passed the Consolidated Appropriations Act of 2023, which includes $950 million in funding for the Biomedical Advanced Research and Development Authority. BARDA leads our Nation's development of medical countermeasures in response to public health emergencies, including chemical, biological, radiological, and nuclear incidents and attacks, as well as outbreaks of emerging infectious diseases. Dr. Yassif, how do comprehensive investments in BARDA safeguard America's public health and security?

Ms. YASSIF. Thank you. Comprehensive investments in BARDA and other parts of the U.S. Government that are investing in medical countermeasure development are critical for protecting the American public and our friends and allies overseas. I said in my testimony that we are experiencing a 21st century biotechnology and bioscience revolution, and it is hard to imagine a place where that could be more important and useful than in development of vaccines.

We have seen with the response to COVID. Fortunately, we were able to develop a medical countermeasure much faster than at least I expected us to be able to, but I think in the future, to be prepared for future pandemics and to be prepared for the unexpected, we need to be much faster. We need to be able to prepare novel medical countermeasures in response to novel unanticipated pathogens. For example, we are looking at the 100-day mission. We want to go from zero to 60 in 100 days. That would make us here in the United States and internationally much safer. Those kinds of investments are critical.

Ms. ROSS. Wonderful. And BARDA also plays a key role in the United States global bio preparedness, as you alluded to, and our partnerships, including on international initiatives to reduce the risk of pandemic influenza through vaccine development, as we discussed, and to advance our arsenal of medical countermeasures against Ebola and other known diseases. What role does BARDA play in fortifying our leadership on pandemic preparedness within the international community? And that is for both of you, but Dr. Yassif first.

Dr. YASSIF. Sure. I will be really quick. I think, in addition to all the benefits that I just described, I think us making investments in our domestic capabilities and talent pool ensures that we have a seat at the table internationally as we are working with our allies and partners to develop a stronger medical countermeasure infrastructure and better capacity generally to detect and respond to pandemics.

Ms. ROSS. Dr. Parker, do you have anything to add to that?

Dr. PARKER. Sure. Yes, BARDA is absolutely essential for our biodefense pandemic preparedness, and, in fact, the Operation Warp Speed and the ability to develop vaccines in 11 months was predicated on the investments in infectious disease research and advanced development from vaccines and technologies and also a commitment to regulatory science, and so we have to continue that, absolutely. But BARDA also plays an international role of actually with a broader ASPR organization and the Office of Global Affairs within HHS. There has been longstanding international collaboration in pandemic preparedness, biodefense, health security, and BARDA is a big player in that within the HHS family and in the interagency family, and it has got to continue.

Ms. ROSS. Thank you so much. Just as a reminder because the last session of Congress seems so long ago, alongside the investments in BARDA and increased protection for BioShield, Democrats in the Consolidated Appropriations Act also directed the Secretary of Health and Human Services to develop strategies to prevent, mitigate, and address threats in biomedical research, including those stemming from undue foreign influence. It strengthened training for personnel handling biological agents and toxins, and it bolstered Federal reporting requirements for the release, loss, or theft of biological agents and toxins. We have much more to do. It appears we will be able to do that in a bipartisan way, but it is nice to remember that some action has been taken. And thank you, Mr. Chair, I yield back.

Chairman COMER. The gentlelady yields back. The Chair now recognizes Mr. Cloud from Texas for 5 minutes.

Mr. CLOUD. Thank you, Chairman. The Federal Government isn't hesitant to insert itself into the daily lives of Americans, whether it is banning gas stoves, restricting their ability to choose their own doctor, pressuring social media companies to censor their constitutionally protected speech. All have been backed by the full force of law. OSHA can slap a small business with thousands of dollars in fines for a misplaced extension cord or for failing to have their first aid kit approved by a physician. We have seen intelligence agencies ban physicians from and medical experts from social media companies. The Department of Labor can impose civil and criminal penalties on mine operators for such transgressions as failing to ensure that miners ride hoist buckets in an orderly manner.

But somehow the government zeal to protect us from the smallest threats to our health and safety standards seems to stop at the doors of these agencies responsible for preventing the hazardous biological research from ongoing, and it is terribly wrong and potentially resulting in global catastrophe. Agencies like the NIH don't have a problem imposing burdensome regulations on everyday Americans, but they fail to monitor the high-containment laboratories that could potentially produce another pandemic.

It is a Federal crime to ride a bicycle, believe it or not, without a horn on NIH grounds, but funneling NIH money to shady foreign labs lacks even the requirements of basic effective reporting. So it is clearly not a lack of conviction from their own authority or the righteousness in their safety standards that the Federal Government has refrained from imposing enforceable standards on dan-

gerous biological research. We have seen far too often in the past few years the current system is designed to allow unelected bureaucrats and self-proclaimed experts shield their conduct from accountability and the taxpayers who fund them.

The world has already suffered large-scale consequences of one biosecurity failure fueled by government corruption. We should be careful to ensure there isn't a second one. We work on funding. Our main job here in Congress is funding, and so the grant process is tremendously opaque, and you couple that with the investigations that happen. And for example, OSHA can show up at a workplace any point, anytime and go through, but our inspections generally will be scheduled way far in advance. The labs cancel them, and so there is not the kind of oversight that we would expect to see from that kind of thing. We can continue, as Congress, to ask the executive branch to continue to put a heavy regulatory burden on it. The other thing that we can do, since our job is the purse string, is to be careful on how we are spending the money.

And so I would ask you, what role we should play in the funding aspect of it? What restrictions? What ideas you would have for us placing restrictions on the government funding going out to make sure that it is not being misused? And one other thought that has been presented, because this happens quite often up here, is that the taxpayers will fund the government that creates a problem, and then the solution is more money toward that problem. I have real concerns when it comes to these international labs getting taxpayer funded money when it comes to that, but if you could help us out with what kind of restrictions we could be looking at, and also how do we provide transparency to the grant writing process?

Dr. PARKER. Well, I think everything that I included in my written testimony about, first, just the need to reexamine top to bottom our biosafety/biosecurity framework and look for efficiencies and then close gaps is absolutely essential and to improving our biosafety and biosecurity. And I would point you again to a comment I made earlier about one of the NSABB recommendations when it came to funding work internationally and any international funded research should comply with the same standards, laws, guidelines that we have in the United States, and that can be done.

We have to be careful. We talk about restricting funding for biomedical research. We are in a global competition for the bioeconomy. Now is not the time to restrict funding for biomedical research when we are in a global competition, and that we need advancements in our healthcare system. And our investments in our healthcare system are underpinned by advancing technology, so we have to be very careful there.

Mr. CLOUD. To that point, that is kind of one of my major concerns that you are touching on is we have U.S. taxpayer dollars funding the research in other countries who are competing against us for preeminence in this, and why we would put that on the American taxpayer is kind of beyond me. It seems like that should be extremely limited, what we are doing with international. I mean, again, we don't have a smoking gun when it comes to the labs, but it is not a stretch to say that U.S. taxpayer dollars helped fund the pandemic with what we do know. We do know that evi-

dence was destroyed. We don't have the smoking gun, but we know that they potentially destroyed the smoking gun.

So why would we put the burden on taxpayer dollars? I am not saying cancel all funding. I am saying we should put restrictions on the funding that is going out. What should those restrictions be? And then when it comes to international, I mean, that seems to me to be very limited. Certainly we shouldn't be investing in labs that are competing against us.

Dr. PARKER. Well, I think the vast majority of our biomedical research dollars go domestically, but international collaboration is also important. And that is also how we are going to be able to enhance norms and enhance behaviors internationally, but how we fund that research is important. I agree with you there. Those are the how and the what research we fund internationally will be an important thing to consider. And I think when we do do international research, especially with hazardous pathogens, we have to make sure that the oversight complies with the same U.S. standards we have here and probably needs onsite inspections and evaluation of that to just improve that oversight. I will end with that.

Mr. CLOUD. Thank you.

Chairman COMER. The gentleman's time has expired. We now recognize Dr. Joyce from Pennsylvania for 5 minutes.

Dr. JOYCE. Thank you Chairman Comer and Ranking Member Ruiz, and thank you for the witnesses for being with us today. We appreciate both your time and your testimony.

This Select Subcommittee has the responsibility of investigating the origins of the coronavirus, and analyzing and scrutinizing the failed policies that arose. And further, we have been charged with holding those public health officials accountable for enforcing those harmful COVID-era policies. More important, what the American people want and what the American people deserve is to know what this body intends to do and how this body intends to safeguard our Nation and protect our citizens from the next public health emergency.

Clearly, the coronavirus pandemic is a direct result of failed biosecurity and failed biosafety regulations. In fact, this Committee held a hearing in July that examined the controversy of proximal origins piece that confused the picture by not allowing the necessary information to come forth by pointing to a lab leak. Even the ODNI report that was released said, "The Department of Energy and the Federal Bureau of Investigation assess that a laboratory associated incident was the most likely cause of the first human infection with SARS-CoV–2." Now more than ever, it is crucial that we strengthen and we secure our regulatory framework as it relates to both biosafety and biosecurity. Only then can we ensure better preparedness and execute a more effective response ahead of that next public health emergency.

Dr. Parker, how important is oversight biosafety and security in foreign countries? Let's carve out because we have been talking about subcontractors. Let's carve out and look at those subcontractors where the initial funding comes from here, comes from United States. Do you feel that U.S. funds should continue to labs that are subcontracted that don't have the same safety standards that we have in the United States?

Dr. PARKER. Well, I think, as I said, any of our work with infectious diseases internationally ought to be compliant with the same guidelines standards that we have in the United States.

Dr. JOYCE. Thank you. I think that is an important message for all of us to take home. Dr. Parker, your extensive background in this area, are you aware that some countries have that inherent lack of biosafety and bioethics that are so important? Should certain countries be excluded?

Dr. PARKER. I think really the issue, and I think I have said it already before, is any country that lacks the institutional norms, the ethical foundation, and the commitment to making sure that these laboratories can operate safely and securely and they are sustained, they have the skilled work force, those are all essential, no matter what country.

Dr. JOYCE. Are there any countries that have come to top of mind that you think should be excluded that currently might function as subcontractors?

Dr. PARKER. Well, I think any country that lacks those institutional norms, and that would be up to the funding agency to verify that they have the right institutional norms.

Dr. JOYCE. So before that funding comes from an NIH grant, which this body approves, those countries should be thoroughly evaluated before any subcontractors are used. Is that your point?

Dr. PARKER. Yes.

Dr. JOYCE. Thank you. Dr. Yassif, you made an incredibly interesting point. In your testimony, you said that the question of a lab leak in China allows a big blinking red light to be present. A big blinking red light to me means stop. How do we stop?

Dr. YASSIF. Thank you for the question. My choice of the big blinking red light is a warning light, not a stoplight, and I think it is——

Dr. JOYCE. Well, I think then we need that clarification because I think most of us as drivers see a big blinking red light to mean stop, and we have seen those concerns. I think that those concerns from this Select Subcommittee continue to exist, and I think in that preparedness, which we are trying to formulate how to protect and be prepared for that next public health emergency, I actually think you were spot on with that assessment. I think a big blinking red light, we have to stop, we have to pause, and we have to make sure that the biosecurity is in place. It is an important role for our charge to make sure that we protect, and each of us representing 750,000 constituents, each of us take that responsibility, incredibly important. I thank both of you for being here today, and, Mr. Chairman, I yield.

Chairman COMER. The gentleman yields back. I will now recognize myself for 5 minutes.

In March 2020, five scientists published Proximal Origin of SARS-CoV–2, which effectively shut down the lab leak theory. However, the authors relied more on political implication than actual science. In uncovered emails, Dr. Rambaut, one of the authors of Proximal Origin, stated that their conclusion downplaying the lab leak theory would limit the chances of new biosafety discussions. Dr. Parker, in your expert opinion, is opposition to increased

biosafety or biosecurity regulations common amongst the scientific community?

Dr. PARKER. I don't think it is common. I think virologists, scientists, everybody working in the infectious disease research community and including hazardous pathogens, they want to do this work safely and securely, those that I know in the United States. I don't think they are trying to avoid oversight, but in their defense, the oversight system is becoming very fragmented, it is confusing.

Chairman COMER. Are you aware of the Proximal Origin paper?

Dr. PARKER. I am.

Chairman COMER. Do you think it is problematic that the author's conclusion may have been, in part, based on the fact that they wanted to avoid more strict biosafety guidelines?

Dr. PARKER. Those emails are black and white, and I will let the Committee interpret those emails.

Chairman COMER. Dr. Yassif, do you agree that constructing scientific conclusions to avoid increased biosafety regulations is inappropriate?

Dr. YASSIF. Conceptually, hypothetically, yes, such an action would be inappropriate, but I am not making a judgment about whether that happened in this instance.

Chairman COMER. The authors were aware that the Wuhan Institute of Virology was conducting risky gain-of-function research with coronaviruses under questionable biosafety conditions, including in BSL–2 laboratories. They were also aware that this research could be done without leaving a trace. Troublingly, the U.S. Government also knew about these concerns. In January 2018, the State Department warned that the Wuhan Lab had serious biosafety issues, specifically that there were serious shortages of appropriately trained technicians and investigators necessary to operate its laboratory. They also noted the research of coronavirus is aiming to make them more transmissible. So, Dr. Parker, to safely conduct this kind of research, is it important to have trained technicians and investigators?

Dr. PARKER. It is important to have a skilled work force, have high-containment labs that are supported by appropriate operations and maintenance, and they have the right biosafety officers, they have the right building engineers for any work with hazardous pathogens.

Chairman COMER. I agree. Would you fund a lab that has a shortage of properly trained technicians and investigators and was operating at a low biosafety level?

Dr. PARKER. No.

Chairman COMER. Dr. Yassif, what about you? Is it important to have properly trained staff while operating a high-containment laboratory?

Dr. YASSIF. Yes.

Chairman COMER. Dr. Parker, do you know if the State Department told the rest of the government about these warnings?

Dr. PARKER. I am sorry. I didn't quite hear.

Chairman COMER. Do you know if the State Department told the rest of the government about these warnings?

Dr. PARKER. I am not aware. The only thing I am aware of is what has been in the media.

Chairman COMER. Do you think that there is a lack of coordination between government agencies regarding biosafety and biosecurity threats?

Dr. PARKER. I think there is a lack of coordination overall in a lot of our pandemic preparedness and biodefense efforts just at large, and that is why leadership is so important. And that is why actually in my written testimony, I do talk about the need for a single focal point somewhere in the Federal Government that can be the focal point for biosafety and biosecurity.

Chairman COMER. So it is clear that China has actively sought to conceal and suppress information related to COVID–19. Dr. Parker, how can we hold foreign laboratories accountable and ensure they are complying with international biosafety standards?

Dr. PARKER. That is one of the challenges we talked about earlier that enforcement is extremely difficult. At the moment, our best tool is to recommit to international diplomacy, work with our strategic international countries, and begin a dialog to make sure that all member-states and the WHO, United Nations family are taking on their responsibilities and accountability for managing and overseeing this important research. Every country has got to assume that responsibility and accountability for that.

Chairman COMER. OK. Thank very much. Dr. Yassif, would you like to answer that in my remaining few seconds?

Dr. YASSIF. No, I have nothing to add. Thank you, sir.

Chairman COMER. Do you all have any other questions? OK. The Chair recognizes the Ranking Member.

Mr. GARCIA. Thank you very much, Mr. Chairman. I am grateful to have a chance to have a substantive discussion today about how we can help the American public and certainly keep us safe from future pandemics.

Earlier, the Chairman was able to clarify at the start of the hearing that we don't know for sure how the COVID–19 pandemic started, and I think it is really important to re-emphasize that point. None of our intelligence agencies have been able to make a determination with complete certainty about the lab leak theory or the theory that COVID was a natural spillover from animals, and so that was good to hear from the Chairman earlier. We should be clear about that and stay within the boundaries of what the evidence tells us.

We know this has not always been the case. In the past, on this Subcommittee or within the Congress, we have had Members in the past publicly stating their beliefs of how the pandemic started without actually any conclusive evidence, which I think is a huge mistake. Now, Dr. Yassif, can you clarify for us just once again, just to end this part of the debate, can any Member of Congress say with absolute certainty that they know how the pandemic was caused, whether a lab leak versus natural transmission, given the available evidence?

Dr. YASSIF. No.

Mr. GARCIA. Thank you. So if any of my colleagues were to say that they know for certain without question that COVID started as

a lab leak or as a bioweapon, that is not consistent with the assessment of our intelligence agencies. Is that correct?

Dr. YASSIF. Yes.

Mr. GARCIA. And that would be speculation on their part?

Dr. YASSIF. I think that there are different people in the community that have looked at this set of evidence and have come to different conclusions with varying degrees of confidence, and so it is a very challenging topic. And different people can look at the same set of evidence and come to different conclusions.

Mr. GARCIA. Thank you. So to say that there is just one certain known or outcome would be incorrect? I mean, obviously, folks——

Dr. YASSIF. That is my view.

Mr. GARCIA. Yes. No, I appreciate that. Thank you. That is my view as well, so I want to thank you for clarifying again.

Now, and this was just also referenced by the Chair, so I want to just be clear. I know that in July, we had an entire hearing where my colleagues had accused Dr. Fauci, that Dr. Fauci persuaded the authors of a key research paper to change their conclusions and cover up evidence that the pandemic had emerged from a lab. They were obviously very serious accusations, and we called several of the paper's authors to Washington to answer questions about Dr. Fauci's involvement. And both in this room under oath and in the documents and written testimony provided to the Committee, the people directly involved all told us that the allegation was simply incorrect. So I just want to repeat that because hopefully now we can put to rest any allegations that we know for certain how the pandemic started at this point.

Just also a quick question for both of our witnesses. Why is it important to strengthen biosafety and biosecurity standards universally, irrespective of where potential pandemic-causing pathogen may emerge?

Dr. YASSIF. I will start. So I think, as I noted in my testimony, we are really only as strong as our weakest link. So a pandemic that is caused, either through a deliberate bioweapons attack or through an accidental release, could emerge anywhere in the world, and infectious diseases, no matter what their origin, don't respect borders. And as we saw with the COVID pandemic, an outbreak can happen in one part of the world, if it is not quickly, rapidly contained, can quickly spread globally, causing vast human casualties, political disruption, and extensive economic damage. And so if we really want to prevent those kinds of events in the future, it is critical to invest in biosafety and biosecurity as a preventative measure, as part of a broader layer defense that is complementary to broader biodefense efforts to detect and rapidly respond, those are all critical.

Mr. GRACIA. Thank you.

Dr. PARKER. And I agree with my colleague a hundred percent. And really, we know enough already that we must take action at the animal-human-environmental interface nexus, whether that is in nature, whether that is in a laboratory. Inaction really is not an option. Thank you.

Mr. GARCIA. Thank you. I just want to add I am also just grateful that the Biden Administration has taken important steps to prioritize biosafety and biosecurity, promote strong biosafety stand-

ards, and make sound investments in biorisk management, disease surveillance, and safe and responsible research. As you both mentioned, there is still a lot of work to be done, which you have mentioned throughout this hearing today. Both of you also specifically mentioned the need for additional funding and investment in these efforts. Democrats in Congress and President Biden agree with you.

Now, earlier this year, the President requested Congress appropriate $6.1 billion for the CDC to enhance domestic and global disease surveillance, biosafety and biosecurity efforts. I know that if we had a Speaker of the House, we could actually vote to advance some of that funding, and hopefully we will get there soon. Democrats in Congress are ready to get to work, but we are, of course, here listening to this important work, not able to move forward because the House is still in a standstill. So hopefully that will end very shortly, and with that Mr. Chairman, I yield back.

Chairman COMER. The gentleman yields back. That concludes our questions. We will now move to closing statement, if the Ranking Member wants to do one. The Ranking Member declines.

I will have a brief closing statement if that is all right. I want to thank the witnesses for being here today.

The purpose of today's hearing was to examine the effectiveness of our current biosecurity and biosafety policies, and discuss ways that we can improve them going forward. Again, the witness testimony today is very appreciated by this Committee. As we move forward, it is vital to properly investigate the gaps in oversight that currently exist for biosafety and biosecurity standards and draw attention to the lack of transparency surrounding lab incidents and safety inspections due to inadequate reporting requirements. Through this investigation, we will determine what policies currently exist, whether those policies are sufficient, how those policies are applied internationally and how to move forward.

The COVID–19 pandemic has highlighted the need to better understand what safeguards are needed to protect ourselves and prevent a future pandemic. While the U.S. has one of the strongest regulatory oversight mechanisms to enforce biosecurity, it only applies to research in this country or research funded by U.S. taxpayer money. As we heard today, if research is conducted outside the U.S., including in China, there is not only limited oversight, but an increased chance that lab leaks and accidents could occur. This current posture is not only wildly unsafe, but it significantly impairs our ability to respond to emerging threats. And as we discussed today, we must be able to effectively respond to and assess risk so that we can be prepared for a future pandemic, including the potential deliberate release of a biological weapon.

As we learned during COVID–19, infectious diseases don't recognize borders, and once there is a containment issue, it may only be a matter of time before it gets to United States. We know that there were sufficient concerns regarding biosecurity and biosafety at the Wuhan Institute of Virology, but nothing was done, and we know that the American taxpayer was likely paying for some of this dangerous research. We cannot afford to have another COVID–19 pandemic. We cannot allow dangerous research to continue

without proper safeguards in place because the next time might be worse.

The Select Subcommittee has been focused on gathering evidence in order to conduct fact-based investigations because Americans deserve answers, and we have been gathering data, recommendations, and information so that we can predict, prepare, protect, and prevent a future public health disaster. This hearing was an essential step in this process because safeguards are lacking. Biosecurity and biosafety standards must be strengthened. We have a chance right now to prepare better to ensure that high risk laboratories are safe as possible, and we need to take advantage of this opportunity. So thank you for being here today, and we look forward to continuing to work with the witnesses on this issue as this Select Subcommittee continues its work.

With that and without objection, all Members will have 5 legislative days within which to submit materials and to submit additional written questions for the witnesses, which will be forwarded to the witnesses for their response.

Chairman COMER. If there is no further business, without objection, the Select Subcommittee stands adjourned.

[Whereupon, at 10:38 a.m., the subcommittee was adjourned.]