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HIF131140

PREPARING FOR AND RESPONDING TO FUTURE PUBLIC HEALTH SECURITY THREATS

THURSDAY, MAY 11, 2023

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:03 a.m. in Room 2322 Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

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

Barragan, Blunt Rochester, Schrier, and Pallone (ex officio).

Also present: Representative Castor.

Staff Present: Kate Arey, Digital Director; Jolie Brochin, Clerk, Health; Jerry Couri, Deputy Chief Counsel for Environment; Grace Graham, Chief Counsel, Health; Tara Hupman, Chief Counsel; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Molly Lolli, Counsel, Health; Emma Schultheis, Staff Assistant; 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 Chief Health Counsel, Innovation, Data, and Commerce; Una Lee, Minority Chief Health Counsel; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; and C.J. Young, Minority Deputy Communications Director.

*Mr. Guthrie. The subcommittee will come to order, and the chair recognizes myself for five minutes for an opening statement.

I want to note today that today marks the official end of the COVID-19 public health emergency. The expiration of the public health emergency comes after more than a year of Republicans on this committee calling for the unwinding of the COVID-19 public health emergency and months since the People's House voted to end the COVID-19 public health emergency. While I believe this should have happened a long time ago, I am glad we are moving beyond this perpetual emergency declaration.

And today marks the end of Title 42 policy. I am extremely concerned about the flow of illicit fentanyl and other drugs into our communities from our southern border, especially without Title 42 in place. More needs to be done to stop illicit fentanyl from being trafficked into our communities, which H.R. 2, the Secure Border Act, would help address.

But as for today's hearing, we are continuing our bipartisan efforts to prepare and respond more effectively to

future public health security threats, including chemical, biological, radiological, nuclear, cyber attacks, or other infectious disease outbreak. This is the third hearing the Energy and Commerce Committee has held in the 118th Congress related to our response framework.

We now have a unique chance to look back and ask ourselves what worked, what failed, and identify bipartisan solutions on how we can improve. We should not use this as a chance to point fingers or lay blame. Instead, today's focus should be on the core elements of our preparedness and response strategy to address all types of hazards. Several key programs and authorities that are crucial to the U.S. preparedness and response will expire on September 30th. These are programs we are examining and considering today.

One area that can be improved is ensuring we are better utilizing the expertise of our private sector partners before a threat or emergency strikes to be better positioned to respond to future threats. For example, the Centers for Disease Control and Prevention did not have contracts with testing kit manufacturers until after the declaration of the COVID-19 public health emergency. This presented significant

challenges when attempting to standing -- to stand up a nationwide testing scheme at the beginning of the pandemic. It caused delays in the delivery of supplies, and negatively impacted patient care, and caused challenges in grasping the full extent of the spread when time was crucial.

When it comes to utilizing private sector partners while responding to a pandemic or another threat, Operation Warp Speed was a successful private-public partnership, and should be viewed as a model going forward.

Fortunately, we have already taken steps to make reforms and restore trust in the core public health agencies. As part of the end-of-year omnibus, we improved the Strategic National Stockpile and put measures in place to hold our public agencies such as the CDC and NIH more accountable. This includes strengthening research integrity protocols at NIH, and requiring Senate confirmation of the CDC director.

We must continue to build off this work by advancing policies to ensure our public health agencies are focused on their core missions. One of these agencies is Administration for Strategic Preparedness Response or ASPR. ASPR announced last year it is moving from a staffing division to an

operating division. I recognize ASPR and this Administration are requesting new authorities in response to this change. However, before this committee can consider expanding the scope of this agency, we need to look at strategically how ASPR handled this most recent public health emergency, the effectiveness of its response, and determine if its already existing current authorities were utilized appropriately.

In closing, public health security is national security. This committee will ensure we are better prepared when the next public health security threat -- strike threats -- threats strike. I look forward to hearing to -- I look forward to hearing the testimony from Administration and expert witnesses today, and working alongside my colleagues on addressing these issues in a bipartisan manner.

[The prepared statement of Mr. Guthrie follows:]

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

*Mr. Guthrie. I now recognize the gentlelady from California, Rep. Eshoo, for five minutes for an opening statement.

*Ms. Eshoo. Thank you, Mr. Chairman, and good morning to you, to colleagues, and to our star witnesses here today. Thank you.

This hearing is an important first step to reauthorizing the Pandemic and All-Hazards Preparedness Act, also known as PAHPA. It is a priority for me that the PAHPA reauthorization is a product of bipartisan negotiation and compromise, and I am proud to work with Congressman Richard Hudson, a terrific partner -- t is a great way to start, when you have a terrific partner -- to pass this law before the September 30th deadline.

Representative Hudson and I issued a bipartisan request for information on February 27th to seek input on PAHPA, and we have received over 250 responses from a full range of medical and public health stakeholders. So this is an important and -- a very important first step and start on this, and we are grateful to all the stakeholders for responding.

My thanks to our witnesses for the valuable perspectives you are going to share with us today, and for your important work on the front lines protecting, preparing, responding to public health emergencies.

In 2001 our country endured the attacks of September 11th, and the anthrax attacks shortly thereafter. That may be deeply buried in the past; it is vivid to me. And at that time Congress realized our country was not prepared to coordinate responses to mass casualty events or chemical attacks.

I authored legislation with then-Representative Richard Burr, who was a member of this committee, that established the Office of the Assistant Secretary for Preparedness and Response, ASPR, to be responsible for coordinating Federal responses, and the Biomedical Advanced Research and Development Authority, BARDA, to be responsible -- and Richard and I did that law together, that legislation -- to be responsible for developing desperately-needed medical countermeasures for chemical, biological, radiological, and nuclear threats.

That important bipartisan legislation was signed into

law in 2006, and was most recently reauthorized in 2019, an effort I led with really another great, great partner -- I miss her to this day -- former Congresswoman Susan Brooks. She really served with distinction on this committee.

Since its creation, BARDA has been hugely successful, and I am enormously proud of that. Its efforts have led to 69 FDA licensures, approvals, and clearances of medical countermeasures. Without BARDA's important work, we would not have been blessed with a safe and effective COVID vaccine as quickly as we were. BARDA now needs additional investments and authorities so that it can continue to develop technologies and platforms that can rapidly produce vaccines, therapeutics, diagnostics, and other tools to protect our nation from potential threats.

This PAHPA reauthorization has to meet the challenges we witnessed during the COVID pandemic and anticipate the challenges of the future. I will never, ever, ever forget the following: turning on my TV set, and seeing our nation's health care workers wrapping themselves in black garbage bags, plastic garbage bags. And it was because they lacked proper personal protective equipment.

Like many Members of Congress, I spent 2020 trying to secure ventilators, other essential supplies for the hospitals in my district. I know that you did it in yours. We have to make sure that our stockpiles are real, and that they are adequate to prevent the chaos that we experienced.

COVID also exposed the fragility of our supply chains, especially for pharmaceutical and medical products. These are critical goods that we can't live without. And our medical supply chain is broken in three devastating ways: shortages, especially during high demand in an emergency; subpar manufacturing; and an over-reliance on foreign production.

So today's hearing is especially meaningful. I will draw my comments to a close because my time is up. I look forward to everything that takes place in this all-important hearing.

[The prepared statement of Ms. Eshoo follows:]

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

*Ms. Eshoo. And I yield back, Mr. Chairman, and thank you for holding this hearing.

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

*The Chair. Today's hearing is the beginning of our legislative process to make sure the Federal Government is prepared to handle any public health hazard threatening Americans' safety and well-being, whether it is chemical, biological, radiological, nuclear, a cyber attack, or another emerging infectious disease like influenza or COVID-19.

We need to be prepared for all types of hazards, whether the cause is deliberate, accidental, or natural. We are evaluating existing programs and authorities originally created under the Pandemic and All-Hazard Preparedness Act, which will expire on September 30th, 2023. Our goal is to ensure America is prepared for and ready to respond to any public health security threat.

I want to join in thanking Representative Hudson and Representative Eshoo for leading the request for information process and the eventual legislation related to this topic

today.

Today's hearing is an opportunity to review the Administration for Strategic Preparedness and Response, or ASPR. ASPR was established in 2006 to serve as the lead agency for our nation's preparedness and response. While the agency and its leadership have been tested over the past two decades, no prior threat amounted to the scope or magnitude of COVID-19. In some ways ASPR stepped up and in other ways the response could be improved.

ASPR's authorities expire this year, and that requires us to review and examine ASPR's role in the preparedness and the response framework, as well as how ASPR should be viewed and operationalized moving forward.

During COVID-19, especially in the early days, we witnessed Herculean efforts in so many of our communities, remarkable stories of Americans' goodwill, resilience, and people coming together during times of incredible stress and fear of the unknown. And these efforts inform what ASPR should be focused on in an emergency: facilitating, coordinating, and supporting innovation and initiative by private sector, local, and state actors.

But we have heard a number of concerns about how ASPR is going about this mission: questions around leadership and communication; questions about use of funding and transparency; questions about management of the Strategic National Stockpile; and generally, questions about whether the agency created to be our nation's lead on preparedness and response was actually able to lead effectively.

We all heard from hospitals and health care providers across the country who struggled to find masks, test kits, and other supplies. I heard from Americans who offered their ideas and services to BARDA to no avail. There is a lack of transparency and communication to medical stakeholders from this agency that has been tasked with developing and maintaining public-private partnerships.

Questions continue to arise around ASPR's next steps. What is ASPR's role, moving forward? How should this agency be defined? How will it operate, both during and outside of public health emergencies? And that is what we are here to discuss today.

I look forward to hearing from Ms. O'Connell on specific gaps exposed by the response to COVID-19, and how to address

them for any type of future public health hazard. I hope better interaction and coordination with the private sector is at the top of the list, as ASPR's early COVID response was one crisis after another.

In addition to the critical role of ASPR, CDC also plays a role in our preparedness and response framework. I recognize the Administration has several requests for new authorities and programs before us today. Before considering any of these requests, this committee has several requests and questions of our own regarding decisions made during the COVID-19 pandemic. Much more has to be done to build back public trust.

Finally, as we saw demonstrated through Operation Warp Speed, FDA plays a role of granting emergency use authorizations to respond to emerging infectious diseases or other threats like smallpox or anthrax. This committee has broad jurisdiction over public health, and we are working on multiple fronts to rebuild trust in public health, in addition to today's work on preparedness.

For example, our Oversight Subcommittee is looking at NIH's continued funding of risky research grant programs; Dr.

Miller-Meeks is leading an effort to look at CDC reform; there is plenty of concern with FDA regarding baby formula shortages, drug shortages, and the lack of therapeutics approved to treat severe cases of COVID-19, just to name a few.

And with the Biden Administration finally ending the COVID-19 public health emergency, and with President Biden ending critical Title 42 border protections, there remain questions about transitioning out of the pandemic and managing the surge of migrants coming to our country.

To start, the House should pass Rep. Lesko's bill that would help address the illicit fentanyl crisis at our border. All our work on these fronts is important for the health and (sic) the American people and to hold government accountable. That work will continue. But the focus today, in particular, is on preparedness and response authority so that we can be better equipped for the immediate response.

It is critical that we work together so that the American people are prepared for the next threat that may come, and I look forward to a productive hearing.

[The prepared statement of The Chair follows:]

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312 **********COMMITTEE INSERT**********

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*The Chair. I yield back.

*Mr. Guthrie. Thank you. The chair yields back, and the chair -- I now recognize the ranking member of the full committee, the gentleman from New Jersey, Rep. Pallone, for five minutes for an opening statement.

*Mr. Pallone. Thank you, Mr. Chairman. I am pleased we are holding this important hearing today to consider the reauthorization of the Pandemic and All-Hazards Preparedness Act.

Reauthorizing PAHPA is of utmost importance for this committee and this Congress before it expires at the end of September, and I am glad we are beginning bipartisan conversations to ensure the programs within this legislation are reauthorized on time.

Now, PAHPA was first enacted in 2006 to improve our nation's public health and medical preparedness and response capabilities in the event of a public health emergency. And since then, the reauthorization of this law has become a critical legislative opportunity to review and consider the Federal Government's health, security, and response capabilities. It gives us the chance to review the current

policy so that we can ensure we are doing everything possible to prepare for future pandemics and public health emergencies, and this includes considering how we can strengthen our public health workforce, enhance our health care supply chains, protect against new and emerging biosecurity threats, including cyber threats, and build a more nimble public health infrastructure that is able to effectively respond in real time.

So today we will be hearing from the leaders of the Centers for Disease Control and Prevention, the Administration for Strategic Preparedness and Response, and the Food and Drug Administration. And these agencies are central to the Federal Government's public health response capabilities. Each serves a unique and critical role in the event of a public health emergency, and I look forward to hearing about each of your agency's priorities as we prepare to reauthorize PAHPA.

This reauthorization is extremely timely. It is the first time we are considering the reauthorization of PAHPA since the COVID-19 pandemic. COVID-19 brought unprecedented challenges to the Federal Government and our public health

agencies. Over the last three years we have seen our public health infrastructure pushed to the limit from medical supply shortages, diagnostic test limitations, communication difficulties, and workforce constraints. We have learned a lot from these challenges during the pandemic, and it is essential that we take this opportunity to ensure we are improving our public health infrastructure. We must do everything we can through this reauthorization to protect our public health institutions and not tear them down.

And this is an important opportunity to strengthen the authorities of our public health agencies where they are needed. I believe one area that needs to be strengthened is the authority to collect public health data in order to respond in real time and provide the most up-to-date guidance to the American people.

It is also important that we explore policies that can better prepare our supply chains for the next public health emergency. This morning our Oversight and Investigations Subcommittee is holding a hearing to look into the critical issue of drug shortages. Shortages of drugs, medical devices, and other supplies repeatedly hampered health

professionals' ability to respond to the COVID-19 pandemic, and I am hopeful that through these two hearings we will explore policies to prevent these shortages in the future.

We also need to examine the implementation of the bipartisan Prevent Pandemics Act, which we passed into law in last year's Consolidated Appropriations Bill. It included important policies to improve our biosecurity, enhance the Strategic National Stockpile, and strengthen our medical response readiness. However, it is clear that we need to do more, and I look forward to working together with my Republican colleagues to ensure a timely reauthorization of PAHPA.

Our nation's public health preparedness and biosecurity cannot and should not be a partisan issue. Effectively protecting our country from the risk of future pandemics and biothreats requires a comprehensive and bipartisan response without ideological brinkmanship. And I hope we can continue to make important progress in good faith on this goal.

So I want to thank Ranking Member Eshoo, Representative Hudson for their leadership on PAHPA reauthorization, and their hard work on the bipartisan request for information

that has allowed interested parties and subject matter experts to weigh in. This is an important part of the process as we work to find common ground on proposed legislative language in the weeks to come. We have to work together to find bipartisan solutions that enable our public health agencies to be prepared to respond to existing health threats, as well as new risks.

So thanks again to the witnesses for being here today. We welcome your statements and questions.

[The prepared statement of Mr. Pallone follows:]

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

*Mr. Pallone. I yield back, Mr. Chairman.

*Mr. Guthrie. Thank you. The gentleman yields back. We now move on to opening statements -- that concludes opening statements. We will now move on to our panelists' opening statements, and we have three witnesses from the Administration today.

We have the Honorable Dawn O'Connell, assistant secretary for preparedness and response at the Administration for Strategic Preparedness and Response.

Our next witness will be Dr. Rochelle Walensky, director of the U.S. Center for Disease Control and Prevention, and administrator of the Agency for Toxic Substances and Disease Registry.

And our final witness on the panel is the Honorable Robert Califf, commissioner of the U.S. Food and Drug Administration.

So we will begin with Secretary O'Connell. You are now recognized for five minutes for an opening statement.

STATEMENT OF THE HON. DAWN O'CONNELL, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE (ASPR), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS); ROCHELLE P. WALENSKY, M.D., MPH, DIRECTOR, U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) AND ADMINISTRATOR, AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS); AND THE HON. ROBERT M. CALIFF, M.D., COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION (FDA), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

STATEMENT OF DAWN O'CONNELL

*Ms. O'Connell. Chair Guthrie, Chair Rodgers, Ranking Member Eshoo, Ranking Member Pallone, and distinguished members of the committee, it is an honor to testify before you today about ASPR's ongoing work and the additional authorities we are seeking in the upcoming PAHPA bill.

We are living in an increasingly interconnected world, where diseases and other threats can travel quickly unnoticed for days. We are also experiencing an increase in the

frequency and intensity of natural disasters. As a result, ASPR is working on more high-consequence, no-fail missions than ever before. We are proud to lead so much important work on behalf of the country, and want to be sure that we have the authorities we need to continue to execute that work with the excellence, efficiency, and expertise the American people deserve.

As we move out of the acute phase of the COVID-19 response, it would be management malpractice for us to look the same and act the same as we did at the start of the pandemic. I have taken several important steps in the last few months to transform our organization and to incorporate lessons learned from the COVID-19 pandemic.

For example, ASPR is now a stand-alone agency within HHS. This important change in our departmental status gives me the independence to build out ASPR's human resources, acquisitions, and finance infrastructure so it better supports our unique mission needs.

I also just completed a structural reorganization that institutionalized important new capabilities that we built during COVID and need to keep using to be more prepared

moving forward, like our domestic manufacturing work.

I also made the Strategic National Stockpile an office that reports directly to me to increase visibility into and accountability of this critically important part of the nation's preparedness and response infrastructure.

With these changes, I have taken the two most transformational steps available to me to build a better preparedness and response organization. And now I need your help to ensure that I have the appropriate authorities to execute our mission faster and stronger. With the authorities I am requesting in PAHPA I am trying to solve three key problems.

The first problem I am trying to solve is how ASPR can procure more quickly the tools and supplies the country needs when responding to a biothreat or disaster. Early in the COVID-19 response it became clear that HHS could not procure the products our country needed at the speed in which our country needed them. As a result, ASPR entered into a memorandum of understanding with the Department of Defense in which they agreed to provide acquisition support on our behalf. Using their unique authorities, DoD executed more

than $90 billion in contracts for us over the 3 years of the acute response.

Our agreement with DoD comes to an end at the end of this fiscal year, which is why I am requesting similar authorities for ASPR. These include the ability to fund promising prototypes, and then move the successful ones through the advanced research pipeline without having to re-compete the contracts like we do now. We are also seeking the ability to quickly procure experimental supplies and important finished products. Each of these new authorities would allow us to do for ourselves moving forward what we had to rely on DoD to do for us during COVID.

The second problem I am trying to solve is how ASPR can continue to invest in the expansion of the domestic industrial base for key PPE and medical supplies. To ensure we are never again in the position we found ourselves in in March 2020, when our doctors and nurses did not have access to the masks, gowns, and gloves they needed, ASPR has used the funds and construction authority given to us in the COVID supplementals to build new factories nationwide to produce the PPE and supplies we need in times of emergency.

These investments also provide good-paying jobs to many hardworking Americans. But once the COVID-19 funds run out, we lose our construction authority and our ability to continue investing in similar projects. That is why I am requesting permanent construction authority for ASPR. It is important that we have funds and construction authority to sustain the work we have started, and to expand this work to other parts of the public health supply chain.

The third problem I am trying to solve is how ASPR can hire staff more quickly to surge critical teams during large response efforts. In the early days of the COVID-19 response, just as we relied on DoD for acquisition support, we also relied on FEMA and the Coast Guard to bolster our response staff. The ability to hire people quickly and compensate them appropriately for their long hours and sometimes hazardous work are important tools missing from ASPR's response toolbox, which is why I am requesting direct hiring and flexible pay authorities for ASPR.

Direct hiring authority will allow me to quickly scale up our response efforts so we have enough people when we need them, and pay flexibilities will go a long way towards

sustaining our staff through these dangerous missions, and ensuring we do not lose these seasoned first responders and subject matter experts to the private sector, who pay much more and often require much less of them.

To solve each of the problems I have just laid out, I have requested important new authorities for ASPR. I look forward to working with you to solve these important problems and many others as you draft the new PAHPA bill.

Thank you again for inviting me to testify today. I look forward to answering your questions.

[The prepared statement of Ms. O'Connell follows:]

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

*Mr. Guthrie. Thank you. I appreciate your opening statement.

The chair now recognizes Dr. Walensky for five minutes for your opening statement.

STATEMENT OF ROCHELLE P. WALENSKY

*Dr. Walensky. Chair McMorris Rodgers, Chairman Guthrie, Ranking Member Pallone, Ranking Member Eshoo, and distinguished members of the subcommittee, it is an honor to be here today.

I want to take a moment to acknowledge that today marks the expiration of the Federal COVID-19 public health emergency. The COVID-19 pandemic, the deadliest in over a century, has been marked by an unprecedented whole-of-government response. COVID remains a leading cause of death in the United States, and CDC will continue our commitment to reducing COVID's impact and leveraging lessons learned to be better prepared for future public health challenges.

No matter the outbreak -- H1N1, Ebola, Zika, COVID-19, Mpox, Polio, or Marburg -- since our founding in 1946, CDC has been offering world-class assistance to our partners in states, tribes, territories, your local communities, and around the globe. These diseases don't respect national or state borders, and the increased frequency of outbreaks means we should not be asking if we will face another serious

public health threat, but when and how many.

For many, life has returned to normal after three years of COVID-19. Public health agencies like CDC and your state and local health department's mission is to continue to remain vigilant and response-ready to protect Americans from any resolving or emerging public threat. We do this by actively supporting the core capabilities of public health, including state-of-the-art laboratories, a diverse public health workforce culturally competent to reflect the communities it serves, world-class data and analytics, rapid response to outbreaks at their source, and strong domestic and global preparedness.

We are enhancing these capabilities through an all-agency review, CDC Moving Forward. We are committed to addressing the lessons learned from COVID-19, increasing accountability, and continuously improving how we deliver information to Americans.

The end of the public health emergency once again reminds us that sustainable policy changes and funding are essential to readiness for future biothreats. CDC will continue to monitor COVID-19 and provide the information to

which we have access. But the end of the PHE will mean that CDC will no longer receive certain data to share information many Americans have actually come to expect.

For example, we announced last week that our COVID-19 community levels will cease because some of the data informing those levels will no longer be submitted to CDC. The COVID-19 community levels are being replaced by hospital admission data uploaded on a weekly basis, which we have been fortunate to demonstrate serve as a reasonable surrogate in this case. At the same time, other data used to make decisions about targeting resources will no longer be available because it is no longer submitted to us.

For example, we will no longer have certain data on race and ethnicity vaccine administration, leaving policymakers with an incomplete national picture of health disparities. We will no longer have data on national test positivity, which is one of the most effective early indicators of disease spread. We will have inconsistent data on vaccine uptake, hindering our ability to measure vaccine impact, particularly urban and rural disparities. We will make do. However, this should worry us all, primarily because of what

it says about the visibility we will have into the next outbreak. We will be back to square one, having to build and negotiate surveillance while we fight a pathogen.

I know members of this committee are interested in advancing policy to better prepare for what comes next. For CDC, this means supporting the public health workforce to recruit the best of the best through improvements to student loan reimbursement authority. We must also be able to surge staff when needed, with simple changes to direct hire legislation and sufficient budget flexibility so bureaucracy doesn't stand in the way when an emerging threat arises.

This also means maintaining the infrastructure our nation stood up during COVID-19 to administer vaccines quickly and effectively. The Vaccines for Adults program not only provides America -- Americans access to 14 lifesaving vaccines, but also supports a response-ready capability that we will lose without continued investment.

Finally, this means modernizing data policy to support access to better quality, standardized, and timely data so individuals and families can make informed decisions about their health, and policymakers can target interventions and

resources to better prevent public health emergencies.

The United States should have the most advanced and capable agency in the world when it comes to disease detection, tracking, and forecasting. It will take a more modernized, nimble, and collaborative CDC, and it will also take partnership with Congress to fully turn CDC into a response-ready agency. I am committed to working with you to better protect Americans and our national security.

Thank you, and I look forward to your questions.

[The prepared statement of Dr. Walensky follows:]

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

*Mr. Guthrie. Thank you for your opening statement.

The chair now recognizes Commissioner Califf for five minutes for your opening statement.

STATEMENT OF ROBERT M. CALIFF

*Dr. Califf. Good morning. Chairs McMorris Rodgers and Guthrie, and ranking members Pallone and Eshoo, and members of the committee, thanks for the opportunity to be here today to discuss the importance of preparedness, and how FDA can work with Congress to ensure the country is ready for the next public health threat.

PAHPA recognizes the key role FDA plays in public health, emergency preparedness, and response. The FDA has effectively used the authority provided under PAHPA to support our nation's preparedness and response capabilities. However, there have been lessons learned about how these authorities could be modernized to ensure our actions can be even more effective.

Providing greater transparency into supply chains, ensuring operational readiness and surge capacity within the FDA Inspectorate and its review staff, and improving laboratory testing regulation are priorities that will enhance national security and improve public health preparedness.

For supply chains, there is a need for greater transparency into the supply chains of our medical products to both improve resiliency and ensure continued access for critical medical products. For example, under the CARES Act, FDA received new authority to require medical device manufacturers to submit shortage notifications during a public health emergency. FDA used this information to help mitigate approximately 350 shortages. Unfortunately, these notifications will no longer be required following the end of the current COVID-19 PHE.

However, we know medical device shortages occur in many situations that are unrelated to PHEs, including natural or human-made disasters, recalls, geopolitical conflicts, production shutdowns, and cybersecurity incidents. We also know that these shortages most often impact our most vulnerable and underserved populations, like children, rural populations, and our veterans in VA hospitals.

Additionally, most drug shortages were historically due to manufacturing issues that disrupted supply for which manufacturers of drugs and active pharmaceutical ingredients are required to notify the FDA. The agency has relied on

these notifications to help prevent supply disruptions -- approximately 220 over the last year -- by working closely with manufacturers, expediting review, and exercising temporary regulatory flexibility.

However, we have recently seen an unprecedented demand for drugs that would benefit from similar notifications. The ability to require drug manufacturers and distributors to report surges in demand to FDA could help the agency prevent or mitigate shortages, including for some critical over-the-counter drugs like we saw this fall.

Additional improvements should include reporting API sources and the extent of manufacturer reliance on certain suppliers in the drug supply chain, and ensuring FDA has an opportunity to inspect certain over-the-counter drug facilities before such products are distributed.

Preventing food shortages is also critical to public health, and we are grateful that Congress included a provision in the fiscal year 2023 omnibus to require manufacturers of infant formulas and medical foods to notify FDA of potential shortages. Looking forward, extending this authority to additional categories of foods during a declared

PHE could help prevent future shortages in the food supply.

Second, ensuring operational readiness and surge capacity is critical in emergencies. For example, FDA could achieve more effective and efficient oversight if it had the authority to require internationally harmonized master files for drug manufacturing sites and improved authorities for conducting remote regulatory assessments. Congress expanded FDA's authority to request records in advance of or in lieu of an inspection to devices and bioresearch monitoring sites in the fiscal year 2023 omnibus. However, the agency could better assure the safety of products, even in times of crisis, if this records request authority were expressly extended to all FDA regulated products.

Additionally, during COVID-19 we saw that FDA staff had to be pulled off other work and I have been working relentlessly on pandemic issues for the past three years, leading to a significant backlog in certain areas and quite a bit of fatigue. Through the creation of the specialized program to defend against emerging pathogens and other threats, the agency would be well positioned to respond in emerging and identified threats of concern.

Third, and finally, the COVID-19 pandemic underscored the importance of both diagnostic test access and test accuracy and the critical need for modernized regulatory framework that applies to all in vitro diagnostics. This will be integral to ensuring the U.S. is better prepared for the next threat, and to realizing the full potential of diagnostic innovation.

When I look at the list of requirements, a striking observation is that these measures would not only help the FDA serve the public well in times of crisis, but they would also enable us to help prevent catastrophic outcomes and conduct our everyday work more effectively and efficiently.

Thanks, and I look forward to your questions.

[The prepared statement of Dr. Califf follows:]

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

*Mr. Guthrie. Thank you. Thank you for your opening statement.

We will now move in -- the period of the subcommittee on -- for member questions. Each member will be recognized for five minutes, and I will begin by recognizing myself for five minutes for the purpose of questions.

Secretary O'Connell, the GAO placed HHS's leadership in coordination of public health emergencies at its high-risk list -- on its high-risk list in January of 2022, in part due to the deficiencies in HHS's management of countermeasures. GAO's analysis of the Strategic National Stockpile Reviews shows the Strategic National Stockpile contained most medical countermeasure types recommended, but often not in the recommended quantities. I know you are familiar with that.

So my questions are, how does ASPR make decisions on which countermeasures are procured and deployed in the stockpile, including how state and local officials engage in the process?

And how does ASPR and the public health emergency countermeasure enterprise ensure products that are not commercially available are involved in stockpiling

determinations?

*Ms. O'Connell. Chair Guthrie, thank you so much for this question.

So focusing on the Strategic National Stockpile has been one of my chief priorities during my tenure as (sic) ASPR. It was really, you know, instructive to see what happened in March 2020, when it didn't have those things that we thought it should need. So I have placed an important emphasis on making sure that it is restocked and ready to go against whatever comes next.

And I have been grateful for the funding Congress has given us in order to do that for PPE. That was one of the capabilities that was missing in the Strategic National Stockpile. They had not purchased PPE since the H1N1 outbreak in the -- you know, 2009. So it had been years, and much of that has expired. So we focused on building that capability and spending the money well that Congress has appropriated for us to be able to do that in the supplementals.

But in the regular order, in the regular annual budget for the Strategic National Stockpile, we are well under-

funded, and it is a worry of mine. We just released the multi-year budget, which is a five-year budget looking at the entire countermeasure enterprise, and in that the Strategic National Stockpile should receive $2 billion a year in order to keep up with countermeasures against the threats that have been identified by the Department of Homeland Security. We currently receive $934 million a year, so we have less than half of what the experts have identified we need in order for us to be prepared.

So my job in this role is to make sure that we all understand that, that given the funding we have we are doing what we can against the threats that we see. But we need additional funding in order to be fully prepared in the way that you expect us to be and I expect us to be. So I have been carrying that message forward. I think it is really important.

*Mr. Guthrie. Okay, thank you.

Dr. Walensky, the CDC's data modernization initiative was launched in 2020. And over the course of the pandemic Congress has appropriated at least a billion for this program. Yet state and local governments have received very

little financial or technical support from CDC as part of this data modernization initiative.

In addition to this, Congress -- this spending, Congress more recently appropriated more money in the CDC consolidated appropriation -- to you in the Consolidated Appropriations Act. Can you detail how the money has been spent by CDC, including how much has been allocated, and what remains unallocated and unobligated?

*Dr. Walensky. Sure, I would be happy to. And we can provide you state information on the moneys that have been put forward.

As you note, it has been about $1 billion. But I will also note that major health systems, including the one that I came from, cost over $1 billion themselves individually in order to upgrade to Epic. So we are talking about $1 billion for the whole country, when a single health system would need that much money in and of itself in order to upgrade their entire system.

What we have been working with -- and in fact, I spoke to our state and local health departments just on Tuesday -- is a North Star architecture, a common architecture where all

of our state and local health departments are using similar data highways such that all of the data can be easily transferred, even if they are not exactly the same, that the highways meet and match so that they are all similarly transferred. The data come in and can be brought out such that when data come in to CDC, we can bring it back and send it back to the local health departments to not only tell them what is happening in their health department, but in all of the areas and regions around them.

And so that is the work of our data modernization initiative. Again, there is not enough money and I have single health departments that have told me they could use the entire CDC budget.

*Mr. Guthrie. Okay, thank you. In addition, Congress gave you more data authorities -- or the CDC more data authorities in the December Consolidated Appropriations Act. Can you provide us an update, a status update on the implementation of the newly-granted authorities that was established just recently?

*Dr. Walensky. I would be happy to chat with you about that. What I will say is we had more responsibility, but not

a lot of more authority. So there was an expectation in that appropriations that we would be able to receive all of those data. But in fact we didn't receive the authorities in order to be able to do so.

So -- and in fact, with the end of the public health emergency, as I know it, we will lose some of those authorities.

We did, in the -- it took six months during the COVID-19 pandemic in order to receive hospitalization data, for example. And it took us about three months in monkeypox in order to receive vaccination data, for example.

For us to be ahead of a pathogen, for us to be ahead of an outbreak, it can't take months for those data to come in. What we would like to see is -- there is a rare thing that is happening in California, and a rare thing is happening in Maryland -- when those both come in to us, we say trigger. That is a -- that is something that we have to act on, these things are happening at the same time. They would otherwise not know. If we don't have those data authorities to see what is happening, we will be behind before we ever get started.

*Mr. Guthrie. Okay. Thank you. Thank you for your comments.

The clock didn't start exactly when I started, so I used my full five minutes. So I will yield back and I will recognize Ranking Member Eshoo for five minutes for questions.

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

Secretary O'Connell, you are in charge of the National Stockpile, BARDA; you are the lead agency for preparedness. So I want to start with you.

The United States and -- has and remains dangerously dependent on foreign countries for our supply of critical, lifesaving drugs, lifesaving equipment. So as a result, during the pandemic we couldn't outfit our first responders -- I raised that in my opening comments -- without relying on China and others to supply us. You have said that ASPR has invested 16 billion in 87 different contracts for the domestic manufacturing of PPE. What have those contracts bought you?

*Ms. O'Connell. Ranking Member, thank you so much for

that question --

*Ms. Eshoo. Because if another health threat happened where there is a high demand for PPE and other essential supplies, do you have the authority to ramp up production of U.S. masks, respirators, syringes, diagnostics?

I mean, I practically became an overnight so-called expert in this, trying to find it and what time -- what some ship was coming in to get something to a major -- you know, major institutions.

*Ms. O'Connell. Ranking Member, thank you so much for that question. This has been an important focus of ours, as you have mentioned, and we are grateful for the support from Congress for the funding and the construction authority we received in order to be able to invest in domestic manufacturing of some of these critical PPE and medical supplies.

*Ms. Eshoo. So where do we stand now, though? What capacity do we have? I mean, do -- would our country have the capacity now to meet that demand for production?

*Ms. O'Connell. So we are continuing to build that capacity, and we are doing it in two ways. We have the

investments in the construction and the manufacturing supply lines, bringing those foreign -- you know, the things that were manufactured in other countries, bringing them here, manufacturing them here, we are doing that with raw --

*Ms. Eshoo. But, I mean, how would you grade the system now, where are we? Are we in the middle of building this capacity? Are we 10 percent there? Are we 72 percent there?

You know, one of my biggest regrets -- not in working with Congresswoman Brooks, but -- we worked so hard on the stockpile. But I am kicking myself that I didn't ask witnesses, "What is in the cupboard? What is in the cupboard?'' Jesus, we got this thing hit, and all hell broke loose. And that is why I am asking this. You know, we need the answer to that to chart what -- where we need to go in the future, so that we do not experience this again.

This is a great nation, and we were on our knees. So tell me where you think we are now.

*Ms. O'Connell. So we have 87 contracts invested in things from raw materials to the consumables to the finished product. But I would agree with you, we are not far enough, and that is the reason why I am requesting construction

authority in the new PAHPA bill. We have gotten a head start, and we are farther than we were.

And we are doing something else, too. The Strategic National Stockpile, as we are restocking it, we are restocking it with the domestically manufactured goods. So we actually have a market, and we are, you know, buying those things. That is where we are going to be able to incentivize --

*Ms. Eshoo. Okay.

*Ms. O'Connell. -- these private companies to ramp up manufacturing.

*Ms. Eshoo. I have 1 minute and 20 seconds left.

Have you submitted to Congress the required report on the contents of the Stockpile for 2022?

*Ms. O'Connell. I just reviewed it, and it is on your way -- on the way to you all.

*Ms. Eshoo. Yes, yes.

*Ms. O'Connell. Thank you.

*Ms. Eshoo. Yes, because it is past due.

*Ms. O'Connell. Yes, thank you.

*Ms. Eshoo. It is past due. Okay.

Dr. Califf, it is great to see you. Can the FDA get the information it needs from manufacturers to identify sources and suppliers of API?

I have been on this API for a long time, and I don't think that the needle has moved. That is my overall take on this.

*Dr. Califf. I know you have limited time, so I will be brief. We can talk at long length.

I have personally worked in the private and university sector in both India and China. The problem we have right now with regard to what you spoke about is we don't have the designation of the source of the API when it gets moved and put into a pill. And we are asking for the authority to require that of the industry, that essentially the chain of custody of the supply chain from the API to the finished pill to the retail store, or however it is distributed --

*Ms. Eshoo. So that is the only way for you to actually know --

*Dr. Califf. Otherwise, we have no way of --

*Ms. Eshoo. You have no way of knowing.

*Dr. Califf. Other than phone calls, which is not a

very efficient way in a crisis.

*Ms. Eshoo. No, or maybe one day API in the United States of America. Do you see that in our future?

*Dr. Califf. It has to be in our future.

*Ms. Eshoo. I mean, we are dependent --

*Dr. Califf. There is a hearing going on about drug shortages --

*Ms. Eshoo. -- totally dependent on China, China and India, and India is dependent on China. I mean, what a --

*Dr. Califf. Well --

*Ms. Eshoo. What a Rube Goldberg plan that is.

*Dr. Califf. We need to work on it. But the hearing also occurring at the same time is going to go through some of the issues.

The economics of this are not favorable for fixing the problem the way it is currently working. So we have some real work to do there.

*Ms. Eshoo. Well, I have been working on it.

*Dr. Califf. Not just tracking things, but the basic fundamentals of the economics.

*Ms. Eshoo. Thank you.

*Dr. Califf. Thanks.

*Ms. Eshoo. I am going to submit, obviously, Dr. Walensky and to each one of you, written questions for the record. Thank you.

[The information follows:]

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

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

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

*The Chair. Director O'Connell, I want to start with you.

Like every state, Washington State currently has a set of crisis standards of care that they can rely on, given serious surges and demands for care. And the COVID-19 pandemic brought to light that many states like Washington State have incredibly discriminatory crisis of care standards that discount the lives of people with disabilities and other marginalized populations. These concerns have been repeatedly reiterated by the Office of Civil Rights and advocates in the disability community who have helped push states to consider alternative measures for their crisis standards.

To this point, I would like to discuss ASPR's request to Congress to extend the National Advisory Committee on Individuals with Disabilities and Disasters until at least September 30th, 2025. Is NAC involved in or working with

other partners, including state and local governments, to ensure that we don't have something like this happen again?

*Ms. O'Connell. We have really benefitted from the view of our outside experts that have served on this committee. And it is very important to me, and I have made that clear in my five-year strategic plan that we are not prepared if everybody is not prepared, if we aren't thinking about those communities and special populations that you mentioned.

So we are continuing to work with -- and are leading experts in this space to make sure that we are accounting for all of their views, and incorporating those in the work that we do ahead.

*The Chair. Okay. Do you support furthering Federal standards that would ensure that these crisis standards of care do not discriminate against people with disabilities?

*Ms. O'Connell. It is really important that we incorporate all of the needs of these special populations as we move forward in preparing for and responding to disasters and emergencies.

*The Chair. Okay, thank you.

On cybersecurity, when this committee last considered

ASPR's authorities in 2018, cyber was a known threat but not really top of mind when it came to preparedness. In the last couple of years we have seen an increasing number of cyber attacks on the health care sector corresponding to an increase in response efforts.

Just earlier this year, ASPR, working in coordination with the Health Sector Coordinating Council Cybersecurity Working Group, released their Cybersecurity Framework Implementation Guide to help public and private sector prevent cybersecurity incidences. Do you view cybersecurity preparedness and response as a primary function and responsibility of ASPR?

And if not ASPR, who at HHS is responsible for cyber threats?

*Ms. O'Connell. Thank you, Chair. So there are other players within our department that have various responsibilities in the cybersecurity space, but we are the sector risk management agency for the health care sector when it comes to cybersecurity. So we do have an important function in coordinating with the health systems and hospitals to make sure that they know best practices, and

that we work them through if they have had vulnerabilities, how we identify those gaps and moving forward.

I don't know that we are doing enough, and I have requested a doubling of my budget in fiscal year 2024 so I can add additional staff to work against this highly complex and evolving problem. So I would welcome the support of this committee in moving that forward.

*The Chair. Well, I would like to work with you on how we make sure that we are addressing this growing and evolving threat.

Dr. Walensky, in 1997 Congress directed the FDA to develop and adopt good guidance practices to provide more transparency and public input. And since the early 2000s FDA has abided by such good guidance practices, and it requires FDA to solicit public comments and responses, including standardized statements regarding the non-binding nature of the guidance, and be publicly posted in a standardized, searchable, and comprehensive database.

In addition, FDA's practices provide exceptions for emergency situations where interim guidance may be appropriate, and a process for revisions in situations where

the guidance may need to be changed.

Throughout COVID-19 and even now, I continue to hear concerns and questions on CDC recommendations and the guidance, whether it is parents, scientists, doctors, others in the community. Does CDC have or has CDC considered adopting something similar to good guidance practices that would dictate how recommendations across CDC are made available, allow for comment, and allow for responses to comments?

*Dr. Walensky. Yes, thank you so much for that question. So much of what we learned in CDC Moving Forward is the importance of accountability and transparency and partnership, and working with people who are going to be the implementers of this guidance.

In terms of public comment, as we are putting out guidance in the context, for example, of a public health emergency, one of the other things that we learned in CDC Moving Forward is that we have to be nimble and we have to be fast, that we were operating too slowly. Of course, a period of public comment would take months, a couple of months to potentially --

*The Chair. Okay, thank you. I am going to run out of time. I am just going to highlight FDA indicates it finalized 114 documents in 2019; 163 in 2020; 91 in 2021. So there is a way that you can do it quickly, but keep it public and available for comment.

I will yield back. My time has expired.

*Mr. Guthrie. The --

*Dr. Walensky. May I just comment that part of what we are doing is standardizing and being more transparent about how we are getting that feedback as part of CDC Moving Forward? So thank you for that question.

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

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

As the COVID-19 public health emergency ends today, we should be applying the lessons we have learned over the last three years when determining how we can build up our public health infrastructure, rather than look for ways to tear it down.

So I wanted to ask each of our three witnesses in terms

of each of your respective agencies: as the public health emergency comes to an end, what is the ongoing vulnerability in our preparedness and response capabilities that you are most concerned about, and how can we address that concern?

And I know each of you could probably talk an hour about it, but we only got five minutes, so I will start from the left, I guess, my left.

*Ms. O'Connell. Well, thank you so much, Ranking Member.

It was very clear to us that we had to rely on other departments for support. Just as I laid out in my opening statement, DoD gave us assisted acquisition support. We couldn't move out fast enough against the needs that we were seeing the country had -- really important that we, as HHS, are able to move out on our own next time. We will -- may not always have the benefit of other departments being able to come in and help. So with our acquisitions authority, DoD came in; we would like similar authority so we can stand on our own.

FEMA and U.S. Coast Guard came in and helped us surge our staff so quickly. There are direct hiring and flexible

pay authorities that I am going to need moving forward because I might not always have FEMA and U.S. Coast Guard available to come in and help -- really important HHS has what it needs, moving forward.

And then construction authority. We have talked about how weak the supply chain was, and how important it is to have domestic manufacturing of these critical medical supplies. But that construction authority that I have right now goes away with the supplemental dollars. As soon as those are spent, I can no longer continue these investments. I would like to have permanent construction authority so I can keep that going, so we no longer have those doctors and nurses wearing the plastic bags Ranking Member Eshoo mentioned.

*Mr. Pallone. Thank you. Dr. Walensky?

*Dr. Walensky. Thank you for that question. So we tackled COVID-19 with a frail and under-invested public health infrastructure, to start. There were some that estimated before the pandemic we had -- we were 60,000 public health workforce in deficit. So our workforce is a big challenge.

The second big challenge in our infrastructure has been our data systems. You have heard me talk about data modernization. We have been getting data through faxes. I know in your state of New Jersey, electronic case reporting increased 66 percent during the pandemic because of the rapid need for data. But in our electronic case reporting we are now up to about 25,000 health systems can do so (sic). That is about 25 percent of our health care systems. So we have a lot of work to do in our data modernization initiative and resources for that.

And then finally, laboratory infrastructure. Lots of interest now in genomic sequencing and wastewater surveillance, and all of these things. We do not have a laboratory infrastructure in this country that can support all of those efforts. And I would urge all of you, if you haven't visited your state lab, to visit your state lab and ask if they can do genomic sequencing. Thank you.

*Mr. Pallone. Thank you, Doctor.

Mr. Califf?

*Dr. Califf. Sure. I am going to mostly echo what has already been said, so I will be very quick.

We got holes in our data that I have highlighted that we need in order to deal with crises when they come up.

We very much need the surge capacity capability, particularly as it relates to pandemic issues that may arise where we need our staff and biologics, for example, to be ready to go with excess capacity to deal with it.

And I am very concerned about laboratory testing. If you don't have good laboratory testing at the front end, you are really in trouble when it comes to figuring out what to do with treatment.

And then finally, as we have already discussed a little bit here, we need to fix our peacetime economics, things like the generic drug industry and the commodities. The less we are able to economically afford to produce the products in the United States, the more we are going to depend on an enormous investment in stockpiling. Stockpiling is time-limited. And so, if we don't fix those fundamental economics, we are going to have -- we are very concerned about it right now.

*Mr. Pallone. Well, thank you. I think I can fit in another question to you, Dr. Califf.

The problem that our members have seen in just the last few months is the shortage of drugs that seem to be related to increases in demand. And currently, drug manufacturers are required to report to FDA when there is a discontinuance or interruption in the supply. However, when the shortage is driven by demand, rather than supply, manufacturers are not required to report to FDA.

So can you explain how FDA can help address drug shortages when they have more information from drug manufacturers?

Can FDA apply those tools if they know of an unanticipated spike in demand?

You have got, like, 20 seconds.

[Laughter.]

*Dr. Califf. All right, very quickly, every company keeps projections on what it needs to produce to meet the demand that it expects. When the demand goes up beyond what they can produce, they need to let us know, so that we can look across companies and see how we can make up for that problem. That is, essentially, the basic issue.

Each company doesn't know what the other company is

doing, because they are competing. When there is a shortage in one company we need to be able to coordinate across these people. Government should not be involved in private enterprise when things are working fine, but when there is a problem we have to have a mechanism for government to help out, as we have seen in many cases over the pandemic.

*Mr. Pallone. Thank you.

Thank you, Mr. Chairman.

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

*Mr. Burgess. Thank you, Mr. Chairman.

I have had this discussion with most of you individually; I may not have had it with you, Ms. O'Connell. You are asking for a lot of things, and we should consider those things, the regulatory authorities, the budgetary authorities. But as I have stressed before, you have a credibility deficit with the public, and we have to remedy that. Mostly, that will come through transparency, I believe.

But at the same time -- and Chair Rodgers mentioned this

-- when you come forward with guidances and proclamations, think about what the impact this is going to have on everyday Americans, because there is a certain amount of pandemic fatigue out there in the country right now, and they tune you out. I am just telling you that. They do not believe you anymore. And that is a serious, serious problem. And so no amount of budgetary authority, no amount of regulatory authority can reestablish that credibility. We need you all to reestablish that credibility through becoming your own centers of excellence and transparency, and just day to day, every member of your agencies must recognize that job one is re-establishing credibility.

Ms. O'Connell, let me ask you, during the run-up to the last reauthorization of the preparedness bill it seems like we had a lot of internal discussions. In fact, some we even had in a classified setting. And -- but placing ASPR at the center of the eye of the storm, if you will, when trouble hit, and that seemed -- if I recall correctly, that seemed to be the consensus that those of us who were on the committee back then -- that is where we arrived. It didn't fare exactly as I would have anticipated then, when real trouble

hit.

So are we doing some sort of ongoing re-evaluation? Should you be the center? Should the ASPR be the center? I believe it should. But are there ways to ensure that you stay at the center of that authority during the time of crisis?

*Ms. O'Connell. Congressman, thank you so much for that question. You know, of course, I wasn't here at the last PAHPA reauthorization, or in this role, and came into this role in June 2021, when the response was already in full swing and structures were already in place.

The Department has been very clear that I am responsible for coordinating our department, and making sure that I am the principal interlocutor with the Secretary on issues around public health emergency and response. And I have played that role since I have been in this seat, and have had the pleasure of coordinating with my fellow panelists today on any number of very complex issues.

I also coordinate very closely with the White House. And, you know, through the various responses I have led and other roles I have played within the department over previous

administrations, I have interacted with either NSC, DPC, now a White House COVID team, and I am pleased to coordinate with however -- whichever president it is chooses to organize the White House, I will be that conduit from the Department to the White House on these issues, and look forward to continuing to play that role.

But again, I have only been in this seat since June 2021, and have been able to do that since that point on.

*Mr. Burgess. And in fact, I think this is your first appearance in our subcommittee. So we welcome you and are grateful for that, and look forward to many more -- many, many more such sessions.

So during the height of the pandemic, HHS and Department of Defense developed a fairly successful partnership. This success relied partially on ASPR's use of existing DoD authorities. Is there a way to look to continuing those authorities so that it doesn't have to be something that is stood up anew at the time of another crisis?

*Ms. O'Connell. Well, that is one of the reasons why I am asking for some of the acquisitions authorities that DoD has for ASPR, because DoD -- we live in a very complex threat

landscape right now, and I think the country is going to need DoD to be able to do DoD things.

*Mr. Burgess. Sure.

*Ms. O'Connell. HHS should do HHS things. So we need similar authorities so I can stand up and get going, and not have to negotiate an agreement with DoD.

*Mr. Burgess. Easier to get you those things if you have credibility. It does go back to that.

Dr. Califf, before I run out of time, we came through this pandemic, we are all glad that the public health emergency is over, but there were a number of flexibilities that were required -- us to give the FDA so we all didn't die. What have you done to sort of codify those flexibilities? And is there a way to make you a more nimble agency, going forward?

*Dr. Califf. Well, of course, as you may have heard me say, we are number one in innovation in the U.S. No one disputes that. And we still are. We intend to keep it that way.

And one of the most important ways is through the constant communications that we have with the industries that

actually invent and produce the products. We don't make them, we just regulate them. So a lot of the methods that have been used, like remote assessments, of some note we have talked about in-person versus virtual meetings. It turns out two-thirds of the time now that we are offering in-person meetings, the industry is choosing virtual because it is easier for them to not have to assemble all those -- their people and have them fly to Silver Spring to meet with us.

So things like that that just make it easier to communicate -- we will still have a role when things are not right to exert our authority to do that. But communication is really the key, and we have learned a lot of lessons in the process.

*Mr. Burgess. Well, I have requested a meeting with you, and I look forward to following up with that. We can speak at the -- to some degree of -- we can get into deeper detail. So thank you.

And I will yield back, Mr. Chairman.

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

*Mr. Cardenas. Thank you very much, Chair Guthrie, and also Ranking Member Eshoo, for holding this hearing to discuss ways to improve our health system preparedness through PAHPA. We call it PAHPA here, but what that means is Pandemic and All-Hazards Preparedness Act reauthorization process.

I also want to thank our witnesses for joining us today and providing testimony on the needs of the Federal Government to best respond to crises.

We have seen the most -- excuse me, we have seen the cost of being flat-footed in the face of a public health emergency in real time. While I think we have learned many lessons from COVID-19, I am still concerned that we have real weak spots in our preparedness, especially when it comes to kids.

This past winter we experienced what public health officials called tripledemic, when cases of RSV, flu, and COVID-19 overlapped, making many of our kids sick, and overwhelming our hospital systems. This tripledemic prompted greater scrutiny of our pediatric care system, and highlighted severe pediatric facility and workforce shortages

which must be addressed.

This is especially problematic because children have a unique set of mental and physical health needs that are separate from adults. We cannot leave our kids behind, and I am worried that if we approach PAHPA reauthorization too narrowly, without expanding pediatric health care capacity, we will repeat mistakes and remain unprepared to protect children in the event of a future emergency.

I have a question for Dr. Walensky.

Doctor, how do pediatric workforce and facility shortages leave us vulnerable in the event of a future pandemic or other public health threat?

*Dr. Walensky. Thank you so much for that question. I am going to sort of speak to it from a public health standpoint and the workforce that we need in public health, as well as in -- at CDC specifically, and just speak to some of the challenges that we have.

We train some of the best people in the world. It is really competitive to get a fellowship at CDC, but we don't have non-competitive fellow conversion. They have to apply for jobs after we have trained them. We don't have tax-

exempt student loan repayment. And I will tell you pediatricians, if you look at the salary scale, are not the highest-paid clinicians out there. We could use direct hire authority. We have pediatricians that go out in the field to care for people or to -- not to care, actually; to do infection control and surveillance in Ebola outbreaks, and yet they don't get danger pay.

So there are a lot of things in our direct -- in our hiring authorities that would really help us sustain a pediatric workforce, especially a workforce that has -- you know, may leave medical school with $200,000 of debt, on average.

*Mr. Cardenas. And -- well, that sets up my next question. What can Congress do to better prioritize the unique needs of children through the PAHPA reauthorization?

*Dr. Walensky. So from a public health standpoint, I would say those hiring authorities and workforce authorities that I just mentioned would go a very long way. And I think, from the clinical standpoint, I would defer to my colleague.

*Mr. Cardenas. Please.

*Ms. O'Connell. Thank you so much, Congressman. So we

have created something called the Regional Pediatric Disaster Care Centers of Excellence, where we bring various experts across the regions to leading children's hospitals, and create a consortium where we are able to share best practices for children in trauma, children in disasters, how to care for them. And it has also become a place where our pediatric care providers can get support, share lessons learned with each other. But it is really critical that we educate all of our providers on how to take care of children in this very unique emergency situation.

We also have the National Advisory Committee on Children and Disasters, and leading experts have been advising us on how to make sure we incorporate their special needs as we move forward and prepare the country to respond to what comes next.

*Mr. Cardenas. Speaking of educating, can you please share with us what you would recommend to Congress what we can do to strengthen the efforts of the National Advisory Committee on Children and Disasters as we work to prepare for future emergencies?

*Ms. O'Connell. The authorization of that committee

will end with this PAHPA bill. And so, as you reauthorize, it would be important to include that.

I have also requested $7 million for the Pediatric Centers of Excellence, and that would be another important thing to fund to make sure those providers that are in our communities have that support in place where they can share best practices.

*Mr. Cardenas. You said 7 million, not 70 million, not 700 million, not 7 billion. Again, how much?

*Ms. O'Connell. Seven million.

*Mr. Cardenas. Seven million.

*Ms. O'Connell. It is part of our National Disaster Medical Services System budget.

*Mr. Cardenas. I love that number.

[Laughter.]

*Mr. Cardenas. I would hope and pray that we can meet that. Thank you so much, and I appreciate all of you very much.

And I yield back the balance of my time.

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

questions.

*Mr. Latta. Well, thank you, Mr. Chairman, and thanks to our witnesses for appearing today.

Secretary O'Connell, your office is looking to end the Centers for Innovation in Advanced Development and Manufacturing Program, and replace it with new programs called BioMaP and IBx. Will you explain to the committee the background and rationale for establishing these programs, and ASPR's plan for implementation?

*Ms. O'Connell. Congressman, thank you so much for that question. It is a really important question.

So the CIADM program that you referenced was established several years ago, and it was to reserve capacity across the country in case we needed to ramp up vaccine or therapeutic manufacturing. It was a way that we had manufacturing lines that were essentially mothballed, but could be turned on when needed.

What we found in the COVID response was capacity is one thing; capability to run those lines is something else. And so what we are looking to do moving forward is not just reserve a manufacturing line, mothball it, you know, keep it

warm until we need it, but make sure that we, in addition to having the manufacturing lines, also have the workforce, the capability to run those lines so mistakes are not being made when vaccines are manufactured. And that is where we are looking to go, and the reason why we are making that change.

*Mr. Latta. Okay, let me just follow up real quick, because I tell you, when I am out in my district -- and I am sure everyone else -- you just mentioned workforce. Every place you go, the same thing. Everybody needs, you know, workers out there. So how are we going to maintain that workforce out there?

Because, I mean, I go to places right now, they could double what they are manufacturing and doing right now. They can't because there is no workforce. So how are we going to do that with what you are advocating?

*Ms. O'Connell. So one of the first things that we are going to do is ensure that the organizations in which we have a relationship with moving forward have a workforce and are able to turn the capability on, as well as the capacity on when moving forward. But you are absolutely right. The skilled workforce is something that we need to invest in.

I know Dr. Walensky has been thinking about that in the public health space, is how we make sure that we have the experts that we need who can run these lines when we need them. And we are -- part of our investments will be in making sure that workforce and capability are there.

*Mr. Latta. Okay, thank you. You know, moving forward we need to preserve domestic drug manufacturing and stockpiling, and mitigate supply chain vulnerabilities to enable continuous manufacturing capabilities and active pharmaceutical ingredients.

Dr. Califf, what steps should Congress take to further protect access to and further safety of pharmaceuticals while preventing supply chain shortages?

*Dr. Califf. Well, as we have already discussed, better information for FDA to coordinate when there is an impending shortage, and basically using talk therapy with the industry to get cooperation and collaboration where it is needed -- because normally, they are competitors.

But in the long run we have got to deal with the fact that many of these commodities and generic products are very low cost. There is a -- there is intense competition. And

when the price gets below what can support -- you mentioned a highly-qualified workforce, investment in facilities -- then the pressure to offshore comes in, which we have also talked about. So we have got to deal with these adverse economics that are occurring.

That is well beyond the FDA's remit, but it is a very important part of it. But we specify in our documents what -- in our requests what we need to fill in, those data parts where we can deal with it with the situation that we are currently in.

*Mr. Latta. Well -- and again, because I know when -- we were all getting calls.

And are there any particular category of drugs we should prioritize first before targeting others? Because again, you are talking about offshore, because I know that when we had committee hearings, we heard about all the different drugs that all of a sudden we didn't have, that we had to have, you know, coming from someplace else.

But what drugs do we absolutely have to essentially have? Do you think that -- we prioritize at the top of the list that we start with, and then we start backfilling

everything else and -- from there?

*Dr. Califf. Sure, there have been several essential medications lists, and there is a global list. We are just finalizing a synthesis of all those. It is pretty much all the same, the things that hospitals and health care facilities would depend on at a time of crisis.

But I should also point out, you know, if you had told me that Tylenol or Ibuprofen would be a major issue, you know -- I am a cardiologist. I am used to dealing with life or death. But it turns out, when the surge went up, there was no way our American manufacturing could meet the demand in the U.S., and it was a global thing.

So we do need to start with the highest priority, and that is what we are doing. But I think we shouldn't fool ourselves to think we can only deal with life-or-death drugs and devices. We are going to have to deal with the whole picture.

*Mr. Latta. Okay, thank you. You know, I look forward to working with my colleagues to reauthorize PAHPA and build off these lessons we have learned from COVID-19.

And lastly, I will be submitting the following QFRs, Mr.

Chairman, regarding clinical laboratory capacity and diagnostic testing for our Strategic National Stockpile.

And I yield back the balance of my time.

*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. Thanks to all of you for your great work, and being here today to share your perspective on how we can be prepared for what comes next.

At the subcommittee's February hearing on the pandemic response, we talked about some of the work CDC is doing to improve data collection and communication channels with state and local public health officials, other partners out there, just to kind of build that picture, that ongoing surveillance of what is happening with disease. And I kind of wanted to build on that a little bit more, maybe broaden it out to talk about all the dimensions of information-sharing that needs to happen, and so forth, because we know one of the big lessons we learned from the pandemic was how indispensable it is to get this information, and to have it at our fingertips real-

time, interoperable, all the rest of it.

We pointed to some efforts that were stood up. Hopkins did a good job with their dashboard that they created. That is being closed down now, as you know. So it makes us think about where does that capacity reside on an ongoing basis. CDC is a natural place for that kind of function.

But even as we are celebrating the -- celebrating is the wrong word -- even as we are exhaling when we see some of the pandemic behind us, I have a sinking feeling in the pit of my stomach that we are closing up shop. We are seeing across the country that the public health officials are sort of closing up shop on what was a pretty impressive, in many instances, ability to respond to pandemic. And going beyond the baseline, we need to maintain. Going below the baseline, we need to maintain in order to be ready for the next thing so we are not just starting from scratch.

So I think, Dr. Walensky, maybe you are the best one on the panel because you have that perspective, that overview to talk about that, and maybe address some of that anxiety. But, you know, I am reading articles every day about local health operations, public health operations, where they are

saying, okay, pandemic is over, we don't need X, we don't need Y, we don't need Z. Well, we might still need X and Y on an ongoing basis to be ready for the next thing. And frankly, we need X and Y just to do public health well. Forget about a pandemic coming.

But I think we are going to lean -- the pendulum is going to go too far in the other direction. So talk about how, both in terms of the data collection, the communication, the workforce that you have talked about, how do we -- like, do we blow a whistle to the local health officials and say, "Stop, look, and listen,'' like, "before you take everything apart again,'' or like, "Put this in a closet somewhere, or out back by the dumpster.'' Like, "Think about whether it could help you in the next round, and think about, frankly, whether it is a critical part of the infrastructure you should have every single day just to have a good public health system across the country''?

So if you could talk to that, I would appreciate it.

*Dr. Walensky. Sure. There is a lot to be said there. Thank you so much for that question.

First, let me say that we have been hard at work on the

data issues. I think COVID-19 unroofed a lot of the challenges that we have in data, data management, data collection across our public health, and integrating within CDC and around the country. We did release a public health data strategy that really looks at bolstering public health data at the local source: visualization, interoperable data. And all of that is part of a two-year public health data strategy.

Your point is really well taken, though, with regard to COVID data. As I mentioned, it took us six months to get to the point that we were getting COVID-related hospitalizations. We will continue to get those. But to this day I can't tell you who is vaccinated in the hospital. We still don't have the capacity to this day. There is an important balance that I think we have to recognize, and that is all of the data that is being collected for COVID and has been collected for COVID is only for COVID. There are many other public health threats out there that we really need to have similar data for. And so the balance is going to be what is enough for COVID, and how do we bolster everything else such that we have that capacity?

I will give you the example of Mpox. We had a public health emergency that was declared for Mpox on August 4th. If you now, in hindsight, look at our epidemiologic curves, we had our maximum number of cases of Mpox in this country three days before the public health emergency was declared. If we wait for that public health emergency in order to get the data authorities that we need, we are already on the down curve, or we are already on the down curve of Mpox.

So we need it, not only for COVID and for preparing for pandemic flu, but we need it for all infectious and non-infectious risks across public health. And that is what we are advocating for here to -- for our data authorities, to be able to have line of sight of that. Thank you.

*Mr. Sarbanes. Thanks very much, and thanks for your service.

And I yield back.

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

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

Our nation's preparedness efforts remain vital. From COVID-19 to Hurricane Ian, over the last five years we have seen our health care system's strengths, as well as some of the biggest challenges. I am sure you all agree.

Unfortunately, this Administration's lack of appropriate communication between the government agencies, siloed work product, duplicative and conflicting agency recommendations, and arduous bureaucracy has been all, in my opinion, on full display.

Dr. Walensky, throughout the course of the COVID-19 pandemic, wastewater-based epidemiology has been used effectively by state and local governments, Federal agencies, universities, private businesses to monitor, spread, inform public health responses and help predict case levels in a community several days in advance. WBE produces cost-effective, aggregated, and anonymized -- I am sorry -- data from the community wastewater samples, avoiding difficult personal data and privacy issues.

It is my understanding that CDC established a national wastewater surveillance system, or NWSS, in late 2021, which has been much -- very successful, and a positive. It has

gotten a positive reception. However, it is also my understanding that NWSS has become siloed within CDC's National Center for Emerging and Zoonotic Infectious Diseases, and is restricted to known infectious diseases. This is unfortunate, considering NWSS could possibly be utilized to track high-risk substances such as fentanyl.

We are in the middle of a fentanyl overdose crisis, as you know. Under the Prevent Pandemics Act passed as part of the fiscal year 2023 omnibus, Congress authorized the CDC directly -- director to continue leveraging public-private partnerships for activities that would include wastewater-based epidemiology.

As we think about CDC being more nimble and evolving to keep pace, can you tell me why CDC is not currently utilizing wastewater epidemiology to its fullest extent?

Why has CDC not engaged with private sector partners to utilize wastewater epidemiology beyond just the Center for Emerging and Zoonotic Infectious Diseases?

If you could, answer that question.

*Dr. Walensky. Yes, I very much appreciate that question, because wastewater has been such an interesting and

informative way that we have been able to track COVID-19 novel, new way, and has a lot of promise for things like antimicrobial resistance and many other things.

As you mentioned, this is a young field. We have, over the last two years, been able to develop now up to 1,400 wastewater sites that cover about 140 million Americans. And through that, not only have we been able to track COVID-19, but we have been using it for polio in our paralytic polio case in New York, as well as for other pathogens like Mpox, which we have been using and tracking with Mpox, as well.

You actually ask a really important question. First, we are engaging in industry partnerships through our wastewater surveillance. It has been important, as we have learned -- been learning and studying. But one of the key questions that you asked is how can we use wastewater in a key area of research for other things?

Importantly, what we really want to know from wastewater is are there metabolites of fentanyl or opioids that we can detect in the wastewater before we might detect them in emergency room surveillance that we could act on?

And so that is actually the research question that we

are asking right now to say would we detect it in the wastewater in a sensitive and specific way that would lead to acute public health action in a way that would be better and faster than the surveillance that we are already doing through our state unintentional drug overdose reporting or our other emergency department surveillance systems. With that question, which we are actively addressing, we intend to sort of expand it in other ways.

The other thing I might say is it is a real important time to comment on laboratory infrastructure. And I would again invite you to go to your state lab and say, "Do we have the capacity in our state lab to do wastewater surveillance here?'' Many of our state labs do not. Really, as we think about these new and novel ways to address infectious and non-infectious threats, do we have the resources across the country in the machinery and the laboratory infrastructure and the analysts in order to scale it up? Thank you.

*Mr. Bilirakis. Thank you. Well, my time has expired, but I will submit the questions for the record.

[The information follows:]

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*Mr. Bilirakis. Please keep us informed on that issue.

*Mr. Guthrie. The gentleman yields back. The chair recognizes Dr. Ruiz for five minutes for questions.

*Mr. Ruiz. Thank you. Thank you for holding this important hearing today.

As we have said many times over the past two years, there is a lot that we learned from the COVID pandemic. It is our responsibility to take those lessons and make the necessary changes so that history doesn't repeat itself.

Before I get to my questions, I would be remiss if I didn't mention a bill that I have worked on for several years with my friend, Dr. Bucshon: the Good Samaritan Health Professionals Act of 2023. The bill would simply expand liability protections for doctors who volunteer during national or public health emergencies by allowing them to help in places of need, regardless of state boundaries. This was passed as part of the CARES Act for doctors to be able to respond to COVID needs, but I urge its full inclusion in the reauthorization of the Pandemic All-Hazards Preparedness Act as the legislation moves forward. I look forward to working with the committee on this in the coming months.

Dr. Walensky, thank you for being here today. It is good to see you again. We have had several conversations over the past couple of years regarding the need for a more robust public health workforce. While health care worker shortages are common across many specialties, there is an acute need when it comes to the public health workforce. Why do we need and what should we be doing to bolster our public health workforce on the local, state, and national level in the context of preparation for future public health emergencies?

*Dr. Walensky. Thank you so much, Dr. Ruiz, for that question.

So much of what we need in our public health workforce is a workforce that is diverse as the communities we serve. It is those trusted people on the ground that can reach and know where to reach communities, and know the culturally competent messages that they need to hear in order to actually get implemented guidances to better public health.

As part of those authorities that we need at CDC, and I would say across public health in general, are things like student loan repayment, non-competitive fellow conversion,

direct hire authority, over-time and danger pay. These are all things that, if we are going to be a response-based agency, that we have to have the same authorities that -- like FEMA has, in terms of being response-based.

*Mr. Ruiz. Thank you. A robust workforce is key to creating and implementing adult vaccine programs, which are a critical component to preparedness. The COVID-19 pandemic highlighted gaps in access to vaccines and treatments for the most vulnerable in our communities. As we think about future outbreaks, it is critical that we make sure everyone has access to these lifesaving therapeutics.

Dr. Walensky, can you say more about how the proposed Vaccine for Adults Program would address these gaps so that, in the case of another pandemic, we are not starting from square one?

*Dr. Walensky. We absolutely -- thank you so much for that question, because we have a really robust Vaccines for Children Program, which has saved trillions of dollars and millions of lives. We do not have a similar vaccine program for adults. That is, there are 14 actively approved and recommended vaccines for adults that uninsured adults do not

have access to in the absence of a Vaccines for Adults program, and we don't have one.

That is why we need for COVID-19 -- a bridge plan for COVID-19 vaccines over the next two years to be able to deliver those vaccines to uninsured adults. But that leaves out influenza vaccines, and shingles vaccines, and pneumococcal vaccines, and hepatitis vaccines. All of those vaccines are uncovered, and we don't -- we are not positioned to be able to sustain this for another public health emergency for flu vaccines, for example. Thank you.

*Mr. Ruiz. Thank you. Pivoting to another important issue that we need to address moving forward, and that is one of data sharing, we have talked about the need for CDC to have better access to data. But as we have heard today, the FDA would also benefit from additional data sharing authorities.

Dr. Califf, what does FDA need in terms of data authorities from states, and why is the current process of working with each state individually ineffective during a public health emergency?

*Dr. Califf. Thanks very much. And, you know, while

CDC is focused on the public health needs, we are focused largely on the biomedical needs for things like vaccines and treatments, how they are doing in the real world. And as I have been listening to this, I have thought of an analogy that may make it easy to understand what the issue is.

We largely do share data sources with CDC and analyses. We talk about them all the time when we have them. CDC inherited, when Dr. Walensky came in, a system where their pipes were corroded. So if you imagine a system where there is a spigot, the data flows into a common receptacle, it gets processed and sent back to people to figure out what to do with, the people controlling the spigot are the states and the counties. And if every time we want to do something we have to go ask every one of those people with every one of those spigots, a huge amount of time goes by, up to months.

And in the meanwhile, we are going down the road, particularly in an emergency, having to make decisions without the data, so much so that I have had to call Israel several times to figure out what is going on, because they have a system with electronic health records, where the data is ready instantaneously. We need that in the United States.

It is not for us. It is not for the public health agencies. It is for the person who gets sick, or has a problem that needs their physician or health care provider to know what happened to other people like them in real time.

*Mr. Ruiz. Hey, thanks for what you do. Thanks for keeping our nation safe, despite the attacks and the personal attacks. It takes courage to be a good, honest, truthful public health expert these days in this country. So thank you for doing it.

*Mr. Guthrie. Thank you. The gentleman yields back, and the chair now recognizes the leader on our side of the dais on this issue, and working well with the Ranking Member Eshoo -- and I just appreciate you all's efforts -- I recognize Mr. Hudson for five minutes for questions.

*Mr. Hudson. Thank you, Chairman Guthrie, and thank you for making this a real priority for our subcommittee. And I want to thank Ranking Member Eshoo for your partnership and leadership. I have learned a lot from you, and I have enjoyed working together, and look forward to all we are going to accomplish working together.

Thank you to our witnesses for your time here today and

your important testimony. I am going to try to cover a lot of ground here, so I am going to dive right in.

My focus on this reauthorization has been a thorough process. And last year, I led the Healthy Futures Task Force Subcommittee on our side of the aisle. We solicited extensive feedback from the private sector, we hosted roundtables with Members, and most recently, working with Representative Eshoo, we put out an RFI to engage stakeholders in ways that our nation can improve and avoid similar mistakes we have made in the past, and capitalize on a lot of the successes that we have had.

But I want to be clear to everyone listening. This is not a COVID response bill. This reauthorization will ensure that our nation is prepared for all public health security threats, including natural disasters, cyber attacks, and biothreats alike, and in that light will focus on overall solutions.

Ms. O'Connell, great to see you again today. Under PREVENT, and as part of the end-of-year omnibus, Congress directed the creation of the White House Office of Pandemic Preparedness and Response Policy. This position is to be

appointed by the president, and serve as the principal advisor to the president on all issues related to pandemic and preparedness policy, including making recommendations and coordinating Federal activities. The director will have limited staff, and serve as a co-chair of PHEMCE, the Public Health Emergency Countermeasures Enterprise, along with you, the person in your position.

The president has yet to appoint a director, nor has there been any word on a possible appointment or plans for an appointment. Can you speak to the status of this appointment process? Are you aware of any timeline for an appointment to this position?

*Ms. O'Connell. Thank you, Congressman. I cannot speak to the status, of course. That is a discussion that the President is having at the White House.

*Mr. Hudson. Well, thank you. Well, how do you see your role as ASPR interfacing and coordinating with this director, both as leads in our nation's pandemic preparedness and response efforts as co-chairs of PHEMCE?

*Ms. O'Connell. Well, I will look forward to the collaboration and the partnership with whoever the President

picks to run that office.

It is important to me that ASPR leads where ASPR can lead, and that we are role players and strong role players where we need to be. And when we are a partner with someone at the White House, that will be just fine, and we will look forward to having a very collaborative relationship with the PHEMCE in this co-chair role.

*Mr. Hudson. Well, currently, in the case of disagreements among PHEMCE members or recommendations, the HHS Secretary has the final decision-making authority. Will this chain of command remain, even as it appears the intent of the new position will be to create a direct line of communication between the director and the president on these issues? Do you -- how do you see this playing out in real time, a real case scenario?

*Ms. O'Connell. Well, as I understand it from the legislation currently, the PHEMCE reports to the Secretary, and that will continue to be -- unless that is changed in the new bill, that will continue to be the way that we do this.

*Mr. Hudson. Well, and I appreciate that, and I think one of the things that this committee has got to kind of

resolve and work through with this reauthorization is what is that really going to look like. And, you know, I would appreciate your feedback through this process, including any concerns you might have about structural problems, or any ideas you have of how we can make the chain of command more clear.

You know, I think, in practice, when we have had emergencies, when we have had outbreaks, the White House always takes control of the communications piece, regardless of whether it is Republicans or Democrats. This -- but in practical terms, they are the ones that the public sees, yet your office is the one that has got the authority to direct, within HHS, the response.

And so, you know, there is -- I think there is a lot of work we need to do and could do to make that work better. And so I would appreciate your feedback as we go through this process. And any thoughts you have that you would like to submit to us, we would welcome those.

Now, I have heard from many stakeholders requesting a mechanism by which industry partners could play a role in PHEMCE, and the feedback we have gotten from private sector

-- there have been some problems. We have heard stakeholders that have faced issues with lack of communication and transparency. I know you have said it is a priority under the 2019 reauthorization. It is -- was codified that there should be this interaction.

Do you -- is there any current formal process by which private industry can interface with PHEMCE?

Do you think having an advisory council formally created for private industry would help any -- I am out of time, but any thoughts you might have?

*Ms. O'Connell. Just real quickly to say we can't do the work of developing these countermeasures without private industry. It is a public-private partnership, and so their role is critically important. I say that every opportunity I can.

I am happy to talk with you as you are thinking this through about what, you know, a mechanism might be, but we bring this to our stakeholders and our private sector partners all the time. It is really important to me that they are engaged.

*Mr. Hudson. Well, I think we have got to figure out

how to do it a little bit better.

But with that, Mr. Chairman, I am way over my time, so I will yield back. Thank you.

*Mr. Guthrie. We appreciate it, and appreciate your efforts on this.

The gentleman yields back, and the chair recognizes Ms. Kuster for five minutes for questions.

[Pause.]

*Ms. Kuster. Sorry, there we go, there we go.

Opportunities where we can do more -- ensuring everyone has access to lifesaving vaccines is a key opportunity for improvement. For centuries we have relied on vaccines to protect and defend against severe illness, and the COVID-19 pandemic demonstrated the importance of effective vaccine information. Sadly, the COVID-19 pandemic also showed that Americans who don't have insurance struggled to get the vaccine. All Americans should have access to vaccines, regardless of their insurance status, and I appreciate that HHS is working to make vaccines available to all Americans through the bridge access program.

However, more must need to be done. As we prepare for

the future, I am working on a proposal to establish an uninsured adults program that would close the gaps in coverage for necessary vaccines. Dr. Walensky, you have previously spoken before E&C about the importance of a robust infrastructure for adult vaccination, including an idea for a Vaccines for Adults program. Can you describe how such a program would help provide greater coverage through expanded access during public health emergencies?

*Dr. Walensky. Thank you so much, Congresswoman. We have had conversations about the critical importance of this. We have a robust Vaccines for Children program that covers uninsured children, and has demonstrated its value in saving millions of lives and trillions of dollars.

We do not have a similar program for adults for the over 20 million adults who are uninsured. They do not have access to a flu vaccine, or a shingles vaccine, or a COVID vaccine. It is because of that that we have needed to build this bridge program. But this is a short-term fix, and it is only for one vaccine. And there is so much that we could do to prevent disease and infectious disease if we had this coverage in a Vaccines for Adults program.

Additionally, it would provide consistent statutory funding for vaccines and an infrastructure such that when we have a new public health threat we have that infrastructure ready to go for the next vaccine that we need to deploy acutely. Thank you.

*Ms. Kuster. Great. Thank you so much. Thank you for your years of leadership at the CDC. We are very grateful.

Dr. Califf, I would like to ask you about how FDA regulates medical devices, and how this changed during public -- changes during public health emergencies.

As we all know, medical device labeling plays a critical role in the use and ongoing safety of medical devices, everything from MRI machines to glucose monitors. As we saw during COVID-19, the FDA was able to use its authority to make changes to medical device labeling electronically. This allowed them to respond to public health needs in real time, and keep patients and providers in touch with the most up-to-date safety information without waiting for an updated paper manual.

However, outside of a public health emergency, existing laws continue to require that device manufacturers distribute

physical paper versions of the updated labeling. Asking Dr. Califf, how would electronic labeling for devices and diagnostics help ensure providers and patients have more timely access to accurate and up-to-date information?

*Dr. Califf. Thanks for raising that. As a graduate of Silicon Valley in my private life, of course, if you can make an instantaneous change for the entire country in a label, that is a good thing. And so we are very much in favor of moving in that direction.

But we also caution that there are parts of America and people who are not facile with the technology, particularly for devices that are used at home by people who still need the paper copy, because that is what they depend on. And so as we move in this direction, I think we all anticipate over the next decade or so more and more electronic labeling is going to be good, but we have got to nestle that in also with maintaining the paper system where appropriate.

*Ms. Kuster. Great. Thank you very much.

And with that, let it reflect that I am yielding back with the 31 seconds that my colleague went over.

[Laughter.]

*Mr. Guthrie. The gentlelady yields back. The chair now recognize Mr. Johnson for five minutes for questions.

*Mr. Johnson. Thank you, Chairman Guthrie, and thank you to our witnesses for being with us here today.

You know, here we are, more than three years removed from the outset of the COVID-19 pandemic. Gone are the days of the 15 days to slow the spread and disjointed, ever-changing recommendations from the CDC about how to go about living our daily lives. Schools were shut down, loved ones isolated, and every day American life was brought to a standstill.

From the outset of this virus, birthed and then covered up by China to now, we have learned a lot. And it is with the benefit of hindsight that we must look at lessons learned to better ensure we are prepared for the next pandemic or natural disaster.

But there were some silver linings. Telehealth, for example, has become a widely used and accepted form of care, reducing barriers to access and ensuring that rural communities like the one I live in and represent are better able to manage their health care.

Another outcome of the COVID-19 pandemic was the Strategic National Stockpile, or SNS. It has largely become a household name. The pandemic highlighted the importance of an appropriately stocked SNS filled with a variety of countermeasures to address a host of health threats that face our country.

This past October the Government Accountability Office released a report titled, "HHS Should Address Strategic National Stockpile Requirements and Inventory Risks.'' In this report GAO found that SNS contained most medical countermeasures types recommended, but often not in the recommended quantities.

American families must live within their budgets, and I believe that the Federal Government must do that, as well. But sadly, this Administration doesn't seem to feel that way. If they did, we wouldn't be in this position with regards to the debt ceiling.

So the answer is not always to just throw more money at the problem. Instead, I think we need to look at how we can better allocate resources to ensure the SNS is adequately stocked with the medical supplies necessary to ensure the

health and safety of the American people.

So my first question is for Ms. O'Connell, and it is a really simple question: Are you meeting all stated requirements, as outlined by the Strategic National Stockpile Material Threat Determinations?

*Ms. O'Connell. We currently do not have funding in order to have all of the requirements filled --

*Mr. Johnson. So you are not.

*Ms. O'Connell. We do not have --

*Mr. Johnson. So you are not meeting those.

*Ms. O'Connell. -- the funding to fill all the requirements.

*Mr. Johnson. Okay. Outside of increased budget requests, how can ASPR ensure it has the appropriate processes in place to ensure the SNS is appropriately supplied?

*Ms. O'Connell. So we have talked a lot about the PHEMCE already, and the PHEMCE is the interagency group of subject matter experts that advises the Strategic National Stockpile and BARDA on what the material threat determinations are that DHS has given us, and what

countermeasures we need in order to prepare the country against those threats.

Now, one of the things I am doing right now is I am reviewing all of the requirements. When I came into this seat in June 2021, some requirements had not been reviewed in 10 years. It is important to me that the stockpile is meeting requirements against current threats. What do we need now? Do we have the right countermeasures for the current threats? Do we need to reprioritize across the current threat landscape? That conversation is happening with our subject matter experts.

*Mr. Johnson. Yes, I -- you just took my question in a different direction. I agree with you that we have to be looking at current threats. But I can tell you from my 27 years in the United States Air Force, it is the threats down the road that we also have to be concerned about. We have got to be able to anticipate threats. I mean, we never anticipated the pandemic, but look where we ended up.

Let me ask you one final question, because I want to be able to yield back some time like my colleague did. How specifically does Administration for Strategic -- how does

ASPR aim to bridge the gaps faced between the required amounts and the current stockpile?

*Ms. O'Connell. So again, we are looking at the requirements to make sure that we have got the right things against the right threats.

We are also asking for additional funding, funding that meets the need, so people understand that as we add more threats, we add more countermeasures, that requires us to pay more for what we have.

But what we are also doing is BARDA is investing in threat-agnostic countermeasures. We are no longer one bug, one drug. We are looking for countermeasures that work against many of the threats we face. And that is one of the things down the line as we continue to innovate that will benefit all of us moving forward, including making sure the stockpile is stocked with those things that we need against the threats we face.

*Mr. Johnson. Okay, thank you. And I will yield back an entire eight seconds, Mr. Chairman.

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

*Ms. Kelly. Thank you, Mr. Chair, and thank you to Chair Guthrie and Ranking Member Eshoo for holding today's hearing, and thank you to all the witnesses for being here today.

Technology has become a significant part of our health care delivery system. In the last few years we have witnessed the increased adoption of telehealth services to the increased usage of remote technologies to monitor vital signs or blood glucose levels. We are no longer in a world where health information is shared with the confines of a building. While our ability to share data is important, our ability to safeguard health information is vital. Cybersecurity breaches compromise our response to coordinate and deliver care.

Dr. Califf, the 2023 omnibus bill that was enacted last December included important provisions regarding cybersecurity, specifically on medical device cybersecurity. The law requires the Secretary of HHS to update public information provided by the FDA regarding improving the cybersecurity of devices within 180 days of enactment. Would you provide an update on how that process is coming along,

and any examples of what FDA is planning to share with the public?

*Dr. Califf. Sure. I appreciate the interest in this, and we have been hard at work, particularly CDRH within the FDA, holding a variety of public sessions, the websites have been updated, videos that are available to the public, and many discussions with the industries that are involved.

So requirements to provide information and guidance to the industry and to the public, I think, is being met as specified in the law. But I do want to emphasize this is a race where the threat continues to increase at a very high level, and we are going to need to add more on our side of the equation to make sure, for example, laboratory-developed tests could be an entry for cyber -- entry into health care systems. And it is all part of a composite picture that we are working on.

*Ms. Kelly. Thank you for your response.

Dr. Walensky, good to see you. Thank you for your service. As today marks the end of the Federal public health emergency for COVID-19, we must ensure that we are prepared, as you know, for any future pandemics. In your testimony you

speak about the need to build a more robust, interoperable data and analytics public health system.

How can the Federal government support your efforts to build out a national data infrastructure for all hazards, whether it is hurricanes, wildfires, tornadoes -- not just pandemics -- that is capable of efficiently sharing important public health information amongst --

[Audio malfunction.]

*Ms. Kelly. -- bad actors do not have unintended access to data?

*Dr. Walensky. Yes, thank you so much for that question.

So we are hard at work in our data modernization efforts to ensure that our data systems are interoperable, that the data highways can flow. And that has been a lot of work that is happening at CDC.

What we need to make sure of after that -- and we need your help with -- is to make sure that there is actually cars on the highway once we build those highways. We don't currently have the authorities for those cars to be on the highways.

If there is an acute rare event that is happening in one state and an acute rare event that is happening in another, if they are not reported to CDC they will not be connected. And what we would like to have the authorities to do is to see those rare events that are occurring or not-so-rare events that are occurring, so that we can actually send the data back to the states, they can recognize maybe we are not alone in this.

I gave the example of Mpox, and I will give it again. We had a public health emergency that allowed us more data authorities on August 4th. We had our peak number of cases of Mpox in this country on August 1st. Things were already trending down before we had line of sight of all the data that we needed. And after we had it, it took us two months to get data use agreements in place so that we could see where vaccine was being utilized.

We also need, from a public health emergency preparedness standpoint and our public health emergency grants, to make sure that we are not simply focused on pandemic flu, that we are focused beyond pandemic flu. Because we have seen, certainly in my last two-and-a-half

years, that there are many more infectious threats, including Mpox, paralytic polio, measles, Ebola that potentially could come our way. So we do need to expand that beyond pandemic flu alone. Thank you.

*Ms. Kelly. Thank you so much for your response and, again, thank all of you for your service.

And I am yielding back 22 seconds.

[Laughter.]

*Mr. Bucshon. [Presiding] The gentlelady yields back. I now recognize myself for five minutes.

I first want to say, Dr. Walensky, thank you for your service to your country. I appreciate it. I appreciate the opportunity to learn more today about many important things our government agencies do to try to prepare for potential hazards. I mean, this is really a critical hearing.

Be it chemical threat, biological threat, cyber attack, or infectious disease, this bill, PAHPA, is about much more than COVID-19. Of course, with the recent COVID-19 pandemic, all of us now have more real-life experience with some of these programs than we probably ever wanted or knew that we needed.

I do think it is important that we assess what happened and learn from those experiences, so I will start with a question related to that. During the course of the COVID-19 pandemic we have heard a lot about testing, diagnostic capabilities, and the challenges that arose when some of these capacities were strained and outright inaccurate.

As my colleagues and Dr. Califf know, I have had some thoughts in the past about how the FDA should restructure to approach diagnostic testing, and I have legislation called the VALID Act, which has specific provisions that would help accelerate FDA review of diagnostic tests in a pandemic situation.

But on a broader level, Assistant Secretary O'Connell, HHS and ASPR does not have a testing and diagnostics preparedness plan in place. Is that correct?

*Ms. O'Connell. We do have a testing and diagnostics working group that sits within our industrial base management and supply chain work that is currently working against the testing challenges that we face.

*Mr. Bucshon. Yes, so that is the one that you are in the process of developing a more definitive plan.

Do you think something explicit along these lines would be helpful to better facilitate future efforts to develop, scale, procure, and distribute diagnostics during a public health emergency, a really specific ASPR plan as it relates to that?

*Ms. O'Connell. We have seen how important it is to have tests and diagnostics available at the beginning of any outbreak or pandemic, and so we continue to work against those challenges to make sure that we are able to provide the tests that are needed.

*Mr. Bucshon. Great. I would also like to ask about the sterilization process.

As you all likely know, EPA has recently issued a proposal on ethylene dioxide, or -- I will call it EtO. I am concerned about these regulations and the potential impact of EtO facility closures, and the subsequent impact on patient safety and device supply.

Dr. Califf, the FDA is on record as having serious concerns about the potential impact of EtO limitations. In 2020 the FDA published a list of critical devices to respond to a pandemic, 60 percent of which were sterilized by

ethylene dioxide. As we examine domestic capability to respond to future health security threats, do you consider domestic medical product sterilization capacity critical to ensuring the U.S. can protect the American people?

*Dr. Califf. The short answer to that is yes.

*Mr. Bucshon. Yes. And so, on this situation with ethylene dioxide, if that -- if the EPA does, for example, restrict that substantially, what do you see as our viable alternatives to maintain our preparedness?

*Dr. Califf. Well, as you know, we do have concerns. And just a sudden restriction would create substantial difficulty with critical medical devices. So EPA is in the lead in this. We are working on it. There is an interagency process.

We are also working with the industry to come up with alternatives. I wish I could say there is a ready alternative in a short period of time.

*Mr. Bucshon. Yes.

*Dr. Califf. There is not, but we need a national investment in those alternatives.

*Mr. Bucshon. Thank you.

Assistant Secretary, do you have any comments on that?

*Ms. O'Connell. We will continue to support our FDA colleagues in this process.

*Mr. Bucshon. Thank you. Good answer. Pretty definitive. Doesn't tell me a lot, but it is still definitive.

[Laughter.]

*Mr. Bucshon. There has been a lot of talk about data today. Unfortunately, the public -- and Dr. Walensky, we have talked about this -- there is a lot of public mistrust, you know, at -- with CDC, which I think is just horribly unfortunate.

I mean -- and so, as it relates to the data and authorities provided during the public health emergency, you know, how are we going to be able to give you more authority, especially when, you know, the situation is -- you still haven't been able to -- what extent those authorities will be used, and how they will be used, I mean, when we have a lack of public confidence?

I had legislation on -- somewhat related to this, and we -- and it really kind of blew up, politically and otherwise.

*Dr. Walensky. Yes, I am really grateful for the question and for your efforts here.

So much of what you commented on early in terms of accountability and transparency has been our efforts in CDC Moving Forward, and we have had discussions about that, increasing our communication towards the American people, moving our data faster, having guidelines that is implementable and on the ground.

In terms of the data authorities, I also want to just highlight that it is the local health departments that need individualized data. It is not the CDC. The CDC is really looking for population-based data. When there is contact tracing that is happening, that is happening at the local level. The data that we are looking for is really population-based data, so that we can actually feed it back to populations.

And so I do really want to be clear. We are not looking for identifiable information --

*Mr. Bucshon. Great.

*Dr. Walensky. That happens at the local level. It is the population-based data we are looking --

*Mr. Bucshon. Right, and I understand that. How do we get that message out is difficult. It is de-identified, population-based data. I understand.

I yield. Now I recognize Ms. Blunt Rochester for five minutes for questions.

*Ms. Blunt Rochester. Thank you, Mr. Chairman, Ranking Member Eshoo, and to our witnesses for your presence, and also for your service.

This hearing focuses us on preparing for and responding to future public health security threats. Although the pandemic highlighted the fragility of our drug supply chains, the United States was dealing with persistent drug shortages prior to the pandemic. We continue to experience drug shortages to this day. Every month my constituents write to me, describing their struggles and frustrations with drug shortages, ranging from Adderall to children's Tylenol to medications for diabetes. They are imploring us to take action.

So I thank you. I thank you all for being here today to explain how the Administration plans to keep Americans safe from existing and future supply chain and public health

disruptions.

Dr. Califf, the FDA is requesting additional transparency authority to require manufacturers to tell you which suppliers provide them with the ingredients they use to manufacture their drugs. Can you describe the gaps FDA still has in its understanding of the drug supply chain, and how what you are requesting will benefit the American people?

*Dr. Califf. Sure, thanks. This is a difficult problem that we are all struggling with, and very noticeable, as you point out.

The primary gap we have is that what we need is the API, active pharmaceutical ingredient. Essentially, the raw material gets processed in one place, sent to another place, where the pill is made, and then sent through a distribution chain to where it eventually lands. We have in sight -- line of sight into parts of that chain, but not all of it. And in particular, the API, which often is coming from India or China right now, we have very little insight into how that is working.

How would we use the information if we had it? As long as things are fine, we have no interest in interfering with

the private business of medical product distribution. But when there is a problem or an impending problem, we need to work across the manufacturers who otherwise don't share data -- it is confidential commercial information -- and we need to get them to coordinate to make up for if there is a deficit one place, to make up for it in another place. And there are four or five ways we do this that we can go into in detail.

*Ms. Blunt Rochester. So why is the data already required to be submitted under current law insufficient to help FDA understand which suppliers the manufacturers rely on?

*Dr. Califf. Because the requirement right now is only for part of the information that we need in particular aspects of the distribution system. We do get -- and when it is required, we get good data, and we have beautiful graphics now to show it. But we are missing these key elements. It is like holes in the system that we can't see that turn out to be critical elements of the system.

*Ms. Blunt Rochester. Yes, I would agree with you. I actually, as part of my comments, mentioned the fact that the

lack of data and the supply chain transparency make it difficult to estimate the precise share of the key U.S. drugs and APIs imported from abroad. But we can guess that a lot of them, as you just suggested, come from China and India.

My legislation, the Supply Chains Act, would support the creation of manufacturing jobs in the United States and the relocation of critical supply chains to the U.S. or U.S. allies and key international partners. So I believe we have the same goals in mind.

In June of 2021 the President released a report that assessed supply chain vulnerabilities across four key products. Pharmaceuticals and APIs were one of them. To reverse the decades-long decline in U.S. manufacturing and economic leadership, Congress has invested heavily in onshoring critical manufacturing.

Dr. Califf, as we ramp up domestic API and pharmaceutical manufacturing, what are the top three things we can do in the short term to address and mitigate drug shortages?

*Dr. Califf. Well, I would put at the top of the list the better information that we talked about. The authority

to make that happen is very important.

And then there is the communication that needs to occur across the companies that I described, very important for us to be able to do.

And then there is coordination within the government.

Also, because Ms. O'Connell and I spend a lot of time talking about this right now, about how to put the pieces together -- because, again, very often with medical supplies you can make up for a shortage by doing something else and compensate for it. But I want to stress again this doesn't solve the fundamental economic problem that --

*Ms. Blunt Rochester. Right.

*Dr. Califf. -- onshoring is going to require that we have a viable system whereby American companies can actually make a profit if they are in the business in peacetime.

*Ms. Blunt Rochester. Yes. Thank you so much.

I just want to end by saying Congressman Buddy Carter and I have introduced the Essential Medicines Strategic Stockpile Act to provide that short-term solution, and I look forward to working with my colleagues across the aisle to make sure we address these issues that affect our health, our

wealth, and our national security.

Thank you, and I yield back.

*Mr. Bucshon. The gentlelady yields back. I now recognize Mr. Carter for five minutes for his line of questions.

*Mr. Carter. Thank you, Mr. Chairman, and thank you all for being here.

Dr. Walensky, I want to thank you for hosting us at the CDC a few weeks back. A delegation of -- the Georgia delegation, as well as members of the Doctors Caucus that I led down there. Thank you very much, and thank you for your service, and good luck in your future endeavors.

Folks, you know, I have always said there is a difference in knowing something and realizing it. And I think that we knew we were too dependent on foreign countries for our pharmaceuticals, for our PPE. But we realized it during the pandemic, when all of a sudden we couldn't get it, and it was a big problem.

One thing that concerned me was that in the Doctors Caucus we were told by, I think a very reliable source, that although we didn't know about the pandemic until about

February of 2020, there was actually a downtick in the amount of PPE that was coming from China that could be traced all the way back to the fall of 2019. They knew that there was a problem. They knew that they had a problem over there, and they were hoarding PPE. That was told to us. So that tells us, and it gives us an important lesson to be learned there, and that is that we need to be prepared. And that is essentially what we have been talking about all day, and essentially, what we are trying to do.

One of the things that I wanted to mention -- and I appreciate Representative Blunt Rochester mentioning this -- is that I have legislation -- she and I together have legislation called the Essential Medicines Strategic Stockpile Act, and this will allow private and public sectors to partner with -- or the private sector to partner with the Federal Government, so that we can stockpile generic drugs that are at a risk of shortage.

We know what this causes. As a pharmacist, I have experienced this. I have seen the horrible situation that we can get into when we have a shortage, particularly now as we are experiencing with amoxicillin, essential antibiotics, and

that.

I wanted to ask you, Ms. O'Connell, I wanted to get your thoughts on this approach of the Essential Medicines Strategic Stockpile Act that, as I say, would give the private sector the opportunity to work with the Federal Government so that we can stockpile generic drugs that we know could be at a risk of shortage.

*Ms. O'Connell. So as the facilitator, of course, of the Strategic National Stockpile, we would be pleased to engage in a technical assistance process as you are thinking about this legislation, some things that have worked, some things that haven't worked, if there is any benefit to -- you know, to doing it as you propose.

You know, one of the things that we are approaching, just so you know, is making sure the supply chain is strong, but that the stockpile is the backstop for that. So we are looking at a continuum across both, and would be really happy to engage with you on that.

*Mr. Carter. Well, and I hope that we will be able to work with you, and I hope that we can have your commitment that you will work with us, and -- because it is something we

need to address, and something -- we certainly feel like this is a good approach to it.

We also have another piece of legislation that deals with state stockpiles. And please understand that this is not to replace the national stockpiles. But instead, it is to complement it. And this is -- this would be a pilot program. And in fact, there were some -- some of the provisions of this were actually passed in the recent legislation and the recent omnibus. And I wanted to ask you, do you know, Ms. O'Connell, if any of this is working or not?

*Ms. O'Connell. So thank you for that provision in the PREVENT bill, and we are aware of that. No additional funding came with that, but we continue to provide that technical assistance to states.

And it is interesting, you know, as states undertake this, there is a challenge on what you keep in, what you move out, how often you replace, how much you need. And we are very happy to work with them to give advice on how we face these complex problems, as well.

*Mr. Carter. Good, thank you.

Dr. Califf, I wanted to ask you, because I am reading a

book now, "China Rx,'' and it talks about the API and how we really -- the labeling process by which the FDA requires the manufacturers to label this, can you explain that to me? Because in the way the book describes it, it is kind of haphazard.

*Dr. Califf. Well, that -- I would hate to describe it as totally haphazard; maybe kind of haphazard in Southern talk.

*Mr. Carter. Kind of. Yes, well --

[Laughter.]

*Dr. Califf. It would be a good description.

*Mr. Carter. We do like Southern talk around here.

[Laughter.]

*Dr. Califf. So you talk of it -- you think of it as a bulk substance, which then is made into a pill. There is no tracking mechanism right now required that we know where that bulk substance comes from, and where it goes as it gets into the final pill which is then distributed in the U.S. and to the public.

So as your colleague pointed out on the other side -- and thank you for working on this together, I think it is

really a good thing -- that means that we can't keep track of how dependent we actually are. We know we are very dependent right now. And I would point out there is a report from FDA in 2019 that lays this out in great detail. And I think, because the pandemic hit shortly after, it sort of -- everyone was swept up in dealing with it.

But having -- just think of it as chain of custody. Like many other things we do in life, we start with the bulk substance. There should be line of sight into the entire chain of custody.

And I would stress again it is commercial confidential information. We do a pretty good job at FDA at keeping commercial confidential information. But if we have to reconstruct it, much like Dr. Walensky was saying, for public health when there is a crisis, it takes forever. We need to be able to look when it is needed to preempt these problems.

*Mr. Carter. Great. Well, I am out of time, but I do want to talk further about this, and see how we can assist you in getting to that common goal.

*Dr. Califf. I look forward to it. I can't resist saying we are almost in seersucker time here again.

*Mr. Carter. We are, almost, and I got mine ready.

*Dr. Califf. I look forward to meeting with you then.

*Mr. Carter. Thank you.

*Ms. Eshoo. Okay.

*Mr. Guthrie. The gentleman yields back.

*Ms. Eshoo. That is enough of Southern talk.

*Mr. Guthrie. I recognize Dr. Schrier for her five minutes.

*Ms. Schrier. Thank you, Mr. Chairman. Thank you for all being here today. I just want to start first by saying we worked a lot, all of us, during the pandemic. And there were frustrations along the way, and lots of challenges. I want to thank you for working with me. And, you know, in retrospect, we really did do, and thanks to you, a pretty remarkable job in dealing with a crisis amid a lot of public pushback and misinformation that made whatever we provided, whether that was masks or tests, a challenge in the real world.

I would love to talk with you today about lessons learned, and I would like to start with Assistant Secretary O'Connell.

We have talked many times before, and, you know I am a pediatrician, so I am focused on children. And I appreciated your answer to Mr. Cardenas. I also wanted to make sure that in future disasters children are a first thought and not an afterthought. They are not just little adults. And part of that is making sure that we have health care providers who are available and ready to surge.

We already have a threatened shortage of pediatricians, and I am not going to ask you a question about how to increase the pipeline for pediatricians. That is a bigger scope. But I am going to ask you, you know, how can we ensure that there is surge capacity to make sure that in an emergency we have the workforce needed to address children's needs?

*Ms. O'Connell. Congresswoman, thank you so much for that question. That is a concern of ours, you know, making sure that the special populations -- the children, the seniors, those with disabilities -- are accounted for in all of our plans moving forward, that their care is taken care of and provided in an appropriate way.

So we have the National Disaster Medical System, which

are, you know, teams of clinicians that go out and decompress hospitals when they are overwhelmed. And we keep pediatricians and pediatric nurses on those teams. And when we need to, we will go into a NICU or a PICU you to make sure that, if those hospitals are overwhelmed like we saw with RSV and flu this winter, that there is a team that can come in and help those care providers on the scenes by adding additional surge capacity, as you suggest -- really important that we don't lose sight of how important that care is in these times.

*Ms. Schrier. And I would even suggest, as a community pediatrician, like, really even more assertive outreach so that people understand that this system exists. And, you know, all pediatric hospitals were strained at the same time, so it is very hard to do without pulling people from outside the hospitals to get them to work in the hospitals. And I am happy to work with you on that.

I had another question. This one is about the Strategic National Stockpile, and making sure that we have enough in order to meet children's needs. This came up when we were even facing a formula shortage and thinking, oh, gosh, you

know, this is kind of like a medicine, kind of like food. We should have this in the stockpile. And so I was just wondering if, you know, what are you doing to make sure that there is appropriately-sized masks, and appropriately-sized intubation kits, formula, other needs, dosing guides for children?

*Ms. O'Connell. So, whenever possible, the stockpile procures the things that children can use in times of emergency. So that is really important. And when that is not possible, they work very closely with subject matter experts and specialists to figure out how to repurpose what they do have in ways that children will be taken care of. But whenever possible, they look to procure things that the children can use.

*Ms. Schrier. Thank you. It is -- this was a disease that mostly hit adults, and we were lucky this time, but we don't know what the next one will bring.

I am not sure where my time is because I think that clock is wrong. But Dr. Califf, I am going to just go to you until you cut me off. I wanted to ask you about -- well, first, thank you for your work with me on tests.

I read in your in your statement, your testimony, about drug shortages, what we are doing to prevent them, how to have an early warning system. So I just perused this morning the list of shortages of medications. And with the eye of a pediatrician, I noticed albuterol solutions on there, lidocaine, epinephrine, amoxicillin, these -- saline. These are a really big deal for kids. And so I am wondering if you have started to make any of the changes to address these shortages. Like, how is it working in this transition period to make sure we don't get in and stay in this situation?

*Dr. Califf. I have described it as plugging the holes in the dike. And we have gotten better and better at that, because if you look at the number of impending shortages it is going like that. We are up in the multiple hundreds, whereas the number of actual shortages is staying at around 40 or so per year. But that is too many. And these impending shortages do create stresses, as you know, in practices and the hospitals.

So we have got to fix the fundamental underlying issues, which I know is the subject of another hearing that was going on this morning. Most of that, we believe, is not in the

purview of the FDA. It has to do with the economics, particularly of sterile, injectable medications and issues like antibiotics, where -- I don't know about you, even in a not-for-profit pediatric practice, if I said I have got a great deal for you, you can see all the patients in the world, and you are going to lose money on every patient you see, I just don't think that that is something that people are going to sign up for very easily.

*Ms. Schrier. Yes, we do need to address --

*Dr. Califf. So we have got to --

*Ms. Schrier. -- the economics, for sure.

*Dr. Califf. Yes.

*Ms. Schrier. Although the economics are pretty darn good for ADHD medications, and we are even in shortages of those.

*Dr. Califf. Well, if I may, I think that is a different issue that is very complicated because of the role of the DEA. And as much as I am in favor of telehealth and very excited about continuing it, there has been a misuse of telehealth by companies giving bonuses for the number of prescriptions written. So I think the Adderall situation is

a very different, complex set of issues. I am happy to discuss --

*Mr. Bucshon. The gentlelady's time has expired.

*Ms. Schrier. I agree, thank you.

*Mr. Bucshon. The gentlelady yields back. I yield to Dr. Dunn for his five minutes.

*Mr. Dunn. Thank you very much, Mr. Chairman. I appreciate the opportunity to begin the discussion surrounding the reauthorization of the Pandemic Preparedness Act.

When I came to Congress I had no idea how many disasters we would be dealing with: hurricanes, war in Europe, and a global pandemic. You know, I appreciate the opportunity to make improvements in this preparedness.

We got many things right with the COVID-19 pandemic, but we got some things wrong, too. Operation Warp Speed was a success. Failures included the unnecessary shutdown of society, much to the detriment of our children, and inconsistent messaging from our public health agencies who thereby lost the trust of the American people.

In Florida our governor questioned the Federal

authorities when appropriate. He followed the science and did what he thought was best for the health and well-being of Florida.

One of the biggest failures of the pandemic was the general lack of attention paid to possible therapeutics, both new and old, off the shelf.

Throughout the course of the COVID-19 pandemic, my staff and I were inundated with offers to help the nation's response, and it was actually inspiring to see the innovation of the American people. It included everything from PPE manufactures, new drugs, old drugs, well known, anything could be repurposed. I was encouraged when we set up BARDA's Tech Watch, which I understood was supposed to field and vet all these offers.

Unfortunately, it seemed the government was only interested in a certain narrow range of vaccines, monoclonals, and new pharmaceuticals. So I -- we often heard from stakeholders that BARDA had told them after meetings that some product didn't meet what they were looking for, although it seemed very successful and useful. You know, the COVID-19 pandemic was evolving and different needs at

different times.

Secretary O'Connell, can you speak to how BARDA Tech prioritizes the research and development of medical countermeasures, including vaccines? Whatever you got on your fingertips: vaccines, therapeutics, diagnostics, or devices.

*Ms. O'Connell. Thank you, Congressman, and thank you for that question and for your interest in BARDA's Tech Watch program.

They open up their doors to those that are looking at innovative solutions to any number of problems that we have, and offer these meetings that can be 30 minutes to an hour to go through the technology that the meeting holder is seeking to put forward. And -- but it is market research that is done. You know, it is understanding what is out there, figuring out what the needs are.

And then there is another system that BARDA has for actually applying for funding. So there is two different ones that is in their BARDA broad agency announcements.

But regardless, if your constituents are having trouble accessing BARDA, please let me know. Please work with my --

have my staff work with your staff, and I would like to make sure that you don't have that problem moving forward, or anybody doesn't have that problem moving forward.

*Mr. Dunn. I appreciate that. We certainly spoke to then-Secretary -- or assistant secretary at the time.

In thinking about this, Secretary O'Connell, if you think about future pandemics -- you mentioned the importance of the seven viral families that are most likely to cause a pandemic, and the need to develop medical countermeasures to defend against these threats.

What is being done, you know, to help BARDA sort of think outside the box when it comes to advanced R&D on these threats?

And specifically, you know, what responsibilities, not just -- in general, not just specific treatments.

*Ms. O'Connell. So it does worry me, the seven viral families, you know, we had this head start with COVID because we had done the work on coronaviruses because of MERS and SARS. And now we know the seven viral families most likely to cause the next pandemic, and we have asked for funding both in fiscal year 2023 and now fiscal year 2024 to be able

to jump start the development of the prototype vaccines, therapeutics, and diagnostics so we can put them on the shelf and pull them down when that viral family hits, should it hit, and be able to ramp up manufacturing very quickly.

So it is part of that preparedness, making sure we have got a library of prototypes available. And in that process we are looking at a lot of different innovations, and appreciate that question. Among them, you know, right now we do vaccines through a needle in a syringe. We are also looking at what it would mean to do a patch with a microneedle, so it is easier to --

*Mr. Dunn. So, if I may, I am concerned there is -- of course, the public is all fascinated with vaccines. But, you know, traditionally the response to an epidemic or pandemic is therapeutics, not vaccines. I mean, medicines, if you will. And, you know, we seem to have fastened on the vaccines almost to the exclusion of other options.

I know we did -- Remdesivir didn't work. I know we did -- Monoclonals are always going to be very, very, very specific and expensive, you know, so, I mean, we could think of, you know, therapeutics in terms of small molecules, like

we do antibiotics.

With that, Mr. Chairman, my time has expired. I yield back.

*Mr. Bucshon. The gentleman yields back. I now recognize Mrs. Trahan for her five minutes.

*Mrs. Trahan. Well, thank you to the witnesses today, and thank you to the chairs and ranking members for holding this important hearing.

We have a unique opportunity to take the lessons learned over the past few years in the course of the COVID-19 pandemic to use them to legislate in a way that better prepares our health system to respond to future unknown public health threats.

Two years ago my colleague across the aisle on the full committee, Mr. Balderson, and I co-founded the bipartisan Pandemic Preparedness Caucus. Now, alongside our co-chairs, including another member of this subcommittee, Mrs. Miller-Meeks, we are coordinating closely with committee members to reauthorize PAHPA. I encourage all the members of the subcommittee to join the caucus and help support policies we want to see in the reauthorization of this critical law.

It is no secret that a major issue during the pandemic was the lack of visibility into the exact quantities of critical medical equipment, supplies, and drugs that were on U.S. soil at any given time. As a result, there was a surplus of products in many parts of the nation, while hard-hit communities were operating in crisis mode.

As we relied on community organizations like Community Health Centers to respond to the pandemic, the lack of clarity into PPE and other supplies was an extreme challenge that hindered provider ability to deliver and inform care. So, Assistant Secretary O'Connell, what were some of the challenges the nation faced due to the lack of clarity into the supply chain?

And how would our future response efforts improve if we established an automated data collection infrastructure that enables real-time, accessible data that expands the visibility into the entire supply chain?

*Ms. O'Connell. Congresswoman, thank you so much for that question. It is exactly one of the problems that we witnessed in March 2020, when everybody needed the exact same thing at the exact same time, and it was manufactured

somewhere else.

So improving on that has been one of the priorities that we have had, and using the COVID dollars that you all have given us over the course of the supplementals, we have continued to invest in domestic manufacturing to bring some of that manufacturing home. That gives us line of sight into what we have. When it is manufactured here it is easier for us to tell what we have and what we don't have.

We also know it was a problem that states and local governments didn't know how to access the Strategic National Stockpile. Now, the Strategic National Stockpile didn't have all the things we needed at that time, but that was -- would have been an important thing for states to understand and to know. And so we have done a lot of education and a lot of outreach to states and local governments to make sure they understand what is in it, and how often they can access it, and under what circumstances.

We -- as part of the PREVENT bill that came through, the omnibus, we released a 60-day guidance for states and locals on how they would access the Strategic National Stockpile.

The SNS is also doing tribal consults to make sure that

those governments understand how to access what they need in the stockpile. So we are trying to do an education in places where we know people didn't have clear visibility.

*Mrs. Trahan. That is helpful. You know, I had a Lessons Learned Pandemic Preparedness roundtable recently in my district, and one thing I heard from those participants is their, you know, frustration with the lack of coordination between, you know, Federal, state, and local governments.

And you brought up what we were doing in the way of awareness and education. And certainly, we want to figure out what that means to us as we legislate. So is there ways that we can leverage, you know, state response capacity to improve our initial emergency response?

And has ASPR -- you know, I think you are thinking through forward-deploying with guardrails some SNS supplies to states during non-emergency times so that they are in a better position to quickly respond to future emergencies. And is there -- and I am just wondering, beyond what you are doing at ASPR, how should we be thinking about legislating that?

*Ms. O'Connell. Well, I think one of the most important

things that we are very aware of -- and I know you are, as well -- is that that -- you know, these outbreaks start locally. And so to have real clear communication between the local governments, the state governments, and the Federal Government is really important for them to know what we are doing, for us to know what they are doing, for them to know what we are not able to do, and what they should be doing. All of that is critical in those early days.

And one of the things that we continue to do where we do our outreach calls, make sure that we are coordinated with our state health officials and others. I know CDC is actively engaged in those communications, as well. We can't have daylight between us. We are in this together.

*Mrs. Trahan. Yes. Well, I appreciate that. I just glanced up at the clock, and I am sorry you saw my eyes move.

I don't have any more time to ask, Dr. Walensky, my question that I had for you, but I will say that you will be missed, although we won't miss you up in Boston. We look forward to having you back. Thanks.

*Mr. Bucshon. The gentlelady yields back. I now recognize Dr. Joyce for his five minutes.

*Mr. Joyce. Thank you for yielding, Mr. Chairman, and thank you for the panel for appearing today.

Dr. Califf, just a few moments ago you mentioned about shortages, and shortages that occurred during the pandemic. I know that you and your colleagues are aware of another potential shortage because the FDA has raised concerns with the EPA about the risks of sterile medical device shortages from their proposals to limit the use of ethylene oxide.

I am concerned that the EPA's rules would limit our domestic sterilization capacity for critical medical and surgical products. I raised these issues with EPA Administrator Regan at yesterday's hearing, and he committed to brief the Energy and Commerce Committee and our staff alongside the FDA to discuss these issues and take steps to ensure that any final rules don't adversely impact physicians' and patients' access to sterile equipment and treatments.

Dr. Califf, would you commit to appearing at a joint briefing for the committee alongside with the EPA administrator before May 24th to address this important issue?

*Dr. Califf. As we discussed earlier with Dr. Bucshon, this is a great concern to us. EPA is in the lead, and there is an interagency process. So we will certainly work with EPA and you to get these issues resolved.

*Mr. Joyce. Thank you. I appreciate that commitment.

Assistant Secretary O'Connell, the Administration has requested another 5 billion for their project, NextGen, for COVID-19 vaccines and therapeutics. As a physician myself, this cost and the Administration's COVID-19 vaccine and drug development track record is not that good.

At the time President Biden chose to dismantle Operation Warp Speed, the country had three approved vaccines across two different vaccine platforms, with a fourth vaccine using a third platform going through approval. And despite unprecedented levels of funding because of decisions by the Biden Administration, unfortunately we only have two vaccines, and both of them using the new mRNA platform.

Therapeutics tell a similar and similarly disappointing story. The Biden Administration's major therapeutic development programs, the NIAID-led Antiviral Program for Pandemics and the joint NIAID-BARDA Antiviral Drug Discovery

Centers for Pathogens have yet to produce a single therapeutic, despite spending 3 billion of taxpayer money and promises in June of 2021 of new treatments by year's end. Paxlovid and Lagevrio are both developmental programs, but they are the only two that remain for COVID-19 therapeutics. We currently have no effective monoclonal antibodies.

Secretary O'Connell, can you provide us with an update of what promising COVID treatments we can expect to have coming out in the programs in the next six months?

*Ms. O'Connell. Congressman, thank you so much. So the next generation of COVID vaccines and therapeutics are critical to keeping the American public safe. You know, we know that we are one or two mutations away from what have been effective vaccines and antivirals from no longer being effective. So it is really important that we continue to seek out this research and development and -- against a virus that has been nothing, if not unpredictable.

One of the things that this program is going to focus on is trying to find a monoclonal that is not -- that is resistant to any of the variants, that -- one of the things that has impacted the monoclonals that we have had are the

various variants and subvariants that have come out and rendered them ineffective. So finding one that does not -- that is not impacted by the variants is going to be critical. So that is one of the places where this program is going to focus.

We do need to have a range of therapeutics available. We are lucky that we have the antivirals right now. But again, we know that this virus has been nothing, if not unpredictable, and really important that we stay ahead of it.

*Mr. Joyce. The first awards were made a year ago, and as best as I can tell the program hasn't generated a single additional approved therapeutic. Can you please keep us apprised as these developments occur?

Because it is necessary that we have all applicable, approved therapeutics available, and I think that you have the resources to provide us with that information. So I would appreciate being informed as this continues to evolve.

Director Walensky, communication with public about infectious disease events, particularly during public health emergencies such as COVID-19, is crucial to a successful response. You have publicly stated this, and I agree with

you on that. For many of my constituents, public trust in the CDC has been decimated due to the guidance and public statements that have been made by the Administration. They don't match the facts. And public data specifically regarding acquired immunity seems to be something that has not been adequately addressed.

Can you please outline specifically efforts that the CDC has in the timeliness and accuracy of guidance and communications to the public, and how we can restore that faith in the CDC?

*Mr. Bucshon. Can --

*Dr. Walensky. Thank --

*Mr. Bucshon. Dr. Walensky, his time is expired. Could you answer that in maybe a written form, or --

*Dr. Walensky. I am happy to.

*Mr. Bucshon. -- maybe as a follow-up on another member's --

*Mr. Joyce. Thank you. I would appreciate that.

[The information follows:]

3079 **********COMMITTEE INSERT**********

3080

*Mr. Joyce. And again, thank you for presenting yourself to us here today.

*Mr. Bucshon. The gentleman yields. I recognize Mrs. Harshbarger for her five minutes.

*Mrs. Harshbarger. Thank you, Mr. Chairman. Can you hear me okay? These allergies, it is bad.

Thank you for being here. Thank you for your service, Dr. Walensky. I enjoyed meeting you and talking with you down at the CDC when we came in April.

My first question is, Dr. Califf, you know I have been a compounding pharmacist for 36 years, and compounded medications played an important role during the pandemic in meeting -- helping to meet these drug shortages, especially in distribution to hospitals and COVID patients, items like hand sanitizers, fentanyl for the ventilators, and I could go on and on where we had to step in and do that due to shortages.

You know, I can look at the FDA website any given day and see hundreds of drug shortages like you talked about, and I have done that over the course of all those years I have been a pharmacist. Shouldn't the FDA have a regulatory

framework in place for compounding pharmacies to help mitigate shortages, including shortages of drugs urgently needed by providers to administer in clinical settings?

*Dr. Califf. Well, thanks for bringing that up. I actually was a compounding physician earlier in my career, when IV nitroglycerin on coronary care units was needed, so we ran a little compounding facility.

*Mrs. Harshbarger. Well, we have that --

*Dr. Califf. So I understand the issues very much.

I think we feel like right now we have a lot of flexibility when there are -- emergencies do occur, as happened here. But your idea of thinking about a permanent solution or guidance on that flexibility, I think, is a good thing to work on.

*Mrs. Harshbarger. Well, I am here to help you, trust me, you know, because right now we have these policy guidances, and they are issued, basically, when you have a drug shortage.

So does the FDA shortage list adequately capture regional shortages and shortages at the wholesale level?

*Dr. Califf. Well, the term "adequate'' is a bit

subjective, but I would say it could be better because, I mean, particularly for rural areas --

*Mrs. Harshbarger. Yes.

*Dr. Califf. -- what we have learned with infant formula, for example, is we are above where we were before the recall, but there is still some rural areas that have shortages.

*Mrs. Harshbarger. Oh, yes.

*Dr. Califf. So understanding the total distribution system is difficult.

*Mrs. Harshbarger. I have -- exactly. And we are here to help you with that, believe me.

Would you consider recognizing the American Society of Health-System Pharmacists' shortage listing? It is even a more complete listing.

*Dr. Califf. Well, I guess -- what is the right political word? Everything is on the table.

*Mrs. Harshbarger. Great, thank you.

*Dr. Califf. We will consider --

*Mrs. Harshbarger. I appreciate that.

*Dr. Califf. I can't commit to anything, of course,

but --

*Mrs. Harshbarger. Okay, no worries.

*Dr. Califf. -- we will talk.

*Mrs. Harshbarger. We will follow up.

Why does the FDA issue guidance related to compounding of certain things like your ibuprofen products, but you haven't taken similar steps to increase the supply of other medications like acetaminophen?

And you mentioned that you are compiling a list of critical medications, a global list. And I hope to goodness you have antibiotic therapies on there, as well as chemotherapy drugs. And, I mean, I could probably make the list myself, but --

*Dr. Califf. You know, I once -- I was involved in trying to recruit Dr. Walensky to come to Duke to head up our infectious disease division.

*Mrs. Harshbarger. Well --

*Dr. Califf. Ever since then --

*Mrs. Harshbarger. She is going to be available, she says.

[Laughter.]

*Dr. Califf. It seems like every time she talks, she reminds me of the antibiotic issue. And we are well aware it is --

*Mrs. Harshbarger. There you go. It is a huge --

*Dr. Califf. It is a very special problem. We -- I mean, on a serious note, antibiotic resistance and the need to have antibiotics in reserve --

*Mrs. Harshbarger. Oh, totally.

*Dr. Califf. -- is a really serious issue.

*Mrs. Harshbarger. Well, that brings me to this. What about a priority on friendshoring with allied nations?

You mentioned that the database in Israel -- how complete the health care database was, and we know that -- for its citizens. Why not create a new staging ground for manufacturing with Israel and the Abraham Accord countries, are you open to that?

*Dr. Califf. I am open to --

*Mrs. Harshbarger. You are open.

*Dr. Califf. Like I say, everything on the table --

*Mrs. Harshbarger. Everything is on the table.

*Dr. Califf. Remember, my career was largely spent

doing international global clinical trials.

*Mrs. Harshbarger. Yes.

*Dr. Califf. And I feel like I have a deep knowledge of what happens in multiple countries. There is a lot to trust.

*Mrs. Harshbarger. Yes.

*Dr. Califf. There is a real opportunity in working --

*Mrs. Harshbarger. A lot of innovation.

*Dr. Califf. -- with people. But, just like with compounding pharmacies, there are things that can go wrong.

*Mrs. Harshbarger. Well --

*Dr. Califf. So we do need --

*Mrs. Harshbarger. -- that is just the world --

*Dr. Califf. We do need regulations and --

*Mrs. Harshbarger. -- that we live in.

*Dr. Califf. -- and checks in the system.

*Mrs. Harshbarger. Yes. Thank you, sir. Yes.

Ms. O'Connell, you know we are looking at things to ensure American taxpayer dollars are not -- are spent not only to prepare for potential disasters, but also prioritize and support domestic production. And, you know, we need to look at tax and trade policies to promote that. It is kind

of like -- what did we just have? We had an amoxicillin shortage. I have the only plant in the country that makes amoxicillin, and it is in my district. But do you know what? They don't have a government contract, and they ship their -- their first line was shipped to another country.

So there is things that we need to look at, and things that I may be able to help you with that -- where we could -- even repurposing drugs, Dr. Neal and I talked to a geneticist. We have 7,500 drugs we can repurpose with the DoD just for such an emergency as the next pandemic. There is a lot -- I have got a lot of ideas, just ask me.

And I know I am out of time.

*Mr. Bucshon. Yes, the gentlelady is out, time has expired.

*Mrs. Harshbarger. Okay. I will get with you later. Thank you.

I yield back --

*Dr. Califf. Could I give one quick anecdote?

*Mr. Bucshon. Yes.

*Dr. Califf. I worked in that plant that you are talking about 30 years ago, when it was SmithKline. So --

*Mrs. Harshbarger. Yes.

*Dr. Califf. And I talked with the CEO multiple times this year, so we will talk.

*Mr. Bucshon. The gentlelady yields back.

[Laughter.]

*Ms. Eshoo. You got a lot of talking to do.

*Mr. Bucshon. I recommend -- I now recognize Dr. Miller-Meeks for her five minutes.

*Mrs. Miller-Meeks. Okay. I don't know how to follow that, but thank you, Mr. Chair, thank you to our panelists for being here.

Dr. Walensky, let me just echo my colleagues in thanking you for your service. Having been the former director of a -- just a mere state department of public health, I think the challenge in coming in to an agency such as the CDC at the height of a pandemic is extraordinarily difficult, and I appreciate your service. That doesn't mean I am going to be easy, or not going to have some concerns and questions.

And first and foremost, since I heard the mention of infection-acquired immunity, I just wanted to have entered into the record a letter from the Doctors Caucus to the CDC

September 28th, 2021, asking for clarification on infection-acquired immunity.

And the reason the issue is important is that we are talking about capacity, surge capacity, allocation of resources. And when our agencies are not nimble enough to look at the science and the research, dissect through that research, and put forward reasonable proposals and recommendations, then we misallocate resources, both personnel, workforce, as well as vaccines or other supplies, especially when they are things that are extraordinarily expensive.

And we have talked about having a surge capacity, and that is not only a workforce surge capacity, that is a testing capacity, as well. And that goes into reagents, swabs, all of the things which we found that we were lacking at the top of this pandemic. And it also is how you allocate the people at your disposal and those who are not under your agencies, which means how do we utilize our research laboratories? How do we utilize our public-private partnerships to have them as part of our surge mechanism? And if those are not in part of our pandemic plan, then

Congress will direct you, because there is plenty of us here that have ideas on both Strategic National Stockpile and workforce issues.

One of the things that I think Dr. Bucshon had mentioned earlier was talking about H.R. 550, and data, and data collection. And so, Dr. Walensky, the CDC continues to engage Congress and push for increased data authority, which has -- it has been a key part of your testimony today. And you also say that the data authority will enable information to travel more seamlessly to those who need it, eliminating duplication, making data-sharing less complex.

The duplicative comment is interesting, because the CDC currently operates over 100 public health surveillance -- and you might have addressed this earlier -- surveillance systems that collect ongoing data from more than 3,000 state, local, territorial, and tribal partners. And this would appear to cause some major reporting burdens, duplication of efforts, discrepancies among the data elements, and the need to use multiple IT systems, which may also lead to increased costs, as well as some difficulty in communication.

It would seem to me that the CDC needs to address its

data systems in house before requesting even more mandated data authority. Do you agree with this or not agree with this?

*Dr. Walensky. Maybe two points. First I just want to address the letter that you had sent to us in September of 2021 on infection-induced immunity, and note that we had our first scientific brief that was posted in October 2021 outlining the totality of the science as we were aware of just a month later. So that was something that has been key on our mind.

*Mrs. Miller-Meeks. -- change recommendations.

*Dr. Walensky. That was -- we can have another -- I mean, I am happy to chat about that. And we have, actually.

You know, I do want to talk about the data, because one of the things that we are -- and we are working to actually streamline the data that comes into us to make it easier. I can give you an example out of Oregon Health Information Systems, where their streamlining in their data modernization saved them 145,000 person hours over just 11 months because they were not doing manual data entry. That is the goal that we are actually working towards, not only distributed across

the states, but within the CDC.

While we are doing that, as we are building those highways and streamlining those, decreasing those person hours so everything is more automated, we will have those highways, but they will be free of data if we don't also have the authorities to get that collection in.

*Mrs. Miller-Meeks. And then I only have a little bit more time. So when we went into our legislative pause as I was a state senator, one of the things I had suggested was, having been in the military, to set up a reserve force. And so I think that we are trying to have that same concept within the CDC. And I am wondering if you can address the U.S. Public Health Service Commissioned Corps, and how were they utilized.

So my understanding is that, at the height of the COVID-19 pandemic, that only half of the officers were actually deployed. So were these officers at the CDC? Were they at regional offices? And why were so few deployed in the actual surveillance mechanisms and vaccination efforts? If you could, address that quickly. Thank you.

*Dr. Walensky. Thank you for that question. I would be

-- first I would love to thank you all in Congress and -- for our ability to actually execute on the Public Health Service AmeriCorps, because that is among the things that we are looking to hire 3,000 reserve public health workers for exactly that reason.

You talk about the Commission Corps, and I am happy to come back to you with some definitive data on that, except to say that many of those Commission Corps within CDC and were deployed within CDC. So I don't know that they would have actually counted as deployment. They were deployed to a response, but they were -- might have been working in our center on, I don't know, meningitis, but they were, you know, deployed to the COVID-19 response, and that might not have been tallied in your numbers. Thank you.

*Mrs. Miller-Meeks. If you could give us in writing some more clarification on that, that would be appreciated.

*Dr. Walensky. I am happy to.

*Mrs. Miller-Meeks. Thank you, Mr. Chair. I yield back my --

*Mr. Bucshon. The gentlelady yields back. I now recognize Mr. Griffith for five minutes.

*Mr. Griffith. I thank the gentleman.

Dr. Califf, in 2020 the CARES Act gave FDA enhanced data collection to help mitigate drug shortages. In your response to our March 27th, 2023 letter on drug shortages, you claimed only 44 percent of registered facilities have complied. Is that correct?

*Dr. Califf. That was true at the time, but it is gradually getting better.

*Mr. Griffith. Have you -- has the FDA enforced any actions against the non-compliant facilities?

*Dr. Califf. I will have to get back with you on that. I am not aware of any particular actions, or exactly what the actions would need to be, other than reminding them of their responsibilities.

*Mr. Griffith. Yes, we -- and I would love for you to get back with me on that, and send me a written response. I would appreciate that.

[The information follows:]

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

*Mr. Griffith. We heard in the drug shortage hearing that was happening downstairs earlier today that the economic pressures are a big factor in causing shortages, particularly in the generic field. This has led to one in four generic medications being filled in the U.S. The companies, one in four, have received FDA warning letters.

Do you agree that there are economic factors at play that we must address, such as group purchasing organizations, if we are going to be able to have a better supply chain for our generic medications?

*Dr. Califf. It sounds like the herring downstairs is getting to the core of the issue. There are economic -- like I was saying before, 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.

So we have got to fix the core economics if we are going to get the situation fixed. We can plug the holes with the things that we have talked about, with better data and

talking to the companies to make up for problems when they occur, but we need to prevent them.

*Mr. Griffith. Well, one of the things that we got into downstairs -- and you never have enough time to get into everything when you only get five minutes of questions, but one of the things we got into was the fact that we are heavily reliant on China and heavily relied on India for the API to make the medications in the United States. Most of it is coming from Asia.

And part of the concern was that we do such a job on inspecting American manufacturers, and holding them to a high level, but then we don't do inspections overseas. And so not only is it cheaper from a labor standpoint, but it is also -- you are not likely to have as many inspections from the FDA at your overseas locations. Doesn't that force our manufacturing offshore, and make it more difficult for us to supply medicines for Americans?

*Dr. Califf. I have had the privilege and experience of working in both China and India in my private and academic life. We inspect in India, and hold India to the same standards as we do the U.S. We have had a problem in China

the last several years, as you well know. And during the pandemic it was also difficult to get to India during times of surges.

But in general, we are holding India to the same standard. And as we are allowed back into China, we will do the same thing there.

*Mr. Griffith. Well, but should we be allowed back into China, and will they let us back into China? I mean, one, I don't know that we want to be dependent on China. Two, under their interpretation of their laws, your inspections may now be a crime in China. So why do we continue to think that that is our answer?

*Dr. Califf. I certainly don't think that is our answer. I have started -- helped start a university in China. I know a lot about Chinese laws and customs.

I will point out two-thirds of the world's population lives between India and China and the ASEAN nations in between. So they need to have their own API manufacturing, all that.

*Mr. Griffith. I am not against them having their own, I --

*Dr. Califf. -- but we need --

*Mr. Griffith. -- just don't want them strangling ours.

*Dr. Califf. We need a balanced system where we do our part in the U.S.

But again, I will just say no American businessman is going to go into a business where the economics say you are going to lose money. And so we have got to fix the fundamental economics.

And if you tell me we shouldn't inspect to make sure of the quality --

*Mr. Griffith. No, no, no, no --

*Dr. Califf. -- I would say no, please, let's don't do that.

*Mr. Griffith. No. And in fact, one of the concerns that I raised downstairs -- and that I think you would agree with -- is that this race to the bottom on pricing has affected the quality and the assurance that we will actually have the medicine available for the American consumer when they get sick.

We had a mom down there testifying that her daughter was going through some leukemia treatment and on three different

occasions during her treatment they did not have the medicine. They did not have the medicine. And while her daughter has survived, she mentioned cases that she knows of -- because she started a non-profit group to help people find the medicine -- where doctors have told her that it impacted the health of the patient or even led to death. This is unacceptable. Don't you agree?

*Dr. Califf. This tears us up at the FDA, and we are frequently caught with these manufacturing issues, but it is an essential medicine.

And you are referring to Cisplatinum, which is a drug that we gave as interns decades ago. I won't say how many decades for you, but it was four decades for me. It should be available. But for all the reasons that you gave, we are seeing lapses due to the economics.

*Mr. Griffith. All right. I yield back. We will work together to fix it.

*Mr. Bucshon. The gentleman yields back. I now recognize Mr. Crenshaw for five minutes.

*Mr. Crenshaw. Thank you, Mr. Chairman. Thank you all for being here. I really want to focus on our ability to

detect diseases, to do surveillance on diseases domestically and globally. You know, it is concerning.

And I will submit this GAO report for the record that, you know, 15 years after we have passed a law that instructs HHS to have these surveillance systems in place, they are really not implemented, not even close.

This comes on the heels of the end of Title 42 this week. You know, recently, New York City health commissioner issued a public letter to New York health care providers urging them to take precautions and conduct additional tests to prevent an alarming trend of diseases spreading among illegal foreign nationals arriving from the southern border. I am submitting that for the record, as well. This letter warns against polio, chickenpox, tuberculosis, et cetera. How are we addressing this?

You know, one of the problems is I am not even sure who I should ask, because this is the problem that is brought up in the GAO report. Is it CDC, or is it Ms. O'Connell?

Like, I -- this is a problem here, where no one seems to be in charge of the detection and surveillance of diseases coming into our country. So whoever answers is fine, but

what are we doing specifically about Title 42 being ended, where is the CDC on this?

*Dr. Walensky. Maybe I will start and say we have a -- numerous platforms of surveillance systems through our emergency departments, through our public health departments.

One of the real challenges, as we have talked about this morning, has been that not all of those surveillance systems have required reporting to the CDC. So even if there is something detected locally that -- we may not know it at the CDC, and we might not be able to actually then give that information back to the neighboring local health departments or across the country to say, "Red flag, we see something out there, you all should be on the lookout for it.''

With regard to Title 42, among the things that we have done and put out as we have seen infectious threats come in is our health alert networks. We have done so when there is a measles outbreak and other things. And likely what happened in New York is similar health alert networks to recognize we may have under-vaccinated people who are settling in communities, and we need to watch out for infectious threats --

*Mr. Crenshaw. I mean, are there --

*Dr. Walensky. -- most clinicians haven't seen yet.

*Mr. Crenshaw. I guess what I am getting at, you got tens of thousands of people, tens of thousands of people coming across the border. Do we have CDC personnel doing what I think any American would expect the Center for Disease Control to be doing, which is, I don't know, randomized testing, right? Randomized testing of wastewater, fecal matter, whatever it is. Do we have teams on the ground that do that kind of thing in order to detect -- or are we completely reliant on the reporting that you get?

*Dr. Walensky. I would -- I am not sure I understand the question, partially because randomized testing of what, who, and where?

There are a lot of --

*Mr. Crenshaw. Well, in this case on the southern border, but --

*Dr. Walensky. -- infectious and non-infectious threats, and wastewater, as you know -- and we are really -- I think is an incredibly promising new diagnostic capacity, but it is not for every infectious threat. And we don't know

for every infectious threat whether, if, and how it is sensitive or specific in detecting it. If you don't see and -- a pathogen in the wastewater, does that mean it is not there? Maybe not for many of these.

*Mr. Crenshaw. But we definitely don't know --

*Dr. Walensky. If you do detect it --

*Mr. Crenshaw. -- if we are not testing it. We definitely don't know.

*Dr. Walensky. We don't necessarily even know what to test for, what fragments to test for. It doesn't come out in whole genome sequences.

*Mr. Crenshaw. Maybe it is not -- maybe that is not the answer, but it seems to me there is no plan.

And again, I want to submit this for the record. So 15 years later, the only thing that has been implemented by HHS is to adopt technical and reporting standards, and that is theme that I always hear back from you all, is, well, you know, we have reporting standards, we have our partners on the ground, whether it is the local public health authorities, whatever it is, they report back. Sometimes they do, sometimes they don't.

Is the CDC just some academic institution, or is it an operational institution?

Here is the one glaring issue that I see in this GAO report. Well, here is the problem: "There is no lead operational division with defined roles and responsibilities for implementing these statutory requirements.''

Who is in charge of this? Who is putting people on the ground, whether it is globally or whether it is at the southern border, where we actually have some kind of legitimate surveillance system on global pandemics or diseases?

*Dr. Walensky. So we at CDC work in 60 countries to prevent and work towards global health security, both in surveillance and disease detection, as well as working towards medical countermeasures in those countries. We are working closely with DHS and, at their request, when they need help on public health in their -- public health support in their entry -- ports of entry.

*Mr. Crenshaw. Okay, but the -- okay. So -- but for Title 42 ending, I didn't see anything in the Administration's plan for CDC at all on the southern border.

Is that correct, or is it --

*Dr. Walensky. Well, we are working with DHS, per their request, for their public health requests.

*Mr. Crenshaw. Doing what?

*Dr. Walensky. You know, I think it depends on the request, and it depends on --

*Mr. Crenshaw. They haven't requested anything yet.

*Dr. Walensky. I would have to get back with you as to the nature of their request.

*Mr. Crenshaw. I am sure --

*Dr. Walensky. We have been working closely with them for the last three years.

*Mr. Crenshaw. Okay. I am out of time, I yield back.

*Mr. Bucshon. Mr. Crenshaw, you have two documents you want to submit for the record?

*Mr. Crenshaw. Correct.

*Mr. Bucshon. Without objection, the documents Mr. Crenshaw -- is being submitted to the record.

[The information follows:]

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

*Mr. Bucshon. The gentleman yields back. I now recognize Ms. Castor for her five minutes.

*Ms. Castor. Well, thank you, Mr. Chairman. Thank you all for being here to help the Energy and Commerce Committee update PAHPA. But mostly, thank you for all of your hard work during the public health emergency. All of your professional teams, we are grateful for all that you do to help keep Americans safe and healthy.

We need to apply some of the lessons learned to the update of PAHPA, and I am sorry that my colleague from Florida already left, and -- because he had said something like Florida was a shining example during the pandemic. And I wanted to remind him that our current surgeon general has been rebuked by medical professionals across the country for spreading COVID-19 misinformation, implying that there were particular health impacts from taking the COVID-19 vaccine that were really debunked across the board.

Plus, in Florida, unfortunately, out of the five largest states, we had the second-highest case rate. We had the second-highest death rate.

One of the problems over time, too, was the -- at the

state level, when some of the data became -- when some of the cases, infection rates, became -- they became -- politicians became very sensitive to it, they started to hide the data. And the only places we could go would be to the hospital reporting and, unfortunately, to medical examiners. And that is, of course, a very late lagging indicator. So it has been apparent even before the COVID-19 pandemic that we have got to modernize data collection across the country. And I know that we have provided significant resources to do it.

But it seems like what I am hearing at home is they are still frustrated with the outdated nature of reporting standardization. They want to be able to compare rural communities and urban communities. They want to be able to get into disparities.

So, Dr. Walensky, you have probably been asked about this already today here, but what else did -- does Congress need to do to provide CDC and our public health officials at home with modern reporting systems?

*Dr. Walensky. I appreciate that question, and I appreciate your recognizing some of the challenges when there is motivation to not report. We don't get those data, and we

can't have full line of sight.

One of the things that we are actively working as part of our CDC Moving Forward -- and really, through this pandemic -- on data modernization across the United States, we have gotten, you know, over $750 million in order to do that. But that means local health departments may only get $10 million in order to modernize their data systems. I can tell you, in the hospitals that I used to work with to upgrade their health care systems to Epic, they required over $1 billion themselves.

So as we think about $1 billion for the country, and recognize that that is not going to go as far as we need to go in our data modernization efforts nationally, we are working really closely -- just Tuesday I had a conversation with our state health officials. We have been working with our state and local epidemiologists, state and territorial epidemiologists to really understand what is the North Star architecture that we are putting together so that all of those data highways connect.

The challenge is -- and that work is ongoing, and we have made huge progress, and we have a public health data

strategy that was just updated for the next two years for that interoperability -- if we don't have authorities, those highways will be empty. Those data highways will be empty, and we will have challenges again. If there is a motivation to not report public health data to CDC, you will continue to be blind because we --

*Ms. Castor. And it is so costly. I mean, this can be a way for taxpayers to save money down the road. I know there is an upfront investment, but there is a significant societal cost if we cannot detect disease, and then stamp out pandemics before they spread.

*Dr. Walensky. I will say it is costly both in terms of dollars, and in terms of sickness and morbidity and mortality.

And the example that I previously gave was in the Mpox outbreak. The Mpox outbreak, we started to be able to get data authorities because of the public health emergency that was declared on August 4th. We had our peak number of cases in Mpox on August 1st. So we were already seeing downward trends in the number of cases before we could even start negotiating with a public health emergency to have data

authorizations.

*Ms. Castor. Well, thank you very much for your service, and you are going to be missed.

Dr. Califf, we had a very good bipartisan hearing on drug shortages, and the witnesses all said that FDA is doing a decent job, but we still have these shortages. They highlighted the importance of building public-private partnerships, giving FDA additional ways to incentivize that behavior, and the transparency of being able -- in real time -- again, this is a data modernization issue to be able to see what is really happening in real-time, and be able to respond.

*Dr. Califf. It is nice to get a compliment. Sometimes we go days without that.

[Laughter.]

*Dr. Califf. So I really, really appreciate that.

*Mr. Bucshon. The last witness -- the last member.

*Dr. Califf. Well --

*Mr. Bucshon. finally, right?

[Laughter.]

*Dr. Califf. Working on it. But I do want to make one

point related to Dr. Walensky, because we share this, and it has come up earlier. She uses highways, I use spigots and faucets.

She inherited a CDC system that I think everyone agrees had corrosive pipes and obstructions, and it just was not a modern system. I got an independent assessment from Micky Tripathi, who is the head of the Office of the National Coordinator for Health IT. They now have shiny pipes, but the spigots are not turned on because of this issue we have between states and counties and the Federal component. And we won't know how good the pipes are, really, until the data starts flowing through.

I grew -- I had a world where I was used to looking at geospatial -- that is, you know, rural, urban, specific areas, and time. And if you want to run a public health system, there is nothing technically holding us back. It is all human interactions now. But Dr. Walensky's counterpart who comes in next, she will be able to say, "Here is exactly where the problem is, and here is where it is going. We are going to deploy forces to that area in real time, not three months later, not six months later.''

*Ms. Castor. Thank you.

*Mr. Bucshon. The gentlelady yields back. This concludes the member questioning, or panel one. I would like to thank all the witnesses for your testimony and for your time, and we will now proceed to the second panel. And so thank you very much.

[Pause.]

*Ms. Eshoo. May the force be with you, Dr. Walensky.

[Laughter.]

*Ms. Eshoo. Thank you.

[Pause.]

*Mr. Guthrie. [Presiding] The subcommittee will come back to order, and I thank all of you for agreeing to testify.

I will introduce our witnesses and call on each one for a five-minutes opening statement.

The first witness will be Tom Inglesby, director of Johns Hopkins Cancer Center -- or Hopkins Center for Health Security and the Bloomberg School of Public Health.

Also we have Randall Lutter, senior fellow at the Manhattan Institute.

Our next witness after that will be Erik Decker, chairman of the cybersecurity working group at the Health Sector Coordinating Council.

Our final witness this morning -- this afternoon now -- is Mary Denigan-Macauley, a director of health care and public health -- and private health markets at the U.S. Government Accountability Office.

So we will begin with opening statements, and I think most of you testified before.

You have five minutes, you will get a yellow light as you approach -- as you see the yellow light, begin to start wrapping up. And the red light will mean your time has expired, and we will try to stick close to that, but we are getting a lot of good information today, so we have been a little lenient with it, but we are going to try to stick close. We have another hearing starting this afternoon.

So I will now -- Dr. Inglesby, I will recognize you for five minutes for your opening statement.

STATEMENT OF TOM INGLESBY, M.D., DIRECTOR, JOHNS HOPKINS CENTER FOR HEALTH SECURITY, BLOOMBERG SCHOOL OF PUBLIC HEALTH; RANDALL LUTTER, PH.D., SENIOR FELLOW, MANHATTAN INSTITUTE FOR POLICY RESEARCH; ERIK DECKER, CHAIR, CYBERSECURITY WORKING GROUP, HEALTH SECTOR COORDINATING COUNCIL (HSCC); AND MARY DENIGAN-MACAULEY, PH.D., DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE (GAO)

STATEMENT OF TOM INGLESBY

*Dr. Inglesby. Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the committee, it is my pleasure to appear before you today to discuss this year's reauthorization of PAHPA. My name is Tom Inglesby. I am the director of the Johns Hopkins Center for Health Security, and Professor in the Department of Environmental Health and Engineering in the Johns Hopkins Bloomberg School of Public Health. And the opinions expressed herein are my own, and do not necessarily reflect the views of Johns Hopkins.

Today I was asked to provide comments on the history of PAHPA, its original intent, how it has changed during prior

reauthorization, and how the COVID-19 pandemic may inform its 2023 reauthorization. I have had the opportunity to testify several times during the original PAHPA and for its reauthorizations, and I am grateful for the chance to testify before you again today, and continue to serve in this trusted capacity for Congress and this committee.

PAHPA has a strong bipartisan history of Congress working together to address our nation's changing health security landscape and protect the American people. The last three PAHPA bills all showed major recurring themes: they adjusted to the changing threat landscape, focused on challenges identified since the prior bill, and considerably strengthened our nation's health security with each reauthorization.

The threat landscape clearly has changed since the last reauthorization. This reauthorization, too, should focus on the challenges identified since the prior bill and learned from COVID-19. I will now summarize the last three PAHPA bills, and then turn to lessons from the COVID-19 pandemic that could be used to inform this year's reauthorization.

The first bill laid the groundwork for national pandemic

and emergency preparedness and response to accidental and deliberate threats. The second bill provided agencies with more flexibility to achieve their missions, and the third implemented a recommendation that I supported, which required assessments of national security threats to guide our health security. It also highlighted the importance of innovation for medical countermeasures and working with local authorities.

Since the last reauthorization, we have learned many new lessons from the COVID-19 pandemic, and I will highlight four.

Number one, we need to make, produce, and distribute medicines, vaccines, and diagnostics more rapidly. That should include investment in platform technologies, placing high priority on medical countermeasures that can protect against the viral families we are most concerned about, and contracting processes that allow the government to rapidly partner with private sector developers and manufacturers.

Number two, we need to better prepare the health care and public health systems to respond rapidly to public health emergencies, and that should include the right protective

equipment for our health care workers in a system that is resilient to supply chain disruptions, ensuring medical care is fully covered for all people in that kind of crisis, and stronger local and public health departments.

Number three, we need to strengthen Federal agencies responsible for preparing for and responding to pandemics. There is really no alternative to a strong ASPR and CDC, for example, which need to be fast-moving, operationally skilled, have the right technology, and the ability to rapidly hire the workforce for the job.

And finally, number four, we need to recognize the great significance of the work being done to prevent future pandemics. To name only some of it, that would include strong early warning systems, a commitment to international data sharing in the earliest hours of a new pandemic, good animal husbandry practices to lower the risk of spillover, prevention of the synthesis of dangerous viruses, strong codes of scientific conduct, and stronger attribution science and planning to make sure we are better prepared to identify the source of future pandemics.

Finally, PAHPA legislation has evolved as our

understanding of different biological and other threats have evolved. It has reflected lessons learned over 15 years of policymaking and on-the-ground experiences on these issues. Its evolution has been a remarkable congressional achievement and a truly bipartisan effort.

Preparedness for biological threats and for responding to national health emergencies is something that can continue to be a priority for all of us. Thank you again for the opportunity to testify, and I look forward to your questions.

[The prepared statement of Dr. Inglesby follows:]

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

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

The chair now recognizes Dr. Lutter for five minutes for your opening statement.

STATEMENT OF RANDALL LUTTER

*Dr. Lutter. To Chair Guthrie and Ranking Member Eshoo, distinguished members of the Subcommittee, I am honored and grateful to have the opportunity to testify about how best to prepare for and respond to future public health security threats. My key points are -- all relate to enhancing private sector biodefense, and may be useful for PAHPA reauthorization.

First, there needs to be more actionable information and financial incentives for effective emergency preparedness and response by the private sector.

Second, there should be more public involvement in CDC's risk communications.

And third, we need greater transparency in federally-supported research about public health and communicable diseases.

Pre-COVID pandemic warnings lacked actionable information. Information on probability and severity of -- was missing, but necessary to calculate the merit of costly additional preventive and mitigation measures. Private

executives could not have justified costly investments in, say, improved indoor ventilation without evaluating their cost effectiveness in protecting building occupants. Such evaluations require information about the probability of a new infectious respiratory disease of given infectivity occurring by a specific date: information that was and still is lacking.

Three complementary approaches to actionable quantitative estimates of pandemic risk are worth pursuing.

First, Bruin and all in 2006, applied structured expert judgment to address pandemic influenza risks from the bird flu known as H5N1. They concluded there was a 15 percent chance of efficient human-to-human transmission within three years. Such explicit and easy-to-interpret estimates are not found in Federal reports on pandemic preparedness, but they could offer useful insights about pandemic risk, especially if issued periodically.

Second, Nobel Prize-winning economists have long argued for prediction markets to aggregate information from large numbers of people about the likelihood of uncertain events. A 2016 study of prediction markets in Taiwan considered 5

disease indicators such as severe and complicated influenza and flu-like illnesses. For three out of five disease indicators, market predictions outperformed conventional surveillance. The longer-lasting markets with more participants might perform even better.

Three, big data solutions would estimate the risk of a pandemic by collecting, organizing, and synthesizing big data through early warning systems. This approach would require upgrading and updating USAID's now-defunct PREDICT program, including surveillance and testing of livestock, poultry, wildlife of special concern for viruses, either novel or of special interest. It would be time consuming and require more investment and international cooperation and new data integration systems, and it would go beyond the 2022 National Biodefense Strategy by explicitly seeking a quantitative risk assessment for new pandemics.

Congress should support all three approaches to improve pandemic risk assessment: the periodic structured expert judgment, prediction markets, and big data solutions.

Catastrophe bonds could offer firms a better way to manage pandemic risks. Such bonds could be modeled in part

on the pandemic catastrophe bonds developed and marketed through the World Bank and benefiting from bank-related subsidies. Medder and Schwarcz recently suggested that unsubsidized pandemic catastrophe bonds for unintentional pandemics could be feasible.

Congress should ensure that there is no legislative or regulatory obstacles inappropriately hindering the development of prediction markets or pandemic catastrophe bonds.

Last year the CDC director acknowledged substantial public dissatisfaction with COVID-19 risk communications in justifying her proposals for reform. FDA's 2,000 good guidance practice regulations is a good model for the CDC to use. That regulation establishes a standardized process for nearly all formal use of statements about what non-Federal entities should or ought to do.

The FDA guidance documents explicitly state that entities need not follow FDA recommendations if they meet existing statutory regulatory requirements. FDA's process requires it to open a public docket to get public comment on all guidance it issues. FDA solicits public comment both on

draft guidance and on final guidance that it determines it must issue without prior public comment, as happened during the pandemic. Congress should direct CDC to adopt good guidance practices rules like those of FDA.

The pandemic undermined confidence in public health policies and in the role of science in informing health policy. Scientific journals controlled by HHS are exceptions to the widespread practice of top scientific journals, including "Proceedings of the National Academy of Sciences'' and "Science,'' to make public access to computer code and data a condition of publication. Emerging Infectious Disease, Environmental Health Perspectives, and Morbidity and Mortality Weekly Report -- all three Federal journals controlled by HHS -- have no comparable transparency policies.

Congress could and should require federally-controlled and supported peer-reviewed health journals to adopt transparency measures comparable to that of the PNAS.

I am happy to take questions. Thank you.

[The prepared statement of Dr. Lutter follows:]

3979 **********COMMITTEE INSERT**********

3980

*Mr. Guthrie. Thank you. Thank you for your testimony. The chair now recognizes Mr. Decker for five minutes for your opening statement.

STATEMENT OF ERIK DECKER

*Mr. Decker. Thank you, Chairman Guthrie, Ranking Member Eshoo, and members of the subcommittee. I am Erik Decker, chairman of the health sector coordinating council cybersecurity working group, and vice president and chief information security officer, Intermountain Health. Thank you for the opportunity to speak on public health security threats, and how this interrelates with the reauthorization of PAHPA.

I believe we are at an inflection point. Our adversaries are becoming increasingly sophisticated at penetrating our cyber defenses, just as we are becoming increasingly reliant on digital data and technology. The ability of our adversaries to monetize and capitalize on our business operations, data, intellectual property, and vulnerabilities is a significant part of the reason why our sector continues to be a top focus for cyber attack.

The study just released this week titled, "The Ransomware Attack Associated with Disruptions at Adjacent Emergency Departments in the U.S.'' suggests secondary

effects occur on hospitals adjacent to those disrupted by cyber attacks, resulting in long wait times, increased census, and increases in high-acuity cases such as strokes. This demonstrates that the need to treat cyber attacks as disasters requiring coordinated planning and response is necessary.

Without proper cyber foundations in place, this velocity of digital transformation could become the equivalent of driving a race car at maximum velocity without brakes. Thus, the mission of the cyber working group is to develop and disseminate, free of charge, sector-wide recommendations and guidance to help facilitate resilience to cybersecurity threats.

Thankfully, the public-private partnership between the health sector and the U.S. Government has matured significantly over the last several years. Despite the partnership's growing strength, certain parts of the health sector, primarily smaller and less resourced entities, lag in their cyber capabilities and must be buttressed. As we like to remember -- remind everyone, cyber safety is patient safety.

Since 2018 the cyber working group has produced 21 best practice publications to aid all 7 subsectors of health and public health. I want to highlight two recent publications jointly branded with HHS. One is called "The Health Industry Cybersecurity Practices,'' otherwise known as HICP. First published in 2018, HICP provides cyber hygiene recommendations for small, medium, and large-sized organizations. It was built in partnership with the HHS 405(d) program and 150 experts across the industry. Last month we released HICP 2023.

Also in April we released the "Hospital Cybersecurity Landscape Analysis,'' another publication. This first-of-a-kind study took on the daunting challenge of determining the current state of the U.S. hospitals' cybersecurity resiliency to thwart cyber attacks. The study found that progress has been made at improving our cyber posture, but significant improvements are needed in core cyber hygiene capabilities. This study would not have been feasible without the direct support of the HHS deputy secretary, the support of the HHS 405(d) program, and the countless hours donated by the cyber working group.

In June of last year, former national cybersecurity director, Chris Inglis, invited the CEOs of the cyber working group to the White House for a cabinet-level cybersecurity summit to discuss how best to secure health care from cyber attacks in the future. Mr. Inglis charged us to set up our critical infrastructure in such a way that we would need to "beat all of us to beat one of us.''

Securing the health sector from cyber attack might seem daunting, but I am confident that we can meet this challenge if we begin with the following three steps.

One, the continuation of the joint five-year strategic planning exercise, which is contemplating what stable condition looks like for cybersecurity in the health sector by 2029.

Two, the continued expansion and improvement of the HHS 405(d) program, which is a core vehicle of partnership with the health sector and HHS. It is a shining example of joint partnership, co-branding, and joint release.

And three, we must continue to build partnership and cohesion between CISA, HHS, and the health sector. CISA, as experts in cybersecurity, produces many useful tools and

services.

With mandated reporting of significant cyber incidents on the horizon, we are excited to work through the specifics of how we will incorporate this threat intelligence consumed and received from all 16 critical infrastructure, and provide them into our proactive defenses. However, since HHS is our sector risk managed agency, we need to leverage HHS as the front door to all Federal agencies.

Thank you for the opportunity to provide my perspective. Several other recommendations are in my written testimony, and I encourage any questions you might have.

[The prepared statement of Mr. Decker follows:]

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

*Mr. Guthrie. Thank you for your testimony.

The chair now recognizes Dr. Denigan-Macauley for five minutes for your opening statement.

*Dr. Denigan-Macauley. Great, thank you.

STATEMENT OF MARY DENIGAN-MACAULEY

*Dr. Denigan-Macauley. Chair Guthrie, Ranking Member Eshoo, and distinguished members of the subcommittee, thank you for the opportunity to discuss GAO's work related to preparedness and response.

Strengthening our nation's capability to prepare for, respond to, and recover from disasters and other emergencies is no small task, particularly with ever-changing threats. This is not something the Federal Government can do alone; it requires a whole-of-nation effort with Federal, state, tribal, territorial, and local authorities, the private sector, non-governmental organizations, and communities all working together from the same playbook. As the past three years have so acutely shown, preparedness and response cannot happen in silos. Instead, we must work together to anticipate, prevent, and prepare for future events, all while responding to ongoing emergencies and other threats as they arise.

GAO's work on the Federal efforts go back decades and embrace the One Health approach by considering human, animal,

plant, and environmental threats. While many plans, some successes, and good intentions underlie these efforts, our work has shown that the Department of Health and Human Services must do better in order to save lives, mitigate severe economic impacts, and prepare the nation to respond to multiple simultaneous threats. In 2020 alone, HHS responded to hurricanes, floods, wildfires, and infectious diseases, and including the pandemic.

The systemic and persistent deficiencies we identified have hindered our nation's response to the COVID-19 pandemic and past emergencies, precisely when Americans rely on seamless and swift action. For example, undefined roles and responsibilities for the myriad of partners involved have created confusion, placing responders and communities at risk.

Delays in testing and incomplete data have prevented HHS from understanding the nationwide spread of disease and targeting response efforts, including those disproportionately affected.

Poor communication and a lack of transparency have eroded trust in the Federal Government.

Not knowing the resources response partners will bring to an emergency have resulted not only in inefficiencies, but the deployment of the wrong resources for critical care.

All of these problems placed lives at risk and slowed response exactly when our nation should have united to move as quickly as possible.

A crisis is not the time to be figuring out what to do. Preparedness needs to happen before the crisis hits. Likewise, a full and timely recovery can only be achieved through sufficient preparedness.

While fundamental in appearance, these deficiencies are complex in nature and complicated by competing priorities. Overcoming them will require many things, including significant coordination within HHS and across all of the response partners identifying the needed resources to get the job done right, including a workforce with the skills and competencies to address the risks raised.

Additionally, it will require strong and sustained leadership. This is concerning, as we have already seen high turnover at FDA -- 10 commissioners in 10 years; NIH without a director; and now the CDC director stepping down in the

midst of reform.

Since 2007 we have made over 150 recommendations to HHS, with more than half of them not addressed. Fixing the systemic deficiencies we have raised will take time. Not knowing when the next threat will arrive can dull our resolve. But inaction is not an option, as a new public health emergency will certainly arrive.

Reform efforts recently announced by HHS agencies have the potential to help address concerns we have raised, if implemented successfully. We have met with HHS to provide guidance based on key practices GAO has identified for successful agency reform. However, given the critical nature of this issue, we placed HHS leadership and coordination of public health emergency on GAO's High Risk List. This risk -- this list includes government operations in need of transformation. In this case, transformation is needed to protect the security of our homeland and to save lives.

Mr. Chair, Ranking Member, distinguished subcommittee members, this concludes my prepared statement. I look forward to our discussion today, and welcome any questions.

[The prepared statement of Dr. Denigan-Macauley

follows:]

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

*Mr. Guthrie. Thank you. That concludes our opening statements. We will move to members' questions, and the chair will recognize Mr. Hudson for -- the leader of this effort on our side of the aisle, along with our Chair Eshoo and -- or Ranking Member Eshoo in a bipartisan way. So thanks.

So, Mr. Hudson.

*Mr. Hudson. Thank you, Mr. Chairman, and thank you for -- again, thank you for making this a priority for our subcommittee.

And thank you to Ranking Member Eshoo for your leadership on this for many years, and for allowing me to work with you.

Thank you to our panel. This is your -- all of your testimonies have been extremely helpful to us. And thank you for making time to be here today. I will start with Dr. Inglesby.

Thank you. Your testimony touching on the history of the legislation, I think, was very helpful. It is also helpful in understanding congressional intent through these authorization processes, as well as kind of the overarching

all-hazard preparedness framework. If -- very briefly, if we were to rerun the clock and we are now having to respond to COVID-19 without PAHPA, without ASPR, BARDA, SNS, what would that world look like?

*Dr. Inglesby. You know, if you kind of -- if you roll back the clock before ASPR and BARDA, we didn't really have a procurement mechanism in place for new medical countermeasures. We didn't have a system of requirement setting for all of these products that we need. We had no diagnostic strategy. We had a small SNS, but it really was focused on very, very specific threats, and it really didn't connect up with the rest of the government.

So all of the structures that have been built over these previous -- the original bill and the reauthorizations have been absolutely fundamental to getting us where we are, even though we have now seen shortcomings. But it is an infinitely stronger base upon which to build the next reauthorization. So --

*Mr. Hudson. Yes, I appreciate that. And as we talk about sort of the architecture of the structure of this, you know, with PREVENT Act last year, we have created this new

White House Office of Pandemic Preparedness and Response Policy. How do you see that structure now working where you have got that office that, unfortunately, hasn't been set up yet, but advisor to the president, you have got ASPR, with their role in advising the secretary, but also administering these other programs. How do you see that working? Do you have any concerns about that? Do you have any suggestions for us as we prepare this reauthorization of how we could improve that structure?

*Dr. Inglesby. Yes, I do think that biosecurity and pandemic response is inherently interagency, because it draws on many elements of HHS, but also intelligence on the delivered side, State, DoD. So it is really important to have a White House presence, a coordinating presence.

And I think we have seen both in the Ebola response some years ago and then in the COVID response the very high value of having White House dedicated, strong leadership helping to coordinate the agencies. I don't think it is a requirement to be day-to-day managing all programs, but certainly in crisis it is very valuable to have White House engaged with leadership at CDC, ASPR, NIH, FDA, other agencies. I do

think it worked fairly well, having been part of that process during COVID and watching, for example, ASPR O'Connell coordinate with the White House and with her colleagues across HHS, I thought, was a really good model.

So instituting this new office and kind of making sure it stays in place, even though COVID is going away, I think, is a very good development. I think it is -- I know the White House is actively searching for leadership and putting its structure in place, but I think it is going to be very valuable.

*Mr. Hudson. Great, I appreciate that.

Dr. Lutter, over the pandemic there were dozens of authorities used across agencies. DoD played a significant role in the development and manufacturing, hiring capabilities that they could bring to the table for procurement. You know, and as we are looking forward now, we have been asked by HHS, by ASPR to give them the authorities that DoD has when it comes to acquisitions.

What I am trying to grapple with personally is what makes the most sense, as far as effectiveness, return on investment for the American taxpayer. Does it make sense to

create an authority that already exists at DoD over at HHS, or does it make more sense to maybe more formalize that relationship in times of emergency that DoD will play this role?

I don't know if you have any thoughts, and I would open it up to anybody else that might be able to help me wrestle with this as we try to figure out -- do you need to give those authorities the DoD has to HHS, particularly ASPR, or is it better just to -- more efficient to keep them where they are, but make sure that it will be available when we need it?

*Dr. Lutter. That is a good question, but I think I am going to kick it to GAO or somebody else who has thought about it more than I have. I wish I could help you.

*Dr. Denigan-Macauley. I can briefly say that we do have concerns of relying on DoD, because they have a separate mission. I mean, if they are called off to a war and they are not available at that time -- we saw that they have stepped in heavily on numerous occasions. So --

*Mr. Hudson. Well, I have run out of my time. If any of you that would like to would answer that in writing,

again, I think that is something that Ms. Eshoo and I are wrestling with, and would love to have your feedback on.

*Dr. Inglesby. Congressman, I am happy to do that because I did have very close interaction with the DoD contracting partners.

*Mr. Guthrie. If you have a half-minute, if nobody objects, because that is a good --

*Ms. Eshoo. Sure, go ahead.

*Mr. Guthrie. Can you give us a quick -- yes.

*Dr. Inglesby. All I would say is that HHS relied very heavily on DoD contracting specialists. DoD had contracting specialists from across the Department of Defense, which they drew in during the emergency. HHS had almost no contracting specialists to be able to do this mission. And DoD has been really very clear with HHS from the beginning that they needed all those people back. And so, even though they have been generous with their people and their experts, they really want those people back. They feel like they have full-time work.

And so I felt very strongly after being at HHS, that HHS needs to have strong contracting capability. They are the

ones -- ASPR, in particular, and BARDA -- need to be able to work with industry very quickly, very, very effectively. And without having to loan -- to work with contracting officers on loan, I think, is a very bad position for them. We expect them to be able to move quickly, and they can't do it now without DoD.

*Mr. Guthrie. Okay, thanks. We would still like your -- any responses you would like to make in writing, as well. Thank you very much for that.

And the chair now -- the gentleman yields back. The chair now recognizes the ranking member, Ms. Eshoo, for five minutes.

*Ms. Eshoo. Thank you very much, Mr. Chairman, and thank you to this panel. Thank you for waiting, for your patience.

To Dr. Denigan-Macauley, based on the GAO's work, does HHS know who in the agency is responsible for different responses in a health disaster?

*Dr. Denigan-Macauley. Clearly, ASPR is designated to work with the secretary during an emergency. But our reports have shown time and time again that there are not clear roles

and responsibilities, and there is a lack of understanding.

*Ms. Eshoo. Thank you.

To Dr. Inglesby, thank you. You said that one goal of the PAHPA legislation is to "put someone in charge.'' What changes should be made in the next iteration of the legislation to make clear who is responsible for biosecurity response?

*Dr. Inglesby. Congresswoman, I think it is very important to have clarity around leadership for different responsibilities. I think within HHS there is clarity around that, but I -- it is also true that, outside the government, that there is confusion at times from state and locals, or from other critical partners. And so I do think there would be value in the secretary or, presumably --

*Ms. Eshoo. Let me ask you this. Yes, let me ask you this.

*Dr. Inglesby. Or -- yes.

*Ms. Eshoo. Do you think that ASPR and CDC are adequately empowered to make stronger and faster decisions in the wake of a health threat?

And if you had the power to make any legislative change

to make the U.S. faster at making vaccines, medicines, diagnostics, what would you do?

*Dr. Inglesby. I think, for the last part of your question, we should establish a program for rapid countermeasure development for unknown threats. I think some people call that a Disease X program, which allows preparation --

*Ms. Eshoo. I understand what it is.

*Dr. Inglesby. -- and moving through viral families quickly. I think that is really important.

I think establishing contracting authorities pre-crisis, so that there is already existing structure between government and industry is very important.

And I think, to you're your first question, I think clarifying what ASPR is in charge of and what CDC is in charge of could be very helpful for -- especially for outside of the government. ASPR clearly is in charge of operational response, contracting private sector response, but CDC is going to need to remain in charge of technical guidance, scientific guidance to the states and locals. So they are going to continue to have leadership responsibilities, as

well.

*Ms. Eshoo. Let me ask you this. Obviously, I think we are rightly focused on pandemic preparedness because, you know, our experience with COVID, I mean, it is --

*Dr. Inglesby. Yes.

*Ms. Eshoo. -- searing experience for everyone in some way, shape, or form, really searing. How do you think we should be preparing for new and evolving health threats?

They have been mentioned today. If you heard some of the things --

*Dr. Inglesby. Yes, yes.

*Ms. Eshoo. -- that were said from the first panel, such as gene synthesis, where a virus can be made from scratch in a laboratory. Many of my Republican colleagues have spoken to that, or the use of open source AI --

*Dr. Inglesby. Yes.

*Ms. Eshoo. -- models to provide a step-by-step guide to create a deadly virus. How would you approach this?

*Dr. Inglesby. Well, first of all, I want to commend you on your letter to the National Security Advisor and to OSTP on the risks of AI and national security. And I think

you were absolutely right to ask the Administration to be developing security -- or to be requiring security and safety guidance for the AI companies that are in this space. And I think there are AI risks that relate in particular to biothreats, which I think is one of the concerns here, and they need to be directly dealt with.

I think in terms of genome sequence screening, I think it is now time for HHS to require, through a regulatory process, that genome synthesis providers are screening both the orders that come in and the people who are requesting those orders. That is something that the U.S. -- most U.S. companies are already doing on a voluntary basis, but to level the playing field around the world and make the entire industry safer, we can't have companies -- some countries in other parts of the world synthesizing dangerous viruses or components of them and sending them around the world so we can recreate smallpox.

*Ms. Eshoo. That is why I am asking you about.

*Dr. Inglesby. Yes. So I think we need a regulatory structure.

*Ms. Eshoo. That is most helpful. Most helpful. Well,

thank you very much.

And I yield back. These are such high-value discussions. It is --

*Mr. Guthrie. Thank you. The --

*Ms. Eshoo. It is exhilarating that we have such brilliant Americans that come and testify.

*Mr. Guthrie. Thank you.

*Ms. Eshoo. And that we draw so much from. Thank you, thank you, Mr. Chairman.

*Mr. Guthrie. The lady yields back, and the gentlelady yields back, and Mr. Johnson from Ohio is recognized for five minutes for questions.

*Mr. Johnson. Thank you, Chairman Guthrie.

As many of my colleagues know, but you folks certainly probably do not, I come from an information technology background. Both of my degrees, graduate and undergraduate, are in computer science, and I spent about 40 years in the business. I have seen this space grow and develop into what it is today.

And cybersecurity is so vitally important to not only preventing ransomware attacks on hospital networks and

ensuring the safety of patients' personal data, but also to our national security. Nobody is on the front lines with that issue more than hospitals are, fighting cyber threats daily.

I believe it is imperative to make cybersecurity an integral part of the conversation on how America responds to pandemics and disasters that occur inside our borders. And as we navigated the pandemic, cyber criminals saw their moment to strike, taking advantage of the chaos and uncertainty by repeatedly going after hospital networks when they were at their most vulnerable.

So what does this mean? It means hospitals are forced to push resources away from other areas where they are desperately needed, away from patient care and more toward their infrastructure or their technology. It means cuts to emergency services, canceled lifesaving procedures, and ultimately increased death rates that would have otherwise been totally avoidable. These cyber criminals are not simply stealing our data or shutting down networks. They are essentially taking American lives with them when they leave, or when they get there.

When this committee last considered PAHPA's reauthorization in 2018, cyber was a known threat, but not truly at the top of anybody's mind when it comes to preparedness, as evidenced by the fact that the last bill only had one provision related to cybersecurity. This provision required HHS to develop a strategy for public health preparedness and response to address cybersecurity threats. In the last couple of years, however, we have seen an increasing number of cyber attacks on the health care sector. Each of you spoke to the seriousness of this rising threat in your testimony.

So Mr. Decker, I would like to go to you. I know the answer to this question, but I want to hear yours: Why should cybersecurity be considered in the context of all-hazards preparedness and response?

*Mr. Decker. Well, cyber is very capable of turning into a kinetic problem. So when situations -- when hospitals are shut down, when they are attacked, when volumes and censuses go up, and the ability to care for patients goes down correspondingly to that, because we are so reliant on the technology these days, and because health care has become

digital, when that technology is disrupted for a prolonged period of time, the hospital systems have a very hard time managing through that for a prolonged period of time.

*Mr. Johnson. Got you. How can Congress, Mr. Decker, use this reauthorization process to improve our nation's cybersecurity preparedness and response?

What do you think we need to do? It is obviously not one measure.

*Mr. Decker. That is correct. This -- it is a combination of multiple things.

I do believe that incentivization is something that needs to continue to be explored, especially for some of the smaller and more medium-sized organizations that do not have the resources to apply, you know, into cyber capabilities. So you could have a small rural or critical access hospital that are -- that is under water. And the choice between an MRI machine or a cyber capability tends to go towards the clinical capability. So there needs to be more incentives, reimbursements, et cetera, to help support and bolster that. And hygiene is incredibly important.

*Mr. Johnson. Got you. Well, in your opinion, how

should cybersecurity roles and responsibilities be structured across HHS?

Does the Department need more organizational structure or clarity to address its own enterprise cybersecurity needs and its responsibilities as the sector risk management agency for the health care sector?

*Mr. Decker. Yes, there has been a lot of work on this, and HHS is, for sure, doubling down on that structure.

I think it is hard for me to answer the question of how HHS should be organized. But for sure, from a sector's perspective, we are looking for that one party to work with and get through that. We are providing them with recommendations on how things can work. But ultimately, I think that is up to HHS.

*Mr. Johnson. It is a never-ending challenge. Thank you very much, Mr. Chair. I yield back.

*Mr. Guthrie. Thank you. The gentleman yields back, and the chair now recognizes Ms. Blunt Rochester for five minutes for questions.

*Ms. Blunt Rochester. Thank you, Mr. Chairman and Ranking member Eshoo, and I appreciate the opportunity to

hear from our witnesses today on this second panel on preparing for and responding to future public health security threats.

The COVID-19 pandemic devastated the global supply chain for medical countermeasures such as masks, gloves, manufacturing components, and many lifesaving drugs. Our reliance on foreign manufacturing made the issue worse. And as a result of these shortages, there were many instances where medical personnel had to treat patients without the proper protection or equipment.

Dr. Inglesby, what concrete actions can Congress take to protect our medical professionals, and ensure that we are less susceptible to supply chain failures during a future pandemic?

*Dr. Inglesby. Congresswoman, thank you for the question. I would suggest two things.

The first is, wherever possible, that we begin to shift to reusable products that do not require us all reaching for the same supply chain needs around the world. The single use disposable products that we use do place enormous burden on the supply chain. And to the extent we can develop, for

example, respiratory devices that can last 100 uses, 1,000 uses, that will decrease pressure on the supply chain.

The second thing I would say is that there is a new office at ASPR, the industrial base and manufacturing supply chain office, which is now organizing -- working to organize supply chain issues. They have said that it will be really important for domestic manufacturing purposes to ensure the stockpile is able to pay for domestic manufacturing, where there is typically a 20 to 30 percent higher cost than international manufacturing. If they don't have the funds to buy domestic products, then even if we set requirements for that, they won't be able to do that. So having an SNS focused on that with the budget.

*Ms. Blunt Rochester. Thank you, thank you. I actually have been working on supply chains legislation, and also stockpile legislation with my Republican colleague, Buddy Carter.

GAO has consistently identified data systems as critical to inform the response to a public health emergency. During the COVID-19 pandemic, GAO noted that HHS relied on incomplete and inconsistent data highlighting the

longstanding concern in this area. GAO has asked HHS to prioritize the development of an interoperable network of systems to allow for real-time public health situational awareness.

Dr. Denigan-Macauley and Dr. Inglesby, as we transition out of the Federal public health emergency declaration, how will HHS's ability to obtain timely and complete public health data be affected?

*Dr. Denigan-Macauley. Thank you. And first of all, I love going back to the state, to my alma mater for a Blue Hen game.

Yes. So we have 12 open recommendations alone just from our recent report. I think we have, like, almost 200 recommendations completely on how they really need to improve on getting this real-time data and getting this system implemented. So it is a very important question, and it is one that we are tracking quite closely. And, I mean, as was discussed earlier, they don't even know who is in charge of it, so it is very concerning.

*Ms. Blunt Rochester. Doctor?

*Dr. Inglesby. I would make two quick recommendations.

The first is that CDC has made very clear that they do not have the authority in many cases to collect the data they need, even simple data: How many people are sick, how many people are dying, what are the trends?

And so, in the example of monkeypox, it took three months from the beginning of monkeypox to the point where they could have data agreements with all states in place. And we expect the data to be there immediately. So the first thing is data authorities for CDC and HHS.

And the second is that in the realm of diagnostics, as people are beginning to report data that is collected -- for example, diagnostics -- we should have, really, one system, one system that HHS has set up in collaboration with the states. We can't have it so that everyone is reporting in 30 or 40 different systems that are not interoperable. So driving towards a single data collection system, I think, should be our vision.

*Ms. Blunt Rochester. Well, first of all, I want to thank you for your answer. But secondly, thank you for preempting my next question, which was really about the authority that is needed.

And I think it is a real message for us in Congress to do our part to make sure that they have that authority and the resources to make sure that our public health system is strong and prepared --

*Dr. Inglesby. Yes.

*Ms. Blunt Rochester. -- for any emergency. Thank you so much.

And I yield back, Mr. Chairman.

*Mr. Guthrie. The gentlelady yields back, and I will now recognize myself for five minutes.

And so Dr. Denigan-Macauley, in August of 2022 GAO reviewed -- there was a GAO review that interviewed eight hospitals throughout the country. The report found that all eight hospitals in GAO's review reported multiple challenges related to staff supplies, space, information.

And under the last PAHPA reauthorization, Congress required HHS to develop guidelines for regional hospitals and other facilities relating to treating patients and increasing medical surge capacity. The reauthorization also created a demo pilot program for regional health care preparedness and response systems. And do you know the status of both the

guidelines and the demo -- demonstration project?

*Dr. Denigan-Macauley. I do. We have recently completed work on this, and the guidelines have been delayed. They have not been implemented. We were actually asked under PAHPA to look at those guidelines, and we were unable to follow through on that.

*Mr. Guthrie. How about the demonstration project?

*Dr. Denigan-Macauley. And the demonstration project, I would have to get back to you on that. I know that we did look at it. I think that they are in the process of trying to determine its applicability going forward to do in more areas.

*Mr. Guthrie. Okay.

*Dr. Denigan-Macauley. But I need to be definitive on that.

*Mr. Guthrie. And do you know who at HHS is responsible for the --

*Dr. Denigan-Macauley. ASPR.

*Mr. Guthrie. ASPR is responsible for the guidelines?

So I -- when the Secretary was here earlier, I asked her a question about -- they were put on the high-risk

designation, GAO's high-risk designation, and the deficiencies you guys described, particularly not -- maybe having product in the Strategic National Stockpile, but not sufficient quantities was the question for that.

Do you have any updates on where they are, or have they worked with you on that at all or reported back?

*Dr. Denigan-Macauley. So we have not seen -- I know she reported out that they had -- that they were in the final review of the 2020 threat-based review that would talk about the stockpiles. We have not seen that, it has not been provided to us or to Congress is my understanding.

So our latest report is that they certainly still have not met their goals.

*Mr. Guthrie. Okay. My other -- I was talking to Dr. Walensky, as well, and she was talking about CDC data collection. And this is for you, as well, this question, and it has been the topic of concern for most of us on the subcommittee and to local health officials, in addition to the public.

And CDC has received billions throughout the pandemic, and in certain cases for purposes of data modernization. So

my question is, has GAO done work to understand which data authorities agencies like CDC and ASPR have, and how these authorities have been used during COVID-19 and other public health emergencies, and whether any existing data authorities CDC and ASPR have are redundant and unnecessary?

*Dr. Denigan-Macauley. I would have to get back to you on the data authorities, whether or not we have reported out on that. I don't have that at my fingertips.

*Mr. Guthrie. Okay. We would just like for you to commit to the committee to work with the subcommittee on tracking all the data collection authorities CDC has accrued during the public health emergency, as well as through the American Rescue Plan Act and December Consolidated Appropriations Act. I am sure we can work together to track these down.

*Dr. Denigan-Macauley. Absolutely.

*Mr. Guthrie. Thank you very much, I appreciate it.

I know there is another committee about to meet, as well, so I am going to step down for just a few seconds. But it seems to me, when we look at the Strategic National Stockpile, we have got two things that we have. We have,

like, anthrax vaccines and so forth that we need to have stockpiled, and we don't need them every day, and we don't ever want to need them, but we want them in case we have them (sic).

We also saw during the pandemic that we had things that hospitals use every day, but no hospital could stay in business if they had to store the inventories required if they had to have a surge. And so that is part of the Strategic National Stockpile.

So I think I am just going to make a point that I think what we need to think about, those types of items, PPE, all the other things that hospitals use every day, instead of going from manufacturer some to the hospital, some to some Strategic National Stockpile, that there just be a buffer between, so -- and you -- and it doesn't go sit in a warehouse and go stale over time.

I know we have some things we won't use every day, and we have to do that and rotate as we need. But they go from the manufacturer to a supplier or so forth that sits for inventory, and then it flows through. So the first in there will be the last out of there. So we are always having

product flow.

But if we just -- I know we need to have substantial inventories at our regional hospitals and other providers in hospitals, but we also need to have excess, just in case. And I think that is something that the government pays for with the Strategic National Stockpile.

And I see you are raising your -- shaking your head, Dr. Inglesby. Do you want to comment on that, that it just -- it is a flow.

*Dr. Inglesby. Yes.

*Mr. Guthrie. It continues to flow with us paying for the inventory.

*Dr. Inglesby. Absolutely. It needs to be a flow, and we have to rotate it through so that it doesn't expire on the shelves. There is a shelf life extension program that can be granted, but in general, I mean, one of the concepts that has been around for a while is this concept of vendor-managed inventory. So the people who are making the products, they actually control them and do exactly as you just described, they move them out. But there is a big bubble of inventory in case the government needs it. The government owns it, it

needs it, but otherwise it doesn't expire.

*Mr. Guthrie. Thank you. I appreciate it for verifying what I have been thinking. So I appreciate it very much, and I will yield back, and the chair will -- I think Dr. Harshbarger is next.

But if you will come to the chair, because I have got to go check into another committee, so I am sorry.

She is going to ask her questions from the chair.

[Pause.]

*Mrs. Harshbarger. [Presiding] Thank you all for being here. Sorry I missed your opening comments, but I want to start out and talk to Dr. Denigan-Macauley.

In a 2022 report, the GAO found significant management challenges related to the Strategic National Stockpile. Specific concerns cited included a three-year gap in the SNS reviews which impacted inventory decision-making; lack of documentation regarding reviews; and SNS management not being in accordance with the 2019 PAHPA reauthorization.

This is my question: If the GAO recommendations are left unaddressed, how might ASPR's ability to prevent, prepare, and respond to health emergencies be compromised?

*Dr. Denigan-Macauley. Yes, we have extensive work related to the Strategic National Stockpile, and pointed out the inconsistencies with what PAHPA was asking them to do. And if they don't fulfill these -- I mean, we have talked about trust in the past panel. We have to have an understanding of what is in the stockpile. We recognize that there are homeland security concerns there --

*Mrs. Harshbarger. Yes.

*Dr. Denigan-Macauley. But we have to understand who all is a part of making that decision, and working with Congress, as well as the stakeholders to ensure that the stockpile has what it is supposed to have, and that they even get their mission. I mean, changing the mission midway in the middle of a pandemic is not the appropriate thing to do.

*Mrs. Harshbarger. Well, I think we learned a lot from the pandemic. And I have been a pharmacist 36 years. So what we found out -- and a compounder, at that -- so when it comes to APIs, we are at the mercy of adversarial nations. And that is just the bottom line.

So this is really for any of the panelists, but mainly Dr. Inglesby. Though not directly related to PAHPA

reauthorization, the issue of our country's dependency on foreign countries for our drug supplies is a continued concern for public health. Do you know approximately what percentage of prescription drugs used by Americans are based on active pharmaceutical ingredients produced in China? Do you know that percentage?

*Dr. Inglesby. I do not know the answer to that. I know that it is a serious concern, but --

*Mrs. Harshbarger. Oh, it is a terrible -- I mean, you know, just from my practice, I know they can say 72 percent in the notes, but I guarantee you it is over 90. And yes, over 90 percent. And it is a problem. You know, the shortages, any given day there will be up to 300 shortages on an FDA list, and so that is when we would step in.

But hypothetically -- now, this can go to anybody -- if China were to cut off that supply, what would the immediate and long-term impacts be on health care in the United States?

Anybody?

Yes, ma'am. Yes, sir.

*Dr. Lutter. I used to work at FDA, and dealt with shortages there.

*Mrs. Harshbarger. Yes.

*Dr. Lutter. So I think the answer is very large, but uncertain. We had some internal analyses indicating for particular drugs, where we knew there was particularly old, old generics --

*Mrs. Harshbarger. Yes.

*Dr. Lutter. -- were the biggest concern, often injectables. And there could be only one API manufacturer that was approved.

FDA lacks data on the -- it knows the number of approved entities, it knows the number of approved facilities, but it doesn't know the output per facility per entity.

*Mrs. Harshbarger. Yes.

*Dr. Lutter. So therefore, if there is one in China, it doesn't know that it is making 10 percent or 90 percent of the total volume. It is blind in that regard.

*Mrs. Harshbarger. Yes.

*Dr. Lutter. However, that doesn't mean to say there is no concern, because the concern is if it is making 90 percent and FDA doesn't even know that, then it could be shut down at substantial risk to public health to the U.S.

*Mrs. Harshbarger. Well, look, we had the facility making 40 percent of the baby formula. That, to me, is not good. You should spread that out, and you should be able to have facilities to take that place at any given time. I can help you. I mean, really, this is something that we have had expertise in in my profession.

But go ahead. Do you have an answer, as well?

*Dr. Inglesby. I really don't have anything to add. I think I do think that FDA really began to change their practices around supply chain inventory and data during COVID, but I don't have the latest information about where they are now.

*Mrs. Harshbarger. Yes.

*Dr. Inglesby. But I share your concern about single entities providing a lion's share of our products.

*Mrs. Harshbarger. Yes, we have got a lot of information.

Yes, ma'am. You had a comment?

*Dr. Denigan-Macauley. I was going to say something similar in that the majority of our manufacturing of our drugs is coming from overseas in China and India. And so

when you have a global pandemic like you saw, where the supplies -- you know, every country needs the same supplies, and whether --

*Mrs. Harshbarger. Yes.

*Dr. Denigan-Macauley. -- it is a drug to be able to treat -- you know, intubation, or whatever the case may be, it can have --

*Mrs. Harshbarger. Yes.

*Dr. Denigan-Macauley. -- a serious impact. And we don't know the number of APIs.

*Mrs. Harshbarger. Yes, the scary thing is they can't track the API into finished products. That is why we have health care systems that have been reported. They are checking their finished product for adulterations. It is crazy. It is crazy.

Well, my time is up, so I guess I will yield back. Okay, now it is your turn, Mrs. Mariannette Miller-Meeks.

*Mrs. Miller-Meeks. Thank you very much, Madam Chair. Thank you all for being here. We know you had to wait through another panel, so we appreciate your being here.

And in some ways, this is the funner part of the hearing

for some of us. The reason I say that is that you were mentioning about vaccines, vaccine-acquired immunity, and the shortcomings of the CDC and the FDA and ASPR, as well, too. And my background is I was 24 years in the military. I was a nurse prior to becoming a physician. And I was the director of the Iowa department of public health. So I filled a variety of those roles in a variety of different capacities.

And one of the things I introduced into the record at the last hearing was a letter that the Doctors Caucus sent to Dr. Walensky of the CDC in September -- I think it was September 28th of 2021 -- asking were they going to recognize -- and I had in May, at a select subcommittee on the coronavirus pandemic, asked Dr. Walensky and Dr. Fauci about infection-acquired and herd immunity. And it was a very non-answer. So we were again asking, as all of the evidence and research came out about infection-acquired immunity.

And the goal was not to tell people to go to COVID-19 parties, as some wanted to allude. It was to allocate resources that were expensive and that were not voluminous. And so it is necessary for proper messaging, proper communication with the public in a pandemic, and then proper

allocation, especially as we know our surge capacity missed.

So Dr. Lutter, you have written extensively on the shortcomings of the CDC's effort to contain COVID-19, and how the Biden Administration has impeded meaningful reform of the agency, which includes reversing a Trump regulation that required CDC to follow certain good guidance practices.

Furthermore, you wrote that the CDC recommendations which led to school closures more likely than not seriously contributed to learning loss among America's students, as well as negative impacts on mental health.

I sent out an RFI to the CDC to hear from -- on the CDC to hear from constituents and stakeholders on how Congress should consider and implement reforms for America's top communicable diseases agency, which included a section on CDC's lack of good guidance practices.

For instance, one of the things we asked was who they communicated with for information. And we were told with a variety of entities. And I said, "Then why didn't you communicate with the Department of Education or the governor of Iowa, who reopened schools in August of 2020?'' And we had no superspreading events or, you know, appreciable

transmission in schools.

So given that, you know, what existing good guidance practices from other agencies or the public, you know, should the CDC use as examples?

*Dr. Lutter. Thank you for the opportunity to answer that. FDA is probably unique among the Federal agencies in having a good guidance practice reg, which dates to the year 2000, I believe. It adopted the reg at the insistence of Congress as part of the Prescription Drug User Fee Act reauthorizations.

And I won't say that it is popular there, but it is very effective, and very commonly cited among agency spokespeople who have to defend why the system works, because it is -- embedded in it is the notion that the agency is not omniscient, and always opens a docket to accept public comment on any formal use of the word "should'' or "ought to'' aimed at regulated entities. And the reg thereby marries, if you will, FDA's obligations to use the best available information with a posture of tell us what more you know on this topic that we don't -- haven't yet received.

Furthermore, the -- so that posture is very important,

but then there is flexibility within the -- within that reg that offers substantial opportunities for agency management to act quickly in times of stress. So the flexibility is that if the agency determines on its own that a issuing a guidance for -- in draft for public comment is infeasible or inappropriate, fairly broad language, then it can go direct and issue the final guidance to take immediate effect, essentially, in emergency situations. But it still must open the docket.

So even in those emergency settings, which were commonly used throughout the COVID pandemic, it still has the posture of tell us how you want us to improve this guidance and, oh, we will come back and revisit it later. And my writings cite several examples where that has been used.

*Mrs. Miller-Meeks. Thank you. My time is actually expiring, however. Thank you for that comment. It sounds like Congress needs to take up that initiative with other agencies, as we heard recently with the EPA's guidance on ethylene dioxide, and how it -- whether or not they have communicated with any hospitals or other individuals on what that impact will be.

And then I would just like to have introduced to the record -- and if you would respond in writing, Dr. Denigan-Macauley -- you -- GAO published a report in January 2020 entitled, "Significant Improvements are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies.'' In the report the GAO states that "HHS's response to the COVID-19 pandemic has highlighted longstanding concerns we raised about its ability to execute leading Federal public health preparedness,'' especially to public health emergencies.

So if you could, detail GAO's existing concerns with HHS's ability to respond to public health emergencies such as COVID-19, as well as why the GAO designated HHS's leadership and coordination of public health emergencies as high risk, if you could respond in writing, that would be tremendously helpful to us. Thank you.

[The information follows:]

4954 **********COMMITTEE INSERT**********

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*Mrs. Miller-Meeks. Thank you. I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair now recognizes Mr. Cardenas from California for five minutes for questions.

*Mr. Cardenas. Thank you, Mr. Chairman.

Welcome, Doctor, Doctor, Mister, Doctor.

[Laughter.]

*Mr. Cardenas. I feel like I am at a hospital. Thank you for sharing your expertise and your opinions with us today, and help to enlighten us to what has been going on and hopefully what we can do to make things happen better in the future.

COVID-19 taught us a lot about the state of health inequity in this country. As we move forward to discuss disaster and pandemic preparedness, we need to ensure we are implementing policy built for populations as diverse as our great country is.

Dr. Inglesby, in your testimony you discussed the importance of addressing social inequities and access to care. How can we include equity considerations into reauthorization of PAHPA in what -- and in what ways can we

improve access to care not just during an emergency, but before emergency occurs?

*Dr. Inglesby. Yes, I think so much has been learned during COVID about how our preexisting inequities are terribly exacerbated in a crisis. And I think for -- over the course of preparedness programs, often at-risk populations or special groups have been kind of an add-on to our preparedness programs. They need to be directly incorporated at the center of our programs, not as a kind of an additional thing.

And part of that is also planning for the data to manage and make sure our products are getting to the right people. If we don't have demographic data, or data on specific groups that are at higher risk when we are in the middle of a crisis, we won't know if vaccine is getting to marginalized groups or to at-risk populations. And I think they had -- a lot of those systems had to be created on the fly during COVID, and it was pretty difficult to do for all the different providers.

So I think making sure that we have all of that data built into our plans, and that we are able to collect it

immediately so we know if we are off track and we are missing really hard-to-reach people.

*Mr. Cardenas. So to adhere to what you just described, in some cases, unfortunately, it does mean the difference between life and death, correct?

*Dr. Inglesby. Absolutely.

*Mr. Cardenas. Okay, thank you. I am also concerned about our health data infrastructure, and how it leaves us vulnerable to worsening inequity in disaster response.

Dr. Denigan-Macauley, you mentioned the importance of complete and consistent data to maintain public health situational awareness. And how might deficiencies in our data infrastructure and limited Federal authority to compel data leave us vulnerable to assess how equitable our response can be?

*Dr. Denigan-Macauley. Yes, there -- the data, as you had mentioned, was not complete, and the data comes in many, many formats. The data is not just being able to track the disease coming from the disparate localities and jurisdictions that are collecting it. They were collecting it in different ways.

We also were trying to track data, for example, during the hurricanes, and unable to follow patient movement. I mean, imagine losing patients as you are transferring them from one area to another during the middle of a hurricane.

So there is many different aspects of data. And some of the authorities that came with COVID helped them to get better data, but some of those authorities are going to expire -- the CDC and others talked about.

*Mr. Cardenas. Also, Doctor, of the recommendations you made to HHS to improve our data systems, which will be most critical to ensuring an equitable response?

*Dr. Denigan-Macauley. Yes, that is a tough question to know which is --

*Mr. Cardenas. I know there is many --

*Dr. Denigan-Macauley. -- the most important. Yes, I mean, we have over 200 recommendations on data, so it is quite -- but I will say that, at the very least, you should be in compliance with the law, and they need to get the surveillance network so that they can get some real-time data.

*Mr. Cardenas. Okay, thank you. We have seen shortages

in critical supplies and even in over-the-counter medications over the course of the COVID-19 public health emergency. How can Congress help to improve transparency and access to information to improve our ability to anticipate and address shortages, Doctor?

*Dr. Denigan-Macauley. Yes, so drug shortages is a very complex issue. And so, as Dr. Califf talked about earlier, we need to ensure that we can -- you have to have trust.

There was a question earlier about -- I mean, you have to be able to get the private sector to want to provide the data. So right now they are compelled to provide some data, but those authorities are going to run out. And so being able to be transparent about what data is needed, how it is going to be used is going to be critically important.

*Mr. Cardenas. So the compelling of data, some people describe that as red tape, it is too much government, et cetera. But in this context, it is really about making sure that the system overall can actually save lives, isn't it?

*Dr. Denigan-Macauley. Exactly, exactly. You need to know where to send your supplies. You need to know, you know, who is vaccinated, who is not, whether it is Mpox or

COVID.

*Mr. Cardenas. Okay. Thank you so much.

My time have been expired. I yield back, Mr. Chair.

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

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

I do want to take a minute to correct the record. Drug manufacturing companies are, in fact -- after CARES was passed in 2020 -- required to report volume as a part of the facility registration. Unfortunately, it is not happening.

The FDA responded on May 9th, 2023 to a letter from the chair of the full committee, Mrs. McMorris Rodgers to you, Mr. Chairman, and myself, as chairman of Oversight, and said that only 44 percent of facilities are complying as of March 28th of this year.

And as a part of this hearing, Mr. Chairman, if there is no objection, I would like to submit the full text of that letter dated May 9th, 2023 to the Committee on Energy and Commerce from U.S. FDA.

*Mr. Guthrie. Seeing no objection --

*Ms. Eshoo. Would the gentleman yield for a moment?

*Mr. Griffith. Yes, ma'am.

*Ms. Eshoo. Yes. I want to thank you for raising this. This was as a result of my getting that into the CARES Act. So we have a dual interest on making sure it works.

*Mr. Griffith. Yes.

*Ms. Eshoo. Thank you.

*Mr. Griffith. And it is important to make sure that we are figuring out -- as was said just a second ago, we have got to have the data to know where some of our problems may be developing on drug manufacturing.

*Mr. Guthrie. Again, without objection, so ordered.

[The information follows:]

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

*Mr. Griffith. Dr. Inglesby, you testified previously -- and as did Dr. Mary Denigan-Macauley in front of the Oversight and Investigations Committee -- where we were -- or our subcommittee on challenges to investigating the origins of pandemics.

When talking about pandemic preparedness, do you think a large focus should be on -- or at least a focus should be on -- ensuring our Federal agencies provide proper oversight into research being done by foreign entities that are funded by U.S. taxpayer dollars?

*Dr. Inglesby. I do. I think it is very important that they are in compliance with all of the rules and guidances that are issued by our own Federal agencies.

In particular, I have concerns about areas of research where viruses are being created that are more dangerous than those that occur in nature.

So absolutely, whether it is domestic researchers or any foreign institutions doing that work, they really need to be governed very rigorously by HHS, and with White House oversight.

*Mr. Griffith. And now I am going to ask you the tough

question and put you on the spot. And if the grantees for a Federal agency doing research on viruses or other significant research that could be a pandemic if something goes awry, if that grantee is not complying with the requirements of the grant, should we both cease giving our money to them, and then keep them from getting any new grants until they comply with the requirements of the old grant?

*Dr. Inglesby. I do think, if it is determined that a grantee is doing work that is out of compliance with Federal guidance, particularly on those issues which are, you know, of particular high consequence and safety concerns, then I don't think they should continue to get funding until they are either in compliance or, if they can't be in compliance, then I don't think they should continue to receive funding.

*Mr. Griffith. Yes, I agree with you. We are having a little spat right now with one of our agencies.

All right. I previously mentioned that you came before the subcommittee that I chair on the pandemic issues, Dr. Denigan-Macauley. Has GAO looked into what incentives are needed to bring more domestic manufacturing to the U.S. so that we are not reliant on foreign countries to produce

certain items and ingredients? API, particularly, is what I am looking at.

And if so, what is needed to help bring more manufacturing to the United States?

*Dr. Denigan-Macauley. We have most certainly, and our most recent report was looking actually at advanced manufacturing. It is what FDA considers to hopefully be able to be faster, and bring that manufacturing home, and realize the cost benefits of it. And so we are watching that quite carefully.

It doesn't work for all drugs, though. And we also don't know, as we talked about before, what APIs that we actually need to be manufactured here. We don't understand the sources of them all. So we continue our work in this area.

*Mr. Griffith. And it was interesting -- I would just get your opinion on it -- one of the witnesses in the hearing that I had previously this morning on drug shortages with -- particularly talking about generics, opined that because we can't bring it all onshore in a short period of time, that we ought to focus on the top 40, and that we take actions to try

to bring the top 40 back onshore so that we have those API being made in this country and those medicines being made in this country.

And of course, then that opens up the possibilities that they have -- as long as they are doing 1 line, they might do 2 lines, and it may be more than just the top 40. But what do you think of taking a look at focusing on those top 40 most popular generic medications, and trying to bring those back as a starter?

*Dr. Denigan-Macauley. Well, I know that we do have a national supply chain strategy that is put in place. And we have taken a look at some of the supply issues that they have had. And if it is implemented successfully, we feel that it will help with bringing that domestic manufacturing home.

I will say, though, that we do have concerns. For example, saline was in short supply after Hurricanes Maria and Irma. So it is very -- just because we bring it home, we still can't put all our eggs in one basket.

So -- but yes, looking at what is the most critical, prioritizing, and then making a plan for how we can bring that onshore, close to shore would be good.

*Mr. Griffith. And I know I am over, Mr. Chairman, but I will just say I have to agree with not putting all of our eggs in one basket, because what we should do is we should have two or three sites across the country on something that is used daily like saline.

I yield back.

*Mr. Guthrie. Thank you. The gentleman yields back. Yes, you were a few seconds over, but you had a colloquy with the ranking member, so I will cede you those seconds there. So thank you.

*Ms. Eshoo. A colloquy?

*Mr. Guthrie. Colloquy.

Dr. Schrier, you are now recognized for five minutes for questions.

*Ms. Schrier. Thank you, Mr. Chairman, and I enjoyed that conversation, as well, so I will give that same allowance.

Thank you all for being here today, and the thoughtfulness that you have put into preparedness and what we can do next time -- because there will be a next time -- to guard our health security.

Mr. Inglesby, it is wonderful to see you again. And in your testimony you discuss a more flexible public health response and adding greater emphasis on at-risk individuals. And I am a pediatrician. One of those special groups is children. And I have reflected many times during this pandemic, however awful it was, I have thought how much worse it would have been had we seen hospitals full of children on ventilators, and children dying from this disease.

And really, COVID was the exception. I mean, when we think about pandemic flu, it is kids and pregnant women who are the hardest hit in many ways. And so children become top of mind to me. I even have thought about whether the public response and resistance to masks and vaccines and those kinds of things would have been different had we seen our children, our neighbors' children at that kind of risk, whether it would have been more like polio.

I was wondering if you could talk a little bit about these flexibilities, and what Congress can do to help you or to help make us better prepared to handle children's needs during the next pandemic or other emergency.

*Dr. Inglesby. Yes, Congresswoman, thank you very much

for the question. And I, first of all, share your concern that we don't move forward with the assumption that the next pandemic will necessarily look like the one we just went through. Kids could be disproportionately affected at higher risk of dying in future events, as they are with many infectious diseases. So I do think we need to be better prepared for pediatric response than we are now.

Many emergency rooms can't handle the load of children they have in a normal flu season. We don't have enough beds for kids in intensive care units in many places in the country. Part of that is because reimbursement is poor for pediatric practices, and that could change, particularly with Medicaid. So I do think we need to be thinking about systemic changes for our health care system for pediatrics.

*Ms. Schrier. Amen.

*Dr. Inglesby. And I think that we also -- FDA has acknowledged the importance of focusing on pediatric products, but often they come last for somewhat understandable reasons. People are concerned about the risks. But in those kinds of environments we have to move as quickly as we can for products that are -- that will work and

be safe for children. And that hasn't always been the case, but we should really press for FDA to have that at the top of their list.

*Ms. Schrier. Thank you, I appreciate that. I mean, we -- I was just listening to the conversation with Mr. Griffith about a shortage of saline, and thinking that if the next thing is a cholera-type issue, and what we need is abundant saline, that is so simple, but we might not have enough in this country.

I wanted to turn to testing. I remember that in the first few weeks of the pandemic we were struggling, like, you know, tens of tests a day, sending them to the CDC. Meanwhile, South Korea was doing 10,000 tests a day, drive-through. And I know we have learned a lot of lessons, and was wondering kind of where you think we are in terms of the next time this hits. Have we learned enough? Do we have enough resources? Do we have companies to call on so that we can ramp up quickly?

*Dr. Inglesby. Congresswoman, I think we have learned an enormous amount about testing over the painful lessons over the last three years. I do think we know now what to do

at a strategic level, but we don't have everything in place, going forward. Some of it is -- will -- has eroded, or will erode at the end of this COVID response. But a couple of those things include what South Korea did, which is having the foundation for contracts in place with companies between government and the private sector before things start.

We can't rely on only public health agencies carrying the entire weight of the country for testing. We have to include and use the testing infrastructure we have around the country, which is enormous. And once it got involved, I think we showed that we could test hundreds of thousands, we -- millions of people a day at one point.

So I think we have the structures. We have to have relationships between industry and government. We should have a forum that is enduring and sustained between government and the testing industry, that includes the leaders from the industry, that is scouting for new problems, ready to rock in the event of a crisis.

We should have the report -- the guidance system available from CDC, so that they are able to indicate to industry how many tests are going to be needed to be

produced, and on what on what scale, what timeframe. So I think we know what to do, but we need to do it.

*Ms. Schrier. Thank you. And I think continuing these relationships that we built this time with universities, public medical centers, even veterinary teaching hospitals, to be able to rally all of those resources. Thank you.

I will submit other questions.

[The information follows:]

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

*Ms. Schrier. And I yield back my time.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair recognizes the chair of the full committee, Chair McMorris Rodgers, for five minutes. The chair is recognized.

*The Chair. Thank you, Mr. Chairman.

Dr. Lutter, we -- earlier this morning I had asked CDC about the possibility of implementing good guidance practices, and they had some concerns. Yet your paper explicitly addresses some of this, about how guidance can still be released in a responsibly -- timely manner. And there is an opportunity for continued revision and public feedback.

Would you explain the origins of FDA's good guidance policy, and how it was initially proposed, passed in a bipartisan fashion?

And would you speak to the specific benefits of potentially adopting a similar policy for CDC?

*Dr. Lutter. Thank you, Chairwoman. The -- there is many benefits.

One is, in an FDA perspective, and it may be less important for CDC, is it allows a clearer distinction between

what is required and what is recommended because the guidance documents state these -- this document contains only recommendations. Requirements that you must abide by are already in statute or regs found elsewhere, and then they are cited. So that is very helpful to avoid a problem of regulation by guidance, which has sometimes befuddled the Federal regulatory agencies. So that is a fairly effective way of avoiding that problem.

Probably more importantly, from a CDC perspective, is simply is there a recognized mechanism for the agency always to solicit comment on what it is recommending others to do. And the advantage of that is it can say publicly, "This is our best guess. We want your advice, your technical information, any data you may have about the benefits and the risks of the recommendations that we are making, and we will pay attention to them. See here in the docket. And based on what we receive there, we will revisit as appropriate and necessary.''

And the FDA good guidance practice reg requires the agency to respond to important -- I think the word might be "influential'' -- public comments that it receives on the

draft guidance. So when it issues the final guidance, in a normal world that is not plagued by a pandemic, it has to offer some response to public comments that it may have received. It is modeled, if you will, on the Administrative Procedures Act, that part of it.

But -- so I think the key virtue, from a CDC perspective, is to increase public confidence -- and this is especially important in this post-pandemic era -- public confidence that the agency is paying attention to information that it may not already have from the public about the merit, the benefits, and the risks of the recommendations that it is making.

*The Chair. Thank you.

Dr. Denigan-Macauley, GAO identified five areas HHS has consistently fallen short during public health emergencies, and two of them, failure to provide clear and consistent communication and failure to establish transparency and accountability in order to build public trust, have been repeated today.

Do you think adoption of good guidance practices at CDC that we were just discussing might be a first step towards

addressing and resolving an -- this area of concern?

And would adoption of these policies help address HHS high-risk designation?

*Dr. Denigan-Macauley. Yes. So we are certainly familiar that -- with FDA, with our work, and understand that they issue guidances. We haven't looked at it specifically to understand how it compares to the CDC, but we have repeatedly said that there has to be transparency. We found significant problems with CDC, not with -- no scientific rationale for the changes in the testing guidelines, for example, for masking policies. So -- and with school, things that the -- so we would strongly support any transparent and science-based communication through guidelines that would help improve communication.

*The Chair. Okay, thank you.

Mr. Decker, we have heard a lot about health security threats today. Cybersecurity continues to be growing, and a serious threat that certainly has the potential to disrupt care, mission critical services. And they are coming from domestic and foreign adversaries.

You speak to the coordination between HHS and the

cybersecurity working group in your testimony today, but also mentioned the need for increased collaboration with the private sector. Would Congress explicitly providing clear -- clearer responsibility authority for a specific entity like HHS to help lead on cybersecurity help?

And what do you see as some of the roadblocks to private sector participation?

*Mr. Decker. Yes, I -- for sure. I think the amplification of messages from the government across all the government, HHS, Congress, et cetera on explaining the need and importance of this is -- would go a long way.

I don't think that this is a problem where people don't understand that cybersecurity could become a risk. I think it is more of a problem of people recognizing when it can become actualized within their own organization. And in some cases, they don't necessarily even know how to engage.

And so the message and the amplification of that engagement would go very far into getting better coverage. I think in my testimony I mentioned we have about 400 organizations that are part of the cyber working group. There are way more than 400 organizations that make up health

care, you know, so we have a lot more to go.

*The Chair. Super. Thank you, thank you, everyone.

I yield back.

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

*Mr. Sarbanes. Thanks very much, Mr. Chairman. Thank you all for being here today.

Dr. Inglesby, thank you for your testimony. I am going to ask you probably an unfair question, but on a scale of 1 to 10, before the pandemic hit, in terms of the amount and quality and usefulness of data, sort of public health data across the country and its -- our ability to roll it up into a kind of surveillance perspective that was useful to us, what would you say -- where would you rate it on a scale of 1 to 10 before the pandemic hit?

*Dr. Inglesby. I would say, depending on the topic, something on the order of three to five.

*Mr. Sarbanes. Okay.

*Dr. Inglesby. I think it got better because of the work that you all did that was temporary and required agency

or states to send data to CDC.

*Mr. Sarbanes. Okay.

*Dr. Inglesby. But that, obviously, is expiring now.

*Mr. Sarbanes. Right, Right.

*Dr. Inglesby. So --

*Mr. Sarbanes. So did we finish at the high point at maybe six or seven? Is that where you would put it because of that work, or --

*Dr. Inglesby. It may -- I would say maybe seven because --

*Mr. Sarbanes. Okay.

*Dr. Inglesby. -- of the requirement of the CARES Act and other --

*Mr. Sarbanes. Yes.

*Dr. Inglesby. -- other work you did.

*Mr. Sarbanes. Okay. So one of my anxieties -- and I expressed this to the first panel -- is that, because the emergency situation is behind us, and I am reading every day articles about local health officials -- "closing up shop'' is the term I am using -- when it comes to their data, when it comes to even some of the other infrastructure they have

built, workforce commitment because it was linked to the pandemic, and what happened was it linked everything about them. Their whole operation got linked to the pandemic.

So now, with some of them putting that in the rear view mirror and our kind of blessing that new perspective to a certain degree, the danger is that a lot of the things that took us from the three to five rating up to maybe a seven will slide backwards again.

And if you could just speak to that sitting where you sit, and whether you have similar anxiety about it, because I think the argument could be, just from a basic public health standpoint, we should always be at a 7 so that, when a pandemic hits, we can get to 8 or 9 or, God forbid, 10. But the risk here is we are going to slide back to a four or a five or a three, and then we are going to face the same challenge the next time out.

So talk about that, because you are reading about how this is shutting down, and that is not happening anymore, and everyone is getting comfortable again, and then we are going to be caught. You know, we are going to be caught off guard.

*Dr. Inglesby. Yes, I think prior CDC director Redfield

said that when he got to CDC and he started hearing reports about data that it was years old. And he said, "I don't -- why are we -- it seems like we are an agency of history here, not a public health agency.'' So I think he himself said it very well. He was seeing data that was three years old, and it was the latest that they had.

So we need to have systems. I think the American people, we all basically expect that our health agencies are collecting data in real time, but they can't if they don't have agreements that are really clear and strong and interoperable between Federal agencies and states.

I think we generally all are on the same -- have the same goals, but unless we --

*Mr. Sarbanes. Are those kinds of agreements ones that those agencies, if they collaborate well, can put in place themselves and create expectations, even if it is for maybe voluntary, not mandated contribution of data and other perspective from locals, or do you feel like there has to be more authorization, more legislation on the books that gives that authority?

*Dr. Inglesby. I do think we need -- CDC needs more

authority. I think the monkeypox experience showed that they started to try to get these data use agreements in June, and they did not have them completed until September, and it was clearly, you know, declared a pandemic early on. So we were trying to collect information, but they didn't have the data they needed to know where vaccine was going and being used.

So I think having something that is set up in statute, authorities that are clear ahead of time would be very valuable for the public health response of the country.

*Mr. Sarbanes. Can you get some percentage of the way towards the standard you would like to see just through administrative collaboration, absent some new authority? How -- what -- how far can you get with that?

*Dr. Inglesby. You can get partial.

*Mr. Sarbanes. Okay.

*Dr. Inglesby. I think some states are going to agree to give data quickly and in a fashion that they and CDC agree to, and other states will have less interest in that or less ability. So I think having a standard playing field across the country so that we can all see what is happening at the same time, so you can see, Congress can see what is

happening, I think, would require new authorities.

*Mr. Sarbanes. Thank you, and I yield back.

*Mr. Guthrie. The gentleman yields back. The chair recognizes 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. I have always said that we need to learn our lessons, what we did right, what we did wrong, what we can do different next time, what we can do better next time. And if we don't do that, then shame on us. So I consider this to be part of that process, and I want to thank you all for participating in that process.

Last year Congress restricted the NIH from funding dangerous experiments that involve pathogens of pandemic potential, or certain biological agents or toxins in foreign countries of concern. And I think that is a good thing. This development materialized out of the growing bipartisan concern for the oversight of U.S. taxpayer-funded experiments.

So even after -- but even after Congress blocked it, you know, the government still funds some research in these

nations around the world. And that is very concerning to me. This hearing here is concerned with preparing for and responding to future public health threats.

Dr. Inglesby, I want to ask you, what steps can we take to be prepared for public health threats that, when we got potentially worrisome experiments being funded beyond our jurisdiction?

I mean, if we have learned anything out of this pandemic, it is that the experiments going on in other countries, particularly countries that are adversarial to us, are very, very dangerous, and should be of concern to us.

*Dr. Inglesby. Yes, Congressman, I absolutely agree that any kinds of experiments -- I think the ones that you may be referring to in this case are experiments where researchers are able to transform pathogens and make them more dangerous than they exist in nature. And for that work, I think they should be following the most strict, rigorous policies that the U.S. Government is putting in place.

I think there is now a review where the policies are going to become more strict, based on this review that White House and NIH led last year. I think that will be very

important. And every country that receives research from our government absolutely should be complying and fully transparent with the work they are doing in that space.

*Mr. Carter. Dr. Macauley, I am sure you are aware -- and we mentioned Dr. Redfield, a good friend, who co-authored an op ed just recently on the potential dangers of gain of function research. And look, I will just be full disclosure. I am not a fan of gain of function research. You know, Einstein said years ago that the only thing more dangerous than ignorance is arrogance. And I consider gain of function research to be nothing more than intellectual arrogance. And I just -- I have no tolerance at all for it.

But just a few months ago there were two National Science Advisory Board for Biosecurity working groups that released their findings, their draft findings and recommendations. And the first finding is that the current definition of a pandemic, potential pathogens, and enhanced pandemic potential pathogens are too narrow and could result in overlooking some research. And definitions are important, and it is important we get them right, and to be all inclusive.

Do you agree? Do you agree that the current standards governing pandemic potential pathogens -- that were put in place in 2017, I might add, before the pandemic -- that they could miss some risky experiments?

*Dr. Denigan-Macauley. Yes, we have work in this area. And actually, HHS is the only agency, to our knowledge, that actually created oversight of this small type of gain of function research that is of concern. And the concern is that the -- it does miss some of the other activities that that could be of high risk.

*Mr. Carter. And HHS, as I understand it, has had a program to ensure that the U.S. could rapidly produce medical countermeasures if this were to happen again. Drugs, vaccines, and public health emergencies. Do you know if HHS has taken action to incorporate the recommendations that GAO made in 2022 to address these kind of shortcomings?

*Dr. Denigan-Macauley. Yes. So developing medical countermeasures is complex. It is not something that the private sector really wants to take on, because there is no return, because it is something that you are creating for a what-if, and if it never comes. So it is something that the

government needs to step up and do.

We said that HHS's efforts were not sufficient. We heard earlier they built for capacity, but not for capability, and we had problems. And so our most recent report came out, and they have not had an opportunity yet to -- it will take time to fulfill all of the -- implement all of the recommendations that we have. But it is an area of concern.

*Mr. Carter. Well, thank you. And again, thank all of you. This is extremely important. All of us have always heard the saying that, you know, fool me once, shame on you, fool me twice, shame on me, and we don't need to be fooled twice. We need to be prepared. And that is why this hearing is so important. And so thank you. Thank you for being here.

Thank you, Mr. Chairman. I will yield back.

*Mr. Guthrie. Thank you. The gentleman yields back, and I see no other members present to ask questions, and thank you all so much. This has been so informative. It is so important, and I can guarantee the American people we are all working together to make sure we prepare better for the

next pandemic in a way that -- you can't think of everything, you can't accomplish everything, but we are certainly going to work together to get as far along as we certainly can.

I do have a unanimous -- I have a unanimous consent request to insert into the record the documents listed on the staff -- that has been distributed before.

Without objection, so ordered.

[The information follows:]

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

*Mr. Guthrie. And I want to remind members they have 10 days to submit questions for the record. I think a couple people have mentioned today they want to submit some questions already. And I ask that you witnesses to respond to the questions promptly. Members should submit their questions by the close of business on May the 25th. So we will have those by May the 25th, and we ask for a prompt response.

We really appreciate the time and effort. It is a -- when you have a two-panel hearing, you are the second panel, it is a long day. But it means a lot to us, and it means a lot to the American people. And we certainly appreciate your time.

And with that, without any other comments, the committee will be adjourned.

[Whereupon, at 2:43 p.m., the subcommittee was adjourned.]