S. HRG. 118–197

PREPARING FOR THE NEXT PUBLIC HEALTH EMERGENCY: REAUTHORIZING THE PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE PREPARING FOR THE NEXT PUBLIC HEALTH EMERGENCY, FOCUSING ON REAUTHORIZING THE PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT

MAY 4, 2023

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C O N T E N T S

STATEMENTS

THURSDAY, MAY 4, 2023

PREPARING FOR THE NEXT PUBLIC HEALTH EMERGENCY: REAUTHORIZING THE PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT

Thursday, May 4, 2023

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 1 p.m., in room 430, Dirksen Senate Office Building, Hon. Bernard Sanders, Chairman of the Committee, presiding.

Present: Senators Sanders [presiding], Murray, Casey, Baldwin, Murphy, Kaine, Hassan, Hickenlooper, Markey, Cassidy, Braun, Marshall, Romney, and Budd.

OPENING STATEMENT OF SENATOR SANDERS

The CHAIR. Okay. Thank you. The Senate Committee on Health, Education, Labor, and Pensions will come to order.

This afternoon, we are going to hear from two panels. We are going to hear from on our first panel, Dawn O'Connell, the Assistant Secretary for Preparedness and Response, Rochelle Walensky, the Director of the Centers for Disease Control, and Dr. Robert Califf, the Commissioner of the Food and Drug Administration.

Our second panel, we are going to be hearing from Dr. Reshma Ramachandran and we will hear from Robert Weissman, and Martin Makary. So, we have two very, very important panels. Let me begin by thanking all of the folks who are on the first panel. All of us know that the last 3 years have been unprecedented in our lifetimes. We dealt with the worst public health crisis in 100 years.

I want to thank all of you under those very difficult circumstances for the work you have done for the American people. Today, what our job is, is to take a hard look at where we are today in terms of preparing, God forbid, for another pandemic, and the need to reauthorize the Pandemic and All Hazards Preparedness Act, or PAHPA, later this year.

I want to take this opportunity to acknowledge the previous leadership on this bill from Senator Murray, who was Chair of the Committee, and Senator Burr, who was the Ranking Member, as well as the PAHPA working group that I have helped convene with Ranking Member Cassidy, which includes Senator Casey and Senator Romney.

All of those Senators have set aside time for their staff to meet with mine every week because we all understand how terribly important the issues are that we are facing in terms of the possibility of future pandemics.

As everybody here knows, tragically, in the United States, we lost over 1 million people from COVID. And putting that in perspective, we lost more people from COVID in the last several years than we did in World War II.

While cases, deaths, and hospitalizations are all declining, COVID is still today the leading cause of death in our Country, with some 250 Americans on average dying every day. The World Health Organization reports that 7 million people have died from COVID globally.

But there are experts who think that is—that underestimates, in fact, the number of people who have died globally. I think, to be honest, as Americans, we can understand that every public official tried their best during COVID.

God knows how hard people worked and what stress they worked under. But the truth is that we were very, very unprepared for what hit us 3 years ago. It took a lot longer for us to effectively respond to that emergency than it should have.

All of us will remember, all of us will remember that months after the pandemic erupted, we all saw pictures of doctors and nurses in overwhelmed hospitals, lacking the personal protective equipment to keep themselves healthy.

We all remember those images and we remember seeing doctors and nurses literally using plastic trash bags because they did not have the personal protective equipment they needed. And we also know that many, many, many hundreds of medical personnel died doing their duty, trying to save their fellow Americans.

During that time, we did not have the tests that we needed to find out who had COVID and who did not. We did not have the infrastructure we needed to deal with the pandemic. All of us remember the overwhelmed hospitals and the intensive care units from one end of this country to the other.

We did not have the vaccines or the treatments that the American people and people throughout the world desperately needed. We all recall that we had to shut down our schools, our businesses, and much of the economy for far too long, causing millions of Americans not only to lose their jobs, but their healthcare as well.

In the middle of a pandemic, millions of people actually lost their healthcare. And here is the scary news, and we have got to face up to it, really do. And that is maybe the most important reason for holding this hearing. What scientists are telling us is that there is a reasonable chance that, God forbid, that a pandemic as deadly as COVID, COVID–19 could occur in 10 years.

All of us hope that will not occur, but our job is to make sure that we are prepared if it does occur. That is what this hearing is about. That is what this legislation is about. The scientists have told us that there are now seven viral families that could cause the next pandemic because they contain viruses that spread to the res-

piratory system and can easily spread from person to person, and our job is to make sure that we are protecting the American people.

You know, we spend huge amounts of money on the military because we say, hey, we have got to protect the American people. You know what? If we want to protect the American people, we have got to deal with this issue as well.

It means that we must have a capable workforce in place, not just nurses and doctors, but also public health officials, our disease detectives, and I think we will hear more about this in a few minutes, who can tell us where to set up a vaccination clinic, for example. If there is an outbreak developing on the West Coast, can we learn about it immediately, so the rest of the country is alerted, etcetera.

Tragically, during the pandemic, nearly one out of—and this is incredible, and it impacts not only this hearing but future hearings. During the pandemic, nearly one out of every five health care workers quit their jobs and are contemplating doing so as a result of the enormous stress and burnout that they have experienced on the job.

Further, we need to have accurate public health data to know who is getting sick. We need to not only have tests, vaccines, and treatments available, we have to be able to get those out to everybody who needs them.

We need to make sure that our medical personnel have the supplies, the masks, the gowns, the gloves that they need. We need to have clear communication to the public, something that has been really very difficult to do. But we need to improve our communications capability.

We need specially to make sure that we protect the most vulnerable people in our society, the seniors in nursing homes, individuals with disabilities, our children, and our infants. So that is where we are right now. We have experienced a terrible pandemic. Our hope is that we have learned something from that and that we will be better prepared as we face an uncertain future. Senator Cassidy.

OPENING STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Thank you, Chair Sanders. Before beginning, Director Walensky, I think we all express sympathy for the family of the CDC employee killed yesterday. It is always a tragedy, but you represent that family. We feel that in particular. Today, we are discussing an important responsibility of the Committee, the reauthorization of the bipartisan Pandemic and All Hazards Preparedness Act, or PAHPA.

Now, many will focus on the word pandemic, which is obviously a big part of the discussion, but we need to keep in mind the wide array of threats that this bill seeks to address, not just diseases, but natural disasters, attacks, accidents, other things that could put our Country at risk.

I feel connected to the origins of this bill, although I was not in Congress at the time. PAHPA was first enacted in 2006, largely to

address the failures of the Federal response following Hurricane Katrina.

Anybody from Louisiana saw firsthand the devastating impact on a community when governments are ill equipped and ill prepared to manage a crisis. So PAHPA sought to support states, local governments, and hospitals so that they would be better prepared for future emergencies. It established the office of the Assistant Secretary for Preparedness and Response, or ASPR, and the Biomedical Advanced Research and Development Authority, BARDA.

A lot of long things—of course you come up with awkward sounding acronyms. And it also made improvements to the Strategic National Stockpile so that vaccines, treatments, and tests could be easily available during an emergency.

In both 2013 and 2019, Congress acted in a bipartisan way to reauthorize the bill, and this year, Senators Romney and Casey are spearheading this work with the Committee. Now, we don't always agree, but we set politics aside and come together on reauthorizing PAHPA. We know PAHPA is critical to protecting the health, safety, and security of us all.

As we saw during the COVID–19 response, the PAHPA framework is far from perfect. Poor management and maintenance of the Strategic National Stockpile meant that doctors and nurses were forced to use expired PPE.

One picture I remember is a huge quantity of masks being dumped right as the pandemic was starting because they were 2 weeks from being expired. It certainly wasn't a first in, first out, manage the inventory situation.

I think we can say that in some ways Government hampered the private sector's ability to quickly launch tests at the onset of the pandemic, and Government clearly failed consistently to communicate with the public. Now, that is past. Let's get better. We made mistakes. We learned some tough lessons.

Let's work together to make it so that next time it isn't on the fly that we are figuring it out. Rather there are systems that we can put into place. Update the playbook and make sure that whatever we do, is flexible enough to address the threats beyond just a pandemic. And emphasizing, we need to look toward a threat to the future, not just prepare for that one, which is already going by.

Being good stewards of limited taxpayer resources and better partners with states and the private sector so that we are all ready and willing to step in when the next public health threat comes our way.

To accomplish this, the Committee will need to work in a bipartisan way to enact meaningful policies to make our Country safer and better prepared, to work toward a consensus. I am committed to getting this bill done. I thank you for being here. I look forward to hearing your testimony. And with that, Mr. Chair, I yield.

The CHAIR. Thank you, Senator Cassidy. Now we are going to hear from our witnesses. Our first witness is Ms. Dawn O'Connell, Assistant Secretary for Preparedness and Response in the Administration for Strategic Preparedness and Response at the Department

of Health and Human Services. Ms. O'Connell, thanks very much for being with us.

STATEMENT OF DAWN O'CONNELL, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Ms. O'CONNELL. Chair Sanders, Ranking Member Cassidy, 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.

But first, let me join the Senator in expressing my condolences for the loss of our CDC colleague. We are very sorry, Rochelle. Please extend our thoughts and prayers. 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 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 excellent 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 response. 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 missions. I also just completed a structural reorganization that institutionalized important new capabilities like our stockpile supply chain and domestic manufacturing work, these capabilities that we built during COVID and need to keep using moving forward.

Like 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 apparatus.

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 bio threat 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 March 2021, ones that you both have recognized, 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 hard 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 search 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 toward 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 these problems I have just laid out, I 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:]

PREPARED STATEMENT OF DAWN O'CONNELL

Chair Sanders, Ranking Member Cassidy, and distinguished members of the Committee, it is an honor to testify before you today regarding areas where additional authorities could strengthen the Administration for Strategic Preparedness and Response's (ASPR) preparedness and response capabilities.

ASPR is working on more high-consequence, no-fail missions than ever before. We are living in an increasingly interconnected world where diseases and other threats can travel quickly, unnoticed for days. With infectious disease outbreaks becoming more frequent, we are also experiencing an increase in the frequency and intensity of public health threats and natural disasters. To keep up with the evolving threat landscape, ASPR must remain nimble and ever vigilant while learning from each response it leads. Following every response, we look internally at processes and operations and identify where improvements can be made. These assessments have revealed areas where additional authorities or modifications to existing authorities would aid our response and help us play a key role in implementing the National Bio-defense Strategy, which lays out a coordinated whole-of-government plan to transform our preparedness for pandemics and deliberate biological threats.

As we move out of the acute phase of the COVID–19 response, I have begun looking at our capabilities and evaluating what additional authorities we need to improve our work going forward. As you may recall, ASPR had to rely on the Department of Defense (DoD) and DHS/FEMA for acquisitions authorities and for surge staffing support during the COVID–19 response—particularly in the early days. With your support, my goal is to position ASPR (and HHS) to stand on our own during large-scale response efforts and not need to rely so heavily on other Departments who have their own missions to run.

Supporting Procurements

Early in the COVID–19 response, it became clear that HHS could not procure the products our country needed at the speed in which it needed them. As a result, we entered into a Memorandum of Understanding (MOU) with DoD in which they agreed to provide assisted acquisitions support on our behalf. DoD executed more than $90 billion in contracts for us over the 3-years of the acute response.

DoD's unique authorities allowed it to save critical time when investing in early stage vaccines, therapies, and tests. DoD could fund promising prototypes and then move the successful ones through the advanced research pipeline, without having to recompete the contracts. This authority was used by DoD to procure five of the six COVID–19 vaccines on behalf of HHS. ASPR's current authorities, on the other hand, require it to stop and recompete the contracts when they move into the next phase of development. The authority to award follow-on production contracts from prototypes without recompeting the requirements would allow ASPR to move more quickly in the future without having to stop to negotiate an agreement for DoD's support. In addition, we know that DoD has its own set of critical national security responsibilities across this complex threat landscape and may not always be in a position to assist ASPR in contracting efforts.

Increasing Domestic Manufacturing

Throughout the acute phase of the pandemic response, supply chain issues emerged as rate-limiting factors again and again. ASPR's industrial base management and supply chain work was borne out of the initial supply chain pinches the country experienced in March 2020 when the whole world needed the exact same supplies at the exact same time and they were all manufactured elsewhere.

Using emergency supplemental appropriations, ASPR is building a program to ensure we have personal protective equipment and critical supplies manufactured in the United States moving forward. COVID–19 supplemental legislation also included language that allowed ASPR to support the physical construction of domestic manufacturing facilities. These construction authorities have been used to support the construction of new factories nationwide for COVID–19 related medical supplies. Once the COVID–19 funds run out we lose that authority and the work will stop. Authority for acquisition, construction, or alteration of non-federally owned facilities would allow ASPR to sustain the work to onshore and build domestic manufacturing capacity for critical medicines that will otherwise be produced in China and to expand this work to other parts of the public health supply chain as appropriate.

Ensuring the People are in Place to Prepare, Respond, and Recover

Throughout the various responses in 2022—ranging from naturally occurring events like tornados and hurricanes to infectious diseases, including Ebola Sudan, COVID–19, and mpox—filling critical workforce gaps across the organization has been a challenge. Similar to our reliance on DOD for contracting support, we relied heavily on FEMA and the Coast Guard to bolster our response staff. Having additional hiring flexibilities would go a long way toward ensuring that we are able to quickly scale up our responses when necessary. For example, we are seeking a permanent extension of the direct hire authority for National Disaster Medical System (NDMS) personnel. Congress has extended this authority multiple times as part of appropriations legislation. We are now seeking to make it a permanent authority. We are also seeking authorities to allow for some pay flexibilities to ensure we are recruiting and retraining the right skilled labor force needed for these high consequence no-fail missions.

Helping States, Localities, Tribes and Territories Augment Their Staff During an Emergency

In addition to having a strong Federal response workforce at ASPR, State, local, tribal, and territorial (SLTT) partners have asked us for additional flexibilities they could use to strengthen their own responses and better support our efforts.

Our State partners have made it clear that providing liability coverage to enrolled Medical Reserve Corps (MRC) volunteers would enhance utilization of the Corps in response and recovery activities. If liability coverage were extended to MRC volunteers, these volunteers—most of whom have some medical credentials—could provide clinical support to local healthcare systems and would serve as volunteers, reducing the overhead for deployment. In addition to providing the States' immediate augmentation support on the ground, this authority would also reduce our need to routinely deploy the more costly and specialized NDMS teams. ASPR already has an operational system to verify MRC volunteers' credentials; we are just need the technical authority to provide the liability coverage to volunteers under this system. If approved, the MRC volunteers could be deployed as a Federal asset, similar to NDMS, allowing us to leverage over 300,000 MRC volunteers nationwide for Federal responses such as hurricanes.

Investing in Process Efficiencies

With the designation of ASPR as an Operating Division in July 2022, ASPR seeks authority to institute a Working Capital Fund (WCF) to support oversight and management of central costs for the agency. A WCF is used by many operating divisions to manage enterprise-wide spending and create transparency across the organization. We began building our WCF when we were still a staff division using delegated the authorities attached to the Office of the Secretary. When ASPR became a standalone agency, it was determined that ASPR could no longer use delegated authority for a WCF but would require direct authorization. Given ASPR's growth over the last few years, it is important that it have a WCF fund to provide greater accountability and transparency in its organization-wide spending.

Hearing From Outside Experts

ASPR is charged with managing the National Advisory Committees focused on needs and considerations for at-risk individuals during times of disasters. These include seniors, children, and those with disabilities. The committees provide valuable insight and perspective into the needs and challenges of these populations in times of emergency, and they help inform the work that we do. We value the work of these committees and are seeking their reauthorization.

Conclusion

At ASPR, we have learned a lot since our last reauthorization, and it is imperative that we apply those lessons to this current effort. We know that it is not a matter of whether we will have another public health emergency or disaster, but a matter of when. With your support, we can be ready. All of the proposals submitted to Congress in the Fiscal Year 2024 President's Budget for consideration in the next iteration of the Pandemic and All-Hazards Preparedness Act will strengthen ASPR and also enhance national security and bio-defense efforts. If authorized, these proposals will ensure ASPR can execute contracts quickly and efficiently to move the needle forward in preparing for future infectious disease threats. ASPR will be posi-

tioned to increase domestic manufacturing. We will be in a place where states, locals, tribes, and territories have additional flexibilities and options to augment public health and medical needs before, during, and after disaster. and last, we will have greater process efficiencies and programs to aid in internal management of resources.

Thank you again for inviting me to testify today to highlight where additional authorities would aid ASPR in responding to future public health emergencies. I look forward to answering your questions and working with you and your staff as we move forward in the 118th Congress.

The CHAIR. Thank you very much. Our next witness is Dr. Rochelle Walensky, Director of the Centers for Disease Control and Prevention. Dr. Walensky.

STATEMENT OF ROCHELLE WALENSKY, M.D., M.P.H., DIRECTOR, UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. WALENSKY. Chair Sanders, Ranking Member Cassidy, and distinguished Members of the Committee, it is an honor to be here with you today. Before I begin, I would like to take a moment to acknowledge that our CDC family suffered a tremendous loss yesterday with the death of Amy Saint-Pierre, who was killed in the shooting in midtown Atlanta.

Amy was a valued member of our team at the Division of Reproductive Health, where she worked every day to save lives of mothers and infants. Our hearts are with her, her family, friends, and our colleagues as they remember her and grieve this tragic loss.

In addition to the work that people like Amy do every day to fight disease and support communities, I am here to talk about how CDC works 24/7 to protect America, and I want to thank you for this important opportunity.

CDC has led public health responses since our founding in 1946, providing expertise, resources, and workforce support to states, tribes, local communities, and territories on the most pressing public health threats in the United States and across the globe.

No matter the outbreak, H1N1, Zika, Ebola, COVID–19, Polio, MPox, or Marburg, CDC has been there offering world class assistance. Alarmingly, these infectious disease threats have been emerging at an increased pace and are increasingly complex.

These diseases don't respect national or state borders, and the increased frequency of outbreaks means that we should not be asking if we will face another serious public health threat, but when.

For many, life has returned to normal after 3 years of COVID–19. Public health agencies like CDC and your state and local health departments' mission is to continue to remain response ready to protect Americans from any resolving or emerging health 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 communities, world class data and analytics, rapid response to outbreaks at their source, and strong domestic and global preparedness.

We are enhancing these capacities through an all-agency review, CDC moving forward. We are committed to addressing the lessons

learned from COVID–19, increasing accountability, and improving how we deliver information to Americans.

The approaching end of the public health emergency once again reminds us that policy changes and funding are essential to the readiness of future bio threats. CDC will continue to closely monitor COVID–19 and provide the information to which we have access.

After 3 years of the pandemic and 3 months to prepare for the end of the PHE, we have worked hard to sustain the data to understand what is happening with the virus in America. But the end of the PHE means the CDC will no longer be able to collect data and share information many Americans have come to expect.

As CDC often does, we will adapt to limitations and utilize tried and true systems to monitor other respiratory diseases to keep our eye on COVID–19. In some cases, CDC will rely on data that we have demonstrated are a reasonable surrogate. But there are data we will no longer have available because they will no longer be submitted to us.

For example, certain data for a national picture of health disparities, both for race and ethnicity, and along urban and rural lines. We will make do. However, this should worry us all, primarily because 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 capacity while we fight a pathogen.

I know the Members of this Committee are interested in advancing policy to close the gaps in our public health response to be better prepared for what comes next. For CDC, this means supporting the public health workforce by allowing us to recruit the best of the best through improvements and 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 effectively and quickly. The Vaccines for Adults Program proposal not only provides Americans access to 14 approved and routinely recommended 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 better target resources to threats before they become 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:]

PREPARED STATEMENT OF ROCHELLE WALENSKY

Chairman Sanders, Ranking Member Cassidy, and distinguished members of the Committee, it is an honor to appear before you today to discuss the Pandemic and All-Hazards Preparedness Act reauthorization, and the Centers for Disease Control and Prevention's (CDC) role in preparedness and response to public health emergencies.

Americans and people around the world rely on CDC to detect and respond to emerging public health threats both foreign and domestic. This requires CDC's world-leading experts to anticipate, prevent, research, track, and mitigate threats to our Nation's health security.

For decades, CDC has been on the front lines of public health response, providing assistance to states, tribes, local communities, and territories on the most pressing infectious disease outbreaks within the United States and across the globe, including H1N1, Ebola, Zika, seasonal influenza, COVID–19, polio, mpox, and Marburg.

While the COVID–19 pandemic was the most serious public health event in over 100 years, the increased frequency of infectious disease outbreaks should highlight the sobering reality that we should not be asking if we will face another serious public health threat, but when.

The health security of the United States depends on the strength of the public health system, and CDC must be ready to play a leading role in any future public health emergency, whether a global pandemic or a natural disaster. CDC will innovate and improve on each response, while building on our existing expertise and successes. This means a CDC that supports the following activities:

- A workforce across the public health system—CDC and our state, tribal, local, and territorial (STLT) partners—that is trained and ready to respond to large, sustained, and concurrent public health emergencies and biosecurity threats.
- Strategic partnerships with the private sector to drive innovation and adoption of data, laboratory systems, and technology for multiplexed and pathogen agnostic early warning and real-time monitoring of biological threats.
- Timely and quality data and making data and science quickly available for Federal, state, and local decisionmakers to translate findings into policy and guidance for communities.
- Integrated early warning systems with global public health partners to expand the perimeter of and advance the technologies for multiplexed and pathogen agnostic detection of potential public health threats in an economy that relies on the movement of people and products across international borders.
- Transparent communication with partners and the American people so that CDC's mission, methods, and recommendations are clear and well understood by everyone.

These activities and the vision for a well-prepared public health system must be built on a foundation of core capabilities in public health including: state-of-the-art laboratories, a diverse public health workforce that reflects the communities it serves, world-class interoperable data & analytics, rapid response to outbreaks at their source, and strong global capacity & domestic preparedness.

State of the Art Laboratories

CDC's unique laboratory expertise lies in its ability to detect and track a broad range of microbes and respond to disease threats from many different pathogens—both well-known infectious diseases and rare or unknown, but equally dangerous threats—and in its ability to work with and support state and local public health partners as they respond to these threats.

For example, the Laboratory Response Network (LRN), a network of thousands of trained labs across the country was founded in 1999 as a partnership between CDC, the Federal Bureau of Investigation, and the Association of Public Health

Laboratories to support the U.S. detection of biological threats and emerging infectious diseases quickly and accurately anywhere in the United States.

Previous investments in domestic preparedness for smallpox through the LRN provided immediate testing capacity across the United States for mpox. In fact, the first case was detected in the Massachusetts Public Health LRN Laboratory using a PCR test developed by CDC and authorized by the Food and Drug Administration (FDA) in 2018. The LRN, in partnership with CDC's high containment laboratory, played a significant role in slowing the outbreak of mpox in the United States, from a peak of 600 cases a day in August to fewer than 10 cases a week since January 21, 2023.

In addition to these efforts in CDC laboratories, CDC's Advanced Molecular Detection (AMD) program has been working with state and local health departments over several years to bring genomic sequencing of pathogens into routine use. The AMD program worked with state and local partners to rapidly scale up COVID–19 sequencing in U.S. public health labs, increasing from 23 labs generating around 17,000 COVID–19 sequences during 2020, to 68 labs generating over 690,000 COVID–19 sequences during 2022.

Efforts like these have also provided an opportunity for CDC to accelerate innovation and partnerships in new ways, harnessing the collective efforts of public health and academic expertise to advance the application of genomics in combating outbreaks including through expanding use of methods such as wastewater surveillance. Two promising partnerships involve the Pathogen Genomics Centers of Excellence (PGCoE) network and the Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES) consortium. Beginning with COVID–19, the SPHERES consortium engaged academic and private sector sequencing laboratories to help us monitor changes in the virus, gain important insights to support contact tracing efforts, provide crucial information to aid in identifying diagnostic and therapeutic targets, and advance public health research in the areas about transmission dynamics, host response, and evolution of the virus. The Centers of Excellence will extend these partnerships and help CDC leverage state-of-the-art laboratory technology and public health innovation to continue to advance genomic surveillance.

Public Health Workforce

State, tribal, local, and territorial health departments are the foundation of the public health system. The infrastructure needs in these health departments are substantial: many public health agencies lack resources for foundational capacities such as operations, communications, and emergency preparedness, which are the building blocks of any future response. To be ready for any biothreat, the public health system in the United States requires a robust and nimble public health infrastructure and a skilled public health workforce ready to respond to emergencies. According to a recent report by the DeBeaumont Foundation [1], state and local health departments need to hire a minimum of 80,000 more workers—an increase of nearly 80 percent—to provide minimum public health services.

CDC has made substantial one-time investments to address these longstanding needs, including $2 billion for immediate emergency crisis response and $3 billion in foundational workforce and infrastructure. These funds not only provide critical support for school-based health programs, public health professional development, and acquisition of important technological upgrades, but they allow state and local jurisdictions to build their workforce to best serve their communities. For example:

- The Ohio Department of Health was able to provide surge staffing during the East Palestine train derailment response, including epidemiologists and other key personnel
- The Vermont Department of Health is retaining staff hired during the COVID–19 response
- The Shelby County, Tennessee Department of Health is supporting 13 employees pursuing public health degrees at the University of Memphis

These investments are a good start, but public health needs remain deep and long-term. As requested in the fiscal year 2024 Budget, sustained investment in our Nation's public health departments and infrastructure must remain an ongoing priority.

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[1] Staffing-Up-FINAL.pdf (debeaumont.org) Workforce Levels Needed to Provide Basic Public Health Services for All Americans. Research Brief—October 2021

Internally, CDC is focused on internal transformation so staff can transition from their daily positions to emergency response rapidly and effectively when needed. In December 2022, CDC launched the new CDC Ready Responder Program with a vision to grow and strengthen a diverse workforce of pre-qualified, trained, and available responders to establish and sustain public health emergency responses regardless of frequency, size, or complexity.

World-class Interoperable Data & Analytics

Additionally, public health entities must be able to rapidly share data within and among jurisdictions, and with CDC, to enable local leaders to make the best decisions for their communities and save lives in dynamic situations. We've made incredible progress from the pre-COVID–19 era. The Response Ready Enterprise Data Integration platform (RREDI), which is the next generation of HHS Protect, is a secure decisionmaking and operations platform developed for the whole-of-government response to the COVID–19 pandemic and is now expanding to support emerging outbreaks such as mpox and future public health responses. RREDI uses and integrates data from more than 300 sources across Federal, state, and local governments and the healthcare industry; and is accessible to 4,500+ unique users across 30+ Federal agencies, 56 states and territories, and the private sector. In addition, CDC's National Healthcare Safety Network (NHSN) has provided essential data on known and emerging threats from more than 38,000 American healthcare facilities, including the U.S. government's first comprehensive look at pathogen-agnostic hospital bed occupancy and capacity data from all U.S. hospitals. CDC continues to leverage systems like NHSN to meet the goals of the National Biodefense Strategy and to build on the lessons learned from the COVID–19 pandemic to maintain and enhance an enduring domestic all-hazards hospital data collection capability. Even with this progress, we have much more to do when it comes to building data infrastructure for both routine and emergency work. Congressional funding and legislative policy changes as requested in the fiscal year 2024 Budget will be necessary to achieve these goals.

Rapid Response to Outbreaks at Their Source

To be effective responders, CDC must implement appropriate, equitable, and immediate early interventions and prevention strategies to prevent an outbreak from becoming an epidemic or a worldwide threat. These interventions must be implemented based on the best available science and informed by the communities where the interventions will take place. Dedicated CDC preparedness funding over the past two decades built many of the basic capacities and capabilities that accelerated the STLT public health response to the COVID–19 pandemic. CDC-funded infrastructure and CDC guidance enabled jurisdictions to stand up emergency operations functions, provide medical-grade warehousing capability and logistics, coordinate mass vaccination and cold chain management functions, and rapidly distribute millions of laboratory test kits, personal protective equipment (PPE), and other critical supplies needed to respond to the COVID–19 pandemic. As just one example, 93 percent of recipients of funding through the Public Health Emergency Preparedness (PHEP) program report that PHEP funding and the capabilities developed through the program built a strong foundation that positioned them to ramp up COVID–19 response activities very rapidly. Some successes include Tennessee leveraging a state flu exercise program into a real-world COVID–19 vaccination campaign, and Vermont using PHEP funding to enhance its emergency management software and expand its capacity to manage numerous vaccine administration-sites during the COVID–19 pandemic.

Strong Global and Domestic Preparedness

In the fight against infectious diseases, no nation can stand alone. When it takes less than 36 hours for an outbreak to spread from a remote village to any major city in the world, protecting U.S. health and national security means making sure other countries have the knowledge and the resources to stop threats before they can spread beyond their borders. Together, we must build these first lines of defense to better prevent, detect, and respond to disease and other biothreats.

CDC must have strong domestic and global capabilities to respond to outbreaks, which are becoming ever more complex and frequent, to protect health, save lives, and protect livelihoods. CDC is strengthening its existing global efforts and working to build capacity among international partners to quickly detect and respond to infectious disease outbreaks. For example, CDC continues to support responses around the world as demonstrated by the recent Ebola (Sudan virus) outbreak in Uganda and the current Marburg outbreaks in Equatorial Guinea and Tanzania.

CDC works 24/7 to protect the health and safety of Americans. CDC is uniquely suited to use our expertise to support partner governments in building health programs, address health threats, enhance and strengthen sustainable and country-owned public health systems, and improve health outcomes for all.

Moving Forward

The future CDC must be prepared to lead the country in these core capabilities and to set ourselves up for success, we must first find ways to address long-standing challenges. Beginning in spring 2022, I launched an extensive review of the agency's organizational structures, systems, and processes to strengthen its ability to deliver on its core mission to equitably protect the health, safety, and security of Americans. In August 2022, based on this review and other substantial internal and external input, I launched the CDC Moving Forward initiative which focuses on the following top improvement areas:

- Share scientific findings and data faster
- Enhance laboratory science and quality
- Translate science into practical, easy to understand policy
- Prioritize public health communications
- Develop a workforce prepared for future emergencies—CDC and nationwide, and
- Promote results-based partnerships

On January 24, 2023, I announced a CDC reorganization, one of several foundational steps to achieve progress in the improvement areas outlined above. This reorganization aims to eliminate bureaucratic reporting layers, break down silos in the agency, promote foundational public health capabilities, and improve accountability at CDC.

Parallel to the reorganization, my leadership team has engaged staff from across the agency on priority actions that will improve how we do our work. This work is ongoing, but I'm proud to say that CDC has already implemented numerous actions, including:

- Improved efficiencies in scientific review by reducing clearance time for CDC publications by 50 percent;
- Initiated the CDC Infectious Disease Test Review Board, an internal group to promote quality assurance prior to national deployment of laboratory tests;
- Established process for institutions to submit applications for access to investigational drugs; reducing the time required for institutions to apply from 14 days to 6 hours—utilized with tecovirimat for mpox; and
- Implemented executive leader performance plan changes that outline expectations for CDC leaders in response participation, data modernization, and scientific quality and timeliness.

New Authorities

As the CDC community tackles challenges internal to the agency, we also need support from Congress consistent with the fiscal year 2024 Budget request, to support revised and new authorities so that CDC can be better prepared and respond to the next emerging disease.

Historically and today, CDC is forced to rely on time-consuming "work-arounds" within our existing authorities and policies to meet operational and programmatic needs when time is of the utmost essence. The COVID–19 pandemic and other outbreaks have only underscored how much these challenges have hampered the agency and continue to do so. If CDC is to play a key role in rapidly detecting pathogens to support all levels of government response to biological threats as envisioned in the new National Biodefense Strategy and Implementation Plan, these gaps must be addressed. In the fiscal year 2024 Budget, we have requested flexibilities and authorities in the context of the PAHPA reauthorization that are critical to the agency's ability to be more effective and responsive during fast moving, large-scale public health outbreaks. These proposals fall under two broad categories: 1) operational readiness and 2) strengthening workforce capacity. On their own, these proposals are not likely to be sufficient to change how CDC responds to the next emerging threat. However, taken together, they offer a roadmap to provide the tools and resources CDC needs to better prepare for, and respond to, the next emerging public

health threat, whether from a local outbreak or a global pandemic. I have highlighted examples of a few authorities below and welcome continued discussion on ways to strengthen CDC to protect our national security through public health.

Data

Data must serve as the foundation for everything we do, particularly in the context of a public health emergency response where critical decisions on where and how to target interventions must be made quickly. Having timely, high-quality data on where disease is spreading, the severity of illness, and the populations most impacted is a critical element of operational readiness. It allows state and local public health and other health care professionals, and policymakers to target resources to mitigate an outbreak and predict future spread. We are grateful that Congress has authorized and funded CDC's newest center, the Center for Forecasting and Outbreak Analytics, to improve the Nation's ability to prepare for and respond to public health threats using data, modeling, and analytics. But if CDC must continue to rely on a decentralized framework for data reporting, subject to a patchwork of individually negotiated Data Use Agreements, we will not be able to provide the best forecasts and modeling in the world.

Where we can, we are making improvements on sharing data. CDC's Center for Forecasting and Outbreak Analytics delivered four technical reports on the mpox outbreak. These reports are publicly available, have been shared widely, and provided timely updates on CDC's response to the outbreak, including our estimates of the trajectory of the outbreak. These reports were developed at the speed of the outbreak, to get the best information we had out to decisionmakers quickly. We included qualitative risk assessment information in these reports to deliver the bottom-line up front while also making it clear the level of confidence we have in our analyses.

However, the way in which public health data are collected and shared has resulted in delayed, fragmented and inconsistent reporting to CDC, and to state and local public health partners. To address this issue and support better data sharing with states, locals, and providers, CDC will need updated legislation as requested in the fiscal year 2024 Budget.

Vaccines For Adults

Unlike the public health infrastructure that exists for children to receive recommended vaccines from their pediatricians, the current infrastructure for adults is not robust. In response to the COVID–19 pandemic, CDC built infrastructure to rapidly deploy safe and effective vaccines to the entire U.S. population. As proposed in the fiscal year 2024 Budget, CDC's Vaccines for Adults (VFA) program would begin to expand access to Advisory Committee on Immunization Practices (ACIP)-recommended routine and outbreak vaccines at no cost for uninsured individuals. Establishing a robust infrastructure for adult vaccination will support response readiness by reducing vaccination coverage disparities, improving outbreak control of vaccine-preventable diseases, and enhancing and maintaining the infrastructure needed for responding to future pandemics.

Strengthening Workforce Capacity

In addition to operational improvements, CDC needs a workforce that is nimble and response ready. CDC is enhancing its work to better prepare and coordinate staff across the agency ahead of emergency events. However, as requested in the fiscal year 2024 Budget, CDC needs additional operational authority to implement policies to address issues such as overtime pay caps, danger pay, loan repayments, and other flexibilities that enable CDC to rapidly respond to urgent public health needs. These authorities would greatly improve CDC's workforce capacity and help build a pipeline for future public health leaders.

Conclusion

In conclusion, CDC is working hard to address challenges identified during the COVID–19 pandemic. We are building on a strong foundation of core capabilities in public health and leveraging our areas of expertise and successes to build systems that are more resilient that can better respond and adapt to emergencies. Yet, to fully enable CDC to better prepare for, and equitably respond to, the next emerging public health threat, the agency needs the support, flexibilities, and authorities as requested in the fiscal year 2024 Budget. We must look for opportunities to apply lessons learned and advance bipartisan solutions to be better prepared for future

public health challenges. Congressional action to support these fiscal year 2024 Budget proposals in the PAHPA reauthorization will improve how CDC responds to future emerging threats and will support the agency's modern-day mission. I look forward to working together to implement the solutions that will make this agency—the work of which is so critical to America's health—and our partners at the state, local, tribal, and territorial level, better prepared for what comes next.

Thank you, and I look forward to your questions.

The CHAIR. Thank you very much. Our final witness is Dr. Robert Califf, Commissioner of the U.S. Food and Drug Administration. Dr. Califf.

STATEMENT OF ROBERT CALIFF, M.D., COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. CALIFF. Good morning, Chair Sanders, Ranking Member Cassidy, 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 of FDA in public health, emergency preparedness, and response. We have 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 can be modernized to ensure our actions could be even more effective. Providing greater transparency in the supply chains and ensuring operational readiness and storage capacity within the FDA inspectorate and review staff and improving laboratory testing regulation are priorities that will enhance national security and improve public health preparedness.

First, 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 public health emergency. 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 cyber security 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, or APIs, are required to notify the FDA.

The agency has relied on these notifications to help prevent supply disruptions by working closely with manufacturers, expediting review, and exercising temporary regulatory flexibility. However,

we have recently seen unprecedented demand for drugs that would benefit from similar notification.

The ability to require drug manufacturers and distributors to report surges in demand to FDA could help the agency to prevent or mitigate shortages, including for some critical over-the-counter drugs like we saw in the 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 to Congress for including 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 storage capacity is critical in emergencies.

For example, FDA could achieve more effective and efficient oversight if it had authority to require internationally harmonized master powers 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 via research 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 requests authority were expressly extended to all FDA regulated products. Additionally, during COVID–19, we saw the FDA staff had to be pulled off other work and have been working relentlessly on pandemic issues, as have our colleagues, for the past 3 years, leading to a significant backlog in certain areas and to fatigue.

Through the creation of specialized programs to defend against emerging pathogens and other threats, the agency would be well-positioned to respond to emerging and identified threats of concern.

Third, and finally, the COVID–19 pandemic underscored the importance of both diagnostic tests access and test accuracy, and the critical need for a 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 this list of improvements, the striking observation is that these measurements 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 efficiently and effectively.

Thank you and I look forward to your questions.

[The prepared statement of Dr. Califf follows:]

PREPARED STATEMENT OF ROBERT CALIFF

Chair Sanders, Ranking Member Cassidy, and distinguished members of the Committee, thank you for the opportunity to testify before you to discuss the Food and Drug Administration's (FDA's or the Agency's) efforts to prepare for the 2023 reauthorization of the Pandemic All Hazards Preparedness Act.

The last 3 years of the COVID–19 pandemic underscore the need to continue to optimize our preparedness and response capabilities. The Agency's continued preparedness for, and capabilities to respond to, public health emergencies and disease threats such as COVID–19, mpox, respiratory syncytial virus, and pandemic influenza have been strengthened by Congress' support of our work. Our efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the Federal Government, to help facilitate the development, authorization, licensure, approval, clearance, and availability of critical, safe, and effective medical products and help ensure the continuity of the food supply to address current and future public health threats. We look forward to continuing work with you this Congress to ensure future readiness.

FDA's Public Health Emergency Preparedness and Response Mission

The Pandemic and All-Hazards Preparedness Act (PAHPA) contains key legal authorities to sustain and strengthen our Nation's preparedness for public health emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, as well as emerging infectious disease threats.

The law, including critical policies from both previous reauthorizations, recognizes the key role FDA plays in public health emergency preparedness and response. Its provisions further FDA's mission of fostering the development and availability of drugs, vaccines, and devices (also referred to as medical countermeasures, or MCMs) for use in these emergencies.

Together, these authorities for FDA have not only supported and facilitated government partners' pre-event planning efforts and pre-positioning of MCMs, but also helped to facilitate MCM development and the efficient and rapid deployment of these medical products in the event of a CBRN emergency or emerging disease health threat - including COVID-19. FDA has effectively used PAHPA provisions to support our nation's preparedness and response capabilities, and continues to provide the highest quality and most timely guidance possible to all stakeholders engaged in MCM product development.

One of the lessons learned from the COVID–19 pandemic was the importance of a swift and agile response coordinated across all levels of government and in collaboration with the private sector. Through effective communication, dexterity, and innovation, we were able to mitigate the impact of the pandemic and prevent innumerable illnesses and deaths. From the beginning of the COVID–19 public health emergency (PHE), FDA has taken a leadership role in the all-of-government response and continues to focus on facilitating the development and availability of MCMs to diagnose, treat, and prevent COVID–19; surveilling the medical product and food supply chains for potential shortages, disruptions, and contaminated or fraudulent products; and helping to mitigate or prevent such impacts. Looking ahead, FDA is committed to continuing to use every tool in our toolbox to prepare for CBRN response activities, fight future public health emergencies, arm ourselves with the best available MCMs, and support U.S. response efforts.

Preparation for future PHEs depends on utilizing the many strategies that led to a successful response as well as the establishment and refinement of authorities and flexibilities that allow the Agency to identify and mitigate risks while promoting innovation. This includes continuing to proactively leverage existing relationships with entities outside of FDA in emergency response situations. For instance, as it relates to the development of COVID–19 testing kits, since January 2020, FDA has engaged with over 1,000 test developers and worked interactively with them to support emergency use authorization (EUA) of over 500 tests for COVID–19, including 35 over-the-counter (OTC) tests. FDA has already been working to strengthen communication strategies and tools that have proved effective for ongoing collaboration with our private sector partners as demonstrated during the COVID–19 PHE, including town halls, webinars, a telephone hotline and email boxes for stakeholder inquiries, templates, and interactions with professional and trade organizations. [1]

[1] *https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/emergency-use-authorization-covid-19-tests-independent-assessment-fdas-response*

FDA entered into a memorandum of understanding (MOU)[2] with the Centers for Disease Control and Prevention (CDC) and laboratory stakeholders (including APHL and ACLA) in May 2022, a formal step in further building collaborative relationships with the lab community. The Agency is fully engaged with CDC and developers under this MOU with respect to mpox. FDA also continues working proactively with the National Institutes of Health (NIH) Independent Test Assessment Program (ITAP)[3] to support developers of at-home COVID-19 tests, including multiplex tests that can also detect influenza. The program is an extension of the NIH Rapid Acceleration of Diagnostics (RADx) Tech program, which supported development of several authorized tests, including the first OTC COVID-19 test. We have consistently seen shorter review times for such EUA requests due to our partnership with ITAP and we are continuing to work with this program to help provide additional testing options for patients.

In addition, FDA leveraged an ongoing partnership with U.S. veterinary diagnostic laboratories to strengthen COVID–19 testing at the height of the COVID–19 pandemic. In ordinary times, this partnership, the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), helps the U.S. animal health infrastructure rapidly respond to animal health incidents. During the critical need for COVID–19 testing, it successfully increased capacity to accurately test both human and animal samples for COVID–19. FDA's capacity to drive future PHE responses depends on maintaining and further building collaborations with regulatory, academic, and industry partners even in the absence of a crisis.

The Administration's National Biodefense Strategy and Implementation Plan on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security describes in detail a set of transformative capabilities the U.S. Government aims to build to defend against future pandemics and biological threats. These include the capability to develop and safely deploy MCMs against novel pathogens much more rapidly than is possible today. and safely deploy MCMs against novel pathogens much more rapidly than is possible today. and safely deploy MCMs against novel pathogens much more rapidly than is possible today. and safely deploy MCMs against novel pathogens much more rapidly than is possible today.

Facilitating Access to Safe and Effective Medical Products

As FDA prepares to combat future threats, ensuring access to safe and effective medical products continues to be of utmost importance. FDA can provide support to this mission through its work in several preparedness areas.

Drug Product Supply Chain

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, including drug products. FDA works within its limited authorities to find ways to prevent and mitigate drug shortages, and worked with manufacturers to successfully prevent 222 shortages in CY 2022. The COVID–19 pandemic served as a reminder that the drug supply chain is extremely vulnerable to supply disruptions and surges in demand. Prior to this pandemic, most shortages were due to manufacturing issues that disrupted supply, for which manufacturers of drugs and active pharmaceutical ingredients (API) are required to notify FDA. This notification requirement provides FDA more time to mitigate or prevent a shortage, and the Agency has relied on these notifications to help prevent supply disruptions. However, during the pandemic we also saw unprecedented demand for drugs and would benefit from similar notifications of supply disruptions based on demand.

Looking to future preparedness, and in accordance with the National Strategy for a Resilient Public Health Supply Chain, it is critical for the U.S. Government to have visibility into the end-to-end supply chain data access. The authorities provided under section 3112 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116–136) enhanced FDA's visibility into drug and medical product supply chains and the tools available to the Agency to help identify, prevent, and mitigate drug shortages. To increase patient access to critically needed medications in shortage or to prevent potential shortages, FDA leveraged available tools medications in shortage or to prevent potential shortages, FDA leveraged available tools

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[2] *https://www.fda.gov/about-fda/domestic-mous/mou-225-922-020*

[3] *https://www.hhs.gov/about/news/2021/10/25/new-hhs-actions-add-biden-administration-efforts-increase-access-easy-use-over-counter-covid-19-tests.html*

(including the authorities and requirements added by the CARES Act), including in CY 2022:

- Expedited reviews of approximately 200 submissions.
- Prioritized certain establishment inspections to address drug shortages.
- Expedited assessments of manufacturing supplements to facilitate the manufacturing capacity for COVID–19 therapeutic biologics.
- Exercised regulatory flexibility and discretion in 87 instances to increase supplies of critically needed medications.

However, we believe there are several areas where Congress could build on our current authorities to improve our visibility into the supply chain, strengthen our ability to oversee the drug supply chain, and ensure continued access to critical drug products. The ability to require drug manufacturers and distributors to report surges in demand to FDA could help the Agency prevent or mitigate shortages, including their severity and impact on patients. Additional improvements in drug supply chain-related authorities could include:

- Requiring labeling of bulk drug substances to include the original manufacturer and requiring labeling of finished drug products to include additional supply chain information to help identify sources of APIs, thereby providing greater insight into the supply chain;
- Enhancing information that manufacturers must report with respect to the amount of listed drugs produced for distribution, including the suppliers they relied on to manufacture the listed drug and the extent of such reliance, to provide more complete supply chain insight. Having this information would allow the Agency to work more proactively to diversify the supply chain and reduce the risk of shortages;
- Ensuring FDA has an opportunity for a facility inspection or evaluation before distribution of certain non-application drug products. Under current law, for drugs that are not subject to premarket approval requirements, FDA typically does not have an opportunity to inspect the manufacturing facilities before such products are shipped to or distributed in the U.S. Providing an opportunity for facility inspection would help enable FDA to identify potential safety issues related to manufacturing before a non-application drug product is distributed;—Requiring facilities at which drugs are manufactured to create, submit, and maintain Site Master Files (SMFs). SMFs are internationally harmonized documents that typically contain specific information about the firm's manufacturing and product activities and quality management and quality control activities at the named site and identify any closely integrated operations at adjacent and nearby buildings. SMFs would improve Agency understanding of manufacturing activities and provide critical information on supply chain management, thereby providing supply chain transparency to reduce the risk of shortages.

Finally, as more manufacturers enter the vaccine and biotherapeutics industries, the ability of ORA's inspectorate to robustly respond to future pandemics will depend on operational readiness and surge capacity. For example, FDA could achieve more effective and efficient oversight if it had improved authorities for conducting remote regulatory assessments. This could include explicitly extending FDA's authority to request records or other information, in advance of or in lieu of inspections, to all FDA-regulated products, as well as authorizing mandatory remote interactive evaluations. In the fiscal year (FY) 2023 Omnibus, Congress recognized that such authorities were key to future preparedness by expanding FDA's authority to request records and other information, in advance of or in lieu of an inspection, to devices and to sites or facilities subject to bioresearch monitoring inspections. However, the Agency could achieve even greater regulatory compliance if this records request authority were expressly extended to all FDA-regulated products and the Agency was provided authority for mandatory remote interactive evaluations. Critical investments in this space are also needed, such as increasing the inspectorate's workforce capacity for oversight of medical products and funding training and continuing education of the inspectorate's workforce.

Medical Device Supply Chain and Safety

Shortages

U.S. preparedness and our national security depend on a strong domestic supply chain for medical devices. Under the CARES Act, FDA received new authority requiring medical device manufacturers to submit information related to a device shortage during a public health emergency [4]. As of December 2022, we have received over 455 potential and actual shortage signals, which translates to hundreds of thousands of device units that have been in shortage. We used the information we collected under these new authorities to help mitigate approximately 350 of the 455 shortages. FDA also used information gathered under these authorities to perform assessments that enabled us to:

- Expedite premarket reviews and inspections
- Issue guidance documents, letters to healthcare providers, and enforcement discretion;
- Publish communication products including conservation strategies to provide end users with information on device shortages; and
- Work with ASPR on Defense Production Act priority ratings and other actions by the U.S. Government—as ASPR, the Department of Defense, the Department of Transportation, and others all depend on the information from FDA to support companies who are trying to help support the U.S. response.

Unfortunately, the requirement for manufacturers to provide this critical information is temporally limited as it is only required to be provided to FDA during or in advance of a PHE. However, medical device shortages occur in many situations that fall outside of or are unrelated to declared PHEs, including certain natural or human-made disasters, recalls, geopolitical conflicts, production shutdowns, and cybersecurity incidents. We know that these shortages most often impact our most vulnerable and underserved populations—like children, rural populations, and our veterans and VA hospitals. As an example, rural hospitals often do not have the funding to purchase multiple types of critical equipment, such as X-ray machines and washers and sterilizers to clean and sterilize reusable medical devices. When these devices and equipment cannot be serviced or replaced because of a lack of parts or materials, patients may have to drive hours, if they can, to other areas to try to seek the care they need. Moreover, as we saw with the onset of COVID–19, by the time there is an emergency, it is often too late to prevent or mitigate shortages.

The fiscal year 2023 Omnibus clarified FDA's ability to receive voluntary notifications from manufacturers about certain device discontinuances and interruptions, but this pandemic has demonstrated that relying on voluntary information-sharing deprives FDA and the public of critical supply chain information. To protect patients, build a more resilient domestic supply chain, and help reduce dependence on foreign sources, it is critical that Congress remove the temporal limitation that only requires manufacturers to notify FDA about interruptions or discontinuances in the manufacture of certain devices during or in advance of a PHE.

Furthermore, COVID–19 also showed us that manufacturers are not always prepared for situations where their ability to manufacture product may be disrupted or may be insufficient to meet increases in demand, especially where they are dependent on one source for a critical raw material or component that was in shortage. A good example of this was the recent tracheostomy tube shortage. The manufacturer was reliant on a single source for a critical raw material component (silicon)—the vast majority of which comes from China. Having a risk management plan in place could have helped the manufacturer and FDA to respond more swiftly to ensure redundancy in suppliers. Risk management plans are commonplace in all types of industries, and mandatory for other medical product areas such as drugs, biologics, and critical foods (the latter of which Congress just enacted in the fiscal year 2023 Omnibus). Providing FDA with statutory authority to require risk management plans would help ensure manufacturers have plans in place to improve resiliency and mitigate future supply chain disruptions—and this includes minimizing reliance on products and components from any one foreign country. For example, the United States continues to import 45 percent of finished medical devices from China, and we are even more dependent on China for raw materials and components that are used to make medical devices.

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[4] Section 506J of FD&C Act (21 U.S.C. 356j)

Our supply chain is too vulnerable and the health care of our patients—our veterans, seniors, children, and underserved populations including those in rural areas and others who often suffer the most when there is a supply chain issue—is too important to rely on voluntary reporting of this critical information.

In Vitro Diagnostics

The past few years have also highlighted the critical need for a modernized regulatory framework that applies to all in vitro diagnostics. The COVID–19 pandemic underscored the importance of both test access and test accuracy. Beyond COVID–19, tests are used for many different purposes and are based on many different types of technologies, and they are becoming increasingly important to our entire health care system. According to CDC, 70 percent of health care decisions are based on clinical lab test results.[5] Some of those tests are the sole determinant of a patient's treatment. A modern oversight framework that is specifically tailored to assuring tests work is critical to position ourselves for the future—whether it is to prepare for the next pandemic or to realize the full potential of diagnostic innovation.

Such a system can balance innovation with assurance of accuracy and reliability for tests. For example, a technology certification approach could provide assurances for most tests without individual FDA review of the tests. These assurances are critical. We have seen many examples of tests that do not work—from COVID–19 tests marketed during the pandemic, to tests that are the sole determinant of which treatment a cancer patient receives. In particular, we are concerned that there may be inaccurate laboratory developed tests, or LDTs, in use today.[6] This puts patient health at risk, undermines our health care system, and hinders the country's ability to effectively address PHEs.

We look forward to continuing our work with Congress and stakeholders to create a modern framework for all tests and to strengthen supply chain authorities. In the meantime, we intend to move forward using our current regulatory authorities to offer providers and patients confidence in the diagnostic tests that they use.

Overseeing Products Critical to Public Health and Fostering Medical Countermeasure Development

We have also seen that a supply disruption for other critical products can have an immense impact on families, as we saw in the infant formula shortage. Preventing food shortages is 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 certain medical foods to notify FDA of potential shortages. Looking forward, parallel authority to require notifications of anticipated interruptions in the supply chain of additional categories of foods designated by FDA during a declared PHE could help prevent future shortages in the food supply.

Further, enhancing FDA's regulatory capabilities and readiness to respond to emerging pathogens, help ensure blood safety and availability, and expeditiously review new vaccines, existing vaccines and other medical products, is vital to the Agency's continued success in PHE preparation and response. Our staff have had to be pulled off other work and have been working relentlessly on pandemic issues for the past 3 years, leading to a significant backlog in certain areas and fatigue. During COVID–19 we have seen that FDA staff need to be prepared to continue to address the current pandemic needs while also preparing for potential future pandemics and staying on top of our daily work to help ensure blood safety and availability and regulate vaccines and other medical products. Through the creation of a specialized program within CBER to defend against emerging pathogens and other threats, the Agency would be well positioned to respond to emerging and identified threats of concern and focus experienced resources to work quickly on MCM development to address these concerns. In consultation with HHS partners, the program could: further accelerate the review of critical MCM product applications, provide recommendations and guidance to developers of vaccines and other medical products and to relevant Federal partners; use real-world data or real-world evidence to study the safety and effectiveness of products for addressing biological incidents and identify which products may be best suited for specific pathogens or for

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[5] *https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html-print*

[6] For example, see: Case studies of 20 LDTs that may have caused patient harm *(http://wayback.archive-it.org/7993/20171114205911/https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm472773.htm)* and FDA's analysis of 125 EUA requests for COVID–19 tests from labs that found 66 percent were not designed or validated appropriately *(https://www.nejm.org/doi/full/10.1056/NEJMp2023830)*.

use in different populations; and facilitate product development including advances in manufacturing. It could also support applied scientific research within CBER that contributes to development and review of biological incidents and emerging pathogens.

FDA's ability to monitor the safety of vaccines would also benefit greatly by a coordinated Federal public health data reporting authority. Through the Biologics Effectiveness and Safety (BEST) Initiative, part of the FDA Sentinel Initiative, FDA can analyze information occurring in millions of health insurance claim submissions or electronic health records (EHR) recorded in large data systems. FDA's contractors assist with this program and analyze the data itself behind their firewall as part of data privacy protections. While the BEST Initiative has been essential for our work and provided us with a robust picture of safety data, our ability to analyze claims information is limited by the fact that some vaccinations are not recorded in health insurance claims data. Further, when insurance claims data bases or EHRs detect an adverse event, FDA often needs to quickly verify information or access additional information to evaluate the adverse events of interest. When we request records to verify adverse events detected by the BEST Initiative data bases it has taken FDA around 8–12 weeks in some cases to receive voluntary access to these records. Additionally, coordinated Federal public health data reporting authority would help the Agency to more swiftly identify adverse event patterns and trends associated with the use of vaccines or other MCMs, and swiftly be able to communicate with health care providers and patients about safety signals.

Finally, across all these areas, FDA's partnerships with state, local, and U.S. territorial governments continue to play an important role in the protection of public health, particularly as FDA partners with them in the regulation of products, helping to ensure the safety and integrity of supply chains, and assisting in enforcement against products that are being unlawfully sold. New provisions for the disclosure of non-public information to these agencies with complementary functions related to FDA-regulated products, and a federally consistent expectation for disclosure, could achieve faster and more effective action to protect the public health during national public health emergencies, other state/local disaster declarations, outbreaks or other public health events, and for routine regulatory oversight.

Conclusion

FDA continues to advance its mission to protect and promote public health by helping to ensure the safety of human and animal food, and the safety and effectiveness of medical products in the COVID–19 pandemic. The Agency is continuing to monitor its policies, the marketplace, and national needs, and will continue to adapt as the circumstances of the pandemic evolve. We take our public health mandate very seriously and will continue to work each day to help end this pandemic and prepare for the next one. We look forward to continuing to work with the Committee on the Agency's public health emergency preparedness and response mission and strengthening FDA's authorities to continue building a resilient supply chain for critical medical products, foods, and medical countermeasures.

Thank you again for the opportunity to testify.

The CHAIR. Thank you very much. Let me start off with a question for Ms. O'Connell and Dr. Walensky. Nobody can predict what the next public health emergency will be. And is our job, and more specifically, your job is to put us in a position where we can react as effectively as we can, so we don't lose over a million people next time around.

My question is a pretty simple question, and maybe Dr. Califf can jump in as well on this one-off. Are we moving forward right now, can you just tell us confidently that we are moving forward as fast as we can with creating the kinds of vaccines we may need in anticipation of the next pandemic?

Do we have the kinds of treatments—are we moving—I know you may not have them today, but are we moving aggressively forward to have the treatments that we need if people become ill? Do we have the workforce infrastructure that we need?

Do we—are you confident in telling us that you can move rapidly when you learn that a pandemic is—that we are facing a pandemic and that you can rally all the resources that you need? Do we have the medical personnel to staff our hospitals if, God forbid, we find ourselves in the same position again? Ms. O'Connell, can you start off with that, please.

Ms. O'CONNELL. Chair Sanders, thank you so much for this question. This is one of my biggest worries, is that we are losing time in preparing for the next pandemic.

It is the reason why the Administration requested $88 billion last year to advance the American pandemic preparedness plan.

We did not receive that funding. We have requested, again, in our Fiscal Year 2024 budget $20 billion of which $10 billion would go to ASPR or BARDA to begin that research into the prototype vaccines, therapeutics, and diagnostics for those seven viral families most likely to cause the next pandemic.

You know, we were so lucky—I know it doesn't feel like it, but the one place we were lucky when it came to the Coronavirus is we had already done a lot of the early work on that because of SARS and MERS. We need to get the same head start——

The CHAIR. Are you telling us that we have not done the kind of work you would like to see us done in preparation for what may be coming?

Ms. O'CONNELL. Correct. Not in all the viral families.

The CHAIR. Okay. Dr. Walensky.

Dr. WALENSKY. Thank you for that question, Chair Sanders. So, we started with a very frail public health infrastructure from years, decades, in fact, of underinvestment. Some have estimated we have 80,000 public health work jobs in deficit right now.

In fact, your own state of Vermont hired 120 people during the COVID–19 pandemic, and through our workforce infrastructure, you are able to retain—our workforce infrastructure grant, you are able to retain 12 of those 120.

It just gives you a sense of how frail, and—of the workforce infrastructure. In addition to vaccines——

The CHAIR. Let me interrupt you. Are you concerned that so many doctors and nurses are leaving the profession for a lot of reasons, but including the burnout and distrust, the experience during COVID?

Dr. WALENSKY. Public health workers. Dearly—yes, deeply. I will also note that——

The CHAIR. I don't mean to be interrupting you all the time. What ideas do you have as to how we can rebuild that critically important workforce?

Dr. WALENSKY. Much of the workforce authorities that we are looking for in public health, specifically things like tax exempt loan repayment, to entice people to come in. We know our laboratory——

The CHAIR. We can do a little bit better than tax exempt loan repayment. We have a massive workforce shortage.

Dr. WALENSKY. We will have——

The CHAIR. We need thousands of new workers.

Dr. WALENSKY. Indeed, we do. And we haven't—many of these physicians, for example, come out of medical school with $200,000 worth of debt.

The CHAIR. So that seems like a very modest, too modest proposal.

Dr. WALENSKY. Work—and direct hire authorities, flexible pay, danger pay, for example. I have with colleagues in Equatorial Guinea right now on the frontlines of a Marburg outbreak, and they are not getting danger pay.

These are the workforce things that we need to do to entice people to come into health and public health. So those are many of the things that we are asking for as part of this——

The CHAIR. What I am hearing you say is, despite good intentions, we—your agency is not as prepared as it should be, if God forbid——

Dr. WALENSKY. I would argue that. Yes.

The CHAIR. Okay. Dr. Califf.

Dr. CALIFF. What I say, Senator, is that when it comes to technology, we are unsurpassed and ready to go with regard to drugs, devices, vaccines, tests. But when there is a profit to be made, the American industry is premier and goes for it and is producing amazing things.

For the public health, we have a gap in translation, which is what my colleagues here are referring to. When there is not a profit at the end of that pipeline, we need to have the funding in order to stimulate the industry to produce these products that we are going to need for the future.

As a former practicing doctor very recently, I am very concerned about the thing that you all referred to. I want to stress the public health workforce, not just the docs and nurses. You lost a very important person yesterday.

This is not—and it is emblematic of how hard this work is. We are way down in the workforce that we need across the board to implement. Just talk to any of your friends trying to get on an appointment in a clinic, particularly in mental health, these days.

The CHAIR. Okay. Senator Cassidy.

Senator CASSIDY. I will defer to Dr. Marshall.

Senator MARSHALL. Thank you, Ranking Member and Chairman. Dr. Walensky, let's—if you don't mind, retrospectively, what do you feel the impact of lockdowns were on mental health in this country?

Dr. WALENSKY. It is—certainly, the impact of lockdowns resulted in lives saved from COVID–19 and also challenges in connectivity, and some—there are reports of some children doing better in school at home, but also some children——

Senator MARSHALL. My question is mental health.

Dr. WALENSKY. Right and the lack of connectivity and challenges in mental health. And we saw increases in mental health challenges before the pandemic. They were rising before the pandemic and certainly the pandemic——

Senator MARSHALL. You are saying the lockdowns had no impact on mental health——

Dr. WALENSKY. No, I am sorry, I am not saying that. What I am saying is that the impact—when you lose 1.1 million people in this country, there is tragedy, there is loss. There was loss of lives. There was loss of housing security, food security. All of these things impact mental health.

Senator MARSHALL. Thank you, thank you. Ms. O'Connell, recently we released a 300-page report on the origins of COVID. Senator Burr helped run that investigation. Want to give credit to the previous ASPR, Dr. Bob Kadlec and his great efforts as well.

That report says that there is a preponderance of evidence that shows that this virus was accidentally released from a lab in Wuhan, and a significant amount of evidence that would suggest it was actually made in that laboratory in Wuhan.

As ASPR, what are you doing to research that same issue? Do you feel it is important that we know the origins of COVID?

Ms. O'CONNELL. This is not—this has not been in the purview of the work that I have done at this point. But I would be happy to take this back to the department and other colleagues that are taking a look at that.

Senator MARSHALL. Do you feel like it is important that we know where this virus came from?

Ms. O'CONNELL. I think it would be useful to know for sure, and I know that work is underway. It is not being done in ASPR, so.

Senator MARSHALL. How would it be useful?

Ms. O'CONNELL. Well, as we work to prepare for whatever comes next, which is my job, it would be important to understand what I am coming up against. But let me be clear, whatever it is, I am responsible for responding to it wherever it came from.

Senator MARSHALL. If a virus was made in a laboratory, your response might be different than if it came from nature.

Ms. O'CONNELL. Well, I think it would help us prevent it from happening again if we knew the source. Regardless of that, my responsibility to the country is to help them respond to whatever comes next.

Senator MARSHALL. Okay. Dr. Califf, I think my next question is for you. You can punt it on if you want to. The NIH did an incredible job in the early days of this COVID pandemic, sequencing the virus and then releasing—and then sharing that with any group that they wanted to, any corporation.

At the end of the day, two or three companies end up with a vaccine that was workable. What—why did the other companies fail? Was there anything that we could have done to help promote it to other companies to be more successful? Why did we end up with just two, maybe three vaccines?

Dr. CALIFF. That is a really great question. I wish we had like 6 hours to discuss it because, I mean, as you well know, 90 percent of drugs that enter phase 1 don't make it to market because mother nature is much more sophisticated and complicated than our brains are as we devise new therapies.

I think it was wise of the Government to make a bet on nine or ten vaccines and two or three made it. We often forget about the ones that didn't. I am not sure that anything we could do would change that equation, because that is pretty much the equation that you are seeing—we are seeing.

That is why we have to do human clinical trials. We develop a therapy. We think it is going to work. All of those 90 percent that don't make it, somebody thought it was going to work and somebody invested. I think Senator Romney used to—I guess you didn't invest in these things. But so——

[Laughter.]

Senator ROMNEY. I tried that too.

Dr. CALIFF. You have to take account of a higher failure rate in this, which I think the Government is very wise to do that.

Senator MARSHALL. There is some value that took what the Government developed to getting it across the finish line. Not everyone was able to do that, and I am not sure what the value is in being able to do that. But you would agree that there was more than just luck getting that across the finish line for those two or three successful companies?

Dr. CALIFF. Oh, the collaboration in the mRNA platform that had been developed over decades, and the sharing of the viral sequence. Just the ability to do the viral sequencing and then to use in silico methods to match vaccine to virus.

That was an amazing feat of science and collaboration that made a huge difference. We would have had maybe one vaccine out of ten, I think, if the mRNA technology had not——

Senator MARSHALL. Some of the companies had already had significant investment in the mRNA technology before the COVID was even around, right?

Dr. CALIFF. That is correct. And that is why we are excited about new platforms that are coming along with regard to cell therapy and gene editing and other areas.

Senator MARSHALL. Thank you. I yield back.

The CHAIR. Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman, for holding this hearing. Thank you. It is good to see all of you again. Dr. Walensky, my condolences to you and all the CDC family as well for yesterday. Ms. O'Connell, I want to start with you.

I am working to reintroduce my Public Health Infrastructure Saves Lives Act, to help provide state and local health departments with the strong, sustained funding that they really need, because we know how critical it is to have well-funded, strong health departments responding to any public health situation.

I have heard from my constituents in Washington State about how Federal resources have helped during floods and wildfires and, of course, COVID. But states and communities still often lack the funding and the flexibility they need when they face a public health threat, especially when it comes to reaching and supporting people with circumstances that put them more at risk.

We saw this during COVID. What can Congress do to help ensure that we strategically support those most at risk in a public health emergency, including people with disabilities, older people, adult, children, families?

Ms. O'CONNELL. Senator Murray, thank you so much for that question. This is top of mind for us, too. We just released an ASPR strategic plan, a 5-year plan, in which we make very clear that the country is not prepared until we are all prepared, all communities.

Those at greatest risk need to be accounted for in all the planning that we do and the response that we do. As part of the Fiscal Year 2024 budget, there is an authority to start a human services response fund, which would quickly move money into various communities to be sure that we have boots on the ground able to respond to the various populations that are most at risk.

I had a wonderful conversation on Tuesday with the head of our ACL about how important this is. So, we have been in communications within the department about making sure that the human services side of our shop is also prepared and ready to respond to account for these at-risk populations.

Then, Senator, you recall as part of the last PAHPA, we authorized—you authorized three advisory committees, one for disasters and seniors, one for disasters and people with disabilities, and one for disasters and children.

We have been meeting regularly with those experts and have really valued their input. So, we continue to keep this work front of mind.

Senator MURRAY. Okay, good. And as you know, with any emergency, we need to be able to get supplies where they are needed most in a quick and effective and equitable manner.

My Prevent Pandemics Act, which was signed into law last year, includes directives to ASPR to assist state and local health departments in accessing the Strategic National Stockpile. Can you just give us a quick update on how ASPR is implementing that provision?

Ms. O'CONNELL. Thank you. The Strategic National Stockpile, making sure that it is squared, that it is fully stocked and ready to go has been one of the big focuses of my tenure in this role.

This is an important question for us. We appreciated the provisions in the PREVENTS bill, and we are working very carefully against them. We just released our 60-day guidance, which is guidance for states and localities on how they might access the Strategic National Stockpile.

We will continue to give technical assistance to those states that are interested in maintaining their own stockpile. What do they need to have and how do they need to switch it out? And then we are looking at all the various innovations for how we might hold our stockpile with vendor manage inventory and other ways to switch in and switch out what we have.

This is all front of mind for us. Thank you for those provisions, and we will continue to keep you and your team updated as we implement them.

Senator MURRAY. Very good. I appreciate that. Dr. Walensky, one of the things we really saw in COVID was that we needed accurate data. You can't get ahead of an emergency and create a response to it if you don't have that. I want to ask you today, can you talk about ways that your agency is working to improve data collection?

Dr. WALENSKY. Yes, maybe I will break this into two parts. One is we are actively working on our data monetization efforts, and that is that our data highways are interoperable, that counties and local health departments can give data swiftly to us on similar highways, and we can offer it straight back to them so they can see what—not only what is happening in their county, but in counties around them.

That has yielded huge returns. So, before the pandemic started, we had 887 health facilities that were doing electronic case reporting. We are now at 25,000. That is about 20 percent of what we need across the country.

So massive strides happening. Also, in syndromic surveillance from our emergency departments, and vital statistics from our death registries, all of this work is ongoing in our data highways. Where we could really use your help is the structure of those data is coming into us.

We receive those data voluntarily. If those data don't come to us, we don't have line of sight and we can't deliver those data back. So that is among the things that we are asking for in this PAHPA reauthorization. Thank you.

Senator MURRAY. Okay. Very good. Thank you. Thank you, Mr. Chairman.

The CHAIR. Senator Budd.

Senator BUDD. Thank you, Chairman. Again, thank you to the witnesses for being here today.

Last October, the GAO said the ASPR, the Assistant Secretary for Preparedness and Response, needs to develop a clear approach for buying medical countermeasures for the National Stockpile, and regardless of whether they received development funding from the—from BARDA, or Biomedical Advanced Research Development Authority.

Assistant Secretary O'Connell, without a clear process in place for the stockpile to buy countermeasures, will you commit to implementing GAO's recommendation to document an approach to make sure there is equal consideration of medical countermeasures?

Ms. O'CONNELL. Senator, thank you so much for that question. Absolutely. We are working closely with GAO to make sure that we can take into account the recommendations they make and implement them.

Of course, making sure the stockpile has what it needs is a focus of mine. And we have the FMC, which is an interagency group of experts that come together to give advice to myself and the Secretary on what should go in there across all of the various material threats that DHS has issued.

Senator BUDD. Thank you for that. You know, Congress created ARPA-H or Advanced Research Projects Agency for Health. As it is currently outlined, many of its authorities overlap with efforts

undertaken by the Assistant Secretary for Preparedness and Response, or ASPR, you. So, what steps can Congress take to increase interagency coordination and remove some of the duplicative efforts between ARPA-H and your agency?

Ms. O'CONNELL. Senator, thanks again for that question. So, we are really proud of the work that BARDA does. And BARDA's work is limited to developing countermeasures to make us more prepared against the threats that we see coming.

ARPA-H has a, as I understand it, a wider remit to develop innovative products against any disease or threat, not necessarily the national security threats that we are responding to. But it is important that we have good collaboration between our fellow agency, and we work very closely together, and continue to stay in touch.

But I see a very clear lane for BARDA, and it is important that BARDA stay in that lane in order to keep this country more prepared and ready to respond moving forward.

Senator BUDD. Thank you. Decentralized clinical trials where trials take place at locations other than at a research center like a patient's home, can make groundbreaking cures more accessible to patients who otherwise wouldn't be able to participate simply because—maybe because of where they live.

We saw how important these flexibilities were during the pandemic. So, Commissioner, what steps can Congress take to reduce the barriers for patients to participate in these trials to improve accessibility for those with rare diseases, maybe they are elderly, or they have mobility issues?

Dr. CALIFF. Thanks, Senator. Being a fellow North Carolinian, which has got some cities, but is also a very rural state——

Senator BUDD. I didn't have your bio in front of me, but I appreciate the accent. I was wondering if we were—live nearby.

Dr. CALIFF. Yes. The big city of Durham is where I have lived most of my life. And this is really important. We just put out a guidance on this. Decentralized trials are on the way. It is dependent on digital technology.

If you ask me, the most important thing you can do is to make sure the funding for internet expansion to all the rural areas. I know the bill has passed, the funding is allocated. We have got to make sure that those digital tech pipes are deployed out there. I think the methods are coming along great.

You know, I spent time at Alphabet. There is no question that we have technology that everyone in this country can use. Almost everyone has a cell phone. So, the methods of doing this are not requiring the big research center, unless it is a specialized area that you need special medical exams. That is the way to go.

Senator BUDD. Very good. Thank you all again. Chair, I yield back.

The CHAIR. We owe you a minute next time.

Senator BUDD. I will take it.

The CHAIR. Thank you.

Senator Casey.

Senator CASEY. Mr. Chairman, thanks very much. I appreciate the work that you are doing, and the Ranking Member Cassidy, on the reauthorization of the Pandemic All Hazards Preparedness Act.

I also want to thank Senator Romney for working with us on this reauthorization. I wanted to start with Dr. Walensky, Director Walensky on supply chains and PPE. We learned a horrible lesson in the pandemic, which—and the way I look at it, kind of a national failure when we couldn't provide the kind of PPE that we needed. We don't ever want to have that transpire again.

We had a buckling of that supply chain in the midst of the worst pandemic in 100 years. It adversely impacted first responders and health care workers, essential workers, as you know. So, I think we all agree, that was totally unacceptable. One factor that contributed was a heavy reliance upon imported PPE and the dependence upon those foreign manufacturers and foreign suppliers is what drove that.

It created a terrible risk that we all know that our families and our communities paid a price for. How can we promote innovation when PPE designs are outdated and then ensure that these innovative new technologies are always available to essential workers, and whether they are in health care or otherwise, especially during a pandemic?

Dr. WALENSKY. Thank you, Senator. I would be happy to have our team touch base with you about all the research that is happening at NIOSH now to ensure that we have innovation in PPE.

One is our National Personal Protective Technology Laboratory that is working in sites like the one in Pittsburgh that looks at new technology for PPE that is used in health care and used in public health emergencies and other environmental hazards.

That work is ongoing. We are working with academia in that work, and I am happy to—I would be happy to brief you and your staff on the work that is happening there. I don't know if the ASPR had anything to add to that with regard to——

Senator CASEY. Sure.

Ms. O'CONNELL. Thank you, Dr. Walensky. Senator Casey, just to say, the ASPR organization has invested $16 billion in 87 different contracts for domestic manufacturing of PPE and other critical supplies.

But when we lose the COVID dollars, we lose our ability to do this construction authority and to continue to invest in similar projects. As we are seeing supply chain pinches, as Rob mentioned, across many different materials and products, it will be important that we maintain this ability to keep this work going.

Senator CASEY. Well, thank you. It will be a huge issue among many difficult issues in this reauthorization. Commissioner Califf, I wanted to ask you a question about device shortages, which is another challenge.

We know that in the midst of the pandemic, that was another significant strain. In particular, we saw a terrible shortage of medical devices. The FDA took advantage of the authorities it had during the health emergency and required manufacturers to notify FDA of potential or actual shortages.

How many devices, if you have this number, how many device shortages has the FDA been able to prevent using this authority?

Dr. CALIFF. Approximately 350. So, it is a large number, and this authority is going to go away. We need it and we need notification both with drugs and devices, not only when manufacturing is disrupted, but also when there is a huge surge in demand so that we can help them make up for it.

Senator CASEY. Thanks very much. Mr. Chairman, I am giving back a minute.

The CHAIR. Thank you, Senator Casey. Senator Cassidy.

Senator CASSIDY. I defer to Senator Romney.

Senator ROMNEY. Thank you, Ranking Member Cassidy. Dr. Walensky, Dr. Califf, I interact with you a number of times. I don't know—Ms. O'Connell as well. But I respect you as individuals and physicians who have demonstrated integrity and capacity and commitment to the oath that you have taken to the Nation, but also to your patients. Let me ask each of you, how many employees do you have that you are responsible for in your agency? Just go down the row—approximately.

Ms. O'CONNELL. About 1,000.

Senator ROMNEY. About 1,000.

Ms. O'CONNELL. About 12,000, and about twice the number of contractors.

Senator ROMNEY. Okay, thank you.

Dr. CALIFF. 19,000.

Senator ROMNEY. Yes. I know there are some people who feel that these individuals must be corrupt or must be bad. They work for the Government. They must have ulterior motives.

My experience in dealing with those that I have dealt with is that they are good people. They are brothers, sisters, moms, dads, and they are trying to do the best job they possibly can. I sometimes worry that a projection that other people are evil somehow creates false impressions about how effective our various agencies are, and hope that you and others recognize that the great majority of us, certainly in this body, respect and admire the work you do.

Let me ask if there are any things you think we need to do to improve the integrity and the credibility that is held by the public for your respective agencies. So, for instance, prohibitions on owning stocks in pharmaceutical companies.

I mean, I hear all the time, oh, the FDA approved that because the people looking at it were investors in that company. Is this an issue that you are concerned about? Does this exist in your various agencies? Dr. Califf.

Dr. CALIFF. Well, since you mentioned FDA specifically, let me just say that FDA officials, our employees, are prohibited from owning any stocks in any of the relevant entities that they regulate.

For us, that is almost it is 20 percent of the economy. So even like airlines, because they serve food and food is a big part of our equation. I take great pride and really appreciate what you said.

What could be done to help the most is say a few nice things about Federal employees.

They work hard, and we can verify they worked extremely hard, particularly during the pandemic. They were doing all the regular, more plus of pandemic work at the same time.

Senator ROMNEY. Thank you.

Dr. Walensky.

Dr. WALENSKY. I would just echo the gratitude for your comments, and just say that I have an agency that is working 24/7 to take care of health and public health. They are not getting credit for it.

They—you know, what happens when there is a massive pandemic that affects 330 million Americans is that they had a frail infrastructure to start with.

They were working 24/7. Their job is to protect the public and public health so that you don't have to worry about it. So, a few nice things I would say would go a really long way.

Senator ROMNEY. Thank you. I was personally concerned, and I know many others were about, the data that was available to the public from our Government about what was happening with COVID, who was getting it, what age groups were getting it.

I was a little dismayed that I went to Johns Hopkins to get the data as opposed to coming to the CDC or NIH or whatever. And you indicated that you are making strides to improve our systems for data collection. You also indicated that for many institutions, the data that comes is only voluntarily provided.

Are you suggesting that we really need to have some kind of mandatory reporting, obviously on a basis where people can't possibly be identified personally? But do we need to do something to do—have a better system of collecting data and providing that to the public, as well as to practitioners?

Dr. WALENSKY. Yes. Let me just note that during the public health—right after the public health emergency, it took CDC 6 months in order to be able to negotiate data use agreements, in order to receive hospitalization data, which is why the web scraping of Johns Hopkins was a very efficient way to do this, while we were working with our lawyers to do data use agreements.

Very similar things happen with Mpox. If we are supposed to and responsible for stopping disease outbreaks before they start, before they become emergencies, we have to have line of sight as to those—when those urgent issues, those infectious threats are sparked, and the only way we do that is by getting the reporting coming into CDC so that we can, again, give it back to the communities, and they know that this rare thing that happened in their county is actually also happening in the county next to them.

Senator ROMNEY. All right. Thank you. I haven't much time. I would love to steal the time from the people who gave it up, but I won't do that. Ms. O'Connell, just to ask a question, it is one thing to stockpile, for instance, masks and PPE, it is another to stockpile the machines that make those things.

Do you make a decision—how do you make a decision about whether to keep productive capacity in place as opposed to just keeping masks in place? And are we making the right choice in that regard from your perspective?

Ms. O'CONNELL. Senator Romney, thank you so much for that question. That is exactly what we are working to do now, which is make sure that the stockpile is only one part of the supply chain continuum.

You know, so what we have on hand in the stockpile is critical in the early hours or weeks of a response while we ramp up what we have in the supply chain. But both should work together.

The hospital employees that had to wear bandanas instead of real masks should have been able to access those on the commercial market, were not able to. Stockpile is there to back that up.

Should have been there to be a backstop for that. But if both are running well and we are investing in our domestic manufacturing so that supply chain is stronger and more resilient, if both are running well, we will not need to stockpile, and we can rely on the supply chain. But when that gets pinched, we will have the stockpile.

Senator ROMNEY. Mr. Chairman, thank you.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. I want to thank our witnesses for all your work during a very, very difficult time. And we are here talking about reauthorization of the Pandemic and All Hazards Preparedness Act.

But I just want to state not in the form of a question, but the juxtaposition of an act taken by the House Republicans last week that would result in drastic cuts to our public health programs and our research initiatives, and cuts that would undermine our Nation's competitiveness, as well as our safety, our public health, and our security, and leave us completely unprepared for the next public health emergency.

I certainly stand with many of my colleagues who have voiced concern about that in opposing the measure that the House Republicans passed last week. Look, in the last Congress, I worked closely with Ranking Member Cassidy on the Tracking Pathogens Act.

It enhances our ability to prepare for future pandemics by strengthening efforts to identify new viral threats through genomic sequencing. Thanks to genomic sequencing, the U.S. has been able to identify, survey, and understand emerging variants of COVID–19 and other diseases, but our work really must continue.

The Tracking Pathogens Act was signed into law as part of the Fiscal Year 2023 omnibus. But unfortunately, there is no sustained funding for this work. Dr. Walensky, can you describe why sustained funding for CDC's sequencing efforts, including through the Advanced Molecular Detection Program, is critical to preparing us for future public health emergencies?

Dr. WALENSKY. Yes. First of all, thank you, Senator Baldwin, for all of your efforts on—your bipartisan efforts in our ability to track

pathogens and to track the Coronavirus through our genomic sequencing.

We were doing at times tens of thousands of sequences a week so we could see, and we continue to do it now biweekly to see where and what pathogens and sub-variants are occurring. It is also the case that we know now that we have this, and we can do this, that we have massive capacity to be able to do this for other viral pathogens, for bacterial pathogens, antimicrobial resistance, and fungal pathogens.

We have a capacity here to make great strides. However, again, once we have ramped up, if we let it run dry, then we will not be taking advantage of all of that capacity. I will also note, I invite all of you to visit your state public health labs. If you go to your state public health labs, and I have been to a lot of them, you will see a really frail public health infrastructure and laboratory infrastructure.

Do you have a genomic epidemiologist that can actually do this work? Do you have a sequencer onsite that can actually do this work in your labs? And part of the construction authorities that I think the ASPR is talking about is to develop that capacity in your own state labs so that we cannot only have the resources to do this genomic sequencing, but then have the places and homegrown people that are. Able to do it. Thank you.

Senator BALDWIN. Thank you. BARDA has recently begun to explore new types of platform capabilities for emerging threats.

I believe that as we work to prepare for the future, we must focus on the development of medical countermeasures for viral families with the greatest pandemic potential. And flexible platforms can rapidly pivot to address previously unknown pandemic threats.

That is why I have led the Disease X Act, which would dedicate resources to this particular goal. Ms. O'Connell, how can Congress support BARDA in better prioritizing the development of medical countermeasures against the viral families that present the greatest pandemic potential?

Ms. O'CONNELL. Senator, thank you so much for that question. You know, BARDA is one of the premier research organizations within the Federal Government, but it is an unsung hero in a lot of ways. It doesn't get a lot of credit. I am grateful for a question and an opportunity to talk about them.

They have begun to pivot, as you have said, to this platform technology, and we are seeing some of the advantages of that in the mRNA vaccine, where you can just clip one little piece of the virus and switch it out and very quickly ramp back up production. So, we are exploring that against a pandemic flu.

What would it mean? We have invested $100 million to see what it would mean to transition that technology into a pandemic flu vaccine. So that work is underway, but BARDA is also asked for in Fiscal Year 2024 $60 million for threat agnostic countermeasures, which are going against the broad—you know, we used to be one bug, one drug, and now we are looking at what we can do for multiple drugs against multiple bugs.

That work is underway. We have it in our budget, and we are continuing to look for different applications of the various countermeasures we are currently developing. Senator Baldwin. Thank you. The Chairman. Thank you. Senator Cassidy. Senator Cassidy. I defer to Senator Braun. Senator Braun. Thank you. I have two questions. One for Dr. Califf and one for Dr. Walensky. I am going to start first with you, Dr. Califf. Senator Johnson and I sent you a letter earlier this week.

You have got an upcoming hearing on cellular tissue and gene therapies through your advisory committee concerning a new muscular dystrophy drug, treating the Duchenne variety of it. Unlike most hearings, this one is being done virtually. It is prohibiting the use of cameras.

It is choosing from the patient segment by lottery who can speak up.

Diseases like this and many others where it is very progressive, maybe has a short prognosis window, especially when there is something happening on the front that may be promising, why would you go from the normal format to this, de-emphasizing the patient component of it?

Dr. CALIFF. Senator, thanks for the question. The technology obviously is exciting. And this is an advisory committee, not a hearing, so to speak. And it is really following all the same rules that we have for all of our advisory committees.

The goal is to have experts to give advice about the assessment of the technology as the company presents its data, and the patients have a chance for their input at the open hearing, but there is a limited amount of time and so that is why there is a lottery.

It is not a deviation from our standard procedure. We are really using our standard procedure.

Senator BRAUN. How long that standard procedure been in place then?

Dr. CALIFF. Years, as best I know. I was an Advisory Committee Chair 20 years ago——

Senator BRAUN. You are not reducing the amount of patient participation?

Dr. CALIFF. Not that I am aware of, but if——

Senator BRAUN. I could look into that. And did you get the letter that we sent to you?

Dr. CALIFF. I am aware that the letter came in, yes.

Senator BRAUN. Okay. I think I have been at the forefront of Promising Pathways Act. To me, on some of these diseases that have clinical trials that are working, drugs that are promising, I probably shouldn't have the same kind of dynamic as something that has less urgency where there are at least other treatments out there.

Do you view that should be maybe looked at, keeping most of the gold standard that you always refer to? But since a lot of these windows don't surpass more than 3 to 5 years, should there be a little different way of doing it?

Dr. CALIFF. Well, I completely agree on that. And in fact, in the user fee agreement that you all approved between us and the industry, we are hiring about 150 people just in this area, additional people to focus on it because it is exploding right now with biological technology that holds great promise.

Senator BRAUN. Well, that is good to hear because it is now bipartisan, bicameral, on a Promising Pathways Act with Senator Gillibrand from New York, which would address this and codify it. I will send it to your office and hopefully we will get your endorsement on it. Thank you.

Dr. Walensky, we have had a conversation several times in the past. Of course, we are lifting the Federal vaccine mandate, the public health emergency here on May 11th. I will not forget easily all the angst that was out in the small business community when we had to put a congressional review act out to make sure you weren't going to force vaccines on employees down to employers of 100 employees.

That had more fright when it was in the rearview mirror and it was coming down, and it took the Supreme Court to come in and thwart that bad idea. I would like to know if that was your recommendation, Dr. Fauci's?

It was a Biden administration that did it. Who was going to push forward that was a good idea before we had to come in and intervene with the Congressional Review Act and then get the Supreme Court to weigh in?

Dr. WALENSKY. Yes, maybe what I will say is, here we are now in 2023, when we have 96 percent of people who have protection by one way or another, either infection, prior infection or by vaccination. At the time, we were seeing our workforce and police departments, first responders who were——

Senator BRAUN. This wasn't that long ago. This was just last year where you had—maybe it wasn't 96 percent, but—when you and I had a conversation, we knew that it ravaged the elderly, and it was clear that it wasn't going much more deeply into the rest of the population.

The trillions of dollars that we spent and the fact that the economy was shut down for that long, I think, led—you know, that was much slower to react to the real science and maybe not the political science.

I am just wondering if you and Dr. Fauci, and who were the ones that kept pushing forward on that one issue of the vaccine mandate for employees, private employers, down to 100 employees?

Dr. WALENSKY. I can tell you that there is a group of us that advises the President on these Presidential proclamations. I will also say that to this day, we know that our Bivalent boosters still have 2.7 times the protection against death if you have gotten a Bivalent boost than if you haven't. So, we still know that these vaccines continue to provide protection for people across all age demographics.

Senator BRAUN. Thank you. By the way, Dr. Fauci, in a lasting interview, said that he would probably never recommend shutting the economy down again for something similar to that, FYI. Thank you.

The CHAIR. Senator Kaine.

Senator KAINE. Thank you, Mr. Chair. And thanks to the witnesses. I am a public health data geek because, like Senator Hickenlooper, I was a Mayor, Governor, Senator, like the Chair who was a Mayor. We have the experience of seeing the silos, local health systems, and state health systems, and in Federal health systems that don't really share that way with each other.

Then you have all the providers too, and that created huge challenges for us early in COVID. I mean, just to kind of run back to tape, at the beginning of COVID, it was hard even to get racial information about those who were getting COVID and dying of it.

It took us a while to realize, and it took a lot of kind of jerry rigging to realize, okay, this was affecting African American and Latino more than others. But we didn't know that right away. And with a better health data system, we would have.

Often minorities are lower income, and so they have had less health care access, which has given them more health comorbidities, which makes them more susceptible to serious cases of COVID. Often, racial minorities were working in professions like home health care aides or grocery store clerks, where they couldn't just go virtual all of a sudden, so they had more exposure to COVID.

But it took us a while to figure that out. Then we did figure it out. And when we started to vaccinate in early 2021, beginning with populations over age 65, we figured out pretty quickly that even though it was equally available, over 65 first come first serve, that it wasn't really equitable and it wasn't effective because the communities that needed it—that were the most vulnerable, need it the most, were not the ones who were sitting on their computer to find the nearest CVS where they could go get a vaccine.

They didn't have computer access. They didn't have the free time to do it the way some people had. But because we had figured that out, we were then able to change vaccination strategies to try to get to not just equality but equity and effectiveness. But it is just an indication of there is a million ways where the lack of a functioning public health data system slows down our response, slows down our ability to have effective interventions keeping people safe.

I have worked with colleagues on this Committee for a long time on something we call the Improving Data in Public Health Act. And some of the pieces of that Act have been included in earlier appropriations omnibuses, but there are other pieces that I still think we need to include.

Dr. Walensky, in your opening testimony, I heard just the back end of it when I came in, talk a little bit—you mentioned the public health data. Talk a little bit about how better public health data systems that interoperate can help the CDC do a better job and help keep us all safe.

Dr. WALENSKY. Thank you, Senator, and thank you for your interest in this. And the State of Virginia, actually. The State of Virginia has been one of those states that has piloted with CDC and

the USDS a combination of case reporting, lab reporting, and surveillance, too, so that we do have a better window.

The case that you brought up with COVID is exactly right. We were unable to see the race and ethnicity data. And oh, by the way, it happened again with Mpox. We have the same challenge with Mpox. We had a public health emergency that was declared 3 days after—that it turns out the peak number of cases, and we again could not see the race and ethnicity data.

We could not see the places where vaccines were going into arms, as we were trying to make decisions about a scarce resource, vaccine deployment with my colleague here to and from the ASPR, as we were making those decisions. We can't act swiftly, nimbly, robustly if we can't see what is happening from a data standpoint.

Those—if we wait for the public health emergencies to be declared, and then state by state data use authorizations and data use agreements to happen, it takes months. It took us 6 months to get hospitalization data in COVID–19.

These things—if we are to be nimble, even if we have remarkably robust interoperable data systems, if there is nothing driving on those highways, we will not be able to be nimble and see what is going on.

Truly, we want to have those data at CDC so that we can give them back to state and local health departments. Thank you.

Senator KAINE. I hope as we find a way to a big win in this area, that we could include much more robust data, that obviously protects people's personal identifying information, but that just gives our health care professionals the tools they need.

Dr. Califf, I have heard a lot from my constituents about drug shortages, and we sent you a letter recently to with about 15 colleagues just asking, hey, what can the FDA do to work with stakeholders to identify factors that lead to shortages? I would just like you to, as I close, just tell me that I hope you are prioritizing this because I am nervous about it.

Dr. CALIFF. As infant formula has gotten better, I have gone now to almost full-time drugs shortages because we have hundreds of short—200, over 200 in the last year we preempted by working with the manufacturers.

But it is, that number is going up. We are keeping the actual shortages at the same level, but our employees can only plug a certain number of holes in a system which has got real problems, particularly the generic drug pipeline.

We have got a lot of work to do. We have asked, as I said in my opening statement, perhaps if we had better data so that we can get out in front of this more. There is a lot more to it than that, and I look forward to working with you on it.

Senator KAINE. Thank you. Thank you, Mr. Chair.

The CHAIR. Senator Cassidy.

Senator CASSIDY. Hey, thank you, again. Let me echo what Senator Romney said. I do think all of your employees were working tirelessly through the pandemic, and I really appreciate that. Ms. O'Connell, you are a Tulane grad.

Congratulations on a great football season. Top ten—that is really good. So let me say that. Ms. O'Connell, we have witnesses on the second panel that are going to suggest drug pricing policies that they say would increase access to medical countermeasures.

Now, I raise that because I hear from experts that medical countermeasure development is uniquely challenging, that many of these companies are small companies, that many of the companies that BARDA contracted with went bankrupt and others got bought by bigger companies, and that bigger companies are getting out of medical countermeasures. Is that a fairly accurate depiction of the state of play?

Ms. O'CONNELL. Senator Casey—Cassidy, thank you for that question and thank you for the good wishes for the Green wave. Appreciate that. We are very proud. It doesn't happen a lot.

But to your question, the type of company that we have to work with are often small biotech companies because there isn't a commercial market for countermeasures, typically. So, we do have to work with the smaller companies that have to come in, are willing to be innovative in a certain way, willing——

Senator CASSIDY. Can I stop you for a second? It is my impression that a lot of those companies are living on venture capital and actually have not turned a profit before their first big product. Again, is that a fair characterization?

Ms. O'CONNELL. We often support the work that they are doing in order for them to be able to be successful.

Senator CASSIDY. If you were to put restrictions on what medical countermeasure developed could be priced for, perhaps without knowing all the variables, and if there are—you know, this is an example, because I think it is a fair example—that there is really no secondary use, it is for this particular issue, would that be encouraging of the financing, the private financing of these firms, or if you will, discouraging?

Ms. O'CONNELL. Well, let me first say that we remain committed to making sure that any Government funded——

Senator CASSIDY. I have limited time.

Ms. O'CONNELL. Countermeasures are available to people—to everyone in America that needs them. So, we are very committed to that. But there is a risk if we were to add some limitations in the contracting, that we limit the number of companies that are willing to come forward and do this work.

Senator CASSIDY. You would limit the number of companies and the number of companies is already limited.

Ms. O'CONNELL. There is a risk.

Senator CASSIDY. Yes. Dr. Califf, good to see you. You are looking fit, man. Let me just compliment you right off the bat. Another suggestion, as regards how to develop some of these products is to incentivize innovation with an x price, a large sum of money. But that would be in lieu of patent and regulatory exclusivity.

I don't know if you can comment on the finances of this, but do you think an x price would be an adequate substitute for one of these companies in lieu of the patent and regulatory exclusivity?

Dr. CALIFF. Well, you know what a complicated question you just asked. And what I will say is the prices of drugs, innovative drugs, I believe, are too high. But the solution to that problem shouldn't, in my view, be to do away with patents.

They serve a vital role in stimulating the kind of thing you were just discussing. But where are the balances between those two and the role of prizes? That is a longer discussion. I don't think it's an either-or situation.

Senator CASSIDY. But in general, the intellectual property protection plays a critical role in incentivizing innovation.

Dr. CALIFF. Absolutely. And we just got sued today, again, by a company over that issue. So, it is very important. If people are going to invest in these companies, there has to be intellectual property protection.

Senator CASSIDY. Ms. O'Connell, I am going to ask you a question somewhat related to the last. There is a conversation about having what is called "reasonable pricing" clauses that would dictate the price of something should it enter into the commercial market. Now in general, is there a commercial market for most of the things which BARDA is funding?

Ms. O'CONNELL. In general, there hasn't been. Of the 70 products that we have had licensed, very few of them are available on the commercial market.

Senator CASSIDY. Now, I think I have data showing that the NIH had reasonable pricing clauses from 1990 to 1995, and after they removed them, the amount of—you know, here is the kind of production of drugs, and then they removed it, and it took off.

Now, that may be an association, not a causation. But in your sense, do you think that a reasonable pricing clause would make a company more or less willing to work with BARDA on medical countermeasures?

Ms. O'CONNELL. We would have to take a look at that. But like I said, there would be a risk in adding an additional contracting element to the work that we are doing.

Senator CASSIDY. I have more questions, but I have no time. Thank you.

The CHAIR. The questions you raised a very interesting and I look forward to discussing them in the future. Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman, very much. So earlier, I think, Dr. Walensky, you said that—by the way, congratulations on the great year that the Harvard football team had up there. So, congratulations.

There is kind of a tale of two pandemics here, with 250 people a day still dying. And so, can you talk about that cohort, who they are, and what the message is to them, as the medical emergency in general ends?

Dr. WALENSKY. Yes. So as the public health emergency is set to end next week, I do want to just reiterate that we at CDC are not changing the steam at which we are working through this resolving public health emergency.

You know, as we look at the kinds of people who continue to pass from COVID–19, they tend to be elderly, they tend to be more vulnerable. They tend to be those who are not vaccinated are not up to date on their vaccines.

As we look at those numbers, they are more fragile people and people who are not up to date. It is the case of the end of the public health emergency, we will have less window as to the data, and that is among the things that we have been talking about. We will lose our percent positivity.

We won't get laboratory reporting, we won't get case reporting. So, we will lose some of that. With regard to what we are doing as we touch as we talked to these vulnerable communities, we have been doing a lot of work in CDC to address our disabled communities, our vulnerable communities, our elderly communities.

Among those things is with every response now we have a chief health equity officer and a disability officer. We have been working with our colleagues at ACL. We actually have a meeting tomorrow to discuss with the disability community the impact of the end of the public health emergency and what that means.

We have been putting disability experts within—working with our partners to put disability experts within states so that they have resources and references within their local communities to understand the impact of COVID–19 and other respiratory threats.

Senator MARKEY. For those—for that cohort, people over 65 people, with preexisting conditions, immunocompromised, they still have to act as though the pandemic is still going on, in terms of protecting themselves.

Because you can be in a culture where everyone else is saying we are back to normal, but for them, it is not back to normal in terms of what they need to do to protect themselves. Is that the message?

Dr. WALENSKY. Last week, actually, we provided an update to the Bivalent boosting recommendations so that community could actually get an access to another dose.

As part of the end of the public health emergency, among the things that we would like to do is provide data on hospitalizations, local data on hospitalizations so people can see the hospitalization rates happening in their communities and make decisions as to whether or when they want to take active measures.

Senator MARKEY. Yes. Thank you. So, they should still act as though they are still in a pandemic in terms of the vaccinations, the bivalent protections. Yes, I think that is a very important signal because it is a tale of two pandemics. Those people are still out there that—it is 250 a day. That is 1,700 a week times 52 weeks a year.

That is a lot of people who are going to be affected. Dr. O'Connell, the planet is sick and there are no emergency rooms for planets, and we see the effects in New Orleans, in other places, with climate change just having devastating impacts on communities, which then affects the health care system in those communities and could be delaying or denying people access, for example,

to opioid treatment methadone treatment, whatever, when the storm hits, when the system collapses.

Can you talk about what you do in order to make sure that system is strengthened or needs strengthening across the country? Because we can really predict, almost guarantee that we are going to see intensifying storms in our Country.

All experts, all meteorologists, climatologists are saying that. What do we need to do for our public health system to make sure that it is more capable of responding?

Ms. O'CONNELL. Senator Markey, thank you so much. We are seeing an increase in storms. In fact, FEMA talks about a poly crisis state where we are seeing the increase in flooding and in fires, the intensity of storms that are happening.

We are continuing to ramp up our response elements. That is one of the reasons why the authorities we have asked for in the new PAHPA bill are so important. They would allow us to hire more responders, get more people on the ground, search quicker, be able to procure the tools we need in a faster way.

We are looking across all of those things in the new landscape that we are living in to make sure that we are strengthening what we need to have on the ground.

Senator MARKEY. Thank you. And thank you all for the historically great work which you did to have our Country respond the way it did. So, thank you so much, and we will try to get you the additional resources you need. I think your recommendations are going to be well received. Thank you.

The CHAIR. Thank you, Senator Markey. Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Mr. Chair. I thank all of you. It has been a while. Dr. Califf, I am not sure you are looking that fit, with all due respect.

Look a little tired, obviously, that you are doing one of the hardest jobs—you all are, and certainly making sure we get PAHPA put back together the right way with the proper resources is going to be a big deal for all of us. So, we take that very, very seriously.

Obviously, it is—how could we do otherwise? Dr. Califf, I wanted to start. Obviously, an effective regulatory partner is key to getting these platform technologies to the public in the context of a pandemic.

The FDA has proposed a specialized program to handle the emerging pathogen preparedness in your priorities for Fiscal Year 2024. Can you speak to your vision specifically how the agency might be able to handle the unique regulatory considerations for these platform technologies?

Dr. CALIFF. Sure. We are constantly looking. We have got a good discussion here today about platforms and how important they are going to be in the future, where you can mix and match, and insert a new element and come up with a new therapy in a very short period of time compared to what it used to be. That is a reality with messenger-RNA, but there are many others.

We are asking for a team of people that are dedicated to this, who can be looking to the future. It is included in some of the

things already in play, but we want to do more of it so that we have these platforms ready to go.

Then you can depend on the platform, you don't have to redo all the regulatory work that you would do if you were developing a drug from scratch. Let me also quickly mention relative to some of the questions, I am 71. I got my Bivalent vaccine a few days ago, which is why I look a little tired.

[Laughter.]

Senator HICKENLOOPER. I was just kidding——

Dr. CALIFF. Trying to saw off a T-shirt as a demonstration project, I still have the band aid, but my staff told me that was not allowed in a Senate hearing.

Senator HICKENLOOPER. Let me suggest you go and have a 4-month-old child at home. Then you will be really tired. Dr. O'Connell, or Assistant Secretary O'Connell, sorry, COVID had obviously these immense costs.

We have gone over again this morning the economic costs, human costs. I do think important work will be done as we look back over the entire arc of this pandemic. And again, I can remember vividly I was just a couple of years out of being the Governor.

I watched the decisions that were being made by Governors all across the country and by all of us in Washington in real time with an unbelievably limited information. The data just wasn't there, the facts wasn't there.

But I think it will be useful to go back and look, given at each time what information we had, did we make the right decisions? I think we should be upfront saying that is—there is no harm in that. Mistakes in a time of crisis—it. Is impossible to get everything right.

One thing we did see was that regional co-ordination and resilience were our key to weathering future pandemics. Colorado, we have got the big city hospital, Denver Health, has been a successful demonstration site for both the Regional Disaster Health Response System and the National Special Pathogens Program.

But neither of these have gotten permanent authorization. They are just test cases. So, can you speak, as Assistant Secretary, as to the success of this process, but also what the likelihood is in terms of getting more continuity there?

Ms. O'CONNELL. Senator, thank you for that. I think you are absolutely right. You know, we built the system where we looked at coalitions locally and then expanded out regionally, and then across nationally.

Frankly, COVID was one of the first major responses we have dealt with, that we have needed a national response immediately. So, to be able to have these strong places within the country to lean on have been really, really important.

You mentioned our regional disaster response health systems. At this point we have only funded four of those. So only four regions have the benefit of what Colorado has. One of the goals I have is to be able to expand that. So, it actually is national, and we have

one of those in each region that can make sure we are coordinating across.

You know, you see how important that is in something like COVID when the ICU was were overwhelmed and one hospital to know where to go within the region. And the next one that could take a bed was critically important.

The RESPTCs, the national special pathogens that you mentioned, those came out of the COVID—of the Ebola response in 2014 when we realized not every hospital could handle an Ebola patient.

We set up this system across the country of regional locations that were able to take those patients. And we have trained them and continue to work them. I am really proud of the success that they have had.

In fact, unfortunately, we have had to exercise them recently with the Ebola Sudan outbreak in Uganda and the Marburg outbreak we are seeing in Tanzania and Equatorial Guinea, in case anyone came back, we needed to be sure we were ready to handle and treat. So, very important capabilities.

Senator HICKENLOOPER. Well, I think we saw a lot of that. Also, the regional response and resilience came from community health centers of all the hospitals, as well as the research places.

I mean, that did show the strength of our public health care system. I will leave you with, each of you, I am out of time, so you just have to think on it. But as we try to build the various platforms and build a pandemic preparedness that is worthy of the words, I think we have also got to be vigilant on the creep of red tape and bureaucracy.

Already I am beginning to hear people saying, oh, my gosh, I have to apply for this or talk about that, that. You know, there is so much paperwork, there is so much process that we have created because people are so worried about making a mistake.

That is why I think it's important as the Senate reviews the strength, the successes, the failures, the misses, the hits, that we realize we are never going to get perfectly, but there is real value to constantly be trying to find ways we can limit the red tape and the bureaucracy. Especially in the FDA, I think there is—there is less work to be done. Anyway, thank you all for your public service.

The CHAIR. Thank you, Senator Hickenlooper. And that is, I think, our last questioner. And we thank the panelists very much for being with us today. And now we will hear from our next panel. Convene our second panel, and we thank our panelists for being here and for sitting through the first panel.

Before I introduce our panelists, let me just say a few words. I think sometimes it is important to take a 30,000-foot look at the systems under which we live, and we don't do that often enough. We deal with a crisis by crisis. In my view, we are living with a health care system which is broken, and which is dysfunctional.

We spend twice as much per capita on health care as any other country on earth. $13,000 every year, which is unsustainable. And yet, despite that, 85 million Americans are uninsured and under-

insured. We are seeing in many parts of this country unbelievably, above and beyond COVID, a decline in our life expectancy.

We have a half a million Americans who every year experience bankruptcy, which is related to the medical debt that they have. And we saw during the pandemic how unprepared we were for the major health care crisis that hit us. There are a lot of reasons for the dysfunctionality of our health care system, but one of them, to me, is the outrageously high cost of prescription drugs in this country.

What that means is that one out of four patients who receive a prescription from their doctor are unable to afford to fill that prescription. How absurd and counterproductive is that? Because in too many cases, these folks are only going to get sicker. Maybe they end up in the emergency room at a higher cost to the system.

We see Medicare costs are extraordinarily high because they pay very high prices for the prescription drugs that they dispense, meaning that our deficit and national debt goes higher. And all that together, we are losing about 60,000 people a year unnecessarily because they can't afford the medicine they need or get to a doctor on time.

The questions that we have got to ask ourselves, well, is our current prescription drug model working? Well, I guess it is working for the pharmaceutical industry and the PBMs, because they make tens and tens of billions of dollars a year. Their CEOs make compensation packages of millions of dollars a year.

Yet millions of people cannot afford the outrageously high prices that we pay. So, the question that we have to ask is how does it happen that we pay by far the highest prices of any major country for prescription drugs? I have been with Americans going to Canada where they got the medicine they needed at one-tenth the price they are paying in the United States, all right.

What I hope we will discuss is the dysfunctionality, in my view, of the current model, and how we advance to another model which does what we all want to do. Do we all believe that it is terribly important that we have cutting edge prescription drugs to save lives, to ease pain? Yes, we do.

Do we all understand that the best drug in the world is meaningless if somebody can't afford it? Do we all understand that we have a huge deficit, which is in some ways attributable to the high cost of health care and prescription drugs in this country?

What are the tools that we need? What should we be doing that other countries do, where they provide prescription drugs to their people at a fraction of the cost that we pay? So those are some of the issues that I hope we will be discussing. Senator Cassidy.

Senator CASSIDY. Thank you, Chair. I have been so efficient, I put away my opening remarks. Let's wing it. Thank you, all. You all each bring a unique perspective to this issue. We emerged from the pandemic with an understanding that however robust PAHPA was in the past, it was not adequately robust for the pandemic through which we just went.

They always say the generals fight the last war. I think our generals actually plan for the next. In a sense, you are the generals

who are helping to plan for the next war. Now, some things that we will be considering here are traditionally a little far afield from PAHPA, but that is just the way the Committee has been convened.

But nonetheless, I look forward to your input, and you all, by the way, have very impressive resume, so let me just thank you all for giving of your time to be here. Thank you.

The CHAIR. Okay. Thank you, Senator Cassidy. Our first witness will be Dr. Reshma Ramachandran, who is an Assistant Professor of Medicine at the Yale School of Medicine, an expert in ensuring equitable patient access to safe and effective health technologies. Dr. Ramachandran, thanks very much for being with us.

STATEMENT OF RESHMA RAMACHANDRAN, M.D., M.P.P., M.H.S., ASSISTANT PROFESSOR OF MEDICINE, YALE SCHOOL OF MEDICINE, NEW HAVEN, CT

Dr. RAMACHANDRAN. Chairman Sanders, Ranking Member Cassidy, and distinguished Members of the Committee, thank you for the invitation to testify today. My name is Reshma Ramachandran.

I am an Assistant Professor of Medicine at Yale School of Medicine, where I co-direct an interdisciplinary research and policy program called the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency.

I am also a primary care physician at a federally qualified health center in New Haven, Connecticut. I am honored to testify before you today. My remarks reflect my own views and not that of my employers, nor the organizations I work with.

In 1 week, the declaration of COVID–19 as a public health emergency will come to an end with this year's reauthorization of paper becomes an opportunity to reflect on this period and utilize the lessons learned from dispersing significant public investment that led to the rapid and successful development of vaccines and therapeutics.

To inform this legislation, Congress should answer the following fundamental question, how can we ensure that the American public has equitable access to medical countermeasures developed in response to public health emergencies in the future?

Looking back at the COVID–19 pandemic, the Federal Government effectively removed manufacturers' risk and developing and producing urgently needed vaccines and treatments by granting direct public investment, as well as access to scientific expertise, and resources across agencies.

In return, however, the American public, who underwrote these investments, have received little guarantee that they will have equitable, sustainable access when the public health emergency period ends. Instead, manufacturers have announced plans to raise prices exorbitantly, ignoring that even lower pandemic prices, they have been able to reap billions in profit.

Without intervention from the Federal Government, my most vulnerable patients, including those without health insurance, as well as those at higher risk of severe illness, will disproportionately bear the burden of such untethered price hikes. While current poli-

cies offer some measure of protection for insured Americans in removing cost sharing for vaccines, they too will likely confront these prices indirectly in the form of higher premiums.

The Federal Government, in procuring vaccines and therapeutics, will also bear these expected increased costs. Further increasing taxpayer spending on these publicly funded medical countermeasures will mean that there will be less money and resources available for other critical public health interventions to prevent future resurgence or address other threats.

Moreover, based on trends that we studied in public and private procurement of another publicly funded vaccine, that of influenza, these initial COVID–19 vaccine prices following the public health emergency period will likely be the floor for continued price hikes in the future.

What must Congress conclude as a part of PAHPA to protect the American public and their investment? First, Congress should empower the Federal Government to exercise necessary leverage when allocating funds for the development of medical countermeasures and negotiating procurement contracts.

Through bulk purchasing agreements, the Government could mitigate the impact of substantial price increases through negotiated lower price, as they did during the COVID–19 pandemic.

To further prevent these prices from continually rising year after year, as they have with other vaccines, the Government should call for a ceiling price to be upheld. Additionally, similarly to what has—what they have been able to negotiate in a few contracts, the Government could also ensure that manufacturers give them the best price compared to that of other high-income countries.

Besides securing reasonable pricing provisions, the Federal Government must not sacrifice access and compliance safeguards within these contracts under the guise of flexibility and speed.

Use of contracting mechanisms such as other transactions authority hinder the ability of the Federal Government to remove unnecessary access barriers to taxpayer funded medical countermeasures such as unaffordable pricing. Instead, allocation of any such funds should be tied to provisions that confirm that the supported medical countermeasure is indeed safe and meaningfully effective.

During an ongoing public health emergency, it may be acceptable for residual uncertainty of these products to remain at the time of market authorization. However, the Federal Government must condition taxpayer funding on the completion of additional studies that verify that they do indeed work as intended, and that answer other important public health questions beyond FDA authorization and approval.

Understanding how different treatments and vaccines compare to one another or across different populations would better inform the Government in determining how many doses to procure of each individual product and at what price. Without a doubt, COVID–19 demonstrated how effective the Government can be in spurring the rapid innovation of medical countermeasures.

However, the success of these efforts should not only be measured by whether these medical products reach the market. Rather, Congress must ensure that success under PAHPA is redefined as a Government acting as an effectual steward of taxpayer funds and ensuring equitable access of truly effective and safe health technologies in return. Thank you.

[The prepared statement of Dr. Ramachandran follows:]

PREPARED STATEMENT OF RESHMA RAMACHANDRAN

Chairman Sanders, Ranking Member Cassidy, and distinguished members of the committee, thank you for the invitation to testify today. My name is Reshma Ramachandran. I am an Assistant Professor at Yale School of Medicine where I co-direct an interdisciplinary research and policy program called the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT). Through CRRIT, we study medical product evaluation, regulation, and coverage and translate these findings with the aim of improving patient health outcomes.

I am also a primary care physician at a federally qualified health center where I see and take care of patients, many of whom are uninsured or underinsured and face significant, but unnecessary barriers to accessing the treatments I prescribe. Additionally, I lead the Doctors for America Food and Drug Administration (FDA) Task Force, which is an independent group of physicians across specialties who provide unbiased expertise in evaluating and responding to the FDA regulatory process in a way that maximizes meaningful clinical outcomes for our patients. My written remarks reflect my own views and not that of my employers nor the organizations I work with.

The past 3 years of the COVID–19 public health emergency have demonstrated the incredible capability of the Federal Government in fostering and supporting targeted innovation to rapidly develop and make available novel health technologies amid a devastating pandemic. Not only did American taxpayers contribute billions in direct funding for the discovery, development, production, and distribution of COVID–19 diagnostics, vaccines, and drugs,[1,2] they also indirectly contributed resources, personnel, and expertise through Federal agencies that enabled the successful innovation of these technologies.[3,4] Now, in just 1 week, the declaration of COVID–19 as a public health emergency will come to an end. With this year's reauthorization of the Pandemic All-Hazards Preparedness Act (PAHPA) comes an opportunity to reflect on this period and utilize the lessons learned from disbursing this significant public investment. To inform this impending legislation, Congress can answer the following fundamental question:

How can we ensure that the American public has equitable access to medical countermeasures developed in response to public health emergencies in the future?

In my written testimony, I will outline a few select principles and policies for lawmakers to consider as part of PAHPA toward enabling a fair return for the Federal Government as well as the American public for the significant public investment made to address public health emergencies.

The Federal Government must require rigorous evidence to be generated of medical countermeasures demonstrating safety and efficacy.

During a public health emergency (PHE) when the American public is at grave risk of disease, FDA can employ flexibilities such as emergency use authorization

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[1] "COVID–19: Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations" (Washington, DC.: Government Accountability Office, November 2020), *https://www.gao.gov/assets/720/710691.pdf.*

[2] Biomedical Advanced Research and Development Authority, "BARDA'S Rapidly Expanding COVID–19 Medical Countermeasure Portfolio," accessed May 2, 2023, *https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx.*

[3] "NIH Launches Clinical Trials Network to Test COVID–19 Vaccines and Other Prevention Tools," NIH.gov, July 8, 2020, *https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trials-network-test-covid–19-vaccines-other-prevention-tools.*

[4] U.S. Food and Drug Administration, "Coronavirus Treatment Acceleration Program (CTAP)," FDA.gov (FDA, January 24, 2023), *https://www.fda.gov/drugs/coronavirus-covid–19-drugs/coronavirus-treatment-acceleration-program-ctap.*

(EUA) to quickly evaluate and authorize unapproved medical products. Over the course of the COVID–19 PHE, FDA awarded numerous EUAs to vaccines, diagnostics, and drugs while continuing to assess additional safety and efficacy data to determine if the product should remain on or be withdrawn from the market.[5] Amid an ongoing PHE, it may be necessary for the FDA to allow market access to medical countermeasures despite having residual uncertainty of their safety and efficacy at the time of authorization or approval. However, this must be coupled with requirements for pharmaceutical companies to conduct studies to confirm that their medical products are indeed safe and meaningfully effective.

For COVID–19 vaccines, FDA established rigorous regulatory standards for EUA of potential candidates, requiring large and diverse participant enrollment into randomized-controlled trials with clinical endpoints.[6] The agency also set parameters for the clinical trial design, calling for them to be placebo-controlled and double-blinded with adequate follow-up of participants. These standards were also discussed publicly with independent experts through the Vaccines and Related Biologic Products Advisory Committee (VRBPAC) and others.[7] FDA also issued draft guidance on these regulatory standards allowing for feedback through a public comment period.[8]

The National Institutes of Health (NIH) also played a pivotal role in ensuring rigorous clinical trial design, particularly through their Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) program.[9] Within ACTIV, NIH worked closely alongside other agencies and the biopharmaceutical industry to develop and implement a coordinated research strategy to move promising technologies more expeditiously from the preclinical to clinical trial stage. Under ACTIV, NIH also established several working groups where they convened public agencies and manufacturers to develop clinical trial protocols and harmonize efficacy trial designs for therapeutics and vaccines. Additionally, NIH funded and led several clinical trials in coordination with pharmaceutical company sponsors, providing critical scientific expertise and access to NIH's own clinical trial networks and others.[10, 11]

However, such regulatory rigor across medical countermeasures has not been consistent. For instance, remdesivir was initially granted an EUA in May 2020 based on evidence that it may be effective for the treatment of severe COVID–19.[12] Just months later in October 2020, FDA granted its first full approval[13] for remdesivir despite conflicting evidence of its effect on time to recovery for patients who are hospitalized and diagnosed with COVID–19. At the time of traditional approval, infectious disease experts could only conclude that remdesivir might work.[14] Although FDA attempted offset this uncertainty through 29 additional required and voluntarily committed studies (more than three to four times the number typically re-

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[5] Office of the Commissioner, "Emergency Use Authorization," FDA.gov (FDA, May 2, 2023), *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

[6] U.S. Food and Drug Administration, "Development and Licensure of Vaccines to Prevent COVID–19: Guidance for Industry," June 2020, *https://www.fda.gov/media/139638/download.*

[7] Ravi Gupta et al., "During COVID–19, FDA's Vaccine Advisory Committee Has Worked To Boost Public Trust—It Can Still Do More," Health Affairs Forefront, accessed May 1, 2023, *https://doi.org/10.1377/forefront.20210225.712221.*

[8] U.S. Food and Drug Administration, "Guidance Documents Related to Coronavirus Disease 2019; Availability," August 3, 2020, *https://www.govinfo.gov/content/pkg/FR–2020–08–03/html/2020–16852.htm.*

[9] "Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV)," National Institutes of Health (NIH), accessed January 19, 2022, *https://www.nih.gov/research-training/medical-research-initiatives/activ.*

[10] "NIH Launches Clinical Trials Network to Test COVID–19 Vaccines and Other Prevention Tools."

[11] Francis Collins et al., "The NIH-Led Research Response to COVID–19," Science 379, no. 6631 (February 3, 2023): 441—44, *https://doi.org/10.1126/science.adf5167.*

[12] "Coronavirus (COVID–19) Update: FDA Issues Emergency Use Authorization for Potential COVID–19 Treatment," FDA.gov (FDA, May 4, 2020), *https://www.fda.gov/news-events/press-announcements/coronavirus-covid–19-update-fda-issues-emergency-use-authorization-potential-covid–19-treatment.*

[13] "FDA Approves First Treatment for COVID–19," FDA.gov (FDA, October 22, 2020), *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid–19.*

[14] Paul Sax, "Does Remdesivir Actually Work?," NEJM Journal Watch, October 18, 2020, *https://blogs.jwatch.org/hiv-id-observations/index.php/does-remdesivir-actually work/2020/10/18/.*

quired or requested) [15], [16], none of the required studies addressed the key question of whether in light contradictory results across clinical studies, remdesivir did indeed decrease time to recovery for hospitalized COVID–19 patients with less severe disease or reduce mortality. [17]

Less than a year later, researchers from the Veterans Health Administration published a study finding that remdesivir was not associated with improved 30-day survival and that instead, it was associated with an increase in time to hospital discharge. [18] Had the FDA required further evidence of the drug's efficacy ahead of traditional approval or had imposed postmarketing requirements to confirm its efficacy with adequate oversight to ensure timely completion, the Federal Government could have possibly saved a substantial amount rather than spending on excessive procurement and reimbursement. [19], [20]

Besides maintaining rigorous standards for FDA regulatory review and approval, the Federal Government could also ensure that further studies are conducted that are scientifically meaningful for public health. For instance, although the Federal Government made several investments across various vaccine candidates and provided scientific guidance, personnel, and additional resources including access to clinical trial networks, manufacturers were not required to conduct head-to-head vaccine trials to compare efficacy and safety were conducted. Such studies would allow the Federal Government to better understand if vaccine products have differential effects across populations. Moreover, this would also allow the Federal Government to be a better steward of public funding when negotiating procurement contracts with manufacturers for bulk purchase agreements to ensure that the American public has access to the most appropriate medical countermeasures.

Case Study: Low FDA regulatory standards for FDA approval of antibiotics have yielded drugs of unclear clinical benefit

Updated estimates paint a sobering picture of the human and economic toll of antimicrobial resistance. In 2019, 1.27 million deaths globally were estimated to be attributable to bacterial antimicrobial resistance [21] and the CDC estimates that 35,000 in the U.S. die because of resistant bacterial infections. [22] Additionally, the CDC in collaboration with academic researchers has estimated that treatment of the six most alarming antibiotic resistant pathogens contribute to more than $4.6 billion in health care costs each year. [23]

While exigency is certainly warranted for addressing antimicrobial resistance, this global public health threat differs from COVID–19 in terms of urgency of action and disbursement of federally funded incentives. COVID–19 with its rapid spread and resulting substantial mortality and morbidity required immediate action with the acceptance of some level of uncertainty in evaluating and authorizing new diagnostics, vaccines, and drugs. In contrast, for antimicrobial resistance, the Federal Government can take strategic steps in allocating public funding and resources

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[15] Joshua D. Wallach et al., "Postmarketing Commitments for Novel Drugs and Biologics Approved by the US Food and Drug Administration: A Cross-Sectional Analysis," BMC Medicine 17, no. 1 (June 17, 2019): 117, *https://doi.org/10.1186/s12916–019–1344–3.*

[16] Joshua D. Wallach et al., "Postmarket Studies Required by the US Food and Drug Administration for New Drugs and Biologics Approved between 2009 and 2012: Cross Sectional Analysis," BMJ 361 (May 24, 2018): k2031, *https://doi.org/10.1136/bmj.k2031.*

[17] John Farley, "NDA Approval Letter for Veklury," October 22, 2020, *https://www.accessdata.fda.gov/drugsatfda—docs/appletter/2020/214787Orig1s000ltr.pdf.*

[18] Michael E. Ohl et al., "Association of Remdesivir Treatment With Survival and Length of Hospital Stay Among US Veterans Hospitalized With COVID–19," JAMA Network Open 4, no. 7 (July 15, 2021): e2114741, *https://doi.org/10.1001/jamanetworkopen.2021.14741.*

[19] Eric M Tichy et al., "National Trends in Prescription Drug Expenditures and Projections for 2022," American Journal of Health-System Pharmacy 79, no. 14 (July 15, 2022): 1158—72, *https://doi.org/10.1093/ajhp/zxac102.*

[20] Karyn Schwartz and 2020, "How Could the Price of Remdesivir Impact Medicare Spending for COVID–19 Patients?," KFF (blog), July 14, 2020, *https://www.kff.org/coronavirus-covid–19/issue-brief/how-could-the-price-of-remdesivir-impact-Medicare-spending-for-covid–19-patients/.*

[21] Christopher JL Murray et al., "Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis," The Lancet 0, no. 0 (January 19, 2022), *https://doi.org/10.1016/S0140–6736(21)02724–0.*

[22] "COVID–19: U.S. Impact on Antimicrobial Resistance, Special Report 2022" (National Center for Emerging and Zoonotic Infectious Diseases, June 14, 2022), *https://doi.org/10.15620/cdc:117915.*

[23] Richard E Nelson et al., "National Estimates of Healthcare Costs Associated With Multidrug-Resistant Bacterial Infections Among Hospitalized Patients in the United States," Clinical Infectious Diseases 72, no. Supplement—1 (January 15, 2021): S17—26, *https://doi.org/10.1093/cid/ciaa1581.*

to ensure equitable access for the American public to truly effective and safe treatments and other health technologies.

Instead, stakeholders including the pharmaceutical industry have urgently called for the adoption of costly pull incentives for drug manufacturers without clear assurance or safeguards that the antimicrobials yielded are clinically beneficial or effective against future resistant pathogens.[24],[25] Under the Pioneering Antimicrobial Subscriptions To End Up surging Resistance (PASTEUR) Act, manufacturers of newly approved antimicrobials would be eligible to receive as much as $3 billion in regular installments over a five to 10 year contract period for an individual drug.[26] An additional $1 billion could also be allocated as an extension of the initially contracted period or given ahead of FDA approval for a promising antimicrobial drug candidate. However, absent from this lucrative award for drug manufacturers is a requirement that eligible drugs improve patient health outcomes. Instead, it is one of several "favored characteristics"; among these is that a drug would be eligible for valuable subscription contract if it has received a prior "transitional subscription contract." Eligibility for such a transitional includes that the drug has received the FDA "qualified infectious disease product" (QIDP) designation and has been developed to treat resistant infections listed within CDC's most recent "Antibiotic Resistant Threats in the United States" report.

Examination of recently approved antimicrobials including those granted the QIDP designation by the FDA has shown that the agency approves treatments of unclear benefit and at worst, antimicrobials that are less effective than what is currently available. Prior characterization of pivotal clinical trials for FDA-approved antibiotics (including a small number awarded the qualified infectious disease product or QIDP designation) between 2010 and 2015 have shown that most of these trials were noninferiority studies with none evaluating direct patient outcomes as a primary endpoint.[27] A more recent study of antibiotics approved by the FDA between 2016 and 2019 found that all drugs, many of which were designated as QIDPs, were approved based on surrogate endpoints. More than half of the pivotal trials supporting their approval also used a non-inferiority design, which means that the drugs can be either marginally better or worse by some amount than older, effective alternatives.[28] The study authors also found these new antibiotics despite uncertainty of their clinical benefit at the time of approval were frequently more expensive than other effective alternatives.

In an ongoing research study examining the evidentiary basis for approval of QIDP indications, we found that over 20 percent were approved based on in vitro studies and a majority were tested in non-inferiority pivotal trials, which as noted earlier, allow for intervention drugs to be less effective compared with older, effective antimicrobials by a prespecified margin.[29] Moreover, nearly half of the QIDP indication pivotal trials failed to enroll patients with potential or confirmed resistance. In fact, the FDA only confirmed efficacy against any resistant pathogens for less than a third of these indications based on their pivotal clinical trials. Moreover, FDA has not required manufacturers to conduct further studies after approval to confirm clinical benefit, superiority compared to other effective alternatives, or clinical efficacy against resistant bacterial infections. This suggests that these financial incentives in the form of assured high revenues may be misaligned, rewarding manufacturers of QIDPs for unclear effectiveness against resistant pathogens, despite receiving this special designation intended for this purpose.

Proponents of the PASTEUR Act claim that the legislation would delink the price of newly approved antimicrobial as well as the volume of doses administered from the drug's development costs. However, the legislation has several fundamental flaws in its design including that it would fail to guarantee the American public ac-

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[24] Andrew Jack, "Drugmakers Eye Government Money to Combat Antibiotic Resistance," Financial Times, October 27, 2022.

[25] Reshma Ramachandran and John H. Powers, "Why the PASTEUR Act Is No Cure for Antimicrobial Resistance—The Hill," The Hill, December 13, 2022, *https://thehill.com/opinion/healthcare/3773180-why-the-pasteur-act-is-no-cure-for-antimicrobial-resistance/*.

[26] Michael F. Bennet, "PASTEUR Act of 2021," Pub. L. No. S. 2076 (2021), *https://www.Congress.gov/bill/117th-congress/senate-bill/2076/text.*

[27] Dalia Deak et al., "Progress in the Fight Against Multidrug-Resistant Bacteria? A Review of U.S. Food and Drug Administration—Approved Antibiotics, 2010—2015," Annals of Internal Medicine 165, no. 5 (September 6, 2016): 363, *https://doi.org/10.7326/M16–0291.*

[28] Mayookha Mitra-Majumdar et al., "Evidence at Time of Regulatory Approval and Cost of New Antibiotics in 2016–19: Cohort Study of FDA Approved Drugs," BMJ Medicine 1, no. 1 (December 1, 2022), *https://doi.org/10.1136/bmjmed–2022–000227.*

[29] Food and Drug Administration, "Non-Inferiority Clinical Trials to Establish Effectiveness: Guidance for Industry," November 2016, *https://www.fda.gov/media/78504/download.*

cess to truly effective and safe antimicrobials. Instead, PASTEUR would guarantee that pharmaceutical companies would be awarded a multi-billion-dollar contract funded by taxpayers. Alternatively, as with COVID–19, the Federal Government should set higher standards for regulatory approval that would lead to novel and effective innovation and focus taxpayer investments earlier in the pipeline including for late-stage clinical trials to yield treatments with proven public health and clinical impact.

Summary of Key Points:

- During COVID–19, the Federal Government through its agencies including FDA, CDC, and NIH demonstrated that even during a public health emergency period, parameters for robust clinical trial design could be set to ensure greater certainty of efficacy and safety of novel medical countermeasures.
- While during the public health emergency period Federal agencies may allow for regulatory flexibility of novel medical countermeasures, they must also put in place requirements for sponsors to provide further data even after initial authorization or approval to confirm the product's efficacy and safety.
- In return for significant public investment and resources directed toward the development of novel medical countermeasures, the Federal Government should require sponsors to conduct additional studies of medical countermeasures to answer important public health questions and more efficiently allocate public funding and resources.
- When developing medical countermeasures outside of a public health emergency, the Federal Government should take strategic steps to ensure that any such public investment yields products that are proven to be safe and effective throughout rigorous and well-designed clinical studies.
    - Erosion of FDA regulatory standards has led to the approval of new antimicrobials of unclear clinical benefit and efficacy against resistant threats with no safeguards in place to confirm whether these drugs are truly effective after approval.
    - Pull incentives such as the recently re-introduced PASTEUR Act fail to guarantee the American public access to truly novel, effective, and safe antimicrobials, but guarantee pharmaceutical manufacturers revenues under multi-billion-dollar subscription contracts.

The Federal Government must ensure that the American public has affordable access to medical countermeasures.

The Federal Government has played an outsized role in financing and supporting the development of medical countermeasures. Yet it has exercised very little leverage in ensuring affordable access and fair pricing of these medical products. As discussed at the recent hearing held by the Senate HELP Committee on March 22, 2023, COVID–19 vaccine manufacturers received significant public funding support for discovery, development, production, and manufacturing activities through Operation Warp Speed and other initiatives.[30] Even predating the pandemic, the U.S. Government invested an estimated $337 million toward early and late stages of development as well as manufacturing capacity of mRNA vaccines.[31] Ahead of confirmation of efficacy and safety, several manufacturers were granted advanced purchase agreements for hundreds of millions of doses without necessitating FDA authorization or approval.[32] Essentially, the Federal Government de-risked several stages of vaccine development and production for manufacturers.

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[30] "Taxpayers Paid Billions For It: So Why Would Moderna Consider Quadrupling the Price of the COVID Vaccine?—The U.S. Senate Committee on Health, Education, Labor & Pensions," March 22, 2023, *https://www.help.senate.gov/hearings/taxpayers-paid-billions-for-it-so-why-would-moderna-consider-quadrupling-the-price-of-the-covid-vaccine.*

[31] Hussain S. Lalani et al., "US Public Investment in Development of MRNA Covid–19 Vaccines: Retrospective Cohort Study," BMJ 380 (March 1, 2023): e073747, *https://doi.org/10.1136/bmj–2022–073747.*

[32] Leila Abboud and Hannah Kuchler, "Why the Three Biggest Vaccine Makers Failed on Covid–19," Financial Times, February 16, 2021, *https://www.ft.com/content/657b123a–78ba–4fba-b18e–23c07e313331.*

Despite this, COVID–19 vaccine manufacturers have been able to negotiate prices with the Federal Government well above the cost of production,[33] reaping multiple billions in profits. Now, as the PHE period comes to an end, these companies have also announced significant price increases to their products.[34] Coupled with the likelihood that COVID–19 will be considered an endemic disease possibly requiring regular booster doses,[35] similar to that of influenza, these anticipated price hikes will translate to significant costs for patients and the Federal Government. Without intervention, uninsured populations will directly face these anticipated vaccine price hikes and deterring many from receiving a potentially necessary prevention measure.

For these populations, manufacturers have promised to establish patient assistance programs.[36] However, to ensure access, these programs as they have been traditionally established and implemented will not be adequate. Not only do such programs often lack a standardized application process, but their applications are onerous and complex often requiring assistance from health professional personnel.[37] Additionally, supply is typically allocated through patients' providers, necessitating an extra step and potentially, an additional payment for a clinic visit to obtain the needed treatment. To realize the intention of these programs of providing equitable and free access to COVID–19 vaccines for uninsured patients, the Federal Government must set minimum requirements for manufacturers to make these products easily accessible without any cost.

Manufacturers have also argued that insured populations will not see these costs in the form of out-of-pocket payments. While this is certainly true under the Affordable Care Act and the Inflation Reduction Act, the Federal Government and private insurers will likely bear the burden of higher post-pandemic prices, which could lead to higher premiums for the insured American public.[38] The Federal Government could continue to purchase vaccine doses in bulk at a lower price as anticipated in the near-term;[39] however, as evidenced by the case of the influenza vaccine which similarly was developed and manufactured with public funding support,[40] even the initial public procurement price will become a floor for continued price increases.

For COVID–19 treatments, pricing following the PHE is less certain. Public procurement prices for antivirals such as molnupiravir (Lagevrio), nirmatrelavir-ritonavir (Paxlovid), and remdesivir (Veklury) have far exceeded their production costs[41],[42],[43] and despite their manufacturers also having received Federal funding

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[33] Zoltan Kis and Zain Rizvi, "How to Make Enough Vaccine for the World in One Year" (Washington, DC.: Public Citizen, May 26, 2021), *https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/*.

[34] Pfizer, "Pfizer Reports Second-Quarter 2021 Results," July 28, 2021, *https://investors.pfizer.com/investor-news/press-release-details/2021/PFIZER-REPORTS-SECOND-QUARTER–2021-RESULTS/default.aspx*.

[35] U.S. Food and Drug Administration, "FDA Briefing Document: Future Vaccination Regimens Addressing COVID–19," January 26, 2023, *https://www.fda.gov/media/164699/download*.

[36] "Moderna's Commitment to Patient Access in the United States," modernatx.com, February 15, 2023, *https://investors.modernatx.com/Statements—Perspectives/Statements—Perspectives-Details/2023/Modernas-Commitment-to-Patient-Access-in-the-United-States/default.aspx*.

[37] Niteesh K. Choudhry et al., "Drug Company—Sponsored Patient Assistance Programs: A Viable Safety Net?," Health Affairs 28, no. 3 (May 1, 2009): 827—34, *https://doi.org/10.1377/hlthaff.28.3.827*.

[38] 2023, "How Much Could COVID–19 Vaccines Cost the U.S. After Commercialization?," KFF (blog), March 10, 2023, *https://www.kff.org/coronavirus-covid–19/issue-brief/how-much-could-covid–19-vaccines-cost-the-u-s-after-commercialization/*.

[39] "Fact Sheet: HHS Announces 'HHS Bridge Access Program For COVID–19 Vaccines and Treatments' to Maintain Access to COVID–19 Care for the Uninsured," Text, HHS.gov, April 18, 2023, *https://www.hhs.gov/about/news/2023/04/18/fact-sheet-hhs-announces-hhs-bridge-access-program-covid–19-vaccines-treatments-maintain-access-covid–19-care-uninsured.html*.

[40] Reshma Ramachandran et al., "Future of Covid–19 Vaccine Pricing: Lessons from Influenza," BMJ 373 (June 22, 2021): n1467, *https://doi.org/10.1136/bmj.n1467*.

[41] Prepared Melissa J Barber and Dzintars Gotham, "Estimated Cost-Based Generic Prices for Molnupiravir for the Treatment of COVID–19 Infection," Working Paper, October 1, 2021.

[42] Prepared Melissa J Barber and Dzintars Gotham, "Estimated Cost-Based Generic Prices for Nirmatrelvir/Ritonavir (Paxlovid)," Working Paper, January 12, 2023.

[43] Andrew Hill et al., "Minimum Costs to Manufacture New Treatments for COVID–19," Journal of Virus Eradication 6, no. 2 (n.d.): 61—69.

[44] ChangWon C. Lee et al., "Origins and Ownership of Remdesivir: Implications for Pricing," The Journal of Law, Medicine & Ethics 48, no. 3 (September 1, 2020): 613—18, *https://doi.org/10.1177/1073110520958890*.

[45] Travis Whitfill, "A Likely New Treatment for Covid–19 Was Made Possible by Government-Funded Innovation," STAT (blog), October 5, 2021, *https://www.statnews.com/2021/10/05/government-funding-backed-molnupiravir-possible-new-covid–19-treatment/*.

support and resources for their development.[44, 45, 46] The CEO of Pfizer, which markets nirmatrelavir-ritonavir referred to the $530 per course price point the Federal Government was able to receive through its initial bulk purchasing agreement as "really very attractive" and indicated the drug will cost significantly more on the commercial market.[47] For these and other COVID–19 treatments, the burden of potentially unaffordable access will fall onto disproportionately on the most vulnerable populations who are at higher risk of developing severe illness.

Other medical countermeasures developed to address public health emergencies have also benefited from significant public funding and resource support for their discovery, basic and preclinical studies, and clinical trials supporting regulatory authorization or approval.[48] The Federal Government has also often secured bulk purchasing agreements ahead of market authorization from the FDA. Such agreements have given the Federal Government leverage to negotiate a likely more reasonable price point with manufacturers. However, few contracts have included provisions guaranteeing such reasonable pricing, particularly in comparison to procurement prices paid by other countries. As part of their agreement with Novavax, the Department of Defense stated that it should receive the lowest, best price for a period of 5 years for purchase of doses administered in the U.S. [49] In exchange for $1.8 billion, Sanofi had been prohibited in its agreement to sell its vaccine to any member of the G7 or Switzerland at a price lower than that of the Federal Government.[50] In their contract with Paxlovid, the Federal Government including a "most-favored nation" pricing clause that would allow them to receive a lower price if one of six other high-income countries were to negotiate a better deal.[51] Such conditions that better safeguard affordable access both during the PHE period as well as afterward should be applied across medical countermeasures by the Federal Government.

Besides conditions directly focused on pricing, the Federal Government should also ensure that public funding and resources granted to pharmaceutical companies and others do not include flexibilities that could preclude access. During COVID–19, the Biomedical Advanced Research and Development Authority (BARDA) along with the Department of Defense routinely utilized the mechanism of Other Transaction Agreements (OTAs) to attract private partners to enter into government contracts granting Federal funding support for the development and production of various medical products.[52] While such flexibilities are employed to hasten contracting with private sector partners, they also remove potentially important safeguards that would enable affordable access. For instance, OTAs are not subject to conditions under the Bayh-Dole Act, which means that when pricing of publicly funded medical countermeasures hinders reasonable access of these products, Federal agencies are unable to exercise march-in rights that would compel the patent owner to license

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[46] Ryan P. Joyce, Vivian W. Hu, and Jun Wang, "The History, Mechanism, and Perspectives of Nirmatrelvir (PF–07321332): An Orally Bioavailable Main Protease Inhibitor Used in Combination with Ritonavir to Reduce COVID–19-Related Hospitalizations," Medicinal Chemistry Research 31, no. 10 (2022): 1637—46, *https://doi.org/10.1007/s00044–022–02951–6.*

[47] Hannah Recht, "COVID–19 Treatment Paxlovid Has Been Free so Far. Next Year, Sticker Shock Awaits," PBS NewsHour, December 18, 2022, *https://www.pbs.org/newshour/health/covid–19-treatment-paxlovid-has-been-free-so-far-next-year-sticker-shock-awaits.*

[48] Michael S. Sinha et al., "Expansion of the Priority Review Voucher Program Under the 21st Century Cures Act: Implications for Innovation and Public Health," American Journal of Law & Medicine 44, no. 2—3 (May 2018): 329—41, *https://doi.org/10.1177/0098858818789430.*

[49] Kathryn Ardizzone, "Novavax and Inovio COVID–19 Vaccine Contracts Limit Prices Companies Can Charge for Their Products," Knowledge Ecology International (blog), January 28, 2021, *https://www.keionline.org/35185.*

[50] Kathryn Ardizzone, "$1.8 Billion Sanofi Vaccine Contract Contains International Reference Pricing Clause, Preserves Standard IP and Data Rights," Knowledge Ecology International (blog), December 2, 2020, *https://www.keionline.org/34776.*

[51] Sydney Lupkin, "Feds' Contract with Pfizer for Paxlovid Has Some Surprises," NPR, February 1, 2022, sec. Treatments, *https://www.npr.org/sections/health-shots/2022/02/01/1075876794/feds-contract-with-pfizer-for-paxlovid-has-some-surprises.*

[52] Eric Steinberg, "Use of Other Transactions at ASPR," accessed May 3, 2023, *https://doi.org/10.1037/e658332011–001.*

[53] Stuart W. Turner, "Other Transactions Authority (OTA): Protests and Disputes," Arnold & Porter, June 28, 2018, *https://www.arnoldporter.com/en/perspectives/advisories/2018/06/other-transactions-authority-ota-protests.*

[54] Assistant Secretary for Preparedness and Response and Biomedical Advanced Research and Development Authority, "BARDA Strategic Plan 2022—2026" (Department of Health and Human Services, May 2022), *https://www.medicalcountermeasures.gov/media/38717/barda-strategic-plan–2022–2026.pdf.*

the pertinent patents to another company such as a generic drug manufacturer.[53] BARDA has proposed as part of their 2022–2026 Strategic Plan to leverage OTAs further as part of their contracting process[54] putting at risk the ability of the Federal Government to intervene to ensure affordable access.

Summary of Key Points:

- Although the Federal Government has played an outsized role in financing and supporting the development of medical countermeasures, it has exercised very little leverage in ensuring affordable access and fair pricing of these medical products even during public health emergency periods.
- Untethered price hikes of COVID–19 vaccines and therapeutics following the public emergency period will a disproportionate and undue impact on those populations who are uninsured and at higher risk of severe illness unless the Federal Government intervenes.
- Although manufacturers argue that insured patients will not face barriers in accessing COVID–19 vaccines due to anticipated price hikes due to policies that prevent cost-sharing of CDC-recommended vaccines for those who are insured, they may face these costs in the form of higher premiums. Additionally, the Federal Government and private insurers in procuring doses from the manufacturers may also face these significant price hikes, precluding allocation of such funds for other necessary public health interventions.
- Although the Federal Government could mitigate the impact of such price hikes through bulk purchasing agreements at a negotiated lower price, the initial public procurement price following the public health emergency period will likely be the floor as evidenced by trends in public and private influenza vaccine pricing over time.
- In a few contracts, the Federal Government has been able to include provisions guaranteeing reasonable pricing in comparison to other wealthy countries, which should also be included in all future purchasing agreements.
- The Federal Government should also ensure that such agreements do not include provisions that remove access safeguards at the expense of flexibility and speed.

The Federal Government must continuously evaluate the success of publicly awarded incentives and sunset those that fail to generate truly innovative, effective, and safe medical countermeasures.

Along the drug and vaccine development pipeline, agencies have awarded various incentives to pharmaceutical companies and other stakeholders ranging from push incentives that lower the cost of development to pull incentives that ensure or increase revenue. While the purpose of such incentives is to enable greater participation from stakeholders including private partners in the development of novel medical countermeasures, there has been little effort to evaluate these incentives once implemented and sunset those that have not been proven to be effective.

One such incentive is the medical countermeasure priority review voucher, created under the 21st Century Cures Act in 2016.[55] Awarded at the time of FDA approval, manufacturers can redeem priority review vouchers allowing for another product in their portfolio. Under the traditional review process, these products would be reviewed by the FDA within 10 months; with a voucher, the product would instead receive priority review without having to meet specific eligibility criteria, shortening regulatory review time to a maximum of 6 months and allowing for earlier market entry. The Government Accountability Office (GAO) analysis of three existing priority review voucher programs including for medical countermeasures gen-

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[51] Sydney Lupkin, "Feds' Contract with Pfizer for Paxlovid Has Some Surprises," NPR, February 1, 2022, sec. Treatments, *https://www.npr.org/sections/health-shots/2022/02/01/1075876794/feds-contract-with-pfizer-for-paxlovid-has-some-surprises.*

[52] Eric Steinberg, "Use of Other Transactions at ASPR," accessed May 3, 2023, *https://doi.org/10.1037/e658332011–001.*

[53] Stuart W. Turner, "Other Transactions Authority (OTA): Protests and Disputes," Arnold & Porter, June 28, 2018, *https://www.arnoldporter.com/en/perspectives/advisories/2018/06/other-transactions-authority-ota-protests.*

erally did not find any effect of these vouchers on innovation.[56] The GAO report also noted another analysis, which found that 25 of the 26 medical countermeasures in clinical trials received public funding for their development, raising questions on the necessity of such vouchers to incentivize innovation.

In a study we published in 2021,[57] we found that all five medical countermeasures initially awarded a priority review voucher were initially developed through public funding—the discovery of four of the five products was underwritten by the Federal Government and the remaining one by the German government. The U.S. Government also sponsored late-stage clinical trials supporting FDA approval of all five products; for three, Federal agencies designed and conducted these trials. FDA also granted all five medical countermeasures additional regulatory incentives including designations allowing these drugs and vaccines to receive expedited review. Additionally, FDA awarded further intellectual property protections in the form of exclusivity periods, barring generic entry for variable periods of time. Finally, the Federal Government also ensured a market for these products through bulk advance purchase agreements, often secured before regulatory approval. Considering that the Federal Government has granted several financial, regulatory, and intellectual property incentives along the medical countermeasure development pipeline, issuance of an additional priority review voucher is likely unnecessary.

Moreover, there may be undue impacts from the awarding of such priority review vouchers, creating an undue burden for patients and clinicians. Redeeming the priority review voucher forces the FDA to more rapidly access the safety and efficacy of a medical product that would otherwise be ineligible for this expedited review designation. Such designations have been associated with increased risk of FDA safety actions after approval[58] as well as lower standards of evidence including fewer pivotal trials, fewer enrolled pivotal trial participants, and more frequent use of surrogate endpoints instead of more clinically relevant ones.[59] As examination of this incentive has failed to effectively promote the development of medical countermeasures and may instead lead to the hasty approval of potentially unsafe medical products of uncertain benefit, legislators should reconsider and even sunset this program altogether.

For antimicrobials, other incentives have been introduced to encourage the development of novel drugs with limited evaluation of their value. Entering into a "subscription" contract under the PASTEUR Act would not disqualify manufacturers from receiving other financial incentives. One such other financial incentive is that of new technology add-on payments from the Centers for Medicare and Medicaid Services (CMS), which in 2019 modified these to be higher and removed the eligibility criteria of "substantial clinical improvement", thus lowering the bar for receiving this additional reimbursement. This payment received by manufacturers when the antimicrobial is dispensed to a patient is effectively a volume-based incentive that is antithetical to the need to conserve these drugs to prevent against further resistance.

Therefore, should the PASTEUR Act be included as part of PAHPA, manufacturers of new antimicrobials would not only be eligible to receive billions in federally awarded subscription contracts, but also additional revenue through new technology add-on payments. This may create a perverse situation in which health systems and hospitals would be incentivized to prescribe more of a new antimicrobial that should be conserved as a last line treatment. Moreover, as the PASTEUR Act only addresses public remuneration of new antimicrobials in the form of regular lump sum payments, manufacturers of these drug products would also potentially be able to receive private payer reimbursement separately as additional revenue, which may incentivize the overuse or misuse of these new treatments.

Such financial incentives that may prompt health systems and hospitals to inappropriately prescribe novel antimicrobials encompassed by the PASTEUR Act would

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[54] Assistant Secretary for Preparedness and Response and Biomedical Advanced Research and Development Authority, "BARDA Strategic Plan 2022—2026" (Department of Health and Human Services, May 2022), *https://www.medicalcountermeasures.gov/media/38717/barda-strategic-plan–2022–2026.pdf.*

[55] "Material Threat Medical Countermeasure Priority Review Vouchers: Draft Guidance" (Rockville, MD: Food and Drug Administration, January 17, 2018), *https://www.fda.gov/media/110193/download.*

[56] Government Accountability Office, "DRUG DEVELOPMENT: FDA's Priority Review Voucher Programs," January 2020, *https://www.gao.gov/assets/710/704207.pdf.*

[57] Reshma Ramachandran, Ravi Gupta, and Jing Luo, "An Unnecessary Gift for COVID–19 Vaccines and Therapeutics: The Medical Countermeasure Priority Review Voucher," American Journal of Public Health, October 14, 2021, e1—4, *https://doi.org/10.2105/AJPH.2021.306495.*

not be offset by the stewardship provisions in the bill.[60] As written, the legislation does not tie specific stewardship efforts to antimicrobials for which a "subscription" contract has been issued, making it unclear how these treatments will be conserved to prevent further antimicrobial resistance. Any such incentive awarded to antimicrobial manufacturers must fully delink the development costs from both the price as well as volume to ensure equitable, affordable access and not excess.[61]

Summary of Key Points:

- The Federal Government has supported the development of several medical countermeasures through push incentives that lower the cost of development as well as pull incentives the ensure or increase revenues. Following the implementation of these incentives, there has been limited evaluation of their success as well as efforts to sunset those that have not been found to be effective.
- There is little evidence that the medical countermeasure priority review voucher is effective in promoting the development of novel products as the Federal Government has granted several other financial, regulatory, and intellectual property incentives to these same health technologies. Granting priority review vouchers may instead lead to the hasty approval of potentially unsafe medical products of uncertain benefit. Therefore, legislators should reconsider and even sunset this program altogether.
- For antimicrobials, pull incentives such as the recent increase in new technology add-on payments awarded by CMS and removal of the "substantial clinical improvement" criteria may incentivize hospitals and health systems to overuse these drugs, which need to be conserved to prevent exacerbating antimicrobial resistance.
- Any incentive awarded to antimicrobial manufacturers must fully delink the development costs from both the price as well as volume to ensure equitable, affordable access and not excess.

Considering Opportunity Costs and Conclusion

Resulting from any allocation of funding and resources by the Federal Government to promote the development of novel medical products will be opportunity costs. For public health emergencies, the wager of awarding financial and other resource incentives can be risky as targeting these toward particular health technologies would preclude their use for other purposes including public health interventions not involving individual products. For instance, much of the focus of Federal funding support to address COVID–19 has been largely for promoting the development of individual diagnostic, vaccine, and therapeutic products with comparatively less Federal investment allotted for other public health prevention strategies.

For antimicrobial resistance, significantly more has also been spent and proposed for innovation of individual drugs compared to other strategies that would prevent the emergence and spread of bacterial resistance and in turn, the need for continuous development of novel antimicrobials effective against the next future resistant pathogen. In fact, the OECD has estimated that three out of four deaths due to antibiotic resistance could be prevented by spending $2 per individual annually on non-pharmacologic interventions such as handwashing, stewardship of antibiotics, and rapid testing.[62]

In view of the Federal Government and taxpayers as critical investors in addressing future public health emergencies, variation within their investment portfolio with balanced allotments for both prevention as well as treatment independent of non-pharmacologic measures will be necessary to ensure a truly effective response. Nevertheless, the Federal Government should continue to support through direct funding and resources across agencies the development of novel medical countermeasures in the form of therapeutics and vaccines. However, the success of these efforts should not be hinged on the authorization or approval of these products, but rather on whether the Federal Government can be an effective steward of taxpayer funds and ensure equitable access to truly effective and safe health technologies.

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[60] Bennet, PASTEUR Act of 2021.

[61] Anthony D. So and Tejen A. Shah, "New Business Models for Antibiotic Innovation," Upsala Journal of Medical Sciences 119, no. 2 (March 19, 2014): 176—80, *https://doi.org/10.3109/03009734.2014.898717.*

[62] "Stemming the Superbug Tide: Just A Few Dollars More," OECD Health Policy Series (OECD, November 7, 2018), *https://www.oecd.org/health/stemming-the-superbug-tide–9789264307599-en.htm.*

[SUMMARY STATEMENT OF RESHMA RAMACHANDRAN]

The Federal Government must require rigorous evidence to be generated of medical countermeasures demonstrating safety and efficacy.

- While during the public health emergency period Federal agencies may allow for regulatory flexibility of novel medical countermeasures, they must also put in place requirements for sponsors to provide further data even after initial authorization or approval to confirm the product's efficacy and safety.
- In return for significant public investment and resources directed toward the development of novel medical countermeasures, the Federal Government should require sponsors to conduct additional studies of medical countermeasures to answer important public health questions and more efficiently allocate public funding and resources.
- When developing medical countermeasures outside of a public health emergency, the Federal Government should take strategic steps to ensure that any such public investment yields products that are proven to be safe and effective throughout rigorous and well-designed clinical studies.

The Federal Government must ensure that the American public has affordable access to medical countermeasures.

- Untethered price hikes of COVID–19 vaccines and therapeutics following the public emergency period will a disproportionate and undue impact on those populations who are uninsured and at higher risk of severe illness unless the Federal Government intervenes.
- Although the Federal Government could mitigate the impact of such price hikes through bulk purchasing agreements at a negotiated lower price, the initial public procurement price following the public health emergency period will likely be the floor as evidenced by trends in public and private influenza vaccine pricing over time.
- In a few contracts, the Federal Government has been able to include provisions guaranteeing reasonable pricing in comparison to other wealthy countries, which should also be included in all future purchasing agreements.
- The Federal Government should also ensure that such agreements do not include provisions that remove access safeguards at the expense of flexibility and speed.

The Federal Government must continuously evaluate the success of publicly awarded incentives and sunset those that fail to generate truly innovative, effective, and safe medical countermeasures.

- The Federal Government has supported the development of several medical countermeasures through push incentives that lower the cost of development as well as pull incentives the ensure or increase revenues. Following the implementation of these incentives, there has been limited evaluation of their success as well as efforts to sunset those that have not been found to be effective.
- There is little evidence that the medical countermeasure priority review voucher is effective in promoting the development of novel products as the Federal Government has granted several other financial, regulatory, and intellectual property incentives to these same health technologies. Granting priority review vouchers may instead lead to the hasty approval of potentially unsafe medical products of uncertain benefit. Therefore, legislators should reconsider and even sunset this program altogether.
- Any incentive awarded to antimicrobial manufacturers must fully delink the development costs from both the price as well as volume to ensure equitable, affordable access and not excess.

The CHAIR. Thank you very much. Our next witness is Mr. Robert Weissman, who is President of Public Citizen. Mr. Weissman is an expert on drug pricing and specifically ensuring equitable access to drugs. Mr. Weissman, thanks a lot for being with us.

STATEMENT OF ROBERT WEISSMAN, PRESIDENT, PUBLIC CITIZEN, WASHINGTON, DC

Mr. WEISSMAN. Thank you very much. Chair Sanders and Ranking Member Cassidy, for the opportunity to be here today. I think it is fair to say that Operation Warp Speed was a great success in speeding the development of COVID vaccines and a validation of the BARDA investment model, to an extent.

But it was also a great failure, and we need to learn that lesson as well. It was a failure in that although the U.S. Government was responsible for funding of the COVID vaccine from before COVID even emerged, through the isolation of the key spike protein, through the clinical trials, and up through the development and production of the vaccine, BARDA imposed effectively no restraint on how Moderna and other partners, but especially Moderna, would operate.

The result was while Moderna executives became billionaires, taxpayers were price gouged. Hundreds of thousands or maybe millions of people lost their lives because we had a global shortage of a vaccine that could have been avoided if we had shared the technology. And now Moderna has announced it plans to quadruple prices, further limiting access, further gouging consumers, further gouging the taxpayer.

As everyone here has agreed, we need to learn the lessons from what happened during the pandemic period and do better going forward. We absolutely need PAHPA, we need BARDA, but we need to do better. What are some key lessons going forward? First, we need more transparency in the contracting process.

Taxpayers should know who they are providing grants to, who are they making acquisitions from, and on what terms. When drug companies and vaccine makers are making co-investments in a product, they should know, taxpayers should know how much is being done on the private sector side along with the public side.

Second, we need to have reasonable pricing for the products that we, the taxpayers, pay for. That should just be common sense. If we pay for it, we ought not to pay for it again with unreasonable prices.

The starting point for reasonable pricing should be that the United States does not pay more than other high-income countries do for a product. But that is just a starting point. We can do much better than that.

In general, the way we should think about reasonable pricing is tailoring a reasonable price to the amount of private sector investment and risk taken. Where the Government pays for the development of a drug all the way through, the reasonable price should be a lot lower than where a private sector partner took on a lot of the risk and made a lot of early stage investments.

Third, we have to guarantee international access. We know that pandemics definitionally mean that everyone around the world needs the products we are talking about. Drug manufacturers, vaccine makers may not have capacity and often don't have interest in serving the global markets.

As such, we should have a proactive requirement for licensing to the World Health Organization of crucial technologies and licensing and sharing of technology and know-how as well, to make sure that other manufacturers can produce products that everyone needs. Last, we should consider as well as the traditional model for supporting research and development, prize models, such as those that you have supported in the past are legislation, Chair Sanders.

We know in the case of BARDA that the patent monopoly model of support innovation by definition doesn't work. That is why BARDA is making the investments, because the private sector model in these cases, as Commissioner Califf said earlier, doesn't work.

It is at least insufficient. Given that, we ought to think creatively about what might work better. Prizes can be calibrated to provide appropriate incentives sufficient to enable manufacturers and researchers to enter the space, while also ensuring affordability and access on the back end.

You can also do other things to promote innovation, like giving people rewards when they don't actually get the final product, but they make contributions along the way. So, these are the some of the lessons I think, that come out of the pandemic and that we must incorporate into PAHPA going forward. Thank you very much.

[The prepared statement of Mr. Weissman follows:]

PREPARED STATEMENT OF ROBERT WEISSMAN

Mr. Chairman and Members of the Committee,

Thank you for the opportunity to testify today on the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). I am Robert Weissman, president of Public Citizen. Public Citizen is a national public interest organization with more than 500,000 members and supporters. For more than 50 years, we have advocated with some considerable success for stronger health, safety and consumer protections; for corporate and government accountability; and for affordable access to essential medicines and biomedical technologies.

Public Citizen strongly supports public investment in public health research and development (R&D), including especially for pandemics and emergency situations. But taxpayers must get a fair return on their investment. That should mean that the products that are the fruit of that investment are widely available and affordable for those who need them, on a global basis.

This testimony has two parts. In the first section, I review the experience with government funding for Covid vaccines. That investment helped get products to market in remarkable time. But the government failed to include conditions in its grant and acquisition agreements, or to make use of other available tools, to ensure that 1) taxpayers were not ripped off; 2) there was sufficient production of mRNA vaccines to meet global need; and 3) taxpayers and patients would be protected from price gouging as the pandemic wound down.

The second section aims to learn from the lessons of the Covid vaccine experience. It recommends building into grant agreement provisions to ensure transparency, affordability and global access. It also encourages the adoption of alternative funding models, such as prize funds, to support innovation. In many cases, especially in the market segments covered by PAHPA, alternative funding models will deliver superior benefits to the patent monopoly approach.

I. Lessons from COVID Vaccine Development

Operation Warp Speed was a great success in speeding the development of lifesaving vaccines and getting them to market. It was proof that the Biomedical Advanced Research and Development Authority (BARDA) model can work.

But it also was proof that the BARDA model needs important refinements, because taxpayers were gouged; hundreds of thousands or perhaps millions of people likely died needlessly because of avoidable vaccine shortages; and now patients and the public are poised to be ripped off further, with vaccines needlessly rationed due to high prices.

Government support underlay the entire Covid vaccine R&D project, beginning decades before Covid appeared and continuing through clinical trials and scaled up production. Covid–19 was not the first infectious disease caused by a coronavirus. NIH invested $700 million in coronavirus research in the two decades after SARS, during which period there was very little private sector investment in the field. In 2019, before Covid, there were only six active coronavirus clinical trials involving pharmaceutical companies. All of them depended crucially on public funding. [1]

The Federal Government's early investment in coronavirus research laid the foundation for the rapid response to Covid, helping accelerate the development of many leading vaccine candidates. [2]

Most of the leading first-generation Covid vaccine candidates—including those by Pfizer/BioNTech, Johnson & Johnson and Moderna—relied on the NIH's approach of "freezing" coronavirus spike proteins in their pre-fusion shape. One vaccine scientist noted that we were "very lucky, actually" that scientists had earlier developed the method for freezing coronavirus spike proteins. [3]

Among the vaccine makers, Moderna uniquely benefited from Federal support, [4] though the company consistently maneuvered to downplay Federal support:

- Moderna tried to file patents on certain vaccine technologies that had been co-invented with NIH. After Public Citizen drew attention to the maneuver, [5] Moderna backed down. [6]
- BARDA gave large-scale grants to Moderna to complete clinical trials and scale up manufacturing. [7]
- Altogether, the U.S. Government spent roughly $2.5 billion on the vaccine that would be called—misleadingly—the Moderna vaccine. It should rightly have been called the NIH-Moderna vaccine (or perhaps simply the NIH vaccine). The U.S. Government paid the entire cost of its development, save for a relatively tiny donation ($1 million) from the singer Dolly Parton. [8]
- While the vaccine was developed through a 4-year partnership with the National Institutes of Health (NIH), Moderna fought against naming Federal scientists co—inventors [9] of the vaccine sequence, as Public Citizen

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[1] Zain Rizvi, "Blind Spot: How the COVID–19 Outbreak Shows the Limits of Pharma's Monopoly Model," Public Citizen, February 19, 2020, *https://www.citizen.org/article/blind-spot.*

[2] Zain Rizvi, "Leading COVID–19 Vaccine Candidates Depend on NIH Technology," Public Citizen, November 10, 2020, *https://www.citizen.org/article/leading-covid–19-vaccines-depend-on-nih-technology.*

[3] Ryan Cross, "The tiny tweak behind COVID–19 vaccines," Chemical & Engineering News, September 29, 2020, *https://tinyurl.com/yxoj472x.*

[4] "'We did the front end. They did the middle. And we did the back end,' said Dr. Barney Graham, a former top NIH official, referring to the process for designing the spike-protein sequence, manufacturing vaccines and running clinical trials." Selam Gebrekidan and Matt Apuzzo, "Rich Countries Signed Away a Chance to Vaccinate the World," New York Times, March 21, 2021, *https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html.*

[5] Peter Maybarduk to Francis Collins, November 2, 2021, *https://www.citizen.org/article/letter-urging-nih-to-reclaim-foundational-role-in-nih-moderna-vaccine.*

[6] Rebecca Robbins and Sheryl Gay Stolberg, "Moderna backs down in its vaccine patent fight with the N.I.H.," New York Times, December 17, 2021, *https://www.nytimes.com/2021/12/17/us/moderna-patent-nih.html.*

[7] Zain Rizvi, "Sharing the NIH-Moderna Vaccine Recipe," Public Citizen, August 10, 2021, *https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe.*

[8] Allie Clouse, "Fact check: Moderna vaccine funded by government spending, with notable private donation," USA Today, November 24, 2020, *https://www.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002.*

[9] Sheryl Gay Stolberg and Rebecca Robbins, "Moderna and U.S. at Odds Over Vaccine Patent Rights," New York Times, November 9, 2021, *https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.*

revealed in 2021.[10] Rather than credit the Federal Government for its role, Moderna quietly abandoned these patents in March 2023.[11]

- In 2020, Public Citizen revealed that Moderna and others also relied on a separate technique discovered by Federal scientists and academic researchers to stabilize spike proteins and elicit an immune response.[12] Columbia Law School clinical professor Christopher Morten demonstrated that Moderna likely infringed the NIH-owned patent.[13] Moderna eventually agreed to pay NIH $400 million plus future royalties for its use of the technique.[14]

All this spending and co-invention status gave the U.S. Government powerful authority to condition how Moderna behaved and to share the technology. It did not do so.

Moderna generated tens of billions in Covid vaccine sales—including roughly $10 billion in advance purchase commitments and purchases by the U.S. government[15]—and several of its executives became billionaires.[16]

Meanwhile, the world went for more than a year with an insufficient vaccine supply. Developing countries were unable to obtain enough vaccines for their people. When they could get access, it was often to lower-quality vaccines, not the high-quality mRNA vaccines of Moderna or Pfizer.

That delay in vaccination likely cost hundreds of thousands and possibly millions of lives.[17] It also made it more likely that new variants would emerge and that COVID would evolve into an endemic disease.[18]

This scenario could have been avoided, or at least mitigated. It was entirely possible to share the mRNA technology controlled by Moderna and scale up vaccine manufacturing in order to have vaccinated the world more quickly.[19]

Even though the development of vaccine technology depended so heavily on U.S. Government support—and entirely, in the case of the NIH-Moderna vaccine—that was the road not taken.

Now, Moderna is jacking up prices further, quadrupling the price for Covid vaccines, which are expected to be needed annually. Public Citizen has estimated it costs $3 or less per dose to manufacture the vaccine. At the height of the pandemic Moderna charged the United States from $15 to $26 per dose, accumulating billions in profits. Moderna's price going forward of $110-$130 per dose is completely unjustified and has no plausible explanation beyond profiteering.

The unavoidable result of Moderna's price spike will be rationing. Uninsured and under-insured people will face a significant cost barrier to accessing vaccines, and—

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[10] Public Citizen letter to NIH Director Francis Collins, November 2, 2021, *https://www.nytimes.com/interactive/2021/11/09/us/public-citizen-nih-moderna-vaccine.html*.

[11] Katherine Ellen Foley and David Lim, "Moderna Quietly Abandons Some MRNA Patents," Politico, March 7, 2023, *https://www.politico.com/newsletters/prescription-pulse/2023/03/07/eli-lilly insulin-cost-cuts–00085724*

[12] Zain Rizvi, "Leading Covid–19 Vaccine Candidates Depend on NIH Technology," Public Citizen, November 10, 2020, *https://www.citizen.org/article/leading-covid–19-vaccines-depend-on-nih-technology/?eType=EmailBlastContent&eId=3dbde9f7–8f59–48e0–99d8–78b49ea5e77e.*

[13] Christopher Morten, et al.., "U.S. 10,960,070: The U.S. Government's Important New Coronavirus Vaccine Patent," Technology Law and Policy Clinic, New York University School of Law, April 14, 2021, *https://www.dropbox.com/s/1om1v1kagg7j9dn/NYU percent20TLP percent20Clinic percent20Report percent20on percent20NIH percent27s percent20070 percent20Patent percent2020210414 percent20 percent28FINAL percent29.pdf?dl=0.*

[14] Benjamin Mueller, "After Long Delay, Moderna Pays NIH for Covid Vaccine Technique," New York Times, February 23, 2023, *https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html*.

[15] Jennifer Kates, Cynthia Cox and Josh Michaud, "How Much Could Covid–19 Vaccines Cost After Commercialization?" KFF, March 10, 2023, *https://www.kff.org/coronavirus-covid–19/issue-brief/how-much-could-covid–19-vaccines-cost-the-u-s-after-commercialization*.

[16] Giacomo Tognini, "Surging Moderna Stock Mints The Vaccine Maker's Fifth Billionaire," Forbes, June 15, 2021, *https://www.forbes.com/sites/giacomotognini/2021/06/15/surging-moderna-stock-mints-the-vaccine-makers-fifth-billionaire*.

[17] Chad Wells and Alison Galvani, "The global impact of disproportionate vaccination coverage on COVID–19 mortality," The Lancet, June 23, 2022, *https://www.thelancet.com/journals/laninf/article/PIIS1473–3099(22)00417–0/fulltext*.

[18] "One Million and Counting: Estimates of Deaths in the United States from Ancestral SARS-CoV–2 and Variants," Public Citizen, June 1, 2022, *https://www.citizen.org/article/one-million-and-counting-estimates-of-deaths-in-the-united-states-from-ancestral-sars-cov–2-and-variants*.

[19] Zoltan Kis and Zain Rizvi, "How to Make Enough Vaccine for the World in One Year," Public Citizen, May 26, 2021, *https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year*.

notwithstanding Moderna's pledge to make vaccines available for free to uninsured and underinsured persons [20]—many simply won't take the vaccine. People will needlessly get sick and die as a result.

Moreover, because many opting for future booster shots will be over 65, Medicare stands to bear a disproportionate burden of payments. Taxpayers will once again bear the expense.

Even for people with private health insurance, price spikes that are picked up by insurance companies could lead to higher premiums. [21]

All of this, too, could and should have been avoided—if safeguards had been written into BARDA and NIH's contracts with Moderna.

We must at least learn from this Covid experience and prevent a repeat with future technologies funded and developed by BARDA and PAHPA investments.

II. Learning from COVID: Measures to Advance Transparency, Affordability and Universal Access

Transparency

The starting point for policy around PAHPA investment in drug, vaccine, therapeutics and diagnostics research, development and acquisition should be proactive transparency. The public should know what it is financing, on what terms and the degree to which private sector partners are contributing to research and development costs.

In general, and building on existing practice, [22] BARDA and other government agencies should continue to aim toward standard-form provisions for R&D investments, licensing terms and acquisition contracts, to avoid wasted time with negotiation, prevent gamesmanship and ensure taxpayer interests are protected robustly. Some variation will be unavoidable, as agencies tailor terms and provisions for different needs and product markets, but the more reliance on standard provisions, the better.

Building on but going beyond what it already has in place, [23] BARDA should maintain a publicly available, downloadable, searchable and sortable data base of all grants it has made and acquisition contracts into which it has entered, with easy public access to the contracts. Proprietary redactions should be minimized. Specific contract terms that should presumptively and proactively be made public include:

- The amount of government grants;
- The ownership and licensing terms for inventions funded directly or indirectly by government grants, not limited to instances in which the government may claim Bayh-Dole rights;
- Provisions on reasonable pricing;
- Reach-through terms to ensure reasonable pricing or other conditions for products incorporating government-funded inventions;
- International access terms; and
- The price paid and volume amount of acquisitions.

Building on existing practice, BARDA contracts should also require affirmative disclosures from contracting parties. These disclosures should include:

- The documented dollar amount of co-funding that contractors and third parties provide for research projects;
- The terms, if any, by which the contractor licenses inventions arising from a government-funded project to third parties; and
- The price that contractors charge third parties for products developed with substantial government support.

The issue of contractor co-funding requires special attention. Rather than accepting just a single claim of total contractor investment, the government should require

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[20] Alexander Tin, "Moderna to Offer Free Covid Vaccines to Uninsured After Emergency Ends," CBS News, February 18, 2023, *https://www.cbsnews.com/news/free-covid-vaccine-moderna-uninsured-after-public-health-emergency-ends*.

[21] Jennifer Kates, Cynthia Cox and Josh Michaud, "How Much Could Covid–19 Vaccines Cost After Commercialization?" KFF, March 10, 2023, *https://www.kff.org/coronavirus-covid–19/issue-brief/how-much-could-covid–19-vaccines-cost-the-u-s-after-commercialization*.

[22] *https://www.phe.gov/about/amcg/BARDA-BAA/Documents/otar-consortium.pdf*

[23] *https://medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx*

disaggregated information. Drawing on expert reviews[24] and prior legislative proposals,[25] we recommend that contractors' total expenditures on R&D be itemized by direct and indirect costs, including for:

- Basic and preclinical research; and
- Clinical research, reported separately for each clinical trial, per patient, per year, comprising:
  - Personnel costs (including salary and benefits)
  - Administrative staff
  - Clinical staff
    - Materials and supplies
    - Clinical procedures
    - Site management
  - Site monitoring costs
  - Site retention
  - Other
    - Central laboratory
    - Equipment
    - Other direct costs
  - Publication Costs
  - Subawards/Consortium/Contractual Costs
  - Other;
    - Development of alternative delivery systems, dosage forms, strengths or combinations; and
    - Other development activities, such as post-approval testing and record and report maintenance.

Affordability and Reasonable Pricing

In funding new drugs, vaccines, therapeutics and diagnostic tools to address emergency or potential emergency solutions, taxpayers aim to bring to market products that otherwise would not be developed or to speed their development. Getting the product to market is essential, but so is ensuring reasonable pricing. If products are going to be purchased by taxpayers, not only is there a taxpayer interest in prudently conserving public funds, but high prices may drain public funds at the expense of other public health benefits or may limit the size of government acquisition and distribution plans. If products are going to be purchased by private insurers and/or directly by individuals, then high prices will unavoidably limit access.

This latter point cannot be emphasized enough: access to essential medical technologies necessarily must take into account affordability, not mere provision in the market. A high-priced medical product is as inaccessible to those who cannot afford it as one that does not exist.

Moreover, in public health crises, it will often be the case that price-based rationing has broader, multiplier impacts beyond the direct impact on those who cannot obtain a product. Rationing due to price or for other reasons may permit pandemics to spread or allow viruses to mutate, for example.

In short, reasonable pricing provisions are vital for PAHPA-related investments.

The first starting point for reasonable pricing is that the United States should not pay more for drugs and products it helped develop than other high-income countries pay. This should be non-controversial. If the U.S. Government helped pay for the invention and development of a drug or biomedical product, then surely it should not be charged prices higher than other rich countries which did not support development of the product.

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[24] NYU Law, Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations (2020), *https://www.law.nyu.edu/centers/engelberg/pubs/2020–08–17-Clinical-Trial-Cost-Transparency-at-the-NIH*

[25] S. 909—Prescription Drug Price Relief Act of 2021, *https://www.Congress.gov/bill/117th-congress/senate-bill/909/text*

The government has, episodically, included "Most Favored Nation" (MFN) clauses in procurement contracts, including in its contract with Pfizer for purchases of the antiviral Paxlovid.[26] The operative MFN provision in that contract reads:

> *If, at any time prior to, or during, the base term and any exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase (i) the same or a lesser volume of Product than the U.S. Government commits to purchase (ii) at a price lower than the price the U.S. Government is obligated to pay for Product under this contract, Contractor shall provide notice of such lower price to the U.S. Government within 30 days of the execution of the Contractor-Covered Nation agreement and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and purchase the Product at that lower price.*[27]

But MFN provisions are just a bare minimum starting point for thinking about affordability and reasonable pricing. The overarching point to understand about reasonable pricing for biomedical products is that manufacturing costs are generally very low relative to overall development costs. The main costs that drug, vaccine and other biomedical corporations must recover are research and development, including cost of failure in pursuing many different ideas.

From this overarching point follows two key principles that should define reasonable pricing. First, a reasonable price should correlate to a manufacturers' development expense and acceptance of risk. If a drug maker can show that it incurred large R&D costs, or that it invested heavily in the riskier, earlier stages of development, then, all other things equal, the reasonable price of a resultant drug should be higher. On the other hand, if the government incurred most of the expense and the manufacturers' actual outlay was small, or if the government primarily funded the early stage work, then a reasonable price should be lower.

Second, at a certain point, a manufacturer has obtained a reasonable return on its original investment and should no longer be entitled to supra-competitive profits. Although we support reasonable pricing conditions and revenue caps for products that are completely developed in the private sector, the situation is qualitatively different with government funding. In the pure private case, the patent monopoly and the possibility of a bonanza payout is, at least in theory, the incentive for undertaking the up-front risky investment. However, where the government has assumed a substantial portion of the risk—including by directly funding the manufacturer to undertake R&D—and where the government guarantees purchases, the manufacturers' risk is greatly lessened. In these circumstances, after a manufacturer secures a certain return on its investment, it should no longer be entitled to supra-competitive profits and an automatic license to manufacture the patented invention (and gain access to needed materials and make use of testing data) should be available to all qualified manufacturers.

Price terms are obviously a central subject of any purchase agreement, but reasonable pricing terms should be included in R&D contracts, covering both later government purchases and provision of products in the private market. As regards government purchases, including reasonable pricing terms will establish market norms and expectations. Not only does this leverage the government's unique power at the point it is making grants and investments in new products, it orients drug maker and market understandings and forecasts. No manufacturer should be blindsided by a government demand for reasonable prices; and no manufacturer should feel empowered to challenge the rule that it is entitled to a reasonable reward, but no more.

It is even more important that reasonable pricing provisions apply to the private market. In the absence of price restraints, Big Pharma pricing models regularly deny people access to necessary treatments, therapies and preventative services. When Big Pharma corporations price drugs to maximize profits, they are necessarily setting prices out of reach for many people, especially those with no insurance, limited insurance or insurance with high co-pays. The median launch price of a new drug in the United States jumped from $2,115 in 2008 to $180,007 in 2021, a 20

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[26] See discussion of the MFN provision at: Claire Cassidy, "Pfizer Agrees to International Reference Pricing in Government Contract for Covid–19 Therapeutic," Knowledge Ecology International, February 2, 2022, *https://www.keionline.org/37294*.

[27] The MFN provision is H.7 in the full contract, which is available here: *https://www.keionline.org/misc-docs/COVID19/Pfizer-Contract-Paxlovid-W58P0522C0001–17Nov2021.pdf*.

percent annual inflation rate, according to researchers at Brigham and Women's Hospital in Boston. [28]

As a result of these soaring prices, non-adherence to drug regimens due to price—the cost of drugs, co-pays and deductibles—is at epidemic levels. Thirty percent of Americans report that they have skipped drug treatments or otherwise haven't taken medicines as prescribed because of cost. [29]

Forced rationing based on excessive pricing is morally appalling and antithetical to good public health policy in any circumstance. The idea that high prices would deny access to care for vital medicines, vaccines or treatments in a time of public health emergency—for products invented and/or developed with support from U.S. taxpayers—should be unthinkable. It certainly shouldn't be tolerated. And it is completely avoidable if BARDA and other relevant agencies operate proactively to ensure reasonable pricing.

Nor should reasonable pricing obligations end with the wind-down of a public health emergency. In cases where the public has made substantial contributions to the development of a product, then the public has every reason to demand that the resultant products remain affordable. The case of the Moderna vaccine is illustrative. Moderna has generated enormous profits during the pandemic and is quadrupling Covid vaccine prices now that the acute phase of the pandemic is over. People will continue to need updated Covid vaccines; Moderna has already generated more than fair returns on its modest investment; and yet the company aims to price gouge consumers. BARDA and other agencies should ensure this scenario never repeats.

International Access

PAHPA support for R&D should be contingent on ensuring that U.S.-supported inventions are available globally on reasonable terms. To be clear, this access need not come at the expense of Americans. The objective should be to expand affordable supply to meet the needs of people around the world.

Guarantees of global accessibility will advance a diverse range of U.S. interests:

First, the United States has a humanitarian interest in ensuring everyone has access to needed drugs, vaccines, therapies and diagnostics. The market alone will not ensure universal access; in fact, relying on the market alone ensures massive disparities in global access. Monopolistic manufacturers of new products may not have capacity on their own to scale up production to meet global needs. Beyond production capacity, Big Pharma routinely overlooks low-income and lower-middle-income countries, which do not have the ability to pay high-income prices for products. Especially for U.S. taxpayer-funded products, the United States has a humanitarian duty to ensure global access.

Second, the United States has a public health interest in ensuring global access. As the waves of Covid variants reminded us, failing to control a highly transmissible virus in one part of the world invites mutations that will inevitably impact the United States. Ensuring people around the world have access to vaccines, drugs, treatments and diagnostics directly assists public health in the United States.

Third, sharing biomedical technology can afford enormous global economic benefits. The Covid pandemic massively disrupted the global economy. Major government intervention in the United States offset the impacts, but the pandemic led to massive reductions in global trade and long-lasting supply chain shocks. [30] To whatever extent sharing of biomedical technology could reduce comparable impacts in the future, the economic benefits would be extraordinary—just shaving months off the period of a pandemic could save hundreds of billions of dollars for the U.S. economy.

Last, sharing technology and ensuring global availability of important biomedical advances would secure tremendous diplomatic gains for the United States. It would evidence not only our technological prowess but our beneficence.

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[28] Robert Langreth, "New Drug Prices Soar to $180,000 a Year on 20 percent Annual Inflation," Bloomberg, June 7, 2022, *https://www.bloomberg.com/news/articles/2022–06–07/new-drug-prices-soar-to–180–000-a-year-on–20-annual-inflation*.

[29] Liz Hamel, Lunna Lopes, Ashley Kirzinger, et al., "Public Opinion on Prescription Drugs and Their Prices," Kaiser Family Foundation, April 5, 2022, *https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices*

[30] "Study Shows Vaccine Nationalism Could Cost Rich Countries US$4.5 Trillion," International Chamber of Commerce, January 25, 2021, *https://iccwbo.org/news-publications/news/study-shows-vaccine-nationalism-could-cost-rich-countries-us4–5-trillion/*; Eleanor Bell, et al.., "Estimates of the Global Burden of Covid–10 and the Value of Access to Covid–19 Vaccines," Vaccines, August 15, 2022, *https://www.mdpi.com/2076–393X/10/8/1320*.

Ensuring affordable global access to new biomedical inventions requires establishing sufficient global manufacturing capacity and taking measures to promote affordability, including especially in lower-income countries. Both these components are crucial. In the case of the pandemic, once the mRNA vaccines were developed, there was very little supply available for poor countries. To a very considerable degree, the shortage was artificial, a result of Moderna and Pfizer refusing to share their technology with other manufacturers. But adequate supply by itself is not enough. Products must be affordable for low-and middle-income countries, otherwise they will remain as inaccessible as if they did not exist.

To this end, PAHPA-related R&D contracts should include the following provisions:

- An automatic license to the World Health Organization (WHO) and efforts such as the WHO's mRNA Technology Transfer Program.[31] Along with a license for relevant intellectual property and testing data, U.S. research and development contracts should require grantees to engage affirmatively in technology transfer, including the sharing of biomaterials, product recipes and manufacturing methods. The affirmative objective should be to buildup manufacturing and development capacity in developing countries.
- A duty for manufacturers to make best efforts to scale up production to meet global need and to license with low and fixed royalties to qualified third parties to manufacture for developing country markets. Licensing for developing countries can be easily arranged through the Medicines Patent Pool, an international institution established for exactly this purpose.[32]
- An obligation for affordable pricing for developing countries. Generally, this should be marginal pricing for low-and middle-income countries and substantially discounted pricing for upper-middle-income nations. Companies should be able to satisfy the pricing obligation by providing non-exclusive licenses, if they prefer. It is important that affordability and licensing arrangements cover middle-income countries to ensure rapid, worldwide availability of critical new products. By way of example, Public Citizen has estimated that the need for the Covid treatment Paxlovid (Nirmatrelvir/ritonavir) in non-high income countries is at least 10 times what has been purchased.[33]

Other Pro-access, Pro-innovation Contract Terms

PAHPA contract terms should include other pro-access, pro-innovation measures, including:

- "Reach-through" provisions, ensuring that any party using a licensed technology must apply the same access and affordability provisions as included in the original contract terms. Reach-through provisions prevent gaming of the affordability and accessibility obligations, for example, through modest alterations of the original product. They also extend the affordability and accessibility benefits to follow-on and combination products, re-paying the taxpayers for their initial investments.
- Duties to license to other qualified drug researchers and manufacturers to facilitate more innovation. The licensing obligation should include intellectual property and data rights for the end product, but also materials needed for conducting research. Additionally, BARDA procurement contracts should include boilerplate language safeguarding the ability to conduct necessary research on existing and next generation products. There is evidence to suggest that companies are restricting access to Covid vaccine that would be used for research purposes, for example, imposing potentially severe impediments to important research.[34]

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[31] "mRNA Technology Transfer Programme Moves to the Next Phase of its Development," World Health Organization, April 20, 2023, *https://www.who.int/news/item/20–04–2023-mrna-technology-transfer-programme-moves-to-the-next-phase-of-its-development*

[32] *https://medicinespatentpool.org/*

[33] Letter to Katherine Hiner, Acting Secretary to the U.S. International Trade Commission, Public Citizen, April 12, 2023, *https://www.citizen.org/article/post-hearing-brief-for-investigation-no–332–596-covid–19-diagnostics-and-therapeutics-and-flexibilities-under-the-trips-agreement/*

[34] "Science Held Hostage: How Pharma is Using mRNA Vaccine Contracts with Government to Delay Future Innovation," PrEP4All, April 2023, *https://static1.squarespace.com/static/*

Prizes and Other Models to Support Biomedical Innovation

The work of BARDA and related agencies is so important because they address market failures. These failures trace to familiar sources and have nothing to do with the behavior or ethics of any individual corporation or researcher. The core problem is that Americans need to support innovation in products that we hope will never be used, or for which market demand is very uncertain. We need biomedical products for pandemics that we hope never occur, and we need to be prepared to scale up for pandemics with a profile different than what we have planned for. We need new antibiotics that we may hold in reserve to prevent resistance. We need countermeasures for biological and chemical weapons that we hope will never be deployed. In such circumstances, the traditional model of incentivizing R&D by the grant of limited term patent monopolies breaks down. PAHPA and BARDA are direct responses to that market failure.

In addition to the contractual measures sketched above, a reauthorized PAHPA should also authorize different approaches to supporting R&D—that is, to move beyond research grants grafted on to the patent monopoly model. PAHPA in fact contemplates such alternative approaches,[35] but these should be more affirmatively supported and required.

One model is to offer prizes in place of patents.[36] Instead of offering a patent monopoly as an incentive for innovation, BARDA and other agencies may offer prizes. Developers may be awarded dollar awards from a prize fund, with all intellectual property and related rights vested in the Federal Government. There are numerous potential benefits to a prize fund. First, it can offer sufficient incentive for research and development work for products for which there may be no apparent market, as described in the cases above. Thus prizes can be used to induce more innovation than patents might. Second, the prize fund can be reasonably calibrated to the public health value of the product or products being developed. This is very different than patents, which are calibrated not to public health value, but market demand. Third, prizes can eliminate price gouging. Innovators are rewarded by prizes, not monopolies, so the resultant products can be licensed broadly to manufacturers and sold as generics. Fourth, prizes can be adjusted to avoid the winner-takes-all problem of patents. Portions of a prize fund may be shared with innovators whose research assisted the development process but did not ultimately lead to a patented invention, an approach proposed in Senator Sanders' Medical Innovation Prize Fund Act as an "open-source dividend." Fifth, prizes can incentivize collaboration, with diverse research centers pooling efforts and sharing the prize, rather than trying to lay claim to a singular patent. Similarly, prizes can overcome the problem of patent thickets.

Prizes are an important alternative to the monopoly incentive model in all circumstances, but they are particularly important—and especially deserving of much more widespread usage—in the PAHPA context, where the temporary monopoly model definitionally fails.

A second model is to lean in more heavily to the research contracting model. This would involve contracting with research centers at universities and corporations to undertake research in service of the U.S. Government, rather than making grants but allowing the grantees to control the fruits of the research. The government would maintain ownership and control of all intellectual property and associated rights; coordinate product development; and license final products on a non-exclusive basis to all qualified manufacturers. In the case of the NIH-Moderna vaccine, where essentially the entire enterprise was funded by the U.S. Government, this is practically what occurred—with the crucial caveat that Moderna was permitted to control the fruits of the research.

5e937afbfd7a75746167b39c/t/643ee03ce3538e2bb5d925bf/1681842236736/PrEP4All+Prevention+Equity+Alert4–2023.pdf

[35] (42 U.S.C. 247d–7e(c)(4)(D)). Perversely, BARDA has used this authority to circumvent the modest existing rules in existing law to promote affordability. A reauthorized PAHPA should explicitly prevent this misuse of "other transition" authority. See Christopher Rowland, "Trump Administration Makes it Easier for Drugmakers to Profit from Publicly Funded Coronavirus Drugs, Advocates Say," Washington Post, July 1, 2020, *https://www.washingtonpost.com/business/2020/07/01/vaccine-coronavirus-barda-trump*.

[36] Senator Sanders has previously introduced legislation to create a prize fund for biomedical research. See the Medical Innovation Prize Fund Act, introduced as S495 in the 115th Congress. *https://www.Congress.gov/bill/115th-congress/senate-bill/495/text's=2&r=1&q= percent7B percent22search percent22 percent3A percent5B percent22Medical+Innovation+Prize+Fund+Act percent22 percent5D percent7D*. For a detailed discussion of innovation prizes, see the work of Knowledge Ecology International, here: *https://www.keionline.org/book/prizes-to-stimulate-innovation.*

A third model is patent and/or know-how buyouts: In a case of a chemical weapon countermeasure, for example, the government would negotiate with the patent holder a fair agreement to purchase all intellectual property and related rights—a one-time payment—and then license multiple manufacturers to produce the countermeasure on a contractual basis. If the U.S. Government is the only purchaser, this is what will effectively happen in any case, but it converts the price negotiation into a more rational process to determine fair compensation to the innovator for the value of their innovation.

These varied approaches may be combined. For example, a prize system can be supplemented with direct grants, with the size of the prize awards effectively adjusted. In a case of patent or know-how buyouts, the payment to the grantee should be adjusted to reflect the grant contributions from the government and the amount of capital risked by the patent holder.

These models, especially combining prize funds and direct grants, are especially appealing to prepare for future threats. The public health imperative is to investigate and prepare for a wide range of threats and to position the country (and the world) to have products already identified and in far-along or completed development stage if any of those threats emerge. Researchers at NIH have identified 20 virus families for which they propose a series of steps that would lead to prototype vaccines.[37] This is not work that will receive drug and vaccine maker investment with a temporary monopoly incentive, because the problems are too speculative and the likelihood of payout too uncertain. But it is exactly the kind of work that PAHPA should be supporting though prize funds and direct research contracting.

Conclusion

The underlying theory of PAHPA was validated by the Covid pandemic, which showed the crucial importance of a real public health infrastructure to prepare for pandemics and emergencies and to make significant investments in biomedical innovation. But so too did the pandemic illustrate the very real costs—in dollars and lives—of failing to act proactively to ensure an adequate supply and affordability of key biomedical products. The reauthorization of PAHPA must be the moment to make our pandemic and emergency preparedness more robust. First, a reauthorized PAHPA should require BARDA and other agencies to build transparency, affordability, production and licensing terms into R&D and acquisition contracts. Second, it should require BARDA and other agencies to adopt prize funds and other creative measures to more efficiently fund biomedical R&D and advance public health objectives.

[SUMMARY STATEMENT OF ROBERT WEISSMAN]

Lessons from Covid Vaccine Development: Operation Warp Speed was a great success in speeding the development of lifesaving vaccines and getting them to market. It was proof that the Biomedical Advanced Research and Development Authority (BARDA) model can work.

But it also was proof that the BARDA model needs important refinements. Government support underlay the entire Covid vaccine R&D project, beginning decades before Covid appeared and continuing through clinical trials and scaled up production. Among the vaccine makers, Moderna uniquely benefited from Federal support. The government's extensive investments and co-invention status for the vaccine made by Moderna gave the U.S. Government powerful authority to condition how Moderna behaved and to share the technology. It did not do so.

As a result, while Moderna executives became billionaires, taxpayers were gouged; hundreds of thousands or perhaps millions of people around the world likely died needlessly because of avoidable vaccine shortages; and now patients and the public are poised to be ripped off further, with vaccines needlessly rationed due to high prices.

Measures to Advance Transparency, Affordability and Universal Access: We must at least learn from this Covid experience and prevent a repeat with future technologies funded and developed by BARDA and PAHPA investments.

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[37] Gina Kolata, "Fauci Wants to Make Vaccines for the Next Pandemic Before it Hits," New York Times, July 25, 2021, *https://www.nytimes.com/2021/07/25/health/fauci-prototype-vaccines.html*; Barney S. Graham and Nancy J. Sullivan, "Emerging Viral Diseases from a Vaccinology Perspective: Preparing for the Next Pandemic," Nature Immunology, 19, 20–28 (2018), *https://www.nature.com/articles/s41590–017–0007–9*.

Transparency: The starting point for policy around PAHPA investment in biomedical R&D and acquisition should be proactive transparency. The public should know what it is financing, on what terms and the degree to which private sector partners are contributing to research and development costs.

Reasonable Pricing: Getting products to market is essential, but so is ensuring reasonable pricing. A high-priced medical product is as inaccessible to those who cannot afford it as one that does not exist. The first starting point for reasonable pricing is that the United States should not pay more for drugs and products it helped develop than other high-income countries pay. Beyond ''Most Favored Nation'' provisions, BARDA should require reasonable pricing for the products it supports, with reasonable pricing scaled to private partner investments and assumption of risk.

International Access: PAHPA support for R&D should be contingent on ensuring that U.S.-supported inventions are available globally on reasonable terms. This access need not come at the expense of Americans. The objective should be to expand affordable supply to meet the needs of people around the world, by requiring licensing of technologies to, and sharing of know-how with, the World Health Organization (WHO) and other international partners.

Prizes and Other Models to Support Biomedical Innovation: Instead of offering a patent monopoly as an incentive for innovation, BARDA and other agencies should, at least in some cases, offer prizes. Developers would be awarded dollar awards from a prize fund, with all intellectual property and related rights vested in the Federal Government. This approach could induce more innovation, while advancing access and affordability objectives.

The CHAIR. Thank you very much. Senator Cassidy, did you want to introduce your panelist?

Senator CASSIDY. Yes. We are joined today by Dr. Martin Makary, a Surgeon, Researcher, and Professor at the Johns Hopkins School of Medicine, a Professor for the Johns Hopkins Carey Business School.

Dr. Makary focuses his research on public health and health care delivery issues ranging from health care costs to COVID–19. He previously worked for the World Health Organization, where he helped develop the surgeon's checklist, which has helped reduce surgery related deaths around the world.

He holds degrees from Bucknell, Thomas Jefferson, and Harvard Universities, completed his medical training at Georgetown and Johns Hopkins, and is the author and coauthor of over 250 peer reviewed papers.

Did I get that right, man? Pretty impressive. I look forward to hearing from you today. Thank you for joining us, doctor.

STATEMENT OF MARTIN MAKARY, M.D., M.P.H., PROFESSOR, JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD

Dr. MAKARY. Thank you. Thank you, Senator Sanders. Thank you, Ranking Member Cassidy. Thank you, Senator Markey. It is a privilege to present. I speak on behalf of myself, not Johns Hopkins University or the National Academy of Medicine, for which I am a member.

Congress should avoid the false narrative that insufficient Federal findings were to blame for our pathetic COVID response. Take, for example, one Johns Hopkins student created a COVID tracker that the world used, and it was not created by the 21,000 employees at the CDC.

As a matter of fact, when HHS met with the CDC, they said it would take months to create such a tracker. Did the CDC need 25,000 employees or 50,000 employees? We just had the head of ASPR, the Assistant Secretary of Preparedness and Response say she needs more hiring power.

How about firing power for incompetence, or both? I mean, 21,000 employees cannot come up with a COVID tracker. More tragically, the NIH has $42 billion. BARDA, which is a part of the PAHPA Act, has another billion dollars and they couldn't do the most basic clinical research we needed done quickly to answer the basic questions, to end the controversies and the conspiracy theories, to finally get out the questions Americans were asking us, how does it spread? Is it from touching surfaces? Do I need to pour 20 gallons of alcohol on my groceries?

Fauci was telling teachers in July to wear gloves and goggles. Or was it spread airborne? That could have been answered in 24 hours in one of our BSL 4 labs, or in 1 week of clinical research to answer the question, when are you most contagious? What is the peak day of viral shedding? How long do you have to quarantine for? Do masks work?

We could have answered this with definitive basic clinical research early. They didn't. And so, I think it's fair to ask how did they do in preparing us for the pandemic? We have spent over $20 billion on PAHPA over the last 20 years. What has that done for us? How many lives were saved during the COVID pandemic because of investments by PAHPA or BARDA?

Now, they have done some good work. I have seen it. But regardless of one's political affiliation, they have got to acknowledge that we, doctors, and the public were flying blind. We had opinion ruling the day on what we should do or not do, when we could have been governed by evidence, policy driven by good basic clinical research.

We didn't have that, and so we had a void of clinical research, and guess what filled that void. Over half a year, a year, 2 years, what filled that void where political opinions. Those controversies could have been ended early. We had the money. And as a result, the COVID pandemic became the most politicized pandemic in U.S. history. It was avoidable. Much of it was avoidable.

My research team at Johns Hopkins did a study of where the NIH spent their money in 2020. They spent 2.2 times more money on aging research than they did on COVID research the year of the pandemic. Now, I am all for aging research, especially as I get older, but not during a global pandemic when 3,000 Americans are dying a day.

Much of this research was misguided, and our study published in the BMJ that I included in the packet showed that it took the NIH after they decided to fund a research study, it took them 5 months to give that money to the researchers. That does not work during a health emergency.

Now, while the NIH is outside of the scope of the reauthorization, BARDA is, and I think the public has a right to ask what has BARDA and what has PAHPA done for them in preparing for COVID? How many lives were saved because of the investment? What is the single best investment BARDA made with that roughly $20 billion before the pandemic, that saved lives during the pandemic?

I think it is fair to ask those questions. How many beds are available today? Do we track the number of beds available? We are going to have more catastrophes, not just viral pandemics. We are going to have mass shootings and floods and other natural disasters.

We have spent a lot of money at BARDA making hospitals, a lot of money, giving them a lot of money, private startup companies making money, contractors making a lot of money. But the question is, where was the basic clinical research?

We have been funding virus hunting internationally, sending teams to get exotic viruses and bringing them back into populated areas. How about funding basic clinical research? Thank you, Senator Sanders and Ranking Member. I look forward to your questions.

[The prepared statement of Dr. Makary follows:]

PREPARED STATEMENT OF MARTIN MAKARY

Chairman Sanders, Ranking Member Cassidy, Members of the Committee, thank you for the invitation to present.

Congress should avoid the false narrative that insufficient Federal funding was to blame for the country's pandemic response. In fact, it was a case study in bureaucratic failure.

One Johns Hopkins student developed a Covid tracker that the CDC, with its 21,000 employees, was unable to create. Was the CDC understaffed? Did the it need 25,000 employees to make a website for the world to track the pandemic? No, the CDC was mired in bureaucracy.

More tragic, the NIH, with a $42 billion budget, failed to conduct basic clinical research in a timely fashion. Critical scientific questions went unanswered—questions that could have been answered with 1 week of clinical study, like:

- Does Covid primarily spread from touching or is it airborne?
- When is the peak day of viral shedding and contagion?
- How long should you quarantine?
- Do masks work?

Leaving many basic scientific questions unanswered for half a year or more, public health officials ruled by opinion in lieu of conducting or funding clinical research quickly.

In July, 2020, Dr. Fauci told the American Federation of Teachers president at a public event that teachers should wear goggles and gloves. He has since said that we didn't know back then because we didn't have the science. But he controlled a $6 billion research budget at NIAID. Did NIAID need $7 billion to find out that Covid was airborne? Did he need an additional $7 billion to tell us if cloth masks on toddlers and 50 million children for 2 years is effective?

Regardless of one's political affiliation, in the absence of good scientific evidence, doctors and the public were flying blind. What filled the void were opinions. That's how Covid became the most political pandemic in U.S. history.

My Johns Hopkins research team went back and found that in 2020, the year the pandemic hit the U.S., the NIH spent 2.2-times more money on aging research than it did on Covid research. I'm all for aging research, especially as I get older, but not when 3,000 Americans are dying everyday. Our study, published in BMJ, also found that when the NIH made a decision to fund a Covid research study, it took them 5 months to actually send the money to the researchers to start the research. In short, the government failed to pivot, not because they didn't have enough resources, but because of a rusty and bloated bureaucracy.

Ironically, while the U.S. failed to fund basic clinical research on the big Covid questions, we were funding labs overseas to engage in the dangerous business of virus hunting, sending people to remote uninhabited rainforests and caves to obtain exotic viruses and bring them to labs in highly populated cities of 8–10 million people—the population of Wuhan. There are at least a million different viruses in the world and a small fraction, roughly fewer than 1 percent, infect humans. Why is

the U.S. funding this dangerous work? The promise of virus hunters that they could use this information to predict future pandemic was a fallacy. It's never happened and never will. We don't need A.I. to prepare for future pandemics, we just need I.

The U.S. needs a rapid response team to conduct or fund clinical research to guide pandemic responses, so we're not simply following opinions.

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NIH funding of COVID-19 research in 2020: a cross-sectional study

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ABSTRACT

Objective This study aims to characterise and evaluate the National Institutes of Health's (NIH's) grant allocation speed and pattern of COVID-19 research.

Design Cross-sectional study.

Setting COVID-19 NIH RePORTER Dataset was used to identify COVID-19 relevant grants.

Participants 1108 grants allocated to COVID-19 research.

Main outcomes and measures The primary outcome was to determine the number of grants and funding amount the NIH allocated for COVID-19 by research type and clinical/scientific area. The secondary outcome was to calculate the time from the funding opportunity announcement to the award notice date.

Results The NIH awarded a total of 56 169 grants in 2020, of which 2.0% (n=1108) wwas allocated for COVID-19 research. The NIH had a US$45.3 billion budget that year, of which 4.9% (US$2.2 billion) was allocated to COVID-19 research. The most common clinical/scientific areas were social determinants of health (n=278, 8.5% of COVID-19 funding), immunology (n=211, 25.8%) and pharmaceutical interventions research (n=208, 47.6%). There were 104 grants studying COVID-19 non-pharmaceutical interventions, of which 2 grants studied the efficacy of face masks and 6 studied the efficacy of social distancing. Of the 83 COVID-19 funded grants on transmission, 5 were awarded to study airborne transmission of COVID-19 and 2 grants on transmission of COVID-19 in schools. The average time from the funding opportunity announcement to the award notice date was 151 days (SD: ±57.9).

Conclusion In the first year of the pandemic, the NIH diverted a small fraction of its budget to COVID-19 research. Future health emergencies will require research funding to pivot in a timely fashion and funding levels to be proportional to the anticipated burden of disease in the population.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our study is the first study to characterise and evaluate the National Institutes of Health's (NIH's) under funding of COVID-19 clinical research in the year the pandemic hit the USA.
⇒ We conducted a cross-sectional study using the NIH Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) datasets of all COVID-19 grants, including grants funded by COVID-19 supplemental appropriations.
⇒ We calculated the number of grants and funding the NIH allocated towards COVID-19 in 2020 to different research types and clinical/scientific areas, and the time from funding opportunity announcement to award notice date.
⇒ We only reviewed abstracts and did not review the entire funded proposals. There were other barriers to clinical research that were not captured here, including slow institutional review boards and long journal peer-review times.

INTRODUCTION

The National Institutes of Health (NIH) is the world's largest funder of biomedical research, employing over 20 000 people with a US$45.3 billion budget in 2020, 41.7 billion appropriated by Congress with an additional 3.6 billion in COVID-19 supplementary funding.[1–3] Prior research suggested that the NIH research funding has not been proportionately aligned with disease burden in the population.[4–7] Throughout the 1990s, NIH funding patterns were under major scrutiny from Congress and the scientific community due to concerns that funding allocations by the NIH failed to adequately reflect the burden of disease on society.[6] In 1998, the Institue of Medicine (IOM) released a groundbreaking report guiding the NIH to improve and develop disease-specific funding processes.[8] A landmark study published in the *New England Journal of Medicine* as well as a follow-up study by Gillum *et al* in 2011 revealed that the NIH disease-specific funding levels were not correlated with several measures of disease burden.[5 6]

The COVID-19 pandemic tested the NIH's ability to fund critical research to answer research questions that significantly affect public health and require urgent scientific clarity. We analysed the relative weight and composition of the NIH research funding of COVID-19 research in 2020 to evaluate the responsiveness of the agency to the pandemic.

METHODS

Study design and settings

We conducted a cross-sectional study using the NIH Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) datasets of all COVID-19 grants, including grants funded by COVID-19 supplemental appropriations.[9 10] We also reviewed the NIH Fiscal Year 2020 budget and NIH Fiscal Year 2020 supplemental appropriations to identify spending on NIH COVID-19 research.[11]

We reviewed all grants funded for COVID-19 research between 1 January 2020 and 31 December 2020. For each grant, we collected the date of funding opportunity announcements (NIH's advertisements of available grant support), award notice date and the amount awarded as listed in the NIH RePORTER dataset.[12] The date of the Funding Opportunity Announcement was obtained from the NIH COVID-19 grant opportunities.[13]

We categorised each grant into one of six research types: basic science, clinical science, translational science, public health, infrastructure and education and other (online supplemental appendix 1). Each NIH-funded grant was screened to identify one or multiple clinical/scientific areas of focus within the abstracts (online supplemental appendix 2). In order to create comprehensive definitions, we adapted definitions for research areas and subcategories of primary research subjects from NIH Research, Condition and Disease Categorization (RCDC) thesaurus and supplemented them using definitions from the Association of American Medical Colleges, National Cancer Institute, Economic Social Research Council, the Department of Health and Human Services and Methods in Educational Research.[14–20]

Each grant was independently reviewed and categorised by at least two independent reviewers (LB, SH, CD, CK, AM, BC). For grants that were categorised differently, a study group discussed the aims of the grant and made a final decision.

Patient and public involvement

No patients were involved in this study.

Data source

RePORTER is an electronic tool developed by the NIH that works in conjunction with the NIH's RePORT website. This tool allows users to generate lists of funded NIH studies based on specific search criteria, such as funding source and research area.[11] To obtain a list of all the grants that funded COVID-19 research in 2020, we used the NIH's pregenerated COVID-19 RePORTER dataset.[9 11] The information describing 2020 NIH funding by research was found on the RCDC RePORTER database.[21]

Outcomes

The primary outcome for this analysis was to calculate the number of grants and funding the NIH allocated towards COVID-19 in 2020 to the six research types and each clinical/scientific area. The secondary outcome was to calculate the time from funding opportunity announcement to award.

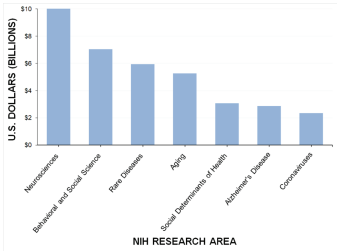

Figure 1 National Institutes of Health funding by research area (2020).

Statistical analysis

We calculated the funding amount for research areas by compiling each grant's total funding amount allocated by the NIH. The funding amount for the clinical/scientific area was calculated based on each grant's categorisation. We plotted the weekly number of COVID-19 grants awarded during 2020. Data cleaning and statistical analyses were conducted using Stata (V.16.0).

RESULTS

In 2020, COVID-19 research accounted for 4.9% (US$2.2 billion) of the annual NIH budget of US$45.3 billion.[3 22] Of the US$2.2 billion that the NIH spent on COVID-19 research, 91.0% was allocated from congressional special appropriations, while the remaining 9.0% of COVID-19 funding originated from the regular NIH annual budget that year. We found that several disease and condition-specific research areas were funded at levels much greater than COVID-19 (figure 1). Rare Diseases research received 2.5-fold more funding than coronavirus research and ageing research received 2.2-fold more research funding than coronavirus research.[21]

There were 1419 NIH COVID-19 grants from the year 2020 in the NIH RePORTER dataset. Of these, we identified 1108 COVID-19 grants with relevance to COVID-19 research, 24 were duplicates appearing in different places and 287 were categorised COVID-19 research; however, COVID-19 was not mentioned in the grant abstract or was not the focus of the grant. Of the 1108 COVID-19 grants identified, 266 grants were able to be matched to their funding opportunity announcement. The remainder had their funding opportunity announcements linked to ongoing projects and were unable to be matched with a current COVID-19 funding opportunity announcement.

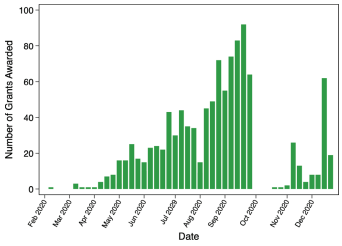

Figure 2 Number of COVID-19 grants approved by National Institutes of Health in 2020.

The average COVID-19 grant was issued funding 151 days (SD:±57.9) after its funding opportunity announcement, with a median of 137 days (IQR: 109–196) and range from 43 to 295 days. In a randomly selected pre-COVID sample of 20 grants in 2018 and 2019, the average time from the funding opportunity announcement to the awarded date was 606 days. There were 535 (48.3%) grants funded through regular 2020 appropriations and 573 (51.7%) funded through supplemental COVID-19) funding.

In the first 3 months of the global pandemic, a total of six grants were awarded for COVID-19 research. In the first half of 2020, a total of 240 grants were awarded funding (figure 2). Accordingly, in the first 3 months of 2020, the NIH spent a total of 0.04% of its annual budget on COVID-19 research. In the first half of 2020, the NIH spent 1.1% of its annual budget on COVID-19 research. The months with the most COVID-19 research grants awarded were August and October.

Regarding the type of COVID-19 research funded, basic science research comprised the greatest number of grants funded by the NIH with a total of 313 grants, compromising 6.9% of total COVID-19 research funding. There were 231 grants awarded for public health research and 231 grants awarded for clinical research, accounting for 5.7% and 26.8% of NIH COVID-19 funding, respectively. The NIH allocated the largest dollar amount to infrastructure and education research with 55.5% of all COVID-19 funds going to these purposes with 216 grants, accounting for 2.7% of the NIH's annual budget (table 1).

There was an average of 1.9 (SD:±1.0) clinical/scientific areas per grant awarded by the NIH. The most common clinical/scientific areas of research were social determinants of health (n=278 grants, 8.5% of COVID-19 funding), immunology (n=211 grants, 25.8% of COVID-19 funding) and pharmaceutical interventions (n=208 grants, 47.6% of COVID-19 funding) (table 2). Of the 208 grants dedicated to pharmaceutical intervention research, 85 grants focused on novel therapeutics development (6.4% of COVID-19 funding), 79 grants focused on existing therapeutics (28.2% of COVID-19 funding) and 69 grants on vaccine development (32.2% of COVID-19 funding). Of the 211 immunology grants, 41 grants studied immunity gained after infection of COVID-19 and 15 grants studied immune response from vaccination. Of 64 neurological grants, 13 grants focused on changes of tastes or smell.

There were 132 grants awarded for COVID-19 testing, compromising 8.5% of all COVID-19 funding. There were 83 grants on COVID-19 transmission, representing 3.5% of COVID-19 funding. Of these, 5 studied airborne transmission, and two grants studied COVID-19 transmission in schools.

A total of 104 grants focused on non-pharmaceutical interventions, with six grants on the efficacy of social distancing and two grants on the efficacy of face masks. Additionally, 92 grants studied the effects of COVID-19 infection in paediatric populations, 10 of which examined inflammatory syndrome in children. Geriatric health and COVID-19 was awarded 68 grants and maternal health and COVID-19 was awarded 41 grants. There were no grants dedicated to studying the efficacy of face masks in children.

DISCUSSION

Despite the escalating public health threat and poorly understood mechanism of transmission of the novel coronavirus in 2020, the NIH only spent 5.3% of their total budget that year on COVID-19 research, extending the prior literature that the NIH funding priorities

Table 1 National Institutes of Health (NIH) grants for COVID-19 research by research type (2020)

	Number of COVID-19 grants (%)	Dollars spent, US$	Percent of all COVID-19 funding (%)	Percent of total NIH annual budget (%)
Basic science	313 (28.25%)	151 252 564	6.85	0.33
Translational	81 (7.31%)	85 436 684	3.87	0.19
Clinical	231 (20.85%)	591 533 574	26.77	1.31
Infrastructure and education	216 (19.49%)	1 235 403 053	55.92	2.73
Public health	231 (20.85%)	124 813 879	5.65	0.28
Other	36 (3.25%)	20 946 874	0.95	0.05
Total	1108	2 209 386 628	100.00	4.88

Table 2 National Institutes of Health (NIH) grants for COVID-19 by clinical/scientific area (2020)*

	Number of grants	Dollars spent, US$	Percent of COVID-19 funding, %	Percent of NIH annual funding, %
Social determinants of health	278	188229016	8.52	0.42
Immunology	211	570461693	25.82	1.26
Pharmaceutical interventions	208	1051790057	47.61	2.32
Impacts on other disease	133	40865572	1.85	0.09
Diagnosis and testing	132	186846477	8.46	0.41
Risk factor analysis	111	55501547	2.51	0.12
Non-pharmaceutical interventions	104	115971759	5.25	0.26
Paediatric health	92	63635942	2.88	0.14
Transmission	83	77675659	3.52	0.17
Other research	83	515823132	23.35	1.14
Virology	79	33601202	1.52	0.07
Geriatric health	68	467815039	21.17	1.03
Neurology	64	21705014	0.98	0.05
Pulmonology	61	37068124	1.68	0.08
Maternal health	41	19633841	0.89	0.04
Gastroenterology	31	12081004	0.55	0.03
Cardiology	18	32997172	1.49	0.07
Nephrology	14	8386775	0.38	0.02

*Each grant can have multiple areas.

misaligned with disease burden in the population.[6 8] The NIH's slow start in funding COVID-19 research was also noted in a February 2021 study in *Health Affairs* by Sampat and Shadlen.[7] They described the current low investment in COVID-19 research as 'small compared with the potential value of these interventions for ameliorating or preventing the disease and securing a return to normalcy'. A stronger research effort could have helped reduce transmission of the infection before a vaccine became available.

Infrastructure and education accounted for 55.9% of NIH COVID-19 funding, yet many of the major clinical questions surrounding COVID-19 transmission were unanswered at that time, such as transmission among children. Significant restrictions have been placed on the nation's 52 million school-aged children, including school closures, 6-foot distancing requirements and outdoor masking while distancing; however, only a few grants were dedicated to studying these questions in this unique population, creating challenges for evidence-based policymaking. It is also concerning that we have identified 287 grants that are categorised as COVID-19 where COVID-19 was not mentioned in the grant abstract or was not the focus of the grant.

The lack of rapid clinical research funding to understand COVID-19 transmission may have contributed to the politicisation of the virus. Some of the most basic questions that were being asked of medical professionals in early 2020, such as how it spreads, when infected individuals are most contagious, and whether masks protect individuals from spreading or getting the virus, went unanswered. In the absence of evidence-based answers to the common questions the public was asking, political opinions filled that vacuum. Patient and public involvement in research prioritisation of funding could help direct a more urgent, focused and equitable response to health emergency.

The social and political climate of the COVID-19 pandemic has been plagued with misinformation hindering important mitigation efforts. Significant funding was made to Biomedical Advanced Research and Development Authority. However, this funding was focused on vaccines and therapeutics rather than clinical research on characteristic COVID-19.[9] A resilient healthcare system in times of crisis should be able to pivot funding towards specific grants answering critical gaps in knowledge. NIH may consider developing procedures to rapidly pivot funding and guidelines for reviewing targeted proposals relevant to addressing a public health emergency.

Our study has several limitations. The type of research and the clinical/scientific areas studied were based on definitions that may not be collectively exhaustive and mutually exclusive. In addition, we only reviewed abstracts and did not review the entire funded proposals, and we did not separate the share of new grants vs continued grants in the analysis. There were other barriers to clinical research that were not captured here, including slow institutional review boards and long journal peer-review

times. A rapid research protocol that protects research subjects with standard ethical principles for research could be developed for the next health emergency.

CONCLUSION

NIH funding patterns for COVID-19 grants did not align with COVID-19 disease burden and were allocated slowly. The NIH should develop mechanisms to rapidly pivot funding to address scientific unknowns associated with a sudden, large-scale health emergency. Supporting sound clinical research aimed at developing evidence-based recommendations is important for public policy and promotes public trust in the medical profession during a pandemic.

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Contributors LB, CD, CW and MM designed the study. LB, CD, AM, SH, CW, CK, BC, and FM collected the data. LB and CD analysed the data. LB, CD, AM, SH and CW prepared the first draft of the manuscript. LB, CD, AM, SH, CW, CK, BC, FM, TD, GB, KS and MM made critical revisions to the manuscript. CD and LB acted as guarantors for the manuscript. All authors reviewed and approved the final draft and agreed to be accountable for all aspects of the manuscript in ensuring that questions related to the accuracy.

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Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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Appendix 1: Definition of Research Types

Research Type	Definition	RCDC/NIH Definition
Basic Science Research	Fundamental laboratory or bench research and provides the foundation of knowledge for applied science and encompasses biochemistry, microbiology, physiology, and pharmacology, and their interplay, and involves laboratory studies with cell cultures, animal studies, or physiological experiments[10] Adapted from Concept ID: 681833, 1511287	Concept Name: Basic Science Concept ID: 681833 Concept Definition: 0.Research aimed at deriving general knowledge, without a direct application toward solving a specific problem. Concept Name: Basic Research Breast Cancer Concept ID: 1511287 Concept Definition: 0.Research on the molecular, genetic, biochemical, cellular, structural, immunological, pharmacological mechanisms and factors as they relate to the causation, progression, diagnosis, and treatment of breast cancer.
Clinical Research	Research conducted with human subjects, or on the material of human origin, in which an investigator directly interacts with human subjects, which are studied to understand health and disease; includes the development of new technologies, mechanism of human diseases, therapy, and clinical trials[11] Adapted from Concept ID: 8972	Concept Name: Clinical Research Concept ID: 8972 Concept Definition: research conducted with human subjects or on material of human origin in which an investigator directly interacts with human subjects; includes development of new technologies, mechanism of human diseases, therapy, clinical trials, epidemiology, behavior and health services research.
Translational Research	Translational research requires interdependence between basic and clinical investigators in both the planning and implementation of research and emphasizes the clinical application of basic research findings with patients and populations. This research has both basic science and clinical components which applies discoveries generated during research in the laboratory and in preclinical studies (basic science research), to the development of trials and studies in humans (clinical research)[12] Adapted from Concept ID: 1519620	Concept Name: Translational Research Concept ID: 1519620 Concept Definition: Translational research requires interdependence between basic and clinical investigators in both the planning and implementation of research and emphasizes clinical application of basic research findings with patients and populations. Translational research also applies clinical findings to advance basic research that ultimately may lead to hypothesis-driven clinical trials or prevention and control interventions (from Specialized Programs Of Research Excellence in Prostate Cancer NIH Guide, Volume 23, Number 33, September 16, 1994, RFA: CA-94-031)

Infrastructure & Education Research	Infrastructure: Research infrastructure refers to the facilities, resources, and services that are used by the research and innovation community to conduct research and foster innovation in their fields, such as increasing testing capacity, shipping and receiving services, waste management, and utilities, or Vaccine and Treatment Evaluation Units[13] Adapted from Concept ID: 1514880 and 1512763 Education: Research related to training and teaching the general public and/or specific populations focused on improving knowledge of COVID-19 and COVID-19 preventative methods. Using systematic investigation, this research also adopts rigorous and well-defined scientific processes and empirical methods to gather and analyze data in order to solve challenges in education.[14] Adapted from Concept ID1514602	**Education:** Concept Name: Public Health Education Concept ID: 1514602 Concept Definition: Health education aimed at the general public **Infrastructure:** Concept Name: Research Infrastructure Concept ID: 1514880 Concept Definition: 0.Refers to the physical structures needed to conduct research as well as the basic services needed for support, eg shipping and receiving services, waste management, and utilities. Synonym Name: Infrastructure Concept Name: Infrastructure Activities Concept ID: 1512763 Concept Definition: 0.NIH Emphasis Area: Infrastructure activities are new or expanded programs in the following: Research Training; Shared Instrumentation and Services; Technology Development; Information Technology and Clinical Research. Again, only new or expanded program initiatives should be reported-e.g., an increase in training related only to the increase in stipends should not be reported as an Infrastructure Initiative. Broader Term: Research Infrastructure
Public Health Research	Public health research tries to improve the health and well-being of people from a population-level perspective including research that addresses mental health and social determinants of health[15] Adapted from Concept ID 34019	Concept Name: Public Health Concept ID: 34019 Concept Definition: Branch of medicine concerned with the prevention and control of disease and disability, and the promotion of physical and mental health of the population on the international, national, state, or municipal level. 1.branch of medicine concerned with the prevention and control of disease and disability, and the promotion of physical and mental health of the population on the international, national, state, or municipal level. 2.The science and practice of protecting and improving the health of a community, as by preventive medicine, health education, control of communicable diseases,

		application of sanitary measures, and monitoring of environmental hazards. (Disability History Museum glossary; http://www.disabilitymuseum.org/glossary.php) Broader Term: Environment and Public Health
Other	Research that does not fit into the above research types. This includes research that has tangential impacts on COVID-19 knowledge or response but is not primarily focused on COVID-19.	

Appendix 2: Definition of Clinical/Scientific Area

Category	Definition	NIH/RCDC Definition
Cardiology	Research that analyzes the effects of COVID-19 on the heart, blood vessels, or circulation. Adapted from Concept ID: 7226	Concept Name: Cardiovascular system Concept ID: 7226 Concept Definition: 0.The HEART and the BLOOD VESSELS by which BLOOD is pumped and circulated through the body. 1.Relating to the heart and the blood vessels or the circulation. 2.Cardiovascular; pertaining to the heart or blood vessels. Synonym Name: Cardio-vascular
Diagnosis and Testing	Research involving the development, improvement, and testing of methods and tools for diagnosing, detecting, and monitoring COVID-19 infection. Adapted from Concept ID: 11900	Concept Name: Diagnosis Concept ID: 11900 Concept Definition: The determination of the nature of a disease or condition or the distinguishing of one disease or condition from another. Assessment may be made through physical examination, laboratory tests, or the like, and may be assisted by computerized programs designed to enhance the decision-making process. 1.general term for detecting and classifying diseases. 2.The investigation, analysis and recognizing of the presence and nature of disease, condition, or injury from expressed signs and symptoms; also, the scientific determination of any kind; the concise description of characterization of a species where the characteristics of an organism are diagnosed to determine which taxonomic classification is suitable to them. In oncology also: the development, improvement, and testing of methods for cancer detection and staging.
Gastroenterology	Research that analyzes the effects of COVID-19 infection on the structures and functions of the gastrointestinal tract, including the esophagus, stomach, small intestine, and large intestine (colon, rectum, and anus) and associated digestive organs (liver, gallbladder, and pancreas)	Concept Name: Gastroenterology Concept ID: 17163 Concept Definition: 0.A subspecialty of internal medicine concerned with the study of the physiology and diseases of the digestive system and related structures (esophagus, liver, gallbladder, and pancreas).

	Adapted from Concept ID: 17163, 17178	Concept Name: Gastrointestinal Diseases Concept ID: 17178 Concept Definition: 0.Diseases in any segment of the GASTROINTESTINAL TRACT from ESOPHAGUS to RECTUM. 1.disorder in any segment of the gastrointestinal tract from the esophagus to the rectum. 2.RAEB: Diseases of the digestive tract (oral cavity to anus) and associated organs (salivary glands, liver, pancreas). 3.RAEB: Use for studies in which the focus is on the digestive tract (oral cavity to anus) and associated organs (salivary glands, liver, pancreas). For most digestive organs there will be no problem; however, liver is frequently used in studies of carcinogens for which it is not normally the target organ. In the latter type case do not code SIC 36. (NCI)
Geriatrics	Research concerned with the physiological and pathological aspects of the aged, including the clinical problems of senescence and senility. This includes clinical research involving human subjects above the age of 65 years. Adapted from Concept ID: 17469	Concept Name: Geriatrics Concept ID: 17469 Concept Definition: 0.The branch of medicine concerned with the physiological and pathological aspects of the aged, including the clinical problems of senescence and senility. 1.field of medicine concerning elderly human health. 2.The branch of medical science that deals with diseases and problems specific to elderly people.
Immunology	Research of the immune system and its reaction to, as well as its malfunctions in response to COVID-19 infection. This includes research that pertains to the identification and characterization of immune factors; immune physiology; diseases of the immune system in conjunction with COVID-19 infection or complications. Adapted from Concept ID: 152036	Concept Name: Immunology Concept ID: 152036 Concept Definition: The occupation or discipline. 1.Immunology is the study of the immune system and its reaction to pathogens, as well as its malfunctions (autoimmune diseases, allergies, rejection of organ transplants). (from Wikipedia) 2.RAEB: Use for any aspect of immunology: identification and characterization of immune factors; immune system development; immune physiology; immunotherapy; immunodiagnosis; tumor or virus antigen studies; vaccine research; diseases of the immune system (immunodeficiencies, autoimmunity, hematopoietic system neoplasia). Not used for research tools such as antibody tagging if the study is otherwise unrelated to immunology. (NCI) Broader Term: Biological Sciences

Impacts on Other Diseases	Research analyzing the impact of the COVID-19 infection and pandemic control measures on the pre-existing disease or condition the patient is diagnosed with. Adapted from Concept ID: 9599	Concept Name: Complication Concept ID: 9566 Concept Definition: 0.something that introduces usually unexpected difficulties, problems, or changes. 1.Any disease or disorder that occurs during the course of (or because of) another disease.
Maternal Health	Research that analyzes the impact of COVID-19 infection, complications, or pandemic control measures on maternal health including pregnancy, prenatal care, labor and delivery, and childcare. Adapted from Concept ID: 1513012, and 33052	Concept Name: Maternal and Child Health Concept ID: 1513012 Usually involves maternal factors (and efforts to modify these factors) that may affect the health of the child or fetus: smoking or exposure to drugs or toxic chemicals during pregnancy, maternal/fetal immunologic interactions. Also use for genetic counseling, pregnancy and/or nursing effects on maternal health. Concept Name: Prenatal Care Concept ID: 33052 Care provided the pregnant woman in order to prevent complications, and decrease the incidence of maternal and perinatal mortality.
Non-Pharmaceutical Interventions	Research regarding investigating the implementation and/or efficacy of non-pharmacological measures to address the COVID-19 pandemic, including programs designed to prevent and control the spread of infection. Adapted from Concept ID: 85557	Concept Name: Infection Control Concept ID: 85557 Concept Definition: Programs of disease surveillance, generally within health care facilities, designed to investigate, prevent, and control the spread of infections and their causative microorganisms.
Nephrology	Research that analyzes the effects of COVID-19 infection on the structures, functions, and diseases of the renal system. Adapted from Concept ID: 27712	Concept Name: Nephrology Concept ID: 27712 Concept Definition: 0.A subspecialty of internal medicine concerned with the anatomy, physiology, and pathology of the kidney.
Neurology	Research that analyzes the effects of COVID-19 infection on the structures, functions, and diseases of the nervous system including effects on senses.	Concept Name: Neurology Concept ID: 27855 Concept Definition: 0.A medical specialty concerned with the study of the structures, functions, and diseases of the nervous system. 1.the branch of

	Adapted from Concept ID: 27855, 36658	medical science that deals with the study of structure, function, and diseases of the nervous system; Concept Name: Esthesia Concept ID: 36658 Concept Definition: 0.Transduction of physical or chemical changes in the external or internal environment into nerve impulses by specialized receptors, transmission of these impulses by afferent neurons to the effectors, either directly or through the CNS. 1.transduction of stimuli from outside the body and those within the body into nerve impulses by receptors, and the transmission of these impulses by afferent neurons to the cerebral cortex. Synonym Name: Sensation
Other Research	Grants that do not fall into other clinical/scientific areas.	
Pediatric Health	Research concerned with maintaining health or providing medical care to children from birth to adolescence in the context of COVID-19 infection, complications, or control measures. Adapted from Concept ID 30755, 1578	Concept Name: Pediatrics Concept ID: 30755 Concept Definition: 0.A medical specialty concerned with maintaining health and providing medical care to children from birth to adolescence. Concept Name: Adolescence Concept ID: 1578 Concept Definition: 0.period of life beginning with the appearance of secondary sex characteristics and terminating with the cessation of somatic growth; typically between 12 and 20 years of age; when school grades are referenced, this age group is typically grade 5 or 6 and above; also index with appropriate human and clinical research terms. 1.Adolescence is the time period between the beginning of puberty and adulthood. 2.The period of life beginning with the appearance of secondary sex characteristics and terminating with the cessation of somatic growth. The years usually referred to as adolescence lie between 13 and 18 years of age.
Pharmaceutical Interventions	These are preclinical and clinical studies analyzing the nature, properties, and actions of drugs as therapeutics for COVID-19 infection. This includes research involving the creation and	Concept Name: New Agents Concept ID: 1518316 Concept Definition: 0.Research into new physical or chemical means to treat disease. Broader Term: Funding Category

	testing of new therapeutics, interventions, vaccines, and repurposing of prior FDA approved therapeutics to treat infection, alleviate symptoms, or offer prophylaxis against COVID-19. Adapted from Concept ID: 1518316, 31330	Concept Name: Pharmacology Concept ID: 31330 Concept Definition: 0.The study of the origin, nature, properties, and actions of drugs and their effects on living organisms. 1.the biological effects of drugs in living organisms or tissues; use this term mainly for intended, desired effects; for harmful or undesired effects, see DRUG ADVERSE EFFECT or TOXICOLOGY. 2.Pharmacology is the study of drugs in all their aspects. It is concerned with the art and science of the preparation, compounding, and dispensing of drugs. (Pharmacology Glossary; http://www.bumc.bu.edu) Broader Term: Biological Sciences
Pulmonology	Research that analyzes the effects of COVID-19 infection on the respiratory system and respiration disorders. Adapted from Concept ID 35204	Concept Name: Respiration Disorders Concept ID: 35204 Concept Definition: Diseases of the respiratory system in general or unspecified or for a specific respiratory disease not available.
Risk Factor Analysis	Research that provides qualitative or quantitative estimation of susceptibility to COVID-19 infection and/or adverse outcomes based on the presence of risk factors, herein defined as inherited, environmental, or behavioral characteristics that affect COVID-19 infection, symptoms, and outcome. Adapted from Concept ID 86930, 35648, 12655	Concept Name: Risk Concept ID: 35647 Concept Definition: 0.The probability that an event will occur. It encompasses a variety of measures of the probability of a generally unfavorable outcome. 1.Risk is the potential future harm that may arise from some present action. It is often combined or confused with the probability of an event which is seen as undesirable. (from WIkipedia) Concept Name: Risk Assessment Concept ID: 86930 Concept Definition: 0.The qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified health hazards or from the absence of beneficial influences. (Last, Dictionary of Epidemiology, 1988) 1.The qualitative or quantitative estimation of the likelihood of adverse effects that may result from exposure to specified health hazards or from the absence of beneficial influences.

		Concept Name: Risk Factors Concept ID: 35648 Concept Definition: 0.An aspect of personal behavior or lifestyle, environmental exposure, or inborn or inherited characteristic, which, on the basis of epidemiologic evidence, is known to be associated with a health-related condition considered important to prevent. Concept Name: Disease susceptibility Concept ID: 12655 Concept Definition: 0.A constitution or condition of the body which makes the tissues react in special ways to certain extrinsic stimuli and thus tends to make the individual more than usually susceptible to certain diseases. 1.factors that affect the probability or predisposition of an individual to the development of a disease(s) or disorder(s).
Social Determinants of Health	Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Research in this area identifies the effect of social determinants on people's health in the context of COVID-19 infection and preventive methods[16] Adapted from Concept ID 1171307, 37470, 26192	Concept Name: health disparity Concept ID: 1171307 Concept Definition: 0.a population-specific difference in the presence of disease, health outcomes or access to care. Concept Name: Infectious Disease Epidemiology Concept ID: 1512717 Concept Definition: 0.Epidemiology as it relates to infectious diseases. Concept Name: Medical Sociology Concept ID: 37470 Concept Definition: 0.The study of the social determinants and social effects of health and disease, and of the social structure of medical institutions or professions. 1.Medical sociology is the study of individual and group behaviors with respect to health and illness. Medical sociology is concerned with individual and group responses aimed at assessing

		well-being, maintaining health, acting upon real or perceived illness, interacting with health care systems, and maximizing health in the face of physiologic or functional derangement. It also analyzes the impact of the psychological conditions resulting from our environment on our health. Concept Name: Minority Groups Concept ID: 26192 Concept Definition: 0.A subgroup having special characteristics within a larger group, often bound together by special ties which distinguish it from the larger group. 1.A minority is a group that is outnumbered by persons who do not belong to it, often people with different nationality, religion, culture or lifestyle from that of the mainstream in the society. (Wikipedia) 2.RAEB: Racial or ethnic groups officially recognized by the U.S. government as minority populations.
Transmission	Research that describes or models the transmission of COVID-19 focusing on where and how transmission occurs. This includes research specifically addressing when infected individuals are most contagious, disease duration, and the period in which infectivity or illness resolves. Adapted from Concept ID 242781, 242649	Concept Name: Disease transmission Concept ID: 242781 Concept Definition: 0.The transmission of infectious disease or pathogens. When transmission is within the same species, the mode can be horizontal (DISEASE TRANSMISSION, HORIZONTAL) or vertical (DISEASE TRANSMISSION, VERTICAL). 1.transmission of an infectious disease by direct contact with an affected individual, the individual's discharges or by indirect means such as by a vector. 2.The transmission of infectious disease or pathogens. When transmission is within the same species, the mode can be horizontal (disease transmission, horizontal) or vertical (disease transmission, vertical). (NCI) Concept Name: Horizontal Disease Transmission Concept ID: 242649 Concept Definition: 0.The transmission of infectious disease or pathogens from one individual to another in the same generation.

Virology	Research analyzing the characteristics of the virus SARS-CoV-2, including molecular viral components pertaining to replication, infectivity, and genetic variability. Adapted from Concept ID 597650, 42774, 34848, 597652, 597653	Concept Name: virus characteristic Concept ID: 597650 Concept Definition: features that help to identify, distinguish or describe recognizably; classification systems of viruses; includes infection routes, staining patterns, replication requirements, etc. Concept Name: Virus Replication Concept ID: 42774 Concept Definition: 0.The process of intracellular viral multiplication, consisting of the synthesis of PROTEINS; NUCLEIC ACIDS; and sometimes LIPIDS, and their assembly into a new infectious particle. 1.process of forming progeny virus from input virus; involves expression and replication of viral genomic nucleic acid and the assembly of progeny virus particles. Concept Name: Virus Receptors Concept ID: 34848 Concept Definition: 0.Specific molecular components of the cell capable of recognizing and interacting with a virus, and which, after binding it, are capable of generating some signal that initiates the chain of events leading to the biological response. 1.viruses must first bind to their target cell's surface before infection can proceed; this is mediated by specific molecular receptors for certain viral antigens, many of which have other known functions; e.g., the MHC-II receptor CD4 is also an HIV receptor. 2.Cell surface molecules that are capable of interacting with virus particles, thereby mediating their entry into the cell or otherwise eliciting a cellular response. Concept Name: virus infection mechanism Concept ID: 597653 Concept Definition: 0.multi-step process by which a virus binds to, enters, and replicates within a host

		cell; includes both surface and intracellular interactions between host and virus. Concept Name: virus genetics Concept ID: 597652 Concept Definition: 0.heredity, especially the mechanisms of hereditary transmission and the variation of inherited characteristics among a virus or viruses; the genetic constitution of viruses. 1.The branch of science concerned with the means and consequences of viral transmission and generation of the components of biological inheritance.

[SUMMARY STATEMENT OF MARTIN MAKARY]

Chairman Sanders, Ranking member Cassidy, members of the committee, thank you for the invitation to present.

Congress should avoid the false narrative that insufficient Federal funding was to blame for the country's pandemic response. In fact, it was a case study in bureaucratic failure.

One Johns Hopkins student developed a Covid tracker that the CDC, with its 21,000 employees, was unable to create. Was the CDC understaffed? Did the it need 25,000 employees to make a website for the world to track the pandemic? No, the CDC was mired in bureaucracy.

More tragic, the NIH, with a $42 billion budget, failed to conduct basic clinical research in a timely fashion. Critical scientific questions went unanswered—questions that could have been answered with 1 week of clinical study, like:

- Does Covid primarily spread from touching or is it airborne?
- When is the peak day of viral shedding and contagion?
- How long should you quarantine?
- Do masks work?

Leaving many basic scientific questions unanswered for half a year or more, public health officials ruled by opinion in lieu of conducting or funding clinical research quickly.

In July, 2020, Dr. Fauci told the American Federation of Teachers president at a public event that teachers should wear goggles and gloves. He has since said that we didn't know back then because we didn't have the science. But he controlled a $6 billion research budget at NIAID. Did NIAID need $7 billion to find out that Covid was airborne? Did he need an additional $7 billion to tell us if cloth masks on toddlers and 50 million children for 2 years is effective?

Regardless of one's political affiliation, in the absence of good scientific evidence, doctors and the public were flying blind. What filled the void were opinions. That's how Covid became the most political pandemic in U.S. history.

My Johns Hopkins research team went back and found that in 2020, the year the pandemic hit the U.S., the NIH spent 2.2-times more money on aging research than it did on Covid research. I'm all for aging research, especially as I get older, but not when 3,000 Americans are dying everyday. Our study, published in BMJ, also found that when the NIH made a decision to fund a Covid research study, it took them 5 months to actually send the money to the researchers to start the research. In short, the government failed to pivot, not because they didn't have enough resources, but because of a rusty and bloated bureaucracy.

Ironically, while the U.S. failed to fund basic clinical research on the big Covid questions, we were funding labs overseas to engage in the dangerous business of virus hunting, sending people to remote uninhabited rainforests and caves to obtain exotic viruses and bring them to labs in highly populated cities of 8–10 million people—the population of Wuhan. There are at least a million different viruses in the world and a small fraction, roughly fewer than 1 percent, infect humans. Why is the U.S. funding this dangerous work? The promise of virus hunters that they could use this information to predict future pandemic was a fallacy. It's never happened and never will. We don't need A.I. to prepare for future pandemics, we just need 'I'.

The U.S. needs a rapid response team to conduct or fund clinical research to guide pandemic responses, so we're not simply following opinions.

The CHAIR. Thanks very much. Let me start off with an issue that has bothered me for a long time. It is kind of a philosophical issue, maybe a moral issue. If I have a product, a prescription drug or a vaccine that can save his life, and I say, Bill, you can have it, but it is going to cost you $100,000.

You say, hey, Bernie, I don't have $100,000. I say, well, I am sorry, Bill. My business model is that is the price it. So, are you going to die? Nice guy. That is the way it is. Now, Mr. Weissman, you were talking about maybe millions of people around the world, poor people dying because they don't have the vaccine. We have it.

I think the vaccine as I understand it, somebody correct me if I am wrong, now costs a couple of dollars to produce. Not a whole lot of money. What is the morality, and I want all three of you to respond to it, of us having a product that cost a few dollars to produce but not making it available to people around the world who are dying, and in our own country as well, but poor people around the world. Doctor.

Dr. RAMACHANDRAN. Senator Sanders, what you are describing, the situation—you know, the hypothetical is the lived reality. I see it pretty much every single time I have a clinic where patients

come to me and say that they can't afford whatever I am prescribing them.

The fact that this could happen with a publicly funded vaccine is frightening, frankly, to me, after the public health emergency period ends. So, absolutely I think it should be unconscionable. It should not be allowed for that to happen.

You know, no one should be poor because they are sick, and no one should be sick because they are poor. So, you know——

The CHAIR. If I have a product that can save your lives that costs me a few bucks to manufacture, should I deny it to you?

Dr. RAMACHANDRAN. No, definitely not.

The CHAIR. Okay. Mr. Weissman.

Mr. WEISSMAN. Well, thank you for the question. It really is a core one. It is obviously an unconscionable scenario that you are describing, I think, when we look at it globally, what is worth underscoring is that there effectively is no market in low middle income countries for big pharma.

They are not holding out to see if someone can pay more. They are just not going to sell there at all. So, leaving aside what we think about to happen in high or in our market, or in high income country markets, in those markets, we just have to figure out ways to get the technology disseminated there.

When it comes to lifesaving technologies like a vaccine, especially a U.S. Government supported vaccine, if they don't want to make it to sell there, fine, but require them to share the technology with other manufacturers, give them the know how so they can make it on their own. That is the least we should obligate.

The CHAIR. Mr. Makary, should people die because they can't afford a product that costs a couple of bucks to manufacture?

Dr. MAKARY. Cost should never be an access—a barrier. However, I must note that there are sacred cows nobody will talk about with drugs in the United States, like——

The CHAIR. Test me.

Dr. MAKARY. Pharmacy benefit managers and group purchasing organizations.

The CHAIR. We will talk about it.

Dr. MAKARY. Thank you for your work on——

The CHAIR. We are going to have them next week. They are going to be sitting exactly where you are sitting along with the three major insulin manufacturers in the world. How is that?

Dr. MAKARY. Great. Sole supplier contracting is also tied into shortages. The FDA Commissioner was just asked about shortages and what he is doing, and he said, we need better data. How about these mass monopoly powers?

We have got three suppliers that supply 85 percent of U.S. hospitals. They enter into these cozy sole supplier contracts. The manufacturer gets a flimsy supply chain. For something like insulin, we have maybe one manufacturer.

The CHAIR. All of the points you are raising are good points. I am going to get it back to you. Tell me about the moral issue. I

have a product, costs me two bucks to manufacturer. Will save his life. He can't afford it. Is that a good—is that a moral business model that we should sustain, in your judgment?

Dr. MAKARY. It is an unacceptable barrier. But I think the best way to lower drug prices in America are to stop taking drugs we don't need and to cut the waste in the system.

The CHAIR. Okay. Senator Cassidy.

Senator CASSIDY. Thank you all for being here. Dr. Makary, what do you really think, man?

[Laughter.]

Senator CASSIDY. Well, of course, the theoretical that was just given is an absurd theoretical. I say that because Moderna has already pledged that they will make this vaccine available. I come from treating a group of patients who are uninsured in Louisiana. I speak with some authority.

Between a Medicaid expansion state and 340(b) and other mechanisms, drugs should be available for those who otherwise would not have. Now, as regards to the vaccine, I could also give you a theoretical. What if we so disincentivize the production of cutting-edge therapies that somebody would not develop it? Well, we have seen that before, haven't we? Now what happens is we end up not having cures.

I think that we have to have a note of reality as we give theoretical. Dr. Makary, in full disclosure, I had a very productive conversation before the last hearing with Dr. Walensky. One concern I had, there seemed to be—and by the way, I think in fairness, we have to say the Federal agencies to which we refer generally conceded didn't do well, did, some of them at least, before the pandemic, but they are making major efforts to reform.

Let's just acknowledge that. And one of the productive conversations I thought we had is how you could have information sharing. That it wouldn't be siloed or if you will, quarantined from others seeing it by a Federal agency, but with sufficient protection of privacy, that there would be access by other researchers who might have a different idea than CDC.

You are a person, I think all three of you are people who have different ideas about how these things should be handled. And so, again, with sufficient protection for privacy, having access to that data base, CDC may maintain it or someone else, but some good researcher at Johns Hopkins who wants to test that thesis could similarly do so, one more time, with appropriate safeguards. What are your thoughts about that?

Dr. MAKARY. Public health officials really downplayed and silenced dissent on many different levels. Why has the Oxford-AstraZeneca vaccine never been approved in the United States, being given to over a billion people? Covaxin, why has it never been approved? What is it with the cozy relationship between regulators——

Senator CASSIDY. Yes, but go back to the information sharing because that is the point of my question. So, is there a way that we can have more—I kind of group outsourcing or group sourcing the

analysis of the data that would allow us to make better public health decisions.

Dr. MAKARY. Yes, we have not had good access to data. We have asked for hospitalization rates in people under 50 by booster versus non booster, just the primary vaccine series. We didn't get it. Why? Probably doesn't support the narrative. Science should not be censored or corrupted.

Senator CASSIDY. I accept that. But I am just—I got limited time, so I don't mean to cut you off. Mr. Weissman, you heard Dr. Califf's concern that if you went to an x prize model, if you did not sufficiently protect intellectual property, that would be a disincentive for companies to make large scale investments, etcetera, etcetera, etcetera. Your thoughts on that?

Mr. WEISSMAN. Yes, I think Dr. Califf is mistaken. You know, in the scenario that you laid out for him, there was no private sector market at all. You are talking about—you were talking about countermeasures where the Government was the sole purchaser.

The intellectual property, the monopoly, that is not what is going on. It is not about how we can charge the most for private individuals. All that does is give the company that the U.S. Government funded more bargaining power with the United States when we purchase from them. That doesn't seem to me like a sensible thing——

Senator CASSIDY. I am not quite sure I am following your logic. I think the original premise was that if you are trying to get the company to commit significant resources to developing something, is it better to give them intellectual property—whether or not the U.S. will be the sole purchaser—but when there is this setting, and of course, we are talking about the initial, we got to jumpstart it.

The premise of the discussion was, is it better to give them an x prize in which you just take it all—you just bet the farm on winning that prize. If not, you lose. Or is it better to give them intellectual property protection and better to give them some sort of kind of traditional intellectual property.

Mr. WEISSMAN. Well, I understood the scenario you laid out to Dr. Califf actually was where the U.S. Government was the purchaser, but I think it is an interesting question also where the U.S. Government is not.

I would actually reverse what you said. To me, the patent monopoly model is the winner take all and it is an uncertain winner take all. So, the one who gets the patent, that is who is the winner. They don't really know the value because you don't know what the market is going to be. You have more certainty with the price because you know the value of it.

But you can calibrate the prize and share actually, incentivize people to get into space, even if they are not the winner. So, you may give an award to someone who drove the research forward but didn't get the final thing that would have become——

Senator CASSIDY. This has a kind of nice group theory kind of approach to it, the idea that everybody would kind of outsource that, I am not sure that—I can already envision the lawsuits over it is my share, not your share, at least with the——

Mr. WEISSMAN. As you know, the patent field is quite full of lawsuits already.

Senator CASSIDY. Oh, sure. But that is a minefield that has already been well tread and people understand. Dr. Ramachandran, again, thank you for your good work. Let me just finish by saying this—and maybe any of you could take this. I have a graph showing that there is a reasonable pricing clause in the Cooperative Research and Development Agreement, which stopped in 1995.

Prior to that point, you had this kind of level of commercialization of research. And then after that removal, there really took off. So, it suggests that, in fact, the conclusion of this is, the primary stimulus for the increase in the cooperative research and development agreements after 95 was the removal of reasonable pricing clauses, etcetera, etcetera.

That is the punch line. Would you disagree with that or lack of familiarity? That is okay, if not.

Dr. RAMACHANDRAN. No, I think any of what you said, mentioned before of this being so possibly an association, but not causation comes into play. Also, during COVID–19, we actually did see the use of reasonable pricing clauses, which companies, including major manufacturers, not just small biotech companies that only have one product in their portfolio, accepted. Pfizer was one of them with Paxlovid that negotiated with U.S. Government.

Actually, within that contract, there was a most favored nation clause, a pricing provision that Pfizer accepted. Similarly, Sanofi and Novavax also had reasonable pricing clauses.

We are also seeing this even outside of the medical countermeasure space. Just recently, University of California, Berkeley, announced reasonable pricing provisions for U.S. populations for their products, and that includes gene therapies that they are developing.

You can see even for products where there is a large commercial market, these sorts of protections could be included. And especially for an agency like NIH that has so much leverage and access to technology that companies do want to have.

Senator CASSIDY. Excellent answer. I yield.

The CHAIR. Thank you. Let me just as a follow-up on Senator Cassidy's point. If I am not mistaken, I think you called my question an absurd hypothetical. All right. It doesn't happen. You say, I suggested that people die or get sick because they can't afford medicine. Do you think that is an absurd hypothesis? I don't know——

Senator CASSIDY. It's not $100 million—charging $100 million for life saving.

The CHAIR. Not 100 million. $100,000. Look, cancer drugs are $100,000 right now, all right. I would like to—doctors, I think we have two doctors and an expert on it, is it an absurd hypothesis to suggest that people are dying or suffering or going bankrupt or having their lives disrupted because they cannot afford the outrageous price of prescription drugs? Doctor.

Dr. RAMACHANDRAN. No, it is not a hypothetical at all. It is the lived reality for so many Americans, especially people around the world.

The CHAIR. You see it in your practice.

Dr. RAMACHANDRAN. All the time.

The CHAIR. Mr. Weissman.

Mr. WEISSMAN. A few points, if I may, Senator. First of all, in the global context, we were talking about, it is commonplace. It is the norm.

The CHAIR. How many people do we think died because they didn't have access to the vaccine in the world? Do we have a guess?

Mr. WEISSMAN. There are very good estimates of between hundreds of thousands and millions. It has hard to sort of pin it down. And most of those who did get vaccinated didn't get the higher quality, mRNA vaccines.

In the U.S., second point is, in the U.S., as you said, 25 to 30 percent of Americans actually ration their prescription drugs because of price. Now, not all of them are dying as a result, but some are. The launch price of new drugs right now is $182,000. So, $100,000 is not a far-out drug—it is actually an underestimate——

The CHAIR. Somebody if I am wrong here, but I think many of the cancer drugs that are out there are over $100,000 a year. Is that correct?

Mr. WEISSMAN. That is correct. And some are now going up to $1 million. I just wanted to say one other thing on the question you had asked to Senator Cassidy about the CRADA agreement and reasonable pricing.

Actually, what happened there is that in 1995, at the point that NIH stopped using the reasonable pricing provisions and CRADAs, they added a new category of CRADA. So, the original category of CRADA were standard CRADAs, these are cooperative research and development agreements. Those stayed roughly consistent after the removal of the reasonable pricing clause.

They added a new category of material CRADAs. So, the numbers that you are looking at that show, this seeming juxtaposition pre 1995 and post 1995 reflect a change in categorization, not to removal of the reasonable pricing clause.

The CHAIR. Dr. Makary, in my—did I pose an absurd hypothesis to Senator Cassidy that people are dying or suffering because they can't afford medicine?

Dr. MAKARY. It happens. The American Cancer Society did a study that 48 percent of cancer patients say they have avoided or delayed future care for fear of the bill. So that is a real problem.

With the promise of the Affordable Care Act lowering costs not panning out, we now have higher deductibles, creating a new problem called the functionally uninsured. They have insurance, but they can't afford the——

The CHAIR. Exactly right. I don't think, Senator Cassidy, that my hypothesis was absurd.

Senator CASSIDY. Well, cancer drugs, of course, have nothing to do with PAHPA. Dr. Ramachandran, of course, refers to the global

environment, that is different. We can talk about vaccines, lack of availability worldwide. That is a different issue than PAHPA. And by the way, most of the patients do have coverage. Yes, there is an occasional who doesn't. But theoretically, Medicare Part D provides coverage for most of those cancer drugs.

The CHAIR. Occasionally, a few who have no coverage. Is that what you said?

Senator CASSIDY. Well, if the Affordable Care Act was successful——

The CHAIR. I am not here to defend the Affordable Care Act.

Senator CASSIDY. Well—obviously, we are way off field from PAHPA.

The CHAIR. All right, that is fine. We are, but that is all right, we have three witnesses here. Late afternoon. We are having an intellectual exercise here. All right, but with that, I think we both have to catch planes.

I want to thank you all for the work you are doing and thank you very much for being with us. And here is my bureaucratic thing here. For any Senators who wish to ask additional questions, questions for the record will be doing 10 business days on May 18th at 5.00 p.m..

Finally, I ask unanimous consent to enter into the record six statements from stakeholder groups outlining their priorities for the Pandemic and all Hazards Preparedness Act.

[The following information can be found on pages 97-121 in Additional Material:]

The CHAIR. Committee stands adjourned. Thank you very, very much.

ADDITIONAL MATERIAL

AMERICAN AMBULANCE ASSOCIATION,
WASHINGTON, DC 20090,
March 28, 2023.

Senator BERNIE SANDERS, Chairman,
Senator BILL CASSIDY, Ranking Member,
Senator BOB CASEY,
Senator MITT ROMNEY,
U.S. Senate Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

DEAR CHAIR SANDERS, RANKING MEMBER CASSIDY, SENATOR CASEY, AND SENATOR ROMNEY:

I am writing on behalf of the American Ambulance Association (AAA) to provide comments on policies the Committee should consider during the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

The members of the AAA provide mobile health care services to more than 75 percent of Americans. These essential mobile health care services include the local operation of the 9–1–1 emergency medical services (EMS) system, as well as both emergent and non-emergency interfacility care transition ambulance services and transportation. Often ground ambulance service organizations are the first medical professionals to interact with individuals in need of a health care encounter. These organizations also serve as the health care safety net for many small communities, especially those located in rural areas where other providers and suppliers have reduced their hours of operation or left the community altogether. As such, these organizations play a critical and unique role in the country's health care infrastructure.

Ground ambulance services are essential to our nation's emergency medical response system, whether they are needed for a pandemic, natural disaster, or ter-

rorist attack. The country's EMS system requires Federal support to ensure the availability of a well-trained workforce to provide these ground ambulance services. Ground ambulance services are also essential to protecting patient access to the right level of facility-based treatment options.

I. Support for Jurisdictional Preparedness and Response Capacity: Hospital Preparedness Program / ASPR activities financed through the general HHP budget

The AAA supports continued funding for the Hospital Preparedness Program (HPP). Our members have been working closely with the Assistant Secretary for Planning and Evaluation (ASPR) to find ways to direct some of the currently allocated HPP dollars to support ground ambulance services, particularly to address the workforce crisis and support expanded recruitment and training for emergency medical technicians (EMTs) and paramedics. During these discussions, it has become clear that more direct language authorizing the use of a specified portion of the HPP funds to support non-governmental and governmental ground ambulance services would allow ASPR to tackle this issue in a timelier manner.

Ground ambulance service organizations are facing crippling staffing challenges that threaten the provision of crucial emergency healthcare services at a time of maximum need. As we face a pandemic that waxes and wanes but does not end, our 9–1–1 infrastructure remains at risk due to these severe workforce shortages. The 2022 Ambulance Employee Workforce Turnover Study by the American Ambulance Association (AAA) and Newton 360—the most sweeping survey of its kind involving nearly 20,000 employees working at 258 EMS organizations—found that overall turnover among paramedics and EMTs ranges from 20 to 30 percent annually with organizations on average having 30 percent of their paramedic positions open and 29 percent of their EMT positions.

The Congress and the President recognized the crisis and the fiscal year 2023 Consolidated Appropriations called on ASRP to address this shortage by implementing a grant program to support non-governmental and governmental ground ambulance suppliers and providers through the HPP to address emergency medical services preparedness and response in light of the workforce shortage. While this language is helpful, the AAA recognizes that authorizing authority would provide a more sustainable approach to support an EMS workforce grant program.

Such a program would be consistent with the goals of ASRP. The fiscal year 2024 HHS Budget in Brief highlights to goal of making "transformative investments in pandemic preparedness and biodefense across HHS public health agencies to enable an agile, coordinated, and comprehensive public health response to future threats and protect American lives, families, and the economy." (HHS Budget in Brief 142). Ground ambulance medical services are an essential part of this preparedness and response goal.

Our nation's ground ambulance service organizations, EMTs, and paramedics need Congress to address the EMS workforce challenges facing these front-line health care workers by including direct authority to use $50 million of the HPP funding to establish an EMS workforce grant program to address the crippling EMS workforce shortage, including in underserved, rural, and tribal areas and/or address health disparities related to accessing prehospital ground ambulance healthcare services, including critical care transport. The grants would be available to governmental and non-governmental EMS organizations to support the recruitment and training of emergency medical technicians and paramedics. The program would emphasize ensuring a well-trained and adequate ground ambulance services workforce in underserved, rural, and tribal areas and/or addressing health disparities related to accessing prehospital ground ambulance health care services.

This program is critically important to supporting the non-governmental and governmental ground ambulance service organizations that are the backbone of the country's first emergency medical response system. The dollars would be used to provide grants directly to non-governmental and governmental ground ambulance service organizations to support training and retention programs, such as paying for initial training; providing tuition for community colleges EMT/ paramedic training courses; paying for required continuing education courses; supporting costs related to licensure and certification; and supporting individuals in underserved areas with transportation, child care, or similar services to promote accessing training.

II. Gaps in Current Activities and Capabilities: Gaps in HHS' capabilities and what activities or authorities needed to fulfill intent of PAHPA and related laws

The most significant gap in PAHPA and HHS on preparedness and readiness activities is the exclusion of non-governmental entities from many of the Federal programs targeted to first responders and EMS. This oversight results in more than one-third of local communities and their citizens not being able to access or benefit from the programs and funding that Congress intended be provided to support them. The AAA requests that the Committee recognize the decisionmaking authority to rely on non-governmental ground ambulance service organizations and provide access to programs that are currently available to governmental organizations.

During the pandemic, non-governmental local community ground ambulance organizations were not permitted to apply for or participant in many of the Federal grant programs in place during the pandemic. As a result, these programs fell short of the goal of supporting preparedness and response activities at the local level.

The distinction between governmental and non-governmental appears to be based on outdated assumptions that first responders are only governmental or not-for-profit entities. This assumption ignores the decisions of State and local governments to contract with private ground ambulance service providers and suppliers to provide 911 or equivalent services. The Federal Government should respect these local decisions and support all ground ambulance services as first-responders and EMS.

One example of this problem is the FEMA public assistance grant program that reimbursed "first responders" for PPE and other expenses related to the response to COVID–19. When non-governmental (including not-for-profit) emergency ambulance service organizations sought direct reimbursement under the program, they were turned away. This differential treatment impacts communities across the United States, including those in Arkansas, California, Colorado, Florida, Georgia, Indiana, Louisiana, Massachusetts, Mississippi, Nevada, New York, Oregon, Texas, and Wisconsin, among others.

Appendix A includes list of some of the program the AAA has identified that should reviewed and updated to include non-governmental entities.

The solution to this problem is to use the more inclusive language that the Congress adopted in the Homeland Security Act of 2002 (6 U.S.C. § 101) on non-governmental and governmental entities within the definition of "emergency response providers." This language provides access to all ground ambulance services and the communities they serve to funding when available to support preparedness and response activities.

III. Conclusion

On behalf of ground ambulance service organizations of the AAA, I want to thank you for the opportunity to provide comments on the PAHPA. We look forward to working with your team as you continue develop these policies.

Sincerely,

RANDY STROZYK,
President.

Appendix A: Grant Program for Review

Assistance to Firefighters Grant (AFG): *http://www.firegrantsupport.com/afg/faq/08/faq—emer.aspx*

The grant program prohibits "for-profit" organizations from applying for grant funding.

Staffing for Adequate Fire and Emergency Response (SAFER):

Retrieved from *http://www.firegrantsupport.com/safer/faq/08/faq—elig.aspx*

Only fire departments and volunteer firefighter interest organizations are eligible for SAFER grants.

Federal Disaster Relief Funds

$45B to reimburse activities such as medical response, procurement of PPE National Guard deployment, coordination of logistics, implementation of safety measures, and provision of community services. According to FEMA, these funds will cover overtime and backfill costs; the costs of supplies, such as disinfectants, medical supplies and PPE; and apparatus usage. (The Federal Government will cover

75 percent of these costs.) NAEMT recommends FEMA's new sheet on *FEMA's Simplified Public Assistance Application*. In addition, you should consult with their State emergency managers to begin the process of being reimbursed. Eligible to apply: Public and some non-profit services.

Emergency Management Baseline Assessment Grant Program

The Emergency Management Baseline Assessment Grant (EMBAG) program provides non-disaster funding to support developing, maintaining, and revising voluntary national-level standards and peer-review assessment processes for emergency management and using these standards and processes to assess state, local, tribal, and territorial emergency management programs and professionals.

Nonprofit Security Grant Program

The Nonprofit Security Grant Program (NSGP) provides funding support for target hardening and other physical security enhancements and activities to nonprofit organizations that are at high risk of terrorist attack.

Siren Act

The Siren Act supports public and non-profit rural EMS agencies through grants to train and recruit staff, fund continuing education, and purchase equipment and supplies from naloxone and first aid kits to power stretchers or new ambulances.

ASPR—National Bioterrorism Hospital Preparedness Program

Eligibility requirements exclude for-profit private EMS.

Public Safety Officers Death Benefit

Public Safety Officers' Benefits Improvements Act of 2011 (S. 1696). Added nonprofits (but still excluded for profits) in the Public Safety Officers' Benefit (PSOB) program. This legislation extended the Federal death benefit coverage to paramedics and emergency medical technicians (EMTs) who work for a private non-profit emergency medical services (EMS) agency and die in the line of duty and thank you for including the language of the Dale Long Emergency Medical Service Providers Protection Act (S. 385) in this new bill. Congress established the Public Safety Officer Benefit program to provide assistance to the survivors of police officers, firefighters and paramedics and emergency medical technicians in the event of their death in the line of duty. The benefit, however, currently only applies to those public safety officers employed by a Federal, state, or local government entity and non-profits.

Urban Area Security Initiative (UASI) & Metropolitan Medical Response System (MMRS)

Retrieved from: *http://www.iowahomelandsecurity.org/Portals/0/CountyCoordinators/Grants/FFY09HSGPguida nce.pdf*

Inclusion of Emergency Medical Services (EMS) Providers

DHS requires State and local governments to include emergency medical services (EMS) providers in their State and Urban Area homeland security plans. In accordance with this requirement, and as States, territories, localities, and tribes complete their application materials for the fiscal year 2009 HSGP, DHS reminds our homeland security partners of the importance for proactive inclusion of various State, regional, and local response disciplines who have important roles and responsibilities in prevention, deterrence, protection, and response activities. Inclusion should take place with respect to planning, organization, equipment, training, and exercise efforts. Response disciplines include, but are not limited to: governmental and nongovernmental emergency medical, firefighting, and law enforcement services; public health; hospitals; emergency management; hazardous materials; public safety communications; public works; and governmental leadership and administration personnel.

Interoperable Communications Grants

Retrieved from: *http://www.fema.gov/government/grant/iecgp/index.shtm*

Eligibility and Funding: The Governor of each State and territory has designated a State Administrative Agency (SAA), which can apply for and administer the funds under IECGP. The SAA is the only agency eligible to apply for IECGP funds.

Technology Transfer Program (CEDAP)

Retrieved from: *http://ojp.usdoj.gov/odp/docs/cedap—factsheet—2008.pdf*

Eligibility: Eligible applicants include law enforcement agencies, fire, and other emergency responders who demonstrate that the equipment will be used to improve their ability and capacity to respond to a major critical incident or work with other first responders. Awardees must not have received technology funding under the Urban Areas Security Initiative, or the Assistance to Firefighters Grants program since Oct. 1, 2006. Organizations must submit applications through the Responder Knowledge Base (RKB) website at ***www.rkb.us.***

AMERICAN PHARMACISTS ASSOCIATION,
WASHINGTON, DC 20037,
May 4, 2023.

Senator BERNIE SANDERS, Chairman,
Senator BILL CASSIDY, Ranking Member,
U.S. Senate Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

DEAR CHAIR SANDERS AND RANKING MEMBER CASSIDY:

APhA appreciates the opportunity to comment on the Senate Health, Education, Labor, and Pensions hearing on "Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All Hazards Preparedness Act (PAHPA)."

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists and pharmacy personnel in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

During the COVID–19 public health emergency (PHE), pharmacists have demonstrated the ability to significantly expand access and equity to health care and will continue to do so if regulatory and statutory barriers are removed. The pandemic has demonstrated how essential and accessible pharmacists are in the United States. While many communities across the country do not have access to a primary care provider, more than 90 percent of Americans live within 5 miles of a pharmacist. A strong body of evidence has shown that including pharmacists on interprofessional patient care teams with physicians, nurses, and other health care providers produces better health outcomes and cost savings. As a result, lifting barriers to access is essential as we continue to look toward ways to improve patient access to critical health care services.

During the most recent pandemic, pharmacists and pharmacies were able to test, treat, and immunize patients for conditions ranging from COVID–19 to the flu. The flexibilities offered by the Federal Government made access to health care easier for pharmacists to provide care to patients during the COVID–19 PHE. The problem is many of these flexibilities and authorities are not considered permanent and further action is needed to expand access to pharmacist-provided services. As you look to reauthorize programs such as PAHPA, we ask that you take into consideration these flexibilities and continue to remove barriers that would prevent pharmacists from providing these essential services as part of the health care team.

To illustrate this urgency, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra recently lengthened the PREP Act authority for pharmacists and pharmacy technicians to administer COVID–19 vaccines and tests, along with flu vaccines until December 2024. Without this extension that authority would have expired on May 11, 2023 when the COVID–19 health emergency officially ends.

The extension of authority and the Secretary's recognition of pharmacist services is a critical first step in expanding access to patient care, but the Federal Government should do more to ensure this authority will remain as pharmacists are clearly relied upon by the Federal Government as a vital part of our nation's public health infrastructure.

One manner in which we can make this authority permanent is by enacting legislation such as H.R. 1770 the Equitable Community Access to Pharmacists Services

Act (ECAPS), led by Representatives Adrian Smith (R-NE), Brad Schneider (D-IL), Larry Bucshon (R-IN), and Doris Matsui (D-CA). This legislation would provide for reimbursement through Medicare Part B for pharmacist's services including the testing of COVID–19, flu, RSV, and strep; treatment of COVID–19, flu, and strep; and the vaccination of COVID–19 and flu.

Despite the fact that many states and Medicaid programs are turning to pharmacists to increase access to health care, Medicare Part B does not cover many of the impactful and valuable patient care services pharmacists can provide. As proven during the COVID–19 pandemic, pharmacists are an underutilized and accessible health care resource who can positively affect beneficiaries' care and the entire Medicare program.

By recognizing pharmacists as providers under Medicare Part B, H.R. 1770 would enable Medicare patients to better access health care through state-licensed pharmacists practicing according to their own state's scope of practice. Helping patients receive the care they need, when they need it, is a common sense and bipartisan solution that will improve outcomes and reduce overall costs.

Public health interventions by pharmacists and teammates averted 1 million deaths, 8 million hospitalizations, and $450 billion in health care costs. Patients have come to expect that they can access these vital health care services at their local pharmacy, particularly *in underserved communities,* where the neighborhood pharmacy may be the only health care provider for miles.

Congress could ensure increased patient access to health care by enacting legislation such as ECAPS and by making permanent some of the temporary authorities mentioned in the PREP Act.

Congress needs to act immediately to make these temporary authorizations, whether authorized by the PREP Act or Federal PHE, permanent to ensure patients will be able to receive the health care services they need at pharmacies across the country during the current and future PHEs.

Accordingly, APhA urges Congress and the Committee to use its authority to pass legislation in PAHPA to make permanent:

- Pharmacists' ability to order, authorize, test, treat, and administer immunizations and therapeutics against infectious diseases;
- Removal of operational barriers that address workforce and workflow issues that previously prevented pharmacists from engaging in patient care; and
- Allowing license portability across State lines, so pharmacists can continue to provide care wherever there are needs across the country.

APhA appreciates the opportunity to offer these comments and are grateful for the Committee's leadership on this issue. Should you have any questions, please contact Doug Huynh, JD, APhA Director of congressional Affairs *(dhuynh@aphanet,org)*.

Sincerely,

MICHAEL BAXTER,
Acting Head of Government Affairs.

AMERICAN PHARMACISTS ASSOCIATION,
WASHINGTON, DC 20037,
May 4, 2023.

Senator BERNIE SANDERS, Chairman,
Senator BILL CASSIDY, Ranking Member,
U.S. Senate Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

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Sincerely,

MICHAEL BAXTER,
Acting Head of Government Affairs.

CHILDREN'S HOSPITAL ASSOCIATION STATEMENT FOR THE RECORD
WASHINGTON, DC 20005
May 4, 2023

Senator BERNIE SANDERS, Chairman,
Senator BILL CASSIDY, Ranking Member,
U.S. Senate Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

On behalf of the nation's children's hospitals and the children and families we serve, thank you for holding this hearing, "Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA)." We applaud your efforts to ensure the U.S. is better prepared to respond to a future pandemic or other public health emergency (PHE) and encourage you to prioritize the distinct needs of children, who represent some 25 percent of the total U.S. population. Ensuring that the unique physical and mental health needs of children are met during a pandemic or other PHE must be a major part of Congress' work in the upcoming PAHPA reauthorization. We welcome the opportunity to provide our input on how best to meet the unique physical, mental, developmental and social needs of children in a pandemic and disaster response framework as you work on this important legislation.

Over the last few years, children's hospitals have experienced unprecedented pediatric volumes driven by a series of PHEs, including a substantial increase in childhood respiratory illnesses like respiratory syncytial virus (RSV) and the ongoing surge in mental health visits. The challenges that confronted children's hospitals and their nimbleness to respond demonstrate how critical it is that the nation's pandemic preparedness system can appropriately account for differences between the way physical and mental health care delivery and support systems are structured for children compared with adults.

Pediatric-specific Needs in an Emergency Preparedness and Response System

Children are not little adults, and their physical and mental health care needs, the delivery system to meet those needs and their support systems (e.g., schools, childcare settings, etc.) are different from those of adults. Children are constantly growing and developing, and child-appropriate care will support that healthy development. Disruptions in their care, trauma, social isolation, financial insecurity, food and housing insecurity, and grief associated with a natural disaster or pandemic can have a significant negative impact on children's mental and physical health and their long-term well-being. This is especially true for children and families in underserved, under-resourced, and racial and ethnic minority communities. Children are also dependent on their caregivers, and the needs of their parent or guardian must be considered in a pediatric care framework.

Furthermore, pediatric care typically requires extra time, monitoring, specialized medications and equipment, and specially trained health care providers who are compassionate and understand kids of all ages and from all backgrounds. Children's hospitals, unlike adult-focused medical facilities, are increasingly the only places in their State and region with the breadth of pediatric specialists and subspecialists, the pediatric-appropriate medical equipment, and other resources required to treat children, particularly those with rare and complex clinical conditions. Given the re-

gionalization of pediatric specialty care, children's hospitals' critical care and "surge" capacity for children is limited during a widespread PHE, such as a pandemic or natural disaster, adding a significant level of complexity to the nation's capacity to meet children's needs.

Targeted pediatric resources and a national pediatric framework that are not dependent on national emergency declarations are needed to meet current and future preparedness and response system challenges. During the recent surges, Federal emergency declarations gave children's hospitals certain flexibilities that provided financial and legal protections to adapt service delivery models to meet immediate needs. However, once those protections expire it is not clear how children's hospitals will maintain that vital flexibility that allows rapid response to a public health threat. Preparedness and response efforts must strengthen pediatric capacity, address pediatric workforce shortages and allow for the triage/consolidation of pediatric patients to centers best designed for their care.

Congressional Action Needed

A key component of the future of pediatric care will be the development of a national disaster response infrastructure that adapts to the changing landscape of health emergencies while remaining focused on the goal of providing comprehensive and high-quality services to deliver optimal child health. Solutions must be pediatric-specific. Several key opportunities within PAHPA to address pediatric pandemic and disaster preparedness and relief strategies are highlighted below.

Strengthen pediatric initiatives within the National Health Security Strategy (NHSS). We urge Congress to ensure that the NHSS builds on, and strengthens, existing pediatric-focused initiatives at the Assistant Secretary for Preparedness and Response (ASPR) and the Health Resources and Services Administration (HRSA), as well as the National Advisory Committee on Children and Disasters (NACCD). In particular, pandemic and disaster relief preparedness strategies must include coordinated pediatric care structures and plans that address the operational capacity of the nation's medical facilities to meet children's unique physical and mental health needs. Pediatric experts should be included in all short-and long-range coordinated care planning efforts.

Bolster the National Advisory Committee on Children and Disasters (NACCD) and the Children's Preparedness Unit (CPU) The NACCD is instrumental to ensuring that the national pandemic and emergency response infrastructure meets the unique needs of children, in a developmentally and socially appropriate manner, across their entire spectrum of their physical, mental, emotional and behavioral well-being. We urge Congress to support bolstering the NACCD and the committee's ability to expand its membership and scope of recommendations of high-impact issues for subsequent reports, such as addressing pediatric workforce issues, supply shortages, and products for the Strategic National Stockpile (SNS). We recommend that ASPR be designated the appropriate funding and authority to fully implement NACCD recommendations and provide adequate resources in a timely manner. These efforts and others throughout government must be aligned, coordinated, strengthened and adequately funded to support a shared pediatric mission and framework.

The CPU is another important component of the emergency response framework. It is critical that Congress empower the CPU to fulfill its mission and be allowed to develop and implement a nimble and appropriate public health response to the ongoing, and any future, pandemics while also having a focus on pediatric preparedness. It is particularly important that CPU be required to work with its partners to help disseminate and amplify key preparedness messages and ensure that children with special health care needs are provided special support services, including medicine, medical equipment and mental health support.

Target Hospital Preparedness Program (HPP) resources to meet pediatric needs. The HPP must target resources for children's hospitals and children's health care systems to plan for and respond to pediatric needs in large-scale emergencies and disasters. The regionalization of pediatric specialty care adds a significant level of complexity to the nation's capacity to meet children's needs. It is imperative that the nation's children's hospitals' critical care capacity is ensured and that communities without a children's hospital have operational capacity to meet children's basic needs.

Immediate targeted HPP support is needed to strengthen pediatric capacity, address pediatric workforce shortages and allow for the triage/consolidation of pediatric patients to centers best designed for their care. The recent surge in RSV, influenza, and COVID–19 cases, the so-called "Tripledemic," stretched pediatric critical

care resources to the breaking point. During the RSV surge, children's hospitals experienced the need for trained pediatric professionals, as well as challenges accessing critically necessary supplies and medications, such as child-sized ventilators, smaller sized, cuffed endotracheal tubes used for advanced airway management and emergent mechanical ventilatory support, as well as smaller doses of albuterol. Systems and plans must be in place to facilitate a streamlined and rapid response that is tailored to children's unique health care needs so specialized pediatric supplies and medications are available in a timely manner.

Therefore, Congress should direct ASPR to develop and disseminate "pediatric toolkits" to non-pediatric hospitals that include equipment, training modules, as well as dosages and usages of therapeutics, to successfully handle surge capacity and any transferred child-patient. All medical facilities should be required to have policies and procedures for the provision of nutrition (e.g., formula), cribs and other appropriate sleeping accommodations, diapers, etc. for infants and toddlers. They also should be equipped to provide accommodations for the families of child patients during pandemic and disaster situations. Furthermore, non-pediatric hospitals should have pediatric interfacility transfer agreements and interoperability capabilities to allow for electronic access to specialized pediatric clinical and mental health care providers for remote consultations.

The HPP must also include mechanisms to allow for the continuation of key pediatric services in the community. These include immunization programs, services for children with special health care needs, child nutrition programs, newborn screening, children's mental health services and other services for at-risk children.

Equip the SNS with pediatric supplies and allocate them to all medical facilities. We urge Congress to require the SNS to include emergency medications in age-appropriate delivery formulations, equipment and related supplies that meet children's needs. The stockpile's distribution system must include a communication structure capable of relaying information about the availability of specific supplies to ensure the appropriate allocation of necessary pediatric supplies to all medical facilities. At a minimum, the SNS should be directed to equip all emergency departments with a basic kit that can be adapted for use with children, and includes infant formula, diapers, safe sleeping facilities and other necessities for the care of infants and toddlers.

Strengthen pediatric-specific readiness within Public Health Emergency Medical Countermeasures Enterprises. For medical countermeasures (MCMs) to meet the needs of children, there must be a strong focus on research, development, procurement, strategy and guidance that can ensure timely access to sufficient pediatric-appropriate equipment, medications and supplies and a quick response to shortages. Pediatric care requires specialized medications, therapeutics, and equipment. For example, many pediatric drugs come in specific formulations that support safer dosing and with practical methods for appropriate delivery for growing children, such as altered concentrations or formats. Pediatric-specific supplies are created with children's sensitive skin, growing bodies, and smaller size in mind.

Drug and supply shortages are particularly challenging in pediatric health care. Given the specific requirements and considerations for children, pediatric and drug products can go into shortage more quickly than adult products. Once in shortage, it can take longer for manufacturers to respond and bring adequate product back to market.

Congress can help ensure that children have access to needed medications and other medical supplies during a PHE in several ways. First, Congress should require resources to be directed to research pediatric dosing and formulations for MCMs that are already approved for adults. Congress should also require properly dosed pediatric medications and delivery mechanisms to be available and ready for rapid deployment. Furthermore, relevant Federal agencies, such as the CDC, ASPR and FDA, should be authorized to develop a process that allows for the advance approval—through the emergency use authorization process—of off-label use of medical countermeasures for children before the declaration of a PHE. Advanced approval or protocols should also be developed that allow for the importation of product in the event of a catastrophic supply event, such as occurred during the recent shortage of infant formula.

It is also critical that Congress extend the requirement for device manufacturers to notify the FDA of significant interruptions and discontinuances of critical devices outside of a PHE. We support FDA authorities to require manufacturers to develop and share risk management plans, particularly for sole-source suppliers, and identify alternate suppliers and manufacturing sites.

Invest in child-focused mental health systems. We urge Congress to develop a strategic plan to specifically address the mental health needs of children and youth, including a strategy to support continued access to, and availability of, mental health and substance use disorder services during PHEs. The effects of the COVID–19 pandemic on children's and teens' mental health painfully illustrate the importance of strengthening investments in child-focused mental health systems of care now to ensure that kids' needs will be adequately addressed when we face another pandemic or PHE. Further, we know that children who live through an emergency, such as COVID–19, have a greater risk of having traumatic experiences, and when families struggle to find mental health care, kids are at greater risk for experiencing long-term impacts on their health and well-being.

Pandemic and disaster preparedness efforts throughout government must be aligned, coordinated, strengthened and adequately funded to support a shared pediatric mission and framework. That framework must ensure the broader capacity of the nation's medical facilities to meet children's physical and mental health needs—as well as those of their entire caregiving/support system—through the delineation of appropriate staffing, specialized equipment, training and other child-centric resources. Thank you again for your commitment to ensuring the needs of children are met during a future pandemic or disaster. Children's hospitals stand ready to partner with you to advance policies that will make measurable improvements in the lives of our nation's children. Children need your help now.

PREMIER INC.,
WASHINGTON, DC,
May 4, 2023.

Senator BERNIE SANDERS, Chairman,
Senator BILL CASSIDY, Ranking Member,
U.S. Senate Committee on Health, Education, Labor, and Pensions,
Washington, DC 20510.

Premier Inc. appreciates the opportunity to submit a statement for the record on the Senate Health, Education, Labor, and Pension Committee (HELP) hearing titled "Preparing for the Next Public Health Emergency: Reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA)" on May 4, 2023. Premier applauds Chair Sanders and Ranking Member Cassidy for holding this hearing. It is vital that we as a nation consider lessons learned during the COVID–19 response and improve the nation's public health infrastructure and preparedness to respond to the next public health threat. Premier further appreciates the thoughtful approach outlined under the HELP Committee leadership to seek stakeholder input as part of the process of developing consensus policy proposals and the acknowledgement that collaboration across the public and private sectors is essential to ensuring the nation's readiness and ability to proactively address future public health threats. Premier previously submitted detailed comments to the Committee's request for information on PAHPA reauthorization.

The existence of PAHPA during the COVID–19 pandemic was instrumental in supporting the nation's rapid response. As a nation we would have been in a much worse situation had PAHPA's infrastructure not been in place. However, lessons learned during the COVID–19 pandemic, and subsequently the Mpox public health emergency, demonstrate that there are opportunities to strengthen PAHPA to be better responsive to public health needs during unprecedented times.

Specifically, Premier recommends revisions to PAHPA to mitigate national security challenges by:

- Modernizing the country's data infrastructure;
- Strengthening the Strategic National Stockpile;
- Incentivizing domestic manufacturing;
- Mitigating drug and device shortages;
- Maintaining supply chain integrity;
- Leveraging technology to prevent infections in nursing homes;
- Finding sustainable solutions to environmental issues impacting patient care;
- Identifying and bundling waivers and flexibilities for expeditious implementation during a future public health emergency;
- Broadening and better organizing lab networks;

- Ensuring emergency efforts account for the needs of disabled individuals and their families; and
- Holding manufacturers accountable for the cybersecurity of their devices.

I. Background on Premier Inc.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,400 U.S. hospitals and health systems and approximately 250,000 continuum of care providers to transform healthcare. Premier's sophisticated technology systems contain robust data from nearly half of U.S. hospitals and 200,000 ambulatory clinicians. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services.

Premier is also a leader in identifying, fulfilling and closing gaps in diverse sources for critical product categories—working directly with manufacturers to incentivize new manufacturers to enter the marketplace—a strategy that proved to be critical as the country looked to increase domestic manufacturing and identify new sources of critical supplies. Premier also identified and solved a major gap for continuum of care providers to obtain PPE and created an e-commerce platform to ensure continuum of care providers could access critical medical supplies.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

I. Assistant Secretary for Preparedness and Response (ASPR)

Since the onset of the COVID–19 pandemic, the Assistant Secretary for Preparedness and Response was elevated to an operating division within HHS in 2022 and is now known as the Administration for Strategic Preparedness and Response (ASPR). With the elevation to an operating division, it was noted that ASPR "leads the nation's medical and public health preparedness for, response to, and recovery from disasters and other public health emergencies." Seemingly, this indicated the ASPR would take point on future pandemic response and alleviate much of the confusion that existed during the early days of the COVID-19 pandemic regarding which Federal agency was leading response efforts.

However, shortly after ASPR's elevation a public health emergency for Mpox was declared. While many anticipated that ASPR would be named to lead response efforts given its newly elevated role and mission, it surprised many when officials from FEMA and CDC were named as the primary and secondary leads for the Mpox response.

Furthermore, the CAA of 2023 establishes within the Executive Office of the President an Office of Pandemic Preparedness and Response Policy creating further confusion regarding the role of this new office versus ASPR.

Therefore, **Premier recommends that PAHPA reauthorization help clarify the roles and responsibilities of the various Federal agencies during a pandemic response and articulate which agency, or agencies, should lead response efforts during a pandemic**.

II. National Health Security Strategy (NHSS)

One of the three primary objectives of the NHSS is to leverage the capabilities of the private sector by:

- Developing and sustaining robust public-private partnerships for MCM development and production;
- Fostering the creation of a resilient medical product supply chain; and
- Incentivizing and sustaining private sector healthcare surge capacity for large-scale incidents.

Premier's comments in this section focus on creating a sustainable medical product supply chain.

Developing a Real-Time Inventory Data Management System

A major failure during the pandemic was the lack of downstream visibility into the exact quantities of critical medical supplies and drugs on US soil at any given time. As a result, there was a surplus of products in many parts of the Nation, for example, while communities in the New York City area were operating in crisis mode and leveraging household products such as garbage bags to protect frontline workers. Moreover, because of the lack of understanding of what product availability risks existed, there was excessive purchasing of products, the emergence of unscrupulous and fraudulent vendors, and hoarding, which created shortages for others.

In response to the urgent need to understand product availability and risks, the Federal Government stood up a health information collection process to determine these factors across the supply chain. However, this system was antiquated and created substantial additional work for healthcare providers, with hospitals being asked to report inventory on hand via the equivalent of Excel files. Furthermore, the system proved to be of little use as inconsistent data nomenclature meant hospitals were reporting "boxes" and "units" differently from one another, and in many cases, many hospitals opted to cease reporting inventory levels due to the administrative burden and fear that available products would be confiscated by the government.

An August 2021 GAO report reviewed this system, pointing to the inadequate and duplicative hospital reporting and data collection system used during the pandemic.[1] The siloed system burdened many public health authorities, practicing physicians and hospitals with time-consuming manual work all the while failing to provide early warnings of supply shortages, putting communities and patients at risk. Compounding these challenges and further splintering the nation's approach was the multitude of data reporting requests from numerous state, local, and private entities, which placed a significant burden on health systems and rendered data that was not real-time, standardized, reliable, actionable or usable for robust analytics.

The GAO report highlighted the limitations and inefficiencies of the system put in place during the pandemic and the need for a better approach to understand the health systems' capacity to provide care and to inform the allocation of resources. Specifically:

- The GAO examined the new data ecosystem HHS launched during the pandemic—HHS Protect—designed to collect and share national and state-level COVID–19 data on hospital capacity and supply of ventilators, PPE and the availability of COVID–19 therapies.
- The GAO found that hospitals' existing workflows often did not align with HHS Protect, requiring them to either create new data workflows or enter and report data manually, which was done via Excel worksheets. Similarly, the way HHS asked hospitals to report on PPE supplies was not consistent with how these data are collected and maintained by hospital systems.
- The GAO observed that "accurate, complete, consistent and timely data are essential for monitoring trends at the State and regional level, and for making informed comparisons between these areas and assessing the effect of public health response measures." This is a need that will persist beyond the pandemic, GAO noted.
- Instead, the nation's incomplete, inconsistent and opaque line of sight on the quantity, location, and production of critical PPE, drugs and other medical supplies left healthcare providers and government officials largely in the dark as they sought to locate needed products in the supply chain.

In addition, a February 2021 report from the Business Executives for National Security (BENS), a group chaired by Senators Hassan and Cassidy, concluded the following:

> *"Shared awareness of fast-developing crisis metrics is indispensable to an informed, effective national response. Yet, stakeholders described struggling to gain a common operating picture during the COVID–19 response. Reported obstacles included minimal data sharing and the lack of an established method to submit requests for resources and track responses in real-time.*

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[1] GAO Report: COVID–19 HHS's Collection of Hospital Capacity Data. August 2021. Available at: *https://www.gao.gov/assets/gao–21–600.pdf*

Compounding this problem, the national emergency response enterprise is characterized by a patchwork of antiquated, non-standard, and non-interoperable IT systems, further inhibiting coordination. Of note, the after-action report on the Crimson Contagion joint exercise expressly noted that HHS' and DHS/FEMA's use of disparate information management systems "hampered their ability to establish and maintain a national common operating picture." Developing interoperable systems, technologies, and capabilities to facilitate robust, resilient communication and data sharing between all Federal, state, and local emergency operations centers will be critical to achieving this goal."[2]

Furthermore, in recent conversations with ASPR, it was noted that only about 50 percent of State stockpiles are currently reporting into the Supply Chain Control Tower under HHS Protect. It was also noted that a major blind spot continues to be hospital inventory.

A key component to an end-to-end supply chain solution is an on-call, nimble automated data collection infrastructure that the Nation can call upon in any future crises similar in magnitude to COVID–19. Rather than standing up an inadequate and duplicative system as we experienced during the pandemic, **the Nation needs a system that can track critical product availability—from the manufacturer, to distribution, to State and national stockpiles, to hospital inventory**. This system would exist behind the scenes and be ready to be "turned on" in a moment's notice. It would provide visibility of supplies in hospital inventories with detailed information that would enable accurate and intelligent decisions about supply allocation and needs at the local, state, regional and national levels. This information would inform dynamic and appropriate product allocation and distribution strategies, minimize hoarding, and allow for powerful and accurate prediction, enabling the Nation to manage supplies during a crisis.

This data infrastructure would also strengthen the Strategic National Stockpile (SNS) by:

- Creating visibility into inventory via a standardized data nomenclature and automated acquisition of data across the SNS, manufacturers, distributors, and within healthcare systems that is tied to real-time resource demand data.
- Providing inventory monitoring and advanced alerts of critical supply inventory levels warranting movement of product from the SNS to points of care, ramping up production of certain supplies, etc.

To accomplish these goals, policy changes are needed to provide data rights to create predictive algorithms and to acquire and utilize data for surveillance. In addition, incentives must be established to encourage reporting such as providing two-way visibility into the medical supply chain to reporting entities.

Consistent with the findings of the GAO report and Premier's recommendations, the bipartisan *Medical and Health Stockpile Accountability Act of 2022 (H.R. 6520, 117th Congress)* would require the HHS Secretary to establish an automated supply chain tracking application that provides near real-time insight into critical supplies available in the SNS and medical and health supply inventories in communities across the country. Development of The Medical and Health Stockpile Accountability Act considered stakeholder feedback from the hospital, distributor, and supplier communities as well as several Federal agencies.

Specifically, the legislation would:

- Establish a system for internal tracking of supplies within the SNS during a public health emergency, natural disaster, or other unforeseen circumstance that impacts the healthcare supply chain. Tracked supplies would include only those considered critical to addressing the emergency.
- Allow for data access during an emergency by the HHS Secretary to the medical and health stockpiles of State, local, and private partners including suppliers, distributors, and hospitals that choose to participate.
- To incentivize participation, authorize $250 million across fiscal year 2022–27 for the HHS Secretary to assist State, local, and private partners in setting up automated reporting systems—creating efficiencies and

[2] Findings and Recommendations of the BENS Commission on the National Response Enterprise: A CALL TO ACTION. February 2021. Available at: *https://www.bens.org/file/national-response-enterprise/CNRE-Report-February–2021.pdf*

easing burden associated with manual reporting during a future emergency.

- Ensure transparent and efficient mechanisms for health care entities, including hospitals, to voluntarily report data in an emergency, including detailed data regarding all relevant supplies secured and available.
- Ensure that (1) HHS protects any data from hospitals, manufacturers and distributors shared through the application; and (2) that Federal data collection is leveraged for monitoring and dynamic allocation and will not be used to remove or re-allocate inventory from organizations.

Premier supports reintroduction of this legislation in the 118th Congress to help ensure that hospitals, doctors, nurses and others responding to health emergencies have the supplies they need when they need them to provide safe, effective care for patients and not be put in harm's way themselves. Armed with information from this inventory monitoring infrastructure, decisionmakers will be better able to plan and allocate PPE, syringes, and rapid testing kits, among other critical items. This will prevent shortfalls and hoarding, move products from the SNS and other stockpiles to points of care, or ramp up production.

Incentivizing Domestic Manufacturing

Regarding domestic manufacturing and reducing the dependence on overseas manufacturing, there are five major barriers that policy proposals must address. These barriers include: 1) capacity; 2) environmental regulations; 3) labor costs; 4) availability of raw materials; and 5) historical policy decisions that advantaged offshoring.

While Premier recognizes a need to incentivize domestic manufacturing, we also recognize a need to ensure global diversity in manufacturing. For example, moving all manufacturing onshore would create a similar overreliance on a single geographical region. Therefore, Premier recommends that there be at least three global suppliers of the final form, ancillary products and raw materials for critical medical supplies and drugs. Global suppliers should be from geographically diverse regions, including at least one domestic supplier.

To stimulate domestic manufacturing, Premier has thought critically about how to incentivize manufacturers to invest in domestic production while also ensuring that domestically manufactured goods are price competitive with globally sourced products. To that end, Premier recommends a two-part approach that leverages tax credits as a mechanism for achieving these goals.

Part I:

- A 30 percent tax incentive for investments to support the domestic manufacturing of critical medical supplies and drugs, including their raw materials. Examples of how the tax incentive could be applied include, but are not limited to:
  - Investments in advanced manufacturing equipment or machinery
  - Investments to repurpose existing abandoned facilities
  - Investments to build new facilities
  - Investments to expand existing facilities
  - Investments to relocate foreign facilities back to the U.S.
  - Investments to upgrade facilities to meet EPA requirements
  - Regulatory filing fees for new domestic entrants to the market (e.g. FDA, NIOSH, etc.)
- The tax incentive should be reevaluated in 5 years to determine its ongoing necessity and whether the incentive level can be lowered or eliminated.

Part II:

- A 10 percent tax credit on the income generated from the sale of domestically manufactured goods to reward manufacturers who have already invested in domestic manufacturing. This would also help lower the cost of goods manufactured domestically and make them price competitive with globally sourced products.
- To be prudent, companies found to be price gouging or selling counterfeit products by the Department of Justice, Federal Trade Commission, or other agency should not be eligible for the tax credit. Guardrails would

help ensure companies aren't artificially increasing their prices to take advantage of the tax credit from higher sales prices and support the integrity of the supply chain.

To truly create a long-term domestic manufacturing infrastructure that is sustainable, incentives for onshoring manufacturing must be coupled with committed purchasing volumes so new entrants to the market have a guaranteed sales channel. To accomplish this goal while cultivating global diversity, Premier recommends that government purchasers be required to contract for critical medical supplies and pharmaceuticals from a mixture of onshore, near-shore (such as Central and South American countries) and off-shore countries. Purchase thresholds based on a geographical region can help prioritize domestic manufacturers while ensuring global diversity and sustainability of the supply chain. In addition, longer-term contracts (at least 3 years in length) will help provide ongoing volume commitments and assurance for suppliers entering the marketplace.

Finally, Premier recommends that Congress consider incentives for healthcare providers to purchase domestically manufactured critical medical supplies and drugs through programs such as tax incentives, CMS bonus payments, etc. to create committed purchasing volume for domestic suppliers and offset higher acquisition costs. For example, CMS recently finalized a Premier-supported payment adjustment to compensate hospitals for the increased cost of domestically produced N95 masks, however, absent congressional action—the payment policy was implemented in a budget-neutral manner, impacting its ability to be applied broadly to additional domestically manufactured critical medical supplies. Therefore, **Premier recommends that Congress provide CMS with statutory authority to implement payment adjustments for domestically manufactured critical medical supplies and pharmaceuticals in a non-budget neutral manner**.

Finally, **to truly support domestic manufacturing, the FDA regulatory framework for approval must be adapted to expedite review of applications and inspections of manufacturing facilities for new domestic entrants**. As manufacturers seek to invest in onshoring the manufacturing of critical medical supplies and pharmaceuticals, it is essential that our nation's regulatory framework support, and not inhibit or deter, repatriation. As such, Congress should consider policies that expedite FDA review for domestically manufactured critical medical supplies and pharmaceuticals.

Mitigating Drug Shortages

Premier applauds congressional action to pass sections 3101, 3111 and 3112 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act to mitigate drug shortages necessary for patient care during the pandemic. Specifically, these provisions:

- Created a priority pathway for the review of drug shortage applications;
- Required a report examining national security risks as a result of drug shortages;
- Strengthened FDASIA Title X reporting requirements to include full disclosure of the problems resulting in a shortage, information concerning the extent of a shortage, its expected durations, and other information the Secretary may require;
- Extended FDASIA Title X reporting requirements to Active Pharmaceutical Ingredient (API) manufacturers; and
- Required manufacturers to maintain redundancy and contingency plans to ensure ongoing supply.

While the provisions included in the CARES Act are monumental to continuing the fight against drug shortages, the pandemic highlighted additional vulnerabilities in the pharmaceutical supply chain warranting a revisit of drug shortages legislation to strengthen the FDA's ability to proactively address and respond to potential shortages. These include:

- **Requiring manufacturers, including API manufacturers, to report the volume of product that is manufactured in each FDA-registered facility**.
  - The FDA currently collects information regarding the number of registered manufacturers in each country, but a blind spot is the actual volume of product that is produced by each facility. For example, FDA data shows that 18 percent of registered API manufacturers are located in India whereas Premier data shows that upwards of 30 percent of the

world's API is manufactured in India. On the contrary, FDA data shows that 28 percent of registered API manufacturers are located in the United States whereas Premier data shows that approximately 15–20 percent of the world's API is manufactured domestically. Furthermore, it is estimated that upwards of 80 percent of the world's raw materials, also known as key starting materials, for pharmaceuticals are manufactured in China. The inability of the FDA to pinpoint the volume of product that is derived in each country results in a lack of transparency in the pharmaceutical supply chain regarding source of raw materials, API and finished dose forms (FDF)—making it difficult to assess the downstream risk to supply disruptions. This lack of transparency creates challenges to assess the true risk to the pharmaceutical supply chain due to manufacturing delays, export bans, global pandemics, etc.

- **Expanding the FDA drug shortage list to include regional shortages as well as shortages based on strength and dosage form.**
  - The FDA drug shortage list currently does not account for regional shortages or shortages based on excipient, strength or dosage form. These limitations created difficulties during the COVID–19 pandemic as drug shortages were rampant in hot spots while the majority of the Nation did not experience the same. This resulted in an inability of providers and manufacturers to move product to areas of greatest need and leverage other statutory and regulatory flexibilities that would have otherwise been applicable in a shortage situation, such as 503B compounding as an interim solution.
- **Modernizing the FDA's data infrastructure to collect shortage signals from the private sector.**
  - Oftentimes, the warning signals of an impending shortage can be seen weeks to months in advance due to discrepancies in demand vs supply data. For example, during the COVID–19 pandemic, Premier shared weekly demand signals with the FDA for approximately 250 critical medications to help the FDA understand what medications were at risk for shortage due to increased demand. Premier's 360-degree view into the demand vs supply signals from a broad swath of our membership across multiple suppliers provided an accurate and predictive model for determining which drug products were at risk of disruption. While individual suppliers could report increases in demand to FDA, as requested in the President's fiscal year 2024 budget, in practice individual demand signals are not telling of a potential disruption and create unnecessary and undue reporting burden on the supplier. Instead, it is critical to work with larger data sets and predictive modeling with artificial intelligence to truly understand medications at risk for disruption. Therefore, to better help the FDA predict shortages before they occur, Premier recommends that Congress provide FDA with funding to modernize its data infrastructure and work with existing private sector data sets to collect and analyze market demand signals.
- **Leveling the playing field for all FDA inspections.**
  - Currently, the FDA assesses whether a facility is in a State of control through periodic inspections that provide an evaluation of manufacturing operations, including their system for quality management. However, not all facilities are treated the same as domestic manufacturers are inspected regularly via unannounced inspections whereas many foreign facilities are inspected less regularly via announced inspections. This dichotomy in inspection authority creates an undue burden for domestic manufacturers and can create an incentive for manufacturers to build their facilities overseas. It is welcome news that the Fiscal Year (FY) 2023 Omnibus Appropriations Bill contains a provision requiring the FDA to establish a pilot program for unannounced foreign inspections, but the quality standard should focus on FDA approval and inspection, with all FDA-registered global manufacturers inspected equitably and consistently via unannounced inspections at the same time intervals. Both domestic and overseas manufacturers of FDFs and APIs should be held to the same standard. To level the playing field, the FDA will require the appropriate resources in highly trained and experienced inspectors and may also need additional statutory authority. Once a level playing field is adopted as policy, the FDA should provide Congress with a 5-year plan, with metrics and annual targets to achieve the desired parity.

- **Expanding drug shortage authorities to vaccines.**
  - While the FDA has statutory authority to mitigate drug shortages, vaccines are currently excluded from those authorities. Therefore, if shortages of COVID, Mpox or other vaccines needed to address and treat a public health emergency were to go into shortage in the future, FDA would have limited authority to mitigate the shortage. Therefore, Premier recommends that Congress expand FDA's statutory authority to address shortages to include vaccines.

Premier urges Congress to provide FDA greater authority to further mitigate drug shortages.

Mitigating Device Shortages

Premier applauds congressional action to pass section 3121 in the CARES Act to mitigate device shortages necessary for patient care during the pandemic. Specifically, these provisions:

- Required device manufacturers to notify the FDA of a permanent discontinuance in the manufacture of the device or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the U.S., and the reasons for such discontinuance or interruption;
- Required FDA to publish a device shortage list with information on the discontinuance or interruption of the manufacture of devices reported; and
- Prioritized and expedited review of applications and inspections for a device that could help mitigate or prevent such shortage.

While these were positive steps in the right direction and created the first-ever device shortage reporting requirements, these provisions are temporary and tied to reporting only during a public health emergency. More can be done to make the device shortage program robust and akin to the drug shortage program at the FDA. This includes:

- **Making permanent the device shortage requirements.**
  - Currently, device manufacturers are only required to report supply disruptions to the FDA for the duration of the public health emergency. COVID–19 exposed weaknesses in the U.S. supply chain and the country's overdependence on medical supplies, devices and components imported from overseas. Shortages persist today and span a variety of categories, including supplies essential for patient care such as blood collection tubes, contrast media, tourniquets, and more. Thanks to the authority granted to FDA in the CARES act, the FDA has been able to better understand and monitor the complex web of supply chains that feed the medical device industry and to solve problems more proactively before they occur. As a result, the FDA has recommended actions that have helped industry, providers and the Nation mitigate potential damage and further disruption. But while the FDA's new authority has been important, it does not cover all situations that can lead to shortages. These can and will arise outside of public health emergencies, such as during natural disasters, device recalls, geopolitical issues, and other unforeseen circumstances impacting the supply chain. Therefore, it is critical that this authority be made permanent so that the FDA can continue this important work and proactively mitigate device shortages before they occur.
- **Requiring device manufacturers to implement risk management plans.**
  - A key component of a resilient supply chain is having a backup plan to ensure redundancy in manufacturing and minimize supply disruptions. Therefore, Premier supports Congress extending FDA's authority to requiring risk management plans on device manufacturers. Congress provided similar statutory authority to the FDA to require risk management plans for drug manufacturers in the CARES Act.

Premier urges Congress to provide FDA greater authority to further mitigate device shortages.

Maintaining Supply Chain Integrity

During the pandemic, unfortunately a lack of clear visibility of distributor fulfillment led to uncertainty on where products where delivered. This continued uncertainty left providers with dwindling confidence in the normal supply chain and proliferated more maverick and forward buying, as well as hoarding. This also led to a rampant gray market and many entities purchasing counterfeit products thereby challenging the integrity of the medical supply chain.

In the CAA 2023, Congress included the INFORM Consumers Act which establishes a national standard, enforced by the Federal Trade Commission (FTC) and State Attorneys General, that requires online platforms that allow for third party sellers of consumer products (including PPE and other medical goods) to verify the identity of high-volume third-party sellers. The CAA 2023 also strengthened FDA enforcement authority against, and increased the penalties for, selling counterfeit medical devices, including PPE, in the United States.

While the CAA 2023 made great strides, to further combat the gray market and ensure supply chain integrity, Premier offers the following recommendations:

- Establish a national, centralized clearinghouse to vet all gray market offers for critical medical supplies, pharmaceuticals and vaccines. A clearinghouse approach would remove the risk and guess work from efforts by healthcare providers, states and other entities to secure a reliable supply of critical medical supplies and drugs. The clearinghouse should:
    1. Hold all payments in escrow until testing is validated;
    2. Test lot samples through a certification process;
    3. Permit the sale of products that are validated; and
    4. Confiscate and take appropriate action against the gray market actor if the product is not validated.
- Require entities associated with the distribution of critical medical supplies and drugs to implement checks and balances systems, similar to suspicious order monitoring requirements for controlled substances, to identify potential diversion of products to the gray market.
- Promote the reporting of gray market offers to the FDA Office of Criminal Investigations and share reported incidents with the Federal Trade Commission (FTC).
- Establish best practices for security to minimize diversion from sites.
- Broaden FDA's authority to destroy counterfeit devices that are imported into the United States.

Premier encourages Congress to consider policies that combat the gray market and ensure supply chain integrity.

III. National Advisory Committee (NAC) on Individuals With Disabilities and Disasters

Recently during recovery efforts for Hurricane Ian, Premier became aware of a lack of emergency services and shelters that can accommodate the specialized needs for individuals with disabilities. For example, many disabled individuals and their families that were in the path of the hurricane were unable to evacuate their homes as shelters did not have the necessary infrastructure and support services needed to care for disabled individuals. This unfortunately resulted in these individuals having to shelter in place and hope for the best. **Premier encourages Congress to work with Federal agencies such as FEMA, and relief organizations such as the American Red Cross, to provide appropriate funding to ensure that emergency efforts during a public health emergency, natural disaster, or other unforeseen circumstance account for the needs of disabled individuals and their families.**

IV. Strategic National Stockpile

Regarding the Strategic National Stockpile (SNS), Premier strongly supports the need to augment the SNS to better respond to global pandemics by enabling public-private partnerships. However, to develop a truly cohesive and holistic national strategy for addressing future global pandemics and stabilizing the U.S. supply chain to respond to surge demand for essential medical supplies and drugs, Premier believes that it is critical to take a broader approach than the SNS was originally designed for by creating a true end-to-end supply chain solution that is transparent,

diverse, and reliable. In addition, it is critical to not only focus on the quantity on hand for critical supplies, but also focus on the time to inventory and ensuring the U.S. has contractual relationships established, including contingency and redundancy plans, to ramp up production expeditiously and efficiently upon identification of need.

The SNS is the supply chain of last resort for health systems, continuum of care providers, and first responders. Therefore, the SNS must be built by providers for providers. The SNS must also leverage analytics and insights to assist providers in the delivery of care during global pandemics that is in the best interest of patients and ensure access to the right supplies at the right time.

Premier's vision for the next generation SNS includes the following elements that can be accomplished via a public-private partnership:

- *Establish a Public-Private Advisory Council:* As outlined in section VI below, Premier urges Congress to amend PHEMCE to create a public-private advisory council.
- *Identify A List of Critical Medical Supplies, Drugs and Other Supplies Necessary to Manage a Surge:* The public-private advisory council should be tasked with:
  - Identifying the list of critical medical supplies, drugs, medical foods and other supplies needed to treat a global pandemic and associated comorbidities that should be included in the SNS, including determining the most cost-effective product where multiple options may exist within a single product category or therapeutic category. This includes broadening the scope of products maintained in the SNS beyond countermeasures to include lifesaving and protective equipment and medications, such as ventilators, PAPRs and medical gas cylinders, and the corresponding consumables, such as breathing circuits, filters and hoses that sustain life or protect front line staff. The list should be inclusive of all products necessary to treat a potential global pandemic, including potential comorbidities, and take into account special patient populations such as pediatrics and geriatrics.
  - Annually, at minimum, assessing, refining and revising the list of critical medical supplies, drugs, medical foods and other supplies contained in the SNS to account for product discontinuations, emerging technologies, changes in clinical guidelines and identification of best practices. The list should be dynamic and regularly updated.
- *Create Transparent and Diverse Sourcing for Critical Medical Supplies and Drugs:* Establishing a transparent, diverse and reliable supply chain is essential for ensuring the U.S. is prepared to respond to future global pandemics. This is critical information to understand vulnerabilities, overseas reliance on manufacturing, and the impact of geopolitical issues such as export bans and manufacturing shutdowns. A robust sourcing strategy for the SNS should:
  - Create transparency by obtaining upstream visibility into the supply chain to determine source of raw materials, ancillary products and finished goods. All manufacturers contracted with the SNS should commit to providing upstream visibility into the sourcing for their products to provide a holistic view.
  - Assure diversity by ensuring there are several suppliers of raw materials, ancillary products and finished goods from geographically diverse regions.
  - Leverage multiple sourcing options including contracting directly with manufacturers, contracting with group purchasing organizations to help aggregate purchasing volume and keep prices competitive, and recruiting and incentivizing the entry of new manufacturers for product categories that lack diversification. Policy changes may be needed to 1) permit the SNS to pursue innovative contracting methodologies to meet the vision of the next generation SNS; and 2) amend the Federal Supply Schedule to incentivize domestic manufacturing and ensure a stable supply at a sustainable price.
  - Identify and contract with at least a primary and secondary manufacturer for each critical medical supply and drug. The contract should stipulate the ability of the manufacturer to meet certain supply requirements within a specified period during surge demand, redundancy and contin-

gency plans for manufacturing, requirements for safety stock and warehousing of the product, and quality standards that must be ensured.

- The Public-Private Advisory Council should be tasked with:
  - Developing criteria for awarding SNS contracts to manufacturers including product specifications;
  - Vetting and approving all SNS contracts to manufacturers to provide an agnostic and unbiased voting process;
  - Providing recommendations for warehousing at the product level; and
  - Prioritizing product categories for domestic manufacturing.
- *Develop a Network of Stockpiles Throughout the Country:* Stockpiles should be designed to create coordination, rather than competition. Stockpiles should also be curated to meet specific needs such as acute, continuum of care, first responders, etc. as each segment of healthcare will have varying needs. Therefore, the SNS should develop a network of stockpiles that creates a "hub-and-spoke" model with the SNS as an anchor offering a full array of services that is complemented by State and local stockpiles to optimize supply and ensure coordination. To further optimize the availability of supplies as close to the point of care as possible, the SNS should explore opportunities to leverage health system and alternate site provider warehouses in major metropolitan areas or in rural areas. Finally, to ensure the network of stockpiles are interoperable and complementary to one another, the public-private advisory council should be tasked with developing national standards that all stockpiles must meet at a minimum.

Better coordination amongst stockpiles would also permit a national infrastructure to absorb excess inventory that exists in State or health system stockpiles versus purchasing net new products.

- *Rotate Inventory:* The SNS should rotate soon-to-expire product out of the SNS. This can be accomplished either by 1) contracting with a third party vendor to rotate inventory; or 2) selling short-dated products to health systems and alternate site providers at a discounted rate, a newly created authority under the CAA 2023; or 3) maintaining a virtual inventory by working with manufacturers or private sector partners to maintain and rotate inventory on behalf of the SNS, akin the Vaccine for Children program that leverages vaccine manufacturers to maintain and rotate inventory. Critical to establishing, maintaining and rotating inventory is to avoid huge bulk purchases as they can create noise and distortion in market demand signaling. In addition, bulk purchases can result in downstream shortages as manufacturers prioritize government fulfillment over standard distribution thereby impacting the availability of products for frontline patient care. Finally, rotation of product should also occur as products are discontinued or removed from the SNS as the list of critical medical supplies and pharmaceuticals is updated annually.
- *Create an Efficient and Dynamic Fulfillment Process:* The current process for accessing the SNS is cumbersome and State specific. Therefore, the SNS should create a single, streamlined and efficient electronic process for submitting requests to the SNS along with a standardized process for responding to requests. It is also critical for the SNS to develop a dynamic distribution methodology that leverages a data-driven approach to ensure products are available in the right place at the right time, versus relying on a historical allocation process as was leveraged during the pandemic. Finally, a nimble and flexible distribution method is also needed to move supplies amongst health systems from areas with excess product or declining need to hot spots or areas with increasing needs.
- *Test the Functionality, Readiness and Reliability of the SNS:* To ensure the next generation SNS can deliver during future global pandemics, it is critical to periodically pressure test the system. Annually, without prior notice, the SNS should require all contracted manufacturers to provide the SNS with a specified quantity of product. An annual test allows the SNS to ensure all contracted manufacturers can expeditiously and efficiently ramp up production to meet surge demand, as well as ensure production lines remain operational and are maintained.
- *Analyze and Report:* Transparency regarding the efficiency and utilization of the SNS is critical to understanding its purpose and continued need.

> The SNS should be transparent regarding distribution of supplies and drugs from the SNS and therefore should provide, at minimum, a detailed monthly report of what supplies were requested versus distributed to where and in what quantities. During a public health emergency, reporting should occur weekly.

Premier urges Congress to take additional steps to modernize the nation's stockpile.

V. Biomedical Advanced Research and Development Authority (BARDA)

Throughout the pandemic, the Industrial Base Management and Supply Chain (IBMSC) Program Office within BARDA invested billions of taxpayer dollars in over 50 manufacturers to "expand, secure, and build resiliency across the entire public health and medical industrial base." In many cases, it appears that these investments were made without a formal request for proposals (RFP) process and bypassed traditional government contracting requirements, potentially cherry-picking award recipients and not providing a fair opportunity for eligible entities to compete. Furthermore, little to no information has been made available publicly regarding the ability of these manufacturers to meet their manufacturing goals and the impact to the supply chain. Therefore, **Premier urges Congress to request an OIG report regarding the distribution of IBMSC funds, the progress to date of award recipients in meeting their contractual obligations and the impact to supply chain resiliency. Furthermore, Premier urges Congress to leverage the OIG findings to develop a process for awarding future IBMSC funds in a transparent manner and for regular public reporting of progress by award recipients.**

VI. Public Health Emergency Medical Countermeasures Enterprises (PHEMCE)

The SNS should establish a public-private advisory council that includes representatives from the private sector such as manufacturers, group purchasing organizations, distributors, physicians, pharmacists, nurses, laboratorians, non-acute providers, patients, professional associations, and others as well as representatives from the public sector such as Federal agencies (HHS, FEMA, ASPR, CDC, CMS, FDA, SAMHSA, the Veterans Health Administration, Indian Health Services, etc.), prisons, first responders, State and local representatives, and others. The advisory council should leverage a multi-committee structure to ensure the appropriate expertise is represented for specific product categories such as pharmacy, lab, nursing homes, pediatrics, etc. The advisory council will be critical to ensuring the SNS is soliciting feedback from a broad range of entities to augment its operations through a data-driven approach, remain unbiased and vendor agnostic, support a collaborative decisionmaking process, identify innovative products, and continuously refine the vision of the SNS. Essentially, the advisory council structure helps ensure the SNS is built by providers for providers.

To accomplish this, statutory changes are required to amend the composition of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the group responsible for dictating the contents of the SNS. The PHEMCE is currently led by ASPR and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA). The PHEMCE currently does not include private sector feedback. This was also highlighted in a recent National Academies of Medicine report, *Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise,* that provides recommendations from an expert committee for a re-envisioned PHEMCE. Therefore, **Premier recommends that Congress amend the composition of PHEMCE to include private sector representation and create a true public-private advisory council.**

VII. Medical Reserve Corps (MRC)

During the pandemic, to help alleviate staffing challenges throughout the country, several Federal resources from HHS, DOD, FEMA, the Public Health Service and other agencies were deployed to provide on-the-ground support to hospitals and health systems. In some situations, this help was welcome and beneficial. However, in certain cases, hospitals have reported that the help may have been duplicative

or not geared toward the specific areas where assistance was needed the most. Premier recommends that Congress direct the GAO to study the effectiveness of federally deployed resources to hospitals and health systems. The study should look at lessons learned, efficiencies created, opportunities for improvement and recommendations for how to optimize Federal resources during future public health emergencies.

VIII. Playbook of Regulatory Flexibilities for Future National Public Emergencies

Throughout the COVID–19 pandemic, Federal agencies provided a host of regulatory waivers and flexibilities that were critical to hospital operations and permitted providers to focus on patient care. While the various waivers and flexibilities were extremely helpful, they were also released in a piecemeal fashion and it was often difficult for providers to keep track of what requirements were being waived. In addition, while some waivers came expeditiously, others took time to establish such as the hospital-at-home waiver that was not established until November 2020. For future pandemics, a recent Premier *survey* found that the expeditious establishment of waivers and flexibilities would be essential to ensuring a prompt response from hospitals.

Specifically, respondents noted that it would be beneficial if a bundle of waivers or flexibilities could be pre-identified as essential to operations during a future pandemic such that they could be immediately implemented, and hospitals would know exactly what to expect. Therefore, **Premier recommends that Congress direct Federal agencies to identify and bundle waivers and flexibilities that would be automatically invoked and could be expeditiously implemented during a future public health emergency to improve patient care and reduce burden on hospitals and other healthcare providers.**

IX. Epidemiology and Laboratory Capacity Grant Program

Early COVID–19 testing was plagued by a lack of testing locations, a shortage of specimen collection swabs, inadequate lab capacity to process tests and sporadic genomic sequencing to monitor for variants. With Mpox, efforts to speed access to testing were swifter as the CDC effectively onboarded commercial labs to expand testing for Mpox within 1 month. While an improvement, that 1 month delay did have consequences creating testing bottlenecks.

As we learned during COVID–19, delays of even a day can have dire effects on limiting transmission. Instead, **the government should broaden and better organize the lab network to include hospitals, academic medical centers, and regional testing laboratories that have the ability and capacity to perform these tests in their communities**. Broadening the lab network will help ensure that regionally based testing can produce more timely results, empowering immediate and effective public health action. It is also critical for the Nation to develop a genomic sequencing strategy for Monkeypox to stay ahead of potential variants.

X. Public Health Situational Awareness and Biosurveillance Network Programs

Syndromic Surveillance to Predict Community Outbreaks

In the early days of the pandemic, Premier leveraged clinical decision support, powered by machine-learning, artificial intelligence and natural language processing, to effectively predict COVID–19 surges and regional flare ups well before patients started showing up at the hospital for treatment. Armed with positive results, Premier advocated for Federal agencies to adopt a national system for syndromic surveillance to better track and predict outbreaks—and quicken response times.

Symptoms are the earliest and most reliable indicator of the emergence of infectious diseases that threaten our nation's public health. Identifying suspected cases early is the best signal of the need to take action. However, a recent Government Accountability Office (GAO) *report* notes how a lack of Federal action to modernize the public health data infrastructure seriously undercut efforts to combat the COVID–19 virus. This is a situation that was unfortunately replayed with the Mpox public health emergency.

America needs an automated, near real-time means to collect symptoms and confirmed case information consistently and comprehensively so that it can be shared between and among multiple public and private stakeholders, including Federal, state, local, Territorial and tribal public health

authorities as well as on-the-ground providers:. Such a system can pull in information on symptoms, comorbidities and other vital information, allowing for targeted tracing and interventions to proactively prevent outbreaks. Earlier recognition of new hot spots speeds quarantining of potentially infected persons, reduces the spread of the virus and saves the Nation money on contact tracing and testing. This reality is possible today and Congress should push Federal agencies to explain how a system that was required under PAHPA in 2006 in still not operational today.

Automated Tracking and Reporting the Spread of Disease

During the COVID–19 pandemic, virtually all reporting was done using paper-based forms that were then faxed back to the State and local public health departments for recording and follow up. Reporting was limited to hospitals providing treatment for the most severe cases and labs that encountered a positive COVID–19 test. This meant public health agencies received no information from milder cases diagnosed in a physician office, or from patients self-diagnosed via at-home tests.

Fast forward to Mpox and some improvements in reporting were made. Any labs performing a Mpox test were required to report all results directly to public health departments and are strongly encouraged to submit this data electronically, as opposed to via paper forms.

However, electronic reporting is still not a requirement and public health case investigation forms used to track the source of transmission are still paper based and very lengthy (e.g. more than six pages long for Mpox). **The Federal Government should require and prioritize efforts for automated, streamlined nationwide public health data collection, exchange and sharing using data and interoperability standards.**

XI. Additional Areas for Consideration

Presidential Advisory Council on Combating Antibiotic-resistance Bacteria (PACCARB)

COVID–19 has brought to the forefront the specific challenges nursing homes face in containing the spread of infectious disease. The virus accelerated at nursing homes because residents are generally vulnerable to its complications and more susceptible in the contained space of facilities. While data about infections in nursing homes is limited, the CDC notes that, even prior to the pandemic, a staggering 1 to 3 million serious infections occur annually in these facilities and as many as 380,000 people die of infections in nursing homes every year.

Infection prevention oversight and training at nursing homes is a challenge in and of itself with limited staffing and several layers or reporting requirements. This challenge is compounded by limited Electronic Health Record (EHR) functionality at the sites. Without a comprehensive infection prevention surveillance workflow, the surveillance, tracking, documenting and reporting of epidemiologically significant organisms and infection is difficult for everyday risks, such as multi-drug resistant organisms, but also when an outbreak like COVID–19 occurs.

Clinical analytics technologies are currently widely leveraged in hospitals and acute setting to detect patient care issues through surveillance, interventions and reporting capabilities that are needed to support antimicrobial stewardship programs. These systems utilize data from EHRs and have significantly helped clinicians and pharmacists in acute settings identify overuse of antibiotics and drug-bug mismatches, reduce time-to-appropriate therapy and enhance therapy for difficult-to-treat pathogens. Those health systems already utilizing clinical surveillance technology were well positioned to respond to COVID–19 before the pandemic hit.

Unfortunately, clinical analytics technologies are currently not widely used in nursing homes and other long-term and post-acute (LTPAC) settings. These settings should have the same access to tools that will help them combat infection spread during any future disease outbreaks and during their day-to-day operations, but unfortunately funding remains a significant barrier as programs authorized and funded under the Health Information Technology for Economic Clinical Health (HITECH) Act excluded LTPAC providers. These entities are already challenged with meeting their more visible needs, such as testing and securing adequate PPE levels at their sites, but a more comprehensive approach is needed to ensure data collection is efficient, non-duplicative and being analyzed in ways that are helpful for facilities. Furthermore, it is critical that lessons learned from meaningful use are applied forward as we develop cohesive solutions to address the lack of EHRs and

clinical surveillance technology in nursing homes and create appropriate incentives for adoption.

Premier encourages Congress to consider policies that incentivize nursing homes and other LTPAC providers to implement EHRs and electronic clinical surveillance technology to provide meaningful assistance with infection control.

Strategy for Public Health Preparedness Response to Address Cybersecurity Threats

Alongside technology innovations and the frequent electronic exchange of health information, cybersecurity for medical devices and equipment has become a top priority for healthcare providers. These cyberattacks not only threaten patient privacy and clinical safety and outcomes, but also a hospital's financial resources. Alongside direct costs related to a breach, providers may see added costs in hardware, software, firmware and labor.

In the CAA of 2023, Congress required manufacturers of cyber devices to develop processes to ensure their devices are secure, have plans to identify and address cybersecurity vulnerabilities, provide a software bill of materials in their labeling, and submit this information to FDA in any premarket submissions. However, these provisions are only applicable to devices going through a traditional 510(k) pathway and it is unclear how devices and other products granted an emergency use authorization during a public health emergency would be required to comply with these provisions. Given heightened cybersecurity concerns during pandemics, Premier urges Congress to clarify the roles and responsibilities of manufacturers granted an emergency use authorization as it relates to cybersecurity of their devices. In addition, **Premier urgers Congress to decrease fines and other civil monetary penalties for healthcare providers if they experience a cybersecurity breach due to a device granted an emergency use authorization that did not comply with FDA cybersecurity requirements.**

Port Congestion and Transportation Delays

During the pandemic, port congestion and delays in global logistics nearly doubled and tripled product lead times. This resulted in supply shortages due to an inability to prioritize cargo ships carrying healthcare supplies. These delays and shortages were further exacerbated due to shortages of drivers and impending discussions of a rail strike.

To help combat this, the private sector piloted a "fast pass" system led by the Health Industry Distributors Association. The pilot was successful in testing the ability of ports to prioritize and expedite the offloading of healthcare supplies. **Premier urges Congress to prioritize and expedite the delivery of healthcare supplies during public health emergencies.**

Contracting and Hiring Authority

Throughout the pandemic, a rate limiting step in Federal agency response was contracting and hiring authority. While some agencies had more flexibility to increase resources to meet the task at hand, other agencies did not have the same authority or flexibility to increase their staff. To better respond to future pandemics, **Premier urges Congress to ensure all Federal agencies with a potential role in response to a future pandemic have similar contracting and hiring authority to expeditiously obtain the resources necessary to adequately carry out their duties.**

[Whereupon, at 3:15 p.m., the hearing was adjourned.]

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