

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

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

APRIL 27, 2023

Serial No. 118–30



Published for the use of the Committee on Energy and Commerce
govinfo.gov/committee/house-energy
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

55–663 PDF

WASHINGTON : 2025

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THE BIOSAFETY OF 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, DC.

The subcommittee met, pursuant to call, at 2:29 p.m. in room 2322, Rayburn House Office Building, Hon. H. Morgan Griffith (chairman of the subcommittee) presiding.

Members present: Representatives Griffith, Burgess, Guthrie, Duncan, Palmer, Lesko, Cammack, Rodgers (ex officio), Castor (subcommittee ranking member), DeGette, 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 5-minute opening statement.

OPENING STATEMENT OF HON. H. MORGAN GRIFFITH, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

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 1 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 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 subgrantee, 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 governmentwide effort to un-

derstand 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:]

Good afternoon and welcome to today's hearing. This is the second in a series of oversight hearings examining pandemic risks.

On February 2nd, the subcommittee held a hearing on how to quickly identify the root cause of a disease outbreak or biological incident. That hearing examined what structures, technologies, and capacities are needed to investigate more effectively the origins of disease outbreaks in the future.

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 these guidelines. The NIH clearly did not enforce those guidelines with EcoHealth Alliance and the Wuhan Institute of Virology into novel coronaviruses.

While the hearing today is not explicitly related to the origins of COVID-19, our examination of biosafety has to be informed by the real possibility, and at this point perhaps the likelihood, that a pandemic which killed over a million Americans was the result of an accident at a laboratory that received NIH funding. The Wuhan Institute of Virology enjoyed close ties to U.S. researchers, and was the beneficiary of technology transfers from the U.S. to China.

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 the perils of this kind 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.

In response to the terrorist attacks on September 11, 2001, and the anthrax mailings, over the last two decades our nation has seen a rapid expansion in the number of high-containment laboratories.

These facilities are expensive and complex to build, maintain, and run. Research conducted in these laboratories involves pathogens that can cause serious, potentially life-threatening disease and, in the case of biosafety level four (BSL-4) laboratories, diseases for which no vaccine or therapy exist. 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.

In 2000, there were less than ten 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 biosafety level 3 (BSL-3) facilities. It is not just increased risks from the number of high-containment labs being built that is concerning. 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.

The motivation for holding this hearing, is that our existing oversight framework for risky research. Whether it's called gain-of-function research or whether it's called research with enhanced potential pandemic pathogens. I fear we have not kept pace.

In fact, 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. It was intended to apply to all executive branch agencies. It has been implemented by exactly one Department, Health and Human Services.

But, HHS has largely delegated implementation to the NIH, a funding entity who has shown a lack of significant oversight towards risky research with their grantee EcoHealth Alliance and subgrantee the 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 U.S. or abroad.

NIH is not only indifferent, but reflexively hostile to outside oversight. NIH has stonewalled and slow-walked our document requests related to the EcoHealth Alliance grant.

As a result of this institutional indifference, an unknown number of accidents at high-containment laboratories are unreported and there is no government-wide effort understand the frequency and nature of laboratory accidents.

Since last October, NIH has not provided the information about an in-house National Institute of Allergy and Infectious Diseases gain-of-function experiment involving a highly lethal clade of monkey pox classified as a federal select agent.

NIH won't even tell us if these experiments have or are taking place. It makes me wonder what the NIH has to hide. How bad is it when they won't even give the authorizing committee the information. We have to assume they are doing something very dangerous.

I'll 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 that NIH is not an enforcement agency.

I'm beginning to think he's right. It may be time for us in Congress to relieve NIH of the burden of conducting risky research at the institutions it funds.

Mr. GRIFFITH. I yield back. I now recognize the ranking member of this subcommittee, Ms. Castor, for her 5 minutes for an opening statement.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

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 multinational 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 on Energy and Commerce

**Opening Statement as Prepared for Delivery
of**

Subcommittee on Oversight and Investigations Ranking Member Kathy Castor

Hearing on "The Biosafety of Risky Research: Examining if Science is Outpacing Policy and Safety"

April 27, 2023

Thank you, Mr. Chairman, and thank you to our 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're 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. There are extensive oversight and safety requirements that already exist in our research centers today, and I hope that our witnesses can help us better understand that.

Americans can be proud of the U.S.-led research in laboratories in the United States and across the world, including with infectious pathogens. When the Covid-19 pandemic hit, we relied on this research to spur vaccine development in record time. 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. When more infectious flu variants—like 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'll discuss at tomorrow's hearing, viral research is critical to helping us prepare for and address the emerging threat of anti-microbial 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, vaccine development, or monitoring viruses. Many of these proposed research restrictions and criticisms target research in other countries, including in some countries where viral outbreaks have originated in the past. But disease knows no borders. Since I've come to the Congress, we have had to address global outbreaks of MERS, Ebola, Zika, and, of course, the 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

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multinational biosafety commitments, so that research in foreign countries can be done safely and up to the same high standards we use in 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 certainly will. 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. 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 discussions we have must be done in a thoughtful manner with the input of the people who actually conduct research on dangerous pathogens every day.

No one has a greater stake in lab safety than researchers working in America's labs. These are the people who do the hard work to develop ground-breaking 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.

I look forward to the discussion today and I yield back.

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 5 minutes for an opening statement.

**OPENING STATEMENT OF HON. CATHY McMORRIS RODGERS,
A REPRESENTATIVE IN CONGRESS FROM THE STATE OF
WASHINGTON**

Mrs. RODGERS. 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 Mrs. Rodgers follows:]

Chair Cathy McMorris Rodgers
House Energy and Commerce Committee
Oversight & Investigations Hearing
"The Biosafety of Risky Research: Examining If Science Is Outpacing
Policy"
April 27, 2023

Mr. Chairman, thank you for holding this hearing on the biosafety of risky research. With a new book out this week about lab accidents, the 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.

COVID-19

We still do not know how the COVID-19 pandemic started. However, more information has heightened our suspicions that the origins of the pandemic were linked to a lab incident. Regardless of one's view of how the pandemic started, we need to scrutinize the biosafety of risky research.

The COVID-19 pandemic has been a catastrophe for the U.S. and the world. More than a million lives have been lost in our nation.

In addition, the pandemic cost the U.S. economy more than \$15 trillion dollars. The thought that this awful event might have been avoided by stronger biosafety practices warrants a hearing on this important topic.

Stymied by public health agencies and leaders

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 the NIH have persisted in foot-dragging, stonewalling, or just not engaging on legitimate questions.

Three years into this pandemic, the NIH still won't provide meaningful information or straight answers to the committee about how the P3CO framework governing risky research was developed, and 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.

EcoHealth's failures

We still do not have complete information about how NIH experts in 2016 allowed EcoHealth Alliance, through its subgrantee 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 in 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 the HHS Inspector General.

Under other circumstances, EcoHealth's failure to stop the experiment and immediately notify the NIH would be called a near-miss safety incident. It may have even been a real incident, but the NIH has no way of knowing because EcoHealth committed another failure – it did not obtain the laboratory notebooks and electronic files from the Wuhan lab. Yet even with these compliance failures NIH holds EcoHealth in good standing and is giving them even more funding. No changes in policy. No lessons learned.

Dangerous mpox experiment unexplained

But NIH's reluctance to deal with biosafety standards is not limited to EcoHealth. A leading scientist at the NIH talked to Science magazine about an experiment he was conducting. The experiment involved transferring a gene from a more lethal but rare version of mpox and putting

it in a more transmissible version of mpox, I and other Republican leaders raised questions with NIH about this experiment. Almost six months later, we still have no engagement from the NIH.

Where is the accountability?

No consequences. No accountability. No seriousness from the NIH, the co-editor of the biosafety manual used by research labs across the U.S. No wonder the credibility of the NIH has suffered.

As we will learn today, we have gaps in policy and in data in the area of biosafety. However, even addressing the 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 that trust is having good-faith, honest discussion about biosafety in laboratories.

We need critical research for cures and medical countermeasures. However, for years this committee, and particularly 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.

I thank the witnesses for their participation, especially testifying in-person on short notice. We appreciate your cooperation.

Mr. GRIFFITH. I thank the gentlelady. I now recognize the ranking member of the full committee, Mr. Pallone, for his 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

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 on Energy and Commerce**Opening Statement as Prepared for Delivery
of
Ranking Member Frank Pallone, Jr.*****Hearing on "The Biosafety of Risky Research: Examining if Science is Outpacing Policy and Safety"*****April 27, 2023**

When the coronavirus pandemic began, many researchers with the training and expertise 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. The public saw the benefits of this research in real time, with vaccinations becoming available at an unprecedented pace.

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. 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 had 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. We should take immense pride in the extent and quality of America's scientific contributions toward understanding and addressing the COVID-19 pandemic. 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 are to have any hope of preventing and defeating future pandemics.

Studying dangerous pathogens requires carefully considered protocols and persistent oversight to ensure that the work is conducted safely. When it comes to risk, the researchers working in high-containment labs are those who have the most to lose when laboratories are not adequately maintained, 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.

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. These actions are harmful and counterproductive because we must have scientists at the table if we want

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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.

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 5 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 5 minutes of opening statement, please.

STATEMENTS OF ROCCO CASAGRANDE, Ph.D., BOARD CHAIR, GRYPHON SCIENTIFIC; GREGORY D. KOBLENTZ, Ph.D., ASSOCIATE PROFESSOR AND DIRECTOR, BIODEFENSE GRADUATE PROGRAMS, GEORGE MASON UNIVERSITY; ANDY PEKOSZ, Ph.D., PROFESSOR OF MOLECULAR MICROBIOLOGY AND IMMUNOLOGY, JOHNS HOPKINS UNIVERSITY BLOOMBERG SCHOOL OF PUBLIC HEALTH; ROBERT J. HAWLEY, Ph.D, CONSULTANT, BIOLOGICAL SAFETY AND SECURITY

STATEMENT OF ROCCO CASAGRANDE, Ph.D.

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 have 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 underresourced 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 pro-

vide 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 event. 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:]

Rocco Casagrande, Ph.D.

Board Chair, Gryphon Scientific

Testimony Before the House Committee on Energy and Commerce

April 27, 2023

Thank you. I am honored that you invited me to speak about such a timely and important topic as laboratory safety.

Overview:

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 research 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:

1. Oversight
2. Research
3. Standards
4. Workforce
5. Resources
6. Mission

Specifics:

Regarding oversight, biosafety authority in the US 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 US without any federal oversight. Theoretically, a privately funded group could work on influenza virus in a makeshift laboratory and attempt to make a 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 and securely, or prevent them from continuing if safety or security is lacking. The US needs a unified biosafety system that can provide oversight for research on all dangerous pathogens (Risk Group 2+) regardless of the funding source or 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 biosafety over the past several decades. We currently lack data on how accidents occur or the factors that can effectively mitigate accidents. Historically, biosafety improvements have always added on to existing equipment, procedures or administration because there were no data suggesting which specific improvements were particularly effective vs 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. [For more information on the need for biosafety research see Ritterson and Casagrande, "Basic Scholarship in Biosafety is Critically Needed to Reduce Risk of Laboratory Accidents",

submitted along with this written testimony because the manuscript is openly available due to the courtesy of the American Society for Microbiology.]

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.

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 been historically under-resourced for various reasons. In most institutions, biosafety staff are paid out of overhead costs, instead of directly from research dollars, meaning that the 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 existing 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 biosafety workforce or providing oversight to all pathogen laboratories regardless of their funding source or specific pathogen

investigated. To fix this issue, either an existing or a new federal agency must be given the comprehensive mission of improving biosafety. [For more information on the need for a single federal entity with unified biosafety authority see Ritterson, et al “A Call for a National Agency for Biorisk Management”, submitted along with this written testimony with permission from the publisher.]

[For more information on other concepts to improve biosafety see Dettmann et al, “Concepts to Bolster Biorisk Management ”, submitted along with this written testimony with permission from the publisher.]

Some have argued that additional oversight of biosafety of the type I 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 bioeconomies. Specifically, Canada, Switzerland, Germany and the UK all have comprehensive oversight of pathogen laboratories. Switzerland’s cell-based biotechnology industry rivals that of the entire US. Both Switzerland and Canada have more laboratories that can study the world’s most dangerous pathogens per capita than the US. These suggestions would simply enable the US to catch up to its peers.

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 \$60M would provide sufficient funding to support this work (this sum is approximately 1% of NIAID’s 6BN annual budget). Moreover, this funding would have a large return on investment as it would lead to the identification of the biosafety measures that are truly valuable (allowing others to fall by the wayside), save every research institution from developing its own standards and training and alleviate difficulties of finding properly trained biosafety staff.

To close the oversight gaps I mentioned and adequately fund biosafety professionals to take on greater responsibilities would require more funding though the funding is clearly justified by the risks. The pandemic, which plausibly could have 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 event. Investments on the scale of a single major weapons program would transform biosafety in the US and more cost effectively mitigate a major risk facing the US. The right answer isn't to draw funds away from pathogen research, which is essential for creating treatments and cures to address the next pandemic, but to consider investments on the scale used to address other threats to the US.

Mr. GRIFFITH. I thank the gentleman for yielding back and now recognize Dr. Koblentz for his 5 minutes of opening statement.

STATEMENT OF GREGORY KOBLENTZ, Ph.D.

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 codirect with Filippa Lentzos at King's College, London. We've spent the last 2 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 12 new BSL-4 labs since the start of the pandemic. For five 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. Koblenz follows:]

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety

Prepared Statement of
Gregory D. Koblentz, MPP, PhD
Associate Professor
Director, Biodefense Graduate Program
Schar School of Policy and Government
George Mason University
April 27, 2023

Chair Rodgers and Subcommittee Chair Griffith, Committee Ranking Member Pallone and Subcommittee Ranking Member Castor, and other members of the Committee, thank you for the chance to speak with you today about the issue of *Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety*. My name is Dr. Gregory D. Koblentz, and I am an associate professor and director of the Biodefense Graduate Program at the Schar School of

Policy and Government at George Mason University
The opinions expressed herein are my own and do not necessarily reflect the views of George Mason University.

I welcome the opportunity to present the latest report of the Global BioLabs Initiative, a project I co-direct with Filippa Lentzos at King's College London. The Global BioLabs Initiative has spent the last two years collecting and analyzing data on high-consequence biological research facilities around the world and the national biorisk management policies that govern these labs. Biorisk management is an integrated approach to addressing the risks associated with the life sciences research enterprise, from accidents and inadvertent actions to deliberate misuse. Our project uses biorisk management as an overarching concept that encompasses biosafety, biosecurity, and the oversight of dual-use research.

The Global BioLabs Initiative, in cooperation with the Bulletin of the Atomic Scientists, created an interactive website GlobalBioLabs.org to document the location and key characteristics of high-consequence biological research facilities (BSL-4 and BSL-3+ labs), improve transparency about these facilities, and educate the public and policy-makers about biosafety, biosecurity, and dual-use research oversight.

Today, I would like to present the key findings from *Global Biolabs Report 2023* which contains our latest research analysis on BSL4 and BSL3+ labs around the world and assessments of the national biorisk management policies in place to ensure that these labs are operated safely, securely, and responsibly.¹ In addition, I will provide recommendations for strengthening global

¹ *Global BioLabs Report 2023* (London and Arlington, VA: King's College London and George Mason University, March 2023),

bio risk management. For more details about our analysis and recommendations, please consult *Global Biolabs Report 2023* available at www.globalbiolabs.org.

Trends and Key Messages

Since its inception in May 2021, the Global BioLabs initiative has identified more than 100 BSL-4 and BSL-3+ labs around the world that conduct high consequence biological research, with more planned and under construction. Europe is home to half of these labs while the United States is home to the single largest concentration of such labs. 11 out of the 20 highest-containment facilities that are planned or under construction are in Asia.

The Global BioLabs Initiative has also identified several trends that raise biosafety and biosecurity concerns given the global boom in construction of these labs, particularly where bio risk management oversight is weak.

BSL-4 Labs

The number of BSL-4 labs is rapidly increasing, with most of the new construction taking place in Asia. In 2021, we identified 59 BSL-4 labs in operation, planned, or under construction in 23 countries. In 2023, there are 69 BSL-4 labs in operation, planned, or under construction in 27 countries. The largest concentration of BSL-4 labs is in Europe with 26 labs, followed by Asia with 20 labs, North America with 15, Australia with three, Africa with three, and South America with one planned lab.

https://static1.squarespace.com/static/62fa334a3a6fe8320f5dcf7e/t/6412d3120ee69a4f4efbec1f/1678955285754/KC_L0680_BioLabs+Report_Digital.pdf

Three-quarters of all BSL4 labs became operational since 2000. This initial building boom was due to the anthrax letter attacks in 2001 and the SARS outbreak in 2003. The COVID-19 pandemic has led to another building boom: 9 countries have announced plans to build 12 new BSL-4 labs since the start of the pandemic. For 5 of these countries, this will be their first BSL-4 lab. Most of these new labs will be built in Asia including in India, Kazakhstan, the Philippines, and Singapore.

We also identified several notable trends regarding specific characteristics of BSL-4 labs. Approximately 75 percent of BSL-4 labs are in cities, where dense populations could exacerbate the impact of an accidental release. Over 60 percent of BSL-4 labs are government-run public health institutions, 15 percent are academic labs, and less than 20 percent are defense-related labs. Most BSL-4 labs are focused on human health. About half of all BSL-4 labs are less than 200 square metres in size, about the size of a tennis court. Only nine BSL-4 labs are more than 1,000 square metres in size.

BSL-3+ Labs

We have identified 57 labs in 28 countries that self-identify as BSL-3+, or BSL-3 enhanced, labs. These are BSL-3 labs that have adopted additional physical and/or operational biosafety and biosecurity precautions for carrying out particularly risky research. Examples of enhancements to BSL-3 labs can include additional training for staff, more rigorous emergency response plans, enhanced respiratory protection for personnel against aerosols, clothing change and shower-out protocols, HEPA filtration of lab exhaust air, effluent decontamination systems, and strengthened access controls and monitoring.

The 57 BSL3+ labs are evenly divided between government-run public health labs and university-based research labs, with 40 percent of labs in each category. 80% of BSL-3+ labs are in urban areas.

The most common pathogen studied in BSL-3+ labs is highly pathogenic avian influenza (HPAI). BSL-3+ labs have also been used to conduct research on novel pathogens such as the reconstruction of the 1918 influenza pandemic virus, as well as to conduct experiments to enhance the virulence or transmissibility of potential pandemic pathogens, more commonly known as ‘gain of function’ research.

However, there is limited national biosafety guidance, and no international guidance, on what constitutes BSL-3+. In addition, there has been little to no research demonstrating that these enhancements provide an adequate level of additional safety commensurate with the higher risk research conducted in these labs.

Assessing National Biorisk Management Governance

While COVID-19 demonstrated that all countries need a strong public health infrastructure to prepare for and respond to a pandemic, it is important to also ensure that pandemic preparedness activities are carried out safely, securely, and responsibly.

The Global BioLabs Initiative has developed a new method for assessing the strength of biorisk management governance—encompassing biosafety, biosecurity, and dual-use oversight—in each of the 27 countries that has, or plans to have, a BSL-4 lab. In 2022, the WHO endorsed biorisk management as an overarching concept for ensuring the responsible use of the life sciences.

The Global BioLabs Initiative's National Biorisk Management Scorecards are designed to provide concrete, quantifiable indicators of how well countries are implementing this concept. These scores are based primarily on whether a country has laws and regulations in place that address the metrics on our list. The scores cannot and should not be interpreted as evaluating how comprehensively or rigorously a country is implementing those laws and regulations or the level of compliance by labs on their territory. On the other hand, since these scores are based on national governance measures, they cannot capture biorisk management policies at lower levels of government or policies and practices within individual labs that are more stringent than national laws and regulations.

The National Biorisk Management Scorecards are based on 41 metrics: 18 for biosafety, 18 for biosecurity, and five for dual-use research. Our metrics were drawn from six international frameworks for biorisk management. Points for metrics were awarded based on publicly available, statutory measures; points were not awarded for guidance documents or voluntary guidelines. We found that biosafety governance was strongest followed by biosecurity while most countries scored poorly on oversight of dual-use research.

Biosafety

We assessed that 21 out of the 27 countries with BSL4 labs—roughly 80 percent—scored high on biosafety governance (see Table 1 in the appendix). Countries with high scores in biosafety have whole-of-government biosafety systems which includes national legislation, a dedicated entity responsible for enforcing this legislation, a national list of dangerous pathogens, whistleblower protection, comprehensive biosafety regulations, and a national biosafety

association. High-scoring countries also demonstrated a high level of engagement with international biosafety initiatives such as the WHO's Joint External Evaluations (JEE), the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), and the Global Health Security Agenda (GHSA) Action Package Prevent-3 (APP3) on Biosafety and Biosecurity. Among the national biosafety regulations we evaluated, the weakest areas were the lack of requirements to maintain an inventory of pathogens and to use personnel protective equipment (PPE).

Biosecurity

We're doing less well on biosecurity. Only 12 out of the 27 countries with BSL-4 labs scored high, with 9 countries scoring medium, and 6 low (Table 2). Countries with high scores in biosecurity have whole-of-government biosecurity systems which included national legislation, a dedicated entity responsible for enforcing this legislation, a national list of dangerous pathogens, whistleblower protection, and comprehensive biosecurity regulations. High-scoring countries also demonstrated a high level of participation in international biosecurity initiatives such as the Biological Weapons Convention (BWC), United Nations Security Council Resolution 1540, the Australia Group, the Biosecurity Working Group (GP BSWG) of the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, the WHO's JEE, the IEGBBR, and the GHSA's APP3. The biggest gap in biosecurity regulations was in screening DNA orders for sequences related to dangerous pathogens—only two countries have such policies in place. Only 11 countries include cybersecurity in their biosecurity requirements and only 12 countries mandate biosecurity risk assessments.

Dual-Use Research Oversight

The picture is even worse for governance of dual-use research. Only 1 country, Canada, scored high (Table 3). Two others scored medium and the other 24 countries we studied all scored low. Many of the countries with a low score received zero points meaning they have no mandatory or voluntary measures to provide oversight of dual-use research in the life sciences. To achieve a high score, a country needs to have national legislation and a dedicated entity with national oversight responsibilities, conduct sustained awareness-raising activities, offer whistleblower protection, and stakeholders that have adopted voluntary self-governance measures.

Overall Assessment of Biorisk Management

Among the 27 countries with BSL-4 labs in operation or under development, only seven of them scored high on biorisk management overall (Table 4). Five countries scored low on biorisk management overall and the rest fell in the medium range. Many of the countries building new labs, some for the first time, scored poorly on biorisk management (marked in bold in Table 3). However, since these labs have not yet been built, there is still time to strengthen their national laws and regulations on biosafety, biosecurity, and dual-use research to bring them up to international standards.

Governance and Stability

The National Biorisk Management Scorecards provide a snapshot of the status of national legislation and regulations, but they do not provide evidence of how well these measures are being complied with or enforced in each country. To provide a general sense of the ability of countries with BSL-4 labs to effectively implement their biorisk management policies, we created two indexes. The Governance index assesses to what extent a country's political system is effective, equitable, accountable, and independent. The Stability index assesses the level of domestic and international conflict, government repression, terrorism, political stability, and perceived government legitimacy, among other factors. These indexes are based on data generated by the World Bank, Transparency International, Freedom House, and others.

In our report, we combined the Governance and Stability index scores to create a National Context score. As seen in Figure 1 in the appendix, there are significantly more operational BSL-4 labs in countries that have a combined National Context score greater than or equal to 50. However, BSL-4 labs planned or under-construction are disproportionately located in countries that score in the bottom half of the National Context ranking. This raises concerns about the ability of these countries to effectively implement new or existing biorisk management laws and regulations.

Key Recommendations

The following recommendations provide concrete steps that laboratories, national governments, non-governmental entities, and international organisations can take to strengthen biorisk management.

Laboratory Level

All labs, but particularly labs conducting high-consequence research, should cultivate a strong culture of safety, security, and responsible research. This does not just apply to BSL-4 labs; high-consequence work with pathogens is also being conducted at BSL3+ labs, and even lower containment level labs should also be nurturing a culture of safe, secure, and responsible working practices. This dedication to biorisk management should encompass all levels, from students and technicians to principal investigators and laboratory directors. Developing a culture of safe, secure, and responsible working practices is not a one-off event, but a continual effort.

A concrete step that labs conducting high-consequence work with pathogens can take to institutionalize the importance of biorisk management is to adopt the international standard for biorisk management known as ISO 35001.² This standard provides a template for establishing a management system to identify and mitigate safety and security risks as part of a continual improvement process. Since the standard is more concerned with the risk assessment and mitigation process than specific containment or security measures, it is compatible with existing national biosafety and biosecurity laws and regulations. For labs operating in countries without comprehensive biosafety and biosecurity laws and regulations, it provides a roadmap to best practices in biorisk management. The standard is low-hanging fruit since it has already been negotiated, is sitting on the shelf, and can be adopted by labs relatively quickly.

National Level

² “ISO 35001:2019 Biorisk management for laboratories and other related organisations,” International Standards Organization, November 2019, <https://www.iso.org/standard/71293.html>

At the national level, all countries with high consequence biological research facilities should have whole-of-government biorisk management systems, including comprehensive laws, regulations, and institutions that require multidisciplinary risk assessments of proposed research for safety, security, and dual-use implications. The gold standard is a national-level government entity or entities with jurisdiction over public and private facilities that can enforce these laws and regulations.

In adopting, implementing, reviewing, and updating national laws, regulations and other measures on biosafety, biosecurity and dual-use research, states should consider incorporating relevant voluntary global standards on biorisk management including the 2022 WHO Global Guidance Framework for the Responsible Use of the Life Sciences,³ the 2019 World Organization for Animal Health (WOAH) Guidelines for Responsible Conduct in Veterinary Research,⁴ and the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists.⁵

Standards for field biosafety are much less developed than for laboratory biosafety. Field biosafety policies and practices are designed to prevent researchers from becoming exposed to an infectious disease while collecting biomedical and environmental samples in the field and

³ World Health Organization, *Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-use Research* (Geneva: World Health Organization, 2022), <https://apps.who.int/iris/rest/bitstreams/1463719/retrieve>

⁴ World Organization for Animal Health, *Guidelines for Responsible Conduct in Veterinary Research: Identifying, Assessing, and Managing Dual Use* (Paris: World Organization for Animal Health, 2019). <https://www.woah.org/app/uploads/2021/03/a-guidelines-veterinary-research.pdf>

⁵ Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists, <https://www.interacademies.org/sites/default/files/2021-07/Tianjin-Biosecurity-Guidelines-Codes-Conduct.pdf>

handling wild animals. Few countries have national field biosafety standards and there is no international guidance available on this subject. As the Director of National Intelligence testified to Congress in February, “A lack of global field biosafety standards and protective measures continues to raise concerns of viral spillover worldwide. Increased interest in field sampling and advanced biological research since the onset of the COVID-19 pandemic, poor training, and lack of international inspection and standardized regulatory requirements have all been implicated in contributing to the risk of contamination and/or breaches in biocontainment.”⁶ Countries should develop field biosafety standards for zoonotic pathogens as a matter of priority.

Countries that do not already have a national biosafety association should encourage and support the creation of one by biosafety and biosecurity professionals. These non-governmental groups can provide valuable support to labs that conduct high-consequence research by providing training and professional certification, sharing best practices, and supporting the expansion of professional networks.

Countries with high consequence research facilities should also provide complete, regular, and transparent reporting as required by the annual confidence building measures of the BWC and under UN Security Council Resolution 1540. While most countries with BSL-4 facilities generally submit these documents, there is no international requirement mandating this information, and countries are not specifically encouraged to submit information on BSL3+ labs. Confidence-building information should be made publicly available by all countries. So far, only nine of the 20 countries with operational BSL-4 labs that submit confidence-building measures

⁶ Office of the Director of National Intelligence, “Annual Threat Assessment of the U.S. Intelligence Community,” February 6, 2023, <https://www.dni.gov/files/ODNI/documents/assessments/ATA-2023-Unclassified-Report.pdf>

make these reports public. Only 45 percent of the operational BSL-4 labs provide links to their publications on their institutional websites. It would not be difficult for governments and labs to increase transparency by making BWC CBMs publicly available since the existence of these facilities is not secret and nearly every BSL-4 laboratory has a website. This measure would strengthen international transparency and confidence, and it would assist further research to strengthen global biorisk management governance. Transparency is also the best antidote to disinformation. Such transparency is more important than ever given how biological research labs in multiple countries have become the targets of disinformation in recent years.

International Level

At the international level, current biorisk management efforts are fragmented across regulatory, public health, and nonproliferation domains with wide variation in the levels of resources and attention devoted to biosafety, biosecurity, and dual-use research oversight. There are few legally binding requirements in any of these three fields and even fewer mechanisms for ensuring compliance with such requirements.

We recommend a two-pronged strategy for strengthening global biological risk management: reinforcing multilateral institutions such as the WHO and the BWC while also capitalizing on the activities of less formal international groups active in this domain.

WHO's role in global biorisk management could be strengthened in at least three ways. First, WHO should use its convening and standard-setting powers to lead an effort to develop guidance on BSL3+ labs to ensure that the physical and procedural safety measures adopted by these labs are evidence-based and commensurate with the level of risk associated with the research they

conduct. Given the number of BSL3+ labs already in operation, the almost complete lack of national guidance on the type of enhancements that such labs need, and the lack of evidence-based research evaluating whether these enhancements provide increased protection commensurate with the level of risk of the research performed at these labs, we sorely need an international effort to specify the BSL-3+ category more clearly.

Second, the safe collection of samples from wild and domesticated animals that may be infected with a zoonotic pathogen is an underdeveloped component of biosafety. There is a great need for better guidance on field biosafety given ongoing and planned large-scale efforts to collect thousands of viral samples to identify novel zoonotic, and potentially pandemic, pathogens. WHO should lead an international effort to develop guidance for field biosafety applicable to Risk Group 4 pathogens and their most common animal reservoirs, hosts, and vectors. This guidance should be incorporated into the next edition of the WHO's Laboratory Biosafety Manual.

Third, WHO should establish collaborating centers for biorisk management in Africa, Southeast Asia, the Eastern Mediterranean, and the Western Pacific so that every WHO region has at least one such center. The purpose of these centers would be to conduct and sponsor applied research in field and laboratory biosafety and laboratory biosecurity, develop biorisk management policies and practices, provide training on biorisk management, assist with capacity-building programs, and serve as forums for exchanging information and sharing lessons learned among the key stakeholders. Together, these centers could form the basis for a WHO-supported 'Global Network for Biorisk Management' which could oversee the process of implementing the WHO's Global Guidance Framework for the Responsible Use of the Life Sciences at the individual, institutional, and national levels.

The BWC can also be leveraged to enhance biorisk management through increased transparency. Once WHO has provided guidance on the criteria for what constitutes a BSL3+ lab, the standard forms for submitting confidence building measures under the BWC should be amended to require declaration of these labs since they are capable of conducting high-consequence research and there is minimal transparency about them. The forms should also be amended to include whether declared labs comply with ISO 35001 or equivalent international standards related to biorisk management, what biorisk management policies are in place at the facility, and whether they have codes of conduct. The CBM forms should also be amended to include declaration of legislation, regulations and other measures relating to oversight of dual-use research as described in the WHO Global Guidance Framework for the Responsible Use of the Life Sciences. In addition, states should be required to provide a description of how they administer and enforce the full range of national implementation measures listed on the CBM forms.

Today's biological threats are too diverse, urgent, and complex to be held hostage by geopolitics and rigid diplomatic rules. The international community can supplement the traditional multilateralism embodied by WHO and the BWC with a minilateral approach.⁷ Minilateralism is a collective action strategy that brings together the smallest number of countries that can have the greatest impact on an issue. Minilateralism seeks to create a 'coalition of the willing' with the capability and motivation to take substantive actions that multilateral institutions cannot or will not undertake because of political, legal, or resource constraints. By starting with a small core group of dedicated states, such a coalition can reach agreements on shared objectives more quickly and avoid problems posed by spoiler states and lowest common denominator outcomes.

⁷ Gregory D. Koblenz and Filippa Lentzos, "A Plan B to Strengthen Biosafety and Biosecurity," *Think Global Health*, November 15, 2022, <https://www.thinkglobalhealth.org/article/plan-b-strengthen-biosafety-and-biosecurity>

As progress is made, such initiatives can expand in scope, raise their standards, and invite new members to join. These groups complement— rather than replace— multilateral regimes, such as the BWC and WHO.

Existing minilateral initiatives on biorisk management, including the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR), the Biosafety Level 4 Zoonotic Laboratory Network (BSL4ZNET), the European Research Infrastructure on Highly Pathogenic Agents (ERINHA), the Australia Group, the Global Health Security Agenda (GHSA), the Biological Security Working Group (BSWG) of the Global Partnership Against Weapons of Mass Destruction, and the International Federation of Biosafety Associations (IFBA), could advance widespread adoption of ISO 35001 by integrating implementation of the standard into their missions. To do so, these groups will need increased resources, revised mandates, and/or expanded authorities. It will also be necessary to improve coordination among these groups, and with multilateral institutions, in order to ensure that investments in biorisk management are properly prioritized.

To maximize the potential of ISO 35001, which like all ISO standards is designed to be validated by an outside entity, there should be an international mechanism to ensure compliance. While national regulators could act as the third-party, this would have limited credibility internationally, especially for jurisdictions without proven track records for transparency and accountability. Given its regulatory expertise, IEGBBR could take on the mission of auditing laboratory compliance with ISO 35001 using a peer-review model. Peer review is the systematic evaluation of the performance of a state by other states for the purpose of helping the reviewed state improve its policies and practices and comply with established international standards. IEGBBR would be able to sponsor not only in-depth reviews of national biorisk management

legislation, regulations, and institutions, but also laboratory-level management systems, policies, and practices as outlined in ISO 35001. A coordinated approach to enhancing global biorisk management that harnesses these multilateral groups to promote adoption and implementation of ISO 35001 would have a powerful synergistic effect.

Conclusion

The biological risk landscape is rapidly evolving and presents significant new challenges to preventing the accidental, reckless, or malicious misuse of biology. At the same time, oversight systems to ensure that life sciences research is conducted safely, securely, and responsibly are falling behind. An urgent overhaul to realign biorisk management with contemporary risks is needed.⁸

The recommendations offered here, and in greater detail in *Global Biolabs Report 2023*, are consistent with the goals of the 2018 National Biodefense Strategy issued by the Trump Administration and with the 2022 National Biodefense Strategy issued by the Biden Administration. Both of these strategies highlighted the need to strengthen biosafety and biosecurity and promote the responsible conduct of biological research to reduce the risks posed by advances in the life sciences and biotechnology.⁹ Furthermore, these recommendations are

⁸ Filippa Lentzos, Gregory D. Koblenz, and Joseph Rodgers, "The Urgent Need for an Overhaul of Global Biorisk Management," *CTC Sentinel*, Vol. 15, No. 4 (April 2022): 23-29, <https://ctc.westpoint.edu/the-urgent-need-for-an-overhaul-of-global-biorisk-management/>

⁹ *National Biodefense Strategy* (Washington, DC: White House, 2018), 14-15; and *National Biodefense Strategy and Implementation Plan* (Washington, DC: White House, 2022), 10, viii-ix.

consistent with Executive Order 14081, “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe and Secure American Bioeconomy,” that was issued on September 12, 2022.¹⁰ This executive order directed the Department of Health and Human Services to establish a Biosafety and Biosecurity Innovation Initiative that would oversee an interagency effort to “elevate biological risk management as a cornerstone of the life cycle of biotechnology and biomanufacturing R&D, including by providing for research and investment in applied biosafety and biosecurity innovation.” At the international level, EO 14081 pledged the United States to work with other countries to develop and promote “biosafety and biosecurity best practices, tools, and resources bilaterally and multilaterally to facilitate appropriate oversight for life sciences, dual-use research of concern, and research involving potentially pandemic and other high-consequence pathogens, and to enhance sound risk management of biotechnology- and biomanufacturing-related R&D globally.”

More countries are building high and maximum containment laboratories, developing dual-use biotechnologies, and conducting potentially risky research with pathogens. The dangers posed by an accidental or deliberate release of a pandemic-capable pathogen means that strengthening international oversight of high-consequence life sciences is critical. Given the growing complexity of the biorisk landscape and the geopolitical constraints on adopting a robust multilateral response, a concerted effort to harness existing informal international mechanisms, while laying the groundwork for future multilateral initiatives, offers the best chance to advance

¹⁰ Executive Order 14081, “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy,” September 12, 2022, <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/>

collective action on ensuring that life sciences research around the world is conducted safely, securely, and responsibly. Achieving these objectives will require strong and active U.S. leadership.

Thank you for the opportunity to speak to you today and I would be pleased to answer any questions you may have.

APPENDIX

Table 1. Biosafety scores by country

Biosafety (% of 20 possible points)			
Country	Score	Country	Score
Australia	100	Kazakhstan	80
Canada	100	South Africa	80
France	95	Switzerland	80
Germany	95	Hungary	75
Japan	95	Republic of Korea	75
United States	95	Russian Federation	75
Brazil	90	Belarus	70
China	90	Czech Republic	55
Italy	90	Philippines	35
Singapore	90	India	25
Spain	90	Côte D'Ivoire	15
Taiwan	90	Gabon	15
United Kingdom	90	Saudi Arabia	5
Sweden	85		

Table 2. Biosecurity scores by country

Biosecurity (% of 18 possible points)			
Country	Score	Country	Score
France	100	Sweden	67
United States	100	Czech Republic	61
Australia	94	Belarus	50
Canada	94	Brazil	50
Japan	94	Germany	50
United Kingdom	94	Italy	33
China	83	Switzerland	33
Taiwan	78	India	28
Kazakhstan	72	Philippines	22
Republic of Korea	72	South Africa	22
Singapore	72	Saudi Arabia	11
Spain	72	Côte D'Ivoire	6
Hungary	67	Gabon	6
Russian Federation	67		

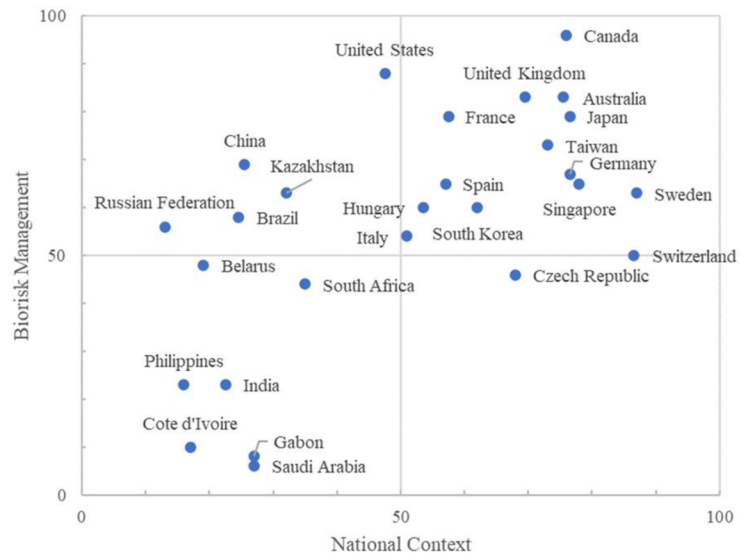
Table 3. Dual-use research oversight scores by country

Dual Use Research (% of 10 possible points)			
Country	Score	Country	Score
Canada	90	Kazakhstan	10
United Kingdom	50	Republic of Korea	10
United States	50	South Africa	10
Germany	40	Sweden	10
Australia	30	Belarus	0
Taiwan	30	China	0
Hungary	20	Czech Republic	0
Italy	20	Gabon	0
Japan	20	Philippines	0
Switzerland	20	Russian Federation	0
Brazil	10	Saudi Arabia	0
Côte D'Ivoire	10	Singapore	0
France	10	Spain	0
India	10		

Table 4. Overall biorisk management score by country

Overall Biorisk Management Score (% of 48 possible points)			
Country	Score	Country	Score
Canada	96	Republic of Korea	60
United States	88	Brazil	58
Australia	83	Russian Federation	56
United Kingdom	83	Italy	54
France	79	Switzerland	50
Japan	79	Belarus	48
Taiwan	73	Czech Republic	46
China	69	South Africa	44
Germany	67	India	23
Singapore	65	Philippines	23
Spain	65	Côte D'Ivoire	10
Kazakhstan	63	Gabon	8
Sweden	63	Saudi Arabia	6
Hungary	60		

Figure 1. Comparison of biorisk management scores with national context



Mr. GRIFFITH. I thank the gentleman.

I now recognize Mr. Pekosz for his 5 minutes of opening statement.

STATEMENT OF ANDY PEKOSZ, Ph.D.

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 nonexistent. 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:]

Testimony for the Record
Submitted to the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
“Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety”

Thursday, April 27, 2023

Andrew Pekosz, PhD
Professor of Molecular Microbiology and Immunology
Johns Hopkins University Bloomberg School of Public Health

Chairman Griffith, Vice Chair Lesko, Ranking Member Castor and members of the Subcommittee, thank you for inviting me to participate in today’s hearing and thank you for devoting your time and effort to topic that is important to our nation’s public health and capability to respond to current and future infectious disease threats. A focus of my professional career has been to understand how viruses infect and cause disease in humans, not only during pandemics but during annual seasonal outbreaks. The public health implications of research in this area are great, as our ability to find methods to reduce infectious disease burden are critical to maintain the health of the US population.

Personal Background

My name is Andrew Pekosz and I am a virologist who has been doing basic research into respiratory viruses including influenza virus, SARS-CoV, SARS-CoV-2, bunyaviruses and hantaviruses for over 30 years. That research has been done at either BSL1, BSL2 or BSL3 levels of containment,

depending on the agent I was working on and the type of experiment. I co-direct the Johns Hopkins Center of Excellence in Influenza Research and Response (JH CEIRR) and direct the Center for Emerging Viruses and Infectious Diseases (CEVID) in addition to being a part of several multi-investigator initiatives, all of which are focused on understanding how respiratory viruses infect humans and are able to continue to spread and cause disease even with the availability of vaccines and antivirals. In addition to my research interests, I have served on numerous review or advisory boards at the institution, state and national level that have 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 state for the record that the opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

Summary Statement

Investigations into the origins of the COVID-19 pandemic have brought increased scrutiny of laboratory biosafety practices and the likelihood that research efforts aimed at microbes that pose a public health concern may inadvertently lead to an epidemic or pandemic. It is important to understand that research on microbes is currently regulated in diverse and complementary ways that continue to be updated and improved upon as technology and methodologies change. Periodic review of biosafety policies, guidelines and definitions of research of concern is welcome and needed to ensure the highest level of safety is being followed while also maintaining the robust and critical response capabilities to a new infectious disease. Clear language defining research of concern, coupled with transparent and open descriptions of review criteria and processes are needed and welcomed by most scientists. For the United States to maintain its position as a world leader in research in infectious diseases, vaccines and antivirals, specific and detailed guidance that will not hinder the vast majority of critical research efforts is needed and I am honored to contribute to that discussion through my testimony at this subcommittee meeting.

Critical issues regarding Biosafety and “Gain of Function” research

Gain of Function is a term that has little utility because it is too broad, ill defined and has historically been applied to research with virtually any microbe. For the rest of this document, I will use the term “research of concern” to focus on experiments that are focused on pathogens that pose a clear, potential public health threat and that are aimed at modifying key features of that pathogen, such as its ability to cause disease, spread in a population, evade antimicrobial drugs or population immunity. My definition runs close to that currently used by the U.S. Government Potential Pandemic Pathogen Care and Oversight (PC3O) and Dual Use Research of Concern (DURC) Policies. It is important to note that research of concern is governed by a number of regulatory groups dependent upon the type of research being proposed.

Basic laboratory research requires institutional approval and training at the BSL1, BSL2, BSL3 and BSL4 levels. Research involving animal models requires additional training and approvals from animal welfare committees. Research involving human subjects involves additional training and approvals from Institutional Research Boards. The trainings need to be documented and refreshed on a regular basis. In addition, all microbes and work with toxic or harmful chemicals requires additional approvals from institutional safety committees that involve clear descriptions of the methods used and safety considerations given. All of these levels of biosafety assessments, trainings and reviews are present to ensure that important research can go forward with the most appropriate and relevant degree of safety.

NSABB guidelines are broad and subject to a wide range of interpretation.

A recent meeting of the National Science Advisory Board for Biosecurity (NSABB) put forth a list of recommendations for improving the oversight and transparency of research of concern. While the intent of the committee was to provide constructive recommendations that would update and

clarify guidelines for research of concern, the language used in the proposal was broad and vague which has led to more confusion rather than clarity with respect to an understanding of what research falls under the proposed increased review and approval processes. Precise, clear definitions of the agents and types of research that fall under the research of concern umbrella are provided in the current P3CO and DURC guidelines. The NSABB recommendations need to be reviewed with an eye to providing more detail and guidance about the specific subsets of research that should be targeted for additional oversight and regulation.

Close loopholes and increase transparency

Regularly assessment of how effective regulatory policies are and whether there are clear needs to update them are necessary. Most scientists would agree that the current process of reviewing research of concern can be more transparent and open. Identifying precisely when research proposals are being reviewed and by what entities is clearly something that can be improved going forward. The fact that the funding source dictates whether a research proposal should undergo increased scrutiny for research of concern makes little sense and is not a policy that most institutions utilize when it comes to biosafety regulations. The biosafety guidelines I utilize are the same, irrespective of the funds used to support the research. These and other points have been discussed by virologists openly and represent areas where we can quickly and significantly improve biosafety.

Closing statement

The US is the global leader in infectious diseases research, vaccine development, and antimicrobial agent development. There is an opportunity for the US to cement that position and serve as the model for how research into pathogens that threaten the human population now or potentially in the future, can be done. That research will better prepare us to deal with the inevitable next pandemic. This subcommittee has the opportunity to be an important part of national and global

plan that will strengthen, or public health preparedness and I am grateful that you have taken the time to consider my thoughts on this topic.

Mr. GRIFFITH. I thank the gentleman for his opening statement. I now recognize Dr. Hawley for his 5 minutes.

STATEMENT OF ROBERT HAWLEY, Ph.D.

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 bio warfare 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 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:]

Congressional Testimony - 27 April 2023 - Bob Hawley

MAJOR POINTS:

➤ The origin of biological safety - Origin at Fort Detrick, Maryland with the efforts of Dr. Arnold Wedum and his promotion of applied biosafety to enhance protection of the workers and environment.

➤ Personal Experiences as Director of Safety and Radiation Protection at the U.S. Army Medical Research Institute of Infectious Diseases and serving as Command Biological Safety Officer for the U.S. Army Medical Research and Development Command.

➤ Accidents, incidents, and mishaps do not just happen - they are caused, usually because of the unsafe behavior of people. They can be avoided or mitigated. There is a need for a centralized database of accidents, illnesses, and mishaps. Analysis of these reports of laboratory incidents could help improve laboratory safety and oversight and determine why the incidents occurred and how they can be prevented in the future.

➤ What is a biosafety professional? A biosafety professional is a competent person capable of identifying existing and predictable hazards in the workplace, or working conditions which are hazardous, or dangerous to employees.

➤ Enthusiasm. A biosafety professional must be enthusiastic about their work and recruit cheerleaders for their profession and promote their profession every day.

TESTIMONY:

- Greeting: Congressman Griffith, members of the committee, colleagues, and friends:

- The origin of biological safety, or biosafety, was at the United States Army Biological Research Laboratories at Camp Detrick, now known as Fort Detrick, in Fredrick, Maryland, by Dr. Arnold G. Wedum, Director of Industrial Health and Safety (1946-1969). Dr. Wedum, who is revered as the person 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 roots in the work promoted by Dr. Wedum. The type of laboratory work, the 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 no one procedure or technique can be used for all laboratory research and development procedures - putting it bluntly, one size does not fit all. A risk assessment is conducted, followed by a risk management procedure whereby the risk is mitigated or eliminated. Also implemented was a Special Procedures 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 occupational infections. Dr. Wedum directed many applied biosafety research projects that allowed us to better understand the interactions of laboratory procedures and workers, and subsequently be able to mitigate the negative impact of these interactions. It is unfortunate that 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 to “Develop 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 with the U.S. Army Safety Program was with the Medical Research and Development Command at Fort Detrick during the period 1988 through 2003. The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) is the Department of Defense's (DoD) 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 of 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 where everyone embraced and practiced a culture of safety. During this time serving as Biosafety Officer at USAMRIID, I was also designated Command Biosafety Officer. In this role, I was tasked to inspect national and international contract and university laboratories to assess their capability and safety program prior to the release of funding. 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 behavior of people. Included in these causes are violation of rules or procedures, inadequate training, failure to understand the 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-mishaps by sharing our experiences - without negative consequences. The Trans Federal Task Force report of 2009 proposed a Centralized Incident-Reporting, Analysis, and Information-Sharing System. The report further stated that an analysis of reports of laboratory incidents could help improve laboratory safety and oversight, determine why the incidents occurred and how they can be prevented in the future. Implementing this recommendation would provide a resource for generating and sharing lessons learned, and promoting the need for new or revised guidelines, practices, or training. Such a national centralized database of laboratory incidents must be characterized by openness and engagement by all involved individuals. The database must be managed and maintained by an organization that provides an independent assessment, and has no vested interest in the organization reporting an incident. Information about incidents within the database must be candid, and truthful. Some examples of such centralized databases include (1) the National Transportation Safety Board Aviation Accident Database and Synopses, (2) the National Automotive Sampling System that is a representative sample of police reported motor vehicle crashes of all types, from minor to fatal, and (3) the National Electronic Injury Surveillance System that collects data on consumer product-related injuries. Many states have a central repository for the collection, analysis, and distribution of motor vehicle accident reports and crime statistics. It is important to realize that such databases are not new - their purpose is to document the exact details of the occurrence. Information on accidents, incidents, and mishaps can be used as an aid to risk assessment helping to develop solutions to potential risks.

- A biosafety professional is defined as a competent person who is capable of identifying existing and predictable hazards in the workplace, or working conditions which are unsanitary, hazardous, or dangerous to employees. This individual is authorized to take prompt corrective measures to eliminate these hazards. A biosafety professional is an individual with post-baccalaureate education, continuing education courses, and credentials such as a Registered Biosafety Professional and a Certified Biological Safety Specialist. These credentials are managed and administered by the American Biological Safety Association International. It is most desirable for a biosafety professional to have laboratory experience. This experience is of great value for communicating with laboratory workers, and is a valuable asset to help an individual earn respect and credibility with the workforce. The requirement for training laboratory workers and biosafety professionals must be continually emphasized. Just as we wish to provide the perfect meal using a proven recipe, in the laboratory we strive for accuracy and perfection of our research or diagnostic outcome by using a proven recipe - this recipe we call a standard operating procedure. This assures that our products are not only consistently similar, but also that other workers can reproduce or validate what was done by others. Although experience can be obtained by formal training, coaching, mentoring, and observation, I emphasize the importance of developing an apprenticeship program - similar to an internship and residency program prior to practicing medicine or dentistry, or a post-doctoral assignment following graduate studies. An apprenticeship provides real-time experience with accomplished and seasoned people offering individuals new to the field additional foundation building blocks such as learning and applying new biosafety principles and practices and furthering their interpersonal and communication skills. An apprenticeship program is very much needed at the present time because of not only the proliferation of high and maximum containment laboratories, but also the

few numbers of individuals entering the biosafety field. It is also prudent to comment that there is a need for additional engineering personnel competent in the operation of these sophisticated laboratories. Although there are opportunities to enroll in short-term courses for continuing education, a concern is the lack of higher education institutes offering coursework leading to an advanced degree in safety or biological safety.

- Biosafety practitioners have to be enthusiastic about their work and recruit cheerleaders for their profession. I hope that my comments will reveal the passion I have for biosafety and the continuing desire to learn from my colleagues.

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 5 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's 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. Oftentimes 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 5 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 3½-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 22 Science article that referenced a potential subproject 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 appears at the conclusion of the hearing.]

Mr. GRIFFITH. For the record, let me respond—we haven’t started your 5 minutes yet, so I am not eating up your time—that that, while we received that response almost 6 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. OK, 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 oftentimes when a member joins my laboratory, for instance, it can be anywhere from a month to 2 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 multiroom 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 oversuit, 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 outerprotective 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, OK, 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 over-

sight 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.

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 [continuing]. Because her time has——

Ms. CASTOR. Since my time ran out.

Mr. GRIFFITH [continuing]. 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 5 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 5 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 4 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. Yes, 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 [continuing]. Difficult to do that.

Ms. DEGETTE. That is right. So Dr. Koblenz, 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. Yes. You know, it is incredibly important to have epidemic and outbreak research be created and shared in near-real time. And those resources, oftentimes, those require multinational 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. OK. 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 3 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. Yes. 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 bio-safety 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 OK. 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 5 minutes of questioning.

Mr. GUTHRIE. Thank you, Mr. Chair.

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

And so, Dr. Koblenz, 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 coordina-

tion 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, governmentwide review. So I do think it is time for that to happen.

Mr. GUTHRIE. OK, 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. OK, thank you.

And Dr. Koblenz, 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. OK, 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. Yes.

Mr. GUTHRIE. Yes, OK, 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. OK, 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. [continuing]. 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 5 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. OK, 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 5 minutes of questioning.

Mrs. RODGERS. 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.

Mrs. RODGERS. OK. 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.

Mrs. RODGERS. 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.

Mrs. RODGERS. 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?

Mrs. RODGERS. 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's 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's many, many steps in between those two that are mitigated by all the measures already in place.

Mrs. RODGERS. 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.

Mrs. RODGERS. OK, 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 5 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. Koblenz, 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. OK. 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 departmentwide—

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 4 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 5 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's 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. OK. 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 subgrants and the oversight that is applied to the labs where those grants or subgrants go?

Dr. CASAGRANDE. Yes. 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 [continuing]. 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 subgrants.

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 5 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's 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 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 oftentimes 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—oftentimes 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, OK.

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 4:15 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

April 26, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chair Rodgers:

Thank you for your March 30, 2023, letter regarding research on mpox, formerly known as monkeypox, and the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH). NIAID and NIH take the safe and secure conduct of research very seriously and have robust guidance, procedures, and protocols in place to ensure that intramural and extramural scientists, including those proposing research on mpox, maintain the highest possible standards for biosafety and biosecurity, as well as follow all applicable laws and regulations. I am pleased to respond on behalf of NIH.

At the outset, I want to respond specifically to the portion of your letter that described a September 2022 *Science* article that referenced a potential sub-project, which you called the “clade 1 study.” This study has not been formally proposed, and NIAID 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.

By way of background, NIH intramural projects are required to follow all applicable NIH policies and procedures, including adherence to biosafety and biosecurity guidance as outlined in the current edition of the Biosafety in Microbiological and Biomedical Laboratories, the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines),¹ the Federal Select Agent Regulations,² and other applicable regulations as appropriate. All NIH intramural research is subject to a standard review process whenever new experimental procedures are scientifically necessary. This standard NIH intramural review process includes specific requirements based upon the proposed experiments and initiates upon submission of a research proposal to the relevant committees. Notably, the proposed research cannot begin until approved by all relevant entities.

¹ NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm

² Federal Select Agent Program. Select Agents Regulations. <https://www.selectagents.gov/regulations/index.htm>

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The NIH Institutional Biosafety Committee (IBC)³ formally reviews any NIH intramural research proposing to use recombinant and/or synthetic nucleic acid molecules in accordance with the NIH Guidelines, in the context of research involving potentially infectious human, plant, or animal materials; human pathogens; and human and non-human primate blood, tissues, and body fluids, including primary human cell cultures. The NIH IBC also determines the required biosafety level and biocontainment measures for any proposed research during this review. Such proposed research then undergoes review by any other appropriate entities, including the Dual Use Research of Concern (DURC) Institutional Review Entity (IRE), if appropriate.

The DURC-IRE is the NIH authority for the oversight and evaluation for proposed research that may fall under the Department of Health and Human Services' (HHS) *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework).⁴ As noted in the HHS P3CO Framework, proposed intramural and extramural life sciences research that is being considered for funding and that has been determined by the funding agency as reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens is subject to additional HHS department-level review.

NIH research involving select agent strains and recombinant work is always performed in close collaboration with the Federal Select Agent Program (FSAP)—which is managed jointly by the Centers for Diseases Control and Prevention and the Department of Agriculture⁵—and the entity Responsible Official to ensure compliance with applicable regulations and subjected to any reviews FSAP deems appropriate.

Your letter inquired about research involving the mpox virus. By way of background, the mpox virus is made up of two genetically distinct clades. Clade I mpox viruses, endemic in the Congo Basin, cause more severe disease than the Clade II mpox viruses, which are endemic to Western Africa. The Clade II mpox virus also consists of two subclades—Clade IIa and IIb. The current global mpox outbreak is driven by a Clade IIb virus, but circulation of both Clade I and Clade IIa in Africa presents an ongoing risk of future regional and global outbreaks of these viruses. The genetic basis for the variability in disease outcomes of the two clades is unknown. Additional research to identify the viral components that account for the observed differences in mpox disease severity between the two clades could help determine key targets within the mpox virus genome for the development of medical countermeasures.

Your letter also referenced a specific NIAID intramural project—*Poxvirus Host Interactions, pathogenesis and immunity*, 1Z1AAI000979. This project includes research on several orthopoxviruses including vaccinia virus, cowpox virus, and mpox virus. The mpox projects include development of a small animal model, investigation of the basis for mpox pathogenicity, assessment of mpox vaccines, and analysis of mpox clade differences. One approach to studying mpox clade differences was proposed and approved in 2015 and involves the generation of chimeric viruses—viruses that incorporate genes from two mpox strains. This ongoing sub-project includes only chimeric viruses created by replacing genes in the more virulent Clade I

³ NIH Policy Manual – Chapter 3035. <https://policymanual.nih.gov/3035>

⁴ HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens. <https://www.phe.gov/s3/dualuse/documents/p3co.pdf>

⁵ Federal Select Agent Program. <https://www.selectagents.gov/>

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virus with genes from the less virulent Clade IIa virus. The project was conceived and approved years before the recent mpox outbreak, and it does not include any studies with the circulating Clade IIb virus.

When the sub-project was proposed in 2015, the proposed experiments were subject to a rigorous review process and were subsequently approved. Since 2009, mpox research within the NIAID intramural program has been registered with the FSAP. As required by the FSAP, the NIAID intramural program FSAP registration was updated to reflect the mpox research when the experiments were approved. During FSAP inspections, all NIH IBC-related documents and minutes are reviewed. This work would not meet the definition of a restricted experiment and was not reviewed by the Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC), all strains created were inventoried and treated as select agents, and the FSAP did not determine ISATTAC review was required based on the project description and detail included in our select agent registration.

After the approval of the proposed experiments in the mpox sub-project investigating clade differences, NIAID investigators generated chimeric viruses by replacing certain genes of Clade I mpox virus with the corresponding genes of Clade IIa virus and infecting an appropriate mouse model with them to determine if any of the genetic changes could decrease the severity of mpox disease caused by the Clade I virus. To date, these experiments have not identified the genetic underpinnings of the observed increased pathogenicity of the Clade I mpox viruses, indicating that further research is necessary to determine these critical genetic factors.

Throughout these experiments, all viruses—including the new chimeric viruses—were handled and inventoried as select agents, and all work with select agent strains was performed in compliance with the requirements in the Federal Select Agent Regulations and NIH policies regarding biological materials. For these experiments, all live viruses were handled at a Biosafety Level 3 (BSL-3) laboratory, in select agent registered facilities, by personnel with approved security risk assessments, and with approval through the NIH Biological Surety Program.⁶ While the experiments were subject to the Federal Select Agent Regulations, including registration of planned recombinant work, none of the experiments meet the definition of a restricted experiment as outlined in Federal regulations.⁷

As stated above, the September 2022 *Science* article noted in your letter referenced a potential sub-project, which your letter refers to as the “clade 1 study,” that has not been formally proposed. This potential sub-project would include the generation of chimeric viruses by replacing genes in the less virulent Clade IIa virus with those in the more virulent Clade I virus. To reiterate, NIAID has no plans to move forward with this research. As detailed above, 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. This review process would specifically include an assessment of whether the research may be subject to the HHS P3CO Framework.

⁶ NIH Policy Manual – Chapter 3037. <https://policymanual.nih.gov/3037>

⁷ Code of Federal Regulations. 42 CFR Part 73.13. <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73/section-73.13>

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The mpox virus causes significant disease and death in the regions in which it is endemic, with an increasing incidence of human infections. Even prior to the ongoing global outbreak of mpox in non-endemic countries, this virus was identified by NIAID and others as an important global health threat in light of sporadic outbreaks associated with international travel. NIAID is conducting and supporting research focused on developing and evaluating treatments and vaccines for mpox, understanding disease transmission and spillover, evaluating immunological characteristics of mpox, and bolstering support for the ongoing public health response. However, NIAID is not supporting research that would include experiments to replace genes in the less virulent Clade IIa virus with those in the more virulent Clade I virus, and there are currently no plans to do so.

Thank you for your interest in NIH's mpox virus research. NIAID and NIH prioritize robust biosafety and biosecurity in intramural research. If you or your staff have any questions, please feel free to contact the Office of the Assistant Secretary for Legislation at (202) 690-7627.

Sincerely,



Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Answers to Additional Questions for the Record

Questions from House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Responses from Dr. Rocco Casagrande, PhD, Executive Chair, Gryphon Scientific

Question from: The Honorable Frank Pallone, Jr.

How could a 22% cut to the National Institutes of Health's budget affect your field, as well as the broader landscape of scientific research and innovation?

Cuts right now to any agency that funds research in the life sciences, especially cuts to the preeminent life sciences funder in the US—the NIH, would be particularly harmful to the economy of the US, its independence and the health of its people.

Regarding the economy: the life sciences are already the basis of a critical sector of the US economy, called the “bioeconomy”, which spans commercialization of discoveries in agriculture, materials, fuels, industrial processes and medicine. The bioeconomy is today an important sector of the US economy and is perhaps one of the most dynamic engines of economic growth in the US. Direct revenues from the bioeconomy contributed more than \$500 billion to the US economy with an annual growth rate of more than 20%.¹ The continued growth of the bioeconomy is dependent on innovation deriving from research in the life sciences, of which the NIH is a critical funder. Cutting funding for any critical life sciences grant-maker right now would imperil the growth of one of the most dynamic sectors of the US economy. Moreover, the bioeconomy of China is close behind that of the US, and China continues to invest heavily in research in the life sciences, suggesting that withdrawing support of research now would greatly strengthen China's relative position. Scientific leadership can lead to long-lasting economic dominance because of the reliance of the bioeconomy on patents, and the protection they offer against derivative technologies. For this reasons, cuts in life-science funding now can lead to Chinese dominance of the sector for the decades to come.

The US failing to invest in its bioeconomy would allow China to become the world leader in biomedicines, which would imperil the independence of the US. If Chinese companies become the only providers of next-generation treatments (cures for cancer, personalized medicine, preventatives for infectious diseases), China could use that dominance to exert pressure on US policies. For example, given the close ties between the Communist Party of China and the private sector, China could threaten exports of critical and uniquely effective biomedicines as part of a broader strategy to influence US decision-making.

Failure to invest in the life sciences would undermine the explosive growth in the development of next-generation treatments and cures for diseases that are just beginning to make dramatic

¹ Bioeconomy Capital, 2023, accessed at <http://www.bioeconomycapital.com/bioeconomy-dashboard>

improvements in the quality of life for Americans. Biotech treatments, based on engineered immune cells, are curing cancer in more and more Americans every year. Cures for many genetic disorders are just now showing promise in the clinic. The unprecedentedly rapid deployment of the SARS-CoV-2 vaccine was the result of a decade-long investment in biomedicine. Undermining investments in biomedicine at the NIH threatens to stop the engine of innovation and halt further discoveries that could improve the health and well-being of millions of Americans in the next decade and better prepare the US to mitigate the next pandemic.

The Honorable Jan Schakowsky

Last year's Consolidated Appropriations Act included a provision directing HHS to support research into the safe conduct of biomedical research. How will investments in biosafety research – like those that Congress made last year – help bring us closer to understanding what can effectively reduce risks?

Research in biosafety can effectively reduce risks arising from laboratory accidents in several ways.

Firstly, research is needed to determine how accidents occur, the factors that lead to accidents and the measures that most effectively mitigate the accidents. Unlike every other human endeavor with significant risks (such as aviation and nuclear power), the life sciences do not have a robust history of safety research, so these data are currently completely lacking. This research can identify experiments that should be altered to reduce risks, training requirements to boost safe work practices and equipment that should be emplaced to prevent releases. For example, in recent work our group published, we determined that snap-cap tubes in the lab create splashes more often than previously thought, suggesting that they should be substituted for screw-cap tubes when scientists are manipulating the most hazardous materials (a change that would cost a few dollars per experiment).

Secondly, biosafety research is needed to make smart investments in biosafety. Currently, because data is lacking, biosafety has traditionally added more and more measures, equipment and training to reduce risk, because the efficacy of any particular mitigation is unknown. Undoubtedly, some of these measures do not meaningfully reduce risk and are wasting funding and the time of researchers. By gathering data on what measures truly mitigate accident risks, laboratories can spend only on the measures, equipment and training that are valuable, and eliminate those that are merely theater. In this way, funding in biosafety could have a significant Return on Investment by making the entire pathogen research community more efficient.

Lastly, safety research data will help boost compliance with safety guidelines. Scientists are focused on data and want to know “why” various measures (some of which are onerous) must be followed to improve safety. Historically, compliance has been difficult to achieve when the scientists themselves are skeptical about the value of the safety measure. Biosafety research can generate the data to objectively demonstrate that costly safety measures are truly necessary. For example, a longstanding biosafety principle suggests that workers decontaminate their workspace every time they have completed their work but many scientists think that they know when they spill a tiny

amount of hazardous substance while working and are therefore resistant to decontaminating their workspace unless they know they had a spill. Our research has demonstrated that even experienced scientists are unaware of about half the spills they make, proving the value of this longstanding recommendation to the researchers themselves.

The Honorable Kathy Castor

The Republicans' proposed Default on America Act may require a 22% cut to the National Institutes of Health's budget as well as significant cuts to the HHS Office of the Inspector General. Can you explain why funding NIH and its oversight mechanisms are important and how cuts of that magnitude could undermine our biosafety goals in the United States and across the world?

In the response to Rep. Pallone above, I described how cuts to the NIH in general would be disastrous, and particularly right now.

Regarding biosafety oversight, because biosafety standards are general, robust oversight from funding agencies is necessary to ensure that grantees are performing research safely and responsibly. Part of a granting agency's job is to ensure that the proposed research can be conducted safely in the laboratory designated and that the work itself doesn't highlight scientific advancements that can be misused by those seeking to do harm with engineered viruses or bacteria. The grant-making agency can suggest changes to the experimental design or the substitution of less hazardous strains to reduce risks. Ideally, the granting agency is a partner to the research institution who can collaboratively craft a research protocol that is safe yet scientifically innovative.

Responses to Additional Questions for the Record

Gregory Koblentz, PhD,
Associate Professor & Director, Biodefense Graduate Programs
Schar School of Policy and Government
George Mason University

June 13, 2013

The Honorable Morgan Griffith

1. Are there any established protocols in biosafety level labs to safely destroy pandemic potential viruses or bacteria in the event of an emergency or natural disaster?

a. If there are no current protocols in place, what are some potential protocols or regulations that can be put into place to ensure a safe destruction of any pandemic potential viruses or bacteria in the case of an emergency or natural disaster?

ANSWER

The Biosafety in Microbiological and Biomedical Laboratories (BMBL) is the foundation for biosafety practices in the United States.¹ The BMBL provides guidance, not regulations, for how laboratories should be designed and operated safely. The BMBL does recommend that all labs have a safety manual that includes an emergency response plan for how to deal with a wide range of emergencies, including both natural and human-made events, and regular emergency response drills for lab employees. Labs that work with live animals are supposed to have a plan for the disposition of animals in the event of an emergency. However, the BMBL does not prescribe the contents of emergency response plans, such as procedures for safely destroying potential pandemic pathogens or how to safely dispose of live animals or carcasses. Such details are left up to the discretion of each laboratory.

For labs that possess Select Agents, there are more detailed requirements for what the lab's incident response plan should include and how often the lab should conduct drills and exercises.² In addition, the CDC and USDA, which are jointly responsible for implementing the

¹ Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition, June 2020, https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

² Federal Select Agent Program, "Incident Response Plan: Regulatory Requirements," August 27, 2021, <https://www.selectagents.gov/compliance/guidance/incident-response/regulatory.htm>; Federal Select Agent Program, "Drills and Exercises Guidance," January 29, 2021, <https://www.selectagents.gov/compliance/guidance/drills/index.htm>

Federal Select Agent Program, have provided guidance to registered labs for how to comply with this portion of the Select Agent Regulations.³ However, neither the Select Agent Regulations nor the accompanying guidance specifies that labs must include procedures for the safe destruction of Select Agents in the event of an emergency in their incident response plan. While specific labs may have such procedures in place, they are not required.

It would be advisable for both the BMBML and the Federal Select Agent Program to update their incident response plan requirements and guidance to include protocols for the safe disposal of pathogens, animals, and carcasses in the event of an emergency that could compromise the lab's safety or security. The Federal Select Agent Program should also review existing incident response plans to assess whether such protocols are included and if any best practices could be shared with the rest of the high containment laboratory community.

2. Your Global Biolabs Report identified 57 biosafety level 3 plus or biosafety level 3 enhanced labs in 28 countries. As you noted, these labs do gain-of-function experiments involving high-path avian influenza and other serious pathogens. I am worried that the BSL-3+ level isn't an adequate substitute and that there is a temptation for researchers to try to do things in BSL-3+ that they should really be doing in BSL-4.

a. Do you believe standards are needed to ensure proper safety in biosafety level 3+ labs?

ANSWER

It is important to note that while BSL-3 enhanced labs have been used to conduct so-called "gain of function" experiments that generate engineered pathogens with enhanced virulence and/or transmissibility, not all such labs conduct such experiments. In addition, this type of research has also been carried out at lower levels of biosafety since there are no international, and frequently no national, standard for the biocontainment level that research with potential pandemic pathogens should be conducted under. In contrast, Canada has decided that research with mammal-transmissible H5N1 influenza should be conducted only in a BSL-4 lab.⁴

The proliferation of labs claiming to be BSL-3 enhanced raises several concerns. First, there is no internationally agreed definition of what BSL-3 enhanced means, allowing different countries to adopt different standards. Second, most countries do not have national regulations or standards for BSL-3 enhanced, allowing different labs within the same country to have differing interpretations about what types of pathogens or experiments should be conducted at BSL-3 enhanced. Third, there has been little to no research performed to demonstrate that these enhancements provide an adequate level of additional safety commensurate with the higher risk

³ Centers for Disease Control and Prevention and U.S. Department of Agriculture, *Incident Response Plan Guidance*, August 2021, https://www.selectagents.gov/compliance/guidance/incident-response/docs/Incident_Response_Plan.pdf

⁴ Public Health Agency of Canada, "Biosafety Advisory: Efficiently Transmissible Engineered Influenza A H5N1 Viruses," February 1, 2012, <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/biosafety-directives-advisories-notifications/biosafety-advisory-efficiently-transmissible-engineered-influenza-a-h5n1-viruses.html>

research conducted in these labs. This is especially important since these labs are being used to conduct research with engineered pathogens that was not envisioned when this biosafety level was first developed by the U.S. Department of Agriculture in the late 1990s. While there have been a number of reviews of laboratory biosafety in the United States, none of them have specifically examined the scientific and empirical basis for the BSL-3 enhanced category or the extent to which these safety enhancements provide adequate safeguards for the research performed in these labs.⁵ I strongly urge that such a review be conducted by the Federal government with the full participation of the high containment laboratory research and biosafety communities.

The Honorable Frank Pallone, Jr.

1. How could a 22% cut to the National Institutes of Health's budget affect your field, as well as the broader landscape of scientific research and innovation?

ANSWER

The National Institutes of Health is the single largest funder of biomedical research in the world. This research is vital to advancing our understanding of human health, the myriad threats to public health, and how to reduce these threats through vaccines, therapeutics, antidotes, diagnostics, non-pharmaceutical interventions, and public policy. The value of this research was demonstrated during the pandemic when the United States was able to successfully develop multiple COVID vaccines based on mRNA technology in less than a year. A 22% cut to the NIH budget would be devastating to the biomedical research enterprise with long-lasting and far-reaching negative effects. Speaking narrowly on the topic of biosafety and biosecurity, a funding cut of this magnitude would likely lead to the closure of some high containment labs. Other labs would find their ability to invest in biosafety and biosecurity reduced. Finally, it would not be possible to fund new initiatives, such as applied biosafety research, in such an austere fiscal environment.

The Honorable Jan Schakowsky

1. You recently wrote in the New York Times that many of your ideas for improving biosafety were consistent with the Biden Administration's national biodefense strategy.

⁵ *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*, July 2009, <https://www.phe.gov/s3/law/boards-committees/biosafety-taskforce/Documents/transfedbiocontainmentrpt092009.pdf>; *Report of the Federal Experts Security Advisory Panel*, December 2014, <https://www.phe.gov/s3/Documents/fesap.pdf>; National Science and Technology Council, *Fast Track Action Committee Report: Biosafety and Biosecurity*, January 2017, <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/NSTC/ftac-bio-report.pdf>; and National Science and Technology Council, *Evidence-Based Laboratory Biorisk Management Science and Technology Roadmap*, April 2022, https://www.whitehouse.gov/wp-content/uploads/2022/04/04-2022-NSTC-ST-Biorisk-Research-Roadmap_FINAL.pdf

What are some of the ideas in the Administration's strategy that you see as most important to implement?

ANSWER

The Biden Administration's National Biodefense Strategy explicitly identified laboratory accidents, alongside biological weapons and bioterrorism, as the major biorisks facing the United States.⁶ One of the main goals of the strategy is to "strengthen biosafety and biosecurity practices and oversight to prevent bioincidents and reduce biological risks associated with life sciences research and development and advances in biotechnology."⁷ To achieve this goal, the strategy emphasizes three objectives that comprise ten specific action items. The first objective is to ensure that biological laboratories in the United States or funded by the U.S. government are "implementing and maintaining effective, transparent, rigorous, and comprehensive oversight, training, and monitoring programs for biosafety, biosecurity, and responsible and ethical conduct in science."⁸ A recent analysis of high-level biosafety and biosecurity reviews conducted during the Obama Administration found that more than half of their recommendations had still not been fully implemented.⁹ The Government Accountability Office (GAO) has identified the lack of a single regulatory agency responsible for biosafety and biosecurity as a key gap in national oversight of high containment laboratories.¹⁰ The most effective way to strengthen oversight of life sciences research would be to create an independent agency responsible for biosafety and biosecurity in U.S. labs.¹¹ Such an agency, modeled on the National Transportation Safety Board (NTSB), National Highway Traffic Safety Administration (NHTSA), Nuclear Regulatory Commission (NRC), or Federal Aviation Administration (FAA), would be able to promulgate national regulations and standards, provide guidance and training to stakeholders, and fund applied research to advance the science of biosafety and biosecurity.

The strategy's second objective is to strengthen the responsible conduct of research in the life sciences by developing and promoting biosafety and biosecurity norms and oversight at the national and international levels.¹² To achieve this objective, the Biden Administration should adopt the National Science Advisory Board for Biosecurity (NSABB)'s March 2023 recommendations for reforming oversight of dual-use research.¹³ The Biden Administration

⁶ Joseph R. Biden, *National Biodefense Strategy and Implementation Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security* (Washington, DC: The White House, October 2022), 6. [hereafter Biden, *National Biodefense Strategy*]

⁷ Biden, *National Biodefense Strategy*, 11.

⁸ Biden, *National Biodefense Strategy*, viii.

⁹ Haines CA, Gronvall GK. "Improving U.S. Biosafety and Biosecurity: Revisiting Recommendations from the Federal Experts Security Advisory Panel and the Fast Track Action Committee on Select Agent Regulations," *Applied Biosafety* Vol. 28, No. 1 (2023):43-54.

¹⁰ Government Accountability Office (GAO), *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574, September 2009, <https://www.gao.gov/assets/gao-09-574.pdf>

¹¹ Ritterston R, Kingston L, Fleming AEJ, Lauer E, Dettmann RA, Casagrande R. "A Call for a National Agency for Biorisk Management," *Health Security* Vol. 22, No. 2 (2022): 1-5.

¹² Biden, *National Biodefense Strategy*, ix.

¹³ National Science Advisory Board for Biosecurity, *Proposed Biosecurity Oversight Framework for the Future of Science*, March 2023, <https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf>

should also work with Congress to extend this oversight to life sciences research conducted in the private sector.¹⁴ In addition, the Biden Administration could enhance biosecurity by requiring recipients of U.S. government grants for life sciences research to purchase synthetic DNA only from suppliers who screen orders for biosecurity purposes, such as members of the International Gene Synthesis Consortium (IGSC).¹⁵ Researchers at public universities in California, the largest recipient of life sciences funding from NIH, are already required to do so under a recent California state law.¹⁶ Adopting a similar policy at the Federal level would level the biosecurity playing field and create a strong incentive for more companies to join IGSC or implement equivalent biosecurity screening protocols in order to maintain their access to the U.S. market.

The third objective is to accelerate biosafety and biosecurity innovation “by supporting efforts to identify and address the research gaps needed to improve evidence-based laboratory biological risk management, both in the United States and globally, and share with international partners.”¹⁷ In a sign of the importance of this issue to the Biden Administration, the strategy charges the National Security Council (NSC) and Office of Science and Technology Policy (OSTP) with overseeing the development of a joint capability plan for biosafety and biosecurity innovation.¹⁸ In addition, in accordance with a September 2002 executive order on the bioeconomy, the Department of Health and Human Services (HHS) has established a Biosafety and Biosecurity Innovation Initiative to invest in applied biosafety research and innovations in biosecurity.¹⁹ The HHS plan for implementing this initiative is overdue.

The Biden Administration could take several steps immediately to incentivize innovation in biosafety and biosecurity. First, the terms and conditions for grants from NIH and other funders of life sciences research could be modified to create line items for biosafety and biosecurity expenses that could be charged to grants. This would end the practice of research institutions having to pay for biosafety and biosecurity out of overhead which creates a perverse incentive for these institutions to minimize these expenses. Second, NIH, or ideally a new independent biorisk management agency, could create a grant program dedicated to applied research in biosafety and biosecurity to encourage this type of research, increase empirical knowledge, and contribute to the development of new science-based biosafety and biosecurity policies. There have been concerted efforts to identify knowledge gaps that need to be filled to improve the theory and practice of biosafety and biosecurity.²⁰ These efforts, however, have not been

¹⁴ Gerald L. Epstein, “Private-sector Research Could Pose a Pandemic Risk. Here’s What to Do About It,” *Bulletin of the Atomic Scientists*, February 16, 2023, <https://thebulletin.org/2023/02/private-sector-research-could-pose-a-pandemic-risk-heres-what-to-do-about-it/>

¹⁵ Gregory D. Koblenz, “The De Novo Synthesis of Horsepox Virus: Implications for Biosecurity and Recommendations for Preventing the Reemergence of Smallpox,” *Health Security*, Vol. 15, No. 5 (August 2017): 1-9.

¹⁶ UC Riverside, “Guidance on Purchasing Gene Synthesis Equipment or Products in Compliance with AB 1963,” April 26, 2023, <https://training.ucr.edu/gene>

¹⁷ Biden, *National Biodefense Strategy*, ix.

¹⁸ Biden, *National Biodefense Strategy* ix.

¹⁹ Department of Health and Human Services, “Fact Sheet: HHS Takes Action on Executive Order Launching a National Biotechnology and Biomanufacturing Initiative,” September 14, 2022, <https://www.hhs.gov/about/news/2022/09/14/fact-sheet-hhs-takes-action-executive-order-launching-national-biotechnology-biomanufacturing-initiative.html>

²⁰ National Science and Technology Council, “Evidence-Based Laboratory Biorisk Management Science and Technology Roadmap”; and Stuart D. Blacksell, et al., “The Biosafety Research Road Map: The Search for

accompanied by funding to conduct the research necessary to fill these knowledge gaps and enable the development of science-based biosafety and biosecurity policies and practices.²¹

Finally, a cross-cutting theme across all of these objectives is the need to strengthen biosafety, biosecurity, and dual-use research oversight in other nations. There are several international initiatives already underway in this space that make important contributions to this objective. However, to achieve greater results, they need increased funding, greater authority, and enhanced coordination. The United States should take a leadership role in redesigning the architecture of global biorisk management. The centerpiece of this architecture should be an international mechanism to audit laboratory compliance with international standards for biosafety and biosecurity.²² This international audit mechanism would increase the confidence of local communities and neighboring countries that high consequence biological research laboratories are operating safely, securely, and responsibly.

Evidence to Support Practices in Human and Veterinary Laboratories,” *Applied Biosafety*, Vol 28, No. 2 (2023): 64-71.

²¹ Rocco Casagrande, “Federal Funding for Biosafety Research Is Critically Needed,” CSIS Brief, August 2019, https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/190802_Casagrande_Biosafety_WEB.pdf; and Ryan Ritterson and Rocco Casagrande, “Basic Scholarship in Biosafety Is Critically Needed To Reduce Risk of Laboratory Accidents,” *mSphere* Vol. 2, No. 2 (March/April 2017): e00010-17.

²² Filippa Lentzos and Gregory D. Koblenz, *Global BioLabs Report 2023* (London, United Kingdom and Arlington, VA: King’s College London and George Mason University, 2023), <https://www.kcl.ac.uk/warstudies/assets/global-biolabs-report-2023.pdf>; and Gregory D. Koblenz and Filippa Lentzos, “A Plan B to Strengthen Biosafety and Biosecurity,” *Think Global Health*, November 15, 2022, <https://www.thinkglobalhealth.org/article/plan-b-strengthen-biosafety-and-biosecurity>

Responses to Additional Questions for the Record from Andrew Pekosz, Ph.D.
"The Biosafety of Risky Research: Examining If Science is Outpacing Policy and Safety"
House Committee on Energy and Commerce, April 27, 2023

Thank you for the opportunity to answer these questions. My answers are in italic font directly beneath the question asked.

The Honorable Dr. Michael Burgess

Mr. Pekosz, continuing my interest in your written testimony about closing the loophole, specifically that “biosafety is independent of funding sources

- 1) Can you expand on your answer and what you believe Congress should do to achieve that goal of independent oversight over biosafety?

Certain biosafety review processes that involved enhanced pathogens and experiments that may increase their disease potential or transmission only apply to NIH-funded grant proposals. Biosafety is independent of funding source so the process of enhanced pathogen review should be applied to specific pathogens and specific types of experiments irrespective of funding source. Congressional actions that expand the NIH review processes already in place to experiments funded by any type of support, at any type of research institute (public, private or government) would increase biosafety tremendously and in a relatively simple way.

The Honorable Morgan Griffith

- 1) During an experiment done in any biosafety level lab, if there is a progress report that is not reported or is delayed in being reported, what are the current protocols to address this issue?

Progress reports for most NIH funded grants involve the investigator and the institution the investigator works at. They are usually asked for at the end of a funding cycle – usually one year – and involve the investigator summarizing the work done with the funds that were spent and the institution reporting on exactly how much was spent and on what particular items (salary, benefits, laboratory supplies, etc.). Research grants from NIH are technically awarded to institutions, so it’s the institution that is responsible for submitting these reports. Since these reports are tied to the end of a fiscal year, the release of funds for the following fiscal year could

be delayed, pending the submission of progress report. So the investigator and institution are responsible for submitting timely and complete progress reports, and the NIH is responsible for approving those reports.

2) Experiments conducted in biosafety level 4, the highest-level containment facilities, are physically demanding on researchers. Researchers typically have to wear full enclosed protective suits that connect to oxygen lines. They can't eat, drink, or go to the bathroom while during the experiment. The bulkiness of the protective equipment slows down movement. The upper limit recommended for working in these conditions is 3 hours. BSL-4 lab space is also in high demand, meaning that experiments have to be scheduled months in advance. a. Is there any oversight into research being done in a biosafety level-3+ lab by federal agencies?

Yes, there is a significant amount of federal oversight done on BSL3/BSL3+ laboratories and additional oversight for BSL3 experiments performed in animal models (ABSL3 research) or in arthropod vectors (ABCL3). Much of this is dependent on the specific agent being used. As an example, my laboratory recently had an inspection from the CDC that went over all the protocols and procedures we use to work with SARS-CoV-2. Animal facilities are inspected by other agencies including the USDA. Any NIH research proposal has to address biosafety and animal experiments and ensure that the appropriate, inspected and fully functioning facilities are present for the proposed work.

b. What are the current protocols to decide to perform research in a biosafety level-3+ labs instead of a biosafety level 4 lab?

The starting point for all discussions of biosafety level is the CDC's Biosafety in Microbiological and Biomedical laboratories manual, or the BMBL (<https://www.cdc.gov/labs/BMBL.html>). That document lays out the basic biosafety and laboratory parameters needed perform specific experiments with specific agents. The investigator wishing to perform this research, then has to obtain Institutional Biosafety Committee (IBC) approval at their institution for the proposed research and level of containment. The IBC takes into account the specific biosafety laboratories

and trained personnel present at the institution before deciding whether to approve a particular set of experiments with a particular agent.

All of these factors incentivize researchers to conduct as much of their experimental work as possible in BSL-2 and BSL-3 facilities. Many research institutes operate what is called BSL-3+ or BSL-3 enhanced laboratories. These are standard BSL-3 facilities that incorporate some but not all of the biosafety and containment measures in BSL-4 labs. However, BSL-3+ is not an official biosafety level and there are no defined standards. Therefore, it is unclear if BSL-3+ facilities have the appropriate level of biosafety measures.

a. Is there any oversight into research being done in a biosafety level-3+ lab by federal agencies?

BSL3+ research is described in the BMBL and the decision on what particular enhancements are added to BSL3 research rests with the IBC of the institution that houses the investigator. There are several different things that fall under the BSL3+ guidance and that is often dependent upon the agent being used and the types of experiments being used. BSL3+ can require rooms that have shower in/shower out capabilities to provide additional assurances that agents aren't brought out of a facility. Another common BSL3+ addition is the type of respiratory protection being used. BSL3+ research may require items like PAPRs instead of N95 masks to provide even more safety.

b. What are the current protocols to decide to perform research in a biosafety level-3+ labs instead of a biosafety level 4 lab?

The BMBL defines the agents and the biosafety level that is appropriate for using those agents. The IBC at an investigator's institution holds the final approval over what biosafety level an experiment is done at and they utilize the BMBL as the primary guidance. For the most part, a particular agent is given a biosafety designation and then that biosafety designation can be modified for specific experiments. As an example, research with most hantaviruses occurs at BSL3, but animal experiments with hantaviruses that have a particularly high fatality rate have

to be performed at BSL4. If an attenuated strain of an agent exists, that is often assigned a slightly lower biosafety level. All of this is laid out in the BMBL, but again, it is the institution's IBC that approves the experiments, and the IBC can either not approve an experiment, or ask that it be done at a higher biosafety level, given their assessment of the institutions infrastructure and personnel training.

The Honorable Frank Pallone, Jr.

1. How could a 22% cut to the National Institutes of Health's budget affect your field, as well as the broader landscape of scientific research and innovation?

The effect would very much depend on how the cuts were implemented, but I assume there would be a reduction in new research grants being funded as well as a cut to grants that were already approved for funding. For new grants funded through the NIAID, the institute I'm most familiar with, only the top 12% of new R01 proposals are funded. This percentage would certainly be decreased, leading to a reduction in new research grants across all infectious disease disciplines --- including those that are currently not considered to be pathogens with pandemic potential. The cut to existing grants would mean that some of the approved research would be cut, leading to reductions in workforce because most laboratory infectious disease workers are funded by NIH grants. NIH budgets have not kept up with the inflation rate seen in biomedical research so investigators are already having difficulty funding projects in a manner that will allow for speedy completion of projects. Research in new initiatives like nasal vaccines or universal coronavirus vaccines would certainly be moving forward at a slower rate because fewer laboratories would be funded to do this work.

2. What scientific breakthroughs have researchers been able to achieve through the research happening in high containment labs?

While there are many important insights scientists have learned about how high containment pathogens infect and cause disease, I think the simplest example is the development of Ebola vaccines. We now have vaccines that have incredibly high efficacy against Ebolavirus mortality

and disease and it was primarily due to the use of Ebolavirus and animal models of Ebolavirus infection – all of which was done in BSL4 labs.

3. What scientific breakthroughs have researchers been able to achieve using enhanced potential pandemic pathogens?

While controversial topics, it is quite clear that work on the transmission of H5N1 viruses and the ability of animal coronaviruses to infect humans have provided important insights into what these viruses. Given the current global increase in H5N1 infections in birds and mammals, it is very clear that work on transmission of H5N1 in ferrets has provided important insights into the types of properties needed for H5N1 to transmit among mammals, along the simple sequencing of viruses to give us insights into how close those viruses are to become a mammalian pathogen. Work with bat coronaviruses has clearly shown that binding to a human cell is not enough to allow for that virus to infect the cells and cause disease. Factors outside of receptor binding – specifically how the virus protein is processed by certain enzymes within a human cell, are incredibly important for allowing bat coronaviruses to jump to humans, and we now can monitor bat virus sequences for those signatures and focus down on the handful of viruses that have high potential for causing human infections.

The Honorable Kathy Castor

1. How have prior funding pauses for research using enhanced potential pandemic pathogens impact the development of flu-related countermeasures and public health preparedness

Prior funding pauses often begin with a very broad group of grants being paused and reviewed. Prior research pauses based on H5N1 influenza or work with bat coronaviruses started with pauses on all influenza and coronavirus work so each grant could be reviewed for potential gain of function work. The review process took several months before work on seasonal influenza viruses and coronaviruses was cleared, most likely because there are a large number of grants to be reviewed and the process had to be thorough and complete. During the 2014 funding pause, my laboratory had work on how influenza vaccines recognized new seasonal influenza viruses

paused, and while my research was paused, the influenza viruses evolved to evade vaccine immunity naturally.

