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BIOSAFETY AND RISKY RESEARCH: EXAMINING IF SCIENCE IS OUTPACING POLICY AND SAFETY

THURSDAY, APRIL 27, 2023

House of Representatives,

Subcommittee on Oversight and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 2:30 p.m. in Room 2322, Rayburn House Office Building, Hon. Morgan Griffith [chairman of the subcommittee] presiding.

Present: Representatives Griffith, Burgess, Guthrie, Duncan, Palmer, Lesko, Cammack, Rodgers (ex officio); Castor,

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Tonko, Ruiz, and Pallone (ex officio).

Staff Present: Sean Brebbia, Chief Counsel, Oversight and Investigations; Lauren Eriksen, Clerk, Oversight and Investigations; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; John Strom, Counsel, Oversight and Investigations; Austin Flack, Minority Junior Professional Staff Member; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Liz Johns, Minority GAO Detailee; Will McAuliffe, Minority Chief Counsel, Oversight and Investigations; Christina Parisi, Minority Professional Staff Member; Greg Pugh, Minority Staff Assistant; Harry Samuels, Minority Oversight Counsel; and Caroline Wood, Minority Research Analyst.

*Mr. Griffith. The Subcommittee on Oversight and Investigations will now come to order, and the chair recognizes himself for a five-minute opening statement.

Good afternoon. Welcome to today's hearing. The subcommittee previously held a hearing on how quickly -- how to quickly identify the root cause of a disease outbreak. Today's hearing will examine biosafety practices at high-containment laboratories handling dangerous pathogens. We will focus on addressing whether advancements in biotech have outpaced our existing biosafety guidelines, and whether or not we are following those guidelines.

The NIH clearly did not enforce those guidelines with research being done for it by EcoHealth Alliance and the Wuhan Institute of Virology into novel coronaviruses. Our examination of biosafety has to be informed by the real possibility that a pandemic which killed over one million Americans was the result of an incident at a laboratory that received NIH funding.

As I have said at past hearings, I believe the available evidence favors COVID-19 emerging due to a lab-related incident. My belief that COVID-19 came from a lab leak is

now shared by the Department of Energy and the FBI. But regardless of our individual opinions as to the origins of COVID-19, we in Congress have a responsibility to understand the potential benefits and perils of this type of research. As the committee with authorizing jurisdiction over Federal biomedical research, all of us here today have a special responsibility to grapple with these issues.

High containment biosafety labs are expensive and complex to build, maintain, and run. Research conducted in these laboratories involves pathogens that can cause serious, potentially life-threatening diseases. And in the case of biosafety level 4, BSL-4 laboratories, diseases which -- for which no vaccine or therapy exists.

It is crazy to me that the Wuhan Institute of Virology appears to have conducted at least some high-risk coronavirus research at a biosafety level 2 lab, and did so with U.S. dollars. In 2000 there were less than 10 BSL-4 labs in the world. There are now 59 in operation, under construction, or planned. In the United States alone, there are over 1,500 hundred biosafety level 3 facilities.

Rapid advances in biotechnology have opened up potential

new cures and expanded our scientific knowledge. But this has also led to the proliferation of new technologies and research techniques that are inherently dual-use, and potentially dangerous if done in inappropriate biosafety conditions. Balancing safety with innovation is an enduring challenge.

Our existing oversight framework for risky research isn't working. Whether we call it gain of function research or whether it is called research with enhanced potential pandemic pathogens, I fear we have not kept pace. The United States doesn't have a comprehensive regulatory system for high containment laboratories. Practically speaking, the research institutions, companies, and universities that operate these facilities police themselves.

Back in 2017, the White House's Office of Science and Technology Policy issued guidance, the Potential Pandemic Pathogen Care and Oversight Framework, but it was intended to apply to all executive agencies. However, it has only been implemented by one department, Health and Human Services. And HHS has largely delegated implementation to the NIH, a funding entity who has shown a lack of significant oversight

towards riskier research with their grantee, EcoHealth Alliance, and sub-grantee, Wuhan Institute of Virology.

As the debacle with EcoHealth Alliance and the Wuhan Institute of Virology makes clear, NIH is neither inclined nor equipped to exercise oversight of the risky research it funds within the United States or abroad. NIH is not only indifferent, but reflexively hostile to outside oversight. NIH has stonewalled and slow-walked our document requests related to EcoHealth Alliance grants.

Further, how many accidents at high containment labs go unreported? There does not appear to be a government-wide effort to understand the frequency and nature of laboratory accidents. Since last October, NIH has not provided key information about an in-house National Institute of Allergy and Infectious Disease gain of function experiment involving a highly lethal clade of monkeypox. NIH won't even tell us about its deliberations about this experiment. It makes me wonder what the NIH has to hide. How bad is it, when they won't even engage with the authorizing committee about this information? We have to assume there is something they don't want us to know about. Perhaps something very, very

dangerous.

I will conclude my opening remarks by noting that the highest ranking NIH official, Dr. Larry Tabak, appeared before this committee in February in response to questions about NIH's failure to enforce biosafety measures it placed on coronavirus research it funded at the Wuhan Institute of Virology. Dr. Tabak testified the NIH is not an enforcement agency. I am beginning to think he is right.

It may be time for us in Congress to relieve the NIH of the burden of conducting risky research at institutions that it funds.

[The prepared statement of Mr. Griffith follows:]

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

*Mr. Griffith. I yield back. I now recognize the ranking member of this subcommittee, Ms. Castor, for her five minutes for an opening statement.

*Ms. Castor. Well, thank you, Mr. Chairman, and thank you to the witnesses for being here today.

There are two important complementary priorities that I look forward to discussing with our witnesses today. The first is to make sure that we are advancing science and research so that we can better protect Americans from disease, achieve scientific breakthroughs, and continue to lead the world in innovation and discovery. The second is to ensure that the safety standards governing our nation's research continue to protect the public and the scientists and researchers involved. Extensive oversight and safety requirements already exist in our research centers today, and I hope that our witnesses can help us better understand that, and how we can continue to modernize.

Americans can be proud of the U.S.-led research in laboratories in the United States and across the world, including with infectious diseases and pathogens. When the COVID-19 pandemic hit, we relied on this research to spur

vaccine development in record time. And each year, researchers across the globe collaborate to study seasonal influenza so that we can better develop vaccines to protect the public based on real-time data in other nations. And when more infectious flu variants like the avian flu emerge, we depend on our researchers to go into high containment labs to study ways to prevent death and disease.

And as we will discuss at tomorrow's hearing, viral research is critical to helping us prepare for and address the emerging threat of antimicrobial resistance. Because this research is so important, Congress should support thoughtful, constructive steps to ensure that it is being conducted safely. We must remain the gold standard of biosafety standards internationally, and continue to improve and modernize. I hope to have a constructive discussion about those potential improvements in this committee, and ensure that any new policies we consider include input from key stakeholders in the research community.

Some of my colleagues on the other side of the aisle have floated broad bans on international collaboration without considering what that would mean for flu

surveillance, for vaccine development, or monitoring viruses. Many of these proposed research restrictions and criticisms target research in other countries, including some countries where viral outbreaks have originated in the past.

But disease knows no borders. Since I have come to Congress we have had to address global outbreaks of MERS, Zika, Ebola, and, of course, COVID-19 and its changing variants. These viruses are threats to everyone, and it is critical that our scientists can partner with public health experts to identify and stop potential pandemics. The Administration's National Biodefense Strategy recognizes the need for America to galvanize support for multi-national biosafety commitments so that research in foreign countries can be done safely and up to the high -- the same high standards that we use in our labs at home.

I also sit on the Select Committee on the Strategic Competition between the United States and the Chinese Communist Party, where we are focused on the threat posed by the CCP and on a plan of action to defend the American people, our economy, and our values. I can tell you that if America does not lead the world in infectious disease

research, the CCP will try to fill that role. If we don't continue to engage and collaborate with the international research community, advise where appropriate on development of labs, and export our best practices and training on lab safety, the CCP will fill that void, for sure. And if they do, we will have little transparency into what work is being done, and how.

Overbroad funding bans will not accomplish our goals, and could have detrimental impacts on future medical advancements and scientific breakthroughs. Any discussion we have must be done in a thoughtful manner, with the input of people who actually conduct research on dangerous pathogens every day.

No one has a greater stake in lab safety than researchers working in American labs. These are the people who do the hard work to develop groundbreaking proposals, study how viruses grow and mutate, and make sure we are protected from the next viral outbreak. I trust that we can support these researchers by forging a bipartisan path forward on lab safety that doesn't stifle the research and international collaboration that all Americans rely on to

protect their health and safety.

[The prepared statement of Ms. Castor follows:]

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

*Ms. Castor. So I look forward to our discussion today, and I yield back.

*Mr. Griffith. The gentlelady yields back. Now I recognize the chair of the full committee, Mrs. McMorris Rodgers, for her five minutes for an opening statement.

*The Chair. Thank you, Mr. Chairman. With several new books out this week about lab accidents, a recently-released Senate report with new details pointing to safety problems at the Wuhan lab and the recent recommendations of an NIH advisory panel on oversight of risky research, this hearing is timely, not to mention the terrifying news that fighters in Sudan have seized the country's National Laboratory for Public Health, which holds samples of risky and deadly diseases, including measles, polio, and cholera, which the World Health Organization has said is a huge biological risk.

This is especially worrisome, considering the CDC has supported this national lab since 2006, including its biosafety protocols, lab quality management, and infrastructure and staff trainings. As recently as 2018, CDC helped to establish the first viral load monitoring facility at this lab. This is a very dangerous situation that we must

monitor closely.

We still do not know how the COVID-19 pandemic started. However, more information has heightened our suspicions that the origin of the pandemic was linked to a lab incident. It raises the importance of our work to oversee biosafety of risky research. Unfortunately, in our pursuit of solutions the conduct of some public health officials and the loss of trust in our public health institutions hampered our response.

Instead of openness and honest discussion, HHS and NIH have persisted in foot-dragging, stonewalling, or flat-out refusing to engage in legitimate questions. Today the NIH still won't provide meaningful information or straight answers to the committee about how the PC3O framework governing risky research was developed, or who at the NIH was responsible for developing the framework. An NIH advisory panel earlier this year found the framework had too many loopholes and too much flexibility to evade independent review.

We still do not have complete information about NIH experts in 2016, how they allowed EcoHealth Alliance, through

its sub-grantee, the Wuhan Institute of Virology, to proceed with a research proposal infecting humanized mice with experimental coronavirus strains. NIH and EcoHealth agreed to go forward with the experiment on the condition that, if excessive virus growth occurred, EcoHealth would immediately stop the experiment and notify the NIH. This condition was incorporated into the grant terms. The experiment went forward. There was excessive virus growth, but immediate stoppage and notification did not occur. This was the conclusion of both the NIH and the Office of Health and Human Services inspector general.

Under other circumstances, EcoHealth's failure to stop the experiment and immediately notify the NIH could be described as a near-miss safety incident. However, we have no way of knowing whether it was a lucky break with no incident or a lab experiment gone wrong. NIH has no way of knowing, because EcoHealth committed another failure. It did not obtain the laboratory notebooks and electronic files from Wuhan lab.

Yet even with these compliance failures, NIH continues to hold EcoHealth to good standing, and continues to provide

them even more funding. No changes in policy, no lessons learned, no consequences, no accountability, no seriousness from the NIH. No wonder the credibility of the NIH has suffered, even after spending $1 billion in taxpayer dollars on public relations. We are going to get to the bottom of that, too.

The American people deserve answers and accountability. Dr. Fauci admitting in The New York Times "something clearly went wrong'' is not going to cut it. As we learned today, we have gaps in biosafety policy and oversight. However, even addressing these gaps will not be sufficient if the NIH only pays lip service to biosafety compliance with no real commitment to implementation. The path forward to restoring public health is having good-faith, honest discussion.

We need critical research for cures and medical countermeasures. For years this committee, and especially this subcommittee, have held oversight hearings about lab accidents and other mishaps. The risk side still has not been adequately dealt with. Today's hearing can be a constructive start, and I thank the witnesses for being here, for your participation, and especially participating on short

notice.

I yield back.

[The prepared statement of The Chair follows:]

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

*Mr. Griffith. I thank the gentlelady. I now recognize the ranking member of the full committee, Mr. Pallone, for his five minutes for an opening statement.

*Mr. Pallone. Thank you, Chairman. When the coronavirus pandemic began, many researchers with the training and experience to examine dangerous viruses put their research on hold to tackle the pandemic. The lab infrastructure that was in place and the research community were essential in identifying the virus, how it worked, and how we could slow its spread and limit its ability to harm Americans. And the public saw the benefits of this research in real time, with vaccinations becoming available at an unprecedented pace.

So we will hear a lot today about the risk of certain kinds of research, and it is important that we examine those risks. At the same time, we need to understand the benefits of certain research in preventing and responding to pandemics, and we also need to discuss the training and safety measures that are already in place in high containment labs to reduce risk.

Thanks to the investments that have been made in

research, the scientific community was able to respond to the COVID-19 pandemic in record time. This included scientists at our public institutions as well as those in the private sector. It was a global effort to solve a global problem, and we should take immense pride to the extent and quality of America's scientific contributions towards understanding and addressing the COVID-19 pandemic.

And one of the many lessons that we should take away from the pandemic is that a well-resourced and well-trained scientific community is essential if we have any hope of preventing and defeating future pandemics.

Now, studying dangerous pathogens requires carefully-considered protocols and persistent oversight to ensure that the work is conducted safely. When it comes to risk, it is the researchers working in high containment labs, they are the ones with the most to lose when labs are not adequately maintained, or corners are cut, or safety protocols are insufficient. They are the ones who are literally in the room with dangerous pathogens so they can study how the pathogens threaten us and how we can protect ourselves.

So we must ensure that scientists feel free to speak up

about any concerns they have that could help improve lab safety. But I am very concerned that the tenor of the current debate on lab safety is having a chilling effect on scientific research and among the scientists at the forefront of disease prevention and response. We have seen scientists, including some of our top public health officials, maligned, marginalized, taken out of context, and accused of covering up the origins of COVID-19. And these actions are harmful and counterproductive, because we must have scientists at the table if we want to stay world leaders in science and research, and if we want researchers to feel comfortable raising safety concerns.

So I am pleased we have a witness at the table today who can help us understand -- I should say witnesses at the table today who can help us understand -- what is working well already, and where there may be a need for additional transparency, consistency, and safety regulation or oversight.

The Biden Administration and House Democrats have taken important steps towards increasing biosafety and biosecurity. Last year's Consolidated Appropriations Act contained

numerous important provisions to improve biosafety, but no Republican on this committee that is here today supported that legislation. And just yesterday the House Republican majority jammed through their default on America act that would strip funding from important programs that could assist with pandemic preparedness and biosafety. It also strips COVID-19 treatment and vaccine development funds, and threatens U.S.-based medical manufacturing. With this legislation, House Republicans, I believe, are threatening a default crisis that would devastate everyday Americans.

So I hope today's hearing demonstrates why continuous investment, rather than misguided funding cuts, is essential to prevent pandemics and respond swiftly when they occur.

[The prepared statement of Mr. Pallone follows:]

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

*Mr. Pallone. And with that, Mr. Chairman, I would yield back.

*Mr. Griffith. I thank the gentleman for yielding back. That concludes member opening statements.

I would like to remind members that, pursuant to committee rules, all members' opening statements will be made a part of the record.

We want to thank all of our witnesses for being here today and taking your time to testify before the subcommittee. Each witness will have an opportunity to give an opening statement, followed by a round of questions from the members.

Our witnesses today are Dr. Rocco Casagrande, executive chairman of Gryphon -- did I say that right -- Scientific; Dr. Robert Hawley, former chief of safety and radiation protection division of the U.S. Army Medical Research Institute, Fort Detrick; Dr. Gregory Koblentz, associate professor and director of biodefense graduate programs for George Mason University; Andy Pekosz, professor of molecular microbiology and immunology, Johns Hopkins University.

We appreciate you being here today, and I look forward

to hearing from you all on this important issue. As you are aware, the committee is holding an oversight hearing. And when we do so, we have the practice of taking our testimony under oath. Do any of you have objections to testifying under oath today?

Seeing no objections, we will proceed. The chair advises you are also entitled to be advised by counsel pursuant to House rules. Do you desire to be advised by counsel during your testimony today?

Seeing that none have requested counsel, please -- if each of you would, please rise and raise your right hand.

[Witnesses sworn.]

*Mr. Griffith. Seeing that all witnesses have responded in the affirmative, you are now sworn in and under oath, subject to the penalties set forth in title 18, section 1001 of the United States Code.

With that, we will now recognize Dr. Rocco Casagrande for five minutes to give an opening statement.

But before you begin your opening statement, if you would, introduce your two high-level staff assistants who have come with you today. I see them sitting behind you.

*Dr. Casagrande. Thank you. My senior advisors are Jack and Kennedy. I hope that doesn't make my comments too partisan.

[Laughter.]

*Mr. Griffith. No, not taken that way at all. But we welcome your senior advisors to be with us today, and we are glad that they are here.

If you would now proceed with your five minutes of opening statement, please.

TESTIMONY OF ROCCO CASAGRANDE, PH.D., EXECUTIVE CHAIRMAN, GRYPHON SCIENTIFIC; GREGORY KOBLENTZ, PHD, ASSOCIATE PROFESSOR & DIRECTOR, BIODEFENSE GRADUATE PROGRAMS, GEORGE MASON UNIVERSITY; ANDY PEKOSZ, PHD, PROFESSOR OF MOLECULAR MICROBIOLOGY AND IMMUNOLOGY, JOHNS HOPKINS UNIVERSITY, BLOOMBERG SCHOOL OF PUBLIC HEALTH; AND ROBERT HAWLEY, PHD, FORMER CHIEF OF SAFETY AND RADIATION PROTECTION DIVISION, U.S. ARMY MEDICAL RESEARCH INSTITUTE, FORT DETRICK

TESTIMONY OF ROCCO CASAGRANDE

*Dr. Casagrande. Thank you, Mr. Chairman. I am honored that you invited me to speak about such a timely and important topic as laboratory safety.

Today I am going to advocate for several improvements that are critically needed to ensure that the laboratories that study the most deadly and transmissible viruses remain safe. This research is essential to prevent and respond to pandemics of the future. However, it is not without risks.

The practice of mitigating such risks is called biosafety. Historically, biosafety has been perceived as

consuming time and money that would otherwise be spent on critical research. But I am also going to argue that needed improvements in biosafety will not stifle or draw away resources, but will help improve the efficiency of the research enterprise if implemented properly. The critical improvements that I will talk about today can be grouped into six categories: oversight, research, standards, workforce, resources, and mission.

Regarding oversight, biosafety authority in the U.S. derives from a patchwork of regulations, laws, and guidance, given the pathogen researched or the source of funding. Currently, some pathogen research is conducted in the U.S. without any Federal oversight. Theoretically, a privately-funded group could work on influenza virus in a makeshift laboratory, and attempt to make the strain more deadly or more transmissible. If they are not using a select agent strain of flu, and they are doing the research for peaceful purposes, there is no Federal entity that could ensure that they are doing their work safely or securely, or prevent them from continuing if safety or security is lacking.

The U.S. needs a unified biosafety system that can

provide oversight for research on all dangerous pathogens, regardless of the funding source or the affiliation of the researchers. Unlike other high-risk endeavors like aviation and nuclear power, biosafety does not have a robust research history because there has been nearly no funding for research in the -- in biosafety over the past several decades. We currently lack data on how accidents occur, or the factors that can effectively mitigate those accidents.

Historically, biosafety improvements has always added onto existing equipment, procedures, or administration because there were no data suggesting which specific improvements were particularly effective versus others available. Investments in biosafety research can determine exactly what measures effectively reduce risk, and which are simply theater, enabling the efficient use of research dollars across the United States.

Using new evidence to eliminate wasteful measures would also make laboratories more sustainable, as money need not be spent maintaining equipment with little value.

Biosafety research can also directly inform laboratory practices on the choice of equipment and procedures that are

inherently safer improving safety in the near term.

Data generated by biosafety research can also boost compliance with safer, but inconvenient practices because scientists are naturally skeptical and data-focused.

Although there are general standards regarding safe practices for research, more standards are needed to cement and communicate best practices, and ensure that the laboratories doing the least don't have an advantage over those taking more measures to be safe.

For example, standards are needed to define how many biosafety professionals are needed to support research facilities of various sizes and complexities, and what type of training is needed to work in containment. Developing these standards and templates for training would save all research facilities from developing their own.

Also, the biosafety workforce is rapidly aging and experiencing burnout due to adopting extra duties to keep campuses and workplaces safe during the COVID pandemic. Fellowships, curricula, and training is needed to recruit scientists into the safety workforce and ready them for a career.

Biosafety has historically been under-resourced for various reasons. In most institutions, biosafety staff are paid out of overhead costs, instead of directly from research dollars, meaning that safety workforce draws resources out of the institution instead of paying for itself. As a colleague of mine has aptly said, "Biosafety has a soft money, soft jobs problem.'' Allowing the maintenance of safe labs as a direct cost on grants would help ensure biosafety is adequately supported.

Moreover, in order to be properly implemented, any additional requirement put on the biosafety workforce, such as those recommended recently by the NSABB, should be accompanied by an increase in funding to ensure that biosafety professionals don't have to do more with the same resources, which itself could hamper safety.

Regarding mission, currently there is no Federal agency that is in charge of biosafety, funding biosafety research, promulgating specific biosafety standards, fostering the workforce, or providing oversight to all pathogen laboratories. To fix this issue, either an existing or new Federal agency must be given the comprehensive mission of

improving biosafety.

Some have argued that the additional oversight of biosafety of the type I have described would stifle research. This position is belied by the fact that countries that have already implemented similar systems have equally robust pathogen research communities and bio-economies. Specifically Canada, Switzerland, Germany, and the UK all have comprehensive oversight of pathogen laboratories and several high containment laboratories.

The resources needed to sponsor research, develop standards, foster the workforce is small compared to the resources spent on pathogen research itself. An annual budget of 60 million would provide sufficient funding to support this work, and the sum is approximately 1 percent of NIAID'S 66 billion annual budget.

To close the oversight gaps I mentioned and adequately fund biosafety professionals to take on greater responsibility would require more funding, though the funding is clearly justified by the risks. The pandemic, which could have plausibly been caused by a laboratory accident, cost more American lives than all wars in my lifetime, and harmed

the economy more than any other single events. Investments on the scale of a single defense program would transform biosafety in the U.S. and more cost effectively mitigate major risks facing the U.S.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Casagrande follows:]

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

*Mr. Griffith. I thank the gentleman for yielding back, and now recognize Dr. Koblentz for his five minutes of opening statement.

TESTIMONY OF GREGORY KOBLENTZ

*Dr. Koblentz. Thank you, Mr. Chairman. Thank you for the chance to speak with the committee today about biosafety, biosecurity, and dual-use research oversight.

I am -- welcome the opportunity to present the results of the Global Bio Labs Initiative, which I co-direct with Filippa Lentzos at King's College, London. We've spent the last two years collecting and analyzing data on high-consequence research facilities located around the world, and evaluating the national biorisk management policies in place in these countries in order to oversee the safe, secure, and responsible operation of these facilities.

In cooperation with the Bulletin of the Atomic Scientists, we have created an interactive website at globalbiolabs.org that contains data on the locations and key characteristics of these BSL-4 and BSL-3 enhanced laboratories, as well as details on the biosafety, biosecurity, and dual-use research oversight policies that these countries have in place.

Today I would like to present the key findings of our

latest report, the Global Biolabs Report 2023, which contains our most recent research analysis on BSL-4 and BSL-3 labs, as well as the state of biorisk management around the world. I am going to start off talking about the BSL-4 labs, and then I will talk about the BSL-3 enhanced labs, and then talk about the recommendations that we have.

Since its launch in 2021, the Global Biolabs Initiative has identified more than 100 high-consequence biological research facilities, meaning BSL-4 and BSL-3 labs, around the world, with more under construction and under development. Among the BSL-4 labs, which are designed to work with the most dangerous pathogens such as Ebola, Marburg, and smallpox, there are currently 69 such labs in operation under construction or planned in 27 countries. That is an increase of 10 labs from our last report in 2021. Today, of those labs, approximately 75 percent are located in urban areas, which exacerbates concerns if there was an accidental release in one of these densely populated areas.

The COVID-19 pandemic has led to a building boom in BSL-4 labs. Nine countries have announced plans to build twelve new BSL-4 labs since the start of the pandemic. For 5 of

these countries, this will be their first BSL-4 lab, and most of these new labs will be built in Asia, including in Kazakhstan, the Philippines, India, and Singapore.

Turning now to the BSL-3 labs, we have identified 57 of these biosafety 3 enhanced laboratories in 28 different countries. These are BSL-3 labs that have adopted additional biosafety and biosecurity measures in order to carry out particularly risky research. The most common pathogen studied in these BSL-3 enhanced laboratories is highly pathogenic avian influenza. These labs have also been used to study the 1918 pandemic influenza virus, as well as to conduct research on potential pandemic pathogens, which is also known as gain of function research.

Eighty percent of the BSL-3 enhanced laboratories that we have identified are located in urban areas. However, there is limited national biosafety guidance, and no international guidance about what constitutes a BSL-3 enhanced laboratory. In addition, there has been little to no research done to determine whether the enhancements that these labs are using are commensurate with providing a commensurate level of biosafety benefits compared to the

riskier research that they are conducting.

The Global Biolabs Initiative is also developing a new method for assessing the strength of biosafety, biosecurity, and dual-use research oversight policies that are used to conduct -- oversee the operations in these labs. We have collected this data on 27 countries that have or plan to have BSL-4 laboratories. Let me discuss each of these in turn.

First, for biosafety, we have assessed that 21 of the 27 countries have scored high on biosafety governance. The weakest areas we identified were lack of requirements for maintaining an inventory of pathogens and for specifying the use of personal protective equipment. We are doing less well on biosecurity. Only 12 of 27 countries with BSL-4 labs have received a high score for biosecurity.

The biggest gap was in screening of DNA orders related to sequencing and synthesis of dangerous pathogens. Only two countries have policies in place to screen orders to make sure that they are not being used to develop dangerous pathogens. Only 11 countries include cybersecurity as part of their biosecurity requirements, and only 12 countries mandate that labs conduct biosecurity risk assessments.

The picture is even worse when it comes to governance of dual-use research. Only one country, Canada, scores high in this category. Two other countries, including the United States, score medium, and the rest of the 24 countries we study score low. Among these low-scoring countries, many of them have a score of zero, meaning they receive no points for having any mandatory or voluntary measures in order to conduct oversight of dual-use research in labs on their territory.

With that review of the virus landscape, let me offer some recommendations for concrete steps that we can take to strengthen biorisk management. At the national level, all countries with high consequence biological research facilities should have whole-of-government biorisk management systems, including comprehensive laws, regulations, institutions to enforce these laws.

States should also be developing national standards for field biosafety. This is an area that has received very little attention so far from the biosafety research community.

And countries that don't have national biosafety

associations should develop one with the support of their local biosafety and biosecurity professionals. Internationally, the World Health Organization and the Biological Weapons Convention can also be leveraged to increase global biorisk management and improve transparency around these facilities.

With that, let me just conclude and say that there are more countries building high containment laboratories, conducting riskier research with potential pandemic pathogens, and developing dual-use biotechnologies. And our biorisk management oversight system has not yet caught up with this changing threat landscape. Thank you.

[The prepared statement of Dr. Koblentz follows:]

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

*Mr. Griffith. I thank the gentleman.

I now recognize Mr. Pekosz for his five minutes of opening statement.

TESTIMONY OF ANDY PEKOSZ

*Dr. Pekosz. Committee Chair Rodgers, Subcommittee Chair Griffith, Vice Chair Lesko, Ranking Subcommittee member Castor, and all members of the subcommittee, thank you for the opportunity to participate in today's hearing and devoting your time and effort to a topic that is important to our nation's public health.

I would like to state for the record that the opinions expressed herein are my own, and do not necessarily reflect the views of Johns Hopkins University.

My name is Andrew Pekosz, and I am a professor of molecular microbiology and immunology at the Johns Hopkins University Bloomberg School of Public Health. I am a virologist who has been doing basic research into viruses, including influenza, SARS-COV, SARS-CoV-2, bunyaviruses, and hantaviruses for over 30 years. That research has been done at biosafety levels 1, 2, or 3, depending on the agent and the type of experiment being used.

In addition to my research interests, I have served on numerous review or advisory boards at the institutional,

state, and national levels, all having been focused on establishing guidelines and biosafety recommendations that would allow critical research to move forward under the most appropriate biosafety conditions. I would like to start by going through the current biosafety measures that are being used in laboratories.

Contrary to what is often described, scientists working with microbes across the United States pay a great deal of attention to biosafety. Keeping their laboratory workers safe is their top priority. Research with microbes undergoes numerous levels of scrutiny before being performed. Pathogen registration forms are reviewed by institutional biosafety committees, which disclose what experiments investigators plan to do and what agents they will be working with. Appropriate guidelines are set based on the organism being used and the type of experiment being proposed.

Work in animal models involves additional reviews, and worker training through animal care and use committees that assess what methods are being used and what alternatives are available to investigators. Work with human samples involves yet more training and reviews from institutional review

boards that ensure that the privacy and safety of investigators and participants are given the highest priority.

The availability of antivirals and vaccines is a critical part of the process of biosafety when they are available. Protocols for dealing with accidents are developed, and make up a significant part of an individual's training.

The vast majority of research with BSL-2 and BSL-3 pathogens occurs at the small scale, and in ways that really do not pose an enhanced risk of infection to laboratory workers. Methods that generate aerosols or utilize needles or other sharp items are minimized or are often non-existent. When there are clear needs for some of these techniques, extra precautions and training are put in place to maintain a safe working environment.

There is an existing framework that targets pathogens with pandemic potential, and research that involves potentially enhancing their disease-causing properties. This is the PC3O mechanism that was mentioned previously. It does lay out the process for identifying research of concern and

how that research will be reviewed, starting at the institutional level and progressing to the national level.

The National Science Advisory Board for Biosecurity, or NSABB, recently released recommendations for updating guidance regarding research of concern. The NSABB's intentions were well-meaning, but the lack of clear definitions regarding the type of research and the agents which would be covered by the guidelines resulted in more, not less, confusion in the scientific community. The risks -- this risks slowing our efforts aimed at current infectious diseases, while not gaining additional protection from future pathogens.

Their report did hit on several important items. Loopholes that allow certain experiments to avoid NIH review because it was funded by private sources need to be closed. Biosafety is independent of funding sources. Increased transparency about the review process and individuals making decisions about approving research of concern would also be welcomed by most scientists in the field.

In closing, I would like to emphasize that the United States is the world leader in infectious disease research,

with the development of antimicrobials and vaccines being the centerpiece of those efforts. We have an opportunity to strengthen the leadership position and expand it to include biosafety and research into emerging and potential pathogens. The U.S. has the engineering and manufacturing expertise to build effective, safe laboratories. It has the scientific, public health, and clinical expertise that can continue to drive forward and improve our abilities to respond to current and future outbreaks.

The U.S. can set the example of how to safely do research with clear public health benefits. This subcommittee will play an important role in determining that path forward, and I am honored and grateful for the opportunity to provide my testimony in support of this initiative. Thank you.

[The prepared statement of Dr. Pekosz follows:]

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

*Mr. Griffith. I thank the gentleman for his opening statement.

I now recognize Dr. Hawley for his five minutes.

TESTIMONY OF ROBERT HAWLEY

*Dr. Hawley. Thank you very much, Chairman Griffith, members of the committee, colleagues, and friends. I am going to address some of the issues that have been mentioned.

The origins of biological safety, or biosafety, was at the United States Army Biological Research laboratories at Camp Detrick, now known as Fort Detrick in Frederick, Maryland, by Dr. Arnold G. Wedum, who was the director of industrial health and safety from 1946 through 1969. Dr. Wedum, who is revered as the person who is most responsible for creating our profession, is considered the father of modern biosafety. Through the efforts of Dr. Wedum we saw the development of safer work practices, the biological safety cabinet, advances in aerobiological safety, and environmental monitoring. The development of biosafety concepts has its roots in the work promoted by Dr. Wedum. The type of laboratory work, principles, and practices used and the type of facilities needed were established on the determination of risk. This was a risk-based approach.

What I want to emphasize is that there is no one

procedure or technique that can be used for all laboratory research and development procedures. Putting it bluntly, no one size fits it all. A risk assessment is conducted, followed by a risk management procedure, whereby the risk is mitigated or eliminated.

Also implemented was a special procedure section that performed medical examinations on personnel assigned to work in the biowarfare sections and the special immunizations program that began as an immunization program to provide an additional measure of protection of laboratory workers against the occupational infections.

Dr. Wedum directed many applied biosafety research projects that allowed us to better understand in the interaction of laboratory procedures and workers, and subsequently be able to mitigate the negative impacts of these interactions.

It is unfortunate that, due to today, we do not continue to pursue applied biosafety research because of funding constraints. The recommendation of the Trans-Federal Task Force Report of 2009, development and maintain a robust program of applied biosafety and biocontainment research to

create additional and update existing evidence-based practices and technologies, has not gained momentum.

My experience at the United States Army program with the Medical Research and Development Command at Fort Detrick during the period 1988 through 2003. The United States Army Medical Research Institute of Infectious Diseases, or USAMRIID, is the Department of Defense lead laboratory for medical biological defense research. USAMRIID was my extended family. Everyone treated each other as family members. As an analogy, we were like spokes in a wheel, moving smoothly to accomplish our mission. That was research for the soldier, protecting the warfighter from biological threats, and also investigating disease outbreaks and threats to public health. We operated within an ideal climate of safety. Everyone embraced and practiced a culture of safety.

During this time serving as biosafety officer at USAMRIID, I was also a designated command biological safety officer. In this role I was tasked to inspect national and international contract and university laboratories to assess their capabilities and safety program prior to the release of fundings. This was an excellent example of command and

control, and also allowed me the opportunity to champion biosafety and learn alternative approaches to challenging situations and policies.

Accidents, incidents, or mishaps in the laboratory or in any workplace environment do not just happen. They are caused -- usually, because of the unsafe behaviors of people. Included in the causes are violation of rules, procedures, inadequate training, failure to understand process, or procedure fatigue and mental status. Most mishaps can be mitigated or eliminated through adequate coaching, mentoring, or training using the best practices for facilities, equipment, and procedures.

I am a firm proponent that we have an opportunity to gain experience from our incidents, mishaps, accidents, or near-misses by sharing our experiences without negative consequences. Trans-Federal Task Force again in 2009 proposed a centralized incident reporting analysis and information sharing system. The report further states that an analysis of -- report of laboratory incidents could help improve laboratory safety and oversight, determine why the accidents occurred, and how they can be prevented in the

future. Implementing this recommendation will provide resources for generating and sharing lessons learned, and promoting the need for new or revised guidelines, practices, or training.

I have a few other things to mention, but because of the time constraints I just wanted to mention lastly that the biosafety practitioner has to be enthusiastic about their work, and recruit, and be a cheerleader for the profession. And I hope that my comments will reveal the passion I have for biosafety and the continuing desire to learn from my colleagues. Thank you very much.

[The prepared statement of Dr. Hawley follows:]

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

*Mr. Griffith. Thank you, and I appreciate the passion of all the witnesses.

We will now begin the question-and-answer portion of the hearing, and I will begin by recognizing myself for five minutes for questions.

Dr. Koblentz, if the NIH is not capable of enforcing, or doesn't or isn't inclined to enforce safety standards at labs doing risky research, who would you recommend take on that responsibility?

*Dr. Koblentz. Thank you, Mr. Chairman. I think what we need in this country is an overhaul of the biosafety, biosecurity, and dual-use research oversight system, which would be best placed in an independent agency that would be able to conduct that oversight, as well as conduct the kind of research that both Dr. Casagrande and Dr. Hawley talked about being needed. This would be an organization similar to Nuclear Regulatory Commission, or the FAA, or the National Transportation Safety Board that would be an independent technical agency that would have responsibility for those activities.

*Mr. Griffith. Several of you indicated that there were

organizations that weren't connected with the NIH or even the U.S. Federal Government that were doing this type of research, or might be doing this type of research. Would it be possible that we set something up that would be not necessarily governmental or quasi-governmental that would be funded by those private organizations that are doing this type of research?

Back to you.

*Dr. Koblentz. That is certainly a possibility. I mean, most of the research is probably being conducted with public funding. But again, as Dr. Casagrande mentioned, there are gaps in the oversight system that would allow a private facility to engage in this research without any kind of oversight whatsoever. And so you would want to have a comprehensive oversight that would include facilities, regardless of whether they are publicly funded or privately funded.

*Mr. Griffith. I appreciate that.

We have incomplete data that suggests -- and some of you all have suggested -- that there are accidents in the biosafety labs that is not necessarily such a rarity. But

how do we start to get a more complete count of the number of accidents and incidents at high containment labs?

Dr. Casagrande, do you want to start?

*Dr. Casagrande. Yes, thank you, Mr. Chairman. A good accounting of not just incidents that have occurred, but also the near misses would help us to learn from the incidents that inevitably will occur, and prevent their repetition, and also start studying their root causes and most effective ways to mitigate them.

*Mr. Griffith. And you think we need Federal legislation that indicates -- I think both you and Dr. Koblentz indicated we need Federal legislation that would require the labs, whether they be government or private, to report these near misses or accidents.

*Dr. Casagrande. A database that is missing a big portion of the data -- that would be what is drawn from the private sector -- would be less robust than one that contains all the data, obviously. And some of the research environment in the private sector is different from the academic sector. For instance, their personnel is much more stable. They don't have as much turnover as you do in

academia, so they are probably going to suffer different risks. So cutting them out would not be adequate.

*Mr. Griffith. All right, I appreciate that.

Mr. Pekosz, can you explain the necessity of progress reports when conducting research in biosafety laboratories?

*Dr. Pekosz. Absolutely. I think it demonstrates progress of research. It demonstrates areas of research and directions of research. Often times directions of research do change from the initial proposal that was submitted. And progress reports are a great way for regulatory agencies, funding agencies to keep track of how those changes are going forward, and whether there is a major change in direction of research.

*Mr. Griffith. And if we are missing progress reports, shouldn't we pause the study or the research until the progress reports can be completed and evaluated?

*Dr. Pekosz. Yes, progress reports are essential, I think, for monitoring research.

*Mr. Griffith. So when you don't have them, you should put a stop to it. All right.

Dr. Hawley, I understand that you reviewed some of the

biosafety sections of the recently-released Senate report, and you were quoted in The Washington Post as saying that the Wuhan Institute of Virology had imprudent laboratory practices. And it was very, very apparent that the Wuhan Institute of Virology's personnel's biological safety training is minimal. Is that correct, and can you expand?

*Dr. Hawley. Yes, that is my belief by reading some of the reports. Of course, I have never visited the facility, but based upon the reports I have read and the approaches they had to implementation or developing biological safety equipment led me to believe that their training was less than perfect.

*Mr. Griffith. And when you say that there was some equipment missing, are you talking about the air incinerator that was not installed until late 2019?

*Dr. Hawley. Yes, sir.

*Mr. Griffith. Yes. That is of real concern, isn't it?

*Dr. Hawley. It is, because the air incinerator technology was replaced by the HEPA filter in the 1950s, early 1960s. We had an air incinerator from our aerobiology building at Fort Detrick, and that was eventually closed

down, again, because of the advent of the HEPA filter. Not only that, because of the cost and maintenance involved.

*Mr. Griffith. So they weren't doing anything, as I understand it. And then they put the air incinerator in, which was 1950s or 1960s technology, when there was better technology available. Isn't that what you are saying?

*Dr. Hawley. Yes, sir.

*Mr. Griffith. And my time is --

*Dr. Hawley. I believe that they implemented the air incineration because of their lack of reliable data regarding the killing of organisms in their primary procedures such as using an autoclave.

*Mr. Griffith. Yes, kind of like shutting the barn door after the horse is already out.

*Dr. Hawley. It was a redundant move, yes.

*Mr. Griffith. Yes, sir. I yield back, and now recognize the ranking member of the full -- excuse me, the ranking member of the subcommittee, Ms. Castor, for her five minutes of questions.

*Ms. Castor. Yes, thank you, Mr. Chairman.

Right off the bat I wanted to correct the record at the

outset. The chair said that HHS had not replied to a request for -- on Mpox. And here, on April 26, 2023, they did have a 3-1/2-page response to the committee that says, "At the outset, I want to respond specifically to the portion of your letter that described a September 22nd Science article that referenced a potential sub-project which you called the Clade I study. This study has not been formally proposed, and the National Institute of Allergy and Infectious Diseases has no plans to move forward with this research. This type of research would require a formal proposal to be submitted for review, and the proposal would need to undergo the rigorous review process described in this letter before it could be initiated.''

So I am -- offer this for the record.

*Mr. Griffith. And without objection, it is accepted.

[The information follows:]

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

*Mr. Griffith. For the record, let me respond -- we haven't started your five minutes yet, so I am not eating up your time -- that that, while we received that response almost six months after our initial request, we still did not get an answer as to what their deliberations were. Clearly, they have now told us they weren't moving forward. The problem is that this is not meaningful cooperation or meaningful input with the committee of jurisdiction. And accordingly, I stand by my opening comments.

All right, back to you, Ms. Castor.

*Ms. Castor. Okay, thanks so much. Well, we all share the goal that our labs at home and abroad must adhere to stringent safety standards.

To design any thoughtful improvements from our perspective, as policymakers, we really need your input and advice. Dr. Pekosz, your research involves working with infectious pathogens to surveil and understand flu. You also oversee a high containment lab used to study particularly infectious viruses. Walk us through the steps that you must take each time you enter a high containment lab to study an infectious pathogen.

*Dr. Pekosz. Absolutely. Thanks for the opportunity to describe this.

I will jump past the training, which is extensive. And often times when a member joins my laboratory, for instance, it can be anywhere from a month to two months before they actually go into our high containment laboratory, because there is about a month or two of training that we do outside of the facility so individuals get comfortable with their techniques and their approaches.

Our high containment laboratory has a security swipe, where only limited individuals have access to the room. It is a multi-room facility. Each of the doors have an interlock system so that only one door can be opened at any one particular time, and the outside door is only controlled by a security access from the outside, as well as emergency -- or security access from the inside.

We enter an area in our room, where -- which we call our gowning room or our ante room, and that is the space that is pathogen free, and that is where we gown to enter into the rooms of our suite where we actually will be working with pathogens. That -- the gowning part involves us putting on a

Tyvek over-suit, which is a moisture-resistant protective barrier. We put on protective gear over our feet. We put on a pair of gloves. We then don what is called an outer-protective gown, which is another sort of apron that is moisture resistant. We put on a second set of gloves, and then we provide protection through something called PPAR, or a PPAR unit. And what that is is it is a unit where we put a hood around our entire heads, we connect it via a hose to a unit on the side of our waist which takes air from the room, purifies it through a HEPA filter, and then sends it through the mask out -- and out the bottom of our --

*Ms. Castor. This is a detailed process.

*Dr. Pekosz. Yes.

*Ms. Castor. And Dr. Koblentz, you said, okay, looking at it, the U.S. and Canada ranked high when it comes to our biorisk management score. But then you highlighted the expansion of labs across the globe in -- after the COVID-19 pandemic. So what is our best way in America to make sure that, as labs open across the globe, what -- is it through the WHO? Is it through our research, our collaboration? What is the way to ensure that, as labs open, they are

adhering to high standards?

*Dr. Koblentz. Thank you for the question. I think we need to take a kind of a two-pronged approach. Working through organizations like the WHO and the Biological Weapons Convention can enable us to set international standards for biosafety, biosecurity, and dual-use research oversight that all countries can aspire to.

But at the same time, we also need to have more focused efforts that are working with the countries that are perhaps developing their first BSL-4 laboratory, and so they need to build up the legal and regulatory infrastructure expertise, as well as the training for their personnel who will be working there, and making sure they are able to work there, you know, safely and securely, and engage that -- provide the kind of training that Dr. Pekosz is talking about.

And I think there are not only bilateral programs the U.S. can do for that, but there are international organizations like the International Federation of Biosafety Associations, the National Experts Group of Biosafety and Biosecurity Regulators that can provide those services, as well, and make sure that labs are operating --

*Ms. Castor. And here is my concern now, because I have heard -- you have made some very important recommendations to us. Some say, oh, create a new agency, do some more oversight. But right now, under the Republicans' default on America proposal, it requires a 22 percent cut to NIH, and significant cuts to the HHS Office of the Inspector General. That -- it would totally undermine the -- those type of efforts, and the ability to provide oversight.

I mean, my time is running out, but for the record, Dr. Casagrande, will you reply to us why funding NIH and its oversight mechanisms are so important, and how are cuts of that magnitude would completely undermine our goals on biosafety in the U.S. and across the world?

*Dr. Casagrande. Thank you for the question, Representative Castor.

Yes, I mean --

*Ms. Castor. My time is up, so I am -- you will have to take that for the record.

[The information follows:]

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

*Dr. Casagrande. I don't understand.

*Mr. Griffith. She is asking that you give a written response later to the question --

*Dr. Casagrande. Oh --

*Mr. Griffith. -- because her time has --

*Ms. Castor. Since my time ran out.

*Mr. Griffith. -- has run out.

*Dr. Casagrande. Sure.

*Ms. Castor. Thank you very much.

*Mr. Griffith. But thank you very much. Thank you. The gentlelady yields back. I now recognize the gentleman from Texas, Dr. Burgess, for five minutes of questioning.

*Mr. Burgess. Thank you, Mr. Chairman, and I don't want to spend my time doing this, but the exchange you just heard is actually factually inaccurate. The appropriations that are done that will be delivered to the NIH, the CDC, all of those are yet TBD. There are no cuts that have been identified. There are overall savings in the budget that will occur over the next several years that are important because we are in a fiscal crisis. But that type of rhetoric does nothing to advance the -- really, what we are here to

discuss today.

Dr. Casagrande, you actually answered my first question spontaneously. I was going to ask which government entity is responsible for regulating high containment or risky research, and I think you have already offered that there actually isn't one. Is that correct?

*Dr. Casagrande. Right. It depends on what the entity is researching, which pathogens, and also where its funding is derived from. But in -- for the highest level of containment, almost all -- well, all those pathogens are select agents. And so it would fall under the select agent program either under the CDC or the USDA. So still two separate entities. But beyond that, it depends on if the agent is a select agent or if the funding is derived from a Federal agency. If it is not a select agent and it is not funded by a Federal agency, then there might not be Federal oversight.

*Mr. Burgess. Well, let me ask Mr. Pekosz -- if I pronounced your name correctly -- you identified loopholes that need to be closed. Is that along the line of what you were describing by closing loopholes?

I think in your written testimony you say that it -- you don't differentiate between -- well, let me just be sure that I have got it correctly, because it -- I thought it was an important point that you made in reference to closing loopholes.

*Dr. Pekosz. Yes, biosafety is independent of funding sources.

*Mr. Burgess. Yes.

*Dr. Pekosz. Essentially, what I was saying.

*Mr. Burgess. Yes.

*Dr. Pekosz. And I think that is a really important point to make. Biosafety is a standard that is dependent upon the experiments you are doing, the pathogens you are working with, and the facilities that you have. We shouldn't be monitoring that -- or changing that, I should say -- in any way based on simply where the money is coming from.

*Mr. Burgess. Yes, I think that is such a valid point.

Dr. Hawley, I really appreciated your historical reading of how things developed at Fort Detrick. You know, I sat in a committee room here -- it was probably 2013 or 2014.

Well, I can remember reading, as a medical student, when

smallpox was eradicated, right? In Ethiopia they had done the ring vaccinations, they isolated the last cases. We are going to beat this disease. We are going to wipe it off the face of the Earth, and then to find out -- many, many years later I am elected to Congress and, oh, yes, we still actually have some stuff. And then, after being on this committee for a while, we had a hearing because the NIH just happened to have some in the back of the fridge that no one knew about.

So when you went through your recitation of the historical development, yes, we -- you can make mistakes. You can have near-misses. And one of the things that really piqued my curiosity was you also said you have a system where it -- what is almost described as a no-fault system for reporting near-misses. Did I understand that correctly?

*Dr. Hawley. Yes, sir. Yes, sir.

*Mr. Burgess. And do you -- well, let's just explore that a little bit. Do you -- is that something you think we can build upon, that type of system?

Like at NASA, if you report a near aeronautical disaster, you actually get a get-out-of-jail-free card from

the FAA because you properly reported it. Is that what you are talking about?

*Dr. Hawley. Well, locally we had a near-miss reporting policy, and then reviewed those near-misses periodically. But what I am calling for -- and I think some of my colleagues have mentioned -- the need for a national database, so that we can all share and learn from what happened without any negative consequences.

There is a lot of punitive action associated with the reporting of an incident nowadays, and that has a tendency to drive these incidents underground so they are never reported. And same with the near misses because of embarrassment or other reasons.

*Mr. Burgess. Right, and -- or you don't want to end up in front of an administrative law judge somewhere with your credentials threatened.

So I -- Mr. Chairman, I hope we can explore that concept. I know we are not a legislative subcommittee, but I think that is so important. And the ability to have the database and to do so without penalty when proper reporting occurs, maybe that could have avoided some of the

difficulties that we see now with EcoHealth Alliance.

But I really appreciate your testimony today. It has been very instructive.

*Dr. Hawley. And to emphasize that -- some of my colleagues have made, that monitoring should be done by an agency that does not provide the funding. Because to me, that is analogous to the fox watching the henhouse. Thank you.

*Mr. Burgess. Important safety tip. Thank you, sir.

*Mr. Griffith. And I suggest you lean over to your colleague to your right, who might have jurisdiction on the legislation.

[Laughter.]

*Mr. Griffith. I now recognize Ms. DeGette of Colorado for her five minutes of questioning.

*Ms. DeGette. Thank you so much, Mr. Chairman. And I really have to thank you for this panel.

The chairman knows I was the chair of this subcommittee the last four years, and we have spent a lot of time talking about what to do about our labs. And I think all of you have really given us a lot of important food for thought.

One of the issues that we have encountered, and one of the reasons why people are building these labs all around the world, it is important to do the research near where these viruses occur. Is that -- Mr. Pekosz, you are nodding your head yes.

*Dr. Pekosz. Yeah, there is such -- especially when it comes to emerging infectious diseases and outbreaks, having the boots on the ground, having the local authorities not only be well prepared, but having the facilities that can deal with this is incredible, because that is the way you can stop these outbreaks early.

*Ms. DeGette. Right.

*Dr. Pekosz. Once outbreaks get too out of control, it becomes incredibly --

*Ms. DeGette. You can't stop it.

*Dr. Pekosz. -- difficult to do that.

*Ms. DeGette. That is right. So Dr. Koblentz, everybody is focusing on you and what you are talking about, the biosafety protocols and so on. And you talked about the WHO and some of the other organizations that could oversee it. But a question that I have is when the U.S. is entering

into partnerships with some of these countries, we could make a condition of our funding and our joint action that they meet certain protocols and also transparency. Wouldn't that be fair to say?

*Dr. Koblentz. Yes, that would be a good approach to take when we are working with other labs and helping them build their capacity, to also make sure that they have in place the right biosafety and biosecurity protocols.

*Ms. DeGette. If they want to work with our scientists, which they all want to work with our scientists and get our money, right?

*Dr. Koblentz. Yes.

*Ms. DeGette. And so, let's see. What would happen, Dr. Pekosz, if we had a ban on some of the international research collaborations, as some of my colleagues on the other side have talked about? Not this colleague, but other ones.

*Dr. Pekosz. Yeah. You know, it is incredibly important to have epidemic and outbreak research be created and shared in near-real-time. And those resources, often times, those require multi-national resources.

I run a center that actually does do surveillance both in Taiwan and in Zambia, and the importance of being on the ground there, training people, having a free flow of information, establishing trust networks between individuals are all critical in terms of being able to do these things effectively.

*Ms. DeGette. Now -- thank you.

Mr. Hawley, you talked about the lapses at the Wuhan Lab, but you haven't actually seen those lapses for yourself. You read about it in a report, isn't that correct?

*Dr. Hawley. That is correct.

*Ms. DeGette. Okay. So the problem is -- and this is the problem the chairman is talking about, and I just read an article in The New York Times the other day about this -- China is not transparent in what is going on at its labs. So that is what we have to try to figure out, what to do with China, but also other countries, too, so we can be assured that the highest levels of lab safety are met, and so that we can make sure that we don't have -- that we are not sitting around here three years later, trying to figure out where the virus came from. And that is really the goal.

So, Dr. Casagrande, I have got a little bit of time left, and so I wanted -- I don't want to be partisan about this, but I do want to give you the opportunity to answer in front of everybody and on the record why funding the NIH and its oversight mechanisms are so important and, if we did have cuts, what that might do to our ability to monitor these labs.

*Dr. Casagrande. Yeah. If you look at human progress over the last century, a lot of it has been due to biomedical advances. And the NIH is probably the premier institution in the world that has fostered those advances and led to the great expansion of life expectancy, quality of life, and reduction of childhood mortality.

Additionally, if you look at the COVID pandemic, had this pandemic happened 10, 15 years ago, we wouldn't have been able to respond as quickly and get back to life as normal and to have our economy recover as fast as it did.

So also, you know, because of the issue I mentioned, that the biosafety jobs are often funded on soft money, cuts on research will probably be hit somewhat hardest on safety staff. And so you might end up accidentally creating a less

safe environment from that purpose.

*Ms. DeGette. And --

*Dr. Casagrande. Conversely, more funding -- sorry.

*Ms. DeGette. No, that is okay. I was going to say we see the same thing with food safety, and this subcommittee has looked a lot at food safety, too, because when you have our food being produced in China, you have to have the inspectors go over there. But frequently, that is one of the first things that gets cut because it is seen as fungible.

Thank you, and I yield back.

*Mr. Griffith. I thank the gentlelady for yielding back, and now recognize the chairman of the Health Subcommittee, Mr. Guthrie, for his five minutes of questioning.

*Mr. Guthrie. Thank you, Mr. Chair.

Thanks for you all being here today. I appreciate it.

And so, Dr. Koblentz, the first question. On the topic of high containment labs, the December 2022 omnibus spending law included a provision requiring the White House Office of Science and Technology Policy to develop a strategy for maintenance and coordination of biosafety levels 3 and 4 labs

that are federally owned and operated. You are familiar with this provision, and support it?

*Dr. Koblentz. Yes, I am.

*Mr. Guthrie. All right. So the question was, what is the current status of the implementation of this provision, and how will this help protect our biosecurity in these facilities?

*Dr. Koblentz. I'm not aware of the status of that review process, but I will speak generally about the need for a comprehensive review of the adequacy of our facilities at the BSL-3 and BSL-4 level, especially in light of our experience with COVID, in light of, you know, Mpox, and the other emerging infectious diseases that we see. There needs to be now a more rational conversation and review within the government to understand what are our capabilities, and what are our gaps, and what are areas maybe that are excessive and don't need to be in place any longer.

And I think we have been growing this infrastructure for so long among multiple different agencies that we haven't had that kind of comprehensive, government-wide review. So I do think it is time for that to happen.

*Mr. Guthrie. Okay, thank you.

And Dr. Casagrande, the omnibus only specified in this provision would apply to federally-owned labs and operate -- federally owned and operated. I know you talked a little bit about this in your opening statement. Would it be helpful to expand this provision in any requirements developed in response to private labs, as well? Would it be helpful? And also, would it be appropriate to do so?

*Dr. Casagrande. Yes. I mean, as was mentioned by my other panelists, that -- biosafety is independent of the funding source. It really depends on what are the manipulations you are doing, what is the pathogen you are working on. And so it doesn't make any sense to have such large gaps in oversight, support, guidance, et cetera.

*Mr. Guthrie. Okay, thank you.

And Dr. Koblentz, I know you are familiar with this because you authored the report, so I will ask you a question. On the BSL-4 laboratories, a group of international researchers you mentioned led by King's College London research that you participated in published the Global Biolabs Report 2023, which noted the number of BSL-4 labs

across the globe grew from 69 -- to 69 across 27 countries in 2022, up from 59 and 2021. So we mentioned that earlier.

But the report further notes the key trend is that the number of labs handling dangerous pathogens is rapidly increasing around the world, but the boom has not been accompanied by sufficient oversight, and raises biosafety and biosecurity concerns.

So the question: As we look to ensure greater maintenance, coordination, and oversight of biosecurity research, how do we ensure we are promoting and requiring similar standards internationally, particularly at those facilities which we are partnering or providing funding?

*Dr. Koblentz. Thank you for the question.

There is an international standard for biorisk management called ISO 35001 that could be adopted by labs around the world, whether they are BSL-2, BSL-3, BSL-4. These are standards that require labs to put in place a management system to ensure they are prioritizing biosafety and biosecurity. So there is a very readily-available standard that could be adopted.

What we haven't really seen is the resources being put

into educating labs about this, providing the training, providing the incentives for labs to do this. And certainly, the U.S. Government could do that by making that a condition of working with labs in terms of capacity building or training that we are doing for public health purposes, or for, you know, our biosecurity engagements.

We could be making more of an effort to ensure that these labs are adopting these standards, and working through internal organizations like the WHO to try and make that standard more of a universally adopted protocol within these labs, and I think that would provide a baseline that would definitely improve the level of biosafety and biosecurity.

*Mr. Guthrie. Okay, thank you.

And Dr. Pekosz or Dr. Hawley, would you like to comment on the question we just talked about? Do you have any -- all right, Dr. Pekosz, have you got a quick comment?

*Dr. Pekosz. Yeah.

*Mr. Guthrie. Yes, okay, yes.

*Dr. Pekosz. I think, you know, scientists around the world talk to each other about these kind of things. The organization of this becomes a political and a national

discussion that really has to involve other parties. But I think there is willingness among scientists to talk to each other internationally about this.

*Mr. Guthrie. Dr. Hawley?

*Dr. Hawley. Yes. I like to go back to the root of the situation. I think what we need is an oversight organization to look at the laboratories in the United States. The composition of that organization should include some laboratory workers, some people from the community, analogous to the membership on an IBC. And I think, when you have this oversight, then you can start adding ISO 35001, as other people have mentioned, or other standards.

Well, we really don't have any standards in biosafety, to the best of my knowledge. We have guidelines, the Biosafety and Microbiological and Biomedical Laboratories. That textbook, so to speak, is a risk-based approach to determine what kind of facilities, equipment, and procedures used for the type of work.

*Mr. Guthrie. Okay, thanks.

*Dr. Hawley. So, to me, an oversight committee or an oversight organization to look at research in the United

States would probably fill a lot of --

*Mr. Guthrie. My time has expired, so I --

*Dr. Hawley. -- identified.

*Mr. Guthrie. Thank you for that. Thank you.

I will yield back, Mr. --

*Mr. Griffith. The gentleman yields back. I now recognize the gentleman from New York, Mr. Tonko, for his five minutes of questioning.

*Mr. Tonko. Thank you, Chair Griffith and Ranking Member Castor, for hosting this hearing. And I thank our witnesses for joining us today and sharing their expertise.

The issue of lab safety is indeed an extremely important one, and worth today's discussion. I greatly value the work of our nation's scientists conducting research vital to protecting public health, and I appreciate the need for vigilance in ensuring that our labs are operated safely, ethically, and certainly, responsibly.

However, I remain concerned that basic science has become so politicized that we can't have a reasoned conversation on how to protect the public from disease without delving into unsupported conspiracies or unfounded

allegations about what scientists are doing in America's labs.

So, Dr. Pekosz, in your experience have reasonable discussions over topics like lab safety become more difficult in recent years due to politics?

*Dr. Pekosz. I think they have. I think institutions remain vigilant. I think the laboratory workers remain vigilant. But sharing this information to the general public has met with some pretty harsh responses in many cases. And under the guise of transparency, I think there is a duty for our scientists to really communicate to the general public what we are doing and how safe it is.

But some of the responses to those initial things have really been quite disturbing, and I think that causes scientists to really then go back into their shell and talk amongst themselves more and, again, not communicate out to the general public, which, again, is a self-fulfilling prophecy, right, in terms of then having mistrust or a lack of trust in those entities when there is no communication.

*Mr. Tonko. Thank you. And I certainly believe that what we do here in policy format needs to be science-based

and evidence-based, absolutely critical that that be the given situation.

So Dr. Koblentz and Dr. Casagrande, you both stated in a recent New York Times op ed that pathogens do not care about politics, and that we need to forge an informed, bipartisan path forward. You also wrote that, even though the weight of the evidence on COVID-19's origins points to an animal-to-human jump, we nonetheless should use the pandemic as an opportunity to examine current lab safety protocols.

While I agree with that sentiment, it sometimes seems like some of my Republican colleagues continue to conflate legitimate issues about lab safety with allegations that some renowned scientists are somehow covering up the origins of COVID-19. So, Dr. Koblentz, why is it important that we move forward with the conversation about lab safety in a politically neutral and evidence-based way?

*Dr. Koblentz. You know, even if this pandemic had no linkage to any laboratory, we know the possibility exists that work with either a, you know, a naturally occurring virus that is brought back into a lab for characterization and understanding its risks to the kinds of work with

potential pathogens that have been conducted previously, right, could result in an accident.

And the fact that we know that is a possibility means we need to be doing more to try and reduce that risk and prevent the possibility from happening. And the fact that we can't rule out the role of the ones who do virology should also provide incentive for us to have better standards and oversight and transparency on these kinds of labs, not just in China, but in the U.S. and around the world.

So I think, for all those reasons, this is an important topic to be addressing, regardless of the specifics of the controversy you are talking about.

*Mr. Tonko. And Dr. Casagrande, would you want to add to that concern?

*Dr. Casagrande. Yes. I think, much like Three Mile Island kind of transformed our thinking about nuclear power and a series of aviation disasters transformed our thinking about aviation safety, I think this pandemic, like Dr. Koblentz said, just illustrates the potential consequences of an accident, even if it had no laboratory origin.

And because the consequences can be so dire, investments

in preventing those consequences on the order of aviation or nuclear power are definitely warranted. And that is not a political question.

*Mr. Tonko. And Dr. Hawley, in your testimony you write that reports on lab incidents must be -- and I quote -- "characterized by openness and engagement by all individuals,'' and you also shared that one of the best ways to reduce risks of an accident is by developing productive relationships with scientists.

How can the politicization of science and maligning of scientists get in the way of efforts to improve biosafety?

*Dr. Hawley. Well, personally, I have spent a lot of time in the former Soviet Union countries looking at laboratories being funded by the Department of Defense in order to redirect some of the efforts of the former biological warfare scientists. And I have found that the development of interpersonal relationships, communications, and trying to earn the individual's trust and enhance transparency -- and I think it begins with the development and sustainment and nurturing of interpersonal relationships. And to me, that is most important. And to the best of my

knowledge, organisms do not have any political affiliation at the present time.

*Mr. Tonko. Okay, we are there. I thank you.

And with that, I yield back.

*Mr. Griffith. The gentleman yields back. I now recognize the chairwoman of the full committee, Mrs. McMorris Rodgers, for five minutes of questioning.

*The Chair. Thank you, Mr. Chairman.

Dr. Koblentz, the United States scored 9 out of 10 on dual-use research governance, while China scored 0. That is obviously concerning, given the dual-use research on pathogens as obvious military applications. Can you explain what factors led to the differences in those scores?

*Dr. Koblentz. Certainly. So the United States scored, I think, 5 out of 10 because our primary mode of oversight is through the NIH review of dual-use research and through the DURC Policy and through the P3CO framework. And so -- and the United States also does awareness-building activities through the National Science Advisory Board for Biosecurity, and we have local stakeholder groups like the American Society for Microbiology that have codes of conduct and codes

of ethics that govern the research being done by their scientists. So those factors are what gave the U.S. the score it got for dual-use research oversight, which is better than most countries, but still not a perfect score by any means.

In contrast, China doesn't have in place now any meaningful oversight of dual-use research. There is on the books a biosecurity law from 2020 that calls for the development of such a system within China. But those regulations have not yet been promulgated within China, and so there is no active oversight over the research that is being done to monitor and oversee it, and whether or not it is -- poses any dual-use risks or not.

So I do hope that that will be forthcoming in the near future, and we will certainly update our report when we do it next if China and the U.S. make progress in those areas.

*The Chair. Okay. Thank you, I appreciate that clarification.

Dr. Casagrande, for risky research involving dangerous pathogens, why is more transparency about biosafety standards and communicating best biosafety practices important?

*Dr. Casagrande. Thank you for the question.

The communication of best practices is important because each lab has very -- has thought leaders who are carefully considering the risks that they face, and has implemented particular mitigations to address all those risks and make them as minimal as possible. This is often due to the creative thought and careful effort of these individuals. And though it is created to address risks that they have found personally in their laboratories, those same mitigations could be beneficial in many, many institutions. But people don't think of sharing those innovations and best practices.

So understanding those and communicating those would enable everyone to benefit from them, instead of reinventing them over and over again. It would be a much more efficient use of labor.

*The Chair. Thank you. Would you speak to how it may benefit the public, more transparency and communication?

*Dr. Casagrande. Sure. The sharing of these best practices would benefit the public by, one, making sure our tax dollars are best spent on doing the actual research, as

opposed to mitigating the risks of the research; and two, making labs across the United States safer without actually having to, you know, do trainings or anything like that. It would be just communicating all the great work that has already been done inside these containment labs.

*The Chair. Would you speak -- would you give us your thoughts on what aspects of lab operations, lab safety could be made more transparent?

*Dr. Casagrande. Could be made more transparent?

*The Chair. Yes, specific -- like, what aspects of the operations and the --

*Dr. Casagrande. Sure. Well, I think the public -- as was mentioned on this panel, I don't think the public appreciates the great effort that is going on already, how much effort is spent on emergency response protocols, how much effort is spent on medical surveillance, how much effort is spent on, if there is an exposure, what those workers do, in addition to all of the engineering controls and equipment that is spent.

People often conflate the concept of an incident in the lab to an outbreak. And in fact, there is an incident that

could occur, and the vast majority of those are mitigated by the equipment and procedures in place and don't result in an infection. But if an infection were to occur, there is a lot of procedures in place to isolate the worker and monitor them so that they don't necessarily infect anyone else. So only a very tiny minority of workplace infections lead to secondary infections.

And so I think, because there is a lack of awareness on all the different measures that exist inside U.S. laboratories, I think people often think that you start at spilling a flask, and then instantly you have a pandemic. And there is many, many steps in between those two that are mitigated by all the measures already in place.

*The Chair. So it sounds like the increased transparency could play a role in actually improving lab safety, also.

*Dr. Casagrande. Yes, especially the public's perception of lab safety. I don't think there is a good appreciation of all the efforts that are currently in place.

*The Chair. Okay, thank you. Thank you all again for being here.

I yield back.

*Mr. Griffith. The gentlelady yields back. I now recognize the chairman of the Energy Subcommittee, Mr. Duncan of South Carolina, for his five minutes.

*Mr. Duncan. Thank you, Mr. Chairman. And I think, when we talk about transparency, the Chinese Government was not transparent about what happened in Wuhan.

And I was amazed to hear Mr. Tonko talk about conspiracy theories. During the pandemic, things that were dubbed as conspiracy theories by the left were actually proven to be correct in the long run. The Wuhan virus was -- originated in Wuhan, China. Whether it was natural or man-made doesn't matter. U.S. tax dollars did go to fund grants at the Wuhan Lab for gain of function research, and that was a conspiracy theory before and now it has been proven. So over and over and over, and I just want to push back on that.

Dr. Koblentz, a year ago today you presented at a meeting held at NIH about oversight of research with potential pandemic pathogens. A section of your written statement dealt with the mishandling of the EcoHealth Alliance proposal and grant. You noted that EcoHealth's

research project concluded in vivo experiments at the Wuhan Institute of Virology to determine the risk of wild bat-related coronaviruses spilling over into human populations.

Hey, we saw that.

This proposal was flagged by the NIH program officer as potentially involving research covered by the 2014 gain of function funding pause. NIH included a requirement in the EcoHealth grant that "if any of the chimeric viruses generated under the grant showed evidence of enhanced virus growth greater than 10 times that of the original virus from which they were created, the grantee must immediately stop all experiments with these viruses, and provide NIH and the Wuhan Lab's Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.''

So wasn't the inclusion of the excessive virus growth policy a tacit admission that -- by the NIH that such research could be -- reasonably be anticipated to produce a virus with enhanced virulence or transmissibility, even if it was unexpected or unintended? Yes or no.

*Dr. Koblentz. Yes, I do think it could have been

reasonably anticipated.

*Mr. Duncan. Okay. Wasn't the proper course of action for NIH to take was to refer this proposal to the HHS P3CO review group to assess the risk and benefits of the research, and recommend how NIH should proceed with the grant? Yes or no.

*Dr. Koblentz. I think that would have been -- the appropriate method would have been to review -- forward that proposal to the department-wide --

*Mr. Duncan. I take that as yes. But the NIH did not make such a referral, isn't that correct?

*Dr. Koblentz. Correct.

*Mr. Duncan. Would you agree that NIH failed to properly monitor the conduct and outcomes of this research?

*Dr. Koblentz. Yes.

*Mr. Duncan. In year four of the EcoHealth grant, the Wuhan Lab conducted this experiment with humanized mice infected with chimeric coronaviruses, and there was excessive virus growth. EcoHealth did not stop the experiment, and did not immediately notify the NIH, as required under the grant terms. Even worse, EcoHealth Alliance did not halt this

research as required, since it reported in its Year 5 Annual Progress Report that, "We continued with the in vivo infection experiments of diverse bat SARS-related coronaviruses on transgenic mice expressing human ACE-2.''

Doesn't this raise serious questions about EcoHealth's compliance with grant rules, and show a breakdown of NIH oversight responsibilities over such experiments of concern?

*Dr. Koblentz. Yes, it calls into question implementation of the grant.

*Mr. Duncan. So there was failure for oversight of the grant, research was done on coronavirus that -- in mice that could be transmitted to humans, there were a lot of mistakes made, and I appreciate your forthcoming with that.

And with that I yield back, Mr. Chairman.

*Mr. Griffith. I thank the gentleman for yielding back, I appreciate his questions, and now recognize the gentleman from Alabama, Mr. Palmer, for his five minutes of questioning.

*Mr. Palmer. Thank you, Mr. Chairman.

According to an excerpt from reporter Allison Young's new book, "Pandora's Gamble,'' a researcher from the

University of Wisconsin nearly contracted a lab-created bird flu virus. I think that was in December 2019. The researcher was accidentally exposed, and potentially -- to potentially contaminated air.

And what concerns me is that, according to Ms. Young's reporting, the state and local health officials weren't notified about the accident. And I really think this is part of what we need to address in terms of oversight and more rigorous controls, is that not only do we want to make sure we don't have an accident like this, but if one does occur we don't sit on it.

So I would like for your response to that from each of you, if you don't mind.

*Dr. Casagrande. I'll be happy to respond, Representative Palmer.

So I think one of the things that we have noticed in work with containment labs across the U.S. is that they have different protocols for what happens after an exposure. And once again, this is partially because of a lack of sharing of innovations or best practices.

In some cases, every worker is given a card that they

can present to the medical system when they are exposed to an extremely unusual virus that that practitioner might not have ever seen in their life about treatments, about risks, et cetera, and then they can present that card directly when they present to the medical system. And that is an innovation that is not copied everywhere. And the reason why it is not copied everywhere is it hasn't been implemented into best practices or standards yet, nor communicated.

There is also different rules about how you isolate at home, and what flu watch looks like, how often you take your temperature. And so these are the exact types of things that better "standards'' or guidance could focus on, more specific guidance and standards.

*Mr. Palmer. In the article that you and your colleague, Dr. Koblentz, wrote, you talked about -- that the U.S. has taken a reactive and haphazard approach preventing lab accidents and misuse of high-risk science. But -- that is part of my concerns about what happened in Wisconsin.

But you also made the point that the U.S. has more labs than any other country. Does the U.S. have these labs that are not located in the United States? Do you know if -- when

you talk about the U.S. has more labs, are they all located in the United States, or do we have labs elsewhere?

*Dr. Casagrande. All the labs we cover in our report, which are BSL-4 and BSL-3 enhanced labs, these are all U.S. labs that are in the United States of America. The United States does have labs overseas, but they are not in this category of BSL-4s or BSL-3 enhanced that are a part of this report.

*Mr. Palmer. Okay. But given your concerns about research in the U.S. -- and I had to step out, so I may have missed some of this, Mr. Chairman -- but do you also have concerns about U.S. funding through grants or sub-grants, and the oversight that is applied to the labs where those grants or sub-grants go?

*Dr. Casagrande. Yeah. I would like to see the U.S. apply the same standards for biosafety and biosecurity that we have here with laboratories that we are working with overseas that might not be -- you know, different countries have different biosafety and biosecurity rules, and this is one of the issues that becomes kind of complicated when you are trying to foster international collaborations. So it

would be advantageous to try and harmonize those biosafety and biosecurity standards in order for us to facilitate international cooperation.

But overall, I think it is the U.S. advantage to use our grants and collaborations as a way to try and increase the level of biosafety and biosecurity in the labs we are working with overseas.

*Mr. Palmer. It would help us do that if we had a really rigorous set of oversight guidelines that we could implement.

And, I mean, you talked about the National Science Advisory Board for Biosecurity unanimously approved some safeguards that I assume haven't been implemented.

*Dr. Casagrande. They have unanimously approved the recommendations that have gone --

*Mr. Palmer. The recommendations, all right.

*Dr. Casagrande. -- to the White House, and they are being considered there. But it will be up to the, you know, the executive branch, with the cooperation of Congress to actually implement the recommendations --

*Mr. Palmer. Well, the main point I would want to make,

Mr. Chairman, is that this board unanimously approved these guidelines. And I think that is where we need to really focus right now for upgrading our biosecurity, and maybe having something rigorous enough that can be applied through the grants and sub-grants.

*Mr. Griffith. I appreciate that.

*Mr. Palmer. And I yield back.

*Mr. Griffith. The gentleman yields back. We will notify everybody that votes have been called. We are going to try to get our last two folks in before that happens, or before we have to leave, so that everybody doesn't have to wait for us to come back.

Mr. Ruiz is now recognized for his five minutes of questioning.

*Mr. Ruiz. Thank you very much.

As ranking member of the Select Subcommittee on the Coronavirus Pandemic, we have been looking at this very issue. So like the issue of how do we balance safety with the necessity of robust scientific research so that we can prevent and respond to public health emergencies like the COVID pandemic.

Hopefully, we can all agree that lab safety is essential, and that there are ways to accomplish a safe lab environment without stifling breakthroughs in innovation and scientific discovery. I appreciate the testimony of our witnesses for highlighting some ways that we might accomplish those complementary goals.

So Dr. Casagrande, one suggestion that you proposed in your testimony is to make sure that privately-funded labs doing work with certain pathogens are subject to similar oversight requirements as publicly-funded ones. Can you explain the importance of uniformity and transparency in lab safety guidance, irrespective of funding sources?

*Dr. Casagrande. Yes. As was mentioned by the other panelists, the risks are independent of the funding source. It relates to the experiments that are being done and the pathogens studied. Also, it is -- it helps level the playing field. The unification of standards helps make sure that the labs that are doing the most to be safe -- and there is many, many safe labs within the U.S. -- aren't -- don't have a competitive disadvantage to the labs that are skating by.

And so standards and, uniform standards that apply

universally, help level the playing field and ensure that the safest labs aren't disadvantaged.

*Mr. Ruiz. Thank you.

Dr. Pekosz, as someone working directly in a lab setting, do you agree that there should be one set of biosafety rules that everyone follows?

*Dr. Pekosz. Absolutely. I think that funding sources should not play a role in terms of setting biosafety guidelines.

I do feel that biosafety guidelines need to be very clear and precise, because there is an area where research with viruses such as influenza, something that is a common concern, might be conflated with research on viruses like Ebola virus. And it is important to note that there are very distinct differences between what we want to do in terms of our biosafety and how we want to monitor for those types of experiments.

*Mr. Ruiz. You know, in addition to that I am concerned that some of the bans and moratoria on research using infectious pathogens that have been proposed by some of my Republican colleagues do not adequately strike the balance

that we need between mitigating risk while making sure we stay well positioned in safe labs to achieve scientific breakthroughs.

So, Dr. Pekosz, do outright bans on research using infectious pathogens strike the right balance between the risks and rewards of infectious disease research?

*Dr. Pekosz. Absolutely not. I mean, not only do they slow progress of research, but they have ripple effects. Trainees that come through the laboratory are less likely to be interested in this type of research because they hear stories about people's research being paused, a Ph.D. student not being able to finish their research because of a of a pause that has been implemented, and that has ripple effects on their ability to want to go into this area and train.

And I think we know from the COVID-19 pandemic we need to strengthen our public health infectious diseases workforce. We can't have people leaving them or being hesitant to go into that. We have seen the benefits that that has.

*Mr. Ruiz. So can you share some examples of proposals for lab safety improvements that, from your perspective,

adequately weigh the risks of certain research against public benefits? And describe why they strike that balance correctly.

*Dr. Pekosz. I think it is important to note that, once a pathogen and a technique has been allocated a certain level of biosafety, that provides a large level of security for an individual. Experiments that were then done in those areas already carry with it a high level of security and a high level of safety.

I think we have to realize that often times the bar is set very high at the beginning. And when we see things later on that are happening -- sometimes this gain of function research is considered that -- often times they still fall underneath the safety considerations that are good to protect the individuals that are working there.

*Mr. Ruiz. Well, let me ask you another question that I am grappling with, as ranking member of the other committee, is that -- you know, how do we build the relationships or the influence, the incentives, or accountability structures to ensure that there is lab safety in other countries and some countries that may not be such allies with us, one.

And two is those countries may very well continue with these other type of research, despite what the U.S. does, which may put us at a vulnerable position in the future if we ever need to investigate a virus that another country has investigated further.

So how do we build the international structures to make sure that labs are safe all around the world?

*Dr. Pekosz. It is a challenging question, but I would say it starts with the scientists. The scientists communicate with each other quite well and quite effectively. If you start with that, and build the consensus as to what needs to be important, what is important to be done, you can then work through the political system to try to get that implemented across board.

*Mr. Ruiz. Thank you.

*Mr. Griffith. The gentleman yields back. I now recognize the gentlelady, vice chair of the subcommittee from Arizona, Mrs. Lesko.

*Mrs. Lesko. Thank you, Mr. Chair. First of all, I want to say thank you to you, Mr. Chair, because this is such an important issue.

And I want to say thank you to all of you, because it is absolutely vital that we pay attention to this issue. You know, my question kind of relates to what Dr. Ruiz was talking about, but I am going to ask it of Dr. Hawley.

In 2014, the Obama Administration paused funding for gain of function research due to the risk and safety incidents at Federal laboratories that year. Then the NIH resumed funding in 2017 for gain of function experiments shortly after NIH, as we have all talked about before, awarded a grant of this type to EcoHealth Alliance. Around $600,000 of that grant went to the Wuhan Institute of Virology.

As you know, COVID-19 happened. We have had different hearings. It seems more likely than not, to me, that COVID-19 came from a lab leak from the Wuhan lab. Dr. Redfield, the former CDC director, has testified he thinks that there were gain of function research that was going on there, and that we partially funded it. And Dr. Redfield actually told the other subcommittee that I am on and the COVID Select Subcommittee, that he thinks we should put a pause on gain of function enhanced potential pandemic

pathogen research until we know -- until we have a broader discussion of it, until we have more biosafety in place. What do you think?

*Dr. Hawley. It is just my opinion, ma'am, but I agree with your comments, and I think it is most important to have an oversight group to take a look at this.

There are gain of function experiments that are very beneficial, and we have to have the appropriate panel of individuals -- scientists and lay members -- to look at that and evaluate that, and based upon -- I keep repeating myself -- the risk-based approach to see whether or not it will be beneficial. But I think we do need some sort of oversight, and there is no question about that.

*Mrs. Lesko. Yes, and since it sounds like, from what all of you said, there is no centralized location in the Federal Government for oversight, and that some private labs don't have any oversight, should we, do you think, pause this very enhanced -- I call it E-triple-P -- research until we get the biosafety apparatus in place?

*Dr. Hawley. Yes. But again, I emphasize the fact that we do need to start with oversight.

*Mrs. Lesko. Yes, okay.

*Dr. Hawley. And we are trying that. There is precedent for not only oversight, but community involvement with the Boston Public Health Commission, the liaison with the people in the community. They know what is going on.

The Containment Laboratory Community Advisory Committee in Frederick, Maryland has an interaction between the laboratories of Fort Detrick and the community members, whereby we can openly have transparency, ask questions, publish near misses, and so forth. So to me, that is a form of oversight and gaining the respect from the community.

*Mrs. Lesko. Thank you. And my last question is for you, too, Mr. Hawley. You had mentioned earlier in your testimony that you don't think a Federal agency that provides grants for bioresearch should be the same one that is in charge of overlooking biosafety. I think that is what you said in so many words. Is that accurate?

And are you talking about the NIH? That is my question.

*Dr. Hawley. I am not going to name any organization, but the bottom answer to your question is yes. I know, when I was at Fort Detrick as a command biosafety officer, we had

labs internationally, and it was my job to go out and look and monitor those labs. So we did have oversight, even though we did provide funding.

*Mrs. Lesko. All right. Well, thank you very much.

Thank you to all of you. Great communication, great information, I should say.

Thank you, and I yield back.

*Mr. Griffith. I thank the gentlelady for yielding back. If there are no further members wishing to ask questions, I would like to thank all of our witnesses again for being here today.

In pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record, and I ask that witnesses submit their response within 10 business days upon receipt of the questions.

I further, in compliance with committee rules, would remind special advisers Kennedy and Jack that they may receive test questions, and we do expect those answers within 10 business days, as well.

[Laughter.]

*Mr. Griffith. That being said, without objection, the

subcommittee is adjourned.

[Whereupon, at 4:14 p.m., the subcommittee was adjourned.]