CHALLENGES AND OPPORTUNITIES TO INVESTIGATING THE ORIGINS OF PANDEMICS AND OTHER BIOLOGICAL EVENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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C O N T E N T S

WITNESSES

SUBMITTED MATERIAL

[1] Four reports submitted by Dr. George have been retained in committee files and are collected in one document at https://docs.house.gov/meetings/IF/IF02/20230201/115347/HHRG-118-IF02-Wstate-GeorgeA-20230201.pdf.

[2] The report has been retained in committee files and is included in the Documents for the Record at https://docs.house.gov/meetings/IF/IF02/20230201/115347/HHRG-118-IF02-20230201-SD002.pdf.

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CHALLENGES AND OPPORTUNITIES TO INVESTIGATING THE ORIGINS OF PANDEMICS AND OTHER BIOLOGICAL EVENTS

WEDNESDAY, FEBRUARY 1, 2023

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 2:16 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, Crenshaw, Armstrong, Cammack, Rodgers (ex officio), Castor (subcommittee ranking member), DeGette, Schakowsky, Tonko, Ruiz, Peters, and Pallone (ex officio).

Also present: Representatives Carter, Miller-Meeks, and Dingell.

Staff present: Kate Arey, Content Manager and Digital Assistant; Sean Brebbia, Chief Counsel, Oversight and Investigations; Sarah Burke, Deputy Staff Director; Lauren Eriksen, Clerk, Oversight and Investigations; Theresa Gambo, Financial and Office Administrator; Grace Graham, Chief Counsel, Health; Nate Hodson, Staff Director; Tara Hupman, Chief Counsel; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Clare Paoletta, Professional Staff Member, Health; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; John Strom, Counsel, Oversight and Investigations; Joanne Thomas, Counsel, Oversight and Investigations; Austin Flack, Minority Junior Professional Staff Member; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Liz Johns, Minority GAO Detailee; Will McAuliffe, Minority Chief Counsel, Oversight and Investigations; Christina Parisi, Minority Professional Staff Member; Harry Samuels, Minority Oversight Counsel; Caroline Wood, Minority Research Analyst; and C.J. Young, Minority Deputy Communications Director.

Mr. GRIFFITH. I call the Subcommittee on Oversight and Investigations to order.

Looks like everybody is seated.

Good afternoon, everyone, and welcome. The Subcommittee on Oversight and Investigations is going to start.

And I will now recognize myself for 5 minutes for an opening statement.

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

I'm Morgan Griffith. Good to be with you all this evening. I welcome you all to our first Oversight and Investigations Subcommittee hearing of the 118th Congress, and I would like to congratulate Ranking Member Kathy Castor on her appointment to that post.

Ms. CASTOR. Thank you.

Mr. GRIFFITH. Thank you. It's good to have—it's good to have somebody to work with.

This afternoon's subcommittee hearing will explore the importance of pandemic origin investigations as a means of bolstering our country's pandemic preparedness and biodefense capabilities.

To date, over 1 million Americans have died from COVID–19. The pandemic brought our country to a standstill. It cost our economy around $15 trillion in economic damage. Businesses were shut down. Schools were closed. The Nation is still recovering from the pandemic's impact and the damage that it caused.

It has been a little over 3 years since COVID–19 emerged, and questions on its origins remain. Given the toll of the virus—that the virus has taken, that's unacceptable.

I believe the substantial circumstantial evidence favors COVID–19 emerging due to a research-related incident, but this committee will continue to investigate the origins of the COVID–19 pandemic since we have jurisdiction over public health and Federal biomedical research.

Today, though, we will look beyond the COVID–19 pandemic and understand what structures, technologies, and capacities are needed to more clearly investigate the origins of disease outbreaks in the future. Being able to quickly identify the root cause of a disease outbreak or biological incident has important benefits ranging from countermeasure development to differentiating between whether an outbreak was due to a deliberate release, an accidental release, or a natural event.

By all accounts, the risk of catastrophic biological incidents and infectious disease pandemics is increasing. As the world becomes more connected, barriers that once helped limit disease from spreading across the globe are being removed.

Further, human-animal interactions are also increasing. The last two decades have seen a global proliferation of laboratories conducting research on potential pandemic pathogens, increasing the possibility that future pandemics may have a research-related origin.

Of the approximately 60 biosafety level 4 labs, which are designed to work on the most dangerous of pathogens that are around the globe, at least 20 have been built in the last decade. More than 75 percent of these labs are located in urban centers where a virus, if it escaped, could spread with ease.

As an aside, the Wuhan Institute of Virology appears to have conducted at least some high-risk coronavirus research at a biosafety level 2 lab.

In the United States, we have recently seen high-risk research done to intentionally modify pathogens, such as NIH's experiments

to enhance monkeypox's virulence, as well as conflicting reports as to what coronavirus research Pfizer is conducting to anticipate future variants.

Although there is little we can do to predict the timing of the next outbreak, there is a lot we can do now to prepare for that next outbreak.

Currently, there is no coordinated whole-of-government plan for investigating the origins of a disease outbreak or a biological incident. However, as our witnesses will testify today, a coordinated approach across the Government, academia, and the private sector is needed.

The focus of today's hearing will be a Government Accountability Office Technical Assessment on the Technologies and Challenges for Investigating the Origins of Pandemics. This study was conducted at the request of all 26 Republicans on the committee in June 2021 and is based on insights GAO gained by working with the National Academies of Science and the leading pandemic experts in the U.S.

This GAO report is significant because it is believed to be the first stand-alone detailed document that specifically identifies what technologies and areas of scientific expertise are needed to conduct rigorous pandemic origin investigations. Existing pandemic preparedness plans have mentioned the need for investigating the origins of pandemics but have neither spelled out the challenges nor the specifics of how to conduct an effective probe.

One of the challenges laid out in the report is the need for investigators to have more access to samples from early cases in order to be effective in determining the pandemic's origin. We must address this issue since some government originations, including the government of the Chinese Communist Party, have a history of withholding this type of information.

This report and the upcoming hearing can provide the basis for a bipartisan effort to improve our biodefense strategies by incorporating details on investigative approaches and taking the recommended actions.

Speaking for the Republicans on this subcommittee, we look forward to working with our Democrat colleagues constructively to deliver solutions and pave a path forward for America to work in a common purpose for the greater good.

I eagerly await today's discussion and learning more about how to best address these complex issues.

I also want to thank the witnesses for being here today and for being a part of this discussion. And I apologize we're starting late, but that's what happens with votes.

And, with that, I yield back to myself and now recognize the gentlelady from Florida, Ms. Castor, for her 5 minutes for an opening statement.

[The prepared statement of Mr. Griffith follows:]

Good afternoon, everyone and welcome to our first Oversight and Investigations Subcommittee Hearing of the 118th Congress. I would like to congratulate Ranking Member Kathy Castor on her appointment.

This afternoon's subcommittee hearing will explore the importance of pandemic origin investigations as a means of bolstering our country's pandemic preparedness and biodefense capabilities.

To date, over 1 million Americans have died from COVID-19.[1] The pandemic brought our country to a standstill. It cost our economy around $15 trillion dollars in economic damage.[2]

Businesses were shut down, schools were closed. The nation is still recovering from the pandemic's impact and the damage it caused.

It has been a little over three years since COVID-19 emerged and questions on its origins remain. Given the toll the virus has taken, that is unacceptable.

[1] https://covid.cdc.gov/covid-data-tracker/#datatracker-home
[2] Richard Bruns & Nikki Teran, *Weighing the Cost of the Pandemic*, Institute for Progress (Apr. 21, 2022), https://progress.institute/weighing-the-cost-of-the-pandemic/.

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Being able to quickly identify the root cause of a disease outbreak or biological incident has important benefits ranging from countermeasure development to differentiating between whether an outbreak was due to a deliberate release, an accidental release or a natural event.

By all accounts, the risk of catastrophic biological incidents and infectious disease pandemics is increasing.

As the world becomes more connected, barriers that once helped limit disease from spreading across the globe are removed. Further, human-animal interactions are increasing as well.

The last two decades have seen a global proliferation of laboratories conducting research on potential pandemic pathogens, increasing the possibility that future pandemics may have a research-related origin.

Of the approximately 60 bio-safety level 4 labs, which are designed to work on the most dangerous of pathogens, around the globe, at least 20 have been built in the last decade.[3] More than 75 percent of these labs are located in urban centers where a virus, if it escaped, could spread with ease.[4]

[3] https://schar.gmu.edu/news/2021-07/new-interactive-map-reveals-where-deadliest-germs-are-studied
[4] Id.

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The focus of today's hearing will be a Government Accountability Office technical assessment on technologies and challenges for investigating the origins of pandemics.

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Speaking for the Republicans on this subcommittee, we look forward to working with our Democrat colleagues constructively to deliver solutions and pave a path forward for America to work in common purpose for the greater good.

I eagerly await today's discussion and learning more about how best to address these complex issues. I thank the witnesses for being here today and being part of this important discussion.

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

Ms. CASTOR. Well, thank you, Chairman Griffith.

I'm pleased to be here as the ranking member for the first hearing of the Subcommittee on Oversight and Investigations in the 118th Congress along with some outstanding Democratic colleagues and our professional staff.

And congratulations to you, my friend and colleague. I look forward to working with you in the months ahead.

This committee's jurisdiction touches on so many critical issues that affect the everyday lives of our neighbors, from the ability to access lifesaving healthcare to ensuring that we provide clean energy solutions at lower cost for consumers and provide a more livable planet for our children and future generations.

We have the ability in this subcommittee to ensure that our policies are carried out in a way that helps Americans in the ways we intended. And, when we shine a light on the challenges and shortcomings, we should work together on solutions that will improve our Government's ability to help our neighbors back home.

Today's hearing addresses one component of our evolving ability to respond to a pandemic—identifying a pandemic's origin and focusing on the tools to prevent the next one.

Understanding the origin of a pandemic is useful to inform the necessary public health response. For example, if a virus is found to have jumped from a particular species of animal to humans, we can take steps to better monitor that species of animal and improve the necessary handling procedures to mitigate future risk. Pinpointing the origin of a disease is a piece of information that can be used in developing public health policies and for conducting further research.

But it must be accompanied by informed leadership that supports good science, that listens to experts and rallies the public to act—act together for the common good, including, for example, encouraging the use of safe and effective vaccines. Putting this information into action requires that government officials, especially our leaders at the State and Federal level, take seriously the threat that a pandemic poses.

I appreciate the work that the Government Accountability Office put into the report at the center of today's hearing. There is a lot in that report to understand, and I look forward to doing that with this expert panel of witnesses.

The GAO makes some sensible policy recommendations that could contribute to a stronger national public health system: increasing collaboration across borders, developing new technologies for researchers, standardizing and improving transparency and collected data, and strengthening our scientific workforce. I hope we can have a continuing discussion in this committee and subcommittee on how we can work towards all of those goals.

I do have to mention that this hearing was sprung on us with short notice before the committee was even formally organized, and I will let others judge whether there really is a good cause that warrants an exception to the notice requirement here. But, either way, it does limit the ability of Members and witnesses to prepare themselves on complicated topics.

In her remarks at the committee organizing meeting yesterday, Chair Rodgers mentioned the importance of trust in doing the work that we do. I agree strongly with that sentiment, and I trust that, going forward, for the sake of constructive oversight work, we can ensure that Members, staff, and witnesses have the lead time necessary to tackle the complex issues that come before this subcommittee, as we have done in the past.

I want to close my remarks by noting that, in December, before the 118th Congress even began, then-incoming chairs of two other subcommittees sent the administration excessive document demands and a laundry list of dozens of public servants at our health agencies who they sought to interview in a witch hunt over the origin of the current pandemic.

That generates the exact kind of hostility and fear in the scientific community that the GAO report warns about, stating that researchers may experience unwanted attention, pressure, harassment, or influence because of their involvement in pandemic origin investigations, and that experienced researchers may refuse to participate in such investigations as a result.

Democrats will not ignore bad-faith efforts to erode trust—trust in science, or impede the work of scientists defending the health and safety of the American people. I appreciate, Chair Rodgers and Chairman Griffith, that this subcommittee has begun its work in a different manner, by bringing in serious witnesses to navigate today's challenging topic. And I truly hope that, as we continue the committee's important oversight work in this area and in others, that we do so in that same spirit.

Thank you, and I yield back my time.

[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 "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events"

February 1, 2023

I am pleased to be here as Ranking Member for the Oversight and Investigation Subcommittee's first hearing of the 118th Congress. This Committee's jurisdiction touches on so many critical issues that affect everyday lives of our neighbors, from their ability to access life-saving health care to ensuring that we provide clean energy solutions that lower costs for consumers and help make for a more livable planet.

We have the ability in this Subcommittee to ensure that our policies are carried out in a way that helps Americans in the way we intended. And when we shine a light on challenges and shortcomings, we should work together on solutions that will improve our government's ability to help our neighbors back home.

Today's hearing addresses one component of our evolving ability to respond to a pandemic: identifying a pandemic's origin.

Understanding the origin of a pandemic can be useful to inform the necessary public health response. For example, if a virus is found to have jumped from a particular species of animal to humans, we can take steps to better monitor that species of animal and improve any necessary handling procedures to mitigate future risk.

Pinpointing the origin of a disease is a piece of information that can be used in developing public health policies and for conducting further research, but it must be accompanied by informed leadership that supports good science, listens to experts, and rallies the public to act together for the common good—including, for example, encouraging the use of safe and effective vaccines. Putting this information into action requires that government officials, especially our leaders at the state and federal level, take seriously the threat that a pandemic poses.

I appreciate the work that the Government Accountability Office put into the report at the center of today's hearing. There is a lot in here to unpack, and I look forward to doing that with this panel of witnesses. The report makes some sensible policy recommendations that could contribute to a stronger national public health system—increasing collaboration across borders, developing new technologies for researchers, standardizing and improving transparency in collected data, and strengthening our scientific workforce. I hope we can have a continuing discussion in this Committee and Subcommittee on how we can work toward all those goals.

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That generates the exact kind of hostility and fear in the scientific community that the GAO report warns about, stating that "Researchers may experience unwanted attention, pressure, harassment, or influence because of their involvement in pandemic origin investigations" and that experienced researchers may refuse to participate in such investigations as a result. Democrats will not ignore bad-faith efforts to erode trust in science or impede the work of scientists defending the health and safety of the American people.

I appreciate, Chair Rodgers and Chairman Griffith, that this Subcommittee has begun its work in a different manner by bringing in serious witnesses to navigate today's challenging topic. And I truly hope that as we continue the Committee's important oversight work in this area and in others that we do so in that same spirit.

Mr. GRIFFITH. I thank the gentlelady and now yield 5 minutes to the chair of the full committee, Mrs. McMorris Rodgers, for her opening statement.

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

Mrs. RODGERS. Thank you, Mr. Chairman.

And I appreciate you convening this hearing about the challenges and the opportunities around investigating the origins of pandemics and other biological events. And congratulations on becoming the chairman of this important subcommittee.

And, to the ranking member——

Mr. GRIFFITH. Thank you for letting me do it.

Mrs. RODGERS [continuing]. Ms. Castor, congratulations on becoming the ranking member.

I look forward to working with you, and I am fully committed to building trust. This week was an exception when it came to the notices for the hearings this week due to issues on both sides of the aisle that had come up at the beginning. But I am committed to abiding by the rules. I want the Members to be prepared fully for every committee hearing.

The COVID–19 pandemic has been catastrophic for the United States and the world. And I think about—I think about the people who have lost loved ones, many times without the chance to say goodbye, the first responders who worked around the clock day and night, and every person who served on the front lines to provide hope and comfort in our communities. Government-enforced lockdowns and school closures have hurt our children's well-being mentally, physically, and academically.

In addition, the pandemic cost the United States economy more than $15 trillion. Consider the hundreds of thousands of people whose businesses were shuttered, whose livelihoods were uprooted, who lost everything. We owe it—we have a responsibility to every American to get to the bottom of the origins of COVID–19.

Investigating the origins of COVID–19 has been very difficult and challenging. Some of the hurdles we face are because of inherent scientific challenges. For reference, it took 13 years to determine the origins of the SARS outbreak. In addition, the Chinese Government has lied to America and the global health community on information related to COVID–19.

This is unacceptable, and my hope is that we will join together in our search for the origins of the pandemic with the same bipartisan unity that an airplane crash investigation or other tragedy would receive. The lesson learned is that we have to treat investigating the origins of pandemics as a part of a pandemic preparedness, with a single point of accountability within the Federal Government.

According to a paper recently released by the Johns Hopkins Center for Health Security, quote: "There does not appear to be a single office within the United States Government that owns the challenge of bio attribution. We need a plan, we need a point person, and we need greater accountability."

In request—in response to a request from the Energy and Commerce Republicans, GAO conducted a technical assessment on the origins of pandemics. This report examined, one, key technologies available for pandemic investigations; two, strengths and limitations of these tools; and, three, the cost—the crosscutting challenges researchers face in determining a pandemic's origin. The GAO's technical assistance is perhaps the first stand-alone document that addresses the issue of investigating the origins of pandemics in great detail.

The need for pandemic origins determinations has been noted in other documents, but preparation for investigating the origins of a pandemic or other serious biological events has not been treated as a major component of biodefense strategy.

The GAO detailed the difficulties with such investigations, including lack of sufficient access to samples and genetic sequence data; lack of standardized processing for submitting, accessing, and using genetic sequence data; lack of experts in certain fields.

Overall, we must be united in our efforts to investigate the origins of COVID–19 pandemic and prepare for future pandemics. It is the public health question of our generation. We cannot afford to be divided. It will hurt our ability to prepare for the next pandemic, which could be more severe.

The evidence and the experts tell us that the risk of pandemic are increasing for various reasons, such as a surge in international travel or more development in remote areas that leads to more human interaction with animals and novel viruses.

We need to be better prepared. Our goal is for today's hearing to inform bipartisan efforts on this committee toward reauthorizing pandemic preparedness legislation.

I thank the witnesses for their participation, and I do thank you for participating on short notice. We appreciate your cooperation and look forward to the hearing.

And I yield back.

[The prepared statement of Mrs. Rodgers follows:]

Chair Cathy McMorris Rodgers
House Energy and Commerce Committee
Oversight & Investigations Hearing
"Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events"
February 1, 2023

Thank you, Chair Griffith, for convening this hearing about challenges and opportunities around investigating the origins of pandemics and other biological events.

And congratulations to becoming chair of this important subcommittee.

Welcome too to Rep. Castor for taking over as Ranking Member.

COVID-19

The COVID-19 pandemic has been a catastrophe for the U.S. and the world.

I think about the people who lost loved ones—many times without the chance to say goodbye....

...the first responders who worked around the clock, day and night…

… and every person who served on the front lines to provide hope and comfort in our communities.

Government-enforced lockdowns and school closures have hurt our children's well-being—mentally, physically, and academically.

In addition, the pandemic cost the U.S. economy more than $15 trillion dollars. Consider the hundreds of thousands of people whose businesses were shuttered... whose livelihoods were uprooted... who lost everything.

We owe it to every American to get to the bottom of the origins of the COVID-19 pandemic.

WHY INVESTIGATING ORIGINS IS HARD

Investigating the origins of COVID-19 has been very difficult and challenging.

Some of the hurdles we face are because of inherent scientific challenges. For reference, it took 13 years to determine the origins of the SARS outbreak..

In addition, the Chinese government has lied to America and the global health community on information related to COVID-19.

LESSONS LEARNED

This is unacceptable. We should be able to join together in our search for the origins of the pandemic with the same bipartisan unity that an airplane crash investigation or other tragedy would receive.

The lesson learned is that we have to treat investigating the origins of pandemics as a major part of pandemic preparedness, with a single point of accountability in the federal government.

According to a paper recently released by the Johns Hopkins Center for Health Security, “there does not appear to be a single office within the U.S. Government that owns the challenge of bioattribution.”

We need a plan. We need a point person. We need greater accountability.

E&C REPUBLICAN MEMBER REQUEST

In response to a request from E&C Republicans...

...the Government Accountability Office (GAO) conducted a technical assessment on the origins of pandemics.

This report examined: (1) key technologies available for pandemic investigations; (2) strengths and limitations of these tools; and (3) the cross-cutting challenges researchers face in determining a pandemic’s origin.

The GAO’s technical assessment is perhaps the first stand-alone document that addresses the issue of investigating the origins of pandemics in great detail.

The need for pandemic origins determinations have been noted in other documents, but preparation for investigating the origins of a pandemic or other serious biological events has not been treated as a major component of biodefense strategy.

GAO FINDINGS ON INVESTIGATIVE CHALLENGES

The GAO detailed the difficulties with such investigations, including:

- Lack of sufficient access to samples and genetic sequence data;
- Lack of standardized processes for submitting, accessing, and using genetic sequence data;
- Lack of experts in certain fields.

PREPARING FOR THE FUTURE

Overall, we must be united in our efforts to investigate the origins of the COVID-19 pandemic and prepare for future pandemics.

It is the public health question of our generation

We cannot afford to be divided. It will hurt our ability to prepare for the next pandemic, which could be more severe.

The evidence and experts tell us that the risks of pandemic are increasing for various reasons...

...such as a surge in international travel, or more development in remote areas that leads to more human interaction with animals and novel viruses.

We need to be better prepared.

Our goal is for today's hearing to inform bipartisan efforts on this Committee towards reauthorizing pandemic preparedness legislation.

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

Mr. GRIFFITH. Thank the gentlelady.

Now recognize the ranking member of the full committee, Mr. Pallone, for his 5 minutes of opening statement.

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

Mr. PALLONE. Thank you, Mr. Chairman.

It's good to see you and our ranking member here today and leading this committee on both sides of the aisle.

I want—welcome the opportunity to begin what I hope will be a constructive Congress overseeing the response to COVID–19 and evaluating lessons learned so that we can be ready to prevent and tackle future biological threats facing Americans.

We all know too well from COVID–19 that biological threats are persistent. They're likely to become even more common due to climate change, urbanization, globalization. In order to improve our response to future pandemics, it is critical that healthcare experts are able to research viruses and where they came from in order to quickly identify sequence and understand emerging diseases. And this research allows us to develop countermeasures to help prevent death and disease.

Now, none of this is possible without ongoing, long-term government support for scientific research. As an example, it was Congress' decades-long investment in basic research that enabled virologists and researchers to develop safe and reliable COVID–19 therapeutics and vaccines in record speed.

And now the Biden administration has taken it one step further with the implementation of its National Biodefense Strategy. This strategy presents another opportunity to encourage collaboration amongst government and research sectors, enhance our capacity to prevent biological incidents before they happen, and respond to pandemics when they occur.

The White House Office of Science and Technology Policy recently convened a group of experts in immunology and virology to discuss how to develop our national expertise in identifying pandemic origins. I understand that at least one of our witnesses was in attendance, and I look forward to hearing about how Congress can further support productive collaboration between the research community and government in the future.

It's important to remember that any inquiry into the origins of pandemics is merely one component of a broader strategy to protect Americans from viral disease and prevent future virological episodes. Therefore, as we discuss the origins inquiry, I think we should keep a couple of principles in mind.

First, investigating pandemic origins is useful insofar as it helps us fulfill government's primary responsibility: protecting the health and well-being of citizens. Understanding past pandemics is essential to understanding future ones. For example, as our witnesses described in their written testimonies, lessons learned from the studies of SARS–1, MERS, and H1N1 gave us the tools and infrastructure to quickly understand SARS–CoV–2 during the early COVID–19 outbreak.

The lessons learned also enabled the record-speed development of monoclonal antibodies and drug therapies. Unfortunately, it's only a matter of time before the next pandemic occurs, and it's critical that we apply the lessons that the research community has learned from COVID–19 to refine our abilities to identify, prevent, and respond to biological threats.

The second principle: We must incorporate origin investigation into holistic funding in support of our public health infrastructure. This includes everything from strengthening our healthcare system, tackling the increase in zoonotic health risks caused by climate change, and creating and enabling an environment for research and scientific collaboration.

Third principle: We must keep politics out of any investigation. Instead, it must be guided by science and evidence rather than conjecture and speculation. And I do have deep concerns that any origins investigation will turn political, which would be extremely harmful to public health. As a recent report by the GAO found, the current acrimony surrounding the overly partisan rhetoric of the COVID–19 origins debate could push researchers out of the field just at a time when we need this critical workforce to be strong.

The broad-based research bans and moratoria have taken the place of constructive conversations about improvements to biosecurity, and this has put a chilling effect on research that the American people depend on to retain our competitive edge globally and to achieve medical and scientific breakthroughs. If we're not following the right evidence, we won't learn the right lessons.

Democrats are committed to following the scientific evidence to where it leads so that we can make sure that any origins inquiry leads to tangible improvements in the life of Americans.

So I welcome this opportunity to examine the remaining barriers to properly identifying pandemic origins as part of our broader efforts to protect the health and well-being of Americans.

And, with that, Mr. Chairman, I will yield back.

[The prepared statement of Mr. Pallone follows:]

Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Ranking Member Frank Pallone, Jr.

Oversight and Investigations Subcommittee Hearing on "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events."

February 1, 2023

I welcome this opportunity to begin what I hope will be a constructive Congress overseeing the ongoing response to COVID-19 and evaluating lessons learned so that we can be ready to prevent and tackle future biological threats facing Americans.

As we know all too well from COVID-19, biological threats are persistent. They are likely to become even more common due to climate change, urbanization, and globalization. In order to improve our response to future pandemics, it is critical that health care experts are able to research viruses and where they come from in order to quickly identify, sequence, and understand emerging diseases. This research allows us to develop countermeasures to help prevent death and disease.

None of this is possible without ongoing, long-term government support for scientific research. As an example, it was Congress's decades-long investments in basic research that enabled virologists and researchers to develop safe and reliable COVID-19 therapeutics and vaccines in record speed.

And now the Biden Administration is taking it one step further with the implementation of its National Biodefense Strategy. This strategy presents another opportunity to encourage collaboration among government and research sectors, enhance our capacity to prevent biological incidents before they happen, and respond to pandemics when they occur.

The White House Office of Science and Technology Policy recently convened a group of experts in immunology and virology to discuss how to develop our national expertise in identifying pandemic origins. I understand that at least one of our witnesses was in attendance, and I look forward to hearing about how Congress can further support productive collaboration between the research community and government in the future.

It is important to remember that any inquiry into the origins of pandemics is merely one component of a broader strategy to protect Americans from viral disease and prevent future virological episodes. Therefore, as we discuss the origins inquiry, I think we should keep a couple of principles in mind.

First, investigating pandemic origins is useful insofar as it helps us fulfill government's primary responsibility: protecting the health and well-being of citizens. Understanding past pandemics is essential to understanding future ones. For example, as our witnesses describe in

their written testimonies, lessons learned from the studies of SARS 1, MERS, and H1N1 gave us the tools and infrastructure to quickly understand SARS-COV-2 during the early COVID-19 outbreak. The lessons learned also enabled the record-speed development of monoclonal antibodies and drug therapies. Unfortunately, it is only a matter of time before the next pandemic occurs, and it is critical that we apply the lessons that the research community has learned from COVID-19 to refine our abilities to identify, prevent, and respond to biological threats.

Second, we must incorporate origin investigations into wholistic funding and support of our public health infrastructure. This includes everything from strengthening our health care system, tackling the increase in zoonotic health risks caused by climate change, and creating an enabling environment for research and scientific collaboration.

Third, we must keep politics out of any investigation. Instead, it must be guided by science and evidence rather than conjecture and speculation. I have deep concerns that any origins investigation will turn political which would be extremely harmful to public health.

As a recent report by the Government Accountability Office found, the current acrimony surrounding the overly partisan rhetoric of the COVID-19 origins debate could push researchers out of the field just at a time when we need this critical workforce to be strong. Broad-based research bans and moratoria have taken the place of constructive conversations about improvements to biosecurity.

This has put a chilling effect on research that the American people depend on to retain our competitive edge globally and to achieve medical and scientific breakthroughs. If we're not following the right evidence, we won't learn the right lessons. Democrats are committed to following the scientific evidence to where it leads us so that we can make sure that any origins inquiry leads to tangible improvements in the life of Americans.

I welcome this opportunity to examine the remaining barriers to properly identifying pandemic origins as part of our broader efforts to protect the health and well-being of Americans.

Mr. GRIFFITH. I thank the gentleman. I thank the gentleman for yielding back.

That now concludes our Member opening statements.

The Chair would like to take this opportunity to remind Members that, pursuant to the committee rules, all Members' opening statements that they would like to submit will be made a part of the record.

All right. Now we want to—we're getting close to you all now. We want to thank you all for being here today and taking the time to testify before this subcommittee. Each witness will have an opportunity to give an opening statement, followed by a round of questions from Members. And I assume that you all know the timing schedule. You have 5 minutes. Yellow light means you've got a minute left. The red light means you're over time, and I may have to call you down, but it won't be harsh.

So, first, let me recognize Dr. Karen L. Howard, Acting Chief—I thought we did that after we introduced them.

Yes. I'll do that afterwards.

So, first, let me introduce Dr. Karen L. Howard, Acting Chief Scientist, Director of Science and Technology Assessment Science, Technology Assessment, Analytics, U.S. Government Accountability Office; Dr. Tom Inglesby, Director of Center for Health Security, Johns Hopkins Bloomberg School of Public Health; Dr. Asha—Asha—thank you—and I apologize—M. George, Executive Director of the Bipartisan Commission on Biodefense.

And, at this point, I would like to recognize Dr. Burgess to introduce our next witness.

Dr. Burgess?

Mr. BURGESS. Thank you, Mr. Chairman.

And I want to thank and introduce Dr. Gerry Parker for testifying today. Dr. Parker brings vast experience, accrued over decades of service in public health, biodefense, and the military. Notably, he was an asset to our Nation's Federal response to COVID–19 and the 2001 anthrax attacks.

He now serves as associate vice president for public health, preparedness, and response, and a principal investigator for the Texas A&M Center for Innovation and Advanced Development and Manufacturing.

Prior to his appointment at Texas A&M, Dr. Parker was Deputy Secretary of Defense for Chemical and Biological Defense and the Principal Deputy Assistant Secretary for Preparedness and Response at Department of Health and Human Services. He also served at the Department of Homeland Security.

Prior to his civilian government service, Dr. Parker held a variety of assignments during his impressive 26-year military career in the United States Army.

Thank you again, Dr. Parker, for your service, and for being willing to testify and help us today.

Thank you.

Mr. GRIFFITH. Thank you, Dr. Burgess.

And now I will introduce—Ms. Dingell had hoped to be here to introduce you. But, as we said earlier, there were a number of meetings going on, and people were bouncing in and out. And I

apologize for that, but I would like to introduce Dr. Michael Imperiale. Did I get that right? Close?

He is the Arthur Thurnau Professor at the University of Michigan Medical School.

Thank you so much for being with us.

And, as you know, the testimony that you are about to give is subject to title 18, section 1001, of the United States Code. When holding an investigative hearing, this committee has the practice of taking testimony under oath.

Does anyone have an objection to testifying under oath?

Seeing no objections, we'll move forward.

And, also, the Chair would advise you that, under the rules of the House and the House—and the rules of this committee, you are entitled to be advised by counsel.

Does anyone wish to be advised by counsel during their testimony today?

Again, based on nods of head, no one has requested the opportunity to have counsel present with them at this time.

In that case, if the witnesses would please rise. This is where we get you standing up again.

And raise your right hand, and I'll swear you in.

[Witnesses sworn.]

Mr. GRIFFITH. All have stated affirmatively that they will tell the truth.

All right. We appreciate it. Now you can remain—you can return to your seats.

Thank you all, and I would now recognize Dr. Howard for 5 minutes to give her opening statement.

STATEMENTS OF KAREN L. HOWARD, PH.D., ACTING CHIEF SCIENTIST AND DIRECTOR, SCIENCE, TECHNOLOGY ASSESSMENT, AND ANALYTICS, GOVERNMENT ACCOUNTABILITY OFFICE; TOM INGLESBY, M.D., DIRECTOR, CENTER FOR HEALTH SECURITY, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH; ASHA M. GEORGE, D.P.H., EXECUTIVE DIRECTOR, BIPARTISAN COMMISSION ON BIODEFENSE; GERALD W. PARKER, D.V.M., PH.D., ASSOCIATE DEAN FOR GLOBAL ONE HEALTH, COLLEGE OF VETERINARY MEDICINE & BIOMEDICAL SCIENCES, TEXAS A&M UNIVERSITY; AND MICHAEL J. IMPERIALE, PH.D., ARTHUR F. THURNAU PROFESSOR, DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY, UNIVERSITY OF MICHIGAN

STATEMENT OF KAREN L. HOWARD, Ph.D.

Dr. HOWARD. Chair Rodgers, Ranking Member Pallone, Chair Griffith, Ranking Member Castor, and members of the subcommittee, I am pleased to be here today to discuss our Report on Technologies, Challenges, and Policy Options for Pandemic Origin Investigations.

In the last 20 years, several pandemics have led to significant loss of life and economic disruption.

Pandemics can arise from natural sources, notably, transmission from animals to humans. Pandemics could also emerge from laboratory work, either through an accidental infection in the lab, or

through release of a pathogen from a lab. By conducting timely, effective pandemic origin investigations, we can learn more about how these diseases arise and reduce high-risk activities to prevent future outbreaks or limit their impact.

In our report, we identified several technologies that can help establish pandemic origins. Chief among these is genetic sequence analysis, which identifies the genetic sequence of a pathogen and compares it to the sequences of known pathogens stored in databases.

Researchers also gather evidence for pandemic origins by analyzing blood samples, tracking the spread of the disease through a population, and conducting laboratory-based studies to better understand how the disease may be transmitted. These techniques are mature and have been used to establish the likely origins of several previous pandemics.

However, experts told us that origin investigations are hindered by three nontechnological challenges: first, the lack of sufficient access to samples and sequence data. There can be many reasons for this. For example, there is often a lack of awareness of the need to collect and store samples for later use, especially early in an outbreak. Other reasons include privacy concerns, national sovereignty, and the possibility of negative consequences for sharing information.

The second challenge is the lack of standardized database processes. There are many databases, both public and private, for storing genetic sequence data. These databases were often designed for other purposes and may not ideally suit the needs of origin investigators.

Experts told us that the user interfaces can be cumbersome, especially when trying to work across multiple databases. Crucial data may be missing or unreliable, and the rapidly increasing volume of data will likely strain the limits of available infrastructure and computing power.

The third challenge is the lack of a sufficient interdisciplinary workforce. The need and the resources to support an appropriate workforce often fluctuate as pandemics rise and then wane.

There is uneven global distribution of the skilled staff we do have. There are silos between the many disciplines needed for this work. And some researchers told us they faced criticism because of their involvement in determining pandemic origins, which can cause skilled researchers to avoid the field.

We've identified five policy options that can help address these challenges. One key option is for policymakers to proactively establish multinational agreements to collect, store, and share samples and data. Taking this step in advance would allow for rapid mobilization of the protocols at the earliest signs of an outbreak when the data and samples are most critical for determining origins. Ideally, such agreements would clearly delineate roles and responsibilities, as well as collaboration and coordination mechanisms.

Other policy options include developing standardized processes for database submission and access, along with improved user interface tools, and investing in the training and retention of skilled staff.

We also identified a fifth crosscutting option: development of a detailed national strategy targeted specifically toward pandemic origin investigations. Such a strategy could address all three key challenges and improve the ability of experts to more effectively investigate future pandemics.

In conclusion, pandemic origin investigations can be facilitated by current technologies but still face key challenges that hinder the ability of the U.S. and other nations to respond effectively and reduce the likelihood and severity of future pandemics.

Chair Rodgers, Ranking Member Pallone, Chair Griffith, Ranking Member Castor, and members of the subcommittee, this concludes my prepared statement.

I would be happy to respond to questions.

[The prepared statement of Dr. Howard follows:]

United States Government Accountability Office

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 2:00 p.m. ET
Wednesday, February 1, 2023

PANDEMIC ORIGINS

Technologies, Challenges, and Policy Options to Support Investigations

Statement of Dr. Karen L. Howard,
Acting Chief Scientist and Director, Science, Technology Assessment, and Analytics

GAO-23-106562

Chair Griffith, Ranking Member Castor, and Members of the Subcommittee

Thank you for the opportunity to discuss our work on pandemic origins. My testimony today summarizes our January 2023 technology assessment entitled *Pandemic Origins: Technologies and Challenges for Biological Investigations*.[1] GAO's technology assessments focus on examining technologies and identifying their challenges and benefits. The report I am discussing today examines technologies—including tools and methods—used to investigate the origin of infectious diseases that lead to pandemics.[2]

Given the magnitude of the health and economic costs of pandemics, there is a need to better understand how and where they originate.[3] According to scientific literature, most pandemics where the origin is known were caused by the natural transmission of a pathogen through animal-to-human contact, also known as zoonotic transmission. A pandemic could also potentially be initiated through the accidental infection of an individual or individuals by a pathogen in a laboratory setting, or infections outside the laboratory caused by an accidental or intentional release of the pathogen from a laboratory. For example, research suggests the 1977-1978 H1N1 influenza pandemic may have been the result of a laboratory accident or other cause.[4] Determining the likely origin of pandemics is challenging and requires information

[1]GAO, *Pandemic Origins: Technologies and Challenges for Biological Investigations*, GAO-23-105406 (Washington, D.C.: January 31, 2023).

[2]Determination of a pandemic's origin has some level of inherent scientific uncertainty. For our January 2023 report and this testimony statement, we use the term "origin" to mean "likely origin," acknowledging this uncertainty.

[3]As of the week ending January 7, 2023, the U.S. had about 1,090,000 reported deaths attributed to COVID-19. A recent assessment estimated the human and economic cost of the COVID-19 pandemic to the U.S. totaled more than $10 trillion. The 2009 H1N1 influenza pandemic resulted in approximately 61 million cases and 12,500 deaths in the U.S. Prior to a successful vaccination campaign that eradicated smallpox in 1980, the disease killed approximately 300 million people globally between 1900 and 1980.

[4]Other causes suggested for the 1977-1978 H1N1 influenza pandemic include deliberate release of the virus or a vaccine trial mishap. See M. Rozo and G.K. Gronvall, "The Reemergent 1977 H1N1 Strain and the Gain-of-Function Debate," *mBio*, vol. 6 (2015):e01013-15.

gathered from established methods for disease outbreak investigations that may, in some cases, take a decade or longer of research to acquire.[5]

Our January 2023 report and my statement today address key technologies available for pandemic origin investigations; strengths and limitations of these technologies; and cross-cutting challenges researchers face in trying to determine a pandemic's origin.[6]

To understand the available technologies and challenges in determining the origins of pandemics, we convened a 3-day meeting of 27 experts in March 2022 with assistance from the National Academies of Sciences, Engineering, and Medicine.[7] We also examined peer-reviewed scientific literature and other documents, including the 2022 National Biodefense Strategy and reports from the World Health Organization, Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC), Office of the Director of National Intelligence, the Johns Hopkins Center for Health Security, and select national laboratories. Further, we interviewed officials and researchers from 11 relevant federal agencies as well as nonfederal experts with a diverse set of perspectives on the science and application of these technologies. Additional information about our scope and methodology can be found in our January 2023 report. We performed the work on which this testimony is based in accordance with all sections of GAO's Quality Assurance Framework that are relevant to technology assessments.

Technologies Are Mature and Can Help Inform Pandemic Origin Investigations

Several key technologies and approaches can help inform investigations of a pandemic's origin, including: genetic sequence analysis; pathogen exposure monitoring and disease tracking; and laboratory-based pathogen studies. However, to effectively apply these technologies, researchers require samples and data obtained from infected people, animals, and the environment in or around outbreak areas from as early in an outbreak as possible.

[5]For example, it took approximately 13 years to determine the origin of the SARS-associated coronavirus (SARS-CoV) pathogen that caused the 2002-2003 SARS pandemic. While the first human outbreak of H1N1 occurred in Mexico in early 2009, it wasn't until 2016 that it was established that the virus jumped from pigs to humans in central Mexico. The origin of the Ebola virus remains inconclusive.

[6]For the purposes of our report, the term "technologies" includes the instruments, techniques, skills, methods, and processes used in pathogen characterization.

[7]Meeting participants were from academia, business, and nonprofit organizations. For a complete list of participants, see Appendix I of this statement.

Genetic sequence analysis. Experts told us that they consider genomic sequencing one of the key technologies for pandemic origin investigations due to its speed, accuracy, and cost. Genomic sequencing allows researchers to generate a pathogen's genetic sequence. This genetic sequence is then analyzed using bioinformatics tools and compared to reference genetic sequences stored in databases to identify matches with other known pathogens, mutations in the sequences, potential genetically-engineered sequences, and likely relationships to the nearest relatives. For example, researchers used genetic sequence analysis to help establish the likely natural origins of the 2002-2003 SARS pandemic, the 2009 H1N1 influenza pandemic, and the initial MERS outbreak in 2012. However, some laboratory-based genetic modifications may be indistinguishable from natural variations. For example, some traditional genetic engineering techniques and newer genome editing tools—such as CRISPR—may not leave readily detectable traces of genetic modification. Further, repeated growth of the pathogen in laboratory animals or cell cultures may result in changes (i.e., mutations) in the pathogen that closely mimic the natural processes of evolution.

Pathogen exposure monitoring and disease tracking. Technologies such as serology (i.e., blood analysis) and epidemiological surveillance—tracking a disease as it moves through a population—are also key technologies for pandemic origin investigations. These technologies allow researchers to monitor pathogen infection and disease occurrence in human and animal populations. For example, serology surveillance in people and camels provided two key pieces of information that contributed to the determination that camels were direct sources of human infection with MERS-CoV.

Laboratory-based pathogen studies. The exact processes by which some pathogens adapt to infect and transmit between humans are not well-understood, which may limit investigators' abilities to establish the origin of a pandemic. Therefore, laboratory-based pathogen studies using cell cultures or animals may provide evidence supporting known natural or unusual patterns of spread. The latter may indicate a possible laboratory-related origin. For example, researchers studying pandemic H1N1 influenza virus in ferrets identified the viral genes, proteins of transmission, and host receptor sites that drive different routes of transmission. The results of these studies supported the conclusion that this virus likely originated from animal-to-human transmission. However, results from controlled laboratory studies may not accurately represent the natural environment, making it difficult for researchers to clearly

distinguish between natural versus laboratory-controlled patterns of spread.

Investigators need access to samples and data, particularly from infected or exposed individuals, from as early in an outbreak and as geographically close to the first reported human disease cases as possible, for these technologies to be effective in determining a pandemic's origin. However, certain countries may refuse or limit researchers' access to field sites, facilities, data, or people. For example, researchers and agency analysts reported that uncertainty still exists about where the first SARS-CoV-2 infections occurred because of a lack of clinical samples available for serological and genetic analyses as well as a lack of epidemiological data from the earliest cases.

Cross-Cutting Challenges that Hinder Pandemic Origin Investigations and Policy Options that May Help Address Them

According to experts, technologies are not the limiting factor for determining the likely origin of a pandemic. Experts identified three cross-cutting key challenges that hinder researchers trying to investigate the origin of a pandemic:

- Lack of sufficient access to samples and genetic sequence data;
- Lack of standardized processes for submitting, accessing, and using genetic sequence data stored in databases around the world; and
- Lack of a sufficient and skilled interdisciplinary workforce.

We identified five policy options that may help address these challenges and help improve the ability of researchers to respond more quickly and effectively to future pandemics.

Challenge: Lack of sufficient access to samples and genetic sequence data. Privacy concerns, general mistrust, perceived infringements on a country's sovereignty, or fear of negative consequences may limit access to samples and data. Further, even if researchers have access to samples and data, their ability to extract suitable information may be limited by a lack of standardized processes. For example, health officials may collect samples for a purpose other than pathogen surveillance, or store and process the data obtained from the samples in a way incompatible with what is needed for effective investigations. Additionally, no one entity is responsible for determining and enforcing standardized processes.

Policy Option: Experts and some agency officials told us that federal policymakers, such as the Department of State, and others could help

address this challenge in advance of future outbreaks by establishing comprehensive multilateral, international agreements for accessing and sharing genetic sequence samples and data. These proactive agreements could include definitions of the roles and responsibilities of international investigation teams and incentives for adherence, helping ensure more timely access to critical information. Negotiating or modifying agreements each time a pandemic occurs is not effective because of the speed with which pandemics spread. That is, agencies do not have months to negotiate a series of bilateral agreements with every country every time an outbreak occurs. Instead, policymakers and others could proactively:

- Develop multilateral sample and data-sharing agreements—for example, agreements which include expectations of timely access to samples and detailed standards for sample collection;
- Work with international health organizations, such as the World Health Organization, to identify and address barriers to establishing multilateral, international agreements for ensuring access to genetic sequence samples and data, and support the development of such agreements; and
- Seek agreement with stakeholders on incentives for participation, such as equitable access to vaccines and therapeutics. These incentives could also include economic assistance and assurances to mitigate stigmatization when promptly sharing samples and genetic sequence data.

A key benefit of establishing these proactive agreements is ensuring timely access to genetic information and samples in the critical beginning stages of a pandemic and throughout an origin investigation. Such access may help in the determination of a pandemic's origin. However, some countries may be unwilling to participate in these agreements because of concerns related to national sovereignty, among other reasons. Further, identifying an appropriate responsible entity to determine and monitor whether countries are following agreed-upon standard processes may be challenging.

Challenge: Lack of standardized processes for genetic sequence databases prevents researchers from analyzing data effectively. To investigate the origin of a pandemic, researchers need access to genetic

sequence data, which may be stored in multiple databases.[8] Experts cited three main issues with working across multiple databases:

- Each genetic sequence database may have different processes for submitting, accessing, and using the data. As a result, gathering all of the data necessary to investigate the origin of a pandemic can be challenging.
- Genetic sequence databases generally lack standardized user interfaces for data submission and access, and some existing user interfaces can be cumbersome. The need for different procedures to submit and retrieve data from relevant databases can be time-consuming and inefficient for researchers.
- Metadata such as the date and location of sample collection are crucial for investigating the origin of a pathogen, but their availability and quality may vary. For example, although GenBank® allows users to report specific locations where samples were collected, a 2017 study estimated that 99 percent of records do not include that information. If the information does exist, researchers may still have to perform additional steps of integrating this information from other fields in the sample's record, which is challenging and may affect the reliability of the location data.

Rapid growth of big data

A 2015 study predicted that, by 2025, genomics research worldwide will generate between 2 and 40 exabytes of data annually. (For reference, 1 exabyte equals 1 billion gigabytes.) This would make genomics one of the most challenging domains of Big Data in terms of data acquisition, storage, distribution, and analysis.

Accommodating the expected growth of genomic data will require advancements in computational speed and power, as well as algorithms optimized for Big Data.

Source: GAO review of literature. | GAO-23-106562

These issues may be exacerbated by the immense scale and continued growth of genetic sequence data. (See text box for a prediction on the future growth of genomic data.)

As the amount of data in each database grows, and as more databases are added, standardized processes are crucial to ensure that researchers can compile, analyze, and share all the genetic sequence data necessary to investigate the origin of a pandemic. However, it is unclear whether the existing infrastructure of the independent databases worldwide can support the growth of genomic data.

Policy Options: Experts identified two possible options policymakers could consider to address this challenge of a lack of standardized processes for genetic sequence databases. First, federal policymakers and others—such as HHS, current database providers, developers, and users—could collaborate to identify and develop standardized processes

[8]These databases include GenBank®, Global Initiative on Sharing All Influenza Data (GISAID), and European Molecular Biology Laboratory-European Bioinformatics Institute (EMBL-EBI).

for submission of and access to data in databases such as GenBank to support pandemic origin investigations. Second, policymakers could encourage the improvement of current, or development of new, genetic sequence database tools—such as user interfaces or application programming interfaces (API)—of current databases, or incentivize the creation of new user interfaces or APIs to help investigators determine a pandemic's origin more effectively.[9]

The key benefits of developing standardized processes and improving interfaces for database use include ensuring the consistency and quality of submitted data to help researchers access and compare genetic sequences and address the projected future growth in genetic sequence data. However, standardized processes and interfaces may be difficult and expensive to develop, and it may be challenging for multiple stakeholders to agree on what data and interface features are important.

Challenge: The global research community lacks a sufficient and skilled interdisciplinary workforce. Pandemic origin investigations require a highly skilled workforce with expertise in multiple fields. We identified four main reasons it can be hard to develop and retain such a workforce:

- Demand for workers in relevant fields tends to increase when pandemics occur and decrease when pandemics end. Likewise, funding for relevant research tends to fluctuate. This makes it challenging to keep the workforce in readiness (i.e., available and proficient) to conduct investigations promptly when pandemics occur.
- Pandemic origin investigations require expertise in multiple fields such as biology, virology, microbiology, immunology, epidemiology, ecology, genomics, bioinformatics, and computer science. However, experts we interviewed told us the current workforce is siloed because of academic structures, funding priorities, and grant processes. This makes it challenging to build and maintain the multidisciplinary workforce necessary to conduct investigations.
- The current uneven global distribution of the workforce leads to political and logistical challenges during a pandemic. For example, a 2021 study of one country concluded that inadequate sequencing

[9]An application programming interface (API) enables machine-to-machine communication, allowing users to obtain real-time data updates.

capacity because of limited skillsets, among other factors, hindered biosurveillance during the COVID-19 pandemic.[10]

- Some researchers told us that they faced criticism because of their involvement in investigating the origin of a pandemic, particularly when their conclusions were considered controversial. These researchers said they and others may be reluctant to participate in further investigations because of personal and professional risks.

Policy Option: To address this challenge, policymakers could incentivize the development, retention, and growth of a workforce—including in areas considered hot spots of emerging infectious disease—with the critical skills to conduct or support the work of characterizing the likely origin of a pandemic. One way to implement this policy option is by creating international partnerships, among other things, and leveraging or creating training programs to encourage workforce growth and retention.

A sufficient and skilled workforce would ensure that the workforce is not concentrated in any geographic region. A trained workforce skilled in origin investigations could also contribute to other areas such as public health, or other related activities. However, the scientific community may resist alteration to current academic structures, and it may be challenging to adapt priorities, processes, and funding in a sufficiently timely manner needed to respond to a pandemic. As a result, attracting qualified people into the necessary workforce fields may be challenging if those fields are marginalized and underfunded.

Cross-Cutting Policy Option: Develop a national pandemic origin strategy. While the first four policy options may help address the specific challenges we identified and help improve the ability of researchers to respond more quickly and effectively to future pandemics, we found that a national strategy could help to address all of these challenges. For example, the 2022 National Biodefense Strategy and Implementation Plan includes an Early Warning priority area that encompasses targets and corresponding actions related to determining the origin of biological events, including infectious disease outbreaks. However, augmenting the 2022 Strategy or developing a separate strategy with more specifics, such as specifying how the lead and support departments and agencies

[10]M. Dzobo et al., "Inadequate SARS-CoV-2 Genetic Sequencing Capacity in Zimbabwe: A Call to Urgently Address this Key Gap to Control Current and Future Waves," *IJID Regions*, vol. 1 (2021): ep. 3-4. https://doi.org/10.1016/j.ijregi.2021.09.004.

will coordinate and collaborate, could better position the nation to play a leading role in pandemic origin investigations. For example,

- Federal policymakers could augment the 2022 National Biodefense Strategy to specify how lead and support departments and agencies will coordinate and collaborate with domestic and international partners to address pandemic origin investigations; or
- Federal policymakers could develop a new, standalone, national strategy focused on pandemic origin investigations that describes how federal entities will coordinate and collaborate with domestic and international partners on such investigations.

The key benefits of a national strategy with federal coordination and collaboration leadership include increasing preparedness for future pandemic origin investigations and mitigating health and economic costs. However, allocating resources and defining how federal agencies and others will collaborate may be challenging because of the number and types of entities with relevant expertise. Further, during nonpandemic periods, other priorities and needs may arise and make it challenging to provide sustained resources and support needed for maintaining a national strategy.

In closing, we found that technologies are mature and available for helping inform the origin of pandemics, but several non-technological challenges hinder such investigations. To address these challenges, we proposed five policy options for consideration. These options would better position our nation to deal with future pandemics, in particular, by crafting multilateral agreements for sample and data sharing and developing a targeted national strategy for pandemic origin investigations.

Chair Griffith, Ranking Member Castor, and Members of the Subcommittee, this concludes my statement. I would be pleased to respond to any questions you or other Members may have.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact Karen L. Howard at (202) 512-6888 or howardk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Key contributors to this testimony include Hayden Huang (Assistant Director), Michael Dickens (Analyst-in-Charge), Calaera Powroznik, Craig Starger, and Adam Wells. Additional contributors to the prior work on which this testimony is based are listed in our January 2023 report.

Appendix I: Expert Meeting Participants

For the report on which this testimony is based, we convened a 3-day meeting of 27 experts with assistance from the National Academies of Sciences, Engineering, and Medicine to inform our work on technologies for determining pandemic origin; the meeting was held virtually March 22–24, 2022. The experts who participated in this meeting are listed below.

David B. Allison, PhD; Dean, Distinguished Professor and Provost Professor, Indiana University–Bloomington School of Public Health

Jesse Bloom, PhD; Professor, Basic Sciences Division; Professor, Herbold Computational Biology Program, Public Health Sciences Division, Fred Hutchinson Cancer Research Center

Roger Brent, PhD; Professor, Basic Sciences Division; Professor, Public Health Sciences Division, Fred Hutchinson Cancer Research Center

James Diggans, PhD; Distinguished Scientist, Bioinformatics and Biosecurity, Twist Bioscience

Joshua Dunn, PhD; Head of Design, Ginkgo Bioworks, Inc.

Livia Schiavinato Eberlin, PhD; Associate Professor, Department of Surgery, Baylor College of Medicine

Patrick Fitch, PhD; Associate Director of Chemical, Earth and Life Sciences, Los Alamos National Laboratory

A. Oveta Fuller, PhD; Associate Professor of Microbiology and Immunology, Medical School at University of Michigan

Gigi Kwik Gronvall, PhD; Senior Scholar, Johns Hopkins Center for Health Security; Associate Professor, Department of Environmental Health and Engineering, Johns Hopkins Bloomberg School of Public Health

India Hook-Barnard, PhD; Executive Director, Engineering Biology Research Consortium

Katrina Kalantar, PhD; Computational Biology Lead, Infectious Diseases, Chan Zuckerberg Initiative

Ali S. Khan, MD, MPH, MBA; Dean, College of Public Health, University of Nebraska Medical Center (UNMC); Former Assistant Surgeon General, U.S. Public Health Service

Andy Kilianski, PhD; Senior Director for Emerging Infectious Diseases, International AIDS Vaccine Initiative (IAVI); Adjunct Professor, Schar School of Policy and Government, George Mason University

Sergios-Orestis Kolokotronis, PhD, MPhil, MA; Assistant Professor, Department of Epidemiology and Biostatistics, School of Public Health, The State University of New York (SUNY) Downstate Health Sciences University

Suresh Kuchipudi, BVSc, MVSc, PhD, PGCHE, FHEA, Dip. ACVM, MBA; Professor and Endowed Chair in Emerging Infectious Diseases, Pennsylvania State University; Associate Director, Penn State Animal Diagnostic Laboratory (ADL)

Jacob Lemieux, MD, DPhil; NIH-funded Physician/Scientist, Division of Infectious Disease, Massachusetts General Hospital (MGH) and Harvard Medical School (HMS)

Bronwyn MacInnis, PhD; Director of Pathogen Genomic Surveillance, Infectious Disease and Microbiome Program, Broad Institute of Massachusetts Institute of Technology (MIT) and Harvard

Alemka Markotić, MD, PhD; Director, University Hospital for Infectious Diseases, Zagreb, Croatia; Head of Department for Research and Head of Clinical Department for Urinary Tract Infections and Full Professor, Medical School, University of Rijeka and Catholic University Zagreb; Associate Member, Croatian Academy

Jonna Mazet, DVM, MPVM, PhD; Vice Provost – Grand Challenges, University of California (UC) Davis; Chancellor's Leadership Professor of Epidemiology and Disease Ecology and Founder, One Health Institute, UC Davis School of Veterinary Medicine

Folker Meyer, PhD; Professor of Data Science, University Hospital, University of Duisburg-Essen

Tara O'Toole, MD, MPH; Senior Fellow, In-Q-Tel; Director, IQT Lab, BiologyNext

Rushika Perera, PhD; Associate Professor, Department of Anatomy, University of California (UC) San Francisco

Brian Plew; Director, Public Health Solutions, Thermo Fisher Scientific

David Relman, MD; Thomas C. and Joan M. Merigan Professor in Medicine, Professor of Microbiology & Immunology, Senior Fellow, Center for International Security and Cooperation, Stanford University; Chief of Infectious Diseases, Veterans Affairs Palo Alto Health Care System

Aaron Streets, PhD; Assistant Professor in Bioengineering, University of California (UC) Berkeley; Core Member, Biophysics Program and Center for Computational Biology, Investigator, Chan Zuckerberg Biohub

David Walt, PhD; Hansjörg Wyss Professor of Bioinspired Engineering, Harvard Medical School; Professor of Pathology, Brigham and Women's Hospital; Core Faculty Member, Wyss Institute at Harvard University

Susan Weiss, PhD; Professor and Vice Chair, Department of Microbiology and Co-Director, Penn Center for Research on Coronaviruses and Other Emerging Pathogens, Perelman School of Medicine, University of Pennsylvania; Governor, American Academy of Microbiology

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Congressional Relations	A. Nicole Clowers, Managing Director, ClowersA@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548
Public Affairs	Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548
Strategic Planning and External Liaison	Stephen J. Sanford, Managing Director, spel@gao.gov, (202) 512-4707 U.S. Government Accountability Office, 441 G Street NW, Room 7814, Washington, DC 20548

Mr. GRIFFITH. Thank you very much.

I now recognize Dr. Inglesby for 5 minutes for an opening statement.

STATEMENT OF TOM INGLESBY, M.D.

Dr. INGLESBY. Chair Rodgers, Ranking Member Pallone, Chair Griffith, Ranking Member Castor, and members of the subcommittee, thank you for the chance to speak with you today.

I want to commend you for focusing on how to build our capacity to determine the source of future pandemic and biological events. This capacity could help us diminish the chance of those events, whether they were to come from a natural source, a lab accident, or the deliberate use of a biological weapon from a U.S. adversary.

If bio attribution efforts around future biological events showed that a certain animal management practice was responsible for an event, that practice could be stopped. If it showed something started in a lab, the responsible lab practices could be ended or changed. If it showed a biological event was deliberately started, it would have national security consequences.

The capacity to determine the source of a biological event will be a form of deterrent against such attacks in the first place, and strong attribution tools could help the U.S. to avoid being deliberately deceived about the source, debunking false-flag efforts by adversaries who try to assign blame to a country that had no responsibility for it.

Attribution science is also critical in the work to grow the U.S. bioeconomy, which is a growing, dynamic part of the U.S. economy. These tools could help us protect the biotech products that the U.S. creates, whether they are crops, food, energy, medicines, or other biologically produced materials.

Biological attribution science relies on a range of approaches and data sets, including genetic sequencing, bioinformatics, and access to genetic databases in the U.S. and around the world.

A recent White House OSTP meeting on strengthening bio attribution highlighted the need for establishing more robust international databases, for funding the science base, applying machine learning tools to this endeavor, and integrating data across government.

I strongly support the five GAO recommendations in their report, including the importance of international sequence sharing, strong standards for databases around the world and in the U.S., improving tools for this work, building the workforce we need, and setting national strategy.

Much of the key science resides outside government, either in research universities or the private sector, so the Government should be funding the development of that science.

The administration's National Biodefense Strategy, which came out in October 2022, does commit to strengthening national attribution capacity. And now, the administration, with the support of Congress, should identify specific agency responsibilities around that work—goals, timelines, and budget requirements. And my intuition is that more funding is needed for this work, and possibly new authorities for data collection are needed, but that obviously

is something that the Congress will be looking into and making conclusions about.

In conclusion, the U.S. doesn't have yet the scientific research and databases, operational plans, or international partnerships that can reliably identify the source of future pandemics and biological events. Building this capacity will have great benefit to protecting health, national security, and the bioeconomy, and so should be a high priority for the administration and Congress now.

Thank you for the opportunity to speak with you, and I'm happy to take questions.

[The prepared statement of Dr. Inglesby follows:]

United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events

Tom Inglesby, MD

Director, Center for Health Security

Johns Hopkins Bloomberg School of Public Health

February 1, 2023

Chair McMorris Rogers 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 *Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events.* My name is Dr. Tom Inglesby, and I am the Director of the Center for Health Security of the Johns Hopkins Bloomberg School of Public Health and a Professor of Public Health and Medicine at Johns Hopkins University. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University or Health System.

Our Center's mission is to protect people's health from major epidemics and disasters and build resilience. We study the organizations, systems, and tools needed to prepare and respond. Today, I am happy to provide testimony on the challenges and opportunities to investigating the origins of pandemics and other biological events.

High importance of these issues

I commend you for focusing on these issues. Strong capability to determine the source of future pandemics and other biological events may help us diminish the chances of those events. Whether a future pandemic has a natural origin, or is the consequence of an accident, or is the result of a deliberate event, it will be critical to do all that can be done to determine its origin. The term "biological attribution science" has also been used to refer to the body of scientific and investigative work that can be used to determine pandemic (or epidemic) origins, and so I

will also use that term in this testimony. Future pandemic or biological threats could emanate from nature in some form. They could arise from a high consequence laboratory accident. Or they could arise from the deliberate use of a biological weapon from a US adversary. All of these could occur without warning and need to be prepared for broadly. One element of that preparedness is the capacity to attribute the source of future pandemics or other biological events as rapidly as possible.

If after a future biological event, biological attribution identifies, for example, that a certain animal management practice is responsible, that should have major consequences for the future of that practice(s). If it were demonstrated through biological attribution that a pandemic or biological event started in a laboratory, that should have very important ramifications for biosafety – it would be critical to understand how the accident originated and how to reduce the risks of additional events. Biological attribution is also crucial for national security – if a pandemic event or another biological event is deliberately started, then the national security of the country requires us doing all that we can to attribute the source of that. A clearly communicated and strong capacity to attribute the source of a deliberate attack using a biological weapon should also serve as a strong deterrent against that happening in the first place. Not only is it crucial for the US government to understand what initiates a deliberate outbreak, but it is also essential for the US government to avoid being deliberately deceived about the origin. Highly effective bioattribution tools could help not only to identify the accurate source of a biological event but also to debunk a false-flag attempt by adversaries who attempt to falsely assign blame to a country or entity which actually had no responsibility for it.

I also want to call out the importance of attribution science in the effort to grow and power the US bioeconomy. A growing, dynamic sector of the U.S. economy is driven by the products that are made through biotechnology, with every expectation that that portion of the economy here and elsewhere in the world will keep expanding quickly in the time ahead. To keep the US moving fast ahead as a contributor to the domestic and global bioeconomy, we will need to advance attribution science to help us defend the provenance and intellectual property related to U.S. biotechnological products.

The Administration's National Biodefense Strategy -- published in October 2022 - commits to strengthening national attribution capacity (on pages V and X). The strategy says that the US will: "Enhance and sustain U.S. Government characterization capabilities for forensics and attribution, serving the U.S. human, animal, plant, and environmental health and national security communities." It places leadership for this work at the Department of Health and Human Services (HHS), and the Federal Bureau of Investigation (FBI), with support from the Department of the Interior (DOI), the U.S. Department of Agriculture (USDA), the Department of Energy (DOE), the Department of Homeland Security (DHS), the Environmental Protection Agency (EPA), the Centers for Disease Control (CDC), and the Intelligence Community (IC). The National Biodefense Strategy also says that the U.S. government will: "Strengthen the capability of the UN Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and

Biological Weapons (UNSGM) to determine the facts, including attribution, regarding the alleged use of biological or toxin weapons." The strategy says that the lead for this work will be the Department of State (DoS), the Department of Defense (DoD), and the FBI.

The range of agencies listed in support of these mission show how multidisciplinary this work must be to succeed, and how distributed the necessary talents and resources are in the U.S. government. Biological attribution requires the capacity for strong, rapid domestic response, as well as the ability to work internationally with other partners with the goal of determining the origin of major biological events.

Important GAO Report analysis and recommendations

The GAO report **Pandemic Origins: Technologies and Challenges for Biological Investigations** provides a highly valuable assessment of the approaches used for biological attribution as well as policy recommendations aimed at advancing national capability in the field.

Biological attribution science relies on a combination of sources and approaches. These include genetic sequencing and bioinformatics and access to genetic databases. As the GAO report describes, the purpose of this kind of sequence analysis is to compare one pathogen's sequence to the sequence of other pathogens in an effort to find matches or pathogens that are more closely related than others. This work, which includes the study of the evolutionary history and relationships among or within groups of organisms, is called phylogenetics and is a critical field of science in biological attribution. The tools that are now available for genetic sequencing are extraordinary and sophisticated. But for sequencing to be of greatest value, access to samples, genetic sequences, and genetic databases will be critical. Data from some areas of the world (e.g., the U.S. and U.K.) are overrepresented in some large genetic databases, with no data included from other parts.

Another major weakness in approaches to biological attribution is that while the tools of genetic sequencing and bioinformatics are quite powerful and accurate, they cannot always reliably distinguish whether a pathogen came from a natural source vs whether it was passaged, edited or engineered in a laboratory. More work remains to develop bioattribution tools that can address critical questions like these.

For instance, other areas of science, including the study of proteins (proteomics), the study of sugars on proteins (glycomics), and the study of environmental factors resulting in modifications of genetic materials (epigenetics) have great potential to provide value to an origins investigation, but they are not yet fully developed in ways that make them central approaches to this work.

The success of bioattribution scientific work may also depend on access to public health surveillance data, animal surveillance data, environmental data, and human clinical data. Epidemiological data about patterns of spread and risk factors for those infected may be pivotal. And all of this data would be critical as early as possible in a novel pandemic or after a

biological event, as close to the initial case or cases as possible, before the data is lost to time, degraded or just no longer possible to obtain. Some human or animal data, like serology data, may not be possible to collect for a substantial period of time because of the time it will take for researchers to identify rigorous serological markers. Field work in collecting the right samples requires people with the necessary skills, materials, technical approaches, and again requires access to the places where samples need to be collected. Biological attribution work will also depend on an investigative process with the highest possible standards, great integrity and trust.

Specifically on the issues of data sharing domestically, it will be important in future events for states to share their clinical and public health data with HHS and CDC so that the federal government can have an integrated picture of what is happening, trends, patterns that could help identify sources. That authority to collect data from around the country and integrate it to develop a full national picture is something that HHS/CDC are seeking.

The GAO report provides concrete findings and recommendations to improve U.S. capabilities, all of which I support. A few brief comments on the report's recommendations:

- **Establish multilateral agreements for accessing and sharing samples and genetic sequence data**

Other than for influenza, we don't yet have international agreements in place to share genetic sequence information at the start of a new epidemic or pandemic. Countries may or may not share that information in the course of a new pandemic.

Multilateral or global agreements for sharing samples, sequence information, bioinformatic information and the other sources of critical data above would be a major step forward. International organizations like the World Health Organization could help to develop those agreements, but it will not be easy work. Some countries have expressed concern about inequitable access to medicines and vaccines that are derived from biological samples taken from their territories. Data sharing agreements would likely need to address those issues and provide incentives for rapid sharing of data and information. HHS Office of Global Affairs and the DoS should make this a priority in their international engagement work, and the U.S. should be a leader in encouraging the implementation of these kind of data sharing agreements.

- **Develop standard processes for genetic sequence database use**

Different genetic sequence databases use different submission tools for sequence information, different processes, different user interfaces, different standards. There are errors in some databases that are difficult to correct and may become permanent. Metadata (time, place of collection etc.) that is provided with sequence information is too vague, variable or missing in places.

To deal with this, federal policymakers, in partnerships with scientists, database administrators and other key stakeholders, should try to drive toward more efficient, standard approaches to database submission, storage, management, metadata requirements, sharing of information, etc. Ultimately since these databases are located and used internationally, this work will also be inherently international and will require close collaboration with the developers and owners or other critical databases around the world.

This work, too, will not be easy or rapid, given the broad distribution of databases, and the widely varying approaches, different institutional approaches and controls, costs etc.

- **Improve current or develop new, genetic sequence database tools**

The GAO report rightly calls out for investment in and advancement of new database tools and user interfaces. This is particularly important because of the anticipated rapid expansion of genetic sequence data in the time ahead.

- **Encourage the development, retention and growth of a workforce with the critical skills needed for pandemic origin investigations**

As the GAO concludes, many skillsets are critical for this work – biology, virology, microbiology, immunology, epidemiology, ecology, genomics, bioinformatics and computer science to name just some. This is inherently multidisciplinary work.

Providing incentives, fellowships, training opportunities to support these fields generally, and to have at least some specialized attention to the study of pandemic origins and biological attribution science will be important. Clearly, this is a long process, but having a strong workforce in these fields will be important in developing and maintaining the right kind of expertise in the country for this mission. Investing in the development of the workforce for this mission would not only be important for the success of this bioattribution work, but would also be valuable in strengthening STEM and biotech capacity of the U.S. and its bioeconomy.

- **Augment or develop a national strategy to better coordinate and collaborate domestically and internationally on pandemic origin investigations**

A commitment to improving biological attribution is in the recently released National Biodefense Strategy. But the GAO rightly calls out that the US does not yet have an articulated strategy for developing the strongest possible national capacity for biological attribution or investigating pandemic origins and other biological events. Having such a strategy, with assignments, milestones, timelines and budgets attached to them would drive national capability forward.

Recent White House Office of Science and Technology Policy bioattribution meeting

In December 2022, the White House Office of Science and Technology Policy convened a group of scientists, policy focused researchers and government officials to assess current national efforts around biological attribution science. A summary of that meeting was prepared by my colleagues and can be found on line at: https://www.centerforhealthsecurity.org/our-work/publications/discussion-on-the-future-science-and-technology-of-biological-attribution

Meeting discussion and take-aways were generally in line with the major points made in the GAO report. However, there were some additional insights provided and recommendations made over the course of the discussion.

- **Genetic Engineering Challenge:** A recently completed and published Genetic Engineering Attribution Challenge (https://pubmed.ncbi.nlm.nih.gov/36450726/) was proposed in the OSTP meeting as one model for driving one component of biological attribution science forward. Colleagues at my Center were part of the team that ran that competition. Teams used different machine learning (ML) approaches to formulate predictions regarding the lab that specific genetically engineered sequences came from, based on sequences that had been previously deposited by those labs in a publicly available database. The winning teams were able to substantially outperform past machine learning approaches that took on this challenge. Not only were these models better at identifying where sequences came from, but they were better at excluding labs where such sequences might have been produced (called negative attribution). This was a relatively small, foundation funded study – larger competitions might drive faster approaches. These kinds of ML approaches would be useful under specific conditions: if a lab is the source of a future pandemic or biological event, this kind of approach would work in identifying a lab source if that lab had previously published its sequences or deposited them in a public database.

- **Gaps in data:** There was substantial emphasis in the OSTP meeting on the paucity of major databases, and on the recognition that, even if more sample collection is funded and supported there will be major gaps in data. Bioattribution science will need to find ways to move ahead despite that challenge. Given their important to future database management and construction, it was advised that responsible officials from NIST and NCBI should be central to future biological attribution discussion and planning. There was also a strong focus on the importance of standardized approaches to data collection and metadata practices. It was emphasized in the meeting that attributing the source of future biological events may require incorporating many different kinds of data – e.g. pathogen characteristics, genetic sequence, evolutionary data, epidemiologic data and others – so anticipating the need for all of this and the need to integrate it in an investigation should be an operating assumption in building this capacity.

- **Federal investment:** The meeting also identified areas in need of additional national investment and attention that could strengthen the U.S. biological attribution capacity, including proteomics, database development, machine learning tools, and new approaches to sharing data from different sources that do not require disclosing proprietary information.

Forward progress and recommendations

Strengthening biological attribution science will strengthen our national capacity to identify the origins of future pandemics, biological attacks, high-consequence laboratory accidents, or other significant biological events. It is important as a tool for understanding whether a threat emanates from nature, or through an accident, or through deliberate misuse. This is critical for public health and national security. Being able to determine who carried out the deliberate use of a biological weapons could serve as a deterrent to those who might consider using biological weapons against the U.S. It could also help to identify efforts of those who might attempt to hide attribution of an event and blame it on another entity (false flag events).

Biological attribution capacity is likely to also be very important, and will become increasingly so, for securing the many elements that are produced by the bioeconomy, whether they are crops, foods, energy, medicines, or other materials or products that biology is helping to create.

Making forward progress on biological attribution will not only be very important for the U.S., it will also be good for all governments. It is in the interest of the international community to understand the source of future biological events, whether natural, accidental or deliberate. The sooner we can understand what caused an event, the faster the international community can work together to diminish the chances it will happen again. And if countries have a strong sense that future manmade events will be attributed to specific countries, or even to laboratories within them, they will be more likely to ensure strong biosafety, biosecurity, and governance systems, and far less likely to consider the use of biological weapons.

Fortunately, strengthening biological attribution science is called out as a priority in the National Biodefense Strategy. The GAO has written a valuable report and provided a series of good recommendations. These developments combined with the interest of this committee in strengthening biological attribution as evidenced by this Hearing, I think suggest there are opportunities for important progress. Substantive progress will require priority setting, financial investment, and sustained collaboration—both domestically and internationally.

In terms of recommendations to this committee, I will start by supporting moving forward on the options that GAO has set out in its report, for reasons noted above. I also have these additional recommendations:

- **Identify lead agencies and where major responsibilities for this work reside:** A key component in developing a national strategy for investigating the origins of pandemics and other biological events should include the identification of the lead agency/program

office(s) in the USG that have responsibility for biological attribution. The National Biodefense Strategy has identified a number of lead offices, and it may be that different offices must lead different elements of building this capability given that there are different critical components of this work that require different skillsets and operations (e.g. research into new tools and scientific approaches; potential new prize grants to drive the field work; machine learning research relevant to this field; operational preparedness to do rapid sequencing, other scientific studies that would contribute, database investigation at the very start of a new biological event; preparedness for investigative work that would stand up in domestic or international settings; preparedness for international collaboration during investigations, etc.).

If it is the case that leadership for biological attribution is distributed to different agencies, a valuable step now is identifying which specific biological attribution responsibilities reside in each. For example, what is the responsibility of HHS vs FBI? Within HHS and FBI, which agency/program is responsible for the work? Similar questions of responsibility apply to the DOD and DOS on international components of this work. And for the other agencies that are listed as in support of this work in the National Biodefense Strategy. As with other national responsibilities that are distributed in the U.S. government, or "whole of government", strong White House interagency management and oversight will remain important.

- **Support scientific research and tool development:** As with most scientific capabilities that underpin a national priority, much of the new science that will occur to move the field forward will reside outside the government, either in research universities or the private sector. Funding, convening and building those external communities of practice that are working toward a better national capacity will be important.

- **Budget Planning**: Another key component for setting the right strategy is to define resource needs for this work. For those U.S. government agencies/offices with responsibility for leading and implementing this work, what are their budgets related to this work now? While the USG does provide some internal and external funding for this work, it's not clear what the budget for this work is currently, or what the budget needs are overall. Should additional funds for critical areas of research, preparedness and operations related work be authorized and appropriated? My intuition is that the answer is likely yes, but it is good that Congress is now seeking more information on this so it will be able to determine what more is needed.

  Strong funding for this work will be important to strengthen the science, the international partnerships, the workforce and the government organization of this work. But in addition, funding is also crucial in allowing the government to do exercises to test its capacities and operations around this work. If the government does not regularly exercise how it will

pursue pandemic origin investigations and attribute the source of future biological events, then it will not have a functioning process in place for future events.

- **Sharing Data:** Congress should also ensure that federal agencies involved in biological attribution science are sharing and combining datasets that are relevant. This is a strategic capability that requires collaboration between different parts of government, and may require a congressional mandate to make such sharing a reality rather than an ideal.

In conclusion, the country does not yet have in place the scientific knowledge, operational plans, investigative process or international partnership that can reliably and assuredly identify the origins of future pandemic and biological events. Building stronger national capacity around the power to identify the origins of future pandemic and biological events, also called attribution science, should be a high priority for the Administration and Congress. I am very pleased to see this committee taking on this issue. As we make forward progress in building this capability, we will be better prepared to investigate future biological events, better able to understand whether events emanated from nature or from laboratory settings, more likely to find where we might need changes in biosafety, better able to deter deliberate biological threats, and better able to protect our U.S. bioeconomy. Thank you for the opportunity to speak to you today and I would be pleased to answer any questions you may have.

Mr. GRIFFITH. Thank you very much.
And we'll now recognize Dr. George for her 5 minutes.

STATEMENT OF ASHA M. GEORGE, D.P.H.

Dr. GEORGE. Thank you, Mr. Chairman.

Chairman Griffith, Ranking Member Castor, and members of the committee, thank you for the opportunity to speak with you today about Federal biological attribution activities, those activities undertaken to investigate the source and cause of pandemics and other biological events.

I also see Chair McMorris Rodgers and Ranking Member Pallone, and very much appreciate your attendance as well.

I am Dr. Asha M. George, executive director of the Bipartisan Commission on Biodefense, which is cochaired by former Senator Joe Lieberman and Governor Tom Ridge. They and the rest of our Commissioners send you their greetings and thank you for examining this critical element of national biodefense today.

Our Commission released its first report, "A National Blueprint for Biodefense," in 2015. In it, we warned that the Nation was catastrophically vulnerable to biological threats and that the Government needed to take bold, immediate action to eliminate those vulnerabilities. Congress and the administrations have taken up a number of our recommendations since 2015, including establishing requirements for a National Biodefense Strategy, an annual biodefense budgetary crosscut, and biological intelligence management, all of which were recommendations we made in our blueprint, but much remains to be done.

We are in the unenviable position of having to prepare for more biological events while still responding to and recovering from COVID–19.

Our experience with this pandemic shows that even a single difficult-to-control disease can produce devastating consequences for the world. We must develop better ways to respond to biological events and better determine how and why they arise.

The anthrax events of 2001, laboratory accidents and various pandemics, such as H1N1, H5N1, Ebola, SARS, MERS, and of course COVID, have time and again revealed our lack of coordination and capability to fully understand and make decisions regarding the origins of biological threats. Regardless, there is still no formal biological attribution apparatus in place.

Many Federal departments and agencies bear responsibility for biological attribution or some part of it, yet most of their efforts remain uncoordinated. Law enforcement, public health, agriculture, intelligence, military, diplomatic, science, commerce, and other communities all have roles to play but largely operate independently.

The Nation needs a robust biological attribution framework, and they need it now.

Our Commission recommends that Congress direct the Secretary of Health and Human Services, in coordination with the Secretary of State, the Secretary of Defense, the Secretary of Agriculture, the Secretary of the Interior, the Attorney General, and the Director of National Intelligence to establish a Federal interagency working group to develop this national biological attribution apparatus with

clearly defined roles, responsibilities, and requirements, and milestones for adjudicating attribution information, and informing decisions following any biological events with national security implications.

The Commission also recommends an overhaul of the Federal Select Agent Program in order to reduce our vulnerability to laboratory accidents and improve our ability to determine whether—to determine whether a laboratory inadvertently released a disease into the environment.

Additionally, the Commission included recommendations in its Athena agenda, about 15 science and technology priority areas that we believe are important to achieve an Apollo program for biodefense. These included genetic sequencing, pathogen surveillance, data analytics, outbreak forecasting, and synthetic biology. All of these could provide valuable contributions to investigations into the origins of pandemics.

We have submitted four of our reports along with my written testimony containing recommendations addressing biological attribution and related enablers for the record and for your consideration. [1]

Later this year, our Commission will release the second edition of the "National Blueprint for Biodefense," taking into account successes and challenges since 2015.

The blueprint will provide a roadmap for continued efforts by the legislative branch and the executive branch to address national biodefense. We hope you will consider these recommendations as you continue the important oversight, investigation, and authorization activities of this committee.

Thank you again for the opportunity to come before you today on behalf of the Bipartisan Commission on Biodefense.

I would like to thank Hudson Institute for serving as our fiscal sponsor, our donors for supporting our work. And, speaking as former congressional staff, I would like to thank the congressional staff for their tireless efforts to address this important topic.

Thank you.

[The prepared statement of Dr. George follows:]

[1] The reports have been retained in committee files and are collected in one document at https://docs.house.gov/meetings/IF/IF02/20230201/115347/HHRG-118-IF02-Wstate-GeorgeA-20230201.pdf.

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

"Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events"

February 1, 2023

Statement for the Record

Asha M. George, DrPH
Executive Director, Bipartisan Commission on Biodefense

Summary

Our experience with COVID-19 proved that even a single, difficult to control disease can produce devastating consequences for the world. As we identify lessons from this event, the government must improve upon our national ability to respond to future biological events, and develop the means to attribute the origin of, and responsibility for, those events. Despite the potential involvement of many federal departments and agencies in attribution activities, the Nation lacks a plan and apparatus for determining how and why biological events began.

In 2015, the Commission released our foundational report, *A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts*, containing 33 recommendations and 87 associated action items for national biodefense. That report included recommendations pertaining to (among other topics) biological attribution, laboratory biosecurity, biological intelligence, and bioforensics – all activities vital to ascertaining the origin of a biological event. In 2022, the Commission also released, *The Athena Agenda: Advancing the Apollo Program for Biodefense.* That report included recommendations that could help inform pandemic origin investigations, for ubiquitous genetic sequencing, minimally and non-invasive infection detection, massively multiplexed detection capabilities, digital pathogen surveillance, a national public health data system, national pathogen surveillance and forecasting, comprehensive laboratory biosafety and biosecurity, and technologies to deter and prevent biological attacks.

Statement

Chairman Griffith, Ranking Member Castor, and other Members of the Committee, thank you for your invitation to provide the perspective of the Bipartisan Commission on Biodefense during today's hearing, "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events." I am honored to talk with you today about federal biological attribution and other activities that comprise these sorts of investigations. My name is Asha M. George, DrPH, and I am the Executive Director of the Bipartisan Commission on Biodefense.

The Commission is co-chaired by former Senator Joe Lieberman and former Secretary of Homeland Security, Governor Tom Ridge; with former Senate Majority Leader Tom Daschle, former Secretary of Health and Human Services, and Representative Donna Shalala; former Representative Fred Upton (a longtime leader of the Committee on Energy and Commerce); former Representative Susan Brooks; former Representative Jim Greenwood (who also chaired this subcommittee); and former Commissioner of the Food and Drug Administration Peggy Hamburg serving as Commissioners. The Commissioners and I have addressed national, homeland, and public health security in various capacities for decades. Although we have left our previous positions, we remain committed to public service and the public health, safety, and security of our Nation.

In 2015, the Commission released our foundational report, *A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts*, containing 33 recommendations and 87 associated action items for eliminating what we identified as serious capability gaps in national biodefense. In the seven years since we released that report, Congress and the Administrations have addressed many of our recommendations, including the creation of a National Biodefense

Strategy (Recommendation 3). We appreciate the original iteration of the Strategy released by the Trump Administration in 2018 and the more recent October 2022 refresh released by the Biden Administration. We eagerly await the Strategy's comprehensive implementation by the federal government. The Office of Management and Budget addressed another Commission recommendation last month when it released the first biodefense budgetary crosscut assessment (Recommendation 4 from the *National Blueprint for Biodefense*) which examined biodefense spending across the federal government. Both accomplishments are the result of Congressional direction – the National Defense Authorization Act for Fiscal Year 2017 (Public Law 114-328) required the creation of the National Biodefense Strategy, and the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283) established the requirement for an annual biodefense budgetary crosscut analysis. Other Commission recommendations have been taken up by a variety of legislative vehicles, including the Farm Bill, the Intelligence Authorization Act, and the Pandemic and All-Hazards Preparedness and Advance Innovation Act. Congressional oversight plays a critical role in ensuring continued high prioritization of these and other biodefense activities.

Despite this progress, the novel coronavirus 2019 (COVID-19) demonstrated that the Nation remains at catastrophic risk of another biological event. Later this year, our Commission will release the second edition of our *National Blueprint for Biodefense*. Drawing from lessons learned from the pandemic, and biodefense successes and challenges since 2015, the updated report and its recommendations will offer a roadmap for continued efforts by the Legislative Branch and Executive Branch to address national biodefense.

COVID-19 proved that a single, difficult to control disease can still produce devastating consequences for the world. As we identify lessons from this event to carry forward, the government must not only improve the ability to respond to future biological events, but also develop the means to better attribute origin of, and responsibility for, those events. The anthrax events of 2001, laboratory accidents across the country and the world, and various pandemics (e.g., H1N1, Ebola, H5N1, MERS) time and again revealed our lack of coordination and capability to comprehend the origins of biological events fully. At the outset of an investigation, decisionmakers will have difficulty understanding whether a pathogen is intentionally introduced, accidentally released, or naturally occurring, further emphasizing the importance of determining the source. Unfortunately, there is no formal apparatus in place to assist leaders in making decisions to address biological crimes, terrorism, warfare, accidents, and naturally occurring events.

First, we must explain what we mean by attribution, as the term covers a number of activities. Biological attribution is the process of identifying an instigating biological agent, where it came from, and – if a biological attack or an accidental release is involved – who might have created and/or disseminated the agent. An attribution apparatus must incorporate diverse activities, across many federal departments and agencies. The nature of those investigations can vary depending on the entities involved. For instance, law enforcement will take a different approach than public health. If we can determine that a biological attack has occurred, not only must we attribute crimes, terrorism, and warfare to particular perpetrators, we must also correctly identify the pathogens and their sources, whether or they are naturally occurring.

Leaders in the White House and throughout the federal government need the best information possible to make far-reaching, globally significant decisions about how to respond to biological crises. The implications of imposing sanctions and embargoes, cutting off diplomatic relations, competing with other countries for scarce resources, and declaring war are too important to leave to a loose set of occasional federal players and policies. This is especially true considering the United States strategy for deterring biological attacks includes possibly responding with nuclear weapons. Although the Department of State, the Department of Defense, the Department of Justice, and other federal departments and agencies possess responsibilities for attribution, there is no structure in place dedicated to directing and coordinating activities to determine the cause of particular biological events, and to provide that information in a usable form to the White House decision-making apparatus.

The law enforcement and public health communities have clear responsibilities for the investigations that fall under their respective domains. The intelligence, defense, and scientific communities also have important roles to play. Representatives from these and other groups must align and support one another's investigations. This must occur despite differences in information sharing norms and requirements among these communities, and there being no one entity in charge for the purposes of attribution. Compounding this challenge is the occasional addition of other communities (e.g., agriculture, commerce, homeland security, wildlife) as well as classification issues that may result in some duplication of effort. The need for close coordination and collaboration is clear, but arrangements among these communities have yet to be formalized for this purpose.

The Department of Homeland Security (DHS) National Biodefense Analysis and Countermeasures Center, located at Fort Detrick in Frederick, Maryland, currently houses the National Bioforensics Analysis Center (NBFAC). The NBFAC conducts biological forensic technical analyses in support of investigations into the use (or suspected use) of biological attacks. The Federal Bureau of Investigation (FBI) is the sole user of the NBFAC. Other federal entities partner with the FBI on their investigations into biological events, choosing to enable the FBI to retain control of their specimens, rather than working directly with the DHS.

The Commission has long advocated for a cohesive national biological attribution capability. Recommendation 9 from our 2015 *National Blueprint for Biodefense* called for strengthening federal support for biological attribution. We determined at the time that the Nation had not yet fully established attribution capability and that there was no formal federal biological attribution apparatus. That recommendation remains as relevant today in 2023 as it did in 2015. We revisited attribution in our 2021 report *Biodefense in Crisis: Immediate Action Needed to Address National Vulnerabilities*, where we further recommended that the Secretary of State, the Secretary of Defense, the Secretary of Homeland Security, the Attorney General, and the Director of National Intelligence jointly develop, plan for, and establish a national biological attribution apparatus to inform decision-making. The Commission continues to believe the federal government must do more to attribute biological events. We recommend that Congress require the establishment of a federal interagency working group to develop a national biological attribution apparatus, with clearly defined roles, responsibilities, and requirements, as well as milestones for adjudicating attribution information and informing decisions following any biological event with national security implications.

Coordinated biological intelligence activities must inform biological attribution. Recommendation 6 from our *National Blueprint for Biodefense* called for establishing a National Intelligence Manager for Biological Threats at the Office of the Director of National Intelligence to coordinate and prioritize biological intelligence activities throughout the Intelligence Community. Congress has taken decisive action on this recommendation recently. As part of Fiscal Year 2022 appropriations, legislators changed the name of the National Counterproliferation Center to the National Counterproliferation and Biosecurity Center, and more importantly, designated the Center's director as the biodefense lead within the Office of the Director of National Intelligence. We hope this development is an important step towards clarifying biological intelligence priorities and informing national biological attribution activities.

As we discuss investigating the origins of pandemics and other biological threats, we must, of course, consider laboratory biosecurity and biosafety, as pandemics could arise from accidental exposures in, and leaks from, laboratories. The primary federal program to prevent the misuse of pathogens and toxins is the Federal Select Agent Program (FSAP), administered jointly by the Department of Agriculture and the Centers for Disease Control and Prevention (CDC). While this program functions somewhat as an impediment to would-be attackers, the regulatory regime of the FSAP does not fully address pathogen safety and security, in that it does not address how to prevent and deal with human error, how to ensure standards for safety and security awareness are met, and how to be more transparent within statutory confines about lapses and problems with the system. Information, knowledge, and equipment to produce pathogens *de novo* (known as synthetic biology) have become increasingly available in the years since the FSAP was established. With every passing day, the FSAP risks becoming increasingly irrelevant as

advances in synthetic biology could enable someone to take a benign pathogen not on the list, and turn it into something horrific. Therefore, restriction of access to pathogens already secured in laboratories has decreased impact today. It is time for a complete review followed by a comprehensive overhaul.

Furthermore, pathogens are not the only problems. Non-pathogens (e.g., bioregulators, small peptides) could also be used in biological weapons but fall outside of the current regulatory regime. FSAP regulations can also reach burdensome levels that make the scientific workforce resistant to conducting much needed biomedical research, and provide minimal or no enhancement of biosafety or biosecurity. FSAP regulations also fail to recognize the reality of select agents presenting in animal diagnostic samples, and the nature of the work that veterinary diagnostic laboratories must, therefore, do to keep the Nation and its animals safe and healthy. Policymakers must address discrepancies in the purpose of the FSAP, rationale for its regulations, and criteria for determining which agents are added or removed from the list; barriers to full implementation of the FSAP; the value of a dynamic, characteristic-based approach for restricted agents and toxins versus the current, static list-based approach; challenges associated with inspections; whether federal and private investments in biodefense are maximized; and how to implement a restorative (rather than punitive) process for addressing difficulties. A different approach to identifying problems and implementing solutions is needed.

Congress recognized the need to review laboratory security and biological research when it authorized the National Science Advisory Board for Biosecurity (NSABB) as part of the recent Consolidated Appropriations Act, Fiscal Year 2023 (Public Law 117-328). Recommendation 32 of our *National Blueprint for Biodefense* recommended that the NSABB engage in a

comprehensive assessment of the FSAP. With statutory authorization newly in-hand, the NSABB should execute such an assessment, with an evaluation of all pertinent strategies, laws, and guidance related to the FSAP, identification of key drivers of safety and security lapses, and identification of regulatory burdens that stifle research and innovation. Based on this review, NSABB should present actionable recommendations to Congress, the Secretary of Health and Human Services, and the Secretary of Agriculture. Ultimately, the Administration should pursue a complete overhaul of the Select Agent Program. The focus of any overhaul to the program should be less about whether we can secure stocks of pathogens, and more about whether we can control the proliferation of information, predict the nature of the changing biological threat, and ingrain a culture of security awareness within the biomedical research community. The Commission also recommended in its report, *The Athena Agenda: Advancing the Apollo Program for Biodefense,* that the Secretary of Health and Human Services, in partnership with Secretary of Defense and the Secretary of Energy, request that the NSABB assess: (1) the potential for innovation in laboratory biosafety; (2) potential outcomes of those innovations; and (3) current goals for next-generation technology in laboratory biosafety. The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, should conduct an annual review of laboratory biosafety capabilities and challenges.

The Commission included recommendations in its *Athena Agenda* about ubiquitous genetic sequencing, minimally and non-invasive infection detection, massively multiplexed detection capabilities, digital pathogen surveillance, a national public health data system, national pathogen surveillance and forecasting, comprehensive laboratory biosafety and biosecurity, and technologies to deter and prevent biological attacks. All of these could provide valuable contributions to investigations into the origins of pandemics. The Commission makes the

following recommendations regarding these topics. Further details can be found in its *Athena Agenda*:

- Increase US sequencing capability and capacity. Congress should amend the 21st Century Cures Act (P.L. 114-255) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Energy, and Secretary of Agriculture to develop a plan to increase pathogen agnostic metagenomic sequencing capability and capacity in the near- and long-term. The plan should: (1) identify where sequencing capability and capacity currently lie in public sector laboratories, academic and research center laboratories, and other laboratory networks; (2) articulate how to identify sequencing capability and capacity in private sector laboratories; (3) provide an estimate of funding needed to expand capability and capacity in these laboratories; (4) explore the use of financial incentives to collect more samples in healthcare and wastewater settings; (5) set standards for the quality of information that should accompany each sample; (6) describe coordination with international partners to further sequencing development; and (7) describe how to achieve ubiquitous sequencing in the next five years. The Secretary of Health and Human Services, Secretary of Defense, and Secretary of Agriculture should deliver this plan to Congress within one year of enactment.
- Identify the need for portable sequencing capabilities. The Secretary of Health and Human Services should, in coordination with the Secretary of Defense, Secretary of Agriculture, and Secretary of Homeland Security, identify portable sequencing end-users and the sequencing capabilities they need in the federal government; states, localities, tribes, and territories (SLTT); healthcare settings; and ports-of-entry. The Secretary should take no longer than 180 days to identify these needs.

- Develop affordable portable sequencing. The Secretary of Health and Human Services should, in coordination with the Secretary of Defense and Secretary of Agriculture, develop a research and development plan that can make fielding portable sequencing in non-laboratory settings more affordable. The plan should (1) identify research efforts to produce portable sequencing devices in the public and private sectors; (2) address the miniaturization of these devices; (3) decrease or eliminate the reagents needed by these devices; and (4) address the integration of sequencing with microfluidics, on-chip sample preparation, and advances in bioinformatics. The Secretary should take no longer than one year to produce this plan.
- Further develop the ability to detect infections with minimally- and non-invasive methods. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, Secretary of Defense, and Secretary of Agriculture to (1) identify ongoing public and private sector research and development of minimally- and non-invasive infection detection technologies; (2) determine their potential for, and challenges with, utilization; (3) develop a funding plan to advance research and development in this arena; (4) identify the data sets and integration and analytics systems needed to draw rapid conclusions from these technologies; and (5) implement newly developed advanced technologies and methods of detection within three years from enactment.
- Advance massively multiplexed detection capabilities. Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to direct the Secretary of Defense, in coordination with the Secretary of Health and Human Services and Secretary of Homeland Security, to develop and advance massively multiplexed detection capabilities. They should (1) assess ongoing research

and development of massively multiplexed detection capabilities across the public and private sectors; (2) identify candidate technologies with the most beneficial performance characteristics for clinical applications, environmental monitoring, detection of novel pathogens by looking for conserved regions, identification of host-based biomarkers, and orthogonal detection mechanisms; (3) develop a five-year plan for funding research and development of such technologies in the public and private sectors; (4) submit an annual progress report to Congress detailing progress, current capabilities, and future directions for research and development; and (5) implement these technologies and methods within five years of enactment.

- Invest in digital pathogen surveillance. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Agriculture, Secretary of the Interior, and Secretary of Veterans Affairs to: (1) identify end-user needs for digital pathogen surveillance systems; (2) define clear performance requirements for the private sector; (3) provide incentives for the private sector to advance capabilities; (4) establish public-private partnerships with industry entities that have demonstrated pathogen surveillance capabilities; and (5) strengthen ongoing digital pathogen surveillance efforts throughout the government.
- Improve data interoperability to enhance information sharing. Congress should amend the Public Health Service Act (P.L. 78 -410) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Agriculture, Secretary of the Interior, and Secretary of Veterans Affairs, in coordination with the Director of National Intelligence, to develop a pathogen data interoperability plan to enhance information sharing among federal departments and agencies, the Intelligence Community, industry, academia, and nongovernmental organizations. This plan should: (1) describe the

structure of an information sharing network among these entities; (2) include data reporting standards to ensure interoperability; (3) consider the potential effects of cyberattacks and mis- and disinformation on these systems; and (4) implement this plan within one year of enactment.

- Establish a National Public Health Data System. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, Secretary of Agriculture, Secretary of Homeland Security, and Secretary of Veterans Affairs, to establish a national public health data system that expands on current data modernization efforts. They should: (1) identify all relevant and available federal, SLTT, and private sector data streams; (2) determine and build the federal and SLTT technological capabilities needed to sustain the system over time; (3) ensure ease of data entry by including end-users in the development and beta-testing process; (4) de-identify personal data and protect privacy; (5) compile and integrate relevant data streams no later than two years after enactment; (6) ensure that the System will support timely and transparent access by the public; (7) provide funding and technical support to SLTT to enable them to contribute to this system; and (8) establish the system no later than three years after enactment.
- Integrate data within the National Public Health Data System. The Secretary of Health and Human Services should develop a plan to integrate data in the National Public Health Data System, (1) describing how information will flow and how federal, SLTT, academic, and healthcare entities will gather data; and (2) setting data reporting and collection standards to ensure interoperability.
- Secure data and ensure data integrity for the National Public Health Data System. The Secretary of Health and Human Services should, in coordination with the Secretary of

Homeland Security, develop a data security and integrity plan for the National Public Health Data System, (1) describing how HHS and DHS will secure and defend the System against cyberattacks; and (2) addressing how HHS and DHS will prevent and respond to the introduction of mis- or disinformation into the System.

- Authorize the Center for Forecasting and Outbreak Analytics. Congress should amend the Public Health Service Act (P.L. 78-410) to authorize the Center for Forecasting and Outbreak Analytics.
- Assess biosurveillance capabilities across the federal government. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, Secretary of Agriculture, and Secretary of Homeland Security, and in collaboration with the national laboratories and the private sector, to (1) assess biosurveillance capabilities and relevant data streams across the government to incorporate into the Center for Forecasting and Outbreak Analytics; (2) develop effective algorithms that produce accurate forecasts for the Center; (3) request an annual review by the National Laboratories and National Academies of Sciences to help identify problems, challenges, and potential improvements, and provide technical assistance to the federal government; (4) develop an interoperability strategy for integrating data into the Center; and (5) develop plans to ensure data interoperability and integration, provide data security and integrity, prevent and respond to cyberattacks on the Center, and prevent and respond to the introduction of mis- or disinformation into the Center's data streams.
- Review adequacy of biosafety and biosecurity standards, practices, and oversight to identify gaps, needs, and upgraded approaches. The Secretary of Health and Human Services, in partnership with the Department of Defense and Department of Energy,

should request the NSABB to assess: (1) the potential for innovation in laboratory biosafety; (2) potential outcomes of those innovations; and (3) current goals for next-generation technology in laboratory biosafety. The Secretary should take no longer than 180 days to complete this assessment.

- Address laboratory biosafety and biosecurity challenges. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, to conduct an annual review of laboratory biosafety capabilities and challenges. The Secretary of Health and Human Services should direct the Director of the Centers for Disease Control and Prevention to (1) conduct this review in coordination with at least one representative from each BSL-4 laboratory in the country; (2) identify potential innovations and policies to improve laboratory biosafety; (3) articulate ongoing challenges in laboratory biosafety, especially with regard to accident prevention, accident reporting, and needed funding for accident detection; and (4) provide goals and milestones for implementing improvements. The Secretary of Health and Human Services should complete and submit the first review within 180 days of enactment.
- Develop and support implementation of a strategy to screen DNA synthesis providers and users. Congress should amend the National Science and Technology Policy, Organization, and Priorities Act of 1976 (P.L. 94-282) to direct the Director of the Office of Science and Technology Policy to develop an updated screening framework with requirements for providers and users of synthetic biology services that meet or exceed those of the current gene sequence and customer screening best practices. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of

Health and Human Services, in coordination with the Secretary of Commerce, to implement the framework.

- Require entities to purchase genetic material from verified vendors. Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283), the Public Health Service Act (P.L. 78-410), the Homeland Security Act (Public Law 107-296), the Agriculture Improvement Act of 2018 (P.L. 115-334), and the National Science Foundation Act of 1950 (P.L. 81-507) to require any entity receiving a federal grant or engaging in a cooperative agreement related to synthesizing DNA and RNA to purchase their materials from vendors that follow gene sequence and customer screening best practices to minimize risk and that address gene synthesis screening, customer screening, record keeping, order refusal and reporting, and regulatory compliance.

This concludes my written remarks. The Bipartisan Commission on Biodefense appreciates the Subcommittee's interest in examining and strengthening federal biodefense activities to better address future biological threats. While this subject is complicated, biological attribution is also achievable and something Congress can accomplish before the next pandemic or other biological event affecting national security occurs. I would also like to take this opportunity to thank Hudson Institute, which serves as our fiscal sponsor, and all the organizations that support our efforts financially and otherwise. With this testimony, I am submitting four of the Commission's reports (*A National Blueprint for Biodefense, Biodefense in Crisis, The Apollo Program for Biodefense,* and *The Athena Agenda*). Thank you again for inviting me to testify today. I look forward to answering your questions and working with you to defend the Nation against biological threats.

Mr. GRIFFITH. I thank the gentlelady.

Now recognize Dr. Parker for his 5-minute opening statement.

STATEMENT OF GERALD W. PARKER, D.V.M., PH.D.

Dr. PARKER. Chairperson Rodgers, Ranking Member Pallone, Chairman Griffith, Ranking Member Castor, and distinguished members of the committee, I am honored to appear before you today for this hearing, "Challenges and Opportunities to Investigating Origin of Pandemics and Other Biological Threats."

Congressman Burgess, I'm honored by the introduction today, so thank you very much for that. And the only thing I might add is I was—I'm also a former commander of USAMRIID, the Army's maximum biocontainment lab. It was 20 years ago. But my experience there, I think, is very relevant to this topic.

Naturally occurring infectious disease outbreaks with pandemic potential are occurring with alarming increased frequency. In addition to natural biological threats, the fusion of advanced technologies, worldwide expansion of high-containment labs with uneven biosafety and biosecurity controls, and access to dangerous pathogens are increasing the possibility of unnatural, accidental, or deliberate outbreaks.

Unfortunately, global capacities and international agreements needed to investigate and rapidly attribute unknown emerging infectious disease outbreaks are inadequate. Outbreak organizations are a core competency of public health, especially where scientists were familiar with known diseases of natural origin within their borders. In cases and within the United States, public health has an exemplary record where their investigations are geared to rapidly find the source, to prevent additional cases and learn how to prevent future outbreaks. That is the same objective for investigating the source of a pandemic, whether natural or unnatural.

Now I would like to share just one example that actually impacted me directly.

Exactly 1 week after the tragic events of September 11, 2001, letters obtaining lethal anthrax spores were postmarked and mailed. The anthrax letter attacks marked the first significant act of bioterrorism in the United States.

That deliberate incident highlighted our vulnerability to rapid onset infectious diseases, whether deliberate, natural, or accidental. The attack also highlighted our inability to rapidly investigate an unnatural outbreak.

As you recall, the FBI attributed the perpetrator to a lone U.S. scientist from the lab I once commanded, USAMRIID. Unfortunately and tragically, the scientist committed suicide as the FBI was planning his indictment in 2008, so the case was never tried in a court of law.

Attribution to determine who is responsible for deliberate or negligent accidental breach that leads to a community outbreak or worse is essential to hold those responsible for their actions, prevent future outbreaks, and serve as a deterrent.

Attribution and supporting microbial forensic science are also important to exonerate and rule out suspected perpetrators or negligent actions. Investigations with forensic rigor for natural out-

breaks that lead to a pandemic are equally important to the enormous toll on societies worldwide.

There must be trust in the outcome of the investigation and confidence a future pandemic will be prevented. The experience with COVID–19 and past precedent confirm there are no effective international agreements, protocols, or guidelines that provide needed authority to rapidly attribute the source of a pandemic or other biological threats.

Multilateral organizations, like the World Health Organization, have mechanisms to aid member states investigate within their own borders, if requested. Biological and Toxin and Weapons Convention has a framework to adjudicate allegations of suspected treaty violations. However, both have inherent limitations that hinder their ability to rapidly investigate transborder infectious diseases. Their inherent limitations are amplified during periods of geopolitical tension and enhanced power rivalries.

The biggest challenge to improving our ability to rapidly attribute the source of a pandemic reside in overcoming these geopolitical forces. Otherwise, samples to tests, database access, and ability to examine all source information will not be available or independently verifiable.

But there are opportunities that reside through enhanced, responsible, international collaboration and application of innovative technologies via multidisciplinary One Health approaches.

In closing, I want to state, above all, the Nation is counting on a strong biodefense and health security leadership with a national leadership structure to drive effective coordination, collaboration, and innovation. This includes implementation of effective microbial science and technologies that were hastily pulled together to support the Amerithrax investigation 20 years ago with far too little attention since then.

Thank you for the opportunity to appear before this hearing. I'll look forward to answering any questions you may have.

[The prepared statement of Dr. Parker follows:]

Hearing of the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

February 1, 2023

Statement for the Record
Attribution for Natural and Unnatural Emerging Infectious Diseases of Unknown Origin

Dr. Gerald W Parker, Jr, DVM, PhD
Associate Dean for Global One Health
College of Veterinary Medicine & Biomedical Sciences

Director, Pandemic and Biosecurity Policy Program
Scowcroft Institute of International Affairs
George H.W. Bush School of Government and Public Service
Texas A&M University

Chairman Griffith, Ranking Member Castor, and distinguished members of the Committee, I am honored to appear before you today for this important hearing, "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events."

I come before you today as an individual who has spent an entire career in biodefense, public health preparedness, and health security from research in a high containment laboratory to strategic, operational, and policy levels; and now mentoring our next generation of public health and biodefense professionals at Texas A&M University.

I will offer insights from my role as a public servant that spanned 26 years of active-duty military service and another ten years in the career senior executive service. During my military career, I had the opportunity to serve in leadership roles, primarily in Army medical research & development at the United States Army Medical Research and Materiel Command and the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). That was followed by executive leadership roles at the Department of Homeland Security (DHS), Department of Health and Human Services (HHS), and the Department of Defense (DOD). I am now a faculty/administrator at Texas A&M University.

But today, the views and opinions I offer are my own, and not representative of past or current organizational affiliations or employers.

Background: The Wuhan Municipal Health Commission, China, reported a cluster of pneumonia cases of unknown etiology in Wuhan, Hubei Province on December 31, 2019. The new illness was subsequently described as COVID-19 caused by the SARS-CoV-2 virus. The first infections and cases of COVID -19 occurred much earlier, likely sometime in the fall of 2019.

The first viral genomic sequence that became available outside China was posted online on January 11, 2020. Since then, viral genomic sequencing capacity has rapidly expanded worldwide, allowing scientists to track the spread of emerging phylogenetic lineages and variants in near-real time. SARS-COV-2 viral isolates have been sequenced more than 14 million times. This enormous, accruing genomic data over the course of an outbreak, epidemic, or pandemic has never been available before. This has provided incredible new capabilities for genomic surveillance and future sequencing capacities needed for pandemic investigations for attribution. COVID-19 will not be our last pandemic or major infectious disease outbreak with regional or global impact.

But today, unfortunately, more than three years later, we still do not know when, where, and the pathway for how a bat virus emerged to become a respiratory pathogen capable of sustained human-to-human and atypical asymptomatic transmission. This has been subject to intense and acrimonious scientific debate. The two-prevailing hypotheses are 1) natural zoonotic emergence or 2) unnatural, accidental research-associated infections. Both are plausible. Definitive evidence conclusively substantiating either hypothesis attributing the pandemic's source remains elusive.

My testimony today will avoid entering the debate about the origin of SARS-CoV-2. However, we must learn from COVID-19 and work to identify, understand, and fix gaps in our ability to investigate and attribute a natural or unnatural emerging infectious disease outbreak wherever it occurs worldwide.

Before COVID-19, naturally emerging and reemerging infectious disease outbreaks and the rise of infectious diseases due to drug resistance were occurring with alarming increased frequency. Examples included SARS1, Ebola, MERS-CoV, Zika, pandemic potential influenza viruses, multi-drug resistant tuberculosis, and others. Globalization of travel and trade, urbanization, wildlife and food-animal close contacts, failing states, and other anthropogenic factors have created the perfect storm triggering public health, animal health, and security risks for the global community. The impact on individual and collective health, as well as animal health, should have been clear. Preparedness authorities and scholars were aware of the growing risks from transboundary infectious diseases, many zoonotic, and the significant economic, humanitarian, and global security implications.

In addition to natural biological threats, ready access to advanced technologies, expansion of high containment laboratories worldwide, and availability of dangerous pathogens were simultaneously increasing the potential for unnatural accidental or deliberate outbreaks with grave consequences.

Just weeks before SARS-CoV-2 emerged in Wuhan, the World Bank and World Health Organization forewarned in their 2019 World at Risk Report about the growing risk of a viral pandemic that could occur through accidental laboratory escape or intentional release after being engineered in a laboratory (WorldBank, 2019).

Despite these warnings and preparedness investments, global capacities, and international agreements necessary to prevent, detect, respond, and rapidly attribute unknown emerging infectious disease threats, whether natural or unnatural in origin remains woefully inadequate.

Public health authorities are on the front line to investigate and attribute emerging disease outbreaks and are most familiar with known diseases of natural origin. Infectious disease outbreak investigations are a core competency of epidemiology and public health. Epidemiological investigations follow protocols to establish a case definition, case confirmation, and rate of background of disease to find new cases. This is followed by collecting data to build descriptive epidemiological characteristics, generate hypotheses, test hypotheses, and propose an analysis of alternatives to attribute the source. Investigations are geared to identify the source of ongoing outbreaks and prevent additional cases. Even when an outbreak is over, a thorough epidemiologic and environmental investigation and analysis enhances knowledge of a given disease to prevent future outbreaks.

Epidemiological investigative methods are a proven strategy to identify and attribute natural disease outbreaks, and traditional epidemiology works well in the United States and many other nations worldwide. But many low-middle-income countries (LMIC) lack sufficient capabilities and capacities to detect, investigate, and rapidly attribute emerging infectious diseases. LMICs on the African continent and Southeast Asia are also disease hot spots for emerging and reemerging pathogens with regional epidemic or pandemic potential.

The World Health Organization (WHO) has existing mechanisms to assist member states in investigating naturally occurring infectious disease outbreaks, and the International Health Regulations (IHR) are legally binding requirements for member states to detect and rapidly report health security threats that could impact other countries. The United Nations Secretary-General has procedures to investigate alleged deliberate use of biological weapons under the Biological Weapons and Toxins Convention (BWC).

These international mechanisms and agreements to aid member states can be effective, provided member states fully cooperate with the WHO to investigate outbreaks with potential that could rapidly spread regionally or globally. However, there have been many instances where member states, especially middle- and high-income nations, fail to cooperate fully. Unfortunately, institutional capability and capacity-building initiatives for LMICs have not achieved IHR required compliance goals. Even IHR compliant middle and high-income countries that have a sufficient laboratory, diagnostic, and reporting infrastructure, enforcement of the IHR is limited when member states fail to timely report health threats that constitute a public health emergency of international concern. Finally, allegations of non-compliance with the Biological Weapons Convention are rarely met with a willingness by a member state to be investigated.

These and other inherent limitations of multilateral organizations and agreements are amplified during periods geopolitical tension. For example, for unknown reasons, the Communist Chinese Party imposed gag orders on their scientists that prevented sharing scientific data on SARS-CoV-

2 origins and reporting knowledge of human-to-human transmission without government approval starting as early as January 2020.

In additional to strong geopolitical forces at play, professional culture, experience, and human nature are also contributing factors, especially for recognizing the potential for an unnatural outbreak source. For example, public health professionals who are on the front line of infectious disease outbreak investigations are not trained in security. Public health scientists reflexively consider natural sources in their investigative hypothesis, and rarely consider an outbreak could have unnatural origins, nor investigate with forensic rigor needed for law enforcement or national command authorities. This is not a criticism but just the nature of public health education, culture, and experience.

There are four unnatural outbreak examples that I will briefly review in chronological order of occurrence that have some aspects of geopolitical tension and professional culture inclinations as past precedents. I will also include one natural outbreak as a past precedent. Lessons observed from past precedent examples should be considered when future requirements are considered to rapidly attribute outbreaks with pandemic potential.

***1977 Russian Flu*:** A novel H1N1 influenza virus strain emerged in 1977 and quickly spread worldwide. Scientists soon determined that the strain was not novel and had previously circulated globally as a decedent of the 1918 influenza pandemic, but disappeared from circulation in the early 1950's. The strain mysteriously reappeared in East Asia near the border of China and the Soviet Union in 1977 as though it had been frozen in time.

The global influenza epidemic, or pandemic, was known as the Russian Flu. The disease had an unusual presentation and the viral strain had unique characteristics consistent with an attenuated vaccine strain. Disease was restricted largely to people under ~21 years of age and impacted military academies, military recruits, and schools the hardest.

Some scientists and public health officials became suspicious that unnatural research associated incident was a possible origin because of the unusual characteristics of this reemergent viral strain. But Soviet and Chinese scientists denied their laboratories had the pandemic virus.

Western governments and scientists soon dropped the laboratory origin claim for geopolitical reasons to avoid additional Cold War tensions and proposed alternative natural etiologies. Western government and public health authorities did not want to risk compromising the World Health Organization's (WHO) Global Influenza Surveillance Network that needed Soviet and Chinese government cooperation (Furmanski, 2014).

Evidence to definitively support H1N1 a/USSR natural emergence was never found. But twenty-seven years later in 2004, a preeminent, senior Chinese virologist confided with his United States colleague that the 1977 Russian Flu's origin was unnatural research associated origin. The exact details remain elusive, but the accidental release is thought by most scholars to be

associated with influenza vaccine clinical trials (Palese, 2004) (Furmanski, 2014) (Basu, 2021) (Gronvall, 2015).

1979 Sverdlovsk Anthrax Accident (USSR): An unusual anthrax epidemic was reported in the secret city Sverdlovsk, Union of Soviet Socialists Republics in 1979. The few news accounts that leaked out of the secret city estimated over a thousand deaths due to an accident at an alleged biological weapons facility. These news accounts could not be verified due to heightened tensions between the United States and the Soviet Union during the Cold War. For over a decade, the Soviet Union military ran a successful deception and denial campaign asserting the epidemic was natural intestinal anthrax disease due to consumption of contaminated meat. The U.S. Central Intelligence Agency suspected the outbreak was tied to an illicit biological weapons facility and biological weapons program in violation of the Biological Weapons Convention (BWC). A prominent geneticist and arms control scientists from Harvard University, Matthew Meselson supported the Soviet Union's claim as plausible (Wade, 1994). Actions were not taken to invoke BWC provisions of this suspected violation. The Soviet Union, the United Kingdom (U.K.), and the United States (U.S.) were among the initial twenty-two member states joining the convention. The BWC went into force just four years earlier in 1975 that likely restrained the use of diplomatic force.

It was not until Soviet Union defectors debriefed U.K. and U.S. intelligence agencies in 1992 that western suspicions were confirmed. Inhalation anthrax caused the epidemic due an accidental biocontainment breach from a military biological weapons facility that was part of a large biological weapons program. A subsequent scientific investigation in 1994 led by Meselson provided an epidemiologic characterization of the outbreak, and documented at least 66 deaths, with many more possible (Matthew Methelson, 1994).

1984 Food borne illness in Dalles Oregon: The Rajneesh cult succeeded with the first documented bioterror incident in the United States in 1984. Their motivation was to influence county elections in Dalles Oregon by contaminating salad bars at restaurants with S. Typhimurium on several occasions before the election.

A community wide outbreak of salmonellosis resulted; at least 751 cases with 45 requiring hospitalizations were documented in a county that typically reports fewer than five cases per year. Although bioterrorism was considered a possibility when the outbreak was being investigated by public health officials, it was considered unlikely despite the obvious epidemiological presentation.

The source of the outbreak became known only after a disavowed cult member confessed the incident was deliberate over a year later. The FBI was called into investigate and found a vial of S. Typhimurium identical to the outbreak strain in a clinical laboratory on the cult's compound. Other members of the cult subsequently admitted to the bioterror crime. Confessions coupled to microbial forensics attributed the outbreak to an unnatural deliberate outbreak. Without the initial confession by the disavowed cult member, law enforcement may never have discovered this bioterror incident.

2001 anthrax letter attacks: Letters containing dried anthrax spores were mailed in the aftermath of the terrorist attacks of September 11, 2001, in New York City, Florida, and Washington, DC. The letter attacks marked the first significant act of bioterrorism in the United States and highlighted our vulnerability to a rapid onset infectious disease outbreak from biological threats, whether intentional, accidental, or natural in origin.

Of note, the first case presented with inhalational anthrax that is exceedingly rare. Public health officials initially attributed the outbreak to natural origin despite this rarity and in the aftermath of the tragic events of September 11, 2001. It was only after other cases presented and mailed letters were discovered containing anthrax spores that the reality of an unnatural bioterror attack set-in. We also seemed hopeless to prevent more attacks.

When the FBI started to investigate a potential domestic source, laboratory scientists denied the spores came from their lab, and argued the anthrax could have been acquired from several places, including from nature. However, as soon as genomic sequencing revealed the *Bacillus anthracis* from the letters were from the Ames strain, it became clear the spores were descended from the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). Deflection turned to disbelief, but it could not be denied. After this revelation, most, including me were more determined than ever to help the FBI find the perpetrator and to take actions to prevent a reoccurrence.

That attack was one of the easiest bioterror attacks to confront, yet the impact was far reaching and severely challenged public health and law enforcement. The attack had international ramification as anthrax spore contaminated mail was discovered at United States' embassy postal facilities across the globe. As bad as it was, it could have been much worse had the pathogen been a contagious agent, resistant to antibiotics, an unknown pathogen, or delivered in a covert widespread aerosol attack across multiple jurisdictions.

As it was, the anthrax letters shut down government buildings for months, wreaked havoc on the Postal Service, reduced business productivity, cost the nation more than one billion dollars, and tragically, took five lives and sickened seventeen more. More than 30,000 people required post-exposure antibiotics.

Many still recall frightening moments experienced during that time, particularly those who were potentially exposed to anthrax spores. The first batch of letters were post marked on September 18, 2001, exactly one week following the terrorist's attacks of September 11th, and greatly elevated already heightened public anxiety and fear. This event also forever changed our notions of laboratory biosecurity, biosafety, and personal reliability for work in high containment laboratories and led to the emerging science of microbial forensics for attribution.

Outbreak investigations to support law enforcement also identified the need for dedicated and specialized high containment laboratories with cleared scientists to conduct investigations. Those capabilities were not available at the start of the Amerithrax investigation.

2002 – 2003 SARS1 Global Epidemic: Clinical cases presenting with an atypical pneumonia of unknown origin began in November 2002 in Guangdong province in southern China. Because of delayed reporting by Chinese government authorities, the international community did not become aware of multiple ongoing outbreaks until February 2003. Atypical pneumonia was subsequently identified to be associated with a novel coronavirus called, severe acute respiratory syndrome (SARS). International collaborations and data sharing began soon after this revelation. In the Guangdong province region, exotic wildlife cuisine was popular and legal. A reported 10,000 palm civets were consumed daily (Ma, 2002) (Pan, 2004). Diagnostic, genomic and serologic forensic evidence was found within 6 months that showed that SARS1 made multiple zoonotic jumps from multiple animals at several different locations indicating the virus was circulating and enzootic in animals for some time before causing human infections. Some zoonotic jumps led to "dead-end" human infections while the virus continued to evolve becoming fit to humans, characteristic of the gradual, natural evolution of zoonotic spillovers (Cheng VC, 2007). The virus finally adapted to humans enabling human-to-human transmission that led to 774 deaths worldwide before the outbreak was contained.

Summary of past precedents: Key past precedent themes characteristic of unnatural infectious disease outbreaks is apparent from these examples. These characteristics are prominent in autocratic regimes but are not limited to autocratic regimes. Regardless, these behavioral characteristics can hinder investigation and rapid attribution of natural and unnatural outbreaks. Institutional, autocratic regime, and cultural themes include, 1) Inherent weakness in multilateral organizations, like the WHO and the United Nations; 2) Denial; 3) Deflection; 4) Obfuscation; and 5) Disbelief; and 6) lack security culture and training in forensic rigor.

On the other hand, the SARS1 outbreak was attributed within six months as zoonotic spillover from palm civets as an intermediate animal host. Horseshoe bats were subsequently determined as a likely reservoir host for SARS-related coronaviruses. There was also strong international collaboration between Chinese scientists, the WHO, and the international community at that time to attribute the source to palm civets and mount effective control measures worldwide.

Discussion. Naturally occurring biological threats pose a grave risk to our health and national security. Globalization, population growth, urbanization and other factors are creating a perfect storm for the emergence of high-consequence infectious diseases with pandemic potential.

But the threat of unnatural outbreaks with pandemic potential is growing too. Research with dangerous pathogens in high containment laboratories using advanced technologies are enabling unprecedented scientific achievements around the world to benefit society. But those same research technologies and information essential for public health preparedness and biodefense could intentionally be misapplied by malevolent actors or lead to unnatural accidental biocontainment breaches through inexperienced staff or inadequately maintained laboratories – *the dual use research of concern threat.*

It is important to note that almost all life science research with pathogens performed in high containment laboratories can be accomplished safely and securely if all staff strictly adheres to biosafety and biosecurity guidelines and best practices. Laboratory and institutional level leadership are essential to instill a culture throughout the lab of accountability, responsibility, and ethical values that enables and promotes transparency to report even the smallest of human errors or potential biocontainment breaches.

For the first time, many are realizing the scope, breathe, and risks of the expansion of high containment laboratories worldwide. Concerns about high containment laboratory expansion are coupled to advancing, readily available technologies with uneven international laboratory safety and security standards. International guidelines and codes of conduct; effective international oversight institutions and leadership; and international governance standards and controls for risky research that could generate potential pandemic pathogens and dual use research are virtually absent.

Fortunately, we have one of the most comprehensive bio-risk management frameworks to govern and oversee life science research in high containment laboratories performed in the United States, but it is not perfect (Young, 2016) (Blake, 2020).

But outbreaks worldwide are unavoidable regardless of source. Global capabilities and capacities are needed to rapidly detect, attribute, and prevent outbreaks from becoming epidemics or a pandemic.

In the United States, the CDC, state, and local public health authorities have an exemplary record investigating and rapidly attributing routine, natural disease outbreaks and foodborne illnesses. But as was described with past precedent incidents, public health authorities do not reflexively consider the potential for an unnatural origin of a disease outbreak.

After the 2001 anthrax letter attacks, the follow-on FBI Amerithrax investigation applied the emerging science of microbial forensics with newly cleared scientists, and along with traditional investigative procedures, ultimately attributed the attack to a lone U.S. scientist from USAMRIID in 2008. Unfortunately, the scientists committed suicide before the FBI indicted him, so the case was never tried in court.

The lessons learned through that investigation led the United States to establish unique capabilities and capacities to rapidly investigate and attribute unnatural, deliberate use of pathogens to meet a forensic standard required by law enforcement and national command authorities. A central component of the capability was design and construction of a unique high containment laboratory, the National Biodefense and Analysis Countermeasures Center (NBACC) that began operations in 2008. I played a major role arguing for the appropriations for this laboratory and served as the first NBACC director while we rented a Biosafety 3 Laboratory suite within USAMRIID starting in 2003 to support the FBI, Intelligence Community, and other stakeholders.

NBACC is dependent upon receiving samples for analysis from law enforcement, intelligence, and public health through strict cold chain procedures so access to materiel and pathogens to test may be dependent upon the willingness of other nations to support an international investigation. Regardless, I cannot overstate the importance of having dedicated, core laboratory capabilities and cleared scientists that are focused on microbial forensics to support attribution for national command authorities. It is not a part-time job, or other duties as assigned function.

Attribution to determine who is responsible for an unnatural deliberate or blatant negligence that leads to an unnatural outbreak with epidemic or pandemic potential is essential to hold those responsible accountable for their actions, prevent future attacks, and serve as a deterrent. Attribution and the supporting microbial forensic sciences are also important to exonerate – and rule out - suspected perpetrators or negligent actions. Attribution with forensic rigor for natural outbreaks that lead to epidemics, or a pandemic is equally important as gross negligence could be a factor that should be considered. For example, was the source due to a natural zoonotic spillover from illegal, inhumane wildlife or endangered species animal trade?

Investigation and rapid attribution of international outbreaks are more difficult depending upon the source country and geopolitical factors.

The first question to ask, what multilateral organization should have responsibility and authority to conduct a credible investigation with forensic rigor that could be subject to independent verification to attribute the source of a pandemic, whether natural or unnatural?

The World Health Organization (WHO) is the specialized health agency within the United Nations whose mission is to promote human health globally and provide technical assistance to 194 member states. The WHO played a leading role in the past with control and eradication of other infectious diseases, such as smallpox. But does the WHO have a recent demonstrated track record to lead international investigations to attribute the source of pandemics? Alternatively, have member states blocked WHO's ability to lead international investigations?

In the early days of the COVID-19 outbreak and before a pandemic was declared, two WHO-China joint missions were conducted in January and February 2020 to gain a better understanding of the epidemiological characteristics, early response efforts, and preparedness strategies to contain the virus. There were no microbial forensic investigations contemplated nor conducted by these delegations.

In reaction to increasing public pressure, the Chinese government agreed to host a Joint WHO-China Study from January 14th to February 10th one year later in 2021. The objective of that mission was the analysis of potential natural zoonotic sources of SARS-CoV-2 and the search for intermediate hosts of this virus. Investigation of an unnatural source was not permitted in the negotiated terms of reference.

The March 2021 report from the Joint WHO – China delegation was widely criticized due to the lack of firm data supporting the conclusions presented, and conflicts of interest by some delegation members. The WHO Director-General did not embrace the report's findings and he made it clear both hypotheses must be investigated whether that turns out to be natural or unnatural origin.

Protocols under the Biological Weapons Convention (BWC) and the United Nation's Secretary-General's Mechanism (UNSGM) have frameworks to investigation allegations of treaty non-compliance and have been considered in the past for both unnatural and natural outbreaks. However, the BWC has no verification mechanism and thus no real provision to rapidly conduct a forensic investigation for attribution. Further, a naturally occurring infectious disease outbreak is not a matter for the BWC.

The experience with COVID-19 and previous outbreaks with international impacts confirm there are currently no international agreements or guidelines that provide authority for forensic investigations of a pandemic, whether natural or unnatural in origin.

Looking to the future, we must continue multilateral diplomatic efforts to support an effective WHO with agreements by all member states to establish a multidisciplinary task force free of conflicts of interests for outbreak investigation and attribution missions. This proposed task force must be able to conduct professional, objective, and transparent pandemic investigations for attribution with forensic rigor that allows for independent verification. The implementation of such a task force that would include member nations with multidisciplinary expertise and experts from the country of interest with agreed upon procedures will be a difficult diplomatic negotiation. There is no promise for success.

The 74th session of the World Health Assembly in May 2021 approved a Special Session to consider a comprehensive international pandemic treaty for prevention, preparedness, and response. Negotiations are ongoing with the next negotiating session scheduled for February 2023. The proposed international pandemic treaty could strengthen the role of the WHO across a spectrum of important activities, including vaccine, therapeutic, and diagnostic access; data and information sharing; intellectual property; laboratory biosafety; animal and land-use management; health care inequities; preparedness financing, and other components important for pandemic preparedness worldwide. The United States has been circumspect regarding a formal treaty, but publicly supports revisions to the International Health Regulations and strengthening governance of the WHO. International negotiations by member states will likely come down to binding versus non-binding resolutions; concerns around national sovereignty; and what is best for individual member state's national interest. These are essential considerations for the United States. Congress and the Administration should work together to find areas of agreement important to support the proposed pandemic treaty but must steadfastly protect vital interests essential to the United States.

Reservations about an international pandemic treaty are warranted, but we must not walk away from our leadership responsibilities in this matter with the WHO and like-minded member

states. We must continue to actively engage and help lead negotiations. Health security and pandemic preparedness diplomacy are a marathon, not a sprint.

Continued international scientific collaboration and development are also essential but how we do such collaboration is equally important.

Despite current geopolitical tensions and critics of scientific collaboration with Chinese scientists, we must consider the importance of maintaining open lines of communication between United States public health authorities and Chinese public health scientists. Naturally occurring infectious diseases will continue to emerge in China and throughout Southeast Asia. Effective international scientific collaborations may provide early warnings for emerging infectious disease outbreaks with pandemic potential. For this reason, we must find a venue to re-establish effective scientific dialogue. For example, research is needed to underpin the establishment of international bio-risk management and biosafety standards. This would be a productive investment for future joint U.S - China scientific collaborations. Better understandings of viral ecology are needed too, but unnecessarily dangerous research must be avoided.

The administration must also accelerate strategies to work with international partners to implement a long-standing need for an international bio-risk management framework. This is urgently needed to assure that research with dangerous pathogens is safe, secure, and built upon an ethical foundation worldwide to decrease the possibility of unnatural, accidental or deliberate pandemics. Harmonized international bio-risk management standards will require effective international collaborations, agreements, and harmonized national legislative regimes appropriate to the life sciences. International agreements must include emphasis on scientific leadership at the laboratory and institutional level. It is necessary to build a culture of accountability and responsibility from the ground up. Promoting and supporting effective leadership at the laboratory level and mentoring next generation scientists are essential to provide effective biosafety and biosecurity assurances to mitigate risks. Leadership and a culture of safe, secure, and responsible science cannot be legislated. It requires leadership and mentorship at institutional levels.

Science and medicine are universal languages at the professional level, even during periods of turbulent geopolitical tension. International collaboration and science diplomacy will help nurture a culture of accountability and responsibility with next generation scientists. Science diplomacy through smart collaborations with responsible university institutions must be a component of a long-term U.S. foreign affairs strategy. Twining of responsible universities in the United States with universities in other countries must become an integral component of international collaboration, science diplomacy, early warning, and attribution for future outbreaks with pandemic potential.

A central component of this approach must include a targeted One Health international development approach that provides aid to LMICs to build basic public health and veterinary institutional capacities. Enhanced One Health capacities and core competencies will strengthen

International Health Regulation compliance. Higher education has an essential role too through global educational outreach to build the ethical foundation for next generation scientists.

Establishing capabilities to facilitate investigations and rapid attribution of outbreaks with pandemic potential will require multiple approaches from policy, international diplomacy, to new technologies.

Stand-off biosurveillance technologies, genomics, diagnostics, satellite imagery, artificial intelligence, health security data management, and reporting systems to name a few are needed. Fortunately, technology solutions are readily available today that were not available previously. The challenge is the political will to target investments that will make a difference.

The biggest challenge to improving our ability investigate and attribute the source of pandemics and other biological threats reside in overcoming geopolitical forces and the behavior characteristic described with the past precedent examples in my testimony. Because of the severe consequences and international nature of pandemic and other biological threats, source attribution requires transparent and objective investigations with forensic rigor supported by scientific findings devoid of conflict of interests with independent verification, whether the offending pathogen emerged naturally or unnaturally. It comes down to individual member state's willingness to act in good faith to support transparent and objective international inquiry. Behavior characteristics that are typically associated with autocratic regimes such as deflection, denial, obfuscation, and non-cooperation are difficult to overcome.

Currently, the WHO is beholden to strong member states that elect not to cooperate with transparent international outbreak investigations and/or International Health Regulations. The Scowcroft Institute of International Affairs at The Texas A&M University's Bush School of Government and Public Service recognized this limitation and previously made a number of recommendations to strengthen the role of the WHO Director General. One recommendation proposed to change organizational lines of authority between regional directors and the Director General to partially mitigate this limitation (Andrew Natsios, 2017). Our recommendations should be reconsidered as a component to help overcome organizational challenges and limitations inherent in the WHO structure.

Detection and attribution must also be tied to response mechanisms, such as rapid diagnostics, vaccine, and therapeutic surge development and manufacture. Congress has an historic opportunity this year through the reauthorization of the Pandemic Preparedness and All Hazards Innovation Reauthorization Act to ensure that the marketplace for medical countermeasures incentivizes the research and investment needed to counter future biological threats. Now is the time to realize a well-resourced and modernized Strategic National Stockpile (SNS). Now is the time to reflect on and learn from OWS's immense successes in quickly accelerating regulatory and manufacturing hurdles. And now is the time to invest in the domestic industrial base, including domestic Active Pharmaceutical Ingredients (API), in order to achieve the goal of manufacturing a new vaccine within 100 days of a future emergency. The country must have a sound infrastructure of warm base manufacturing alongside surge capacity

when pharmaceutical interventions are needed. All of this can and must be done with public-private collaboration, enabling, and ensuring equitable access for all Americans.

In closing, I want to state that above all, the nation is counting on strong biodefense and health security leadership and a national leadership structure that ties together components in the National Security Council and Office of Science and Technology Policy. Strong leadership is essential to drive effective coordination, collaboration, communication, and innovation across the vast United States government interagency, as well as with state, local, tribal governments, the private sector, universities, other non-government organizations, and with strategic international partners.

Thank you for the opportunity to appear before you and share my experiences on this important national security topic.

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Mr. GRIFFITH. Thank the gentleman.

Now recognize Dr. Imperiale for his 5-minute opening statement.

STATEMENT OF MICHAEL J. IMPERIALE, PH.D.

Dr. IMPERIALE. Thank you.

Chairwoman Rodgers, Ranking Member Pallone, Chairman Griffith, Ranking Member Castor, members of the subcommittee, thank you for inviting me to meet with you today to discuss this important topic.

I will focus on the need to maintain and invest in a strong life sciences research program to tackle future pandemics, including determining attribution. The Life Science Research Enterprise in the U.S. is second to none, providing understanding of and cures for diseases, supporting more than half a million jobs, and contributing in many other ways to the economy.

Much of the success can be traced to recommendations made in 1945 by Vannevar Bush, the first Presidential science advisor. He recognized that Federal funding of research at universities would amplify the return on investment. Not only would cutting-edge research get done, but students would be involved, and they would go on to become the next generation of scientists.

The results of this strategy are no better illustrated than by our response to COVID–19. In the spring of 2020, hundreds of university laboratories pivoted their efforts to tackle this disease. Government and private-sector investments in Operation Warp Speed spurred new public-private partnerships.

Working from the extremely strong foundation laid by decades-long U.S. Government investments in basic research, we made tremendous progress in a short period of time. We were vaccinating people before the end of the year. Monoclonal antibody and drug therapies soon followed. We must acknowledge the hard work and creativity of thousands of scientists in the U.S. and around the world. These ongoing efforts are allowing us to emerge from the pandemic relatively quickly. The loss of life and effects on the economy could have been much worse.

Recognition of these substantial accomplishments is taking a back seat to concerns about the possibility that another pandemic may arise due to inadvertent release of a pathogen from a laboratory that is working to protect us from these threats. Some even contend that scientists are not considering the potential risks.

Scientists are committed to biosafety. In the 1970s, it was concerned scientists who assembled the group of experts to debate the benefits and risks of recombinant DNA, leading to guidelines for safe conduct of this work. Infectious disease researchers prioritize biosafety, because we know the harm these agents can cause to ourselves and our communities. This is why we study infectious agents.

We work with biosafety professionals to implement the appropriate equipment and procedures to perform the work safely. Through increased research and investment in applied biosafety, we can continue to improve in this area. A related concern about potential risks of studying pathogens surrounds the concept of gain-of-function experiments. Gain-of-function covers a broad area of experimentation in which, as the term states, an organism is

given or requires a new property. In the vast majority of cases, these properties are innocuous or, indeed, beneficial. Engineering bacteria to synthesize insulin has greatly facilitated its production and its use in millions of patients. This is gain-of-function research.

Nature does this experiment all the time. Antibiotic resistance is a gain of function. There is value in gain-of-function research. The question is how we address concerns that an experiment might result in a pathogen with potential to cause severe harm or even a pandemic if it gets out of the laboratory, either accidentally or through malfeasance. Clearly such research needs careful consideration.

These experiments should only be performed when they are addressing a significant biomedical question of pressing concern, other approaches are not available or are severely suboptimal, and the work can be performed safely.

To conclude, I'd like to return to where I began. The U.S. Science Research Enterprise has been so successful because of the investments you and your predecessors have made, allowing the best scientists to contribute to the betterment of humankind and saving countless lives. Regardless of the origin of the next pandemic, we must invest in a strong public health infrastructure that will allow for surveillance for the next threat and a robust response when that threat arises. The scientific community understands the responsibility it has to the public, who both fund our research and are the recipients of the benefits of that research.

Other countries see the success of our strategy and are copying it. Now, their research programs are thriving. To ensure that the U.S. maintains its prominence in performing this lifesaving research, we must be careful not to throw sand in the gears that may slow our progress, dissuade U.S. scientists from conducting this research, or discourage young people in our country from being a part of our amazing scientific system.

And we absolutely must continue this research. This is the only way we will be better prepared the next time an infectious agent jumps from nature into the human population. Our national and economic security depend on our continued leadership in life sciences research.

Thank you.

[The prepared statement of Dr. Imperiale follows:]

Written Testimony of

Michael J. Imperiale, Ph.D.

Arthur F. Thurnau Professor

Department of Microbiology and Immunology

University of Michigan

Committee on Energy and Commerce

Oversight and Investigations Subcommittee Hearing

"Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events"

February 1, 2023

Chairman Griffith, Ranking Member Castor, Members of the Subcommittee, thank you for inviting me to meet with you today to discuss this important topic. I am Michael Imperiale, and in addition to my position at the University of Michigan, I am the Editor-in-Chief of *mSphere*; a member of both the American Society for Microbiology and the American Society for Virology; and a Fellow of the American Academy of Microbiology and of the American Association for the Advancement of Science. I would like to focus my remarks on the importance of maintaining a strong life sciences research program for being able to deal with pandemics in the future.

I have been studying viruses for more than forty years, and for almost two decades I have been involved in science policy efforts relating to biosecurity and biosafety, in Washington, DC and

internationally. My thoughts and opinions are therefore informed by my scientific expertise, countless hours of discussion with scientists and policy experts within and outside of the U.S. government, and what I feel are my obligations as a scientist to the public.

The life science research enterprise in the United States is second to none, providing understanding of and cures for diseases including infectious diseases, supporting more than half a million jobs in all 50 states and the District of Columbia, and contributing in many other ways to our economy. The bioeconomy is growing at a fast pace. Much of this success can be traced back to recommendations put forth in the report published in 1945 entitled “Science The Endless Frontier,” which was written by Vannevar Bush, the Director of the Office of Scientific Research and Development at that time – he was the first presidential science advisor, during World War II. Bush’s key recommendation was that the federal government invest in scientific research at universities. He recognized that this could lead to an amplification of the return on the investment because not only would cutting edge research get done, but students and other trainees would be involved, and they would go on to become the next generations of scientists. He has been proven correct time and again.

The results of this strategy are perhaps no better illustrated than by our response to the COVID-19 pandemic. In the spring of 2020, hundreds of virology laboratories, as well as laboratories in allied fields, pivoted their efforts to tackle this disease. Working from the extremely strong foundation laid by decades-long investments in basic research, largely by the US government, we made tremendous progress in a short period of time. Much of this groundwork came from studies of other viruses such as SARS and MERS coronaviruses, which are just as virulent but fortunately did not cause pandemics because of effective public health measures. If you had asked me during that spring how long it would take to develop and test a vaccine, I would have said at least a couple of years. Yet, we were putting shots in arms before the end of the year.

This is a remarkable accomplishment that would not have been possible without longstanding U.S. leadership in science and innovative public-private partnerships. Monoclonal antibody and drug therapies soon followed. The hard work and creativity of thousands of scientists, in the U.S. and around the world, must be acknowledged for allowing us to be emerging from the pandemic as quickly as we are. The loss of life and effects on the economy could have been much worse. For example, it has been estimated that the vaccines alone saved 20 million lives in their first year.

However, recognition of these substantial accomplishments of the scientific community, along with ongoing efforts to improve the ability of this community to respond even more effectively to future public health emergencies, appears to be taking a back seat to concerns about the possibility that another pandemic may arise due to inadvertent release of a dangerous pathogen from a laboratory that is working to protect us from these threats. Some even contend that scientists are not thinking about the potential risks. This rhetoric has been amplified on social and traditional media platforms. Even reasoned debate has been drowned out by uninformed discourse. I know of colleagues studying these viruses who have received threats to their lives. I can only imagine the second thoughts they may be having about continuing their important work, and if they were to step away it would be a great loss to society and our economy, leaving us less well-prepared for future threats.

This characterization of the scientific community is wrong. Scientists have always paid close attention to biosafety and biosecurity: in the early days of recombinant DNA research, it was concerned scientists who assembled a group of scientific and non-scientific experts to debate the benefits and risks of this new technology. This led to the development of the NIH Guidelines for Research Involving Recombinant DNA Molecules, which to this day are followed in order to minimize the risks of this type of research. I would argue that no group of scientists pays more

attention to biosafety than those of us who study infectious agents, because we know the harm they can cause to ourselves in the laboratories and to our communities if such agents were accidentally released from our laboratories. Working together with biosafety professionals at our institutions, we have the appropriate equipment and procedures in place to perform the work safely. I would note to the subcommittee that despite all the precautions we take in our laboratories, there is a tremendous opportunity for improvement in this area with increased research and investment in applied biosafety. I thank Congress for passing key provisions from the bipartisan PREVENT Pandemics Act last year, which will help facilitate some necessary improvements related to biosecurity and public health preparedness, including work to bolster biosafety research. We in the U.S. should take a leadership role among our international partners and collaborators to help them continue to improve the safety and security of their facilities as well.

The related concern regarding potential risks of working with pathogens surrounds the concept of gain of function experiments. Unfortunately, this term is widely misunderstood. “Gain of function” covers a very broad area of experimentation in which, as the term states, an organism or cell or infectious agent is given or acquires a new property. In the vast majority of cases, these properties are innocuous or, indeed, beneficial. For example, engineering bacteria to synthesize insulin has greatly facilitated its production and its use in millions of patients. Adenovirus, a common respiratory virus, has been engineered to produce the SARS-CoV-2 Spike protein for use as a COVID-19 vaccine. Nature itself carries out this type of experiment all the time: antibiotic resistance is a gain of function. The question is whether a laboratory gain of function experiment might result in a pathogen that has the potential to cause severe harm or even a pandemic if it were to get out of the laboratory, either accidentally or through an act of malfeasance. Clearly such research projects need careful consideration before being started and as they are being conducted. These experiments should only be performed when they are

addressing a significant biomedical question of pressing concern, other approaches are not available or are scientifically suboptimal, and the work can be performed safely.

To conclude, I would like to return to where I began. The U.S. life science research enterprise has been so successful over the years because of the generous investments you and your predecessors have made, providing financial resources and creating a welcoming and supportive environment that has allowed the best scientists from our nation and around the world to contribute to the betterment of humankind. This has enabled us to lead the world in science and innovation, and in the field of microbiology, we have saved countless lives through the development of diagnostics, vaccines, and therapeutics to target infectious disease threats. Regardless of the origin of the next pandemic, we need to invest in a strong public health infrastructure that will allow for surveillance for the next threat and a robust response when that threat arises. The scientific community understands the responsibility it has to the public, who both fund our laboratories and are the recipients of the benefits of the research we perform. Not surprisingly, however, other countries have recognized our strategy and have been emulating it, such that now their research programs are thriving. The U.S. is not always the automatic first choice of location for scientists to perform their research, and for American students to train to be the next generation of innovators. As we look to ensure that the U.S. maintains its prominence, performing this life saving research with appropriate safety and security parameters in place, we must be careful to not throw sand in the gears that may slow down our progress, dissuade U.S. scientists from conducting the research, and discourage young people in our country as well as international talent from wanting to be part of our amazing system. In this way, we can be better prepared the next time an infectious agent jumps from nature into the human population. Our national and economic security depend on our continued leadership in life sciences research.

Mr. GRIFFITH. I thank you very much. That now concludes our opening statements.

At this time, I would ask unanimous consent of the committee for the following Energy and Commerce Committee members to be allowed to participate in today's hearing. In keeping with our tradition, Representative Carter, Representative Miller-Meeks, and Representative Dingell have asked to waive on.

And, without objection, that will be the order of the day.

As a reminder, these Members will be recognized to ask questions after all other subcommittee members have been recognized.

All right. Point of order just for a second, so that folks know my philosophy on this committee, I believe our job is to get the facts. Obviously that requires a lot of information. So we will aggressively pursue getting facts so this committee can make decisions. And, once we have the facts, documents, and data, then we can have our disagreements based on our philosophical perspective.

Now, that should not intimidate young research scientists. It should not intimidate people in telecom or in energy and any of the areas that we're going into. But sometimes research shows us things that we weren't expecting to find, and sometimes that can be controversial. And I was sitting up here listening and immediately thought of Galileo and Copernicus.

So we need the research. Sometimes we'll get answers that we like. Sometimes we'll get answers that we don't like.

All right. That being said, I will recognize myself for 5 minutes to begin the questioning phase of this hearing.

Dr. Imperiale, please explain the difference in intentional modifications that pathogens were created using genetic engineering and serial passaging, which gets to your gain-of-function part of your testimony just now.

Dr. IMPERIALE. Yes. So—so deliberate engineering requires some sort of forethought and knowledge as to what types of changes need to be made to achieve whatever the goal of that experiment might be, all right? So it's really kind of a deliberate attempt to modify an organism, whereas successive passaging, you're selecting for a phenotype, right, or a behavior of that pathogen.

And we don't know necessarily from the outset what that's going to be. You know, sometimes we're trying to achieve a specific goal, but—but the—the results are always not what we anticipate.

Mr. GRIFFITH. And so—but—and I liked your definition of gain of function. I think that's easy for people to understand.

So both of these in certain circumstances—certainly genetic engineering but also serial passaging—could be gain-of-function research. Isn't that true?

Dr. IMPERIALE. That's correct, but what I wanted to make the point is that not all gain-of-function research is going to make something more dangerous.

Mr. GRIFFITH. Oh, absolutely. And—and that doesn't mean we shouldn't look at it. We've just got to be careful with it.

Do you know if they were doing either of these intentional modifications at the Wuhan laboratory?

Dr. IMPERIALE. I do not. I am not that familiar——

Mr. GRIFFITH. Fair enough.

Dr. IMPERIALE [continuing]. With the work that was going on there.

Mr. GRIFFITH. Do you know if they are doing—are doing or were doing either of these intentional modifications on monkeypox at the National Institute of Allergy and Infectious Diseases within the NIH?

Dr. IMPERIALE. I also do not know that.

Mr. GRIFFITH. OK. Does anybody know the answers to those questions? It's fine if you don't. I'm just trying to get info. Sometimes you've got to ask the question to find out. All right.

Dr. George——

Dr. INGLESBY. Chair—Chairman?

Mr. GRIFFITH. Oh, yes.

Dr. INGLESBY. I don't know—I don't have——

Mr. GRIFFITH. Dr. Inglesby?

Dr. INGLESBY [continuing]. Any personal understanding of what happened regarding the monkeypox research you talked about, but there is a public account of that in Science Magazine which describes work combining different clades of monkeypox, the characteristics of one clade which is more—more virulent with one clade that's more transmissible.

Mr. GRIFFITH. Thank you very much. You just gave the homework assignment to my staff. Find me the article. They'll do that.

Dr. George, based on the track record of the Chinese Communist Party's government, we really can't rely on them getting—we can't rely on them giving us early case data in a potential pandemic situation. Accordingly, should we allow any of our U.S. research dollars on potential pandemic pathogens to go to institutions that are predominantly controlled by the Chinese Communist Party?

Dr. GEORGE. Well, I would say two things.

First, it's not just China that doesn't do a great job of reporting out. Many countries don't for many, many various reasons.

Secondly, I would say, when it comes to issuing grants, whether they're Federal grants or somebody else's grants, the Government has the opportunity to put in a requirement in advance. It can be a requirement for anything, and they could put in a requirement to say, in order to get——

Mr. GRIFFITH. OK.

Dr. GEORGE [continuing]. These grant dollars——

Mr. GRIFFITH. So——

Dr. GEORGE [continuing]. You have to——

Mr. GRIFFITH [continuing]. That leads me to another question that's down the list a little ways. We had that in our—in our dollars that were sent to—ultimately to—ended up in the Wuhan lab through EcoHealth Alliance, and NIH didn't properly monitor it.

So do we need—one, do we need additional teeth in addition to your recommendation that we have somebody who is—who is a point person in a team to make sure that we have people taking a look at these things when we're dealing with dangerous pathogens?

Dr. GEORGE. I think we need to make sure that we are emphasizing biosurveillance throughout the world, and this is part of it, which——

Mr. GRIFFITH. Yes, ma'am. And let me say, I really appreciated your comment that it's not just the Chinese Communist Party that's—that's got issues. There were lots of organizations, and that's why, in my opening statement, I said government—I included the Chinese specifically, but I also referenced other governmental entities, because we—this is a problem that we need to get straightened out worldwide. And I appreciate your testimony on that as well.

OK. According—Dr. Howard, according to the GAO report, it was stated that we need more early samples from those with potential pandemic disease to be effective in determining pandemic origins. How do we better address this issue to ensure that foreign countries comply with what we were just talking about in getting us that data?

Dr. HOWARD. As we mentioned in our report, we do recommend and have proposed policy options that would encourage the development of multilateral agreements in advance of any pandemic that would encourage multinational sharing of samples and data. That would hopefully help address that issue.

Mr. GRIFFITH. Do they—do they respond to financial negatives if they don't? Is that something that works in that community?

Dr. HOWARD. The experts we spoke with did mention to us that there are incentives that might be useful in some cases.

Mr. GRIFFITH. I'm looking at negative incentives, but I appreciate it.

My time is up, and I yield back to myself.

I recognize—and now recognize the gentlelady from Florida, Ms. Castor, for her 5 minutes of questioning.

Ms. CASTOR. Well, thank you, Mr. Chairman.

And thanks again to all of our witnesses. You've really helped set the table for an examination of the tools we need to prevent the next pandemic.

And I heard you loud and clear. Good leadership and good science are essential in preventing and responding to pandemics. I guess, simply put, understanding the origin of pandemics can help us prevent the next one. For example, understanding the origin of SARS, MERS, and H1N1, that was critical in jump-starting the scientific community's response to COVID–19.

Dr. Imperiale, in a recent piece in the Journal of Virology, you wrote that, when we were facing a colossal crisis in the early days of the COVID–19 pandemic, scientists were able to draw on previous research on coronaviruses to understand SARS–CoV–2 more quickly. This, in turn, saved lives and prevented further economic destruction by facilitating the rapid development of vaccines, tests, therapies. We really got shots in the arms in a record time.

How did researchers' understanding of the origins of prior coronaviruses help the scientific community understand COVID, and what impact did it have on the Nation that was struggling to confront this pandemic?

Dr. IMPERIALE. Thank you.

I think the main impact there was that, since we knew where those previous viruses came from, it sort of gave us the obvious place to look for the origins of the current coronavirus, because we know that these viruses exist in certain places in nature, in bats

in particular. They generally move through an intermediate host before they can jump into the human population. And so, using that foundational knowledge, we were able to then kind of, you know, look for the places where it was most likely to have arisen.

Ms. CASTOR. And then, Dr. Inglesby, how does knowing the origin of a pandemic contribute to an effective public health response and help policymakers know how to best protect the public from a pandemic disease?

Dr. INGLESBY. Yes. Well, I think the more that we have confidence in the source of a future biological event, the more that we will have—can develop strategy to try and prevent future events along the same line.

So, if there is an animal husbandry practice that has in some way resulted in an epidemic or a biological event, then that could be changed. Similarly, if there is a laboratory practice, that could be changed.

So I think the more that we understand where it came from, the more that we have a chance of trying to diminishing the risks for that particular source in the future.

Ms. CASTOR. And the—the GAO details in its report that there are many challenges to determining the origin of a pathogen. They found that such investigations take time, noting that it took approximately 13 years to determine the origin of the 2002–2003 SARS pandemic.

Dr. Imperiale, in a 2021 report, you stated: In the absence of clear-cut answers, we need to continue to study these viruses because science is the best defense against pandemics. So how can we make sure that the scientific community has the resources, and how important—we're going to focus on the—the genomic sequencing and—and—but it seems like, still, the very basic data gathering on the ground of samples and just having—again, having that skilled workforce and collaboration with scientists and epidemiologists around the globe will remain vital to preventing future pandemics.

Dr. IMPERIALE. So, first and foremost, Congress has to maintain its strong support for research in our—in our Nation. And, if we want to be able to continue to learn more about these pathogens and learn more about the characteristics that allow them to infect humans, and that then will inform what we should be looking for in terms of what's out there in nature and what we should be thinking about in terms of what's being worked on in laboratories.

So I think that's the biggest thing, is that we have to continue to increase our knowledge. And I think we also have to make investments in more work where we can start to be able to better predict what the characteristics are of a virus that may allow us to make that jump and be virulent and be transmissible and have all these properties that we're concerned about.

We—we don't have good computational tools at the present time to be able to just take a sequence from a virus and say, "Oh, yes, based on that sequence, I know exactly how that's going to behave." Oftentimes we have to do the experiment in the laboratory to understand that behavior.

Ms. CASTOR. Thank you very much.

I yield back.

Mr. GRIFFITH. The gentlelady yields back.

I now recognize Chairwoman McMorris Rodgers.

Mrs. RODGERS. Thank you, Mr. Chairman.

And again, thank you, everyone, for being here and sharing your insights.

I wanted to start with Dr. Inglesby. There does not appear to be a single office within the United States Government that owns the challenge of bio attribution. How would having one official who can be held accountable in the United States Government for coordinating the Federal efforts on determining attribution make a difference in the effort to investigate the origins of pandemics?

Dr. INGLESBY. Well, I mean, I think as a general principle, the more that we understand who is responsible for the strategy, the budget, the execution of a program, the more that we increase the chances of success and for progress.

I think right now the National Biodefense Strategy does identity key agencies, which I think is a big step forward and didn't really exist before. So that is a big step. But there are many agencies, as we've talked about here, there are many agencies that are involved and have important responsibilities, and ultimately that, I think in the ideal case, would roll out to a single office that then could coordinate that.

There are science parts of this process, investigative parts of this. There's science diplomacy internationally. So, ultimately, it is going to require the efforts of many agencies and offices, but if we have one central place where this is responsible, one leader for responsibility, I think there's a higher chance of success and more rapid forward movement.

Mrs. RODGERS. Thank you.

You referenced the administration's National Biodefense Strategy. It does not include the National Institutes of Health. It includes a lot of agencies but not the National—at least, NIH is not listed.

Given the vast networks that NIH has within the research community and the connections of the NIH internationally, shouldn't the NIH be playing a role in the Federal efforts to investigate pandemic origins?

Dr. INGLESBY. Yes, I do. I assumed that, when HHS was identified as the lead agency in the strategy, that that would include elements of NIH science as part of that. CDC is also included. But you're right, it isn't articulated. And I do think it would be certainly a big part of it.

Mrs. RODGERS. OK. Thank you for that.

Now, this is a question to each of the witnesses. I'll start with Dr. Howard. Does the science exist to know, from looking at the genetic sequence, whether a pandemic had a natural origin or came from a laboratory?

Dr. HOWARD. With certainty, no.

Mrs. RODGERS. OK.

Dr. HOWARD. In most cases, when you look at the results of a pandemic origin investigation, they talk about likely origin, and the science, the community is comfortable with where they land but very rarely would they say they are certain.

Mrs. RODGERS. OK.

Go ahead.

Dr. INGLESBY. I agree, and I think that there's almost two questions—there are two questions of different levels of complexity. The first is natural versus engineered. And then the second question is: If engineered, where on Earth did it come from? And both of those questions are very hard, and I think most scientists will agree that it is—even the first question, natural versus engineered, can be very difficult to determine just from sequence, because engineering is sophisticated enough so that we—it is possible to obscure the signals of engineering.

I'm sure Dr. Imperiale would have more to say about that, but that's the view.

Mrs. RODGERS. OK. Thank you.

Dr. GEORGE.

Dr. GEORGE. I would say that I agree with my colleagues, and also, when we're talking about investigations, any kind of investigation, that's just one piece of information. It would be like asking, well, if we have fingerprint evidence, is that enough to say for sure somebody did something?

We would always say that we need a lot of data from a lot of different sources. They come together to make that determination.

Mrs. RODGERS. Thank you.

Dr. PARKER. And I'll use the anthrax letter example, and that was the case where there was a lot of genomic sequence information of the anthrax strain, but it took all of the other investigative pieces of information that finally allowed the FBI to make the conclusion that they did.

Mrs. RODGERS. Thank you.

Dr. IMPERIALE. I would agree that right now we can't say with certainty what the origin was, but I think that the vast majority of the evidence right now points towards a natural exposure in Wuhan that did not occur in the laboratory. And I could go through a very long laundry list——

Mrs. RODGERS. OK, that's fine.

Dr. IMPERIALE [continuing]. Of the evidence for and against that, but I won't do that.

But I want to just remind the committee that scientific knowledge is provisional, right. So we learn things, and we come to a conclusion, and then we learn more, and we modify our conclusions, and that's the way that this——

Mrs. RODGERS. Thank you. I have one more question I want to get to.

The Federal Government funds virus hunting activities in the field where researchers come into contact with bats harboring unknown viruses. Do these research activities pose a risk of human spillover?

And I wanted to ask Dr. Parker that question.

Dr. PARKER. Well, I would say certainly if the people who are not—collecting the viruses are wearing proper PPE and adhering to all the safety requirements. So that's a must that they need to do that, and there's too many examples that we've seen that maybe that's not happening—particularly, I would say, in low-to-middle-income countries.

Mrs. RODGERS. I yield back.

Mr. GRIFFITH. The gentlelady yields back.

I now recognize the ranking member of the full committee, Mr. Pallone, for his 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

Democrats on this committee have long prioritized a response to pandemic preparedness and response, and over the past 2 years we've taken steps to foster a resilient public health workforce, protect disproportionately impacted communities, tackle the effects of climate change, zoonotic disease transmission, and empower researchers to understand how outbreaks begin and spread.

Now today's panel is well-suited to help us understand how Congress can foster the type of collaboration necessary with the research community in a way that provides scientific breakthroughs while maintaining public confidence.

So I wanted to ask two questions. I'll start—I don't know if I'll get to everybody. I might move around. But first let me start with Dr. Howard. But I have to tell you before I ask these two questions, when I listened to you, and you explained all the pitfalls to finding things, I wondered whether we ever would find anything, because there were so many sort of pitfalls that you mentioned there.

But, with that in mind, what are the most effective tools that Congress could be providing the research community so that we can better identify the origins of pandemics and maybe get around some of the pitfalls that you mentioned?

And then, secondly, how can we use those findings to benefit the health and well-being of the public?

Dr. HOWARD. The policy options that we propose in our report are intended to address those same challenges that I enumerated in my statements. So, for example, developing better database interfaces, standardized processes so that researchers can work across a range of databases in a more efficient manner, incentivizing the retention and training of the experienced workforce that we need. And we really do believe that a national strategy would be very helpful, a strategy focused on pandemic origin investigations.

It's easy in the larger world of biodefense for pandemic origin investigations to get lost a little bit as a very specific subset, and we believe that a strategy that is targeted towards those investigations would be more effective.

Mr. PALLONE. All right.

Well, now since you and Dr. Imperiale sort of volunteered there that you thought that this—or that the evidence shows that this started in Wuhan but not in a lab, I ask you the same questions. In other words, again, is it—are there more effective tools that Congress could be providing the research community so we can better identify origins, particularly in light of what you just said about COVID?

And, again, how can we use those findings to benefit the health and well-being of Americans?

Dr. IMPERIALE. I agree very much with what my colleague just said. I think Congress can invest in better tools with which to do surveillance, better tools to which to analyze the data. We're really good at collecting data, but we're not quite as good as really fig-

uring out how to pull the relevant information out of those data to make informed decisions.

So those are two of the areas that I would recommend.

Mr. PALLONE. I guess I'll just go to the others.

Dr. George, perhaps, the same questions?

Dr. GEORGE. Mr. Pallone, we could give you a list of all the nifty things that are out there that could use some more investments, and we're happy to provide the committee with that, but I think we're talking about two types of investment. One would be for the science and the scientific tools that you're talking about: better genetic sequencing, better laboratory tests and so forth.

The other has to do with just the normal, everyday public health stuff that people have to do, things that would help with epidemiology and biostatistics, things that would help with data management, data analytics, modernizing some of the systems we have that—you know, here, in the United States, we're still—some people are still using fax machines to get data around, I think. You know, I can tell you that they probably need some computers and some connectivity to switch over to something else.

Mr. PALLONE. Well, let me just ask Dr. Imperiale. There's less than a minute left.

What kind of long-term investments by Congress are necessary to help researchers and public health officials prepare for or respond to prevent the next pandemic?

Mr. IMPERIALE. So I think that one of the main responsibilities of any government is to protect its citizens, and we put a lot of effort into our Department of Defense in protecting us from those kinds of threats, but I think we don't put the same sort of emphasis into our public health infrastructure to protect us from not just these kinds of events but the everyday sorts of medical occurrences that we need better work on for our people.

So I think we need to really make a strong investment in public health infrastructure. And, as you know, right, public health infrastructure is distributed. There's the Federal part of it, there's State, there's local, and there's got to be a better way then to figure out how to coordinate that.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Mr. GRIFFITH. Thank you. The gentleman yields back.

Now I recognize Dr. Burgess from Texas for his 5 minutes of questioning.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Parker, I'm so glad to have you here today. As a fellow Texan, you get it, that you never want to attribute anything to coincidence if there's a natural explanation and conspiracy theory.

So you provided us the four instances where you cataloged the outbreak, unnatural outbreak examples in your written testimony, and I just wondered, you know, after reading those—and I appreciate you providing those to the committee—what are your thoughts on what happened or didn't happen at the Wuhan Institute of Virology?

Dr. PARKER. Well, first, you know, I provided those examples because I think they provided some examples and insights on past precedent for the challenges with unnatural outbreaks and some of

the issues that get to what I think are the real challenges for understanding how to investigate and attribute in the international stage, and that is the lack of the—the inherent limitations.

Say, in the WHO, they have to be invited into a member state. Same with the BWC. In fact, the BWC really doesn't apply to a natural outbreak, but they give some insights also to the behavioral characteristics like denial, deflection, obstruction that are hard to overcome when we're thinking about the future and how we're going to solve some of these things and the problem.

And I just, in my written testimony, I gave—and I'll—my written testimony stands for the record, and both hypotheses are possible, and I think that's where I'll leave it.

Mr. BURGESS. Well, you wouldn't have known—like the 1977 Russian flu outbreak. It was only much later in the timeline that you learned because someone came forward who wasn't forthcoming in 1977. Is that correct?

Dr. PARKER. Confession is another characteristic, you know, and the Rajneeshee bioterror incident in the United States, that's another incident of confession that happened much later. In fact, that incident, it was attributed to a normal foodborne illness. There were some suspicions that it might be bioterror or intentional, and it wasn't until a devoted cult member admitted almost a year later, and the FBI came back in and investigated it and determined that the cult member was telling the truth.

Mr. BURGESS. And then there was a further incident with the former Soviet Union with anthrax that did not come to light until I guess after, what, the breakup of the Soviet Union when someone came forward?

Dr. PARKER. It was after the breakup of the Soviet Union. It happened in 1979 in Sverdlovsk. That was essentially a maintenance issue that somebody left the HEPA filter out, according to the person who debriefed the intelligence community in the U.S. and the United Kingdom.

And, for over a decade, it was a campaign of deflection, denial, obfuscation until the factor came out and debriefed and determined it was a malfunction in the—in inhalational anthrax, not contaminated meat.

Mr. BURGESS. Well, you know, you just—I think the point is that, in spite of everything that we put into it, you know, maybe you come back to the John Stewart theory. You have an outbreak of chocolaty goodness in Hershey, Pennsylvania, and maybe the culprit is the chocolate factory, not a steam shovel bathing with a cocoa bean. I mean, there is that aspect of it.

This thing seemed to line up that—and, look, I'll share with you, I was very concerned about this early on in the sequence of the pandemic. In fact, several of us on the Doctors Caucus had a classified briefing down in the SCIF and asked that very question: Is this truly just a novel coronavirus that has now come upon the scene? And we were assured by everyone who was there at that briefing that that was, indeed, the case, that there was no cause for concern.

I didn't know about your four cases at that time, or I might have been much more suspicious than I was.

Dr. PARKER. Well, they're not my four cases, but.

Mr. BURGESS. Right. The four cases that you've brought to the committee. And I appreciate you. I appreciate you doing that.

Back in the first bird flu in 2005, I had the opportunity to go to Geneva, Switzerland, and talk to the good people at the World Health Organization, and I will tell you my takeaway from that was that, if it were not for the United States Center for Disease Control, there wasn't much there for the World Health Organization and their global outbreak alert response network. It was really the boots on the ground as far as providing us protection on—from a global perspective, but it was CDC personnel that would not—I don't—my opinion, that would not have existed in the World Health Organization, just by itself.

Dr. PARKER. Agreed.

Mr. BURGESS. Thank you, Mr. Chairman. I'll yield back.

Mr. GRIFFITH. I thank the gentleman for yielding back.

I now recognize the gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you very much.

I'm just concerned that, in the conversations that are around the potential risks of certain research, that it has created—that there's been these myths around virologists and their research. And these inaccurate, inaccurate portrayals undermine our broad goal of protecting the public and their health, and I'm just concerned that we go down the wrong path.

So—let me get it right. Dr. Im-per-ah-tay?

Mr. IMPERIALE. Imperiale.

Ms. SCHAKOWSKY. Imperiale. Thank you.

So you actually recently wrote that the current discussion on the origin of COVID–19 ushered in, and I quote, "ill-informed condemnation of virology."

And I'm wondering if you can describe the type of research that's been happening around and including the research that you're doing at the University of Michigan and why some of the myths that are surrounding these discussions are inaccurate.

Dr. IMPERIALE. Thank you.

So I think there are two things that contribute to this inaccuracy. The first is, again, this debate about whether it was a natural exposure or a lab leak. Just by saying the possibility that there was a lab leak immediately throws suspicion on the research community. So there is that part of it.

And then there was this other issue that I mentioned about gain-of-function experiments and whether those were being done or not. And that also then, basically, led to this word out there, and it wasn't just kind of a rational debate, which has been going on for many years, but now social media, the traditional media saying that, you know, there are these scientists out there, and they're doing these Wild West experiments with no consideration of what the potential risks are for those experiments.

And I can tell you that, first of all, that's not true. We care very much about those risks, as I mentioned earlier, but moreover what I'm concerned about is that I have a number of colleagues who study these viruses, these very viruses that may cause the next pandemic, who are receiving threats on their lives because of this misinformation that's out there about virologists just not being—not doing the right thing.

And that very much concerns me because, if those individuals get discouraged from continuing this type of research and if that sort of behavior discourages young people from entering into the field, that's going to leave us in a less better place in the future.

Ms. SCHAKOWSKY. So let me ask you this, too. In a paper you wrote, you warned that, while maybe some changes need to be improved or reassessed, that there could—that we have to watch out for unintended consequences. And could you describe—so what are those unintended consequence that we have to watch out for?

Mr. IMPERIALE. Sure.

So, you know, so, first of all, we should always be improving the way we do things in general, but certainly it applies to the safety of our laboratory research. So there's no doubt there.

One of the most fascinating things about science is we have a hypothesis, and we do an experiment, and we get a result that's completely out there that we did not anticipate at all, and that's really exciting sometimes. But I can imagine where that type of result could mean, hey, look, we just created something that might be dangerous.

And so we have to always be cognizant that we might get that unanticipated result and then be taking the appropriate, responsible actions to figure out what do we do now with that information.

Ms. SCHAKOWSKY. Have you seen any of those kinds of consequences? Are there students, are there researchers who are discouraged by this conversation to get involved?

Dr. IMPERIALE. I don't know of any specific examples, but I know, about 10 years ago, when we were having these discussions about the H5N1 transmissibility experiments, that a colleague of mine did a survey of students, and many of them indicated that this was causing them to rethink whether they wanted to go into these areas of research.

Ms. SCHAKOWSKY. I think that's a shame.

And I yield back.

Mr. GRIFFITH. The gentlelady yields back.

I now recognize Mr. Palmer for his 5 minutes.

Mr. PALMER. I thank the chairman, and I thank the witnesses for being here today.

I'll pull back from my microphone a little bit. There seems to be an echo.

I want to go a little bit in a different direction here. I've got some concerns about organizations, agencies that are responsible for protecting the public and the world, really, from pandemics like this.

And Taiwan reported, as early as late December 2019, concerns of human-to-human transmission. They submitted some—an inquiry to the WHO that really wasn't transmitted to the rest of the world in a timely manner. And I just wonder—and, Dr. Howard, you talked about early access to many sequences of the virus. I don't think anybody would argue that it is extremely important that, when there's concerns like this, that everyone should have been informed.

And we should be concerned about any organization that is responsible for protecting us from things like this being intimidated and withholding that information.

Dr. HOWARD. As we noted in our policy options, we do think it's really important that that national strategy does assign roles and responsibilities for the various stakeholders. Who's going to be the lead? What are the support agencies? What are their specific tasks? Who does what? And that those processes are in place in advance of a pandemic so that protocols can immediately be activated once something like that comes into play.

Mr. PALMER. Well, we've already seen instances of other pandemics, SARS and things like that, that I just don't think we're at a point now where we can ignore anyone—legitimate concerns being raised.

And I would say that the Taiwanese CDC, their version of the CDC would be someone who should legitimately been listened to, and that should have been followed up on by WHO.

I just—your response from any of you. Obviously, I mean, I don't think anyone would disagree with that.

The other concern that I have is how China has responded to us. They, obviously, withheld information.

And there is a report. I don't know if you're familiar with it, from Internet 2.0, that indicates that the Chinese, particularly in Wuhan, were buying massive amounts of polymerase chain reaction tests, PCR tests, as early as May of 2019. I think it went up fivefold in some places. In Hubei Province, it maybe went up tenfold. I'm not sure on that last number.

But I don't know when that information first became available, but it seems to me if they're ordering that number of tests, then the Chinese, as early as May of 2019, probably had some concerns about human-to-human transmission. Would that be a reasonable assumption?

Dr. HOWARD. Our report did not look at the origins or any particular pandemic. Instead, we were more forward-looking at how to address the challenges to the field as a whole.

So I would defer to my other colleagues.

Mr. PALMER. Dr. Howard? Any view? Am I treading in ground that you don't want to walk on? I mean——

Dr. GEORGE. I would say that PCR tests and technology are used for many, many things. I don't think that one piece is evidence in and of itself can lead you directly to the Chinese knowing about this——

Mr. PALMER. Well, why would they buy fivefold amount in that one month if they weren't concerned about something? And particularly—I mean, this is clearly abnormal. I don't think they were stockpiling.

So I think it's something that we've got to take into account in this, and as we go forward in looking into this, I mean, it's obvious that I don't think we can count on—at any point that the Chinese are going to be forthcoming about how this started and how—when they first knew it.

Dr. GEORGE. Mr. Palmer, I would just say I agree that this is an important piece of information that needs to be added to all the other pieces of information when we're talking about an investigation into this pandemic or any pandemic, and it really points to the need to have a variety of people involved in the investigation.

Who would have found out about that? Is it somebody on the finance side? Is it somebody who's understanding supply chains or export control? That's not necessarily your public health person, you know, over at the CDC. It's not necessarily a scientist at NIH. So it points to the need to have a varied group of people involved in the investigation.

Mr. PALMER. You just, I think, validated the point I'm trying to make. This has got to be a broad-ranging investigation.

And, with that, Mr. Chairman, I appreciate the opportunity to raise these questions.

Mr. GRIFFITH. I thank the gentleman. He yields back.

I now recognize the gentlelady from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you very much, Mr. Chairman. Congratulations on taking the gavel.

And congratulations to our ranking member. I know you're going to do a wonderful job, Kathy, and I'm happy you're there at the helm.

As the chairman alluded to earlier, we had a number of investigations on the source of the coronavirus, and we did have blockages because it's difficult to get information from China, and that's why, Dr. Howard, I was really happy to see report where you're looking forward about what we can do in the future.

But I was also very intrigued, Dr. Imperiale, to hear you responding to Congresswoman Schakowsky's questions about the politicization of this research, because this is very—I think you'll agree with me, this research is really important towards developing vaccines and other ways to combat future unknown pandemics. Wouldn't that be accurate to say?

Dr. IMPERIALE. Very much so.

Ms. DEGETTE. And, Dr. Parker, I saw you nodding along when Congresswoman Schakowsky was asking about the politicization. I'm wondering if you can expand on your views on that.

Dr. PARKER. Sure. I think it's extremely unfortunate this has become so politicized and acrimonious. It's very unfortunate.

And I agree with Dr. Imperiale that the vast majority, almost all of our scientists and virologists are responsible individuals. They are responsible scientists, but we still—our biocontainment, our biosafety enterprise has been evolving over the last 40, 50 years. Probably the most significant was the 1974, 1975 that was mentioned when we first began to put guidance in for genetic engineering.

And we've evolved over those years, and we're in an evolving point right now with—the NSABB released a report last week that addresses some of these issues with research that might generate an enhanced potential pandemic pathogen——

Ms. DEGETTE. And when we have—I guess I would ask the two of you. When we have this politicization of a pandemic like this, that's really going to inhibit—and, again, Dr. Imperiale, you talked about that a little bit. It's going to inhibit our ability to in a thoughtful way develop the research that we need to prevent and treat it. Wouldn't that be fair to say?

Dr. PARKER. Well, I hope not. You know, somehow we've got to get rid of this acrimonious, you know, debate and discussion, but

we also have to look and try to find as best we possible can how did SARS–2 emerge.

Ms. DEGETTE. Right.

Dr. PARKER. I mean, we cannot ignore that. How did SARS–2 emerge? We need—we owe that to the American public and the rest of the world to try to understand to the best of our ability. We may not, ultimately, get dispositive or definitive information, but we need to understand as best we can, but we need do that in a way that's not so acrimonious.

Ms. DEGETTE. I completely agree with you, and it's a frustrating endeavor because you are dealing with—and the chairman and I have talked about this many a time. You're dealing with a country, the country from which it emerged, which is not—you know, which is not—which is opaque. It's not transparent.

And so the WHO and everybody else has been doing yeoman's work trying to get this information, but we may never have definitive information. Instead, in my view, what we should be doing is what Dr. Howard and the GAO are recommending—and, frankly, the scientific community at large—which is developing these strict guidelines.

And the U.S. can develop strict guidelines for how we deal with labs doing this research.

Yes, go ahead.

Dr. PARKER. Yes, and I think it's very important that the United States actually demonstrate some leadership in biosafety, biosecurity in research with enhanced potential pandemic pathogens. That's been something that's been kind of a gap for quite some time. And so I think we're at a point, too, if we can try to improve our own policies here in the United States, then we're in a better position to provide leadership worldwide because really the issue is on the international stage.

Ms. DEGETTE. That's right.

Dr. PARKER. I have complete confidence, actually, in our labs in the United States, in our high containment enterprise. It's not perfect, but I have much more confidence than around the world.

Ms. DEGETTE. Right.

Mr. PALMER. But we've got to work——

Ms. DEGETTE. Dr. Imperiale, do you agree with that?

Dr. IMPERIALE. I would agree with that. I think we have to play a leadership role here. You know, I have not seen containment facilities outside of the U.S., but I've heard, you know, anecdotal stories that they do not adhere to the same standards that we do.

And we have to remember. This has to be an international effort——

Ms. DEGETTE. Yep.

Dr. IMPERIALE [continuing]. To study these organisms.

Ms. DEGETTE. Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. GRIFFITH. Thank you, gentlelady.

And I now recognize the gentleman from Kentucky, Mr. Guthrie.

Mr. GUTHRIE. Thank you very much. Thanks for the recognition.

And I apologize. I like to listen to all the testimony and then try to form my questions from that.

We also have another committee, a subcommittee that was meeting, which I chair, so my obligation was to be there most of the time. But I did get to hear—and it's the Health Subcommittee, so it's important to what we're talking about today.

I did hear a little bit of Dr. Imperiale's testimony and about gain-of-function research because, you know, we need to ban what needs to be banned, and we need to—and you defined it—it's been defined so differently. And I remember I was going to have a—it wasn't in a public setting. We didn't have hearings with some of the more prominent people you see in NIH.

So I only—so I had—but I had a private phone call, and I was kind of advised when I was going to talk to him. He says, "If you ask them about gain-of-function research, they're going to say no. But if you say, could have anything been done to the virus, if it came from a bat to a human, could anything have been done anywhere artificially in a lab or so forth that happened, and just kind of broaden it with a"—he said that's possible. That was a time when you were still banned from Twitter if you thought it came from the Wuhan lab.

And so, you know, it kind of gets to if somebody says, "Is this gain-of-function research?," it's so technical, some people can say no when 99 percent of America would say yes, that was gain-of-function research in the way that we want to define it.

So I guess what I'm getting at, we've got to do some reforms of NIH and CDC and others. And could I just maybe get a—I think, Dr. Imperiale, you even said—I heard you say that gain of function—this is gain-of-function research. I can't remember exactly what you said, and that's OK, but this other is and it's not.

And so it just seems—or can—just go down the panel and start with you. Can you give a concise or reasonable definition in laymen's terms—I'm not a scientist—of what gain-of-function research is and what it's not?

Dr. IMPERIALE. Sure. So gain-of-function research is any research in which an organism or a cell or a virus or bacterium acquires a new function. And so antibiotic resistance is an example. That's not research, but that's natural.

So much of this research is very innocuous. A lot of genetics labs do this kind of research all the time to try to understand functions of genes and things like that, but there is a small fraction of this research that involves these types of pathogens that we're talking about today that does need added consideration as to whether it should be done and can it be done safely.

So that would be my definition.

Mr. GUTHRIE. If any of you have anything to add, I would love to hear different perspectives.

Dr. PARKER. I totally agree with that, and it is a confusing definition, but by far the vast majority of research that virology or the biologists will do with gain of function is actually helpful. There is that very small subset that could possibly generate a pandemic potential pathogen that requires additional consideration.

Mr. GUTHRIE. But you don't stumble onto that, right? When you're going into your research, you could say, "Well, I know I'm going to study a gene to see if I can gain this function so it can go kill cancer cells." I mean, that—but you know going in that

you're risking—is it a risk, or could it be, wow, "I stumbled upon this"?

Dr. PARKER. It depends on the research and the goals of the research and so forth, but, yes, the investigator should have that—I'll use the definition in the policy—reasonable anticipation, which is, you know, hard to define, too, but they would have some reasonable anticipation that it could.

And, when they're thinking about that and proposing that type of research, it should require more conversation, and hopefully that conversation starts at the PI level, because the PI in the institution I think actually knows more about the research and the way to mitigate risk at that level.

But if it could potentially generate, then it ought to be reviewed at the funding level and maybe reviewed at the department level, too, because the consequences could be so great.

Mr. GUTHRIE. Should the funding agency do the review, or should it be independent?

Dr. PARKER. I believe the review ought to be from the continuum from the institution, the funding agency. And if it really could generate an EPP, or enhanced potential pandemic pathogen, then the department level should review it as well as a final review.

Now, the review continuum and the processes and procedures need to be better streamlined so they're not delayed and et cetera, et cetera. So—and the benefits really need to be clarified, that the—as was said, that the research truly, if it could generate a potential——

Mr. GUTHRIE. I'm kind of running out of time. Dr. Inglesby, you look like you're ready to say something.

Dr. INGLESBY. I was just going to say that the science community——

Mr. GUTHRIE. I don't mean to skip you, Dr. George.

Dr. INGLESBY. In the last years has, in general, moved away from that term "gain of function" because it does encompass so much and really focused on this term "enhanced potential pandemic pathogen research."

If a researcher proposes to make a pathogen more transmissible or more virulent or if that could be the result of the work, that's the area of work where I think, you know, we all have a lot of concern about making sure that we do it right and do it safely. But it's a very, very specific area of work. It's not gain of function writ large.

Mr. GUTHRIE. Thank you. I appreciate that. That's very enlightening, and I appreciate your time.

And I yield back.

Mr. GRIFFITH. The gentleman yields back.

Now recognizing the gentleman from New York, Mr. Tonko.

Mr. TONKO. Thank you, Mr. Chair.

While most viruses emerge from outside the U.S., viruses know no borders, as we all know. As a result, much virus-related research takes place in other countries. Ensuring that American scientists can collaborate internationally in research strengthens the health and economic security of the American public and also allows us to answer critical questions about where pandemics originate.

According to Dr. Howard's testimony, GAO has found that, while researchers already have the technologies to determine the origins of a pandemic, better international collaboration is necessary if we want to get evidence-based answers about how pandemics, indeed, start.

So, Dr. Howard, how would improving international collaboration increase our ability to determine the origins of a pandemic?

Dr. HOWARD. The policy option that we proposed in our report was to proactively establish multinational agreements on data sharing, sample sharing, and roles and responsibilities in the event of a pandemic origin investigation, the outbreak of a pandemic.

Mr. TONKO. Thank you.

And I can imagine such collaboration can also be useful in other aspects of pandemic research and response.

Dr. Imperiale, how do the American people benefit from collaboration with researchers abroad? And what tangible scientific advancements in pandemic preparedness and response have been made through international collaboration?

Dr. IMPERIALE. We benefit from collaboration because it's the nature of how science has become in the modern age. No one laboratory really has the ability to address all aspects of any given question that needs to be answered in order to develop these approaches, and so we need that sort of collaboration, and oftentimes those collaborators are not within the United States.

And so the way these collaborations started, they're very organic. I will read the literature, and I'll see, oh, you know, researcher X in country Y is working on the same sort of thing, and I will reach out to that person and say, "Do you want to collaborate?"

So we have to be able to take advantage of the global expertise that's available.

Mr. TONKO. And we need, I would think, to ensure that virus-related research outside of the U.S. is done safely.

So, Dr. Inglesby, you have written extensively about the need to be—to thoughtfully balance investments in international research capable of generating scientific breakthroughs with concerns about national security and public safety. So how can the U.S. work productively and constructively with governments and researchers abroad to ensure that research is being conducted safely?

Dr. INGLESBY. Well, I think one major step forward is the policy review process underway right now. The White House NIH are leading with the input of NSABB and Dr. Parker. That's well along. I think we will have a stronger policy at the end of that.

And I think, after we have that in place, it will be important for the U.S. to be working with other governments to ensure that they also are thinking about the risks and benefits of this kind of work.

In general, international collaboration. I absolutely agree with what's already been said. International collaboration is really essential around this work to try and improve our protection against infectious disease risks. Infectious disease risks come from around the world. Scientists are doing important work around the world. The more that we know what other scientists are doing, the better we will do, the more we're engaged in the event there's a crisis, and we have personal connections or collaborations underway that can help.

But in that very particular area of dual-use research and enhanced potential pandemic pathogen research, that's where we should be working as a government with other governments to try and develop a common approach to dealing with this in the time ahead. Because the U.S. has been ahead of other governments, and I think it would be useful to help other governments think about it.

Mr. TONKO. OK. Are there any barriers from the other countries joining in that international compact?

Dr. INGLESBY. I think some countries are much less likely to be interested in sharing data than others. We've talked a bit about that already, but the more that we have scientific collaboration going, the more chance we have, I think, around sharing data.

And there is now the beginning of this pandemic treaty negotiation that's going on in Geneva, and part of that is a discussion about how we can share data better around the beginning, if possible, epidemic origins.

Mr. TONKO. It sounds encouraging.

I do hope that we can continue to have a rigorous conversation about biosecurity, and investigating the origins of pandemics, we ensure that well-founded concerns about safety are addressed alongside the need for critical collaboration with our international partners.

And, with that, Mr. Chair, I yield back.

Madam Chair, I'm sorry. I yield back.

Ms. LESKO [presiding]. I switched on you.

Mr. TONKO. Yes. Thank you.

Ms. LESKO. I'm going to call on myself. I'm Debbie Lesko from Arizona.

First, I want to thank all of you. Very informative, very complicated issue but very important issue.

My first question is for Dr. Parker. On September 12, 2019, the Wuhan Institute of Virology took down its online depository of data and viral sequences. The database was intermittently accessible from December 2019 to February 2020, before being permanently taken offline in February of 2020.

Do you think that the U.S. should continue to fund any type of research that they were doing in the Wuhan Institute on the virus in China?

Dr. PARKER. Well, first, I don't have any more information than you have on the database, but I have read that U.S. funds probably contributed some to that database. So that raises, certainly raises a question of if we contributed some funds to that, not all but some funds, we should have access to that database.

Ms. LESKO. I agree.

Dr. George, I have a question for you. It has come to light through Freedom of Information Act litigation that State Department cables from our Beijing Embassy in March of 2018 warned that biosafety practices at the Wuhan Institute of Virology were inadequate. Yet there is no evidence that information reached NIH, who continued to fund research at the WIV.

How can we ensure better coordination and information sharing?

Dr. GEORGE. Madam Vice Chair, it's an excellent question.

There are all kinds of examples of what you just gave with all different departments and agencies, people picking up on something, maybe communicating to somebody else, and then that information doesn't go anywhere else.

I think that, sadly, because of COVID, people are more sensitized now. And perhaps, in the future, if somebody had that same sort of assessment, even if they thought, "Gee, I'm not 100 percent sure, I'm over here at the State Department," I think they might be more inclined to not necessarily go from an embassy or consulate directly to NIH but, instead, at least go all the way up to the State Department and over to HHS.

That needs to happen across the entire Federal Government.

Ms. LESKO. I agree. We certainly learned that.

Dr. Parker, the GAO report cites a sampling effort in China aimed at tracing the origins of two pandemic pathogens, SARS and SARS–2, where despite generating a database of over 17,500 animal samples, researchers did not find any closely related coronaviruses.

Wouldn't you expect to find a closely related coronavirus?

Dr. PARKER. I'm not sure I'm familiar with that data—or that report from the GAO report. So I'm not sure if I should comment on that.

Ms. LESKO. OK.

Anyone else have any—do you want to add anything?

Dr. IMPERIALE. Yes, I would add that, yes, we have not yet found a virus that's an exact match to SARS–CoV–2, right, that arose in the early part of the pandemic. But the epidemiological data of where the cases clustered early on all point towards the live animal market in Wuhan.

I can also tell you that there is no evidence that the Wuhan lab was working on any virus that has a sequence that's close enough to SARS–CoV–2 to say that it arose from there. So sequence data here, based on what we have, is not helping.

As someone mentioned earlier, it took us over 10 years to find the exact match to the first SARS.

Ms. LESKO. Thank you.

Dr. Parker, do you have any doubt that COVID–19 emerged in China?

Dr. PARKER. All of the genomic data points back to Wuhan.

Ms. LESKO. Thank you.

And I yield back.

Yes. Next up, I'll call on Mr. Peters from California.

Mr. PETERS. Thank you, Madam Chair.

One of the benefits of being down here is that everyone has asked a lot of the questions already, but I do want to follow up on something before.

I wanted to talk about biomedical research safeguards that currently exist to manage the effects of potentially risk—risk in the United States, and I just wanted to follow up on an exchange earlier between Dr. Parker and Dr. Burgess about an anthrax outbreak in the '70s.

My understanding is that, Dr. Parker, you believe that this testimony—your testimony was that this occurred due to an incident in a Soviet lab. Do you recall that testimony?

Dr. PARKER. Yes, it was a Soviet lab in Sverdlovsk.

Mr. PETERS. And just to be clear, how would you—would you compare—how would you compare the biosecurity standards in a Soviet lab during the Cold War with U.S. standards today?

Dr. PARKER. Well, I was too young to——

Mr. PETERS. OK.

Dr. PARKER. I had not entered into the biodefense field in 1979. So it's kind of hard for me to comment on that.

However, you know, I would say, during the—you know, after the fall of the Soviet Union, I made a number of trips to Biopreparat, the—kind of the civilian equivalent of the military, MoD, military defense facilities. They're good scientists, former Soviet and now Russian scientists. They are very good scientists, but their laboratories were in great disrepair at that time because they didn't have funding because of the situation of the collapse of the government.

And so we were very concerned about——

Mr. PETERS. Nineteen seventy-nine is a long time ago, but would it be fair to say that it's wrong to assume that they're the same, the standards? We wouldn't have evidence that they're the same, would we?

Dr. PARKER. No. We didn't have eyes on the ground.

Mr. PETERS. I'd be suspicious myself that they're the same.

But, in any event, Dr. Imperiale, maybe you can describe the steps that researchers and institutions already take to mitigate risks and design safe research projects and how they might be improved.

Dr. IMPERIALE. Right. So, first of all, I can tell you that biosafety in the United States has been constantly improving over the years. I mean, the precautions that we take, the equipment that we have today are much superior than when I started as a researcher in graduate school in the late 1970s. So that's—there's that.

We also have these different levels of biocontainment from 1, the lowest level, to 4, and we assign the appropriate level of containment based on the nature of the pathogen being worked on. And so the most dangerous pathogens are worked at with the highest level of containment.

I had the opportunity to visit a BSL–4 laboratory in Boston a few years back, and it's remarkable to me how that building was designed, the procedures they have in place to protect us.

And so, if the facility is designed properly and the procedures are being followed the way they're supposed to be, the chances of an accident are very, very small.

Mr. PETERS. Actually, I think I saw similar things in our visit to the CDC, which we took as a committee, a lot of the same containment features.

What role do you think Congress can play in making sure that the public and other policymakers are distinguishing between legitimate concerns about risk and ill-informed fears based on conspiracy theories or supposition?

Dr. IMPERIALE. That's a good question. You can't legislate this. And I guess it's more just the way that, you know, you all talk about these things when you're making statements to the public and such to ensure that, you know, we're not overgeneralizing

things, that we're—you know, again, I'll come back to the gain-of-function thing, right. We're not painting this whole area of research as having potential risk.

As Dr. Inglesby said, there's a very, very small number of experiments here where we need to be carefully considering what we're doing there.

So I think it's more of the way the communication occurs. It's the way we talk about things. And also, then, when misinformation is put out there, pushing back against it.

Mr. PETERS. I'll just say I appreciate very much the witnesses. I think that this committee will be looking at ways to make sure that we're prepared next time. This is an important part of that discussion, as is making sure we're getting vaccines early, as is making sure we deal with supply chain issues that we've discovered during the pandemic.

And I appreciate the hearing and the witnesses.

And I yield back.

Mr. GRIFFITH [presiding]. The gentleman yields back.

And now I will recognize Mr. Duncan of South Carolina.

And everybody needs to lean into their mikes. We're having a little bit of a mike problem.

Mr. DUNCAN. Yes, thanks. That mike was janky.

If SARS–CoV–2 naturally spilled over in Wuhan, that's a heck of a coincidence. It means that SARS–CoV–2 reached Wuhan undetected and spilled over basically at the front door of China's premier coronavirus research facility without leaving behind any affected animals.

WIV scientists who have been studying coronaviruses for 20-plus years never expected to have one emerge in Wuhan. Based on the research, they expected a virus like SARS–CoV–2 to emerge 1,600 miles away in a rural area of southern China.

Laying aside those coincidences for a moment, if SARS–CoV–2 emerged naturally, it really seems to undermine the rationale for projects like Global Virome Project. Governments have spent hundreds of millions of dollars on researchers collecting viruses from caves and other remote areas, but it doesn't seem to have resulted in us being any better prepared.

So, Dr. Peters, is there some other part of the human-animal interface we should be focusing on?

Dr. PARKER. I think you meant Parker?

Mr. DUNCAN. Parker. I'm sorry. It's been a long day, sir. I'm sorry.

Dr. PARKER. I have to admit, when I first was briefed about the Global Virome Project very specifically, actually at a conference we hosted at Texas A&M several years ago, it looked impressive, but the more I thought about it and I talked to other people—including, actually, Christian Anderson was briefed the following year—and although there could be some merit to something like that, I think the available dollars that we have would be much better used at basic public health, animal health, diagnostics, surveillance, reporting systems, particularly in low/middle-income countries.

That's where some of these viruses are really going to emerge, in the low/middle-income countries and disease hotspots, and we really need to use our aid dollars because some of this was not

aid—it was using aid development dollars, U.S. aid. And I think the objectives of our aid dollars ought to be going to development and low/middle-income countries and then, specifically, for public health and animal health capacities.

Mr. DUNCAN. So, just as a sidebar question, you know, we've been studying and working on Ebola. Do we have any of these type labs set up in Africa that maybe we should be concerned about viruses escaping from that you know of, Dr. Parker?

Dr. PARKER. Certainly, we've had—I'm not sure if we have actually U.S.-funded labs, but we need collaborations on the African Continent with the scientists there to be on the ground. And I would say we also—education is very important, and having an opportunity to collaborate with universities and having 20 opportunities with U.S. universities and universities that are in low/middle-income countries specifically so that we can actually work on degree education.

We do a lot of training, but training may be necessary but not sufficient. And what we can do to actually grow the intellectual capacity of some of these countries will be——

Mr. DUNCAN. But no labs that you know of that are similar to Wuhan that you're aware of?

Dr. PARKER. On the African Continent, no.

Mr. DUNCAN. Yes, sir.

Dr. PARKER. Well——

Mr. DUNCAN. Close to Ebola.

Dr. PARKER. South Africa has a long history and has a very distinguished scientific record in South Africa.

Mr. DUNCAN. Right. Thank you.

I'm going to shift gears.

We had mentioned academia will play a large role in bio attribution investigations. However, academics can be subject to pressure from colleagues, funding agencies, and irate members of the public who disagree with their findings. It is essential that dissenting voices not be censored or intimidated.

How can Congress sponsor collaboration and data sharing between researchers and others in academia under those understandings? And what initiatives are currently constructive, and what's nonconstructive?

And I'll direct that back to Dr. Parker, but if anyone would like to chime in in 2 minutes.

Dr. PARKER. Sure. Thank you.

One, I think continue just to—recognition of the importance of academia and university-based research and how university-based research needs to be fully supported and the life sciences need to be fully supported. So I think just that recognition and continued discussion will be very helpful. Certainly, funding is absolutely necessary. It can't be done without resources.

Mr. DUNCAN. Yes, but we see all times funding directs the outcome and sometimes changes the hypothesis from the very beginning, or at least by the end date, so——

I know we've beat a horse here for the last couple of hours that we've been on this hearing, but I think Americans and my constituents want to make sure the United States Government investigates the origin of COVID–19 that took so many lives and is not negating

the understanding and empathy, sympathy for the lost individuals and the pain that the families felt and the strain it put on the hospitals, our healthcare workers and whatnot.

But coming to the conclusion of what happened in Wuhan, how it escaped or how it occurred naturally is very, very important. I think personally that it escaped from the lab, it wasn't natural. And that was in my initial comments.

I'm glad to see what GAO has put forth. I want to wish you guys, as researchers, the best of luck as you anticipate and collaborate on the origin of COVID–19 so we can get an answer so we can keep this tragedy from happening.

We're never going to stop a pandemic from happening. We always—my best friend is a doctor. He told me we were due for a pandemic, and he wasn't surprised when this one happened and sweeped across the globe. But to find out that it may have been manufactured and may have escaped the lab is kind of alarming to so many people. We need to make sure that doesn't happen again.

With that, Mr. Chairman, I yield back.

Mr. GRIFFITH. Thank you to the gentleman.

Now recognizing the gentleman from California, Mr. Ruiz, for his 5 minutes.

Mr. RUIZ. Thank you, Mr. Chairman.

I think we can all agree that biomedical research is critically important to improving our understanding about how pandemics begin, developing effective vaccines and therapeutics, and creating policies to contain future outbreaks. Ensuring that research is conducted safely with robust biosecurity standards is essential to the safety of researchers and the public alike.

Clear standards can help us weigh the benefits of potential research against its risk and gives us guidance for making reasoned, evidence-based decisions about which research is appropriate and under what conditions.

Dr. Imperiale, how should Congress weigh the risks that certain types of research carries against the benefits? And how can clear biosafety guidelines help in that evaluation?

Dr. IMPERIALE. I think that Congress has to listen very carefully to the experts in these areas who are doing this research so that they can understand why we want to do these experiments, how we're going to do it, and that—whether or not we've got the appropriate protocols in place to perform it safely. So I think that, you know, a dialogue and a partnership between Congress and the research community would really go a long way here.

Mr. RUIZ. So I know that there are a lot of ethical boards in doing clinical research. In terms of the biomedical research, aren't there certain guidelines for safety already that exist, or do you think that we need to create more robust safety guidelines?

Dr. IMPERIALE. Yes, very much so. As I alluded to, there are guidelines for working with recombinant DNA and also with infectious agents. These are—come out of the NIH. They come out of the CDC. Institutions are required to follow those guidelines as a term and condition of Federal grant support. And so we have committees that review these, you know, experiments before they're being performed.

We, in the laboratory, look at these things very carefully before we're performing these experiments. When we propose grants, there's that review at the NIH level and, when necessary, at a higher level if it is this very specialized category.

So these—this research is being reviewed extensively at multiple levels and also throughout the lifespan of the research.

Mr. RUIZ. And so how can we, you know, design a thoughtful biosecurity framework, right, that offers robust safeguards and risk-management strategies that also doesn't stifle potential innovative and biomedical breakthroughs?

Dr. IMPERIALE. So for me again?

Mr. RUIZ. Yes, it's you.

Dr. IMPERIALE. Sure. OK, so, yes, I think it comes down to what we've all been talking about here, right, which is that we need to, first of all, understand what experiments are important to do. What are the really important questions that need to be answered?

So I would make the argument, if someone wants to do an experiment because they think, "Wow, you know, I think this would be interesting to answer question X," but they can't convince me that there's a compelling need to answer that question, except to, perhaps, you know, add to our knowledge base in a more existential manner, then I think we can't take risks under those types of circumstances, right.

But if there's an experiment and even maybe a gain-of-function experiment that is going to give us critical information that may be necessary to prevent a pandemic or develop a therapeutic or deal with antibiotic resistance in bacteria, then I think we have to be willing to maybe take a little bit higher risk because of the importance of answering that question.

But we have to make sure that we've got the appropriate precautions in place to mitigate that risk and make it as minimal as possible.

Mr. RUIZ. So, one, we have different levels of that kind of risk research at the CDC, and they have their equipment. But one other thing that Dr. Parker said was that oftentimes the higher-risk locations of the origins of any pandemic are in low-to-middle-class-income countries where the risks of communicable diseases are higher, and you're talking about making sure we have safety in our protocols.

Well, that's going to require collaboration with other countries, with investments in other countries, to ensure that research is done at the site in order—and identification is done at the site in order to contain it. And I just need to make a comment here that this is very important to understand, that global health security is our health security, and taking an American-only approach to withdraw from other countries in global health and investing in those underserved countries is only putting ourselves at risk and doesn't meet the national security interests of our Nation.

So I think it's very important to understand that this requires also investments in biosecurity and infrastructure in those other countries as well.

And I—with that, I yield back my time.

Mr. GRIFFITH. I appreciate the gentleman yielding back.

I now recognize the gentleman from Texas, Mr. Crenshaw.

Mr. CRENSHAW. Thank you, Mr. Chairman.

I was—I don't want to spend too much time on this, but I was a little surprised to hear that the new consensus is that it's a wet market. It seems the consensus before that was—with a lot of pretty good evidence, was lab leak theory.

What was the new evidence exactly? Why is it so compelling that it's—it's no longer the Wuhan Institute of Virology's fault for their—for their shoddy parameters and standards of cleanliness, but now it's the wet market when that had been thoroughly debunked in late 2020 after looking at the data and testing animals in the wet market, all of that?

Dr. IMPERIALE. Yes. So—so there are a few pieces of evidence there. So the first is that the epidemiological evidence, where the original clusters of cases occurred, all mapped to that market, OK? So that's the first piece of evidence.

Mr. CRENSHAW. That's Chinese data, just to be clear.

Dr. IMPERIALE. No, no, no, no. This is U.S. data.

Mr. CRENSHAW. Well, I just read it, just now.

Dr. IMPERIALE. It's consistent data. Secondly——

Mr. CRENSHAW. Provided by China.

Dr. IMPERIALE. Secondly—secondly, there is evidence now that there may have been two independent introductions of the virus into the population. And the chances that two independent introductions occurred in the laboratory are pretty small. We can't rule it out, but they're pretty small.

And, as I mentioned before, there is absolutely no evidence that that laboratory was working with SARS–CoV–2, OK? So—now, we haven't found an animal with SARS–CoV–2, right, but we can apply Occam's razor here, right?

Mr. CRENSHAW. I don't know. Occam's razor says——

Dr. IMPERIALE. In the past——

Mr. CRENSHAW [continuing]. You know, we have a—we have a chocolate flood, and there is a Hershey plant nearby. Maybe it's the Hershey plant. I don't know. So——

Dr. IMPERIALE. Well——

Mr. CRENSHAW [continuing]. Maybe—maybe we don't know. I don't want to spend too much time on it because we're arguing about things I don't think we can possibly know. Let's get to my real line of questioning, please, Doctor.

Dr. IMPERIALE. Can I make a point, though, if you don't mind? I——

Mr. CRENSHAW. No, I do mind, because they're giving us 4 minutes now instead of 5.

So I think—I don't know—I think we don't know, and I think that's—what we're trying to figure out is how we can assure ourselves that we will know in the future.

So, Dr. George, I want to go back to you now.

You've called for a Federal biological attribution apparatus. Multiple administrations have failed to heed this. So we wouldn't have this argument right now. We would have a group of—a Federal agency that's designated to do this.

Can you talk through that? Why is that so important? Do we have the tools to do that, and is it just a matter of making sure

that those tools are working together for this common cause of attribution that would help policymakers?

Dr. GEORGE. Yes, sir, and yes, sir. I think—we have a lot of tools. Of course, we could—we could have more. We could have better technology.

We have a variety of Federal departments and agencies and others who are doing work in this space. You know, again, the FBI going down one path when it comes to law enforcement issues. You've got Department of Defense going off on another path when it comes to biological weapons. You have CDC going off on another path looking at public health things.

Mr. CRENSHAW. And, you know, does the intelligence community have a directive currently to say we need intelligence on virology labs in China? Like, is—would that even be on their radar?

I know recently we've been successful in implementing a national intelligence manager for biological threats at the ODNI. That seems like a good step forward. So do you think that will improve things and provide those kind of requirements that I was just talked about?

Dr. GEORGE. I think it will improve. It will improve things. However, there are more parts of the intelligence community that are addressing biological threats, and they all need to be further strengthened.

I do think they have more directives now. I don't know that they're specific to virology versus bio in general. But I think that they need to be engaged sooner. I don't think we should be letting things roll down the pike, and then suddenly, you know, a year, 2 years later, say, "Gee, we think there might be something else to be gained by engaging the intelligence community," and then asking them——

Mr. CRENSHAW. Right.

Dr. GEORGE [continuing]. To come in belatedly.

Mr. CRENSHAW. I'm sort of out of time, but, Dr. Parker, you're nodding your head like you wanted to say something. You're from Texas A&M, so I've got to let you.

Dr. PARKER. Yes. It's—I think back. We actually only had one laboratory in the United States. It was kind of built and designed for these kinds of things, and that's the NBACC lab at Fort Detrick. Unfortunately, I don't, you know, think it has its same kind of mission focus as it was originally envisioned. It would be a laboratory that could support microbial forensics investigations for attribution that would support the law enforcement and intelligence community, and I think today is probably only focused on law enforcement, which is necessary.

Mr. CRENSHAW. Well, that will be a future question. Do we create a whole new program or agency for this, or can we build upon something that already exists?

Dr. PARKER. We have to just—you know, I think it's just we have to put the leadership focus on microbial attributions and the scientists that support that. And—but I don't think we—we need to be thinking about how this also supports multiple things—day-to-day surveillance, genomics—that can support both public health needs and the investigations that go for attribution. And Dr.

George may have a different opinion than me, but that's OK. We differ on——

Mr. GRIFFITH. We'll have to get that opinion later.

The gentleman yields back.

Recognize Mr. Armstrong for his 5 minutes.

Mr. ARMSTRONG. Thank you, Mr. Chair. Academia, science, is going to play a huge role in how we could deal with the next pandemic. Nobody should be penalized or politicized for any of these decisions. We like science. We have the greatest healthcare, the greatest food supply in the history of the world. Science is the reason for all of those things.

But the—but there is another problem with science. And it's almost like you take—everything you design in order to get a real result is to eliminate confirmation bias, and then you lock everybody in their house, and you give them 6 more hours a day with these little machines in their hand that are only designed to enhance their confirmation bias. And you continue to have these things continue to move forward and continue to move forward, not the least of which it was called a novel coronavirus. So we were learning as we were going, and there's two different sides of this. There is U.S.—the U.S. portion and the global response.

But the GAO report mentions concerns over academics being subject to pressure from people who disagree with their findings. And I think it is important to acknowledge the pressures felt by academics on both sides of the COVID–19 debate.

While scientists at the NIH have taken a lot of criticism over their origins theories, it was also unacceptable to see scientists and academics who argued in favor of the lab leak COVID–19 theory—a theory at least everyone knows now is at least viable—were censored, ridiculed, and criticized.

So the criticism of academics happens on all sides of the origin question. We need to protect researchers, academics, and other professionals who are often controversial—who offer controversial findings and conclusions on origin investigations from workplace consideration and retaliation.

And then, on the international stage, we said we have to take—but the question is we have to take advantage of global expertise, but the second part of that question is without being taken advantage of.

Dr. Parker, you said denial, deflection, obstruction. The WHO's constitution states that the health of all people is fundamental to the attainment of peace and security and is dependent upon the fullest cooperation of the individual states. The problem is, for over the last 3 years, the WHO has not received the honest cooperation from the CCP in regards to investigating the origins of the COVID–19 pandemic. In fact, WHO itself, veiled behind public praise for the CCP's COVID response, expressed frustration over significant delays in receiving complete information, data, and genomes related to COVID–19.

WHO praised the CCP despite the CCP delaying information sharing that hamstrung global responses to the pandemic. If the WHO pursued an appeasement strategy with the CCP to get cooperation, it didn't work. Instead, we got deflection, denial, and obstruction.

I think it's clear that the United States having information early is important to determine the origin so that we can respond appropriately to the next pandemic. Offline, my colleague and I here were talking about, before this had ever happened, how much that early information would have really worked on the street in Dickinson, North Dakota. I am not entirely sure my constituents would have locked down before a single case got here.

But it's happened now, and we know it now. And so I have one question. And I think it's important. Has the CCP's obstruction and WHO's refusal to address the obstruction set a precedent for other state actors to refuse cooperation? What can we do in the future to make sure we take advantage of the global expertise without getting taken advantage of?

Dr. Parker?

Dr. PARKER. That is a good question. And I'm not sure I have a good answer, but I know one thing that we cannot do is walk away from the international stage—and continue to engage in these discussions. I know—and some of these diplomatic discussions may not lead to where we would like it to go, but we're not going to get there at all unless we—if we walk away from the diplomatic stage and these negotiations.

Diplomacy is hard, and diplomacy in this area is very hard. But we—I don't think we're going to be creating another WHO or whatever, but we have to make the WHO that we have work. And that will take diplomacy and negotiations. And those negotiations should, maybe first and foremost, make sure that we are protecting the vital, essential United States interests.

Mr. ARMSTRONG. Well, and Dr. George talked about positive reinforcements and the Chair talked about negative reinforcements, but it's really important because we can't do it as a government if our citizens don't trust this. And they don't trust it right now. And there is plenty of blame to go around on that, but some of it exists with the institutions that we put in place to trust.

And, with that, I yield back.

Mr. GRIFFITH. Appreciate the gentleman yielding back.

Now recognize the gentlelady from Florida, Mrs. Cammack.

Mrs. CAMMACK. Thank you, Mr. Chairman.

I'll jump right in.

So this question has already been posed by one of my colleagues, but I want to follow up on this. It is about the GAO report which cites the sampling effort in China that was aimed at tracing the origin of the two pandemic pathogens.

Now, there was a database of 17,500 animal samples. It was said—and I think it was you, Dr. Parker, that said you weren't familiar with that report. It is page 15, last sentence, second paragraph.

This states that 17,500 animal samples were used, and not one had a closely related trigger to coronavirus.

I am not a scientist, so educate me. How many animal samples would it take? Because what we're hearing today, to the point that my colleague from Texas is saying, is that this is now something from a wet lab, contrary to everything we've been briefed on for the last 2 years.

Dr. PARKER. Well, I think animal samples doesn't tell me what genomic samples are in those animal samples. I think that must be referring to the September database that went offline, perhaps? I don't know. But, just because there is—they're animal samples or clinical samples, whether they be fecal, oral, tissue samples, doesn't tell me what genomic samples were identified in there. But I think—you know, so that——

Mrs. CAMMACK. And, because we're short on time, I'm going to jump to the next one.

This is for really the panel at large: How much money is invested in research projects either in China or in collaboration with Chinese researchers? Who is responsible for tracking this research? And, to the comment that was made earlier about critical communication between scientists and researchers, how do we protect United States' data—health data and populations, particularly when the Chinese Government at the highest levels is suppressing information, withholding information, even to the WHO in the middle of a pandemic?

Don't all jump in at once.

Dr. IMPERIALE. I do not know how much U.S. dollars is going into research at China. I'm sorry.

Mrs. CAMMACK. OK. Dr. Parker?

Dr. PARKER. Yes, I don't know that number either, but, you know, I think that's a number that should be asked of—of the Federal funding agencies that work there.

Mrs. CAMMACK. Dr. George?

Dr. GEORGE. I think that whoever is taking a look at China's bioeconomy probably has more information about that. But I also think that, on the point of the role of the Chinese Federal Government and what they're doing, it's not—it's not just about denial of information and sharing with other people. Let's not forget they—they are looking for genetic information from a whole lot of people all throughout the world——

Mrs. CAMMACK. Yes.

Dr. GEORGE [continuing]. With some very popular genetic tests. I think we need to broaden our awareness. And we need somebody to be—to be—to be paying attention to all of this.

Mrs. CAMMACK. Thank you, Dr. George.

Dr. INGLESBY. Yes. And they're really fair questions. I unfortunately don't know the funding level for the Chinese science enterprise. I do think collaboration between the U.S. and China has the potential to be useful in the future but with appropriate safeguards and disclosure and accountability and transparency.

I do think, to your other question about how do we keep putting pressure on the system, working with other partners around the world to continue to ask for information about what happened basically—or in animal sampling and, you know, the environmental sampling and in the laboratory is—continues to be very important.

The WHO now is in that position, is asking for that information from China. I think Director General even a month ago said: All hypotheses remain on the table. China needs to provide additional information.

And, to Dr. George's last point, I completely agree that China has a strategy of acquiring genomic information from around the

world, including in the U.S., but has laws against other countries acquiring genomic information from within China. And so I think we should all be playing on a level playing field and be much more aware of where our information in the bioeconomy and personal information is going, in particular to China, but to other countries.

Mrs. CAMMACK. Thank you.

Dr. Howard, as quickly as you can.

Dr. HOWARD. Our work was not designed to look at the resources being extended on particular research.

Mrs. CAMMACK. Thank you.

I yield.

Mr. GRIFFITH. Thank the gentlelady for yielding.

Seeing no other witnesses of the regular subcommittee here, I would now recognize the gentleman from Georgia, Mr. Carter.

And so that the committee members will know, or so that the witnesses will know what's happening, is they've called for votes, and that's why people have been picking it up a little bit and why everybody's going to leave except myself and my colleague, the ranking member, except—and Buddy, who is going to ask questions.

Go ahead, Buddy. You're up.

Mr. CARTER. All right. I—well, thank you, first of all. Thank you all for being here.

Mr. Chairman, thank you for allowing me to waive on, and thank you for having this hearing as our first oversight hearing. How appropriate after suffering through the last 3 years, 2 years or whatever without having these type of hearings that we want on this subject matter.

And I'll be very quick. I've just got a couple of questions. We all know—it's gone over how much this has cost us in the way of lives, how much it's cost us in money. We don't know yet the impact that the lockdowns and everything else and the lack of children going to school has had, but we know that it's going to be tremendous in the future.

I want to ask you, Dr. Howard, in your work, have you ever compared oversight and compliance in U.S. taxpayer-funded research facilities in foreign countries to that in domestic institutions?

Dr. HOWARD. I'm not familiar with prior GAO work in that area, but we can do a little research and get back to you.

Mr. CARTER. I'd appreciate that, because it's my understanding that the NIH, for instance, exempts foreign animal labs from compliance with U.S. laws. And that's very concerning, especially if they're sending money over for research in places like the Wuhan Lab of Virology and other labs in China and Russia. This is something that I'm very concerned about.

Dr. Inglesby, I want to ask you—and this will be my last question. I'll go real quick, but thank you for being here, first of all.

The Center for Health Security released a report in 2018 that was titled "The Characteristics of Pandemic Pathogens." This point isn't too far in. It's the executive summary, but I think it's a good one. It says, "Although most classes of microbe could evolve and/or be manipulated in ways that would cause a catastrophic risk to humans, viruses are the most likely class of microorganism to have this capacity."

Let's assume we read nothing else in that report except for this. Can we just take that point away from this to say that we need the most—we need to be most careful when we—with Federal policy covering viral research as opposed to other research?

Dr. INGLESBY. I think it—Federal policy needs to be most careful around proposals to make pathogens—in particular, viruses—more transmissible or more lethal, and that's the—what we call enhanced potential pandemic pathogen research.

I think a lot of viral research poses no obvious risk at all within a laboratory, but there is a very specific area of viral research around making viruses more transmissible, which requires, I think, very special attention, very special review by the Government.

Mr. CARTER. You know, I know there is a danger in generalizing, and I know you all have defined gain-of-function research as being much more than probably what most people think of it as, but I've got to tell you I've got serious reservations. I don't think I'm the only one. I think Americans have serious reservations about this.

With all due respect to research—and I do have a great respect for research. I'm a pharmacist. I went through pharmacy school, saw researchers working diligently. And what has happened through research and development in my career as a pharmacist is nothing short of miraculous.

But, at the same time, when we talk about gain-of-function research, I can't help but think—you know, a quote from—from Einstein was the only thing more dangerous than ignorance is arrogance. And, in my opinion, gain-of-function research is nothing more than intellectual arrogance. And I think there is a real danger there, and I don't think I'm the only one who believes that. I think there are a lot of Americans right now who believe that.

So, having said that, Mr. Chairman, thank you for—again, for allowing me to participate, and thank all of you for being here.

Mr. GRIFFITH. Thank you very much. That concludes our witnesses who we have asked today.

I would remind all the Members that they have 10 business days to submit additional questions for the record, and I ask the witnesses to submit their responses within 10 days of receipt of those questions.

Without objection, the subcommittee is adjourned.

Thank you all very much.

[Whereupon, at 4:36 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Center for Health Security

Discussion on the Future Science and Technology of Biological Attribution

Summary of 6 December 2022 meeting organized by the Office of Science and Technology Policy

January 24, 2023

JOHNS HOPKINS
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Center for Health Security

Meeting summary prepared by:

Matthew E. Walsh
PhD Student, Johns Hopkins Bloomberg School of Public Health

Gigi Kwik Gronvall, PhD
Senior Scholar, Johns Hopkins Center for Health Security

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Contents

Introduction

After a biological incident—whether it is natural, deliberate, accidental, or undetermined—there is an imperative to investigate and identify the cause of the incident, and attribute who, if anyone, is responsible. The ability to attribute responsibility for a biological incident (bioattribution) helps to ensure that the deliberate use of biological weapons may be fully prosecuted and those responsible are held accountable. Bioattribution capabilities may also serve as a deterrent for use of biological weapons. Such a capability is the result of an attribution investigation that integrates multiple data sources, including information collected by law enforcement and public health officials, intelligence information, and technical information about the biological agent and other biological and environmental samples collected. The process is complicated; it relies on technical methodology and social systems (ie, the ability to get samples and to have a trusted process) to produce the technical information and sampling for attribution. It is important to routinely evaluate the state of the science available for bioattribution to ensure that investigations may leverage state-of-the-art technology and that efforts are being made to overcome technical challenges.

Summary

On 6 December 2022, the Office of Science and Technology Policy (OSTP) hosted an unclassified, not-for-attribution roundtable discussion on the future of science and technology of biological attribution, including ~15 technical experts and US government (USG) stakeholders. The purpose of the daylong meeting was to provide OSTP and other USG stakeholders an opportunity to obtain information and viewpoints from individual subject matter experts from industry, academia, and national laboratories on the technical aspects—largely, laboratory analysis—of bioattribution. The technical experts came from a diverse range of backgrounds covering genomics, proteomics, bioanalytical chemistry, immunology, bioinformatics, virology, and synthetic biology. Discussions in the morning session focused on the current state of bioattribution technical capabilities with an emphasis on laboratory analysis of biological samples and ideal operating scenarios, and the afternoon discussion focused on pragmatic steps for the bioattribution field in the future. Early on, there was a discussion focused on whether an effort to exhaustively sequence all biological agents of interest to create a reference database was feasible and/or worthwhile. It was recognized that such an effort to exhaustively sequence everything of interest was not practical and that the future of technical bioattribution would need to operate without such a resource.

Significant discussion was dedicated to sample analysis techniques and identifying mid-term (5-10 years) technology development goals. Sample analysis methods generate significant amounts of data and rely on even greater amounts of public data.

Considering how that data is generated, processed, stored, shared, and represented was a common theme throughout the meeting, as it is the underpinning of bioattribution. The Genetic Engineering Attribution Challenge was discussed as an example of how public competitions could be used to make rapid advancements in the field as well as a case study for understanding data needs for building machine learning models for effective bioattribution. Machine learning methods are likely to gain prevalence and popularity in coming years, and it was discussed that the selection of a machine learning model will need to consider the intended use of the output information. Given the accepted lack of an exhaustive reference database, there was discussion on how to maximize the value of multiple pieces of data that each provide some unique insight. Lastly, experts thought that the role of the USG in bioattribution science and technology should be clarified and expanded—it was thought that the government could play a catalytic role in advancing bioattribution technology.

Dedicated research and development efforts are needed to overcome technical challenges in bioattribution, and it was noted that current incentive structures do not support developing a workforce to pursue careers in bioattribution. The technical experts agreed that continued conversation is needed and that the field needs to have more advancement as a community, and the experts expressed enthusiasm in continuing to work together. There was a positive sense in the room in support of future meetings, roundtable discussions, conferences, and community challenges to strengthen bioattribution capabilities.

Meeting Themes

The following themes were present in discussion throughout the day:

Methods: Laboratory analysis of biological samples was categorized into 3 fields of study: genomics, proteomics, and metabolomics. Analysis methods from these fields of study are needed to characterize complex mixtures/samples that may or may not contain living organisms. Capabilities within the field of genomics generally exceed those of proteomics and proteomics capabilities far exceed those of metabolomics. As opposed to PCR-based methods, today's genomic methods focus on sequencing the whole genome. A shortfall of current proteomic methods is the throughput, owing to the time required to run the analysis and the time required to reconfigure and prepare instrumentation between samples. It was noted that multiple independent measures providing the same result would be particularly helpful for attribution, and the ability to identify connectedness among samples from separate events would be valuable in identifying networks of individuals with malintent. Validated methods and core technologies in the public domain would provide an additional element of trust in the results.

Reference samples, databases, and big data: Much of the work surrounding bioattribution relies on matching the analytical output of an unknown sample to a previously collected reference sample or information in an existing database. However, it will not be possible to a priori categorize all of biology to create a database expansive enough to adequately address all future needs. There was discussion about making this problem tractable by investing in understanding smaller, representative subsets of different genera of organisms, for example, to develop a general understanding the genus. Some large databases do exist within industry but are the proprietary information of the companies that own them and should not be considered an available resource to others. It was noted that criminal prosecution relies on publicly available data.

There was general agreement that researchers should endeavor to publish any collected data in a reproducible and transparent manner. In addition to the data itself, there is a desire to include metadata in a standardized fashion. The conversation did not progress to the specificity of exactly what data and metadata would be most valuable in this context. However, some data repositories are growing unsustainably fast and are on pace to become less useful in the coming 2–5 years. Such efforts could be supported by the National Institute of Standards and Technology (NIST) and the National Center for Biotechnology Information (NCBI), and it was suggested that representatives from NIST and NCBI be included in future attribution conversations. There was discussion about cloud-based solutions in academia and industry, but, due to security practices, these solutions may not be feasible for all USG stakeholders. Dual use concerns surrounding what data is collected and aggregated, and how that information could be misused, will also need to be considered.

Genetic Engineering Attribution: One of the more notable activities in the field of bioattribution in recent years is the Genetic Engineering Attribution Challenge that occurred in 2020.[1] This public competition was intended to build upon an earlier academic publication in which the authors demonstrate an ability to predict the lab-of-origin of an engineered DNA plasmid.[2] Prize money was awarded to teams with the highest accuracy in predicting the lab-of-origin. This challenge served as a case study that was referenced during discussion throughout the day. This challenge used data from the nonprofit organization AddGene. The characteristics of the dataset that made it well suited for the challenge were 1) its size, 2) its public availability, 3) its standardized metadata, and 4) the distribution of entries across many academic laboratories. Competitors produced machine learning models that were marked improvements from the earlier publication. There are practical limitations to this work as the concept of operations relies on a bad actor having published their work, deposited their information in a public database, like AddGene, or someone having a priori knowledge of that actor's prior genetic engineering history. Additionally, this work is predicting who designed a sequence and not necessarily who made the sequence.

"Black box" machine learning methods: There are differences between technical and policy experts in their expectations for bioattribution data.[3] Some users of bioattribution data need and expect a rationale for why a machine learning algorithm produced a specific result, something that remains an inherent challenge of using deep learning based methods. One interesting finding from the Genetic Engineering Attribution Challenge was that neural networks perform well on attribution but that traditional machine learning methods also perform well. This suggests that there may not be a meaningful tradeoff in accuracy and explainability, and that technology development should proceed with the needs of the end users in mind. The use of deep learning methods may still provide value in pointing investigators in the right direction but likely would be insufficient as a standalone method of bioattribution. While noted as important, there was limited discussion as to the ideal level of human involvement in the operation of the machine learning algorithms.

Partial solutions: While there was a sense that a perfect solution will remain elusive, there was discussion on how helpful information can be generated from a sample. Such information includes if the pathogen had characteristics of being grown in a laboratory setting, if it underwent directed evolution, if the evolutionary chronometry aligns with what would be expected in nature, if there are abnormalities in the epidemiological data, and sometimes the function of the organism (or molecule). To support these goals, there was a desire to better understand how much variability exists in nature (ie, a baseline) and how much of the knowledge space is unknown. Although none of these processes will individually and conclusively link a biological weapons attack to the responsible party, the collective set of information may be able to.

Role of government: There does not appear to be a single office within the USG that "owns" the challenge of bioattribution. Having a dedicated responsible USG entity would be beneficial to technology research and development. There was a similar roundtable discussion held by the UK government several weeks prior to the USG meeting and intergovernmental collaboration would be beneficial. There are limited incentives for industry and academia, particularly early career scientists, to operate in this space; government can play a role to catalyze careers in bioattribution.

Moving Forward

This roundtable discussion will be the start of continued discussion and engagement. Moving forward, USG, industry, and academia all have roles to play:

Technological development: One clear gap identified was the throughput of proteomics assays. With such shortcomings being known and success metrics easily defined, the USG should invest in a program to develop technologies to more rapidly or cost

effectively generate data required for investigations. Additionally, there was some discussion about exploring federated learning, a method that would allow one entity to use another entity's data to train a machine learning model without exchanging the data, to overcome expressed concerns about disclosing propriety data. Work has been started in this space[4] and additional conversations among the technology developers (bioinformatics and cryptographic experts) and government and industry stakeholders would be required to determine if this is a viable path toward a generalizable and acceptable means for the USG to leverage industry-owned data in support of bioattribution.

Partial solutions: Given the acceptance that an exhaustive reference database will not be available, focus should be on how to maximize the contributions of information that answers questions tangential to identifying a specific individual or entity responsible for a biological event. These methods should be developed with the intent on integrating them into a generalized workflow and efforts should simultaneously be made on maximizing the value of the integration. The USG should consider funding such efforts in industry and academia.

Standardization: Future conversation will need to become more specific with regards to what data is collected, how it is processed, annotated, stored, and shared. This work could be coordinated through NIST or NCBI.

Conferences: The American Society for Microbiology (ASM) has previously hosted ASM Biothreats, an annual scientific conference dedicated to emerging research in the field of biothreats. The 2023 meeting could include a session on bioattribution to inspire broader audience engagement.

Community challenges: The Genetic Engineering Attribution Challenge demonstrated the ability to engage with individuals outside of the biology community and to make technical progress on defined problems in exchange for the possibility of winning a relatively small monetary prize. Future challenges could be developed and conducted to be more realistic of bioattribution activities by including less-than-perfect data sources. Additionally, such a challenge could require participants to curate and publicize data resources for future bioattribution work.

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March 7, 2023

Karen L. Howard, Ph.D.
Acting Chief Scientist
Director of Science and Technology Assessment
Science, Technology Assessment, and Analytics (STAA)

Answers to Questions for the Record
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biologic Events
February 1, 2023

The Honorable Dr. Burgess

A simple yes or no please:

1. In your professional experience, could we have known the origins of the COVID-19 pandemic by March of 2020?

No.

For context, our research has shown that multiple lines of evidence are often needed to establish a pandemic's likely origin. In some cases, it may take decades of research to acquire such evidence. For example, we note in our recent technology assessment that it took approximately 12 years to determine the origin of the 2002-2003 SARS pandemic and approximately 7 years to determine the origin of the 2009 H1N1 pandemic. (See GAO-23-105406)

March 3, 2023

Lauren Eriksen, Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Ms. Eriksen:

I submit this letter in response to a question for the record submitted by Representative Michael Burgess for a February 1, 2023 hearing before the Subcommittee on Oversight and Investigations entitled "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events."

The question states: "A simple yes or no please. 1. In your professional experience, could we have known the origins of the COVID-19 pandemic by March of 2020?"

My response: No.

If you should have any further questions regarding this response, please contact Melissa Hopkins of my team at melissa.hopkins@jhu.edu.

Sincerely,

Tom Inglesby, MD
Director, Johns Hopkins Center for Health Security
Professor, Environmental Health and Engineering
Johns Hopkins Bloomberg School of Public Health
Joint Appointment, Medicine, Johns Hopkins School of Medicine

Post-Hearing Questions for the Record
Submitted to Dr. Asha M. George

"Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events"

February 1, 2023

The Honorable Mr. Carter

In the Bipartisan Commission on Biodefense's March 2021 Biodefense in Crisis report, Recommendation 32 suggests a Congressional review and overhaul of the Select Agent Program. There has been discussion of expanding the program to include types of research to be regulated by the program, say research with the potential to cause a pandemic.

1. **Dr. George - How big of an effect on oversight would this inclusion have?**

   Recommendation 32 from the Commission's *National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* calls for the National Science Advisory Board for Biosecurity (NSABB) to review the Federal Select Agent Program and make recommendations to the Department of Health and Human Services, the Department of Agriculture, and ultimately Congress for how to overhaul the program. The Commission felt it important to address the fast-moving landscape of biological science and biotechnology and how advances in synthetic biology necessitate a comprehensive reevaluation of how the federal government identifies, categorizes, and secures biological agents in the 21st Century, particularly those that are used in research.

   Congress saw fit to authorize the NSABB for the first time as part of the Consolidated Appropriations Act, 2023 (Public Law 117-328). The Board is well-situated to conduct an assessment of the Federal Select Agent Program. Any review of the Program should consider whether additional categories of research should fall under the Program, including studies on pathogens or activities not currently considered Select Agents.

   NSABB recently explored how better to safeguard dual use research. In January 2023, the Board released its Proposed Biosecurity Oversight Framework for the Future of Science, which included recommendations for dual use research of concern, including pathogens with pandemic potential. Those findings suggest additional resources and policy will be necessary to support federal review of these research activities. Increasing the scope of the Select Agent Program could similarly necessitate additional resources and inspections, particularly with an increase in the number of research activities that need to comply with the program.

For oversight purposes, expanding the scope of the Federal Select Agent Program to apply to research with the potential to cause a pandemic would offer Congress and the Administration more insight into the large volume of research occurring in this space, and a better understanding of what controls are in place to prevent specimens from that research from leaving the laboratory environment. Congress would need to require timely and comprehensive reports about the Federal Select Agent Program in order to conduct effective oversight, and would also need to keep up with rapid advances in the field of biological science.

As we investigate the origins of COVID, the U.S. intelligence community regularly reminds Congress about the ongoing threat posed by chemical, biological, radiological, and nuclear (CBRN) weapons. We can't take our eye off the COVID investigation, but HHS/ASPR's mission of protecting Americans from deliberate threats – like smallpox and anthrax – has never been more important.

2. **Dr. George - Given the threat posed by CBRN weapons, what do you think HHS/ASPR should be doing to ensure Americans are protected against these threats in the future?**

Through the Pandemic and All-Hazards Preparedness Act and other actions, Congress has made clear that the Department of Health and Human Services (including, but not limited to the Administration for Strategic Preparedness and Response) bears responsibility for preparing for, protecting against, responding to, recovering from, and mitigating the impacts of CBRN weapons, especially biological. President Joseph R. Biden and his Administration also delineated significant biodefense responsibilities to the Department of Health and Human Services in the October 2022 iteration of the National Biodefense Strategy and Implementation Plan. Recommendation 3 from the Commission's *National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* called for the creation of a National Biodefense Strategy. The Commission commends the Biden Administration and the Administration of former President Donald J. Trump (which produced the first National Biodefense Strategy in 2018) for answering the call and addressing this recommendation.

Under the National Biodefense Strategy, Department of Health and Human Service biodefense responsibilities include biosurveillance, biological detection, medical countermeasure development, manufacturing and stockpiling, stockpile distribution and public health infrastructure capacity building. All of these activities are important for reducing biological (and to some extent chemical, radiological, and nuclear) threats to the Nation, and for protecting the American people. Any strategy will only be as effective as its implementation process, and Congress has a strong oversight role in ensuring that the Department of Health and Human Services carries out its responsibilities under the Strategy.

The Commission recommended in its report *The Athena Agenda: Advancing the Apollo Program for Biodefense* that the Department should develop a diagnostics

response plan. This plan should outline a clear process to rapidly approve, develop, scale, acquire, procure, and deploy point-of-use diagnostic tests throughout the Nation in response to a biological event. The plan should: (1) require the development of rapid point-of-use diagnostics following the initiation of diagnostics that require laboratory confirmation for a novel biological threat; (2) delineate the activities of the National Institutes of Health Rapid Acceleration of Diagnostics Executive Committee, Tech Governance Committee, Tech Working Group, and Underserved Populations Governance Committees in engaging with the Department of Defense and the private sector to develop and scale diagnostic capabilities rapidly; (3) describe the processes for quick approval, acquisition, and procurement of rapid point-of-use diagnostics; (4) detail how these committees will rapidly deploy diagnostics; (5) describe the process for making instructions for using diagnostics easier to understand and less complicated; and (6) simplify reporting to public health departments.

The Commission also recommended in its report *Biodefense in Crisis: Immediate Action Needed to Address National Vulnerabilities* that the Department of Health and Human Services should conduct a comprehensive review of existing medical countermeasure programs, policies, and assets, including the Centers for Innovation in Advanced Development and Manufacturing. A recommendation from the Commission's report *The Athena Agenda: Advancing the Apollo Program for Biodefense* calls for the Secretary of Health and Human Services to develop a plan for expanding advanced manufacturing capability for platform technologies. The plan should: (1) articulate how many advanced manufacturing centers the Nation needs to rapidly scale up production of medical countermeasures; (2) identify potential private sector partners who could host these centers; and (3) articulate how these centers should operate during non-crisis periods to ensure their ability to respond quickly during an emergency.

3. **Dr. George - What does the Bipartisan Commission on Biodefense recommend regarding preparedness for America's stockpile of critical CBRN vaccines and treatments?**

The Commission addressed the Strategic National Stockpile (SNS) and its contents in two recommendations in its *National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. Recommendation 22 from the *Blueprint* calls for a joint effort between the Department of Health and Human Services and the Federal Emergency Management Agency to develop and implement a Medical Countermeasures Response Framework. This framework would guide distribution and disbursement of SNS medical countermeasures in response to any chemical, biological, radiological, or nuclear event. Recommendation 23 from the Commission's *Blueprint* advocates for the forward deployment of SNS assets to state and local jurisdictions that have demonstrated the capability to appropriately handle SNS contents. By moving assets to the state and local level in advance, the federal government can speed distribution of critical medical countermeasures, supplies and equipment in the early response to a biological event. Recent congressional proposals

that would establish and support state-level stockpiles would address the spirit of this recommendation.

The Commission also places great emphasis on the value of intelligence and information regarding CBRN threats and the need to take these into account when determining the contents of the SNS and other national stockpiles. Vaccines, other medical countermeasures, equipment, and essential medical supplies to address extremely high consequence events (such as a biological event involving weaponized smallpox) must be added to, and maintained within, our national stockpiles. While the certain contents may be utilized to respond to public health crises (e.g., using extant smallpox vaccine from the SNS to combat the spread of monkeypox in the United States), Congress and the Administration must make certain that contents removed from the SNS for such purposes are replenished in a timely manner. Further, Congress must ensure that funds appropriated for the SNS are not diverted to address other public health issues.

The Honorable Dr. Burgess

Dr. George - This Committee will be considering the reauthorization of the Pandemic and All-Hazards Preparedness Act this year.

1. **Are any of our public agencies currently equipped to handle these types of major investigations?**

Many federal departments and agencies bear responsibilities for biological attribution activities, with the Department of Health and Human Services and its subordinate agencies serving an important role through its biosurveillance activities and public health investigations conducted by the Centers for Disease Control and Prevention. However, each federal entity has a specific role, and there is no federal biological attribution apparatus to coordinate these activities.

Recommendation 9 from the Commission's *National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* would establish a national biological attribution decision-making apparatus. Such an apparatus would strengthen our ability to investigate and determine the origins of biological events by leveraging and coordinating existing attribution activities at the Department of State, Department of Defense, Department of Health and Human Service, Department of Homeland Security, Department of Justice, and various elements of the Intelligence Community. The government should inform this attribution apparatus with: (1) standard/burdens of proof in the U.S. criminal justice system; (2) evidence, information, and intelligence regarding the source; (3) accuracy, reliability, timeliness, credibility and defensibility of that evidence, information, and intelligence; and (4) national security considerations. This apparatus should be exercised to inform decisions and to ensure that these decisions are defensible.

The Commission recommended in its report *Biodefense in Crisis: Immediate Action Needed to Address National Vulnerabilities* that Congress or the Administration could begin the development of a biological attribution apparatus by requiring the relevant federal departments and agencies to convene to begin planning for what such an apparatus would look like. The plan should articulate department and agency roles, responsibilities, and requirements, as well as milestones for adjudicating attribution information and informing decisions following any biological event with national security implications.

Full Committee Question – A simple yes or no please.

2. In your professional experience, could we have known the origins of the COVID-19 pandemic by March of 2020?

No.

March 9, 2023

The Honorable Michael Burgess, MD
U.S. House of Representatives
2161 Rayburn House Office Building
Washington, DC 20515-6115

Subject: Response to Questions for the Record, E&C Subcommittee on O&I

Dear Congressman Burgess,

Thank you for the opportunity to appear before the House Energy and Commerce Subcommittee on Oversight and Investigations. You are undertaking vital work by directing Congressional attention to the Challenges and Opportunities of Investigating the Origins of Pandemics and Other Biological Threats.

After the 2001 Anthrax letter attacks, new programs were established for microbial forensics, and the National Biodefense Analysis and Countermeasures Center (NBACC) was designed and constructed to support biological attribution. Unfortunately, while the complexity of biological threats has rapidly expanded since 2001, attention to the challenges of biological attribution over the last decade has been insufficient.

Addressing these complex and novel biological threats requires that we reimagine our approach to develop capacities to investigate natural and unnatural (accidental or deliberate) outbreaks for attribution. Importantly, this requires much closer coordination between public health, law enforcement, and the intelligence community.

Whether natural, accidental, or deliberate, we must do everything we can to rapidly determine the source of a community outbreak, epidemic, or pandemic. This is essential to prevent a future recurrence and to mitigate continued disease transmission once a novel pathogen emerges. Biological attribution is an essential component of our preparedness and response enterprise.

Question 1. What can Congress do to promote increased interagency coordination when investigating serious public health incidents?

> **Answer**. As I stated in my written testimony, current multilateral agreements and organizations, such as the World Health Organization, have inherent weaknesses that limit their ability to investigate and attribute biological threats in member states around the world unless invited in by member states to provide technical assistance. This is not a criticism of the World Health Organization. Rather, in the case of COVID-19, it is a criticism of the Chinese Communist Party for silencing Chinese scientists and not permitting a comprehensive, transparent, multilateral investigation to assess the natural origin and research associated hypotheses with forensic rigor alongside Chinese scientists, that can be independently verified.

But as we look beyond COVID-19 and the need to establish new capabilities and procedures in the United States to investigate and attribute outbreaks at home or abroad, we must first take action to galvanize interagency governance structures to enable effective policy leadership, coordination, collaboration, and innovation. This must also be accomplished in a manner that does not impede effective implementation and management of programs at department/agency levels.

I testified previously before the United States Senate Committee on Homeland Security and Governmental Affairs and the United States House of Representatives Committee on Homeland Security's Subcommittee on Emergency Preparedness, Response, and Communications about the importance of interagency leadership, governance, and capabilities needed for attribution (Parker, 2022) (Parker, 2017). My comments in those testimonies are still relevant for Congressional consideration today.

The 2022 PREVENT Pandemics Act provides new authority for the administration to establish a White House Office of Pandemic Preparedness and Response Policy. This is an important development. If implemented well, it could address interagency policy coordination and related issues I discussed in my previous testimonies, which others have highlighted. However, it is unclear how the administration plans to implement this new authority and how current domestic and international preparedness and response policies, global health security, and the new National Strategy for Biodefense will be consolidated under this new office. It is also unclear how much authority the new office will have in practice. Will the Departments of Defense, Health and Human Services, Agriculture, Homeland Security, State, and Justice, the Intelligence Community, and other departments support and believe this new office has the authority to coordinate and direct resources on priority requirements during the annual budget process on behalf of the President?

The 2022 National Biodefense Strategy calls for strengthening national attribution capacity for natural and unnatural infectious disease outbreaks. The strategy places leadership with the Department of Health and Human Services and the Federal Bureau of Investigation with support from the Departments of Interior, Agriculture, Energy, Homeland Security, State, The Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Intelligence Community. The range of agencies and disciplines involved will require strong interagency coordination and leadership.

The complexity of 21st century biological threats will challenge our ability to distinguish natural from unnatural sources, at least initially. Thus, the starting assumptions of any suspicious infectious disease outbreak domestically or internationally should include the possibilities of natural or unnatural origins until proven otherwise, requiring much closer coordination between public health, law enforcement, diplomatic and scientific agencies, and the intelligence community. As I mentioned in my written testimony, public health authorities do not reflexively consider unnatural origins.

Regarding Congressional action, in my experience and professional expertise, there are two gaps that require immediate consideration.

First, biological attribution is not highlighted as a specific priority in the PREVENT Pandemics Act.

This gap in the PREVENT Pandemics Act must be closed in the Pandemic, and All-Hazards Preparedness Act scheduled to be reauthorized in 2023.

Second, Congressional action is warranted to provide oversight, or additional legislation, if necessary, to ensure the new White House Office of Pandemic Preparedness and Response Policy is implemented in a manner that provides effective interagency governance, coordination, and leadership for the entire interagency biodefense, global health security, and pandemic preparedness and response enterprise, domestically and internationally. This must include oversight to ensure that the administration implements new programs required to establish capacities for biological attribution and to ensure effective governance and coordination mechanisms are put in place to optimize the investigative authorities, expertise, and laboratory capabilities of relevant agencies to determine the source of infectious disease outbreaks rapidly.

2. **In your professional experience, could we have known the origins of the COVID-19 pandemic by March 2020? A simple yes or no answer.**

Answer. Yes

Respectively,

Gerald W Parker, DVM, PhD

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Michael J. Imperiale, Ph.D.
Department of Microbiology and Immunology
1150 West Medical Center Drive
5724A Medical Science Building II, SPC 5620
Ann Arbor, MI 48109
+1 734-763-9162
imperial@umich.edu

February 27, 2023

Hon. H. Morgan Griffith
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Griffith:

Thank you for your letter dated February 23, 2023, in which you asked for a response to a follow up question from Rep. Dr. Burgess relating to my testimony to the Subcommittee on February 1, 2023.

I thank the Subcommittee once again for asking me to testify on this important topic.

Sincerely yours,

Michael J. Imperiale, Ph.D.
Arthur F. Thurnau Professor

Dr. Burgess' question is:

In your professional experience, could we have known the origins of the COVID-19 pandemic by March of 2020?

My response is:

Based on the information available at that time, no.

○