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LEGISLATIVE SOLUTIONS TO BOLSTER PREPAREDNESS AND RESPONSE FOR ALL HAZARDS AND PUBLIC HEALTH SECURITY THREATS

TUESDAY, JUNE 13, 2023

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:30 a.m. in Room 2322 of the Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Burgess, Latta, Griffith, Bilirakis, Johnson, Bucshon, Hudson, Carter, Dunn, Pence, Crenshaw, Joyce, Harshbarger, Miller-Meeks, Obernolte, Rodgers (ex officio); Eshoo, Sarbanes, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Craig, Schrier, Trahan, and

Pallone (ex officio).

Also present: Representatives Balderson; and Castor.

Staff Present: Jolie Brochin, Clerk, Health; Sarah Burke, Deputy Staff Director; Seth Gold, Professional Staff Member, Health; Grace Graham, Chief Counsel, Health; Sydney Greene, Director of Operations; Nate Hodson, Staff Director; Tara Hupman, Chief Counsel; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Molly Lolli, Counsel, Health; Clare Paoletta, Professional Staff Member, Health; Carla Rafael, Senior Staff Assistant; Emma Schultheis, Staff Assistant; Michael Taggart, Policy Director; Lydia Abma, Minority Policy Analyst; Jacquelyn Bolen, Minority Health Counsel; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Stephen Holland, Minority Senior Health Counsel; Una Lee, Minority Chief Health Counsel; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; Tristen Tellman, Minority Health Fellow; and Anthony Choi, Minority Intern.

*Mr. Guthrie. The subcommittee will come to order.

And for when we ask questions and so forth, I just would -- the clock in the back of the room is not working, so there is a clock that is facing us that you will see on the table for everybody. Pay attention as we look to try to keep order as we move forward, so we can get to everybody's questions.

But the subcommittee is now in order, and the chair recognizes himself for five minutes for an opening statement.

This is the fourth hearing the Energy and Commerce Committee has held in the 118th Congress related to our response framework. I want to express, you know, concern and disappointment today that the bill before us, PAHPA, is not bipartisan as we now speak. I know that we have worked hard to try to make it that way. Hopefully, we will, as we move forward. And I look forward to engaging my colleagues on systematic CDC reforms and comprehensive effort to examine the root causes of the drug shortage that we are now facing, which is serious, absolutely serious.

I am grateful to Representative Miller-Meeks for taking the lead on CDC reform by publicly issuing a request for information on this issue. I look forward to hearing from

her about the responses she receives from her RFI and addressing the many issues highlighted in a future CDC reform effort. We will start these conversations today, and we will have to -- work to do across the Health Subcommittee's jurisdiction that necessitates a separate process and larger conversation outside the scope of this authorization.

So hopefully, we can go back to focusing on this authorization, and I look forward to working together on the other issues that have arisen the last few days.

The legislation before us today is designed to generate broad consensus around streamlining improvements to our preparedness and response infrastructure at the Administration for Strategic Preparedness and Response, or ASPR. We are continuing our efforts to prepare for and respond more effectively to future public health security threats. These threats include chemical, biological, radiological, nuclear or cyber attacks, or any infectious disease outbreak.

Many of the bills today are bipartisan. This includes legislation focused on evaluating and shoring up our diagnostic testing infrastructure and domestic manufacturing

capacity for medical countermeasures during a public health emergency. These two components hampered our initial response to the COVID-19 pandemic.

We also have several pieces of legislation focused on improvements to our National Strategic Stockpile. This includes reaffirming our commitment to supporting states' efforts, working to ensure streamlined insight into our stockpile supply chain, and clarifying ASPR's responsibility over the Strategic National Stockpile.

We are considering legislation to improve transparency and communication between our Federal agencies and private-sector partners. For example, we are examining the benefits of establishing an advisory committee to provide a forum for private-sector input into our medical countermeasures procurement.

We must also demand proper accountability and communication from our public health agencies to our constituents. That is why I am pleased to see Chair Rodgers' discussion draft to require CDC to issue good guidance practices included in the hearing today. This would establish public participation requirements prior to

finalization or implementation of major guidance pushed out by the CDC.

It also clarifies that these guidances are non-binding and do not create, restrict, or revoke any person's rights or responsibility. This also does not have the force or effect of law, which is a standard that other public health agencies already must meet.

The public deserves to have visibility and a seat at the table to allow them to make decisions best for themselves and their families.

To build on the importance of accountability and improved processes, I am to partner with the Representative Peters on bipartisan legislation to examine the Department of Health and Human Services's existing data authorities and data collection efforts. This includes the Federal funds used for such purposes.

Local authorities don't need new, top-down, heavy-handed data-sharing mandates that won't help them respond to their local needs, nor should the American people's sensitive information be collected and potentially used in a punitive fashion. This bill will ensure the agency is held

accountable for any over-utilization of such authorities, including any redundancies. We have already heard from stakeholders on how important this review is, and hopefully we can move forward -- hopefully move it forward as part of this process.

In closing, I would like to extend my sincere thanks to Representative Hudson, his staff, and our dedicated committee staff for their work over the past several months to deliver this strong discussion draft. We must ensure these critical preparedness and response activities are authorized in a timely manner.

I am happy to get to work on other topics, as shown by a number of hearings and bills we have already moved through this subcommittee. However, trying to attach other issues into this reauthorization with broader topics will undermine its ultimate passage.

[The prepared statement of Mr. Guthrie follows:]

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

*Mr. Guthrie. I thank you, and I yield back.

The Chair now recognizes the ranking member for five minutes for questions -- for an opening statement, sorry.

*Ms. Eshoo. Thank you, Mr. Chairman, and good morning, colleagues and our witnesses that are here today. Thank you for being with us.

During my floor speech on the passage of the original Pandemic and All-Hazards Preparedness Act in 2006 I said, "This bill demonstrates the good that can come out of bipartisan teamwork.'' Today, as the only original author of PAHPA still serving in Congress, I ask that members recommit to bipartisan teamwork so that we can pass a reauthorization bill to ensure our country is doing its best to prepare for the worst.

The 2023 PAHPA reauthorization must meet the challenges we witnessed during the COVID pandemic, and anticipate the challenges of the future. There is clear demand from stakeholders for improvements to the legislation. Over 250 organizations replied to the request for information on PAHPA that Representative Hudson and I published.

One critical area where our country is unprepared is our

medical supply chain. During the pandemic we saw that our medical supply chain is broken in three devastating ways: shortages of lifesaving supplies, especially when met with high demand during an emergency; subpar manufacturing; and an over-reliance on foreign production.

It is in the DNA of PAHPA to address gaps in supply. Project BioShield, the Biomedical Advanced Research and Development Authority, and the Strategic National Stockpile are authorized in PAHPA with the express purpose of ensuring access to medical countermeasures in times of emergency.

This year's PAHPA reauthorization is another opportunity to fix the vulnerabilities of our drug and device supply chains. For example, as Dr. Califf of the FDA testified to during our topical hearing last month, the Federal Government does not have the information it needs to identify the sources of Active Pharmaceutical Ingredients -- we all shorthand it, API -- leaving who supplies many critical drug elements a mystery. My legislation, the Drug Origin Transparency Act, fills these gaps in knowledge so we can move more secure in our ability to respond to a health threat.

To help prevent shortages, the FDA also needs notifications of supply interruptions for medical devices or unanticipated spikes in demand for drugs. If a drug goes into shortage, the FDA should be able to use data from the drug manufacturers to safely extend the shelf life date.

Finally, the FDA should be able to recall drugs that are either maliciously or accidentally contaminated in the same way it can recall biologics, devices, and food.

I also support policy that would create a buffer stock for critical oncology drugs that are often in shortage due to quality problems for sterile injectable drugs, and I look forward to hearing from the oncologists on today's panel about this issue. Currently, we don't have a bipartisan agreement to include these policies in the bill, and I think it is critical.

Let me just say this again. I think it is critical that we commit to move these policies forward in PAHPA. Chair Rodgers, Chair Guthrie, Representative Hudson, I hope you will work with me. I am asking you, I am really begging you to work with me to find a bipartisan path forward. That is how serious these issues are.

I am pleased that today we will consider important legislation to improve CDC's public health data, create a diagnostic preparedness plan, and provide BARDA with many of the important contract authorities that Assistant Secretary O'Connell described during our last hearing.

I am hopeful we can include these common-sense policies, as well as address concerns about the medical supply chains in the final reauthorization. Our nation's health and our nation's security depend on it.

[The prepared statement of Ms. Eshoo follows:]

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

*Ms. Eshoo. I yield back, Mr. Chairman.

*Mr. Guthrie. The gentlelady yields back. The chair now recognizes the chair of the full committee, Chair McMorris Rodgers, for five minutes for her opening statement.

*The Chair. Today we are considering several pieces of legislation critical to our national public security -- public health security. This conversation could not come at a more pressing or relevant time. America is facing public health security threats on many fronts.

For example, a recent State Department report confirmed North Korea continues to develop genetically-engineered biological weapons, including bacteria, viruses, and toxins. According to one report, nearly 60 million patient records were compromised last year through over 900 data breach incidences.

And we continue to learn lessons from the unprecedented COVID-19 worldwide pandemic. We must be prepared for and ready to respond to these threats -- chemical, biological, radiological, nuclear, or cyber attacks -- by taking an all-hazards and threat-agnostic approach. That is the focus of the solutions we are considering today that Mr. Guthrie

discussed in detail.

I understand that some of my Democratic colleagues are upset that we are not considering legislation related to drug shortages and larger supply chain issues. I will say to them I welcome that discussion. Just last week, the FDA announced that more than 130 drugs were in short supply, 14 of which are cancer treatments. Clearly, this must be addressed.

A few weeks ago the Oversight Subcommittee held a hearing on this exact topic. And just yesterday Senate Finance Ranking Member Crapo and I released a public request for information to solicit information and ideas on the underlying economic causes of drug shortages, the potential role of Federal programs in contributing to drug shortage, and possible solutions.

Finding solutions for drug shortages are broader than this reauthorization and FDA, and outside the scope of this preparedness reauthorization. I welcome my colleagues, Democratic colleagues and Republican, to work together on this effort. And I remind them that the focus of today's legislative hearing is on ensuring we reauthorize immediate preparedness and response programs.

For many of these threats, from catastrophic natural disaster to a biological threat to cyber attack, the question is not if, but when. And I thank many members for their hard work on the reforms we are considering today.

I especially want to express appreciation to Congressman Richard Hudson for his leadership to provide the framework for these discussions, and commend him and his team for their hard work.

[The prepared statement of The Chair follows:]

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

*The Chair. I am going to yield now to Congressman Hudson to further speak to these efforts and what happens if we fail to come together to pass this reauthorization on time.

*Mr. Hudson. Well, I thank the chairwoman. You know, after years of preparing for this reauthorization, I have been proud to work with my Republican and Democrat colleagues to ensure that our nation is best prepared and able to respond to any future public health security threat.

At the beginning of this year I put out a request for information, along with my colleague, Ranking Member Anna Eshoo, to solicit important stakeholder feedback on this reauthorization. I am honored to work with the Ranking Member Eshoo, a four-time champion of PAHPA, someone who knows the critical importance of getting this bill across the finish line.

With that being said, I worry that my colleagues are losing sight of the need to pass this bill this year. From the beginning I have worked in good faith with the Democrats on negotiating a bill that can pass the House, particularly considering the current dynamics of this Congress. I have

been clear since the start of my priorities and the confines we are working under. It is disappointing to me that the Democrats have recently decided to walk away from this conversation and force a one-year extension of PAHPA.

We are running out the clock debating issues that, while absolutely need to be addressed, have never been included before in this reauthorization. And I have made the unequivocal commitment to Ranking Member Eshoo to work on these issues.

We admittedly saw countless mistakes in the response to COVID. However, it is important to remember that without these key authorities and programs and the foresight of the previous champions of this bill -- Representatives Eshoo, Burr, Rodgers, Brooks, and others -- it terrifies me to think of what could have happened: no Operation Warp Speed, no public-private partnerships to rush test and therapeutics and PPE procurement and acquisition. This reauthorization is absolutely critical to prepare for the next disaster, as the chairwoman laid out very eloquently in her remarks.

I want to see this bill continue to move forward in a bipartisan manner, and I would ask my Democrat colleagues to

return to the table, and let's continue to negotiate in good faith.

I also want to say I appreciate -- I look forward to hearing from our witnesses, particularly Dr. Washington from Mecklenburg County, North Carolina, and Mr. Okon, who happens to be my constituent. Thank you all for being here today.

[The prepared statement of Mr. Hudson follows:]

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

*Mr. Hudson. And with that, I yield back.

*Mr. Guthrie. The gentlelady yields back?

*The Chair. I yield back.

*Mr. Guthrie. The chair now recognizes the ranking member of the full committee, Mr. Pallone, for five minutes for an opening statement.

*Mr. Pallone. Thank you, Mr. Chairman.

When COVID-19 hit, the Federal Government was not adequately prepared, and we have not done enough to prepare for the next threat. Unfortunately, the legislation the Republican majority has noticed for today continues to leave us vulnerable to future threats. It fails to make any significant new investments in our pandemic preparedness. It further politicizes public health by overriding the scientific decision-making of our public health agencies. And Republicans have refused to include any legislation at this hearing to strengthen the resilience of the supply chain.

Now, throughout the public health emergency, health care providers, states, and emergency responders faced supply shortages of ventilators, PPE, critical medication, and

testing supplies. And now we are seeing shortages of chemotherapy drugs that are threatening the path to recovery for so many patients battling cancer. Weeks ago, Democrats introduced five bills that would help us strengthen the supply chain, and none of these bills were included in today's hearing.

Ranking Member Eshoo introduced a bill that would bring transparency to drug manufacturing. The United States is over-reliant on foreign suppliers for critical drugs, and unfortunately, we don't even know how bad the problem is, or what -- or which drugs rely on foreign suppliers. And Ranking Member Eshoo's legislation would help the FDA understand the entirety of the drug supply chain, which would be beneficial if there is manufacturing -- or a manufacturing or quality issue that could lead to a shortage. FDA would then know what suppliers drug manufacturers are relying on, so that it could quickly address the problem.

When drug shortages happen, FDA can work with sponsors to extend the shelf life of the drugs available in the market to the latest possible date without losing drug quality, effectiveness, or safety. However, obtaining scientific

information from drug sponsors to support an expiration date change can sometimes take weeks or months. That is time patients may not have. The Ensuring Access to Lifesaving Drugs Act, introduced by Representative Slotkin, would streamline this process.

Additionally, we know that there are times when FDA is not even aware that a shortage of a product is coming. When there are unforeseen demand spikes, FDA has little insight into these issues until the problem is already impacting patients. Bipartisan legislation from Representative Jacobs and Mills would ensure manufacturers notify FDA when these demand spikes occur. Right now there is also no requirement in place for medical device manufacturers to notify FDA of supply problems. Representative Castor has introduced a bill to fix that.

We also requested that the Republican majority finally take on the glaring drug safety risk that exists when a dangerous or contaminated drug must be recalled. But FDA has no power to put -- to take it from the shelves. And this committee has worked to fix this problem before on a bipartisan basis, and it is time we finally get this done.

I honestly think that the Republican majority's refusal to include these bills at today's legislative hearing is irresponsible. You know, I have heard the arguments. Mr. Hudson said -- sort of suggested that the disarray on the floor makes this impossible for us to move ahead with a lot of things, or to do much at one time.

I don't want to put words in your mouth, but that is how I interpreted what you say. And, you know, I am sorry, but the Republican disarray on the floor should not be the basis for us not to act because, I don't know, at any given day -- I mean, we had four days pass without voting on anything. So what does that mean, I am just supposed to not introduce bills or try to act on anything because, you know, some people on the right are going to take down the Speaker?

I mean, we can't act on that. I mean, we can't proceed based on that. And PAHPA is a must-pass bill. So if we don't include legislation addressing drug shortages now, it is just not going to happen. There is not going to be enough time. So that is why we continue to insist that these bills dealing with the shortages be included.

Now, while the majority was not willing to include drug

and device policies, a few bills noticed for today's hearing would make strides toward improving our public health response.

A bill introduced by Representative Underwood would strengthen real-time, standardized data availability of emerging public health threats at the CDC. As Dr. Walensky and others have testified, during the COVID-19 and Mpox public health emergencies CDC was often left with incomplete, inconsistent, and out-of-date data that hindered our response. And this legislation would clarify their authorities, helping us to prepare for emerging threats going forward.

We are also considering my bill to remove the requirement that the Senate confirm the CDC director, a misguided change that the Senate insisted on, including in our omnibus package at the end of last year. When President Biden took office, it was important that he was able to immediately appoint a CDC director to lead the agency during the COVID pandemic. And it is critical to have an expert CDC director in place right away to respond to the public health threats with speed, focus, and foresight, and without

furthering the politicization of public health that has become too commonplace. And we all know that the Senate doesn't do anything quickly.

So, again, I have serious concerns about policies that would allow congressional interference in the termination of a public health emergency, new and unworkable requirements for CDC guidance, and industry decision-making of the PHEMCE. While it concerns me that the Republican majority doesn't seem to appreciate the full scope of the challenges we face, I hope we can find a way to move forward in a comprehensive, bipartisan way, because it is important that we come together to learn the lessons of COVID-19 and reauthorize PAHPA on time.

[The prepared statement of Mr. Pallone follows:]

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

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

*Mr. Guthrie. Thank you. The gentleman yields back. That concludes our opening statements, and we will now turn to the panel for five minutes for their opening statements.

I will introduce you all, then call on you one at a time.

You will notice the clock system. You have five minutes. It will be green. I think with a minute to go it turns yellow, and then that will kind of give you a hint that your time is approaching. And then, if it turns red, begin to wrap up. I appreciate your being here. And I will introduce all the witnesses first.

We are going to have -- before us today will be Dr. Gerald Parker, the associate dean for Global One Health and director of the Pandemic and Biosecurity Policy Program at Texas A&M University.

Next is Dr. Raynard Washington, director of the public health department in Mecklenburg County, North Carolina, as has already been noted by our favorite Tar Heel here today. And I mean that as a citizen of the state, not as a graduate.

[Laughter.]

*Mr. Guthrie. I know his college.

Our next witness is Ms. Phyllis Arthur, senior vice president of infection [sic], disease, and emerging science policy at Biotechnology Innovation Organization.

Our witness will follow with Dr. Julie Gralow, chief medical officer and executive vice president of the American Society of Clinical Oncology.

And then our final witness this morning will be Ted Okon, executive director of Community Oncology Alliance.

I will begin -- we will begin to recognize our first witness, Dr. Parker.

You are recognized for five minutes for an opening statement.

STATEMENT OF GERALD PARKER, DVM, PHD, ASSOCIATE DEAN FOR GLOBAL ONE HEALTH AND DIRECTOR FOR THE PANDEMIC AND BIOSECURITY POLICY PROGRAM, TEXAS A&M UNIVERSITY; RAYNARD WASHINGTON, PHD, MPH, DIRECTOR, PUBLIC HEALTH DEPARTMENT, MECKLENBURG, COUNTY HEALTH AND HUMAN SERVICES AGENCY MECKLENBURG COUNTY, NORTH CAROLINA; PHYLLIS ARTHUR, MBA, SENIOR VICE PRESIDENT, INFECTIOUS DISEASE AND EMERGING SCIENCE POLICY, BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO); JULIE R. GRALOW, MD, FACP, FASCO, CHIEF MEDICAL OFFICER AND EXECUTIVE VICE PRESIDENT, AMERICAN SOCIETY OF CLINICAL ONCOLOGY; AND TED OKON, MBA, EXECUTIVE DIRECTOR, COMMUNITY ONCOLOGY ALLIANCE

STATEMENT OF GERALD PARKER

*Dr. Parker. Well, thank you, Chairman Guthrie and Ranking Members -- Ranking Member Eshoo, for the opportunity to come before you today. I am Dr. Gerald Parker.

Today -- but today -- I am from Texas A&M University, but today the views and opinions I offer are my own, but are informed by serving in career executive leadership positions

in the military and the Federal Government. I appreciate the opportunity to come here today, because you are working on one of the most important bills in Congress this year: the reauthorization to PAHPA.

We live in a dangerous world. The threats we face range from terrorism, chemical, biological, radiological, nuclear, cyber, natural disasters, climate change, pandemics, and more that we do not even yet grasp their understanding. These are hard problems, and we must have the right tools to confront an ever-expanding list of potentially catastrophic threats, whether natural, accidental, or deliberate. And in this new, dangerous era of global power rivalry, we were -- conflict, economic conflict, war, and even the threat of an adversarial nation state's use of weapons of mass destruction cannot be discounted.

You have the opportunity to meet this moment. Don't waste it. The risk we face certainly won't wait for us to be prepared. Now, with that dire warning, I have four central recommendations for your consideration.

First, ASPR's relationships with state, local, tribal, and territorial, emergency response, hospital, health care,

and public health departments must be strengthened. Any successful response requires a close working relationship between the Federal Government and state and local partners who are on the front line.

Second, it will be critical for PAHPA to address the supply chain control tower capacity and concept by encouraging a warm-base and a surgical situational awareness supply chain and early warning capability that can be immediately activated when the next health security crisis starts. ASPR must be able to anticipate the needs of state and local partners, hospitals, and the health care system, and fulfill their requirements, especially when resources are scarce.

Third, the importance of leadership cannot be overstated. And when I say leadership, I mean an organizational structure authorized by Congress that empowers an individual with the ear of the President and the OMB director. Without an effective leadership structure that bridges the seams in the Federal bureaucracy, even the best of leaders will not be effective.

I commend Congress for taking a major step toward these

goals through authorization to the White House Office of Pandemic Preparedness and Response Policy. This is a good starting point, but should be expanded to include biodefense and global health security.

And to share a recommendation from a colleague of mine, Dr. Ken Bernard, this office should be led by a full-time equivalent of a combatant commander, a deputy assistant to the President for biosecurity at the White House to lead and prepare to battle our next national security health crisis.

Fourth, in regard to ASPR, I would like to direct the committee's attention to the 12 findings and recommendations in the National Science Advisory Board for Biosecurity's 2023 report regarding dual-use research concern and enhanced potential pandemic research. We need to take a more active approach to harmonize biosafety and biosecurity standards worldwide and keeping sound practices at home. Other countries look to us, and Congress and the Administration have an opportunity to lead.

In conclusion, we can not only prepare for risks like SARS-CoV-2; we must prepare for advanced dual-use technologies and emerging infectious diseases with properties

that could make existing preparedness efforts useless if they are based on only our latest response to the latest pandemic.

As the Office of the Director of National Intelligence 2023 Annual Threat Assessment plainly states, "Rapid advances in dual-use technology, including bioinformatics, synthetic biology, nanotechnology, and genomic editing could enable the development of novel biological weapons that complicate detection, attribution, and treatment.'' And I will add the likelihood of misuse or accidents are increasing, as laboratories expand worldwide with ready access to dual-use technologies, and without adequate international standards.

We have entered an extremely dangerous era. There is one thing we can be assured of in the future: We will be surprised. We must avoid fighting the last war, and we must avoid complacency.

Thank you for the opportunity to be appear before the committee. I would be glad to answer any of your questions. Thank you.

[The prepared statement of Dr. Parker follows:]

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

*Mr. Guthrie. Thank you, Dr. Parker. I appreciate your testimony.

Dr. Washington, you are now recognized for five minutes for an opening statement.

STATEMENT OF RAYNARD WASHINGTON

*Dr. Washington. Perfect. Good morning. Thank you, Chairman Guthrie, Ranking Member Eshoo, and members of the Health Subcommittee. Thank you for having me today to discuss the reauthorization of PAHPA. I am Doctor Raynard Washington, the public health director in Mecklenburg County, which serves the City of Charlotte and the surrounding county in the great State of North Carolina.

I also have the pleasure of serving as vice chair of the Big Cities Health Coalition, an organization of health officials who lead 35 of the nation's largest metropolitan health departments. Together we serve more than 61 million Americans and nearly 20 percent of the country.

I am an epidemiologist by training, and bring with me more than 15 years of experience in public health at both the Federal and local levels. Prior to Charlotte, I served as the health -- deputy health commissioner and chief epidemiologist for the City of Philadelphia.

My health department is responsible for protecting and promoting health for more than 1.1 million North Carolinians

and our diverse and rapidly growing community, and our health department team has grown to close to 900 over the last few years.

Local public health departments are on the front lines of preparing for, responding to, and supporting residents during emergencies. There are very few, if any, emergencies that don't have some impact on the public's health. And maintaining coordinated networks and preparing partners on the ground for emergencies before they happen is the only way we can respond quickly. This is a very unique role of local public health.

Just last week there was an acute public health response to the Canadian fire smoke traveling across this region. Public health departments at the state and local level were able to respond because of the work they had put into maintaining a true, all-hazards response, which is critical to our nation's health.

As we see the resurgence of infectious diseases like measles and polio in pockets across the country, it is clear that all-hazards preparedness must be at the forefront of our nation's public health system. And as we move out of the

COVID-19 pandemic, it is a timely opportunity to take steps to improve the system using what we have learned over the last few years. To that end, I firmly believe that the reauthorization of PAHPA is a critical component for preparing for the next emergency in this country.

It is essential that Federal agencies have clear preparedness and response roles well in advance of an emergency. At the same time, while Federal leadership and resources are vital, a top-down approach to public health is simply not sufficient. To truly function as a system, public health leaders must be involved at every level of government -- local, state, and Federal -- and information, data, and resources must flow quickly and efficiently to and from each of those levels. Unless and until that happens, we will remain under-prepared for the health and health security challenges we face.

A few highlights on various PAHPA components.

First, the public health preparedness program that was created after 9/11 to support preparedness infrastructure is critical to having a response-ready workforce at the local level. However, despite the increase in emerging and

reemerging infectious diseases, it has been cut by nearly 30 percent over the last 20 years.

In Mecklenburg, we have had to increase our public health preparedness staff from one FTE to three since the start of the pandemic to meet our needs. These vital human resources, which may sound small, allow us to train clinical and non-clinical staff, and maintain and implement when necessary local response plans for every type of hazard.

Likewise, the Hospital Preparedness Program, which has also been cut by more than half over the last 20 years, prepares the nation's health care system to save lives during emergencies and disasters. HPP supports regional health care coalitions like the Metrolina Healthcare Preparedness Coalition in our region in North Carolina. They are responsible for assessing risk and needs, providing training, and maintaining preparedness among organizations who might otherwise see themselves as competitors. Or, for example, like during the pandemic, deploying mobile hospitals due to the crushing demand on acute care facilities.

Additionally, now is the time to authorize an adult vaccine program akin to the Vaccines for Children program.

As we learned from the pandemic, a comprehensive vaccine infrastructure is needed to protect Americans against both known and emerging infectious disease. During the Mpox response we received no Federal support at the local level for vaccine administration, but our department successfully, like others, mobilized partnerships with LGBT+ community and social organizations to contain the situation.

On the other hand, our progress during COVID was only possible because vaccine cost was not a barrier for our residents.

Finally, and most importantly, as an epidemiologist it is critical that we have timely, accurate, and actionable data at the local, state, and Federal level. Our systems for early detection and surveillance need upgrading and modernizing. CDC must have -- collaborate with other HHS divisions and partners across all levels of government to strengthen our public health data systems with better technologies and leveraging both the private-sector knowledge and expertise.

From the perspective of local health departments, CDC absolutely must have the authority to effectively collect and

coordinate public health data necessary to serve its mission. We are collectively tasked to make million, billion, and even trillion-dollar decisions with the current framework for collecting and sharing public health data that results in fragmented and inconsistent reporting to CDC and to the state and local agencies. Expanded data authority for CDC will allow for more complete and timely data sharing to support decision-making at the Federal, state, and local levels.

In closing, I want to emphasize that a well-functioning public health system is a -- is pandemic preparedness, and must be well-resourced at all levels of government before, during, and after emergencies. Diseases and disasters don't recognize city, county, or state boundaries, and across the nation each community is only as prepared as its weakest neighboring community.

Thank you.

[The prepared statement of Dr. Washington follows:]

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

*Mr. Guthrie. Thank you, Dr. Washington, thank you for your testimony.

Ms. Arthur, you are now recognized for five minutes for an opening statement.

STATEMENT OF PHYLLIS ARTHUR

*Ms. Arthur. Thank you. Chairman Guthrie, Ranking Member Eshoo, and members of the subcommittee, thank you so much for inviting me to testify today. My name again is Phyllis Arthur. I am the senior vice president for infectious diseases and emerging science policy at BIO, the Biotechnology Innovation Organization.

This is an important moment for our nation as we emerge from a multi-year global pandemic. We have an opportunity to use what we have learned to ensure we are better prepared in the future. While we hope that the COVID pandemic is a once-in-a-generation occurrence, that is not certain. Over the past decade we have faced near-miss pandemics, from SARS to Zika to avian flu.

While our response to the pandemic was incredible in scale and successful in its aims to rapidly and safely develop vaccines and therapeutics for a novel pathogen, there is no guarantee that we could replicate that success again without making permanent the pieces of the response that led to that success. In fact, during the pandemic we had to

respond to monkeypox, Ebola, and Marburg outbreaks, and provide support to our allies for chem, bio, rad, and nuke threats.

Now is not the time to rest. Now is the time to improve our systems and commit to public-private partnerships that will continuously usher in innovation that can help keep us safe. It is not only critical that we reauthorize PAHPA, but that we strengthen the law, as well.

Following the terror attacks of September 11th, our government acted swiftly and comprehensively to protect our citizens. Similarly, following the 2001 anthrax attacks, Congress acted to create Project BioShield and, later, BARDA, which are foundational to our protection from biological threats. These laws built the important structural and financial changes needed to develop medical countermeasures for an expanding set of natural, accidental, and deliberate threats.

However, BARDA and the Strategic National Stockpile remain under-funded, and our surveillance tools are under-developed. To better respond to the next inevitable threat, we must use the PAHPA reauthorization action to make

substantive improvements in the PHEMCE.

First, BIO strongly recommends that Congress increase funding for key ASPR programs to the levels of the PHEMCE multi-year budget. The BARDA Advanced Research and Development, the Project BioShield Special Reserve Fund, and the Strategic National Stockpile should all be authorized at over $1.5 billion each to ensure that there are ample funds for the development, procurement, lifecycle management, and manufacturing support for a broad array of medical countermeasures.

Separate funding of at least $330 million is needed to support continued development and sustainment of pandemic influenza vaccines, antivirals, and diagnostics, as pandemic flu remains one of our most persistent global threats.

Lastly, BIO recommends that funding be allocated to BARDA to enable a pathogen-agnostic viral family approach to R&D and manufacturing. This approach will help us better prepare for a broad set of emerging pathogens of pandemic potential by leveraging novel platform technologies and novel mechanisms for new vaccines, monoclonal antibodies, and oral antivirals.

Second, BIO recommends several policies that will help incentivize industry and strengthen the partnership between the government and developers. We recommend increasing the transparency of the SNS by encouraging the sharing of MCM requirements. This should be done with private-sector partners on a regular basis.

We also strongly recommend that Congress eliminate the sunset of the MCM Priority Review Voucher Program, as this program is an important incentive for the development of novel MCMs.

And lastly, we strongly encourage the inclusion of the PASTEUR Act to spur the development of much-needed novel antimicrobials.

Third, BIO recommends that ASPR be granted new authorities that expand their use of the other transactions authority, that they have authorities to enable domestic manufacturing investment, and allow for rapid procurement and acquisition.

Fourth, given the vital role of a strong public health infrastructure to our national response, BIO recommends increased funding for surveillance capabilities at the CDC to

better detect, monitor, and respond to outbreaks and emerging pathogens around the world.

We also support funding CDC's ability to partner with states to expand and strengthen state immunization infrastructure, especially for adult immunization.

In reauthorizing PAHPA, Congress must continue to send a strong signal that it is committed to prioritizing national health security by providing the resources and authorities needed to fully prepare for and defend against biological threats. Investments in preparedness and medical countermeasure development will enhance our response efforts, save lives, and be more cost effective to our economy in an emergency.

Thank you.

[The prepared statement of Ms. Arthur follows:]

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

*Mr. Guthrie. Thank you, I appreciate it, Ms. Arthur, your testimony.

The Chair now recognizes Dr. Gralow for five minutes for your opening statement.

STATEMENT OF JULIE R. GRALOW

*Dr. Gralow. Chairman Guthrie, Ranking Member Eshoo, and members of the subcommittee, thank you for the opportunity to discuss the Pandemic and All-Hazards Preparedness Act and its potential to help address the cancer drug shortages crisis.

I am Dr. Julie Gralow, chief medical officer and executive vice president of the Association for Clinical Oncology. Prior to joining ASCO I was a practicing medical oncologist and professor in Washington State for three decades.

ASCO represents over 45,000 oncology professionals who are dedicated to improving cancer care. We appreciate the subcommittee's efforts to improve the programs in PAHPA to better prepare the U.S. for future public health crises.

The pandemic exacerbated longstanding issues that threaten the resilience of our health care supply chain. While the Strategic National Stockpile and other programs authorized under PAHPA aided the health care community during the public health emergency, more must be done. Drug

shortages will worsen without intervention. This is especially true for sterile injectables, many of which are oncology drugs.

These drugs are expensive to make, they have a low profit margin, and they lead manufacturers to reduce or discontinue production. Active Pharmaceutical Ingredient sourcing is a weak point. Many manufacturers use the same API source. If that source experiences quality issues causing a production shutdown, or runs out of critical components, drug shortages are a likely outcome.

Visibility into the supply chain regarding APIs is lacking. The FDA does not have authority to require manufacturers to provide API sourcing information. This means shortages can emerge without warning. Today's shortages are the worst that I have seen in my 30-year career.

I am in regular communication with colleagues at the University of Washington and Fred Hutchinson Cancer Research Center in Seattle. Initially, they were optimistic that, with dose modifications and substitutions, they had enough supply of these platinum agents to ride the shortage out.

Then, however, many of the state's smaller cancer centers began running out of the drug and sending their patients to the UW, depleting their supply.

I spoke to a patient diagnosed with endometrial cancer, whose team recommended a chemotherapy course that included a platinum agent. She studied the drugs and their side effects. She had a game plan, and she did well through her first cycle of treatment, much to her relief. Then, when arriving for her second dose, one of the agents was no longer available. You can imagine the anxiety this caused. Even when there are acceptable and proven alternatives, switching a planned course of treatment adds fear and stress to that already caused by a cancer diagnosis.

Eleven oncology drugs, maybe fourteen, are currently in shortage. Four of these -- cisplatin, carboplatin, methotrexate, and fludarabine -- are commonly used to treat cancer in adults and children. In 2022, 100,000 Americans were diagnosed with ovarian, bladder, and testicular cancers, cancers for which cisplatin and carboplatin are recommended. These drugs are also commonly used in cervical, endometrial, lung, head and neck, esophageal, gastric, and breast cancers.

The number of U.S. patients at risk could be as high as 500,000 a year.

Drug shortage risks also extend to pediatric patients. From 2010 to 2020, 8 of the 10 most frequently-used drugs to treat acute lymphoblastic leukemia, the most common childhood cancer, were at some point unavailable.

Beyond drugs, we have experienced essential supply shortages, including glass vials, IV tubing, saline bags, and more. Shortages place providers in a moral dilemma, prioritizing drug use for patients who are curable versus those who are not. Patients worry about whether they will receive their next treatment, or if switching to another treatment will shorten their lives.

The PAHPA reauthorization is an opportunity to advance solutions to improve the supply chain, especially during public health crises. ASCO makes the following recommendations detailed in my written statement: improve the function and composition of the National Strategic Stockpile; enhance multi-national collaboration on supply chain resilience; incentivize manufacturers to improve quality and transparency; reduce reliance on other countries

for critical ingredients; analyze domestic drug and device manufacturing capability and capacity for critical products to avert national security threats.

I appreciate the subcommittee's efforts to enhance the supply chain to protect our national security and our patients' health. ASCO stands ready to collaborate with you to ensure individuals with cancer receive the lifesaving and life-prolonging treatments they require. This is a crisis. Cancer patients' lives are on the line.

Thank you.

[The prepared statement of Dr. Gralow follows:]

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

*Mr. Guthrie. Thank you, Dr. Gralow. I appreciate your testimony.

We now -- the chair now recognizes Mr. Okon for five minutes for an opening statement.

STATEMENT OF TED OKON

*Mr. Okon. Chairman Guthrie, Ranking Member Eshoo, and members of the Energy and Commerce Health Subcommittee, I am the executive director of the Community Oncology Alliance, a non-profit organization dedicated to cancer patients and their independent oncology providers.

My wife, Susan, practiced as an oncology nurse for 10 years, and we have family and friends with cancer living with it and dying from the disease. I want to make it very clear that my over-riding goal is to ensure that every American with cancer, regardless of demographic, financial, or any other status has access to the highest quality, most affordable cancer care close to home.

Let me get right to the point. There is a growing crisis of a severe shortage of low-cost generic drugs used to treat cancer, including carboplatinum, cisplatin, and Efu. Although decades old, these are mainstay treatments for many types of cancers, including curable cancers. As a result of these drug shortages, Americans with cancer are facing treatment delays, potentially receiving inferior treatments,

and even having their treatments stopped. What is heartbreaking is that Americans with potentially curable cancers may miss treatments and even a cure because of these shortages.

Our inaction in fundamentally solving the cancer drug shortage problem, which has existed for years but is now the most severe we have ever faced, has already likely signed a death sentence for some Americans. Frustration and outright anger do not begin to describe how I feel in reading heartbreak stories of patients with cancer not being able to receive treatment due to shortages of decades-old, low-cost generic drugs.

I testified to Congress 12 years ago, nearly 12 years ago, of the then-cancer-drug shortage. I said then, and I repeat today, "The fundamental root cause of cancer drug shortages is financial.''

Unfortunately, recent solutions deal with symptoms of the problem, but none address the underlying financial cause of shortages. Imagine being very diligent about staying out of the sun and getting regular skin checkups. If you had a suspicious looking mole, had it biopsied, and found that you

had melanoma, you would not be in denial and simply put a Band-Aid on it. You would have the underlying cancer treated.

The problem is that many of the solutions being advanced is that they involve tracking early warning signs of shortages and placing even more regulations on generic drug manufacturers, which can actually have unintended consequences of exacerbating the problem. At best, these are mere Band-Aids.

Denial of the financial cause of these shortages is once again costing Americans hope, and even lives. Understanding the underlying problem does not require a Ph.D. in economics. If a generic drug manufacturer cannot make a profit on a drug, it will simply stop making the drug. If a manufacturer makes a small margin on the drug, it will cut manufacturing costs, which makes it more prone to the types of problems that result in FDA inspections shutting down plants. Unfortunately, given that many of the drugs in short supply are money losers, we have seen more manufacturers leave the market. Today, not only is there no manufacturing redundancy at the manufacturing level, but there is little or no

redundancy in the market as a whole.

These cancer drugs are injectables administered intravenously or by similar means. These are not pills or tablets. The manufacturing involved in producing sterile injectable drugs is far more involved and exacting, as well as capital intensive than making pills or tablets.

As I explained in my written testimony, the fundamental financial problems for generic drug manufacturers are the Medicare Part B drug reimbursement system based on average sales price, which is also used by commercial payers, caps drug prices.

Additionally, mandatory 340B drug pricing discounts and Medicaid rebates erode drug prices, and the Inflation Reduction Act price inflation caps further put downward pressure on injectable generic drug prices. These products are, at best, so unprofitable that there is little to no margin to invest in manufacturing upgrades. At worst, there is little manufacturing redundancy as manufacturers leave the market.

We need to face the reality that price caps, discounts, rebates, and regulation need to be stripped from the market,

or shortages will worsen. Congress needs to stop Band-Aiding the problem and fix the fundamental financial problem, as well as bring manufacturing back to the United States.

The stories I am hearing from oncologists about these shortages are beyond heartbreaking. We owe it to the 32-year-old mother with aggressive breast cancer and her 3 children to get her the treatment she needs now, but is blocked from because of these shortages.

It is tough enough dealing with cancer. Americans should not lose hope or, worse, their lives fighting this terrible disease. We all need to work together to fix the fundamental financial cause of drug shortages. Every American with cancer is counting on us.

Thank you for the opportunity to testify, and I welcome your questions.

[The prepared statement of Mr. Okon follows:]

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

*Mr. Guthrie. Thank you, Mr. Okon, for your testimony.

That completes witnesses' opening statements, and we will begin the questioning period for a five-minute round of -- five minutes for questions. And I will recognize myself for five minutes.

So, Ms. Arthur, would you talk about how important the impact of Operation Warp Speed was at the beginning of COVID?

And what do you believe is the correct role for the private sector to play in our nation's preparedness and response?

And do you believe the proposed PHEMCE Advisory Committee Act will help us address gaps in our preparation for and response to -- future responses?

*Ms. Arthur. Thank you, Chairman Guthrie, for that question.

Operation Warp Speed was actually an excellent example of what we would like to see happen with the law in PAHPA. The work that was done between the Federal Government and industry partners was exceptional. Government actually drove the activities of industry in a collaborative way. We were partners; we weren't vendors.

We actually worked very closely with the FDA, with the CDC, with Operation Warp Speed leadership in DoD and ASPR, and actually came up with the strategy for driving very increased scalability of manufacturing. Clinical trial guidance from the FDA actually helped us deliver safe vaccines that had diversity in the clinical trials that allowed us to tell people they were getting something safe in record time, and that led to vaccines being available in 300 days. This is incredible.

So that kind of partnership, where the expertise and experience of industry for manufacturing, clinical trial development, knowing how to manufacture products well was really coupled well with the government's leadership in facilitating that process. And this is the kind of partnership that we need in the interpandemic period, so that we are actually ready to go in less time than one year, with the next time we have to respond to a pandemic. Operation Warp Speed is a really good example of that.

*Mr. Guthrie. Okay. Thank you, thank you for that. I want to move on to Dr. Parker.

The Government Accountability Office reported that the

CDC never established contracts with private-sector vendors to quickly roll out a testing regime, and that left us hamstrung.

I have legislation before us today. How do you believe the -- so the legislation before us today -- clinical labs' ability to enter into certain contracts and cooperative agreements. So how do you believe this legislation will help us more effectively respond to future threats?

*Dr. Parker. Well, I think, actually, it is in line with what Phyllis just said about the public-private partnerships and involving private industry the sooner the better. And so I think we need to do the same thing in our diagnostic world and our diagnostic enterprise.

We cannot just rely on our Federal Government or state government public health laboratories to take care of the whole job, and so we need to have our private-sector engagement in these laboratory and diagnostics from the start.

And it is most important -- also, it is in the interepidemic period that we need to do this. We cannot wait until there is a crisis to do this. So I support the effort

to try to get the private sector engaged during the interepidemic period in these efforts.

*Mr. Guthrie. Okay, thanks. I have been concerned about -- Dr. Parker, this for you, as well -- I have been concerned about just the executive authority declaring emergencies, and having kind of unlimited time moving forward. Some states -- I know my home state went in and put a limit on what the governor could do. We had emergencies, and so we can't just govern by fiat. And we had an emergency with record flooding in Appalachia, we called the General Assembly together. Instead of one person choosing to spend hundreds of millions of dollars, they came together as a group and said -- and rose to the occasion.

You know, some people want to dismiss Congress and just turn everything over to the experts. We know the experts got a lot wrong. They got a lot right and they got a lot wrong that is going to have a lasting impact. And I do believe that the legislative authority shouldn't just be dismissed and say, well, let's just turn it over because it is too difficult to bring everybody together. Well, that is what our founding fathers wanted to do.

So one of my bills would allow Congress to vote to extend the public health emergency for six months after it has been declared. Would you talk about the role for Congress in this, and what you see in that bill?

*Dr. Parker. Yes. Well, certainly, maybe I am not a constitutional expert, but certainly there is a definite role for all three branches of government, including congressional oversight. It is absolutely essential. And I would say, actually, there is a role for investigative journalism, as well, to keep us all honest, too, in the -- and I am talking as a former government employee.

But I think maybe one thing that perhaps may have been lacking that -- I think back to the H5N1 influenza preparedness days between 2006 and 2009 -- there were kind of like clear triggers and metrics of the phases of the pandemic that -- I think we kind of lost that, you know, before COVID-19. And I think maybe one way to exercise the congressional oversight is to make sure our pandemic plans and strategies have clear triggers and metrics of, one, when a crisis and a public health emergency should be declared, and then what are the clear metrics and triggers of when it

ends, when the public health emergency declaration ends. So I think that would help a lot.

You know, I probably should stay out of the political thing and that.

*Mr. Guthrie. Okay, thanks.

*Dr. Parker. But I think -- but certainly, there is a place for congressional oversight, and I think our plans ought to have clear triggers and metrics of when it starts and when it ends.

*Mr. Guthrie. Well, thank you. I appreciate that. And my time has expired, so I will yield back, and the chair now recognizes the Ranking Member Eshoo for five minutes for questions.

*Ms. Eshoo. Thank you, Mr. Chairman, and thank you to each one of the witnesses.

To Dr. Gralow, on drug origin transparency, information on the supply chain for prescription drug products in New Zealand -- I am really fascinated by this -- is publicly disclosed and transparent.

New Zealand collects and makes public the name and location of the API and the finished drug manufacturers. The

data on the New Zealand Medsafe Public Access website can be analyzed to quickly determine which ones have the highest dependance on a certain geographic location, such as Wuhan, China. Within hours of the news of a plant closure, New Zealand could know which drug products will be affected, and can look for other producers of the same drug to supplement the country's drug supply.

How would your ability to treat your patients be impacted if the United States adopted a similar transparency policy where the FDA, hospitals, doctors, public policy analysts could monitor the U.S. upstream pharmaceutical supply chain to identify potential trigger points that could lead to supply chain vulnerability and to predict drug products that may face shortages?

*Dr. Gralow. Thank you for that question. I think that level of transparency to all, the ability to know where manufacturers are getting their raw materials from for everyone to know would give us much more lead time when a problem exists. We would have much more time to be able to ramp up again, to look for alternative sources, to start to look toward importation -- the expanded shelf life, for

example. It just would give us a much bigger time period to adjust and, hopefully, avert a crisis in that setting.

*Ms. Eshoo. Right.

*Dr. Gralow. We don't have that kind of information available at the raw materials level, the API level.

*Ms. Eshoo. Right. About achieving a stable supply of oncology drugs, in your testimony you propose the government contract with manufacturers to create a buffer stock to achieve a short-term supply of oncology drugs. Can you speak to how that buffer stock would help address the acute shortages we are seeing now in oncology drugs?

*Dr. Gralow. Having, for example, a six month supply -- whatever we would agree to -- on board, whether it is at the manufacturer level or the government or the buyer level, that constantly rotates -- it would have to keep rotating because these agents have short half-lives. Having six months would, again, give us much more time to ramp up and deal with the shortage.

So on the one hand, having greater visibility when the problem first occurs, and then on the other hand having at least six months to gear up again would be a great help, and

likely avert many of these crises.

*Ms. Eshoo. Well, I appreciate each one of the testimony of each one of the witnesses.

I have never extracted my authorship or support before. This is major, major legislation. But colleagues, this is affecting -- this drug shortage supply is affecting every single one of our congressional districts. This is not a Democratic idea. This is a national need, and it is a national crisis. This is, as Mr. Hudson said -- and I have loved working with him -- this is a must-pass bill, PAHPA is.

I think addressing these shortages -- I mean, it is just jaw-dropping to me when you say a shortage of pediatric oncology drugs. We can do this. I just -- it is -- it really is a must.

So thank you again to the witnesses.

I will work with anyone on this committee to get this over the finish line. I am not suggesting that we have a section relative to the FDA in this legislation that is larger than the rest of the PAHPA legislation. But this is a crisis that needs to be addressed, and we need to answer to all of our constituents on it.

And with that, I yield back the balance of my time.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair now recognizes Chair Rodgers for five minutes for questions.

*The Chair. Thank you, Mr. Chairman.

[Audio malfunction.]

*The Chair. -- and we will continue to work with you on that. I think it is a question of what is in this bill before us today, and how we go about doing it. So we will keep those conversations going.

Dr. Parker, during your time as principal deputy assistant secretary for preparedness and response, can you explain your interaction with the National Council Advisory Committee on Individuals with Disabilities and Disasters, or any of the other national advisory committees?

*Dr. Parker. Sure, and I -- actually, I think my experience when I was the ASPR -- and before ASPR was formed, in the Office of Public Health Emergency Preparedness, was actually during Hurricane Katrina, Rita, Wilma, and that may have preceded the actual establishment of the NAC Advisory Committee.

But the experience of Hurricane Katrina certainly formed our need of how we better take care of special needs, special medical needs population, and it was just really a horrible situation in New Orleans when pre-storm, post-storm, local authorities really didn't know where some of these special needs people lived, and how do we evacuate those that need to be taken and taken care of that just need special help. And so I think that really helped to form why we need outside advisory bodies that have the expertise to -- that maybe those in government do not, and to help us, you know, think about whether -- new policies and programs that we need to do that.

So in general, from my perspective, having outside Federal advisory boards was always very beneficial to me when I was in government. And since I have been out of government, I have served on several advisory boards, and I know the people who were asked to serve on advisory boards very much like the opportunity to be able to share their expertise with the Federal Government.

One cautionary note I would say, though, as you consider any kind of further legislation, it is important how the

executive branch uses advisory boards. And I have seen examples of some advisory boards being taken very seriously, and run very well, where there is clear findings and recommendations, and the government acts on them.

*The Chair. Thank you.

*Dr. Parker. So it is just how --

*The Chair. Yes, thank you. I appreciate those insights, and I am pleased -- I have some other questions I want to get to, but I am really pleased that, in Congressman Richard Hudson's draft, there is several changes to better incorporate non-Federal expert stakeholder input and perspectives, and it includes people with disabilities, as well as health care professionals with expertise.

This question is for Dr. Parker and Ms. Arthur. You know, as I mentioned in my opening statement, our goal is to ensure America is prepared for everything, from a hurricane to a cyber attack to a chemical attack by an adversary. And it is critical that we take an all-hazards approach as we consider this reauthorization. Would you speak briefly as to what if these authorizations were allowed to lapse?

*Ms. Arthur. Thank you, Chair Rodgers, for that

question.

I think three really important things would happen if we do not pass PAHPA. We will not be better prepared. We will not have the incentives that we need to make medical countermeasures for the next inevitable pandemic. I think it is really, really important to note that we will not -- we will lose some of the incentives that would be reauthorized. And literally, we will miss an opportunity to really instill the lessons we learned from COVID into our better laws.

*The Chair. Okay, thank you. Actually, I am going to move on because I want to get to Mr. Okon, too, and give him a chance to talk a little bit about the drug shortages, because this is not a new issue, and I know that it is worse now than from the last time you testified over 10 years ago.

Your testimony indicates that the economics of the sterile, generic drug market is at the heart of this issue. And I just wanted to ask if you would speak some more to that issue, and how we can help patients afford health care, while making sure that companies invest in manufacturing and get this back into the United States.

*Mr. Okon. Well, I will read you a quote from the FDA

Commissioner, Chair Rodgers, who testified in front of Energy and Commerce last month: "If I offered you the chance to produce a drug, and guaranteed you would lose money on every pill you made, it is unlikely you would go into that business, and you might also skimp on your quality systems and manufacturing, which then leads, when we do inspections, to find problems.''

I am not saying that some of the solutions advanced in terms of early warning and signs and things like that aren't important to know. But I believe very strongly -- and 11 years ago, Scott Gottlieb, Dr. Scott Gottlieb, who testified next to me, we didn't know each other -- came to the same conclusions. If you listen to Dr. Gottlieb on different news shows lately, he is saying the same thing: the root cause of this is financial.

*The Chair. Thank you.

*Mr. Okon. And we need to we need to bring manufacturing back to the United States.

*The Chair. More to come, for sure, but I just want to end by saying that I am troubled that less than half of the FDA-registered facilities are complying with existing

requirements to report the volume of what is made in each facility. Companies need to be complying with current law, and FDA needs to be enforcing before we consider new requirements and authorities.

I yield back.

*Mr. Guthrie. Thank you. The chair yields back. The chair now recognizes the ranking member of the full committee for five minutes for questions.

*Mr. Pallone. Thank you, Mr. Chairman, and I just want to repeat that I do not agree with my Republican colleagues that PAHPA reauthorization legislation isn't the place to address our vulnerable supply chain. And unfortunately, they have instead focused on this partisan request for information process that I think kicks the can down the road and refuses to address the challenges with any urgency. Unfortunately, they don't seem to appreciate the security threat that is posed by having a constant rotation of critical drugs and medical devices in short supply.

So, Dr. Gralow, quickly, because I have other questions, can you explain why the American Society of Clinical Oncology views drug shortages as a matter of national security, and

why we should address it through the PAHPA reauthorization?

*Dr. Gralow. We have viewed this as a matter of national security for years and years now, actually had a summit with all stakeholders back in 2018, where we called this a matter of national security. Not having the drugs we need available to our patients, to the American public, is a matter of national security.

*Mr. Pallone. And did the drug shortage get worse during the COVID-19 pandemic?

And how did that affect patient care? Again, quickly, if you could.

*Dr. Gralow. There are some very specific drugs that were made worse during the pandemic, not to the degree that we have right now with these two drugs, cisplatin and carboplatin. But the pandemic disrupted supply chains, et cetera, and we were very vulnerable. It is actually amazing we didn't do worse with many of our drugs, getting them into our country during the pandemic.

*Mr. Pallone. Well, thank you.

You know, I have to say, Mr. Okon, I am not going to ask you a question, but it just seems like you just, you know,

blame everything in this drug shortage on financial problems that the drug companies face. And, you know, at one point you said that, you know, they are not making enough money, they -- you know, we shouldn't have price caps, we shouldn't have rebates.

You know, if the suggestion here -- maybe it is not -- is that we should just give them all the money they need, and we should just keep paying them more and more, I mean, I just categorically reject that.

And keep in mind, I mean, you said that this is a financial problem, and I agree it is, but it is not a financial problem for the drug companies, it is a financial problem for the people who can't afford the drugs. And if -- the fact of the matter is, if drugs are not affordable, people aren't going to have access to them, and they are not going to be able to do -- to have that medication.

So, you know, it is -- and I know you didn't say this, but it does bother me that in the last week now we have had two companies -- one, Merck, which is actually very close to my district, and then the Chamber of Commerce -- sue over the IRA provision that provides for negotiated prices. It just

seems like there is this constant effort by drug companies and their supporters -- the Chamber of Commerce and others -- to simply say that there shouldn't be any restrictions, no rebates, no caps, no negotiated prices. And I just categorically reject that, because if we don't do those things, then these drugs are not going to be affordable to the people. It is very nice to say the drug companies need more money, but as they continue to raise their prices, people just can't afford the drugs and they go without.

But in any case, I probably took up too much time. But I just wanted to say that I think it is -- well, let me just say that, even with their current authorities, FDA has reported that in 2021 the agency worked with manufacturers to prevent more than 300 shortages. But the agency recognizes they can do more if processes were streamlined and the agency could access better information.

So let me just ask you, Dr. Gralow, do you think it is overly burdensome to ask drug manufacturers to report, disclose the foreign suppliers they rely on to make their drugs, or to require drug manufacturers to notify the agency if there is an unexpected uptick in demand that could lead to

a shortage?

*Dr. Gralow. No, I don't think that is overly burdensome. I think it is critical. I think we need transparency, and we need to know whether we have redundancy in where we get the raw ingredients from. We know we have four or five manufacturers of a drug, but if they all get it from the same basic place, and that one plant goes down, we don't know that. We need that transparency, and that is not overly burdensome to know that.

*Mr. Pallone. And thank you. And, you know, I would just tell -- say to our Republican leadership on the committee we came together on price transparency provisions a couple of weeks ago dealing with hospitals, dealing with PBMs, dealing with so many things. I don't think it is -- that asking to deal with the transparency in this case is really any different, and should be something that is done now.

But thank you, and I yield back.

*Mr. Guthrie. The ranking member yields back. The chair now recognizes Mr. Burgess for five minutes for questions.

*Mr. Burgess. Thank you so much to get to -- and I will probably run out of time, so I will just warn you in advance I will be submitting significant questions for written responses.

You know, as I sit here and listen to this discussion -- and I get some deja vu -- in 2017 and 2018 we actually worked on the Pandemic All-Hazard Preparedness Act. Because of a hold by a Senator who will be -- remain nameless, it didn't actually pass that Congress, it passed immediately in the next Congress. It was signed into law. And then six months later, we have the pandemic, and this committee never did an implementation hearing of the last version of the Pandemic All-Hazard Preparedness Act. So I certainly welcome this discussion today. It is long overdue. Heaven help us if we don't learn some of the lessons from last time.

Dr. Parker, thank you for being here today. As always, you provide very insightful testimony. I noted in your written testimony you talked about the appropriation that was made -- I think it was the Department of Defense appropriation in 2005 -- to provide the migration from egg-based flu vaccine to cell-based flu vaccine. I am still

waiting. I appreciate your work on that, but it has -- that has been slow in development. But it just underscores how important these issues are, and why we need to focus on them, and we can't let them out of our sight.

Now, one of the bills that we have got in front of us, the so-called Disease X bill, providing some countermeasures for emerging viral pathogens and viral families, how would this authority have affected our ability to respond during this last coronavirus pandemic?

*Dr. Parker. Well, I think, had we had Disease X five years before the pandemic, we would have been better prepared. You know, nonetheless, Operation Warp Speed was -- I think history will show -- it was a tremendous success. But having the ability to think about being -- we will be surprised in the future, and that is why we need Disease X authorization appropriations. That is the bottom line.

*Mr. Burgess. Yes, I -- the thing that keeps me up at night is I don't know how many emergency use authorizations it took from the FDA to keep us alive in the last pandemic. If we need, what, 250 relaxations of the regulations in order to not die during a pandemic, maybe we ought to emulate the

Operation Warp Speed model that you continually address. And I couldn't agree more with you about that.

On the pandemic itself -- and staying with you, Dr. Parker -- the -- one of the problems in lack of preparedness was diagnostic testing. Are we in a position to do better if something happens in the future?

*Dr. Parker. Well, that is a good question. Thank you. And I don't have the confidence to say we would do better. I think I think the community, the diagnostic community, is -- certainly those lessons observed are fresh on everybody's mind, so we probably will. But I think anything you can do in the PAHPA reauthorizations to more guarantee that we will do better, and engage the private sector very early in the diagnostics -- but, you know, before we have a crisis -- will help us.

*Mr. Burgess. It is just hard to prepare for that when the CDC's test absolutely failed first crack out of the box, and we really weren't given any information on that for the first month of the pandemic, and we lost a lot of time that South Korea didn't lose, Japan didn't lose, and then we were always compared unfavorably with the response of other

countries.

Mr. Okon, thank you for being here today, and I do remember your testimony from 12 years ago, and I think we talked about Doxil during that, and now we have got -- Doxil is an anti-cancer drug that, because of a manufacturing problem, the manufacturer just said, "I am sorry, I am out,'' and so it wasn't available to your patients in this country. And we do need to do better on that.

But many of the drugs that you went through in your testimony, these are infused drugs. These are what I call part B drugs. They are generally given in a doctor's office. And I was really concerned we did the Inflation Reduction Act and the movement from average sales price to the maximum fair price, which is actually just a made-up number by the Secretary of Health, and how this would impact not just the availability of drugs themselves, but the availability of providers to provide those drugs. Was I correct to be concerned about that?

*Mr. Okon. You were, but especially on the side of creating a different reimbursement rate, but especially related to the sterile, low-cost injectable generics. We

have taken the pricing power. These are not brands, these are not the Merck brands and the other brands, as you know, Dr. Burgess. These are very low-cost, sterile drugs that have been around for decades.

*Mr. Burgess. Thanks, Mr. Chairman. I will submit my further questions for the record. Thank you.

[The information follows:]

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

*Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes Mr. Sarbanes for five minutes for questions.

*Mr. Sarbanes. Thank you very much, Mr. Chairman. Thank all of you.

As we have all made very clear, the PAHPA reauthorization provides the perfect opportunity to take a good, hard look at the lessons learned from the pandemic, and leverage them to ensure we are all the more prepared to effectively, efficiently, and nimbly respond to the next public health crisis.

Public health departments are often the first line of defense against emerging outbreaks. We saw this during the pandemic and other public health threats, yet they have been severely under-resourced for decades. I mean, this is an old narrative. And it took significant effort to build them up during the pandemic. We were not starting from a strong baseline, and it was a very uneven baseline across the country. We lost a lot of time as a result of that.

But similarly, data collection and sharing efforts are a very -- and I think most -- effective way of spotting trends,

understanding where we need public health resources, and when we need them. Public and private entities expanded significant energy to create these new systems during the pandemic that allowed us to track the spread of COVID-19 vaccines and other resources across communities, the country, and the world. There were some very effective dashboards built in that regard, as you know.

While we all recognize we are in a very different place now than we were just three years ago today, it is critical that we not let our guard down -- this is much of the theme of today's hearing -- as we draw down our emergency postures. If we are going to be ready for the next public health crisis, we need to ensure that we maintain a base level infrastructure of the public health workforce data and other capacities that we built up during the pandemic.

Dr. Washington, as an epidemiologist and the vice chair of the Big Cities Health Coalition, you, of course, are acutely aware of the challenges that have faced public health departments during the pandemic and those that will face them in the future. In your testimony you said it is [sic] best "a well-functioning public health system is pandemic

preparedness, and must be well resourced at all levels of government before, during, and after emergencies.'' As I say, I think you said that best.

What does it look like to strike the necessary balance between a return to normalcy, which we all seek -- crave, really -- and maintaining adequate preparedness for the next public health crisis? And how can we achieve this in PAHPA reauthorization?

*Dr. Washington. Certainly. So I think we are -- the most important thing is we have learned a ton of lessons in COVID, and we made a lot of investments in COVID. Many of those investments are short term and term limited, and many of them come in various mechanisms, and they are fragmented a lot of different ways. And so it is really important for us to recognize that we did all that for a reason: because the emergency required us to do it, and we needed those things to respond. And so shame on us to not have a system in place already for the next emergency, which could come next month or later this year. And so we need to -- us in public health, we must maintain that emergency posture, we must have preparedness plans, we must be in place.

Currently, we don't receive direct funding for many of our preparedness initiatives. Much of that goes directly to the state, and then eventually comes to us from the state. As you can imagine, that is tons of administrative burden that it takes to get funding from the Feds to the state to us. And we -- if we are not prepared, I fear that the next pandemic will have a similar kind of response.

*Mr. Sarbanes. I appreciate that. And the pandemic made clear that we have to work hand in glove with our state and local partners to truly adopt a system-wide, whole-of-government approach to public health preparedness.

Dr. Gralow, why is it so important that we capitalize on the opportunity we have before us with PAHPA reauthorization to fully address both supply and demand-side lessons learned from the pandemic?

If we do one without the other, we will be sacrificing the overall efficacy of our public health preparedness efforts. Isn't that correct?

*Dr. Gralow. I would agree. I think this is a crisis. It is a different kind of crisis. It is definitely intertwined with pandemic-related issues. The

vulnerabilities, the transparency that we are asking for are -- were exacerbated by the pandemic.

I think this is a national security issue. I think it ties into many of the issues that we have been dealing with throughout the whole pandemic and the authorizations that have been provided.

*Mr. Sarbanes. I mean, really, it is shame on us if we don't maximize our learning opportunity here from what we just went through to make sure, again, we create a new floor or foundation baseline in terms of how we build the public health and response infrastructure across the country, so that when the next challenge comes we are not going from a deficit up to where we need to be, we are starting from a strong baseline.

Thank you all for your testimony. I yield back.

*Mr. Griffith. [Presiding] I now recognize the gentleman from Ohio, Mr. Latta, for five minutes of questioning.

*Mr. Latta. Well, thank you, Mr. Chairman, and thanks for -- our witnesses, for your testimony today. We all appreciate you being here.

I have been a member of this committee the last two reauthorizations of PAHPA, and look forward to supporting the much-needed provisions to improve the legislation so Americans are safer and our nation is better prepared to respond to any future public health emergencies.

To that end, I am proud that my legislation, the Healing Response Act, that I am co-leading with my good friend from Illinois, was included in today's hearing. It is crucial that Congress has a formal review examining HHS's efforts to ensure that the U.S. is prepared to rapidly produce medical countermeasures in the event of a public health emergency, and better understand risks and challenges associated with advanced development.

I also appreciate the committee's longstanding bipartisan work and our ability to work together for the American people.

I also believe there are some critical improvements to ensure BARDA and SNS obtain feedback from all sectors in responding to threats through my colleague Mr. Hudson's PHEMCE Advisory Committee Act.

However, although great steps are being made in PAHPA to

address future emergency, I am concerned that HHS isn't funding programs that improve oral antivirals or next-generation antivirals. Over $5 billion was pumped into the Biden Administration's next-gen program. They are spending vast amounts of taxpayer dollars to reinforce existing programs like vaccine antibodies that contain limitations we have all seen clearly over the last five years. The -- it is imperative that taxpayer dollars are spent appropriately, and we must ensure that we have access to more therapies and treatments now, not at some point down the road.

And Dr. Parker and Ms. Arthur, if I could ask you both the same question, and I will start with Ms. Arthur. What is the role Congress should play to invite private-sector solutions and new advancements in treating rare diseases into the decision-making today, and ensure our tax dollars are spent more wisely?

*Ms. Arthur. Thank you for that question. I am not a rare disease expert, but I think that incentives are always important with regard to encouraging the development of novel products. Many of our companies are very committed to this space, and find that it is important to have those incentives

at the FDA, and also with other parts of the U.S. Government to help development of rare disease products.

*Mr. Latta. Dr. Parker?

*Dr. Parker. Yes, the same thing. I think you have to have the clear incentives to bring industry in. But I think, from the government side, you also have to have effective leadership that is going to establish what are the priorities, what are the milestones, what are the metrics, and hold the executive branch accountable for delivering.

*Mr. Latta. Well, let me follow up with what you just said, because this is going to lead into my next question, because when you look at the regulatory issues or legislative barriers that are hindering private-sector innovations, how does the private sector communicating with the Federal Government and the Federal agencies make sure that those barriers are overcome?

*Dr. Parker. Well, you know, I am not going to -- there are actually -- there are opportunities for the private sector and, say, BARD to communicate. They have mechanisms to do that. I think we always have to work on how we can make those better, and how does our Federal funding agencies

-- are they listening to industry when they express their concerns and barriers that they have to face?

So we are -- always have to push and make our communication channels better.

*Mr. Latta. Ms. Arthur, would you like to follow up on that?

*Ms. Arthur. Yes, thank you. I think, first, I very much support what Representative Hudson has put forward as far as the PHEMCE Advisory group. I think that is an example of the kind of work we can do as industry, where we actually, through our trade associations and -- directly, actually, can give guidance to the Federal Government on those things that would make it easier, or facilitate the development of products that have an unmet medical need.

This is really what we like to do; we respond to guidance from the FDA, we work closely with those advisory groups in order to say this will help us deliver on the need that has been expressed.

*Mr. Latta. Well, thank you very much.

And Mr. Chairman, I yield back the balance of my time.

*Mr. Guthrie. [Presiding] The gentleman yields back.

The chair recognizes Mr. Cardenas for five minutes for questions.

*Mr. Cardenas. Thank you very much, Chairman Guthrie, and also I want to thank Ranking Member Eshoo for holding this hearing, and to all of our witnesses for sharing your perspectives and expertise on hazard preparedness.

I spoke in the last hearing about the vulnerabilities of pediatric populations during emergencies. I remain concerned that our health care infrastructure is not equipped to handle surges when hazards impact children -- especially children.

Since this past winter, when we saw skyrocketing cases of RSV flu and COVID-19, little investment has been made in building capacity to address these needs in the future. And looking at existing programs and resources, I want to ask about some creative ways that we might be able to leverage our current systems and better address the needs of our kids.

Dr. Washington, you have been on the front lines of COVID-19 responses in your community. In your experience responding to the needs of children during these public health emergencies, how critical is it to have trained health care professionals to address the unique needs of kids?

And what challenges have you witnessed in recruiting and retaining a workforce with pediatric-specific knowledge?

*Dr. Washington. Great, thank you for the question. I think it is certainly important that we have folks with experience to be able to care for children.

And I know one real opportunity for us is on the pediatric infectious disease doctor front. It is really important to have those available to us. We are fortunate to have some in our community, but I know that is not the case for many communities in the country, and it remains really important.

The most important workforce issue, though, as it relates to our response, really is our nursing and clinical support and having nursing available. As you know, we are experiencing a national shortage of nurses. We have the same experience in Mecklenburg in the State of North Carolina. And having nurses available to deliver vaccines, to work in shelters, to provide care to families, to work in schools, all really critical, important, and must be addressed as we think about preparing our workforce.

*Mr. Cardenas. Thank you. To what extent would

something like pediatric toolkits, which would include, for example, equipment, training modules, and pediatric dosages of therapeutics help to handle a surge capacity for children during a crisis?

*Dr. Washington. I think those are really -- toolkits are really important guidance documents to help clinicians and non-clinician settings to be able to provide care for children during emergencies.

I think back to COVID, where we had to have guidance documents for child care facilities, for example, where you have non-clinical staff working to serve and care for kids every day. Having appropriate guidance for those individuals to be able to care for those kids while experiencing a pandemic is so critical to our response.

*Mr. Cardenas. Thank you. I was also -- I wanted to discuss the need to improve reliability of our drug supply chains. It is a glaring, missed opportunity that the Republican majority is leaving the FDA out of the process. Partisan RFI is not the same as taking action, especially not when the FDA has proposed a number of improvements to help them deal with drug shortages.

Over the course of the pandemic we saw how quickly critical supplies and over-the-counter medications could become scarce. Now we are confronting a shortage of oncology drugs so serious physicians are rationing drugs or delaying care to patients in dire need.

It is undeniable that FDA could have more of a role to play in preventing these types of shortages in the future, and the omission of FDA-related authority is stunning, which leads me to a question to you, Dr. Gralow.

What kind of FDA authorities would have been most helpful in avoiding the existing shortage, and what could help FDA mitigate the current shortage?

*Dr. Gralow. Again, I think most helpful would be to have the authority to know where manufacturers source their active pharmaceutical ingredients, and being able to view whether we actually have redundancy in our system or not. Knowing at the first time point that a plant has gone down, and then understanding that it impacts five of the manufacturers or one of the manufacturers is critical. And that is what we are hoping FDA will get authority to do.

*Mr. Cardenas. Yes, one of the things that,

unfortunately, I think most Americans see as a bad term is redundancy. Like, why would you want to duplicate something? But in this context it is critical, and it would be lifesaving, and it is something that systems in general are required to do. Unfortunately, we can do a better job in this country. Hopefully, we will get there.

You note, Dr. Gralow, that shortages today are the worst you have seen in over 30 years -- in your 30-year career. Without congressional action, how likely or frequent would we expect these shortages to be in the future?

*Dr. Gralow. They are increasing regularly. And, you know, rest of world does not have a shortage of these two primary drugs that we are dealing with right now, and it is because of many of the other systems' better redundancy, et cetera, that they don't. This is -- cisplatin, carboplatin, this is a U.S. problem.

*Mr. Cardenas. Thank you very much.

My time having expired, I yield back, Mr. Chairman.

*Mr. Guthrie. The gentleman yields back. The chair now recognizes Mr. Griffith for five minutes for questions.

*Mr. Griffith. Thank you, Mr. Chairman, and I beg your

forgiveness and the forgiveness of the witnesses because I am going to go on a little bit of a tirade for just a minute.

One of my colleagues on the other side of the aisle seemed somewhat surprised, chagrined that Merck has filed suit against the so-called negotiation process that they set up. When that bill first came into this body, into this committee, this subcommittee three years ago, on first blush I raised the issue that when you take between 65 and 95 percent of the total sales of a medication, it is, on its face, unconstitutional and would likely face a challenge in the courts. I raised it again in full committee. I raised it on the floor. And for three years, every time it came up, I raised it and it was included in the IRA. And to say today that you are somehow surprised took me by surprise, because my thought is of course Merck sued, and every drug manufacturer probably ought to sue because it is, on its face, an unconstitutional taking.

All right. Now the questions I actually had prepared. Thank you, Mr. Chairman. Thank you, witnesses.

In my district, a company had a contract facilitated by HHS to produce nitrile, butadiene, rubber -- the main

ingredient in disposable gloves -- as well as the finished gloves. They were directed by the Federal Government officials to submit two separate proposals to both the Department of Defense and the Assistant Secretary for Preparedness and Response, or ASPR. They were assured that this was for process reasons, and funds would be available for them to complete the contract, which included new construction to expand their production capabilities.

So the county donated hundreds of acres of land valued at over 17 million, and the Commonwealth of Virginia provided tens of millions of dollars' worth of incentives. Since then the company has only received partial funding, and has had to halt construction, and my district is left with hundreds of acres unused, and half -- and a half-built manufacturing facility. This was largely due, in part, to a lack communications between ASPR and the Department of Defense, and a lack -- and a lapse and a lack of transparency.

Now, in the flowchart -- this is mostly for folks back home; I know you all know this -- but in the flowchart of responsibility, both the Biomedical Advanced Research and Development Authority, BARDA, and the Strategic National

Stockpile, SNS, are directly under ASPR. Accordingly, I have two bills in front of us this hearing that will provide structure around contract duration, as well as require 90-day notification requirement to vendors in the case of any modifications, renewals, extensions, or terminations of contracts with the Biomedical Advanced Research and Development Authority and the Strategic National Stockpile. It is my understanding this contract notice requirement is already required for contracts under the SNS's Special Reserve Fund.

Dr. Parker, can you please explain what processes are in place currently within ASPR to notify companies of any modification or changes to their existing contracts?

*Dr. Parker. Well, I am not currently in ASPR or --

*Mr. Griffith. I understand.

*Dr. Parker. -- or Federal Government, it has been a while.

But what you just described sounds like a reasonable thing to have in place that, you know, it just -- increasing the transparency with the private sector, with those who are doing business with the government, it is a two-way street

between the private sector and the Federal funding agency.

*Mr. Griffith. And it is along the same line, but can you explain why providing more stability and certainty for companies when contracting with ASPR, BARDA, SNS would be beneficial for both taxpayers and also the company who initially receives the contract?

And I probably already answered it in my description of what is happening in my district, but go ahead.

*Dr. Parker. Yes, and I am not familiar with the case in your district, but that sounds very, very unfortunate, and it sounds like a huge communication issue. But I do think that speaks to the issue of the fragmentation between the Federal interagency -- you know, the interagency and, you know, in this case DoD and HHS. So that needs to be fixed.

*Mr. Griffith. Yes, and I appreciate that, and we are going to try to fix that.

And to go back and harp some more, it wasn't just me, there were others who came forward on the situation with the drug pricing so-called negotiations. When you put a gun to somebody's head, it is not really a negotiation. And even the Congressional Research Service came out with a statement

that they thought it was not only an unconstitutional taking -- was possibly, because they are never going to commit to the final result of the court -- but not only was it possibly an unlawful taking, but it was also probably in violation of the excessive prohibitions that are found elsewhere in the first 10 amendments of the United States Constitution.

And interestingly, Merck has also sued because there -- apparently, there is a regulation or a rule that has come out you are not supposed to talk about how unfair it is, and you could even lose your rights to sell other medicines to the Federal Government, all of which seems atrocious, and I expect the courts to knock it down, and I am shocked that anybody would not understand there is at least a huge argument to be made in the courts.

And I yield back.

*Mr. Guthrie. The gentleman yields back. The chair recognizes the gentlelady from Michigan, Mrs. Dingell, for five minutes.

*Mrs. Dingell. Thank you, Mr. Chairman and Ranking Member Eshoo. This is an important hearing, and I thank all the witnesses.

The reauthorization of the Pandemic and All-Hazards Preparedness Act, or PAHPA, comes at a very critical moment. Our nation is emerging from a three-year public health emergency, the worst health care crisis we have experienced in a century. And it is our obligation to improve our nation's preparedness and response capabilities to ensure we are ready for future pandemics.

We have to learn from our shortcomings, address the gaps in our nation's health security, and remain entirely focused on mitigating the effects of the next possible threat. That is not a matter of if; it is a matter of when. And that is why I am so very disappointed that this markup is not considering any legislation to address the FDA.

I remain seriously troubled about the fragility of the pharmaceutical supply chain. It is not only compromising our response to future pandemics, but, as we all know, it is harming Americans now. We are in the midst of an oncology drug shortage that is jeopardizing the health of cancer patients across the nation. And in Michigan we are experiencing it very seriously. A number of our hospitals have already canceled appointments for cancer patients

because there isn't even a substitute medicine. They are being switched to alternative medications that aren't effective, either.

Dr. Gralow, in the wake of a drug shortage, what are the implications of switching an oncology patient to a new medication?

*Dr. Gralow. In some cases the agents that are in shortage or out, they not on the shelves right now, are critical to getting cures.

Testicular cancer is an example. Even metastatic testicular cancer, when it spread to other parts of the body, can be cured. But a critical component of that cure is cisplatin. So at this point, not having that drug -- we have no substitutes for that drug in this particular case, in testicular cancer, a chance where -- a cancer where, if we do have this drug, you can be cured even when it has spread, you know, beyond the origin.

So this is critical, impacting maybe as many as half a million Americans with just these two drugs. And there are many other drugs that are vulnerable right now that are on the list of impending shortage or problems brewing.

*Mrs. Dingell. Thank you. Unfortunately, many patients don't have weeks or months to wait for these lifesaving drugs, and we are passing up a critical opportunity to address this problem in earnest today.

A crucial piece of this puzzle is examining the FDA's role in mitigating drug shortages, and I urge my colleagues in a bipartisan way for us to seriously consider improvements to the FDA in the weeks ahead.

But now let me turn to another issue: our nation's testing capacity. Getting swift test results was vital in our pandemic response and keeping our loved ones safe. But during the peaks of the pandemic we all heard these alarming reports of it taking up for two weeks to patients to receive their test results, indicating whether they had tested positive for COVID-19.

Dr. Parker, in your testimony you mentioned the need for improved surgical situational awareness and supply chain resiliency that can be activated immediately. This has to include our lab testing capabilities. Dr. Parker, are our country's public labs designed to process a large volume of tests?

And were they able to handle the testing surges we experienced throughout the public health emergency?

*Dr. Parker. Well, I think clearly, at the beginning of the pandemic, that was -- the answer was no.

I think we have to prepare our -- in the future that they will be, and they have to be able to surge into the private sector to help that. I think the example earlier, South Korea was better prepared, but I think they also had a pretty good integration between their public health laboratories and the private sector that helped them out. We need to do something very similar.

*Mrs. Dingell. Thank you, Dr. Parker.

The Secretary is permitted to enter into contracts or cooperative agreements with vendors to maintain the Strategic National Stockpile and ensure it is ready to handle surges. However, clinical laboratories are not directly included, which is alarming, since we need robust lab capacity to process these important tests. That is why I am glad a bill I am leading with Representative Dunn was included as part of this hearing: the Ensuring Sufficient Supply of Testing Act.

And thank you, Rep. Dunn, for your partnership on this

important effort.

This bill will expressly clarify that the Secretary can enter into contracts with clinical labs to strengthen our testing capacity.

I am almost out of time, but Dr. Parker, some estimates say private labs handled up to 85 percent of U.S. COVID-19 tests. Can we better leverage their capabilities to improve testing capacity during surges?

*Dr. Parker. Well, the answer is yes, and the answer is we have to. And we also -- there is a lot of university hospital laboratories that need to be considered into this -- into that equation, too.

*Mrs. Dingell. Thank you, Dr. Parker.

I yield back, Mr. Chair.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair recognizes the gentleman from Florida, Mr. Bilirakis, for five minutes for questions.

*Mr. Bilirakis. Thank you, Mr. Chairman, I appreciate it.

Mr. Arthur, your testimony brought up a sobering question: As a nation, are we more prepared to do -- are we

more prepared than we were in 2019?

And that, unfortunately, I don't think we are. I think part of this reason is due to the Administration's red tape and reliance on bureaucracy. What we should be doing is replicating one of our COVID successes through public-private sector partnerships, in my opinion.

Could you elaborate on the agile nature of the private sector, and specifically your members? What does their nimbleness mean in the testing and diagnostics space?

*Ms. Arthur. I think -- thank you very much for that question.

I think, across the board, industry actually does several things really well. They analyze what they can do to solve a problem. They understand what the -- what they need to do to bring the best product to market that is going to serve the need, that unmet medical need, being met. And more importantly, they move really swiftly to make go/no-go decisions.

So you build a test, you see if it works, you understand if there is safety issues, and you move on to the next step clearly and swiftly. And I think that is what we saw with

Operation Warp Speed was there was that facilitated environment by the U.S. Government, and then expertise brought to bear by industry on how to make those very rapid go/no-go decisions, all within the confines of very clear guidance for manufacturers of vaccines, tests, and therapeutics, such that companies were delivering products swiftly, but still very safely, and manufactured at high quality.

*Mr. Bilirakis. Excellent. Dr. Parker, you similarly speak to the role that coordination plays in responding to novel threats that could catch us flat-footed and unprepared, God forbid, specifically the importance of relationships not only between the Federal Government and the private sector, but also with state and local governments.

The Countermeasures Advisory Committee bill also requires the Public Health Emergency Medical Countermeasures Enterprise to solicit state and local feedback as part of its decision-making. Can you discuss the role of state and local feedback in addressing a community's specific needs during the acute emergent situations such as natural disasters or disease outbreaks?

*Dr. Parker. Sure, and Dr. Washington is on the front line, and it is absolutely essential that the Federal Government include input from those that are on the front line in state, local public health, particularly tribal and territorial and tribal communities as well. It is just absolutely essential, and we need to have that input. Essentially, they are setting the requirements.

I always think of things in the requirements space, and that drives what our funding should do. So they should be helping us drive those requirements.

*Mr. Bilirakis. Thank you.

Mr. Okon, on the topic of preparedness and prevention of supply chain disruptions, you talk in your testimony about the need to incentivize -- and we went over this, but I want to ask you -- again, the need to incentivize generic drug injectable manufacturing, reshoring here in the United States through value-based incentives. Can you elaborate more on this idea, sir?

*Mr. Okon. Well, value-based, Mr. Bilirakis, value-based is the name in health care now.

And basically, over 75 percent of these drugs are

manufactured overseas. We need to bring it back in the United States, and we need to basically have acceptable quality measures which are agreed upon. And when a manufacturer hits those quality measures, keeps the products going, keeps the production lines going, then they would basically get an incentive there.

Let me just make this very clear. This is not about big name, expensive, brand drugs. This is about low-cost, sterile injectables. It is a very different animal. And the people and the companies that are making this are very different than some of the large manufacturers out there. These come from China, India, and whatnot.

So I think, if we thought creatively in terms of value-based arrangements, we would be able to bring manufacturing back in the United States. But the fact of the matter is, again, the FDA commissioner said it: If no one is going to make money on these drugs, they are not going to produce them. It is as simple as that.

And I am not against any of the warning signals, the things that the FDA should be doing and whatnot, but the problem is, until we realize the fact that there is a basic

financial issue here, we are going to have more shortages.

*Mr. Bilirakis. Okay, thank you very much. I appreciate that answer.

And I should probably yield back the balance of my time in the interest of time. Thank you.

*Mr. Guthrie. Thank you. The gentleman's time has expired. The gentleman yields back. The chair now recognizes the gentlelady from Illinois, Ms. Kelly, for five minutes for questions.

*Ms. Kelly. Thank you, Mr. Chair.

The COVID-19 pandemic really highlighted the need to support and protect our public health infrastructure. COVID-19 was, hopefully, a once-in-100-year phenomenon, but we continue to see that there is always a public health threat looming, from the yearly flu season to the continued threat of Mpox. Just last week there was the air quality threat in the northeastern part of the country. Regardless of what and where it is, our public health infrastructure stands ready to confront the situation and ensure that Americans say stay safe and healthy.

Dr. Washington, in your testimony you speak about the

need to build a more robust, interoperable data and analytic public health system. How can the Federal Government support the efforts to build out a national data infrastructure for all hazards -- hurricanes, wildfires, tornadoes, not just pandemics -- that is capable of efficiently sharing important public health information among providers and Federal, state, and local agencies?

*Dr. Washington. Thank you for that question.

It is so essential that we have a reliable data system. I akin it to being a pilot or without data on wind or weather, right, in trying to fly a plane. I don't think any of us would get on a plane without the pilot having that information to make decisions. And so I feel like our public health system has got to have the same kind of infrastructure in place to be able to make decisions not just at the Federal level, but also at the state and local levels.

And we have got to make intentional investments in those systems that exist both at the Federal level, state, and at the local level, and it has to happen at all three levels. We can't just have a Federal system, we can't just have data systems at the state level. We have got to all have access

to information that can flow very quickly, so that we are not making decisions a month later from the information that we have in front of us. And so I think it is so vital.

And I do think it is important, though, as it has been highlighted in this hearing today, that we also partner with the private sector. There is a lots of analytic capability, technology solutions that the private sector has to offer, and we should leverage that for the good of government and to protect our people.

*Ms. Kelly. And would -- can you also speak a bit on what additional cybersecurity enhancements need to happen currently while we are building out the national data infrastructure?

*Dr. Washington. Yes, I think any national data infrastructure has got to have, as a priority, as part of its requirements, appropriate guardrails for cybersecurity. Living in a jurisdiction that has had a hack before, it is so important that we prioritize, just like we prioritize any other health care information, data security. And so it is essential that those systems that are built address cybersecurity and protect that information, just like we

would any other information, both health, financial, or otherwise.

*Ms. Kelly. Thank you.

As we take this moment to reflect on what this country experienced, the lingering question is if we are prepared to address another pandemic. This is one of the many reasons that I am proud to cosponsor, as my colleague said, H.R. 3703, the Healing Act of 2023, with Rep. Bob Latta, which would direct the U.S. Comptroller General to review and issue recommendations regarding the current status of existing efforts and programs rapidly to produce medical countermeasures domestically.

Dr. Parker, in your testimony you speak about the need for near-real-time situational awareness in the countermeasure resiliency efforts. Can you expand on the current gaps of our public health structure to have the near-real-time situational awareness?

And what additional authorities does Congress need to give it to ensure that we have better visibility into our system?

*Dr. Parker. Well, sure, and it is very similar to Dr.

Washington. You know, the need to have modern data systems that can protect intellectual property and competitive information, but when the need comes can be turned on to share the appropriate information for the entire response enterprise.

And I want to just share something during COVID-19 that few people saw. You know, it took about six months to set up, but within HHS and the whole family of HHS and the interagency, the data systems were remarkable. And many of us were calling that the heartbeat of the response because of the visibility and the control tower concept that we could almost begin to anticipate where needs were before the request even came in. And we need that kind of system, the control tower system. We need to protect intellectual property and competitive information, but we have done it, we can do this again in the future, and make this institutionalized.

*Ms. Kelly. Thank you so much.

And with that, I yield back.

*Mr. Guthrie. The gentlelady yields back. The chair now recognizes Mr. Johnson from Ohio for five minutes.

*Mr. Johnson. Well, thank you, Chairman Guthrie. I appreciate it for this very important hearing.

You know, it is with the power of hindsight that we are here today talking about how we can be better prepared for the next disaster, be it a hurricane, a tornado, or another pandemic. The last time the Energy and Commerce Committee looked at the Pandemic and All-Hazards Preparedness Act, it was 2018. And nobody in this room now or then could have predicted what was to come, COVID-19.

Now that we have the coronavirus squarely in our rearview mirror, we must take lessons learned. We got to consider what those are, both good and bad, and ensure that we are in a stronger position to fight the next natural disaster or health crisis. But if there is one silver lining, it is the National Disaster Medical System, NDMS, or, as I like to think of them, the National Guard of medical professionals. When disaster strikes and the need for urgent medical care is required, the men and women of NDMS are called to action.

And it is easy to forget that disaster response personnel from NDMS respond to all kinds of disasters, not

just pandemics. For example, just last month those volunteer medical professionals were dispatched to Guam in response to a typhoon that hit the island. Over 45 NDMS health and medical task force and incident management team personnel were deployed to support emergency response efforts and ease the burden on local health systems, inevitably saving lives.

The NDMS represents a network of intermittent Federal employees who are medical professionals serving within their communities, while jumping into action to serve our nation by deploying during natural or man-made disasters. In their everyday life, they are the doctors and nurses each of us see in our local health systems in our communities.

Under the last reauthorization, Congress provided direct hiring authority to the Administration for strategic preparedness and response for the NDMS workforce through September 2021. To allow for the most flexibility during COVID-19, and to combat the dire workforce needs, we have continuously extended this authority through one-off, must-pass bills since then.

Jumping from short-term extension to short-term extension is not sustainable. We need some certainty. And

it hurts their overarching recruitment and retainment efforts. So it is for these reasons Representative Schrier and I have introduced the Doctors at the Ready Act, which will provide for stability and certainty at ASPR to ensure this program has the flexibility needed to provide for a properly-staffed NDMS in the case of an emergency.

So question number one goes to Doctor Parker.

You know Dr. Parker, like you I served for 26 years in the United States military in the Air Force. So thank you, first and foremost, for your service to our country.

But based on your experience as principal deputy assistant secretary for preparedness and response, could you further elaborate on the challenges posed by this intermittent hiring cycle and its impact on the continuity of our preparedness and response framework and operations?

The legislation that Representative Schrier and I have introduced would eliminate the sunset permanently, thereby providing more stability and flexibility for the program. The goal would be to ensure we have civil servants ready to deploy when we need them. So can you respond to that --

*Dr. Parker. Sure.

*Mr. Johnson. -- the challenges?

*Dr. Parker. Sure, and thank you for the question and for your -- and I commend you for the bill to do this, to strengthen NDMS. It is absolutely essential that we do that.

The NDMS, what makes NDMS work is the health professionals across our United States that are volunteering to become intermittent civil servants to deploy to help our nation in need. So this is needed, and I would commend any other things that would strengthen NDMS. NDMS is a unique national asset that the public is not aware of. And we need to strengthen it, and we need to think about what does NDMS 2.0 look like.

*Mr. Johnson. Okay. Do you think it is going to help? I mean, is it going to have the impact that we are hoping it does, particularly around recruitment?

*Dr. Parker. Anything you can do to make it more long-term and to incentivize the volunteers of our health professionals to sign up and participate will be helpful. I think we need to think about what other incentives -- and I don't know what they are right now, off the top of my head, but we need to think about other incentives, as well, to make

sure that we have a robust, diverse workforce that will volunteer for NDMS service in the future.

*Mr. Johnson. All right. Well, great. Well, thank you very much.

And Mr. Chairman, I urge support for H.R. 3613, the Doctors at the Ready Act. And with that I yield back. Thank you.

*Mr. Guthrie. The gentleman yields back, and the chair recognizes Ms. Barragan from California for five minutes.

*Ms. Barragan. Thank you, Mr. Chairman.

Anti-microbial resistance is costing patients their lives, and significantly increasing our health care costs, with an estimated $4.6 billion spent annually on treating just 6 of the most common, multi-drug resistant pathogens in the United States. For all Americans, and especially those who face chronic infections, like individuals living with cystic fibrosis, this is a public health crisis that Congress can no longer ignore.

As we consider the reauthorization of the Pandemic and All-Hazards Preparedness Act, or PAHPA, I think this is a missed opportunity for the committee to not include the

PASTEUR Act, or at least certain parts of it. Innovation is urgently needed to address the shortage of effective antimicrobials to treat a range of resistant infections.

For example, in California, Valley Fever is a growing fungal threat, and lacks appropriate antifungal treatment. From the perspective of these patients, some of whom are my constituents, we are unprepared to meet their treatment needs.

Dr. Arthur, thank you for your testimony. Thank you for including this as part of your testimony, your written testimony. You provide in it that you believe that we should be including the PASTEUR Act in the reauthorization of the Pandemic and All-Hazards Preparedness Act. I would just ask that you elaborate on why it is important that we do that.

*Ms. Arthur. Thank you so much for the question.

The antimicrobials market is a broken market. And having antibiotics available to us is not just pivotal to our public health, everyday delivery of public health and surgeries, it is also vital in our all-hazards response. When people are injured in a fire or other -- they can often suffer from opportunistic infections. So having antibiotics

and antifungals to actually treat people in a rapid way is really important.

What the PASTEUR Act does that is unique is it actually enables a marketplace for these products that are being developed by industry, sometimes in partnership with BARDA and the government. And so we need to have these products not just get developed, but go into a place where they can actually be sustained and be available to us.

But that also has to be coupled with very important stewardship. We don't want to overuse these. It will drive resistance. So you need to actually have both the stewardship component and a marketplace that actually helps these products be available to us. So it is really important to do something like PASTEUR as a policy that will help drive that.

*Ms. Barragan. Well, thank you. And I understand that this legislation has broad support of over 230 stakeholder organizations representing health care providers, public health professionals, scientists, patients, and pharmaceutical and diagnostics industries per your testimony, is that correct?

*Ms. Arthur. That is actually correct. There are many different diseases where antimicrobial infections can cause death. So it is really important to support these products.

*Ms. Barragan. Yes, and I also saw at the end of 2022 that this bill had over 60 bipartisan cosponsors, which makes it, I think, ripe for us to really take a look at and making sure it is included. Thank you for that.

Dr. Washington, in your written testimony you stated that -- and I am quoting -- "The hospital preparedness program has been cut by more than 50 percent over the last 20 years, and remains stretched due to prolonged emergency responses, increased preparedness and response requirements, and annual discretionary funding not keeping pace with inflation.''

As the only source of Federal funding for health care system readiness, I am concerned that the stagnant funding will decrease the ability of local hospitals to serve all the patients who need care during emergency or disaster. What are the practical implications and/or limitations of stagnant funding for the hospital preparedness program, and is there more Congress can do to help?

*Dr. Washington. So I think there are tons of implications specifically for being ready to go. What -- as we saw during COVID, our healthcare -- our acute care facilities were literally crushed with demand. Our emergency departments had waits that were extending well beyond 10 to 12 hours. And the ability to be able to care for people in a timely fashion was almost impossible.

One of the things that our Preparedness Coalition did that is funded by HPP in Mecklenburg and our region was to mobilize a mobile hospital. We can't just purchase a mobile hospital in real time for an emergency. We have to have those things ready to go, they have to be well maintained, and they have to be ready to activate as quickly as we need to to be able to respond and provide care to folks.

And so increasing investments in the preparedness of our health care systems is really, really important. And we haven't kept up, and so we need to catch up in order to be able to make sure we stay prepared.

*Ms. Barragan. Great. Thank you.

With that, Mr. Chairman, I yield back.

*Mr. Burgess. [Presiding] The chair thanks the

gentlelady, the gentlelady yields back. The chair now recognizes Chairman Hudson for five minutes.

*Mr. Hudson. Thank you very much, and thank you to the witnesses. Outstanding testimony today. I think it has been a great discussion. I appreciate your time being here today.

If it wasn't obvious before, COVID has shown us that public health security is national security, and all of us in Congress owe it to our constituents to get this reauthorization of PAHPA done on time this year.

Ms. Arthur was asked what happens if we don't, and I thought you gave a great answer: number one, we will not be better prepared for the next pandemic; number two, private industry will not have the incentives necessary to produce the next generation of countermeasures; and number three, we lose the opportunity to implement lessons learned from COVID. I think those options are factual, and I think they are totally unacceptable.

We have a responsibility to move this legislation forward, and I appreciate the partnership I have had with Ranking Member Eshoo. We have worked very hard to make this a bipartisan process. There are a lot of factors that I

would like to take in a different direction, and I am frankly just baffled at the place we are now.

You know, drug shortages is a critical issue. It is an issue that Republicans have been addressing, we will continue to address. The PREVENTS [sic] Act just passed about six months ago had provisions dealing with drug shortages. It was a bipartisan bill led by Richard Burr from the Senate, our ranking member at the time, chairman -- chairwoman, now -- Cathy McMorris Rodgers worked very hard on that, working together with Democrats. We have had hearings on this issue. We will continue to have hearings on this issue. I have personally given assurances that I will make this a priority, and we will work together.

But I think being given a list of bills that we have to include or else when I think testimony today showed we are not really dealing with the root causes, we -- I think we need to examine this further to really, truly address this in a comprehensive and bipartisan way. I am committed to doing that.

But loading PAHPA up with this issue that has never been part of PAHPA reauthorization is the wrong way to go.

Because if we open up PAHPA, there is a whole lot of other important issues that Members of Congress would like to include, including bans to gain-of-function research, including dealing with the politicization at CDC that happened during the pandemic, including discussing mask mandates and other mandates. These are all important issues that a lot of my colleagues want to discuss, and would love to include in PAHPA. But this is not the proper place. PAHPA is too important. We have to stay narrowly focused on reauthorization to get this thing through the House.

And it is going to be tough. This is not going to be an easy path. These are not easy issues. But if we stick together, and we do this in a bipartisan way, we can do this, and we owe it to our constituents to do that. And so I just ask Ranking Member Eshoo and my colleagues on the other side, please work with us. Please keep the process moving. We will work together on drug shortages and a whole lot of other issues this year, and I believe this committee has a long track record of getting things done. I think we can do both things, and I think we will.

You know, I have worked very hard to solicit feedback

from the private sector, from Federal, state, and local partners, constituents on the necessary changes that we need in this reauthorization language as we look at the entire preparedness enterprise. And I have emphasized in the past that involving the private sector is almost always the best way to get things done. Private-public partnerships flourished in North Carolina during COVID, and to me it is -- the best way to replicate these is to continue to strengthen these kind of partnerships. In the dozens of RFI responses, public-private partnerships are mentioned with the goal of enhancing them and improving the transparency for the Administration for these relationships.

One of my bills noticed for this hearing would establish a PHEMCE advisory committee to receive input from industry and improve communications and transparency from PHEMCE to private industry. I would welcome a Democrat that would like to cosponsor this with us to make sure this is bipartisan going forward. I think there has been a lot of support expressed today for it.

Another issue that I think is really important is cybersecurity in our health systems. This is a bigger

problem that surpasses PAHPA, but as it relates to our nation's preparedness I think it is something we can build out.

I have used up a lot of my time, but Dr. Parker, are there any specific actions we should look towards to address cybersecurity as it relates to our health preparedness?

*Dr. Parker. Sure. I mean, you -- I will simply just say we have got to hardwire cybersecurity security protection into our information systems as we think about health security preparedness. That is the simplest way to say it.

*Mr. Hudson. Well, I think it is well said, and I appreciate that, and we do have -- we do address that in this PAHPA reauthorization, and we will -- that is something we are going to have to continue to work together on to -- I like what you say, we have got to hardwire it into the process.

So with that Mr. Chair, I will yield back.

*Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair now recognizes Dr. Schrier for five minutes for questions.

*Ms. Schrier. Thank you, Dr. Burgess, and thank you

very much to the witnesses for being here today.

Many of my colleagues have already highlighted lessons learned from the pandemic, and how that should really inform our reauthorization of the preparedness programs.

One lesson that we learned is we can't take our health care workforce for granted, and our providers on the front lines have been highly impacted by this pandemic, leading to burnout, resignations, early retirements. And we don't ever want to find ourselves unprepared to rise to the needs of our patients in the next disaster or the next catastrophe. That is why I was proud to introduce the Doctors at the Ready Act, with Representative Johnson, which you just heard about, to prevent lags in hiring medical providers that could render the country under-resourced at a time of need.

And this bipartisan legislation will allow ASPR, the Assistant Secretary for Preparedness and Response, to directly hire health care professionals into the National Disaster Medical System. This means talent can be retained, and they can move through the process with a faster timeline, and there will be more providers when we need them.

Dr. Parker, you already answered the questions that I

had in how important this is, so I just want to thank you for your responses, and I will move on to another topic, which is testing. This was another important lesson learned in the pandemic.

For years, many of the colleagues in this room have heard me talk about the importance of rapid testing, and I could not wait to get this rolled out and into the hands of people as quickly as possible. There was a lot of frustration there.

But we also remember how frustrating it was right at the start of the pandemic, when the U.S. was doing fewer than 100 tests a day, everything had to get shipped to the CDC, and meanwhile, in Korea, they had drive-through testing sites and were doing 10,000 tests per day, which was key to containing the disease.

And so, you know, at each stage it seemed like there were all kinds of barriers -- running out of reagent, not having the right supplies -- and barriers that, with the right panel of public health and industry advisors, could have been resolved quickly. So I wanted to just highlight the bipartisan Diagnostic Testing Preparedness Plan Act with

Representatives Pence, Carson, and Bucshon. It directs HHS and related agencies to develop a plan for rapid development and scaling up of testing in a public health emergency.

Dr. Washington, as a public health director, can you talk about having -- how having rapid access to labs, rapid tests ready to go would help with future disaster response?

*Dr. Washington. I mean, it is absolutely critical. As you have already outlined, testing at the beginning of COVID pandemic was almost virtually impossible. And so we struggled. And again, it is one of those things where you are kind of flying blind. If you don't have information about who has a condition of any kind, you can't contact trace, you can't isolate individuals, and you can't do what we need to do to be able to disrupt transmission. And so it is absolutely vital.

And it is important to be able to activate it quickly, as you have already described. And I think having mechanisms in place with both public and private laboratories is really essential.

And the last piece I will say before I am quiet about this is the workforce. Beyond the laboratory workforce, it

is absolutely essential to have the workforce in the community that can actually do the testing, which was a huge challenge for us during the pandemic, because we didn't have folks who could do swabbing, and we had to extend capacity for different types, different levels of medical providers to do that. And I think all those things are really essential for us to prepare for now.

*Ms. Schrier. Amen. Thank you.

The last issue -- I have just a bit over a minute -- we have recently been -- have had highlighted for us the shortage of oncology drugs. And cancer drug shortages are at an all-time high. There are many causes. The Seattle Times earlier this month ran an article citing that hospitals across Washington State and the country are seeing these shortages, and the changes that they are having to make, like, to reduce people's dosing, which could compromise their care. This is happening at Seattle Children's Hospital, it is happening at other hospitals.

And as a provider, this is alarming as, potentially, a patient one day -- I hope not, but that is incredibly alarming, and we need these treatments to be available.

Dr. Gralow, it is wonderful to see you again in this capacity. I was wondering if you could talk a little bit about how the Federal Government can help in response to these cancer drug and other drug -- we could even go to ADHD medications, these shortages. Thank you.

*Dr. Gralow. Well, we in the oncology community do believe we are in the midst of a severe health crisis. Right now it is cancer drugs. Previously, it has been asthma drugs and diabetes drugs. It could be infectious disease drugs tomorrow. The kinds of things that we are asking for relate to drugs to treat every kind of disease. It is just cancer right now.

We are asking -- not a lot more regulation, but a little more regulation. There are a few legislative fixes.

We agree that this is a market failure, first and foremost, and we need to work together to get high-quality manufacturers in the United States. We need to figure out the incentives. So it is a mix of legislative, regulatory, market issues that are going to solve this problem, not just for cancer, but for every disease.

*Ms. Schrier. Thank you.

Thank you. I yield back.

*Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady. The chair now recognizes the gentleman from Georgia, Mr. Carter, for five minutes for questions.

*Mr. Carter. Thank you, Mr. Chairman, and thank all of you for being here. This is extremely important.

You know, I like to say that there is a difference in knowing something and realizing something. We have known for many years that we are too dependent on other countries, particularly adversarial countries, for our PPE, for our drugs and medical needs. But we realized it during the pandemic, when it became real.

In fact, as a member of the Doctors Caucus, I was disturbed to learn -- and I learned about it during a time that we were talking with the ASPR at that time, and he told us that, even though we didn't know about the virus until about February of 2020, they saw a downtick in the amount of PPE and drugs that were coming from China as far back as the fall of 2019. That shows us that they were hoarding that, and they were going to use it for their own selves and not

send it to us. That should be a lesson that we should learn and not to let happen again.

And as we know, each state has certain needs. Some states may have needed ventilators, some states may have needed PPE. Every state is different, and that is why I have introduced the state stockpile bill. Obviously, we need a robust Federal stockpile, and this is not to replace that, and instead this is to supplement it. And certain parts of that were passed last year. But I have still got another bill this year that -- H.R. 3631, the State Strategic Stockpile Act, and it is being considered today, and it would extend the matching program through the -- what was approved last year was a two-year program, but this would extend it through 2028, and it would coincide with the timeframe of PAHPA reauthorization.

Dr. Parker, I want to ask you, would you agree that states need to be better prepared for the next public health emergency, in terms of having access to critical medical countermeasures such as diagnostics, PPE, treatments, et cetera?

*Dr. Parker. Well, some states are doing it already.

My state is taking those kind of actions. So I think, one, we absolutely need to make sure and bolster the Strategic National Stockpile that is managed by ASPR, no doubt about that, and improve that.

But, you know, I think if a state feels that they need to also have -- to not be completely dependent upon the SNS, that they need to take the actions that they need to do.

And I just remember during the H5N1 pandemic exercise preparedness in 2006 to 2009, one of the policy activities that Secretary Leavitt at the time was stockpiling antivirals was -- the concept was skin in the game.

*Mr. Carter. Absolutely.

*Dr. Parker. So the Federal Government, you know, paid three quarters of the stockpile, and the states paid 25 percent. So there was this policy of skin in the game for the stockpile of antivirals.

*Mr. Carter. Right.

*Dr. Parker. That was something you can go back and look at history.

*Mr. Carter. Well, again, my bill, parts of it were adopted last year in a two-year extension, so this will just

be another extension to get us through 2028.

Ms. Arthur, I wanted to ask you, what are -- what do you think the benefits are of states having the ability to stockpile products like this?

*Ms. Arthur. Well, thank you, Mr. Carter. Actually, this is an important opportunity for states.

All the states don't have the same necessary risks and exposures. So there are states that actually could be exposed to very different emerging infectious diseases that come to their region from areas that are close to them. This would allow those states to, for example, stockpile certain vaccines or antivirals specific to their needs for their population, where they may face different epidemiological risks than in other states.

*Mr. Carter. Good, thank you for that. Now, very quickly, I want to turn my attention to drug shortages.

And Mr. Okon, I wanted to ask you, can you talk about the recently passed so-called Inflation Reduction Act, and how it could impact drug shortages further?

*Mr. Okon. So the idea, Mr. Carter, of having a rebate on the inflation side of a brand name drug and a very

expensive brand name drug, fine, that makes sense. We supported that. But the idea of a low-cost, generic, where a generic manufacturer now is going to have no price control at all, that is a bad thing.

And the problem here is we call a drug a drug. And as a Member of the Congress who is a pharmacist, you understand it is very different in terms of these generic drugs, especially the injectable drugs, than these, you know, brand name drugs. And I think we need to realize that, and we need to change our view here, because when you simply add and you price-control these manufacturers, they are handcuffed, they are not going to do anything.

And let me just say one other fast thing. I will give you an early warning sign right now. I had a pharmacist from Dayton, Ohio this morning -- who is here, up on the Hill, talking about PBMs -- talk to the largest generic drug manufacturer out there. And this manufacturer says, "I am going to give you the list of the drugs that we are going to stop making,'' and those are cancer drugs. So this is a crisis. It is absolutely a crisis.

*Mr. Carter. Okay.

*Mr. Okon. We have to realize these are low-cost products that we are making literally not profitable at all.

*Mr. Carter. Absolutely. Well, thank you, and thank all of you again. This is extremely important, and we appreciate you being here.

And I yield back, Mr. Chairman.

*Mr. Burgess. The gentleman yields back. The chair thanks the gentleman, and the chair recognizes the gentlelady from Massachusetts for five minutes for questions.

*Mrs. Trahan. Thank you, Mr. Chairman.

As a co-founder and co-chair of the bipartisan Pandemic Preparedness Caucus, I have taken every opportunity in hearings like this one to highlight the unique opportunity that we have before us to take the lessons learned through the COVID-19 pandemic and apply them in a way that better prepares our health care system to respond to future unknown threats to our public health. So I am glad to see that the committee noticed some bipartisan policies for this hearing today, including my bill, the Disease X Act.

But I am disappointed that the majority has decided to move forward with flat funding for the preparedness programs

that sit within PAHPA, as well as exclude numerous FDA supply chain policies.

Mr. Chairman, I am concerned with static funding that falls well short of what frontline health workers, public health experts, and infectious disease specialists have said is necessary to prevent another COVID level pandemic.

How many times did the predicted death toll change over the course of the pandemic? First it was 50 to 60,000 deaths, then it was 100,000. Every month the projection went higher, while we heard countless cases of nurses and doctors reusing masks and wearing trash bags to protect themselves as states raced against each other and the Federal Government for shipments of PPE, as hospitals begged ventilator companies for just one more machine to help keep patients alive.

Now, three-and-a-half years later, after the first COVID case was discovered in the United States, more than one million Americans have tragically lost their lives to the virus. We can and we should be looking for ways to do better, moving forward, to ensure that we are never caught flat-footed again.

I am grateful to my colleagues on both sides of the aisle who recognize the importance and the urgency in achieving that goal. Last week I introduced the Disease X Act alongside Dr. Burgess, Congressman Crenshaw, and Congresswoman Lee to establish a Disease X medical countermeasures program at BARDA for unknown viral threats with pandemic potential.

Current funding constraints at BARDA only allow the agency to go so far. With much of BARDA's MCM development work focused on a defined list of chemicals, biological, radiological, and nuclear threat agents, as well as influenza, we may not be prepared to develop and manufacture at scale future drugs and vaccines against unknown viral threats that can lead to devastating pandemics. The Disease X Act will help BARDA to fully focus on their full list of priorities, including an increased emphasis on emerging infectious diseases with pandemic potential.

Ms. Arthur, BIO supported the introduction of the bipartisan Disease X Act, and I am hoping you can explain the importance of this bill, given the difference in the threat landscape now compared with the last PAHPA reauthorization.

*Ms. Arthur. Well, thank you, Congresswoman Trahan, for introducing that bill.

This is actually an opportunity to do activities in R&D and manufacturing scale-up during the interpandemic period that could make us better prepared in the future. We actually learned this lesson, even if you look at our response to monkeypox. The great investments made by the partnership between industry and BARDA and the NIH to make the smallpox antivirals and the smallpox vaccines actually allowed us, because of that viral family, to have the products for Mpox that we needed.

So taking that same approach here, we would actually work on platform technologies, monoclonal antibodies, and mechanisms for new oral antivirals, and put those to work against a host of known pandemic threats. And then those particular products might result in products for known threats, but actually would allow us to respond maybe within 100 days to an unknown threat.

*Mrs. Trahan. And just continuing on with the proposed Disease X program at BARDA, how important do you think it will be to have dedicated funding authorized for this

program, rather than just pulling funding from BARDA's general medical countermeasures pot?

*Ms. Arthur. We think it is actually very important that this have its own dedicated funding line. If that is not possible, although I think that is the right approach, really scaling up BARDA's overall number to more like what is in the PHEMCE multi-year budget, 1.5 to $1.6 billion, would give them the flexibility to work on what we know is already part of their strategy, which is to do platform-agnostic work around viral families. So a separate line item would be optimal, but scaling up the budget would also be important.

*Mrs. Trahan. Thank you, Ms. Arthur.

Everyone here today represents a family who lost a loved one to COVID-19. And each of us represents a small business owner who was forced to close their doors, some for good, because of the emergency. We represent children who lost out on a valuable in-person learning so that they could keep themselves and their families safe when we knew next to nothing about the virus. So as members of this committee, we have an obligation to take lessons learned from the past three years and make investments now to prevent another

catastrophic pandemic. And the Disease Act [sic] will help us get there.

So I look forward to working with members of the committee to pass this legislation with the funding it requires. Thank you, Mr. Chairman. I yield back.

*Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady. The chair recognizes Dr. Joyce for five minutes for questions.

*Mr. Joyce. Thank you, Mr. Chairman, and thanks to our panel for appearing here today.

It is disappointing that we are not meeting today to examine a bipartisan reauthorization of PAHPA. As our nation emerges from one of the largest and worst global pandemics in recorded history, we need to be moving together on this.

With that said, Mr. Okon, thank you for your testimony because I believe it adds important context to the drugs and the issues that we are facing today. I have heard from health providers in my district in Pennsylvania from as large as the University of Pittsburgh Medical Center, which is the largest health care provider in Pennsylvania, to small individual practices about the acute shortages of both

carboplatin and cisplatin. This is a serious issue, as you alluded to previously in your testimony, with potential to cause delays in cares for patients, which are detrimental to outcomes when it comes to treating cancer.

These shortages, they are not a new phenomenon, and they have been known to occur because of poor policy decisions that have hollowed out the generic manufacturing capacity right here in the United States.

Mr. Okon, can you please elaborate on the impact of both the 340B drug pricing program and the IRA, and what they are having on the economics of generic manufacturing?

And do you feel that Congress needs to address these matters holistically to avoid these shortfalls continuing?

*Mr. Okon. Dr. Joyce, let me state for the record, because I always get misquoted on this, the 340B drug discount program is an essential program to help communities and, basically, patients in need.

*Mr. Joyce. I concur with that.

*Mr. Okon. And I know you do. And the problem is, though, when you take discounts and rebates, and you apply them to what is a very low-priced drug to begin with, in many

cases these drugs are underwater.

Likewise, on the Inflation Reduction Act, which I just told Mr. Carter -- on the brand name, the inflation reduction piece of that on brand names, that may be a good policy. But the problem is on the generic side you take away the pricing power. So if you have a generic manufacturer that has to literally invest more in their facilities and do the things the FDA is telling them to do, you have taken away their pricing power because, again, we are talking about very low-cost drugs.

So you don't want to constrain them. And in fact, the reimbursement system, the -- literally, that provision of the Inflation Reduction Act and these mandatory discounts and rebates are pushing these products all overseas, and even overseas you have manufacturers that are stopping their capacity.

*Mr. Joyce. Thank you. And I want to finally ask you to address the wholesale overhaul of generic drug manufacturing and reimbursement. And is that appropriately done in legislation that is supposedly narrowly targeted on emergency preparedness?

*Mr. Okon. We need comprehensive legislation to literally address the drug shortages. And if we don't, they are going to get worse, and Americans are going to die, even more than the half-million Americans that Dr. Gralow said.

So we need to literally strip away the denial, we need to realize that, yes, there are warning signs, there are definite things that Dr. Gralow talked about that are important, but we need to address this root financial cause, and that should be in comprehensive legislation, and should be a top priority of this committee.

*Mr. Joyce. Thank you, Mr. Okon.

The Pandemic All-Hazards Preparedness Act is not just about preparing for emerging infectious diseases, but ensuring that our country is prepared to respond to a myriad of threats, including nuclear, chemical, and bioterrorism.

According to the unclassified version of the Annual Threat Assessment of the U.S. intelligence community released by the Director of National Intelligence this year, the lack of preparedness and response in questions around COVID origins -- and I quote -- "may inspire some adversaries to consider options related to the development of biologic

weapons.'' This unclassified report specifically calls out China, Iran, North Korea, and Russia.

Dr. Parker, given your background and work with both DoD and the U.S. Army Medical Research Institute of Infectious Diseases, how well equipped are ASPR and BARDA to prepare for and respond to a myriad of threats, including biological weapons? And if not, what should be done?

*Dr. Parker. Well, first we are much better prepared than we used to be going back, say, 20 years ago, before the Administration and Congress began to provide new authorities and appropriations, things like Project BioShield and so forth. So we are better prepared than we were 20 years ago, but we still have a long way to go.

I have been studying the biological threat, either the intentional, whether bioterrorism, biological warfare, for quite some time. And there is no doubt that, unfortunately, our experience with COVID probably has increased our risk to biological threat from an unnatural cause.

And so we have to take -- the work that you are doing in this committee is absolutely essential to help give ASPR, BARDA the additional tools and appropriations so we can be

better prepared, because we will be surprised.

*Mr. Joyce. My time has expired, but I would like to agree with you that those additional tools need to come through this committee.

Thank you, Mr. Chair, and I yield.

*Mr. Burgess. The gentleman's time has expired. The chair thanks the gentleman. The chair now recognizes Dr. Ruiz for five minutes for questions, please.

*Mr. Ruiz. Thank you.

As an emergency medicine physician trained in humanitarian disaster aid, I have seen firsthand how critical preparedness is to mobilizing an effective emergency response. And as we have talked about numerous times in this committee, COVID has taught us numerous lessons about how to better be prepared for the next public health emergency.

Leading up to the COVID-19 pandemic, funding for public health programs had declined significantly over time. We saw the consequences of that under-investment when the pandemic hit, and public health departments across the country did not have the staff or resources to respond.

Now, I am not suggesting that we need the same level of

funding on an annual basis than we do in the throes of a pandemic. I do, however, feel that it is important to our conversation here today that -- discuss the implication of years of under-funding that landed us in a place where we were not as prepared as we could and should have been. We would be foolish not to course-correct now.

And if now, on the heels of the largest pandemic in 100 years, during which over a million Americans have lost their lives and countless others continue to suffer from long COVID, if we can't make smart, robust investments into our public health systems, did we really learn our lesson at all?

So I urge the majority, as we move forward in this reauthorization process, to help ensure that history doesn't repeat itself, and that the next time we have a robust -- that we have a robust, well-funded system to meet challenges as they arrive.

Of course, I am not suggesting that we simply throw money at the problem. Our investments must be smart and strategic, and investment goes beyond funding. It is also about investing in smart policies that make our public health systems more efficient and effective. Included in that

bucket is addressing our policies surrounding data sharing, both from state and local health systems to the Federal Government and the other way around.

Science is guided by data, and public health decisions are guided by science. Guidelines and recommendations and next-step decisions are more effective when they use scientific data to inform them. And we saw how barriers to data sharing really hurt our public health officials throughout all levels, from the head of the CDC to the local health departments.

Dr. Washington, in your written testimony you talk about the importance of giving CDC the authority to collect and coordinate public health data necessary to serve its mission, and state that, "The current framework for collecting and sharing public health data has resulted in fragmented and inconsistent reporting to CDC and to state and local partners.'' Can you tell us how the Data and Public Health Act under consideration today would address those problems?

*Dr. Washington. Certainly. So I will say -- and I agree with a lot of what you just said, and I appreciate the comments. We must have an ability to collect information,

and we have to have the ability to collect it in a timely fashion. And having the authority to collect that information without having to negotiate agreements with every single institution, every single state, every single local jurisdiction to be able to share information is a huge administrative and highly inefficient way for us to be able to achieve our goals and to actually have a system where data flows freely between those institutions.

I am not saying it should just flow. It, obviously, should be as needed. But we have got to have the connectivity, we have got to have the authority that allows us to then move as quickly as possible.

When COVID happened, we had to authorize that data about COVID could be collected. It was not a known condition, and so it wasn't reportable. So we had to go through the regulatory process to make it reportable, which takes time.

*Mr. Ruiz. You know, we often talk about the importance of the CDC being able to collect data from state and local health officials. But often lost in that discussion is the importance of two-way data sharing, not simply CDC collecting the data, but also being able to share data to the folks on

the ground.

Dr. Washington, can you tell us how this kind of data sharing for you at the city level can help public health officials navigate through the various stages of a public health emergency like COVID or Mpox?

*Dr. Washington. It is absolutely essential. So I will take Mpox as an example.

So CDC allocates -- allocated vaccines to jurisdictions based on the disease burden in their communities. If the data that they are making those decisions on is not real-time and up to date -- for example, we had a couple of cases, but within a matter of a few weeks that went from a couple of cases to almost 100. And so the decision -- and we didn't get enough vaccine to be able to respond on the ground, because they were using data that was out of date. And so it is really important for us to have access --

*Mr. Ruiz. One last question. You know, I spoke about the importance of adequate investment in public health and updating our public health data system. What barriers did you face that would be addressed simply by investing in new data system technologies?

*Dr. Washington. So the reporting to the public, for one, was a great example where people were not receiving information. We had three different numbers from local, state, and Federal partners in terms of what the disease burden was. And that is why we have to have that chain that flows up and down between us all at the same time.

*Mr. Ruiz. Thank you.

I yield back.

*Mr. Burgess. The chair thanks the gentleman, the gentleman yields back. The chair now recognizes the gentlelady from Tennessee, Mrs. Harshbarger, for five minutes for questions.

*Mrs. Harshbarger. Thank you, Mr. Chairman. Thank you all for being here because I got a lot of questions, but I will have to submit a lot for the record.

[The information follows:]

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

*Mrs. Harshbarger. I want to start by talking about emerging infectious diseases, and the primary purpose and mission of ASPR is to ensure our nation in preparing for all hazards, including those posed by deliberate chemical, biological, nuclear, and radiological, or CBRN, threats. And, you know, the escalating actions by Russia -- you know, invading Ukraine -- and threats of chemical warfare are -- you know, that is on everybody's mind. And I have been a compounding pharmacists for 36 years, and I remember after 9/11 I had people lining up at my door for iodine tablets because they were afraid of nuclear fallout.

So I guess my question is what are your thoughts on how BARDA should best be engaging with the private-sector partners to prioritize America's stockpile of critical CBRN vaccines, treatments, PPE, and ensuring they are well maintained, and also to ensure there is no disruption in the availability of these supplies?

And I guess I could ask you, Dr. Parker, and then I will go to you, Ms. Arthur.

*Dr. Parker. Sure, and BARDA has focused on the CBRN threat for quite some time. In fact, I recall my time in

ASPR even before it was ASPR -- it was called OPHEP -- but we were very concerned about the nuclear threat.

*Mrs. Harshbarger. Yes.

*Dr. Parker. And the radiation threat. And actually, some of the acquisition programs started back then for stockpiling some drugs that are now in the SNS for the nuclear threat.

And I think, you know, the current-day -- we cannot discount the nuclear threat, weapons of mass destruction, and chem and bio. So we cannot be complacent about that. BARDA has programs to interface with the private sector and those kind of programs, and Project BioShield was originally enacted very specifically for the biological threat, but all weapons of mass destruction.

So we just need to -- we need to keep emphasizing those programs, and emphasizing that is a problem. And states and locals also have to exercise because it is a huge, huge problem when you think about what happens if there is a nuclear detonation in one of our communities. It is huge. And I have been in several national exercises, and it is -- we not -- we should not be complacent.

*Mrs. Harshbarger. No, we can't be complacent.

Ms. Arthur?

*Ms. Arthur. No, of course, I agree with Dr. Parker. Thanks for that question.

I think industry actually really wants to bring some novel technologies to bear in this space. They are working on products that could help, like wearables, to help notice that you have been exposed to chemical agents or nerve agents, working both with the DoD and BARDA together. And I think this is a place, in particular, where DoD, in partnership with industry, actually could give us products that could help us, the warfighter as well as national security defense.

*Mrs. Harshbarger. Yes, I have talked to some innovative companies that work on oral medications, too, to help with some of that.

Mr. Okon, you know, I have talked to you many, many times.

And Dr. Gralow, listen, we know the FDA. Even the drug shortage list is not comprehensive. They don't keep a comprehensive list. I have compounded sterile products for

many years. At any given time there is 300 drug shortages on a list, okay?

We need to reform some of the things with the FDA, and especially with, you know, the -- just like you said, Ted, it is about the reimbursement. Nobody is going to make a product if they lose money. That is just not going to happen. And we need to reform that and, you know, get an updated list. There is many, many things we can work on -- 340B programs, things like that.

You know, one of the things -- Ms. Arthur, I have the only plant in the country, a penicillin-producing plant in the country, and I had to go through the designation of getting that designated as critical infrastructure. That is another thing we may look at doing for different facilities -- antibiotic resistance, like Representative Barragan was talking about. There is -- and I talked to someone in the Biden Administration about having 20 antibiotics on a list that we have to have for 330 million Americans.

There is a lot of things we need to do, Ted. And I just read an article -- and it was dated June 2nd -- that the FDA is going to allow an unapproved cisplatin to be used in this

country. They haven't even been inspected since 2019 in that facility. That is what we are coming up to. And we have 503(b) facilities, compounding facilities that are FDA registered, that can fill that gap. But the price is going to be enormous.

We can be on the front lines as compounding pharmacists and, you know, take care of those patients, but they have to allow us to do that, and some of the reduced regulations. So I will talk to you all about that later. There is a lot we have to think about.

And thank you all for your time. And with that I will yield back.

*Mr. Guthrie. [Presiding] The gentlelady yields back. The chair now recognizes the gentleman from Indiana, Mr. Pence, for five minutes for questions.

*Mr. Pence. Thank you, Chairman Guthrie and everyone appearing here today.

I am proud to lead the Diagnostic Testing Preparedness Plan Act with my colleagues Congressman Bucshon, Congressman Carson, and Congresswoman Schrier.

Diagnostic testing capabilities are crucial for the

successful disease outbreak containment during a public health emergency. Our country relies on diagnostic testing as a critical component of our medical countermeasures response strategy. Innovators in the Hoosier State such as Roche Diagnostics have been leading the charge to ensure the nation has safe and reliable diagnostics.

It is important for HHS have a blueprint that would facilitate the innovation and development of diagnostics during a PHE. This bill would direct HHS to develop a plan describing the process of rapid development, approval, scaling, procurement, and distribution of diagnostics.

In addition, my legislation would ensure HHS is prepared to communicate and collaborate with the private and public sectors to ensure diagnostics are readily available.

I look forward to working with my colleagues on the Energy and Commerce Committee to get this legislation across the finish line.

Dr. Parker, based on your time as principal deputy assistant secretary for preparedness and response, can you explain the importance of ASPR coordinating with the private sector to meet the demand for diagnostic testing during

public health emergencies?

*Dr. Parker. Yes, absolutely, and it is absolutely essential that we have these, and we have talked about this a lot today, about the importance of the private sector and the importance of public-private partnerships. And I think ASPR and BARDA over the years have done a lot to improve their ability to interact with the private sector, but we can always do better.

And this is a -- the diagnostics is one that is -- they are all important, but this is certainly essential, because this really guides a lot of our decision-making early in a pandemic, early in an outbreak, and to rapidly surge and to make sure that we have distributed diagnostics and point-of-need diagnostics and home diagnostics is essential.

So the plan is well warranted. I support the initiative, and we just do everything we can to improve those public-private partnerships, make them functional.

*Mr. Pence. Okay, thank you.

Ms. Arthur, I heard you state earlier the -- that you think increased coordination and collaboration with the private sector would improve the country's response during

future public health emergencies. How would the United States benefit from a pre-approved diagnostic testing preparedness plan?

*Ms. Arthur. Thank you for that question. It is actually really important to have a plan. It actually guides industry in what can be developed, and actually allows industry to work on some of those things during peacetime. And I think this is one of the advantages.

Now that we have had innovation in diagnostics and tests and tooling, including home tests, which we never had before, that actually can springboard into even more investment in actually technologies like that. So having that public-private partnership where the government sets out what they are trying to achieve in a pandemic allows industry to work towards that goal in partnership with them.

*Mr. Pence. Okay, thank you.

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

*Mr. Guthrie. The gentleman yields back. The chair now recognizes Dr. Dunn for five minutes for the purpose of questions.

*Mr. Dunn. Sorry, I didn't know I was next.

[Laughter.]

*Mr. Dunn. Thank you, Mr. Chairman. I appreciate the opportunity to analyze the legislation that may accompany the reauthorization of the Pandemic Preparedness Act. The expiration of this important bill comes at a time when we have learned many valuable lessons about enduring a pandemic, and now we have an opportunity to put those lessons into practice.

It is important to ensure the Strategic National Stockpile, BARDA, Project BioShield, other programs designed to assist in Federal response, that they are all retuned for a more timely, coordinated, and successful response next time, because, unfortunately, there will be a next time.

I appreciate the transparency measures put forth by Chair Rodgers, which will ensure that the CDC guidance has integrity and does not jeopardize the well-being of American citizens. We have learned of undue influences over the agency during the COVID-19 pandemic and the grave dangers and damage associated with extended lockdowns. We must never allow a Federal agency to issue such sweeping, binding, and inaccurate guidance in an emergency again.

Other important measures included in the discussion drafts before us today will ensure proper congressional oversight, and shed light on the decision-making of health agency bureaucrats. I appreciate my colleague, Congresswoman Dingell, for working with me on the Ensuring Sufficient Supply of Testing Act, which will ensure that key diagnostic testing supplies and equipment needed to develop and run testing at scale are available and accessible to clinical laboratories in times of emergency.

This bill will ensure that clinical laboratories will be able to enter the Strategic National Stockpile contracts.

It is also critically important that the Strategic National Stockpile include test kits, reagents, precision plastics, and other tools that labs rely on to rapidly scale their responses. Labs played a critical role in response to the SARS-CoV-2 pandemic. In the early days of the spread of COVID-19, testing was one of the few tools at our disposal to understand the nature of the pathogen.

Testing is also an important aspect of surveillance, which is an area where improvement and increased coordination is greatly needed. I would also like to thank my colleagues,

Representative Crenshaw and Peters, for putting on a discussion draft on this very topic: the Bio Early Warning Plan.

We need better coordination between public health agencies and the intelligence community. We may have avoided the entire pandemic, had the intel community had more visibility into the grants that NIH was funding. A more coordinated effort is needed for a whole-of-government defense and response to future pandemics.

Dr. Washington, you have discussed at length today the problems that your department had accessing testing early in the pandemic. I hope that the bills that you -- have been proposed by myself, Representative Dingell, Representative Pence, and others, I hope that these bills will prevent that in your -- happening to you in the future. I certainly feel your pain.

Dr. Parker, it is always good to see you, a fellow USAMRIID staffer from the old days. I appreciate your written testimony in some detail. I have read that and reviewed it. Thank you for that input. Your emphasis on the national security considerations and the need for

coordination between DoD and health agencies is very well outlined. And you also outlined many gaps in the coordination, and made some smart recommendations that can truly help us be prepared for the next pandemic.

Let me ask you, what would your recommendations be to encourage more coordination before -- before -- a pandemic breaks out? Clearly, we had a blind spot when it came to the Wuhan Institute of Virology.

*Dr. Parker. Well, I mean, that is the issue, I think, across the whole preparedness enterprise, whatever component we are thinking about, is how do we make progress during the inter-crisis period, if it is all hazards or emerging infectious diseases. That is where we have been challenged over the years. We cannot sustain our efforts after a crisis is over, and so that -- we have to figure that out. We just really have to figure that out, taking actions during the -- between crisis.

Now, there is -- the health community and the intelligence community and the law enforcement community, we absolutely have to figure out how to better coordinate. Now, there has been coordination over the years. I know my

career, I -- that is why I call myself -- I have worked in health security, because I spanned those -- that gap pretty well during my career. But we have to span that gap.

And I would say that some of our science agencies, our health agencies, we need to make sure that some of the leaders actually are pretty aware of some of the more detailed information that may be in the DNI's annual threat assessments that is on the classified side. So I think our health agencies need to be more aware of some of the security concerns, and need to be more security aware and have more of a security culture.

*Mr. Dunn. Well, we are both familiar with some routine surveillance technologies that were in place, even back when I was at USAMRIID. So thank you very much for your information, your insights.

I thank all the panel for your comments today, a terrific panel, really outstanding.

Mr. Chair, I yield back.

*Mr. Guthrie. The gentleman yields back. The chair now recognizes the gentleman from Texas, Mr. Crenshaw, for five minutes.

*Mr. Crenshaw. Thank you, Mr. Chair.

I think every American should be concerned about the next pandemic because of how terribly our government handled the last one. Not only did the government lock down schools and businesses and mislead the public, but we were caught flat-footed at the outset of the pandemic. We were unable to identify the threat we were facing, and where that threat was coming from, and that had pretty severe consequences for the way we responded to COVID. And I think this committee should aim to fix that.

Moving forward, the American Government must be able to quickly identify the source and severity of an emerging public health threat. That capability is required under law right now that we are still falling short of where we need to be. In fact, the Government Accountability Office found that "more than 15 years after the law initially mandated it, the Federal Government does not yet have this needed situational awareness capability'' to identify and respond to these threats.

Moreover, the Government Accountability Office says we need a "lead operational division to address this deficiency

in our response capabilities,'' and I will be filing this report for the record.

So, you know, to sum it up, there is no one in charge, and that is a problem.

For Dr. Parker I have this question: Should the Administration for Strategic Preparedness and Response create a strategy and implementation plan to aid our preparedness and attribute future threats?

*Dr. Parker. Well, yes, we absolutely need a strategy for attribution, and we need -- an attribution is important, whether it is natural or unnatural. Kind of, the attribution kind of gets more in the unnatural. And I think about national command authority authorities. So whether ASPR, at the end of the day, is in charge of the unnatural attribution, I am not sure about that. But nonetheless, this committee could certainly require that HHS, DHS, DoD, DNI, DoE -- who has actually some very good laboratory capabilities -- develop a strategy for attribution.

*Mr. Crenshaw. Attribution and a kind of a single point of action and coordination, as well, would you agree with that?

*Dr. Parker. I think that strategy would have to identify that. You would -- you should identify that they need to develop a strategy, and develop then who will be in charge.

*Mr. Crenshaw. Right. Well, and for that reason I am working on legislation called the Bio Early Warning Act with Representative Peters from California.

And our bill is really simple. It does create an operational strategy and supports private-sector technology that helps us identify every aspect of an emerging threat: where is it coming from, how serious is it, what should our response be. And we do this by, one, making sure the Department of Health and Human Services and the intelligence community are actually working together and sharing information, rather than working in silos; two, creating a government strategy for attributing threats; and three, having the Administration for Strategic Preparedness and Response work with the private sector to create and deploy defenses that might be needed to respond to whatever threat we face. And this could be anything from advancements in genetic sequencing to diagnostic testing to wastewater

surveillance.

It should be clear -- because there has been some misinformation put out by one three-letter agency -- that this bill does not take away authority from the agencies that are currently doing this work. We just need a singular point of action and accountability to coordinate this work, and that is what the bill does. It is what GAO has called for.

You know, we can't afford to have the same information failures we had with COVID, so we have to work to identify and respond to the dangerous threat landscape that is always evolving.

And another way to think of this is a joint operating environment in the military. It is confusing. You had Army, Navy, Marines, Air Force there sometimes -- not sure why --

[Laughter.]

*Mr. Crenshaw. But you always have a joint operating environment, and you have what is called combatant commands who is in charge of everyone in that operating environment working together. And you need -- you absolutely need something along those lines when you are talking about a pandemic, or a chemical attack, or a biological attack.

And of course, so I asked for my friend, Representative Richard -- also known as the admiral from Texas, also known as Dan Crenshaw's biggest fan -- Hudson, asked for his commitment to work with me to ensure that this is addressed in this year's PAHPA.

And with that, I yield back.

*Mr. Guthrie. The gentleman yields back. The chair now recognizes the gentlelady from Iowa, Dr. Miller-Meeks, for five minutes for questions.

*Ms. Meyers. Thank you, Mr. Chair, and I want to thank all the witnesses for testifying before the committee today.

[Pause.]

*Mrs. Miller-Meeks. This is a jerry-rigged system. No.

[Laughter.]

*Mrs. Miller-Meeks. From my time in the Army.

I am a physician, a former director of a department of public health, and I know how -- both how serious, how predictable another pandemic is; not when, but we know it will occur. And I also was, I think, the only Member of Congress, when we were passing the ARRP, or the second COVID bill in March of 2021, that spoke numerous times, both on the

floor of Congress and in committee, about the necessity of funding the non-competitive grants that go directly to local public health care agencies, not to the CDC, not to some other, you know, three-letter government agency, but non-competitive grants directly to local public health care.

And I am glad to see that my bill, H.R. 3837, the Improving Public Health Preparedness Act, is included in the hearing. And I thank my colleagues, Congressman Buddy Carter and Congressman Balderson, for cosponsoring the bill.

H.R. 3837 requires the HHS Secretary to delegate the maintenance and administration of the Strategic National Stockpile to the Administration for Strategic Preparedness and Response, which further enhances ASPR's authority over the SNS.

SNS had a few homes since it was established in 1999 -- CDC, DHS, back to CDC, and then to ASPR in 2013 -- and operates most effectively under ASPR's jurisdiction, which is why their authority was expanded in 2018 under the last Pandemic and All-Hazards Preparedness Act, or PAHPA. This legislation is a clean codification of SNS's current authority, which would bring welcomed stability and clarity.

Furthermore, it seeks to demonstrate ASPR's leadership as the lead agency for our nation's preparedness and response to public health security threats, as we just heard through the last question and response.

Dr. Parker, in your written testimony you say the SNS, along with other offices, belong together under ASPR, and that they are each better served in this structure. Can you please explain why you believe this?

*Dr. Parker. Sure. I mean, I think it is very -- and I am really happy to see this legislation.

It makes a lot of sense to have BARDA, the Strategic National Stockpile, the industrial base supply management components of ASPR consolidated under the ASPR.

And I think, you know, then how is the ASPR also going to manage and integrate -- make sure that there is an integrated, seamless flow between the development of medical countermeasures, the acquisition, the procurement, the stockpiling, and also ensuring that the industrial supply chains are more resilient?

So it makes -- it is just logical that they are together. And it is also logical -- we talked about in NDMS

and the support of the health care system also -- they are just logical that they are together.

*Mrs. Miller-Meeks. Yes, I couldn't agree more. I had a bill in the last term on medical countermeasures that went through Homeland Security, as I was a member of Homeland Security. So having this -- efforts that are helping to coordinate coordinated, I think, would be beneficial.

Ms. Arthur, in your testimony you state that the SNS needs adequate resources to allow ASPR to manage the full lifecycle of all medical countermeasures developed under BARDA. Using existing funding and resources, do you believe that SNS is most equipped to manage medical countermeasures while under ASPR's authority?

And what changes in SNS's structure would Congress consider to ensure we are stockpiling the most modern and effective MCMs?

*Ms. Arthur. Thank you so much for the question.

I agree with Dr. Parker. This is an extremely important aspect of the role of ASPR. They actually work closely with their industry partners to manage the lifecycle of particularly those medical countermeasures that are going to

be stockpiled in the SNS. And so having that end-to-end view of how those products will be used, how they are stockpiled, sharing the requirements, doing replenishment is a core role of ASPR. And anything that can strengthen their ability to share those requirements with their industry partners and do active replenishment with the right funding for the SNS will be a support for pandemic preparedness.

*Mrs. Miller-Meeks. Thank you.

I yield back and thank you, Chair, for this important hearing.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair now recognizes the gentleman from Indiana, Dr. Bucshon, for five minutes.

*Mr. Bucshon. Thank you very much, a lot going on today, thank you for being here, I appreciate it. And thanks, Chairman and, again, thanks for all the witnesses being here.

I think it -- you know, as we go through today's hearing and -- we keep our focus on the topic of preparedness and understand that the types of threats that we are preparing for are the types that we hope we never actually have to

respond to.

However, having just lived through the worst global pandemic in over a century, we have all seen just how important it is that we not only get this bill right, but that we keep it tightly focused on the real threats we face and need to prepare for. Ultimately, I believe that, here, that less is more. The less we turn our preparedness efforts into the usual Washington, D.C. -- what we call the Christmas tree of policies that result in the government doing a bunch of things, and some of which we won't do well.

So first, Ms. Arthur, BARDA has historically been very successful partnering with industry on medical countermeasures, leading to 77 FDA approvals. During the COVID-19 pandemic we saw how -- just how critical innovation was to saving lives and getting us back to normal.

And some of this you may have already answered, I apologize, but how would changes to Barda and the SNS, or the Strategic National Stockpile, contracts to include reasonable pricing, or IP, march-in provisions impact how private sector industry works with ASPR, BARDA, and the SNS in the future?

*Ms. Arthur. Thank you very much for this question. It

is very important.

So policies on reasonable pricing and march-in rights have actually been tried in other programs, other public and private programs, and they have actually had a huge dampening effect on innovation, very negative effect.

In the medical countermeasures space, this could actually be even worse, because these are products that already have a high risk to their development and, in general, have a limited marketplace that -- and a major buyer, which is the U.S. Government. So if suddenly companies that wanted to bring their novel technologies to bear on an unmet medical need identified for the government for national security purposes faced IP risk or challenges to their pricing for products that generally did not have a guaranteed commercial market, you would see companies have a very hard time deciding to work on these key products.

*Mr. Bucshon. Yes, it would stifle innovation and that type of thing. Thank you for that.

And Mr. Okon, the COVID-19 pandemic demonstrated that -- the critical need to have the supply chain and manufacturing capacity in place to be able to quickly respond to a future

threat. I think we all know that. Unfortunately, the supply chain and the manufacturing capacity challenges were longstanding prior to COVID-19. We all know that. And while a lot of the focus will be spent on incentives in this space, I think we also need to look at how existing Federal policies can negatively impact the supply chain and manufacturing capacity.

You mentioned 340B drug discounts are contributing to cancer drug shortages. Can you walk me through why this is the case?

*Mr. Okon. You know, I said for -- and I will repeat it again, because it is on the record, Dr. Bucshon, as I know you do, believe that the 340B is a valuable program. And the problem is, when you take a low-cost drug to begin with, and you demand other rebates and discounts like 340B discounts on top of it, you are going to produce a product that, in many cases, has a negative return for these generic manufacturers. It is not worth them producing it.

And I think it was Dr. Gralow actually said this is a U.S. problem, what we are seeing. The problem is nowhere in the world do you see the discounts and the rebates that we

end up having here. And we have to realize that 340B Medicaid rebates -- valuable, I mean, valuable programs, but pushed down these very low-cost products to such a level that they are simply unprofitable to make.

*Mr. Bucshon. Yes, I mean, I understand that. As I think most of the people know in Washington, I am working on a level of transparency in the 340B program that just lets us all know, you know, how it is functioning, and how the congressional intent of the original creation of the program is being followed. And there is some evidence that that is not the case, and it may be challenging the program's future.

And again, I am a huge supporter of 340B. My smaller, rural hospitals absolutely have to have this program. So I think -- I just want to make it clear again on the record that I am a big supporter. But we do need a level of transparency, I think. And you know who else said that? Secretary Becerra. And who else said that? President Biden, in his budget. So, you know, drug shortages is one area, but also formulary access to lower-cost drugs, where generics can't get on formulas because there is not a big enough rebate and the list price isn't high enough.

So thank you for that answer.

And with that, Chairman, I yield back.

*Mr. Guthrie. Dr. Bucshon yields back. We have now completed members of the subcommittee, and we have one member of the full committee waiving on, and that is Mr. Balderson of Ohio.

You are recognized for five minutes for questions.

*Mr. Balderson. Thank you, Mr. Chairman. I didn't know you called me out like that.

[Laughter.]

*Mr. Balderson. I am waived on, so thank you for allowing me the opportunity to do this. My first question is for Dr. Parker. Thank you all for being here, though.

But I want to thank Richard Hudson for his leadership on this issue, and for introducing the Medical and Health Stockpile Accountability Act. I was proud to cosponsor this bill, along with Mr. Gottheimer and my fellow co-chair of the Pandemic Preparedness Caucus Mrs. Trahan. This important bill will provide real-time updates of medical and health supply inventories nationwide. This will eliminate the delays and errors we saw during the COVID pandemic, and

ensure that our local health care providers have the supplies they need when they need them.

Dr. Parker, I agree with you on your assessment that our pandemic response lacks a central authority to set the agenda and provide direction across multiple departments and agencies. I am concerned, though, that President Biden has not -- still not appointed a director for the White House Office of Pandemic Preparedness and Response.

Dr. Parker, how can Congress differentiate and prevent duplicative work between ASPR and this new White House officer?

*Dr. Parker. Well, yes, and I have some comments in my written testimony about that, and I think, one, you know, I do think it is a great idea that at least we have authorized a pandemic preparedness and response policy office in the White House. It is unclear, though, how it is going to be implemented. And I think that now is the opportunity to consider how can biodefense and global health security and pandemic preparedness be consolidated under a leadership structure at the National Security Council Office of Science and -- Policy, however that is going to be done.

It is the opportunity now to consolidate it and appoint a person that -- I am going to use the analogy -- a combatant commander-type person that can focus on what are the policies, what are the budgetary priorities, and what are the plans and strategies that are going to be needed and an implementation plan across this space of biodefense and pandemic preparedness and global health security that can then drive better milestone outcomes, provide the guidance that is needed for industry, and align medical countermeasure -- in the case of medical countermeasures, the DoD programs, the HHS programs into a more singular focus.

You still need to allow, though, for decentralized execution at the department agency levels. You don't want to micromanage from the White House, but you can do this. You need the combatant commander that will provide the vision, the strategy, and an implementation plan, and hold the Department and agencies accountable. And Congress can also hold the Department and agencies accountable for meeting their milestones and metrics.

*Mr. Balderson. Thank you. Follow up. I appreciate and agree with your statements on the better integrating and

training state and local staff. Are there current examples of preparedness exercises or programs between state and local officials that we can look at as to a model?

*Dr. Parker. Well, I think over the years there has been a lot of, you know, like, national exercise, you know, and FEMA runs a national exercise program, and that usually involves state and local communities. And so we just need to do more of that. We don't do enough of it. And I think we need to be thinking about what are the scenarios that we might face, and -- because we might face some of these scenarios that I have talked about in my testimony, and we have done these -- our nation has done these in the past. But I think we need to go back and look at what are some of the truly catastrophic scenarios that we may face in the dangerous era that we find ourselves in now.

*Mr. Balderson. Okay, thank you.

Ms. Arthur, since I am the waiver-on guy, I don't want to be over my timeframe, so I am going to be pretty brief with you. I see that you chair the Healthcare Ready, which works with government, non-profit, and medical supply chains to strengthen health care systems before, during, and after

disasters.

We all know that it is the private sector, not the government, that leads, innovates, and advances. Can you explain when public-private partnerships are essential for resiliency versus times when Federal Government is in a way that is distracting?

*Ms. Arthur. Absolutely. So really, the health care system in America and the health care supply chain, in particular, is a private-sector endeavor. And that is what Healthcare Ready supports. It is extremely important, actually, therefore, that all the aspects, end to end, of the supply chain integrate with the Federal Government, state, and local governments, as well, in terms of making sure we can have all hands on deck when we need to respond to an emergency situation.

*Mr. Balderson. Thank you very much, and thank you all for being here today.

Mr. Chairman.

*Mr. Guthrie. Thank you. There is nothing you would have to apologize for waiving on. It is certainly within the right of the committee. I just want to make sure everybody

knew we have asked -- let everybody ask questions moving forward. So thanks, thanks, Mr. -- Troy, for being here today.

And so we have concluded members' questions. Thank you so much for your answers that have been very informative and been very helpful.

But first, a couple of things for business.

I ask unanimous consent to insert in the record the documents included on the staff hearing documents list, the list I just shared with you.

Without objection, that will be in order.

[The information follows:]

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

*Ms. Eshoo. So ordered.

*Mr. Guthrie. And I want to remind members that they have 10 business days to submit for the record questions for the record, and so that you could still receive questions, even after the hearing. And so we just ask that you respond to any questions in writing promptly. Members should submit their questions by the close of business on the 27th of June.

Again, thank you so much. I know it takes a lot of time and a lot of effort to be here to testify. It is very valuable. It really informs our decision-making, and it means a lot to -- for you to take the time and the effort that you may. Some of you travel some good distances to be here, and we appreciate it very much.

And without objection, the subcommittee is adjourned.

[Whereupon, at 1:39 p.m., the subcommittee was adjourned.]