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THE PATH FORWARD: BUILDING ON LESSONS LEARNED FROM THE COVID–19 PANDEMIC

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING BUILDING ON LESSONS LEARNED FROM THE COVID-19 PANDEMIC, FOCUSING ON THE PATH FORWARD

JULY 27, 2021

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C O N T E N T S

STATEMENTS

TUESDAY, JULY 27, 2021

THE PATH FORWARD: BUILDING ON LESSONS LEARNED FROM THE COVID–19 PANDEMIC

Tuesday, July 27, 2021

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

The Committee met, pursuant to notice, at 10 a.m., in room 430, Dirksen Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

Present: Senators Murray, Casey, Baldwin, Murphy, Kaine, Smith, Rosen, Lujan, Hickenlooper, Burr, Cassidy, Braun, Marshall, Scott, Romney, and Tuberville.

OPENING STATEMENT OF SENATOR MURRAY

The CHAIR. Good morning. The Senate Health, Education, Labor, and Pensions Committee will please come to order. Today, we are holding a hearing on lessons learned from the COVID–19 pandemic and how we make sure we are never in this situation again. Ranking Member Burr and I will each have an opening statement, then we will introduce our witnesses. And after they give their testimony, Senators will each have 5 minutes for a round of questions. While we are unable to have the hearing fully open to the public or media for in-person attendance, live video is available on our Committee website at *help.senate.gov*. And if anyone is in need of accommodations, including closed captioning, please reach out to the Committee or the Office of Congressional Accessibility Services.

Before I begin my opening remarks, I do just want to personally comment on our loss in the Senate of former Senator Mike Enzi. He sat in this seat. I had the opportunity to work with him many times, especially on workforce issues. He chaired the Budget Committee. He was always—believed in his philosophy, which is everyone is right, but he was accommodating, he was a listener, and I know I speak on behalf of all my Democratic colleagues, and I am sure my Republican colleagues as well, that our thoughts and prayers are with his family today.

Earlier this year, Patti Hayes, who is the Director of Public Health for Seattle and King County, reflected on the pandemic and noted one of the big things that the entire country realized, that if you allow your public health infrastructure to be dismantled, then when you have an emergency of this sort, it is not ready to handle it. And she is right. I have been pushing for greater investments in public health for years because even before this pandemic,

the diminished state of our public health infrastructure was incredibly alarming. Since 2010, spending for state public health departments has dropped by 16 percent and spending for local health departments by 18 percent. In 2019, less than half of our state spent even $40 per person on public health, with only a few states spending over $100 per person.

Even though our health care spending was over $11,000 per person nationwide, local and state health departments have lost nearly a quarter of their workforce since 2008. In other words, before the pandemic struck, public health departments across the country were woefully understaffed and underfunded, and our Nation was unprepared. How are we supposed to test for diseases like COVID–19 and sequence four new variants without modernized data systems and adequate lab capacity? How are health departments supposed to do contract tracing when a single case can have over 70 contacts? But a city like Detroit, with 670,000 people, has only 200 workers in its public health department. How are we supposed to track disparities when we don't have a consistent, standardized way of reporting the data we get?

When Federal data doesn't often accurately identify some communities like Pacific Islanders, beyond inequities, how are we supposed to track cases at all when data is coming into health departments by fax, thousands of printed pages at a time? Last July, in my home State of Washington, we brought in members of the National Guard just to help manually enter data from tests that weren't reported electronically. And then beyond the challenge of getting all that crucial data, how are we supposed to make good use of that data to fight public health threats when only 28 percent of local health departments have an epidemiologist or statistician?

How are our communities supposed to get clear, science based guidance on public health issues, coordinate vaccination efforts to reach our most distant and vulnerable communities, or fight a deluge of misinformation about safe, effective vaccines when only half of all people in this country are served by a comprehensive public health system? We have to end the cycle of crisis and complacency in public health that led us here.

As a public health leader in Kansas put it, we don't say to the fire department, oh, I am sorry, there were no fires last year, so we are going to take 30 percent of your budget away. And we shouldn't be doing that to public health either. We need to dramatically rebuild our public health infrastructure and we need to build it to last. We need to invest in modern technology in our health departments and hospitals. We need to invest in addressing inequities and making sure our data includes everyone, our vaccines reach everyone, and our health departments are building trust in communities of color, which we know are often hit the hardest when disaster strikes. And to do all this, we also desperately need more people like Patti Hayes. However, as Hayes retired from the health department this May, she is not alone.

A survey taken before the pandemic showed nearly half of public health workers were considering retiring in the next 5 years. That is why it is so critical we take steps to build our public health workforce, including steps to help address the reality that outside of big cities, more than a fifth of local public health workers earn

less than $35,000 a year. In her comments earlier this year, Ms. Hayes went on to say, and I quote, "I am hoping that the wisdom will prevail to really invest in the core public health infrastructure so that we are faster, better coordinated, and ready for the next thing." I am hoping for that, too, and I am pushing as hard as I can to make it happen, which is why I introduced the Public Health Infrastructure Saves Lives Act so we can finally end the cycle of crisis and complacency in public health funding. It is why I have been pushing so hard for Congress to invest in public health in our COVID response bills. And that is why I have been pushing for bipartisan work to reflect lessons learned from this pandemic.

Of course, while the value of strong public health infrastructure may be the most important lesson we have to learn from this pandemic, there are many others we should be addressing as well, like the need to address supply chain disruptions, improve our stockpile of critical medical supplies, improve health equity, fight misinformation, prevent hospitals from being overwhelmed, and support and expand our health care and public health workforce. Additionally, Congress should enact an independent, comprehensive assessment of our Nation's COVID–19 response to make sure we have a full accounting of this chapter in our history and never repeat it.

I know that is a goal that we all share, and I look forward to hearing from our all of our witnesses today. Thank you all so much for being here today. We look forward to your testimony. We look forward to learning what we can learn from this pandemic. And we will work with colleagues on both sides of the aisle to act on those lessons. With that, I will turn it over to Ranking Member Burr.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Madam Chair. Welcome to our witnesses today. I would also like to take a minute at the beginning to talk about our former colleague, Mike Enzi. Michael is a good friend. He is a great Senator. Mike was Chairman of this Committee and Ted Kennedy was the Ranking Member at the time, and I think Ted Kennedy taught Mike a really important thing, it is called the 80–20 rule, that this Committee can find 80 percent that we can agree on, and we can agree that 20 percent of it we will never find a solution to.

Mike and I work together on many bills, especially with our good friend Tom Coburn, when Tom was alive. We worked on Ryan White program that helped provide affordable treatment to America's HIV and AIDS patients. He was a leader on protecting Americans from discrimination based upon their genetics in the GINA Act. He was a leader and a partner in pandemic preparedness.

He was a thought leader with biology—with biologics legislation that created biosimilars—a biosimilar pathway at the FDA, which has allowed more drugs to be available that cure cancer, breast cancer, lymphoma, Crohn's disease, and many other things on the horizon. Most importantly, Mike was a good friend. He was a loving husband, and he was a devoted grandfather. Not only will we miss him, but his family misses him today. I urge my colleagues to keep he and Diane in your prayers.

Madam Chair, I thank you for holding this hearing today. Even before the first case was identified in America, this Committee had

been extremely dedicated in a bipartisan manner to understanding the impact of the COVID pandemic. Just last week, we heard from our Federal response team about the ongoing outbreak and what our next round of challenges may be. I am particularly looking forward to today's hearing because we are focused on this question, where do we go from here? I have worked on preparedness issues for as long a time and can see pretty clearly where some of our Country's vulnerabilities lie.

My first priority is no secret. The CDC is desperately in need of reform. Primary reform CDC needs is to its culture. It is critical that CDC engage with the private sector, with academia, and integrate new technologies to keep the American people safe from 21st century public health threats. The culture change is always the most difficult, but it is possible. I know it because I have accomplished it. I went through it in 1997 with the FDA. The culture reform over 20 years ago and other laws along the way gave the agencies the tools it needed to quickly respond and fight COVID.

The FDA was a shining success, vaccines, treatments, and tests approved in record time while maintaining the gold standard of safety and efficacy over the last year. The Committee's learned that the CDC, one, did not have the surveillance tools in place to track the spread of the virus in near real time. Two, and had not hired the experts to meet its bio-surveillance mission despite congressional authority to do so. Three, experienced massive and systematic failures in deploying tests to public health labs, which delayed our testing in critical early days of the response and cost lives. Four, poorly communicated with Americans and was too often two steps behind the science.

Last, its leadership is reluctant to meet with innovators raising their hands to say I want to help. While I am critical of the CDC, it is because I believe that we have a responsibility to protect the public health, and I want to help the CDC do it better. As a result of COVID–19, the agency has new resources and new tools to be the world's premier public health agency once again.

We need to make sure they know what their mission is and focus the CDC on the right priorities. Business as usual has to be over. I am looking forward to hearing from our witnesses today on this extremely important task. We all witnessed the breaks in our medical supply chain during COVID–19. Our just in time inventory system that supported our health care providers were overwhelmed in the early days of the response. I have no doubt that every Member of this Committee received the same heartbreaking calls I did from their hospitals, brave, tired frontline workers asking for help that we could provide to get mask, gowns, and other medical supplies.

I have mentioned in previous hearings the need to closely examine the effects of the pandemic that we did not anticipate, and our supply chain is the best example. Who would have expected companies like Heinz in my state to make masks or for Merck to offer their durum manufacturing facility to another drug company to make their vaccine? The efforts of the private sector to meet the demands was truly unprecedented.

As the Federal Government, our ability to affect the supply chain for medical supplies, however, is limited. The Federal Government

is just 4 percent of the purchases of PPE. The other 96 percent belongs to the private sector, who have far greater capabilities to increase our preparedness if leveraged appropriately. Our reforms need to focus on sustainable policies that endure after the attention of this response fades. When we designed the stockpile, it was a bioterror event in mind.

The stockpile should serve as a bridge for acute time, limited events, not as the primary source for surge level medical needs. It houses our countermeasures for Ebola, anthrax, and smallpox. But we never maintain the level of PPE and ancillary medical supplies that we have purchased for COVID in the long term. And that was never the goal of the stockpile. As the author of BARDA and a big fan of Project Bioshield, I remember how we had to fight for every bit of funding for these programs during peacetime. Remember that Bob? We cannot put our simple supply chain needs in the same position.

We need to keep the private sector nimble and creative at meeting demands and to retain the market incentives, not Government commands. With COVID–19, we had no choice but to innovate. There were no shelf-ready tests, treatments, or vaccines. There was no humming manufacturing line capable of making vaccines to combat this novel virus. Even with our investments over the years in BARDA, the ASPR, and the stockpile, we need lead-time.

A clear gap in our readiness capability is the work on the front end for countermeasures. Early stage discovery like what occurred through NIH and BARDA's RADx initiative, and NIH's newly announced AVID Program, will help build our library of medical platforms and technologies that we can pull off the shelf when the next novel pathogen arrives on our doorstep. But these programs need partners. And the engagement of academia alongside the private sector can produce the innovative products we need to be ahead of the curve. Once we develop the countermeasures, we also need to manufacture them at scale, which will depend on private sector partners to once again rise to the challenge.

The FDA is a key partner in this enterprise and was prepared with the tools needed to truly rise to the challenge facing COVID. FDA has reviewed and authorized almost 400 tests, 11 therapeutics, and 3 vaccines for emergency use that have changed the trajectory of COVID–19 pandemic. Two of the vaccines depend on a brand new platform. In fact, many of the countermeasures used to tackle COVID–19 use platform based technologies. Most of these countermeasures were developed for COVID–19 in less than 1 year, a process that usually takes more than three times that amount of time. The agency's actions helped speed deployment of needed medicines, send signals to innovators that FDA can be more nimble, more approachable and more efficient in its ability to bring new hope to all America's patients, not just in response to COVID. But it doesn't stop once these products are authorized.

We need to get them in the hands of doctors and nurses to help patients just as urgently today to address the delta variant as we did previously in this response. Senator Murray and I know our priorities are big undertakings. The lessons we have learned from this pandemic and the solutions at hand will likely be different for each state, locality, and community. The HELP Committee has a

long bipartisan history of putting in the work to bring together the right answers to solve problems facing Americans.

Our goal is to provide a targeted legislative response this fall to the biggest gaps in our preparedness architecture. To our witnesses today, your part—you are a very important part of that process. Your testimony can help us understand where you all witnessed the biggest gaps in our preparedness and response framework, and how best to address these gaps so that we can leave our framework better prepared than in fact we found it. With that, I thank the Chair and I yield back.

The CHAIR. Thank you, Senator Burr. Again, welcome to all of our witnesses. We will now introduce them. Our first witness is Mr. Les Becker. He is the Deputy Secretary of Innovation at Washington State Department of Health. His work leading the Department's first ever Office of Innovation and Technology includes overseeing data, informatics, and health technology.

Before joining us in Washington State, Mr. Becker worked on public health in Harris County, Texas, leading the county's nationally acclaimed Public Health Innovation Lab. Mr. Becker, thank you for being here with us today. Next, I would like to introduce Ms. Phyllis Arthur, Vice President of Infectious Diseases and Diagnostics Policy at the Biotechnology Innovation Organization, or BIO for short. Ms. Arthur first joined BIO back in July 2009 as Director of Health Care Regulatory Affairs.

In her role at the organization, she works with member companies in the areas of vaccines, molecular diagnostics, and biodefense. Prior to joining BIO, she worked for Merck in their vaccine division. Ms. Arthur, thank you for joining us. I look forward to your testimony. Dr. Janz is our next witness. He will be introduced by Senator Cassidy.

Senator CASSIDY. I think this is the fourth person I have had the privilege to introduce to whom I lectured on diarrhea and hepatitis. So it is—I was famous for that lecture—lectures. But anyway, I had the privilege of representing Dr. David Janz, who is the Director of Medical Critical Care Services at University Medical Center in New Orleans. And Dr. Janz has seen firsthand what works and does not work in the COVID–19 pandemic response.

On the front line, he helped direct the response—remember, New Orleans was terribly one of the first places that was hit right after Mardi Gras, where presumably it was introduced. And so as New York was higher in profile, we were also having our troubles. And Dr. Janz on the front line helped direct the response at the medical center and across Louisiana, hosting regular conference calls, updating colleagues on best practices. He continues to help coordinate Louisiana's statewide critical care response as a member of the Louisiana Department of Health Critical Care Task Force.

With Dr. Janz, the Critical Care Task Force has developed easy to use patient care tools and operational solutions for hospitals across Louisiana. These have later been rolled out nationally, helping hospitals across the country fight the pandemic. Before the pandemic, Dr. Janz started with a medical degree from LSU School of Medicine and Internal Medicine Residency Critical Care Fellowship and Master of Science and Clinical Investigations at Vanderbilt.

As we, elected officials, weigh the economic, social, and physical health impacts of proposed policies, it is valuable to hear from medical experts. I look forward to Dr. Janz's testimony. And with that, I yield.

The CHAIR. Thank you, Dr. Janz. Welcome to you. Our final witness today is Anita Cicero. She is the Deputy Director of the Center for Health Security at the Johns Hopkins Bloomberg School of Public Health. As Deputy Director, Ms. Cicero has expanded the Center's efforts in epidemic preparedness, global biological risk issues, and international biosecurity.

She also currently chairs multiple World Health Organization working groups on research and has 30 years of experience as a health lawyer. Ms. Cicero, thank you for joining us today. I am pleased to have you as well. With that, we will begin our witness testimony. And Mr. Becker, we will begin with you.

STATEMENT OF LES BECKER, DEPUTY SECRETARY OF INNOVATION, WASHINGTON STATE DEPARTMENT OF HEALTH, OLYMPIA, WA

Mr. BECKER. Good morning, Chair Murray, Ranking Member Burr, and Members of the Committee. Thank you for your leadership and inviting me to testify today to share lessons learned from COVID–19. Let me start by acknowledging that this pandemic is far from over. When my boss, Dr. Shah, Washington State Secretary of Health testified to this Committee in March, he noted 500,000 Americans have lost their lives. I would be remiss not to acknowledge the tragic loss of another 100,000 since then.

I want to thank Dr. Janz and all the other health care and public health professionals on the front lines across our Nation that are helping to keep our communities safe as we respond to this pandemic. While we still have a long way to go, I believe there are lessons that we have learned that can shape a public health system built for the 21st century to protect the safety of all Americans. My name is Less Becker, and I was recently hired from the private sector as the new Deputy Secretary of Innovation and Technology for Washington State Department of Health.

Previously, I worked at Harris County Public Health for 11 years with Dr. Shah, and we innovated, and we increased data systems and we use technology to make our work better, building one of the best local health departments in the country. I come at public health and innovation and technology from a slightly different perspective of some of my colleagues. My background is grounded in technology, business management, project management, and finance. I don't believe that people recognize how decrepit and desperate our current public health data systems are, and that it will take a lot of work, time and resources to modernize them.

I believe to build and maintain strong public health infrastructure, we need to apply innovative practices that ensure efficient use of resources, achieve desired outcomes, and foster a continuous improvement environment that bridges the Federal Government, State Government, and local public health divide. Today, I want to touch on three main points, the criticality interoperable data systems, the value of public private-partnerships, and the need to in-

vest in well-coordinated local, state and Federal data systems through regional innovation hubs.

First, we need policies that incentivize interoperability to connect public health data systems with a broad range of partner systems, including health care. For example, in Washington, WA Health was developed quickly as a public-private partnership with public health, our health care system, and Microsoft to provide actionable data for preparedness and response during the pandemic. WA Health provided decision-makers with real time input from Washington's hospital system for staffing, emergency department availability, PPE, and other items needed during the response.

When the need arose, WA Health was expanded to collect data from approximately 1,800 providers to feed the state's vaccine data locator system, and that included data on wheelchair accessibility and language translation options onsite. Second, we need to incentivize private partners to stay the course post pandemic. Through this pandemic, we have seen the amazing accomplishments industry and public health can achieve when we all come together.

In Washington, one example of this is the Vaccine Action Command and Coordination Center, or VACS, which brought together health care organizations including Kaiser Permanente and countless private business partners such as Amazon, Costco, Microsoft, and Starbucks to figure out how to distribute vaccines equitably and efficiently across Washington State. Finally, we did an investment and well-coordinated local, state, and Federal data systems through regional innovation hubs. Right now we are funding siloed programmatic data systems that are not suited to handle the needs of today or tomorrow.

Moving forward, we need a strong and empowered team of Federal, state, and local public health agencies to come together at one table, shaping the 21st century data systems of tomorrow. Let me close by saying, if nothing changes, we will get more of the same, systems without the robust capabilities and capacity to respond to the next emergency. And we are at a crossroads. Either we can act now and invest in public health, or we can react later. I hope COVID–19 will move us to action.

Federal legislation like Chair Murray's Public Health Infrastructure Saves Lives Act could help make that hope a reality. On behalf of the State of Washington, Asato, and my colleagues across the Nation, I appreciate the opportunity to testify today. Thank you.

[The prepared statement of Mr. Becker follows:]

PREPARED STATEMENT OF LES BECKER

Let me start by expressing my sincere gratitude to Committee Chair Patty Murray, Ranking Member Richard Burr, and distinguished Members of the Committee, for the opportunity to appear before the Senate Committee on Health, Education, Labor, and Pensions to discuss lessons learned from the COVID–19 pandemic to innovate public health.

The COVID–19 pandemic is the most significant public health emergency in the last century. More than 600,000 Americans have lost their lives to COVID–19,[1]

[1] Source: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home* (Accessed July 21, 2021).

which is approximately the same population as Baltimore.[2] To quote Chair Murray, "[w]e have to make sure we learn from this history and take action so we never repeat it. This crisis has cost too much, has taken too many lives, for us to do anything less."[3] And to quote Ranking Member Burr, "[t]he window to update our public health and medical preparedness policies is now." In America, we can do anything if we do it together.

Speaking on behalf of my colleagues in public health at the state and local level, thank you for the time and energy being devoted by this Committee to craft bipartisan policies to strengthen our public health infrastructure and invest in preparedness now to prevent and better prepare for future public health threats. As you know, to date, the state of Washington has had one of the Nation's most successful responses to COVID–19 under the leadership of Governor Jay Inslee, and I am proud to be a part of this response.

As the new Deputy Secretary of Innovation & Technology for the Washington state Department of Health (DOH), I was recently hired from the private sector by Dr. Umair A. Shah, Washington's Secretary of Health, to join DOH in this immensely important time in our state's history and in this new and exciting role for our agency and the people of the Washington. This is a newly created role for a newly created office that sits at the highest level of DOH executive leadership, recognizing the importance of innovation and use of technology in our public health mission. In this role, I am responsible for building and supporting innovation work across the agency (and beyond) including overseeing our existing data/informatics and health technology services areas while building the ***Innovation First*** culture of tomorrow.

Prior to my private sector role, I previously worked at Harris County Public Health (HCPH) in public service leadership serving the Nation's third largest county in Texas. At HCPH, I worked with Dr. Shah in his previous role as executive director of HCPH to advance an array of innovation, data systems, and technology work building one of the best local public health departments in the Nation. Our work included creating the nationally acclaimed *Public Health Innovation (PHI) Lab*, which focused on developing novel public health interventions into sustainable projects that improved the health of the community. We implemented an award-winning data warehouse used to deliver timely data for key public health decision across many domains. In my role there, I also led key areas of advancement including the Medicaid 1115 transformation waiver implementation, public health accreditation and the agency's strategic plan development. I am excited to bring my experience to DOH and work with Secretary Shah in championing his vision of applying the cornerstone values of equity, innovation, and engagement to Washington and its public health systems.

We all know that everyone, everywhere, in all communities, should be able to rely on a strong public health system that is able to support them when emergencies strike, and even beyond those emergencies—in their everyday lives. Indeed, Federal legislation like Chair Murray's *Public Health Infrastructure Saves Lives Act*[4] could help make this a reality. Public health activities and services must be delivered efficiently and effectively, making the best use of innovation, technology, science, expertise, and reliance on a qualified and dedicated public health workforce that is truly valued and supported. While there have been so many uncertainties with the COVID–19 pandemic, one thing is certain: this pandemic would have played out very differently if the capacity of the public health system across this Nation was better able to support the needs of communities everywhere, and if this capacity was adequately built and in place in advance of this crisis.

I come at the notion of public health innovation and technology from a different perspective than some of my colleagues because my background is grounded in project management, technology, and finance. While my experience may be different than others in the field of public health, I believe this expertise is critical to build the structures to transform our Nation's aging public health ecosystem. I have worked to develop plans to guide and prioritize work to align with strategically set goals and include strong performance measures to innovate our public health systems.

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[2] Source: *https://www.census.gov/data/tables/time-series/demo/popest/2010's-total-cities-and-towns.html* (Accessed July 21, 2021).

[3] *https://www.help.senate.gov/hearings/the-path-forward-a-Federal-perspective-on-the-covid–19-response* (Accessed July 21, 2021).

[4] *https://www.help.senate.gov/ranking/newsroom/press/murray-introduces-legislation-to-build-and-maintain-core-public-health-infrastructure-needed-to-save-lives-fight-threats-like-covid–19*.

The chronic underfunding of public health infrastructure is well documented, as well as examples of outdated technology that have hamstrung local, state, and Federal public health responses to the COVID–19 pandemic.[5] And yet, we have heard many stories about how Americans came together, rose to the challenge, and persevered. In my own journey, I transitioned from the field of public health during the pandemic last year, but stayed connected to what was happening in the field and then rejoined to apply my expertise in the process of rebuilding what is necessary to advance our work. I want to highlight some of the progress we have made to improve public health systems in Washington state that exemplify structures and principles we can learn from and share some additional concepts I recommend the Committee consider as it looks ahead.

Examples of Success—the Washington Experience

WA HEALTH (Washington's Healthcare and Emergency Logistics Tracking Hub)

WA HEALTH was developed as a public-private partnership with our health care system and Microsoft to provide actionable data for public health and medical preparedness.[6] WA HEALTH data categories were aligned with U.S. Department of Health and Human Services (HHS) hospital reporting requirements.[7] WA HEALTH is a testament to what we can accomplish through public-private partnerships and innovation. DOH had to overcome several hurdles to operationalize WA HEALTH.

The first hurdle was the lack of digital bridges between public health and health system electronic health records (EHRs). EHRs are generally not built to send data to public health systems automatically. Likewise, few public health departments participate in the U.S. Centers for Disease Control and Prevention (CDC) program to develop digital bridges due to lack of funding and capacity within health[8] departments.[9] In 2009, the Federal Government invested $27 billion to encourage the health system to adopt EHRs, but a similar investment was not made in public health and public health department needs were not considered when these systems were developed.[10]

To maintain WA HEALTH, hospital staff must run reports and send this data to the state public health data system. This is a labor-intensive solution and once the emergency goes away, it is feared that the hospital participation and associated data will likely go away as well. WA HEALTH has demonstrated the benefit of digital bridges between public health and health systems that we must build upon in a sustainable and automated way.

Going forward, it is critical that we operationalize rapidly configurable systems with the capacity to capture data quickly and share case data across states in a standardized way. To address the lack of digital bridges between public health and health system EHRs, Federal funding for electronic case reporting (eCR) could (1) initiate broad-scale, secure reporting from EHRs in clinical care organizations to public health agencies across all jurisdictions; (2) support interoperable and intelligent real-time reporting from multiple sources; and, (3) eliminate paper-based reporting.

The second hurdle was the fact that data systems amongst entities such as hospitals, laboratories, and public health data systems, are not always interoperable. These data systems do not consistently rely on the same data standards (e.g. FHIR or HL7), so they cannot connect. During the COVID–19 response, DOH worked closely with hospitals to develop necessary mechanisms for exchange. Going forward, public health must ensure vendors are held responsible for standardization for transport protocols. Transfer protocols need to be built in to contracts, which

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[5] *https://www.help.senate.gov/hearings/examining-our-covid–19-response-an-update-from-the-frontlines* (Accessed July 21, 2021).

[6] *https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/WAHealth*.

[7] *https://www.hhs.gov/sites/default/files/covid–19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf*.

[8] Centers for Disease Control and Prevention. 2020. *Bridging Public Health and Health Care*. Available at: *https://www.cdc.gov/surveillance/projects/bridging-public-health-and-health-care-better-exchange-better-data.html* (Accessed July 22, 2021).

[9] Miri, A., and D. P. O'Neill. 2020. Accelerating Data Infrastructure for COVID–19 Surveillance and Management. *Health Affairs Blog*. *https://dponeill.com/2020/04/14/Accelerating-Data-Infrastructure-For-COVID-19-Surveillance-And-Management.html*.

[10] Gold, M., & McLaughlin, C. (2016). Assessing HITECH Implementation and Lessons: 5 Years Later. *The Milbank quarterly, 94*(3), 654–687. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5020152/*.

need to be standardized through granting agency requirements. In today's world, interoperability is a bare necessity of a minimum viable product.

To address interoperability of data systems amongst hospitals, laboratories, and public health data systems, Federal funding for areas such as syndromic surveillance and beyond should be ready to do the following: (1) expand the number of hospitals participating; (2) enhance reporting to other health system entry points such as urgent care centers; and, (3) add predictive analytics and artificial intelligence to uncover changes in the occurrence of illness and injuries.

The third hurdle was having outdated public health case management data systems. These public health data systems were not set up to rapidly add new diseases or data variables. Many of the data systems used by public health labs or in epidemiology were created decades ago—some as old as forty years ago. Often these technologies have not matured and are certainly not as mature as hospitals or private labs. For example, the data surveillance system used by Washington and other public health jurisdictions faced challenges in capacity to upgrade this critical system rapidly. In addition, when data systems are hardware bound, they are not scalable to an emergency on the scale of the COVID–19 pandemic. With the additional data variables required for Federal reporting of COVID–19, there was a lot of work that had to go on behind the scenes because the data systems did not align with the mission and myriad needs.

Going forward, we need sustained investment for entities to work across siloes, especially in bringing the private sector to the table to help maturate these critical public health data systems. Public health data systems must be "cloud-based" to allow for rapid scalability to respond to a host of issues including the most ominous one before us, namely a global pandemic in real-time. Funding must be systematic and sustained, while also being smart and strategic. We truly must have public health data systems that are scrappy and scalable; that are built for the 21st century.

In our state, WA HEALTH informatics and visibility were used to allocate critical medical supplies and support health care capacity. It provided decision-makers with real-time input from Washington's hospitals for staffing, emergency department availability, room availability, personal protective equipment (PPE), and other needed items for preparedness and response. When the need arose, WA HEALTH was expanded to collect data from 1,800 vaccine providers to help with our vaccine efforts. The example of WA HEALTH shows that public health has the capability to develop modernized data systems and actionable dashboards when the structures for success are aligned.

2. VACCS Center (Vaccine Action Command and Coordination System Center)

The VACCS Center is a unique public-private partnership launched in early 2021 to support efficient and equitable access to COVID–19 vaccinations across Washington.[11] VACCS is scheduled to demobilize on July 30, 2021. This effort built on a history of strong public-private partnership in the state of Washington through efforts like *Challenge Seattle*, a coalition of regional employers that worked closely with Governor Inslee to address regional challenges throughout the COVID–19 pandemic.

The VACCS Center was created by Secretary Shah as part of DOH's pandemic response, during the critical time of vaccine dissemination. Led by VACCS Center Director Dan Laster, who arrived to DOH with an array of private sector experience, the VACCS Center brought together key stakeholders within state government all the way up to the Governor's Office and extended beyond to critical partners such as health care organizations, including Kaiser Permanente and countless Washington large-scale private business partners, including Amazon, Costco, Microsoft, and Starbucks, as well as those representing community pharmacies, clinics, and others.

The VACCS Center had five complementary workstreams co-led by representatives from the public and private sectors: technology and data, communications, business processes, supply and logistics deployment, and situational awareness. Since launch, the partnership was incredibly successful, creating multiple integrated solutions to address early challenges, including an enhanced vaccine locator tool, an

[11] Building Public-Private Partnerships to Support Efficient and Equitable COVID–19 Vaccine Distribution, Access, and Uptake. Margolis Center for Health Policy. April 2021. *https://healthpolicy.duke.edu/publications/building-public-private-partnerships-support-efficient-and-equitable-covid-19-vaccine* (Accessed July 21, 2021).

expanded 211 Call Center, and a Vaccine Playbook for Public-Private Partnerships. An example of synergy included having partners from Starbucks visit the state-led mass vaccinationsites set up in early 2021, to review and enhance process flow and the consumer experience with respect to vaccine delivery at these sites.

The VACCS Center acted as an intermediary between the public and private sectors ensuring private sector solutions are relevant to the needs of the public sector. The VACCS Center's structure worked to surface problem statements and needs, and then worked across participating organizations to identify opportunities to leverage resources and expertise. The VACCS Center served as a "translator" between sectors and matched the public sector's needs with the private sector's capabilities. This coordination structure was critical for the facilitation of meaningful and pragmatic partnerships. Not only was the VACCS Center's work recognized nationally, but it held true to its mission of ensuring that private sector solutions could be applied to public sector challenges in the area of vaccine delivery.

The VACCS Center is an excellent example of the need for engagement through public-private partnerships. The public sector is often not nimble enough to assess effectively private sector resources and match relevant offerings with state needs; however, during a public health emergency many barriers are removed in order to get to the work at hand. I hope the Committee considers ways to support states and regions to establish and sustain coordination structures to help convene public and private sector interested parties, develop solutions, and direct resources where they can have the most impact. We must have Federal policies that permit flexibility in structure and incentives in place to allow state public health systems to sustain public-private partnerships once the emergency that brings the entities together passes.

3. Washington's Notifiable Disease Surveillance System

There are two ways to stop the spread of a pathogen like a flu virus, HIV, or COVID–19.[12] Hard science examines the chemistry, the biology, and the response to the immune system of the pathogen. Epidemiology looks at the circumstances surrounding a disease or outbreak. The state of Washington, like other states across the country, has worked to increase visibility and improve data system collection of demographic data for COVID–19 and other notifiable conditions, so we can better understand the circumstances surrounding a disease and respond accordingly.

When there is insufficient data, the problem remains invisible, and the initial lack of demographic data around morbidity and mortality from COVID–19 allowed some people to turn a blind eye to inequities. Standing up data systems that could handle demographic data for COVID–19 was critical to reveal the disparate toll COVID–19 was particularly taking on Washington's African-American, Native Hawaiian, Asian-American, Pacific Islander, and Hispanic communities, amongst other1A[13] groups.[14] HHS COVID–19 demographic data guidance provided minimum standards to states.

In Washington, we complied with both HHS guidance and Washington State Board of Health (WSBOH) notifiable condition regulations for health care providers, hospitals, and laboratories, including demographic data reporting requirements for patient race and ethnicity.[15] During the COVID–19 pandemic, we had hoped to adopt more expansive categories for race and ethnicity to understand better the populations impacted by COVID–19, but ran into technical challenges with data collection and interoperability. Gaps in data collection, analysis, and dissemination, including in key areas such as data aggregation, can mask "at-risk" populations that may be disproportionately affected by a public health threat.

In the midst of the pandemic, DOH had to enhance data systems to accept the demographic data established by HHS guidance and often had to manually go back in to add demographic data because providers did not submit the information initially or data systems were not interoperable. Since then, DOH has found ways to address these technical challenges. Additionally, DOH and WSBOH came together to engage community partners and WSBOH adopted new notifiable condition regu-

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[12] Richtel, M. (2020). *An elegant defense: the extraordinary new science of the immune system: a tale in four lives*. William Morrow.

[13] Arias, E., Tejada-Vera, B., Ahmad, F., & Kochanek, K. D. (2021). Provisional Life Expectancy Estimates for 2020.

[14] *https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/data-tables/COVID-19MorbidityMortalityRaceEthnicityLanguageWAState.pdf*.

[15] *https://sboh.wa.gov/News/Articles/ID/2856/Board-Adopts-Fourth-Emergency-Rule-to-Extend-COVID-19-Reporting-Requirements*.

lations which include 71 reporting categories for race and ethnicity that were community-informed and incorporated standards established by the U.S. Office of Management and Budget and HHS Office of Minority Health. [16]

Through ongoing community engagement processes, additional demographic variables were identified that must be prioritized in future policy making, including but not limited to Tribal affiliation, disability status, and housing status. Getting these data categories correct requires meaningful engagement with a variety of communities, which takes time, resources, and trust. We must continue to develop frameworks for more equitable engagement and collaboration in order to promote health and achieve health equity for all of our communities.

We know when dealing with health, a person's environment, physical, social, and emotional needs, all contribute to their immediate and future resiliency. Understanding these social determinant variables are crucial to decision-making. Data reporting for variables that reflect the social determinants of health is less mature and certainly not inter-connected as it should be. Moving forward, we absolutely need to be specific with the standards for housing, food insecurity, and other social determinant variables to get meaningful and usable data. Data governance will be critical. In addition, data related to social determinants is often being collected downstream in other disparate data systems. Data is being siloed, and we need to create public health data systems that reduce duplication of efforts or match the data to improve outcomes.

In 2021, the Washington State legislature passed House Bill 1272 that includes requirements for hospitals to submit patient discharge information to DOH that identify the patient's race, ethnicity, gender identity, sexual orientation, preferred language, any disability, and zip code of primary residence. [17] Both the public and decision-makers demand informatics and information about community health and well-being. I believe we must develop data systems that provide the same level of protection from a variety of threats whether infectious disease in nature such as a pandemic, or chronic disease related, or environmental in nature, regardless of where you live, who you are, or what your income is, because of our experience expanding reporting requirements and our ability to implement structures for public-private partnership and community engagement.

The issue of standardizing demographic data reporting practices is a challenge across the U.S. [18] Currently, demographic categories and definitions differ between states. To understand the population's health, we need data systems that reflect the public we serve. To identify these demographic categories, state and local public health must be at the table because ultimately, we know our communities best.

Federal funding to support a national notifiable disease surveillance system would improve: (1) data security across the infrastructure; (2) automated electronic receipt of data (existing and new data sources); (3) integrated, real-time analytics of data from multiple sources (clinical, lab, epidemiologic); and, (4) seamless, efficient communication and sharing of robust data to and from health care providers to public health agencies and onto CDC.

To date, Washington's DOH has received approximately $120 million in Federal COVID–19 funds for data systems to support critical efforts such as disease surveillance and reporting, testing, case investigation and contact tracing, and vaccine distribution. Through 14 response missions and 38 data system projects, we have invested in a public health "cloud" environment, engaged countless vendor partners in development and modernization of essential infrastructure and systems, brought in new tools and resources, and ultimately identified over a hundred staff members to be trained to support these new capabilities. Essential costs include new equipment, cloud hosting, software licensing and maintenance. Without systematic and sustained funding, we will not be able to keep the forward progress made to innovate public health.

Looking Ahead—A Long Journey

The stories above reflect some of the successes we have had in Washington while simultaneously protecting the public from the COVID–19 pandemic in one of the Nation's most successful responses. They reflect DOH's cornerstone values of **equity**, **innovation**, **engagement** in practice. While these efforts are noteworthy, we know even after we are through this crisis, our work is far from over. We require

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[16] https://sboh.wa.gov/Rulemaking/CurrentRulesandActivity/NotifiableConditions.

[17] *https://app.leg.wa.gov/billsummary?BillNumber=1272&Year=2021&Initiative=false*.

[18] Blauer, B. (2021) *Data disarray damages COVID–19 response, expert says*. The Hub. *https://hub.jhu.edu/2021/06/17/beth-blauer-data-disarray-in-covid-reporting/*.

investments, strategies and structures in place at every level of government to strengthen our public health systems to use sequencing technology efficiently and effectively, modernize data systems to track the spread of diseases and monitor the success of key initiatives such as vaccination efforts, standing up of testing and contact tracing to stop disease outbreaks, build partnerships in hard to reach communities, and build trust as communicators to fight misinformation.

Looking ahead, we must think about ways to innovate data management, systems changes, and operational strategies to create a modern 21st century governmental public health system that we can all be proud of and rely on during times of emergency and beyond.

1. Data Management

Significant work is needed to innovate public health data management, including governance and consensus-based standards. Prior to COVID–19, most people saw the systems that collected data and governance of that data as singular, but as we moved in to COVID–19 and cloud-based analytics, data and systems are increasingly being separated. When data is housed outside of the original data system, we need optimal governance to protect people's privacy and the security of this data while leveraging these insights to protect our communities. With these shifts, all levels of public health will require an equally strong and supported workforce that can help navigate and lead on these critical issues.

Meanwhile, numerous organizations are developing public health data standards and technical roadmaps, including the Office of the National Coordinator for Health Information (ONC) and the Healthcare Information and Management Systems Society (HIMSS). They are working on the technical side of data systems. I believe we will need an equal focus on how to operationalize these standards. There are significantly different maturity levels for data systems across our federated public health ecosystem. As I follow the work of these technical groups on data standards, I believe we will need a substantial investment in resources to operationalize these standards and move forward from a long-term sustainability standpoint. I believe that most state, territory, local and Tribal public health entities may struggle with the organizational systems change needed to implement these vital frameworks and standards. We must consider new mechanisms for funding, incubating, and maturing all levels of the system.

2. Systems Change

Federal funding in public health data systems and infrastructure needs to move away from programmatic siloed funding to enterprise-wide systems and shareable systems. We need to set aside pre-conceived expectations for how funds flow into these programs to build a 21st century governmental public health system that is connected, resilient, adaptable, and sustainable—a 'pandemic-ready' system that can help us solve problems before they happen and reduce the harm caused by the problems that do happen.

Currently most Federal funding channels provide for specific programs (e.g. immunization or STD prevention). The Public Health Emergency Preparedness cooperative agreement funding is used to create infrastructure to respond to emergencies, including capacity and supply. When we go into a public health emergency response, there is not always alignment between this programmatic funding and the emergency response needs. During an emergency, one must work with each program to realign personnel and IT systems, so it is hard to pivot. Programmatically siloed funding for data infrastructure and data systems creates barriers for innovation and barriers for emergency response.

In addition to a shift toward investment in enterprise-wide systems and shareable systems, I believe we should consider funding and support that brings multiple states together to form regional innovation hubs. There is regional variance in both capacity and capabilities across America, as well as gaps in systems and workforce. The most efficient path to address this complexity is through regional innovation hubs.

Placing the responsibility and decision-making at the regional level can best shepherd this modernization for the immediate and future needs of the impacted communities. These regional centers could bring together Federal, state, local, and Tribal governmental agencies in partnership with community stakeholders, academia, and private sector partners to innovate the way public health is delivered to their communities. These regional hubs should have the ability to direct and redirect re-

sources while being held accountable for maturing the systems and demonstrating outcomes.

One of the primary tenants of this type of approach would be having a Federal presence in the regional innovation hub that can communicate, bridge, and coordinate the myriad Federal agencies and programs that fund and support public health. The decentralization of the decision-making will align public health at all levels to be nimble, cost effective, and outcome oriented.

The reality is that there are regional differences in all aspects of community, health, resources, challenges, opportunities, and types of emergencies we face. Our Federal system provides ample opportunity for taking risks in our work with respect to innovation. Regional innovation hubs could provide a "laboratory" structure to implement public health data infrastructure strategically for the 21st century. Thanks to robust visualization tools, we have all been able to see the geographic uniqueness of this pandemic. After witnessing the pain and suffering COVID–19 has caused, we have an opportunity to acknowledge that uniqueness with a Federal approach that recognizes, embraces, and supports those unique regional public health needs.

Operational Strategies

Data modernization is not just about the technologies, it requires operational strategies to implement successfully. More funding alone will not bring public health data systems in to the 21st century. State, territorial, local, and Tribal public health agencies will need increased organizational operational capacity, modernized enterprise IT architecture, and a culture of innovation to build the **Innovation First** culture of tomorrow. I hope the examples and concepts shared throughout my testimony capture these operational strategies.

We will only be able to build a 21st century governmental public health system if we have the workforce to do it. During the COVID–19 pandemic, as many public health entities across the Nation, DOH had to expand its own workforce rapidly. This translated into the hiring of over 500 staff members and the contracting of over 500 additional personnel, including for work in laboratory settings, case investigation and contact tracing, surveillance and informatics, outbreak response, public affairs/communications, diagnostic testing, and incident management command and control for dealing with the logistics of testing, contact tracing, PPE distribution and vaccinations. This "just in time" building of capacity in the midst of a crisis is no rational way of preparing our Nation for future emergencies.

Technology's potential can only be realized if public health agencies are equipped to harness it. We must have systematic and sustained funding to increase salary caps to recruit and retain optimal staff and create new jobs in the public and private sector across jurisdictions, new curricula, professional development, post-graduate fellowships, and on-the-job training. Funding would help the public health system achieve full capacity to understand and securely integrate health data to: (1) provide more complete, accurate, and timely population-level monitoring; (2) ensure optimal health security through robust public health surveillance to prevent death and disease; (3) move data to action by driving policy and practice to accelerate health improvement; (4) reduce provider reporting burden; and, (5) bolster and maintain cybersecurity. The growth and retention of the public health workforce should contain a specific focus on diversity—racial, ethnic and beyond—to address issues of trust, confidence, and representation of the diversity of the residents served by the public health agency in both rural and urban areas. The very health, well-being, and resiliency of that workforce must also be maintained and supported.

Congress should explore alternative funding models to ensure predictable and sustained funding over the next decade. These funding models could potentially be outside of discretionary appropriations and provided through a "public health infrastructure fund" approach, which is a critical component of Chair Murray's *Public Health Infrastructure Saves Lives Act*. Rather than constraining states by defining what types of occupations and how many individuals should be employed, workforce dollars should be flexibly administered to states either via block grants or an alternative mechanism for use in hiring the public health professionals and experts needed to meet both the current and future workforce needs of the jurisdiction. Ensuring key flexibility is critical to enabling public health agencies to recruit and retain staff.

Conclusion: The Future Is Achievable

Moving forward, I am excited by what innovation and technology can bring to the issues at hand within public health and beyond. I recommend the following for fur-

ther policy consideration by the U.S. Senate Committee on Health, Education, Labor, and Pensions, to improve our Nation's public health system:

1. **Coordinate policies, consensus-based standards, decision-making, and invest in enterprise-level IT and data infrastructure** that supports cloud-based platforms, shared cross disease systems and real-time data automation. This includes closer integration of state and Federal partners including the CDC to develop interoperable systems that allow for efficient data exchange and the development of more timely, efficient and effective automated reporting systems to report results to state (and local) health agencies.

2. **Create a system-wide environment of structured innovation** that modernizes public health systems and enables new public-private partnerships with healthcare providers, private sector, and other entities to create new tools that serve communities, patients, and consumers.

3. **Create regional innovation hubs for systems modernization** that allow for states to achieve economies of scale, small enough to develop data standards to collect data that is meaningful to communities, engage and leverage private sector expertise located in the region and enable a unified Federal voice that can be nimble within a localized structure that actually operationalize state and local public health systems/data modernization efforts that are accountable.

In closing, COVID–19 is the challenge of our lifetime, but it is also a watershed event to improve the health and well-being of all individuals through more robust, smart, and sustained investment in our public health system. There are critical investments that need to be made and innovative policies that should be considered to meaningfully modernize our public health system. On behalf of our state and my colleagues at ASTHO and across the public health system in this Nation (and beyond), we stand ready to work with you to begin the process of innovatively investing in public health. It is what our Nation needs and what our Nation requires to move forward successfully.

Thank you for holding this hearing to discuss lessons learned from the COVID–19 pandemic as this Committee develops legislation to define the vision and capabilities for a 21st century governmental public health system that promotes health, prevents disease, and protects all communities across the country.

[SUMMARY STATEMENT OF LES BECKER]

The U.S. public health system has worked around the clock to respond to the COVID–19 pandemic since the first identified U.S. case was confirmed in our State of Washington in January 2020. As you know, to date, the State of Washington has had one of the Nation's most successful responses to COVID–19 under the leadership of Governor Jay Inslee, and I am proud to be a part of this response. I want to highlight some of the progress we made to improve public health systems in the State of Washington and discuss ways to innovate data management, systems changes, and operational strategies to create a 21st century governmental public health system to better prepare the U.S. for future public health emergencies.

Public health has the capability to develop modern data systems and actionable dashboards when the structures for success are aligned. One example is WA HEALTH which was developed as a public-private partnership with our health care system and Microsoft to provide actionable data for public health and medical preparedness. It provides decision-makers with real time input from Washington's hospital system for staffing, ER availability, room availability, PPE, and other needed items for preparedness and response. More recently, WA HEALTH was expanded to collect data from 1,800 vaccine providers to feed into the state's Vaccine Locator tool and included data on wheelchair accessibility and language interpreters onsite. Another example is standing up data systems that could handle demographic data for COVID–19 which was critical to reveal the disparate toll COVID–19 was particularly taking on Black, native Hawaiian and Pacific Islander, Asian-American, and Hispanic communities, amongst other groups. Washington recently adopted new notifiable condition regulations which include 71 reporting categories for race and ethnicity that were community-informed. We need data systems that reflect the public we serve.

Public health emergencies strike and funding spikes; however, the funding is temporary and targeted and does not address the sustained, longitudinal needs of our public health system, including a 21st century public health workforce and modern-

izing public health data systems. Everyone, everywhere, in all communities, should be able to rely on a strong public health system that is able to support them when emergencies strike. Indeed, Federal legislation like Chair Murray's *Public Health Infrastructure Saves Lives Act* [1] could help make this hope a reality.

The CHAIR. Thank you very much.

Ms. Arthur.

STATEMENT OF PHYLLIS ARTHUR, VICE PRESIDENT, INFECTIOUS DISEASES AND DIAGNOSTICS POLICY, BIOTECHNOLOGY INNOVATION ORGANIZATION, WASHINGTON, DC

Ms. ARTHUR. Good morning, Chair Murray, Ranking Member Burr, and Members of the Committee. My name is Phyllis Arthur. I am the Vice President of Infectious Diseases and Emerging Science Policy at the Biotechnology Innovation Organization, or BIO. Thank you for the opportunity to share our thoughts regarding lessons learned from the COVID–19 pandemic.

Since January 2020, our industry has initiated over 950 unique therapeutics and vaccines against COVID–19, demonstrating our commitment to the critical research, development, and manufacturing of medicines that help save lives in a public health emergency. COVID–19 will not be our last public health emergency. We face numerous bio threats from natural and bioterror threats. Strong support for medical countermeasures R&D is critical to protecting our National Security.

Today, I will share BIO's thoughts on how to strengthen our national preparedness through coordinated leadership, expanded partnership with industry, and better public health infrastructure. We applaud the success of the Government partnerships in developing and distributing vaccines and therapeutics. BIO believes a stronger PHEMCE led by the ASPR could accomplish similar success in the future given the health emergency expertise within ASPR. An interagency PHEMCE should prioritize products, move products swiftly through agencies for development, and procure MCMs through the SNS. Appropriate funding levels must be provided for early stage development through large clinical trials, manufacturing scale up, and procurement.

Second, maintaining a permanent framework for MCM clinical trials such as ACTIV to rapidly evaluate products for emergency situations is the best way to rapidly respond. Third, our Government must work with industry on communicating clear product priorities and requirements, as well as strategies for maintaining excess capacity for emergencies through multiple partnerships. Any payment for this capacity should be viewed as a cost effective insurance policy for national preparedness.

BIO agrees with the strategic focus of the American Jobs Act that proposes investment in the U.S. supply chain and domestic production. Congress should also consider several bills offered by the Ways and Means Committee that seek to incentivize investment in domestic manufacturing. Fourth, the Government must ex-

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[1] *https://www.help.senate.gov/ranking/newsroom/press/murray-introduces-legislation-to-build-and-maintain-core-public-health-infrastructure-needed-to-save-lives-fight-threats-like-covid-19-.*

pand partnerships across a host of threats. PAHPAIA included authorities allowing strategic investments for novel platforms and manufacturing advancements. Congress should authorize BARDA funding for platforms to provide the most shots on goal for potential threats.

Establishing partnerships with platform companies to work on a predetermined set of infectious diseases will shorten the development timelines for the next pandemic. Congress should also work with the FDA to clarify the regulatory mechanisms by which platforms can be authorized or approved when deployed against subsequent pathogens. There must also be continued investments in novel antiviral mechanisms. BIO is encouraged by the launch of the antivirals program for pandemics and UNC's READDI Program, which could stimulate early stage development. These programs then must be supported by BARDA funding for later stage development and manufacturing support.

These initiatives must be in addition to the ongoing programs to develop, produce, and stockpile MCMs for specific CBRN and biological threats, preparing for all possible scenarios. This includes support of therapeutics that treat severe consequences like acute respiratory distress syndrome and antibiotic resistant infections. COVID–19 infections reinforce the urgent need for antimicrobial products as both major public health and a National Security threat.

We therefore encourage the inclusion of PASTEUR and DISARM as part of the legislative effort. Last, we must invest in public health infrastructure by expanding CDC surveillance capabilities for viral testing and genomic sequencing, and also the HHS systems that capture utilization and demographic data for MCMs during an emergency, while sustaining the infrastructure improvements made this past year for delivery of therapeutics and adult vaccines.

This will ensure that communities can get vaccines and treatments not only during a pandemic but also on a routine basis. BIO and our members are committed to working with Congress on these issues. And we thank you again for the opportunity to testify today.

[The prepared statement of Ms. Arthur follows:]

PREPARED STATEMENT OF PHYLLIS ARTHUR

Good morning Chair Murray, Ranking Member Burr and Members of the Committee. My name is Phyllis Arthur and I am the Vice President of Infectious Diseases and Emerging Science Policy at the Biotechnology Innovation Organization, or BIO. Thank you for the opportunity to share our thoughts on the topic of the lessons learned from the COVID–19 pandemic.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States and over 30 nations. Our mission is to advance biotechnology innovation by promoting sound public policy and fostering collaboration, both locally and globally. Our members range from entrepreneurial companies developing their first product to Fortune 500 multinational companies.

BIO and our members appreciate that the Committee is proactively working to collect lessons learned from the COVID–19 pandemic and put forward legislation to prepare for future pandemics. As companies investing in novel therapeutics, vaccines, diagnostics, and platform technologies to help save lives from all types of biological threats, our members are committed to continuing to strengthen the public-private partnerships enabling this critical research, development, and production, and we welcome the opportunity to provide comments on how to bolster our pandemic preparedness. To this effect, the global biopharmaceutical industry has initi-

ated over 900 unique therapeutics and vaccines against COVID–19 since January 2020.

Our national biodefense enterprise supports medical countermeasure (MCM) development for a host of known and unknown threats: chemical, biological, radiological, and nuclear (CBRN), pandemic influenza, emerging infectious diseases, and antimicrobial resistance (AMR). Pandemic preparedness relies on the Nation's ability to develop, procure, and deliver the necessary medicines and diagnostics to combat biological threats. The U.S. needs to maintain a robust stockpile of MCMs for each of these risks. We know that periodic threats, such as a 100-year pandemic like COVID–19, will occur but each individual threat has such a rare occurrence rate that commercial markets for such countermeasures do not exist. That is why the U.S. Government, through the Biomedical Advanced Research and Development Authority (BARDA), the Project BioShield Special Reserve Fund (SRF), and the Strategic National Stockpile (SNS), must invest in and procure the necessary MCMs to be ready for the next pandemic and other biological threats.

The Department of Health and Human Services (HHS) and the Department of Defense (DOD) work in partnership with the private sector on the development of vaccines, therapeutics, diagnostics, and platforms to protect the American people against these threats. As BARDA's portfolio has grown to include 61 approved products, funding levels for HHS Assistant Secretary for Preparedness and Response (ASPR) and BARDA initiatives have remained largely stagnant over the past decade. Recent iterations of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multi-Year Budget have shown increased projections of necessary funding for BARDA advanced research and development (ARD), pandemic influenza, Project BioShield, and the SNS, and BIO would expect further increases projected in the next iteration of the Multi-Year Budget.

Leadership

Role of the ASPR and the PHEMCE

Current statute clearly places authority for pandemic preparedness and response with the ASPR. The ASPR has the most appropriate expertise and statutory responsibilities for coordinating a public health emergency response, given their relationship across the healthcare supply chain, the pharmaceutical industry and public health preparedness leaders. This was the intent of the original Pandemic and All-Hazards Preparedness Act (PAHPA), which was further codified in PAHPA's subsequent bipartisan reauthorizations passed during the Obama & Trump Administrations. The ASPR should be empowered to lead the coordination of government preparedness initiatives, public health emergency and pandemic responses. Since the ASPR is intended to be the leader of the PHEMCE, in partnership with the DOD, other relevant agencies should work in collaboration and coordination with the ASPR.

The ASPR currently lacks the authority to clearly direct the actions of the PHEMCE. While we certainly applaud the success of both Operation Warp Speed and the current White House COVID–19 Taskforce in developing and distributing COVID–19 vaccines and therapeutics, BIO believes a stronger PHEMCE could have accomplished similar goals without the delays of building new organizational structures. The roles within the PHEMCE should be clearly defined, with a clear, centralized power structure, in advance of a public health emergency. Legislation ought to clarify the responsibilities and authorities of the many actors for pandemic preparedness and response and determine the chain of command so that directives come from a single top-down source or inter-agency group. Confusion regarding leadership undermined the government's ability to clearly communicate with industry during its COVID–19 response, and a proper pre-planned organizational structure and procedures could help prevent these issues from occurring in the future.

Leadership and Management of the Strategic National Stockpile

Another specific area of concern is leadership of the SNS. As we learned during the COVID–19 pandemic, the SNS is vital for many healthcare products from personal protective equipment (PPE) to generic essential medicines to complex biologicals and vaccines. BIO strongly believes that the SNS must remain under the ASPR's jurisdiction with funding levels that account for the breadth of products in the Stockpile and the complexity of managing the myriad roles the SNS must play. For many MCMs, such as smallpox vaccines, anthrax antitoxins, and pandemic influenza products, the Federal government is the primary customer through procurements by the SNS and the SRF. The ASPR is best equipped to manage all of the

products included in the Stockpile, especially MCMs, given the role of the office in setting requirements, coordinating responses to many types of health emergencies, leading BARDA investments in product development, and planning lifecycle management and stockpile operations. For MCMs, future stockpiling strategies must be applicable to each specific product being procured, based upon characteristics such as the market size, use, timelines for manufacturing, and the speed of pathogen spread for the different medical countermeasures.

With respect to state and hospital-based stockpiles, BIO believes that they may be suitable for some products such as PPE, antibiotics, or threats endemic to the region, but they are not replacements for the national stockpile for specific MCMs for national security threats, like anthrax. Investment in state and hospital stockpiles does provide value to the preparedness of the Nation, though money spent on any potentially new state stockpiles should not come at the expense of the investment in, or replenishment and maintenance of, classic or non-commercial MCMs within the Federal SNS.

Communications With Stakeholders

The ASPR and PHEMCE leadership need to strengthen communications systems surrounding pandemic preparedness. Clarity on the distribution plan of an MCM is important for Federal, state, and local response to public health emergencies, and industry often has a role to play in communicating around and facilitating product distribution. Federal, state, and local government public health responses are intimately interconnected. There must be the infrastructure and resources to allow seamless communication and coordination between all parties for the fastest possible response. The ASPR and the Centers for Disease Control and Prevention (CDC) must be unencumbered in their ability to ensure coordination and communication between Federal, state, local, and industry partners when time matters most.

Threat Assessment and Awareness

Congress must take steps to ensure its awareness of the threat assessments that drive PHEMCE's MCM requirements and decisions. Currently, this information is not regularly shared with Members of Congress, even though statute requires an annual submission of a threat-based review to Congress. To our knowledge, the threat-based review report required by the most recent PAHPA reauthorization has never been submitted to the appropriate congressional committees. BIO believes that a better understanding of these threat assessments would help Congress better understand the role played by the PHEMCE and the changes in the threat matrix on a year-to-year basis. Regular visibility into the threat assessment process would assist Congress in evaluating appropriate levels of funding to ensure the PHEMCE fulfills its statutory requirements. Congress would also be better able to perform its oversight role with an improved understanding of all biological threats, whether naturally occurring, deliberate, or accidental.

Commitment to Public Private Partnerships

Private sector partners must be treated as true partners rather than vendors. This means understanding the business needs of partners so that the private sector can be sustained and therefore all products can be available over time. These relationships should not be only transactional.

Clear Communication on Product Requirements

Industry partners need clarity around product requirements, plans for product replenishment, and when the U.S. Government thinks that a requirement or threat is fulfilled or completed. When there are changes in prioritization, those changes must be communicated with industry partners in a timely manner. The ASPR should use the Multi-Year Budget process to communicate the short-and long-term strategy and priorities of the U.S. Government for the development and procurement of MCMs.

Staffing for BARDA Contracting

Another key aspect of the public-private partnership is the length and complexity of contracting timelines. Legislation should facilitate ASPR/BARDA to quickly bring in contracting staff from other Federal agencies or other implement other solutions for expedited contract reviews. This was recommended by the Bipartisan Commis-

sion on Biodefense and implemented by the last Administration. Contracting authority should principally remain with BARDA.

The billions of dollars recently appropriated to ASPR and BARDA for COVID–19 response necessitates an increase in BARDA support staff. Limited contracting staff is a bottleneck to rapidly issuing contracts and other agreements to accelerate development of drugs, vaccines, and diagnostics that can save lives during a public health emergency. Additional contracting staff can enable not only a standard review process but an expedited process that is badly needed.

Under usual circumstances, contract timelines at BARDA have been lengthy. At best, new contracts have taken about 60 days for very small awards (under $750,000) for BARDA's Division of Research Innovation and Ventures (DRIVe) program. For larger awards under routine BARDA programs, contract decisions can take 6–9 months.

This is a bureaucratic issue but also fundamentally a staffing issue. Over the last several years (before COVID–19), companies interfacing with BARDA have experienced a severe shortage of experienced contracting staff within the agency. Several companies have reported up to four contracting manager changes in under a year.

Increasing Domestic Biopharmaceutical Manufacturing

The public-private partnerships for MCM research & development, manufacturing, and stockpiling are critical to the health security of the U.S. Neither the U.S. Government nor industry would be successful in this effort alone, and the investments made by the U.S. Government are important to sustaining and bolstering our national preparedness. The health security provided by a robust domestic market for medical products, along with the economic impact of high paying jobs, is of the utmost value to the United States. Fair and competitive markets are important for maintaining the rigor and vitality of the industry, and Executive Order 14005 (Ensuring the Future Is Made in All of America by All of America's Workers) includes many provisions to improve upon the economic ecosystem.

There is a need to incentivize future investment in U.S. manufacturing capabilities, to ensure that the United States is the best place in the world to locate global biomanufacturing facilities. BIO recommends that Congress consider providing targeted incentives to grow and maintain the U.S. domestic biopharma manufacturing sector. Legislation should require clarity from the U.S. Government related to the requirements for MCMs, so Congress has needed visibility and private sector partners can accurately assess the government's needs.

One model to consider strengthening is the Centers for Innovation in Advanced Development and Manufacturing (CIADM) program, which was created in 2012. This program, which had seen inadequate government investment over many years, has unfortunately resulted in the sale and exit from the program of one of the three facilities due to the unsustainability of the model as actually funded and supported.

The American Jobs Act proposes investment in both the U.S. supply chain and domestic production, and currently the House Ways and Means Committee has several bills, including the "Start-Ups for Cures Act," the "More Cures Act," the "Infectious Disease Therapies Research & Innovation Act," and the "IP Repatriation Act" that seek to incentivize onshoring and continued investment in domestic medical manufacturing. Passage of these bills would help ensure that the U.S. has a robust medical supply chain and the necessary domestic manufacturing capacity needed to combat the next pandemic.

Investments also should be made in workforce development and training. Onshoring and growing the domestic manufacturing industry is more than just a health security priority, it is also a jobs and economic priority. One of the United States' major national strengths has been the high-quality workforce that manufactures our medicines and supply chain inputs through a diverse network of job training and occupational expertise respected around the world.

We believe the United States should create a national industry/academic preparation clearinghouse focused on new curricula and programs that incentivize an adequate supply of management, sales, marketing, and regulatory personnel experienced in manufacturing for the biotechnology industry.

The US must also invest more significantly in science and Science, Technology, Engineering, and Math (STEM) education at all levels but especially at the college and graduate level. The rapid evolution of life science knowledge is a driving force in the biopharmaceutical industry and should be viewed as a core national security and domestic policy priority. These efforts should be complemented with a sound

foundation of immigration policies that attract and retain the best technologists, scientists, and innovators from around the world.

BIO supports increasing U.S.-based manufacturing of critically needed medicines, but not a broad mandate requiring MCMs, essential medicines, and related active pharmaceutical ingredients (API) to be made in the United States. There are numerous challenges to relying solely on U.S. manufacturing, including lack of access to certain raw materials, gaps in specialized workforce needs, and governmental regulations that would make it extremely challenging to produce in the United States without significant regulatory changes and cost considerations. This is especially important for those MCMs targeted to specific biological threats with limited demand. These medicines are generally made in one facility and shifting them to a U.S. production site may cause undue cost, delays, and manufacturing inefficiencies. Also, any changes would take significant time for companies to implement, as supply chains, including the facilities for manufacturing API, often are established years in advance of a product's launch, from the base of global regulatory filings/approvals, and are designed with global access and resiliency in mind.

Any policies to incentivize U.S. medical supply manufacturing must be targeted and recognize the complex nature and inherent global aspects of the biopharmaceutical supply chain. The medical supply chain is incredibly delicate and complex. The many products in supply chain are unique and have their own market intricacies, and so BIO would caution against any one-size-fits-all or product-blind policy for managing the supply chain. At the same time, there is, of course, a need for redundancy built into the supply chain. When determining where redundancy is required, it is important to keep in mind production capability and the complexity of certain products.

Investment across the whole supply chain, along with an incentive structure that rewards market entry as well as rewards those who choose to stay in the MCM market, is needed to create a domestic supply chain that is sustainable and secure.

Private companies have solutions related to supply chain and manufacturing challenges, but the U.S. Government must be a transparent, communicative, and cooperative partner. The U.S. Government must work with industry to find strategies for maintaining some level of excess capacity for emergencies, a sustainable infrastructure that can surge during a public health crisis. To reserve manufacturer capacity to use when needed, the government would need to pay for that reserved capacity and ensure it is not double-booked for other clients. To ensure adequate capacity is achieved, the U.S. Government should pursue multiple partnerships, build excess manufacturing capacity into the system, and pay for capacity on top of existing demand—not supplant existing demand. These manufacturing partnerships should be viewed as a cost-effective insurance policy for national preparedness. Additionally, public-private partnerships to stockpile ancillary materiel such as glass vials and syringes that will be needed for fill-finish capabilities for a variety of products should also be utilized.

Strategies That Support MCM Development

Platform Technologies for Vaccines and Therapeutics

COVID–19 will not be the last emerging infectious disease that the U.S. will need to respond to. Support for capacity and capability building for MCMs and our public health system is critical to protecting our national health security from emerging infectious disease threats. Investments must be made now in new technologies to ensure our national health security through preparedness and quick resolution of an outbreak when any emerging pathogen arises. The 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) included clear authorities for ASPR and BARDA related to strategic innovation in countermeasures for emerging infectious diseases, especially through support of novel platform technologies and manufacturing advancements. The PHEMCE Multi-Year Budget has long highlighted the need for dedicated emerging infectious disease funding, but neither Congress nor multiple Administrations have called for annual investments to better address this critical need. Funding during a crisis is often too late, as development of drugs, vaccines, diagnostics, and platform technologies takes time. Even with accelerated timelines during the COVID–19 pandemic, biotechnology innovations took the better part of a year to bring to FDA authorization. As COVID–19 demonstrated, that delay risks lives and causes trillions of dollars in losses to our economy—considerably more than any upfront investments in these MCMs and rapid response capabilities.

Establishing flexible partnerships with industry, particularly those with established vaccine, therapeutic, and diagnostic platforms, to then work on developing MCMs for a pre-determined set of emerging infectious diseases and families of viruses that have pandemic or even regional outbreak potential, will shorten the development timelines for the next outbreak or pandemic. When an outbreak of a novel pathogen occurs, companies can then pivot to applying that platform to the novel pathogen.

Congress should specifically authorize funding within BARDA to allow for investments in numerous platforms (such as mRNA, protein subunit vaccines, monoclonal antibodies) so that the U.S. has the most "shots on goal" to be able to respond quickly and effectively to any potential threat. BARDA should, in collaboration with the National Institutes of Health (NIH) and the DOD, create a prioritized list of emerging infectious diseases and viral families with outbreak potential, including vector-borne diseases. This list should be incorporated into the MCM advanced research and development and procurement programs at HHS and DOD, including the SNS, to ensure the U.S. can meet a surge in demand when outbreaks occur.

Additionally, Congress should work with FDA to clarify the regulatory mechanisms by which platforms can be authorized or approved in a timely manner for the next pathogen. Platforms that are tested and proven for a certain pathogen hold the promise of potentially shortening timelines for other pathogens, but FDA's thinking about how they are viewing regulatory considerations for the base platform in addition to review and approval for specific products could help spur further innovation in novel technologies.

Investment in Novel Antivirals and Therapeutics

Investments in novel mechanisms for developing antivirals as well as treatments for the secondary consequences of infections can make future public health emergency responses more efficient and potentially faster. Almost 20 percent of the therapeutics tested against SARS-CoV–2 were repurposed from other fields and served as a model for not only quickly understanding the virus but also for directing the development of novel clinical products designed specifically to counter the unique nature of the virus.

BIO is encouraged by important programs like the Antivirals Program for Pandemics and the University of North Carolina Rapidly Emerging Antiviral Drug Development Initiative (READDI). These programs will help invest in new antiviral technologies through partnerships between government, academic, and industry scientific leaders. These programs must be accompanied by funding at BARDA for later stage development and manufacturing support for the most promising technologies, especially those that could be applied to both commercial and pandemic pathogens.

While there is a need for more R&D in versatile products that can address an array of threats, such as antivirals, the government must continue to stockpile and invest in MCMs for *specific* CBRN and biologic threats so that the Nation is prepared for all possible predictable scenarios. Novel therapeutics for the treatment of the severe consequences of a serious infection should be supported and developed as well. Many of these products developed during the COVID–19 pandemic may be effective for treating the same or similar consequences of other respiratory illnesses, like a bad influenza season. BARDA and the SNS must balance their investment between specific countermeasures and versatile ones to fully prepare for any future threat.

Additionally, investments in novel and more accessible delivery systems for MCMs can improve the emergency response of the Nation and provide better outcomes for patients. Less invasive MCMs and easier delivery mechanisms improve access for Americans, especially in underserved or rural communities where, for example, access to infusion centers may be difficult to reach.

Pandemic Influenza Strategy

Pandemic influenza remains as likely a threat as it has ever been, and investments through BARDA, NIH, and the CDC are critical to preparing the Nation and the world for a pandemic influenza event. The development and manufacturing of influenza vaccines, therapeutics, and diagnostics by industry is dependent on Federal funding to support the scale and scope of U.S. Government requirements. There is no commercial market for pandemic influenza vaccines. Continued investment is necessary to maintain a robust R&D pipeline and sustain the capabilities the U.S. has developed.

The September 2019 "Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health" acknowledges that the current domestic enterprise for manufacturing influenza vaccines has critical shortcomings. Further funding for BARDA's pandemic influenza activities will support work on the development of more effective, longer lasting vaccines, as well as novel antivirals and therapeutics and rapid diagnostics. These additional funds are critical to meeting the needs and objectives expressed in the Executive Order with respect to preventing the spread of influenza viruses and protecting the United States from future pandemics.

Antimicrobial Resistance (AMR) as a National Security Threat

Antimicrobial resistance (AMR) represents a major public health and national security threat. The CDC estimates almost 3 million Americans suffer from AMR-relevant infections annually, with over 48,000 deaths resulting from those infections. As the COVID–19 pandemic continues, a sizable minority of patients are suffering from secondary infections, with the CDC identifying resistant secondary infection outbreaks in COVID–19 units. This reinforces the urgent need for access to effective antimicrobial products as a part of our pandemic preparedness and response.

A key component of addressing AMR is to address the market challenges that have caused a deterioration of the antimicrobial medicines pipeline. The Government Accountability Office (GAO)'s 2019 "Antibiotic Resistance Report" concluded that pull incentives as well as reimbursement reform are needed to ensure the Nation has the AMR medicines it needs. While BARDA's CARB-X program makes investments to help support R&D, HHS has indicated it does not have the authority to implement the policies to reform these market challenges. However, Congress has put forward two pieces of legislation, the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act of 2021, which address reimbursement barriers to patient access, as well as The Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act, which creates a sustainable return on successful R&D investments into AMR. BIO believes both policies are key steps to address the market challenges of AMR and should be included in any pandemic preparedness package.

MCM Marketplace and SNS Investments

For many MCMs, the SNS is the only market. Industry partners have invested in these technologies in part due to the guarantee that there is a sustained government market. In order for the SNS to be properly prepared for the next pandemic, it must be fully funded. For the last 10 years, funding of the SNS has been flat while new FDA approved MCMs have been added to the Stockpile. Though the President's fiscal year 22 budget and the draft budget in the House do propose an increase in funding, it still lags behind the amount recommended by the professional judgment in the PHEMCE Multi-Year Budget. Because of this deficit in funding, many products have not been replenished as they should have been. This is particularly true for MCMs against biological threats like smallpox and anthrax. Adequate, sustainable funding for the SNS keeps the MCM manufacturers in the countermeasure space, allows for companies to properly plan for long-term development, and propels competition and innovation.

Additionally, ASPR and BARDA play a critical role in managing the lifecycle of an MCM as the entities responsible for late-stage countermeasure development and procurement. When funded effectively, they facilitate the transition of every medical countermeasures from BioShield to sustainable procurement by the SNS, which is vital for the continued health of the MCM marketplace.

MCM Priority Review Voucher (PRV)

BIO is supportive of the Medical Countermeasure PRV program created by the 21st Century Cures Act and sees the program as an important incentive for the research and development of medical countermeasures. However, the current five-year sunset of the program will likely offset any incentive that the program offers. The program should be extended through the removal of the sunset.

Clinical Trials for Pandemic Response

During the COVID–19 pandemic, the NIH established the Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) program, which is managed by the Foundation for the National Institutes of Health (FNIH) and includes BARDA, the CDC, FDA, DOD, the Department of Veterans Affairs (VA), "The Operation"

(formerly known as Operation Warp Speed), the European Medicines Agency (EMA), and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies.

This public-private partnership seeks to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. The problem that it sought to address was that there were numerous products in development, all competing for patients to participate in clinical studies. ACTIV worked to coordinate and streamline processes to make the best use of biomedical research resources and testing of preclinical and clinical compounds. It also worked to prioritize the most promising candidates and move them into clinical trials in a way that was safe and efficient.

This coordination across agencies and with industry led to many of the successful products, especially the therapeutics, being used today to combat the pandemic. The fast-tracking framework gave needed guidance to industry, led to the development and use of master protocols, and also expedited the trials process while maintain the highest standards of safety and oversight.

Setting up and maintaining a permanent structure for a clinical trial framework to rapidly evaluate products for emergency situations is the best way to rapidly respond to emerging health threats. NIH, FDA and BARDA should lead, and coordinate with international partners (e.g., the Coalition for Epidemic Preparedness Innovations (CEPI), the Foundation for Innovative New Diagnostics (FIND), European Health Emergency Preparedness and Response Authority (HERA)), in the identification of priority pathogens and the creation of a global research agenda to accelerate the development of therapeutics, vaccines, and diagnostics against emerging infectious diseases. There is no reason to disassemble or abandon this successful program, only to have to rebuild it again sometime in the future. An ACTIV-like program as a long-term part of the pandemic preparedness infrastructure will ensure the fastest, safest, and best-planned pathways to vaccines, treatments and diagnostics in the future.

Also, diversity in clinical trials was an important aspect of the COVID–19 response and must be prioritized going forward. Prioritizing diversity in trials not only leads to better data generation and more effective outcomes, but it also strengthens the public confidence in the products across the many groups represented in the trials.

Strengthen and Clarify the Emergency Use Authorization (EUA) Process

The EUA process functioned largely as designed during the COVID–19 pandemic. Since going through the process in a pandemic setting, it may be of value to set up an emergency response framework to more rapidly get decisions made by FDA, NIH, CDC, and/or the Advisory Committee on Immunization Practices (ACIP). Expedient communication with industry and stakeholders is paramount to an effective EUA process. Making the process standardized and providing as much transparency to the public as possible will ensure a successful response in the future and help to combat vaccine hesitancy by helping to ensure the American people understand the safety, effectiveness, and quality of any vaccines and therapeutics that receive EUA. This should be coordinated with promotional outreach efforts for EUA products that could help with the uptake or use of vaccines and therapeutics to directly combat misinformation.

However, the EUA process proved to be more complex and challenging in terms of providing requirements and authorization to a number of manufacturing facilities—even with a significant, frequent, and sometimes embedded presence from the FDA as well as Operation Warp Speed representatives from HHS and DOD.

Health Defense Operations (HDO) Budget Designation

Congress should authorize an HDO budget designation for a narrow set of programs, projects, and activities critical to our Nation's health security. The HDO designation would exempt certain programs from statutory (and deemed) budget caps to ensure Congress is able to appropriate sufficient sums to protect our national health security. In order to understand the true need of agencies, Congress should require agencies to provide a bypass professional judgment budget that is not constrained by spending caps.

Public Health Infrastructure

U.S. Surveillance Systems

As our Nation's public health agency, CDC is the lead for viral surveillance. CDC's efforts help to provide early warnings of emerging infectious diseases and emergent variant strains of infectious diseases. More funding is needed to support and expand CDC's viral testing, genomic sequencing, and surveillance capabilities so that we continue to have an accurate picture of disease epidemiology and circulating viral strains to properly direct public health response. This is pivotal to track the evolution of SARS-CoV–2 but also emerging infections, both viral and bacterial.

We must remain vigilant against other infectious diseases during the COVID–19 pandemic by increasing surveillance of seasonal and pandemic influenza and other novel viruses and bacteria.

To improve our understanding of emerging infectious diseases in the U.S., Congress should improve CDC surveillance by expanding the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Vector-Borne Diseases' ArboNet system to enhance active data collection and analysis of vector-borne diseases, within our borders or from returning travelers into the U.S. and enhance collection of information on geographic and behavioral risk factors. In addition, Congress should ensure adequate funds are authorized for the CDC for the collection, sequencing, and analysis of viruses with outbreak or pandemic potential and improve overall data collection by directing the CDC to request that States and territories include serious vector-borne diseases, as "reportable" diseases.

Data Generation

Over the course of the COVID–19 pandemic, ASPR worked closely with hospitals, public health departments, and other organizations to distribute therapeutics. However, the data systems used to track the distribution, availability, and use of COVID–19 medicines were not robust enough to help industry truly understand where, how, and in which populations federally purchased doses of vaccines and therapeutics were being utilized.

HHS should invest in more robust systems that capture complex and important data on the location, utilization, and patient demographics for all MCMs.

Immunization Information Systems

Our national public health infrastructure is not only vital in "normal" times, it is the backbone of our pandemic response and recovery system. Investing in this infrastructure by increasing support for state, local, and territorial health departments and state data systems, like immunization registries, can help track immunization uptake, ensure individuals receive all of their necessary doses, and help restore our routine immunization rates. Taking action here will also enhance our ability to respond better to outbreaks of vaccine-preventable diseases as well responses to future pandemics.

One way that Congress can support public health is by strengthening the functionality and interoperability of state immunization information systems (IIS) by including H.R. 550, the "Immunization Infrastructure Modernization Act." Immunization information systems are computerized, multi-faceted systems that operate in 62 jurisdictions, and have the ability to maintain immunization records across the lifespan. They can be used by providers to order vaccines and maintain an accounting of inventory, project what a patient needs based on what they have received previously (preventing both over-and under-vaccination), remind patients when they are due to receive a recommended vaccine, and, at a population level, track coverage and identify areas where there are low immunization rates so public health programs can develop targeted immunization efforts in response. IIS are managed at the state level, creating a patchwork of these systems' functionality across the country. Having immunization data systems that are able to efficiently and effectively manage vaccine ordering, inventory, and patient records, and securely exchange information across providers, health systems, and public health agencies in real-time is essential to COVID–19 vaccine efforts, as well as routine vaccination efforts.

Strengthen the Adult Immunization Program

The COVID pandemic and mass vaccination efforts has driven substantial immunization infrastructure investments at the state and local level that includes systems, provider recruitment and developing relationships and partnerships with com-

munity-based organizations that supports the diverse needs of adult populations. Adult immunization infrastructure improvements and investments in the CDC Immunization Program made during the pandemic must be sustained for routine vaccination beyond COVID–19. It is vital for public health and pandemic preparedness that adult immunization infrastructure remains a priority over the long-term if we are going to have a life course approach to immunization. This infrastructure is also critical to replicating the success of high childhood immunization rates for the adult population. It is important that communities can get vaccines to where people are, whether it's through a community provider, pharmacy, health care center, senior center, or through a mobile van that can go to remote areas or provide vaccine services to disabled and homebound individuals. This capability is essential not only during a pandemic, but also for routine immunizations, such as annual flu vaccine campaigns. Having a reliable immunization network for adults will also ensure that this form of preventive health is available those who otherwise would not be able to afford it.

Conclusion

Thank you for considering BIO's recommendations on pandemic preparedness. BIO, along with the rest of the country, learned a lot from the experience of COVID–19, and we hope that our insights shared here can help prepare us better for the next pandemic. BIO and our member companies are committed to working with the HELP Committee as it drafts legislation on these issues and would be happy to serve a resource. Thank you again for the opportunity to provide testimony for today's hearing.

The CHAIR. Thank you.
Dr. Janz.

STATEMENT OF DAVID JANZ, M.D., DIRECTOR, MEDICAL CRITICAL CARE SERVICES, UNIVERSITY MEDICAL CENTER NEW ORLEANS, NEW ORLEANS, LA

Dr. JANZ. Chair Murray, Ranking Member Burr, and the distinguished Senators of the Committee, I am grateful to have the opportunity to testify today and discuss important lessons that have been learned during the COVID–19 pandemic, and how might these lessons inform future pandemics and other crises in health care. These lessons learned from my experience at University Medical Center in New Orleans as the Director of Medical Care Services, as a health care worker who has treated hundreds of critically ill adults with COVID–19.

University Medical Center in New Orleans cares for a diverse and underserved patient population, including uninsured patients in low income communities. The first lesson I would like to discuss is that learning in real time from forward positions in a pandemic prepares locations which will soon experience a similar strain in their health care system. In March 2020, New Orleans had a rate of rise of COVID positive patients similar to the Lombardy region of Italy, which was already experiencing marked strain in their ability to deliver health care.

An early description from this region, not just of what illness coronavirus causes, but how large numbers of patients with this disease impact the health care system was critical to our preparation. These operational reports early in the pandemic made it clear that early in the fight against this disease, success would be driven by public health measures and a hospital's ability to manage what is called hospital strain. Hospital strain is defined as an excess of demand on the resources or abilities of a hospital and is a problem that has existed in health care for decades. For example, what sys-

tems are in place to respond when emergency department is full of patients and there is a large number of patients in the waiting room? How does a hospital manage mass casualty incidents, or how do we care for critically ill adults when intensive care units are full? Hospital strain occurs much earlier than the nightmare scenarios of running out of ventilators.

Even more worrisome, hospital strain is associated with worse patient outcomes. At University Medical Center in New Orleans, we responded to the soon to come strain by scaling critical care services for COVID–19, adding personnel such as nurses and physicians, giving them evidence based patient care tools that allowed them to provide high value critical care to a large number of patients. Strain will continue to affect hospitals in various ways in the future, and successful responses to strain may avoid poor patient outcomes. The ability for us and others to share these operational successes with other hospitals via seminars conducted by the Louisiana Department of Health and the Department of Health and Human Services was vital to smaller, more resource limited hospitals to aid them during times of current and future strain.

The past year and a half has also been characterized by an unprecedented repair and discovery of effective vaccines and treatments for COVID–19 due to an integration of clinical research into health care systems. Another key response to future pandemics will be high quality clinical research conducted efficiently alongside clinical care to develop new preventive and treatment strategies for future pandemics.

The final lesson learned I like to discuss today is the lesson that worries me most today in my home city of New Orleans and home State of Louisiana. That is specifically caring for the caregiver is a vital component to crisis response. We have asked a lot of health care providers caring for COVID–19 patients over the past year and a half, a first, second, and now third, and now fourth wave. We have strained the human beings providing this care to a critical point. 43 percent of nurses around the Nation are considering leaving the health care profession this year. The past and current COVID–19 surges and future health care crises will likely be characterized by running out of health care workers rather than running out of ventilators.

Beyond COVID–19, how do we improve care for underserved patient populations, increase access to care, make inroads in decrease cardiovascular disease and diabetes when—and improve many other aspects of health care when health care is asked repeatedly instead to focus on COVID–19 surges? Over one-third of health care workers are experiencing anxiety or depression. As many as one in four are experiencing symptoms of post-traumatic stress disorder. And symptoms of burnout experience over half of critical care physicians. This is the state of the workforce asked to return to the COVID–19 front lines for a second, third, and now fourth wave.

We will continue to confront this current wave that we are experiencing, which is our duty, knowing that our physical and mental health is the cost that we will continually pay. But we are still focused on saving the patients in front of us who unfortunately may pay a higher price. However, in this time, when almost all of this

suffering may be prevented by a vaccine, we ask, why is this suffering unnecessary and when will it end?

In conclusion, learning from the front lines, health care systems responding effectively to strain, rapid dissemination of medical evidence, understanding that good clinical research results in better clinical care, and taking better care of the caregivers are just a few of many approaches to future crises in health care.

Let's continue to develop the national resolve to end this current crisis by embracing the gift medical science has repeatedly provided to humanity for hundreds of years, that gift being vaccinations.

[The prepared statement of Dr. Janz follows:]

PREPARED STATEMENT OF DAVID JANZ

Chair Murray, Ranking Member Burr, and distinguished Senators of the Committee. I am grateful to have the opportunity to testify before this Committee and discuss my opinion as to what important lessons have been learned during the COVID–19 pandemic and how might these lessons inform our response to future pandemics and other crises in healthcare. I offer my testimony as only one member of the healthcare community, a community which certainly has a wealth of lessons from this pandemic we can all learn from, and we should continue to elicit these lessons from all of my colleagues beyond my testimony today. These lessons learned I present to the Committee are from my experience at University Medical Center New Orleans as an Intensive Care Unit physician, the Director of Medical Critical Care Services, and as a healthcare worker who has treated hundreds of critically ill adults with COVID–19. University Medical Center New Orleans is a public-private partnership with the State of Louisiana carrying on the legacy of Charity Hospital in the city of New Orleans and aims to provide the best possible care for a diverse and underserved patient population, including the uninsured and low-income populations.

Learning in real-time from "forward positions" during a pandemic prepares locations which will soon experience similar strain in their healthcare system.

Pandemic preparation in early 2020 had been well underway prior to the first positive test in the New Orleans area on March 9, 2020. Existing guidelines [1] for care and hospital organization were being incorporated into pandemic planning; however, at the time there was relatively little known about how the COVID–19 pandemic could strain the healthcare system. When large numbers of patients seek healthcare for an illness that has the potential to cause severe disease, where would we see the healthcare system strain under that new weight?

In March 2020, New Orleans had a rate of rise of positive SARS-CoV–2 tests [2] similar to New York City and the Lombardy Region of Italy. [3] The Lombardy Region was already experiencing marked strain in their ability to deliver healthcare due to this rapid influx of patients with COVID–19. This was, perhaps, not just a forward position in the fight against COVID–19 with early experience with this disease, but also one of the first regions to report how the pandemic was straining their healthcare infrastructure. Importantly, this experience was relayed to the world in not just the news media but also rapidly in the scientific literature. While New Orleans was experiencing our first positive cases and seeing an exponential rise, on March 13, 2020, physicians from the Lombardy Region reported their experience in the ***Journal of the American Medical Association*** about how patient surges were affecting hospital operations. It was an early description not just of what illness SARS-CoV–2 causes, but how large numbers of patients with this disease impact a healthcare system. Among groups of healthcare personnel in New Or-

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[1] Hick JL, Einav S, Hanfling D, et al. Surge Capacity Principles Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement. ***Chest***. 2014;146(4):e1S-e16S. doi:10.1378/chest.14–0733.

[2] Zeller M, Gangavarapu K, Anderson C, et al. Emergence of an early SARS-CoV 2 epidemic in the United States. ***Medrxiv***. Published online 2021:2021.02.05.21251235. doi:10.1101/2021.02.05.21251235.

[3] Grasselli G, Pesenti A, Cecconi M. Critical Care Utilization for the COVID–19 Outbreak in Lombardy, Italy. ***Jama***. 2020;323(16):1545–1546. doi:10.1001/jama.2020.4031.

leans planning a response to a potential surge of patients, their report on forecasting ICU demand was both shocking and critical to our own preparatory work.

Nothing captured our attention more than the forecast modeling included in the publication suggesting that if an exponential growth model predicting possible ICU demand was accurate, as many as 14,542 ICU admissions would occur in the Lombardy Region in the next 7 days. From our perspective as healthcare personnel in New Orleans planning how to respond to a surge in COVID-19 patients, we were alarmed that a similar exponential rise in positive cases had begun in New Orleans and there is not a healthcare system in the world that can manage the influx of thousands of critically ill adults over such a short period of time.

The Lombardy region went on to experience marked strain in their healthcare system during March 2020; however thankfully not to the degree that their exponential forecast modeling predicted.[4] Of critical importance to our preparations at University Medical Center New Orleans and other hospitals in the region was being able to learn, in almost real-time, not just information from the lay press media but also actionable information on operations in healthcare systems currently experiencing strain and their response to that strain. Furthermore, if operational impact occurred, potential mitigation strategies, countermeasures, and predictive modeling could be used to estimate the potential scope of the problem.

Planning for future COVID–19 surges and for any new crisis that will impact the healthcare system worldwide should involve organized, intentional information gathering from locations currently experiencing the crisis. Information collected should be beyond what is reported in the lay media and include specific operational information of local healthcare systems, the degree of strain in each operational unit, identification of common problems, and elucidation of solutions. This information should be available to other hospital systems in real-time and disseminated not only in medical journals but also in an open-access, nationally centralized method, so that healthcare systems planning their response to an emerging problem can get information from a single location on the experiences of systems currently responding to the crisis. Our ability to learn from the experiences in Italy and New York City was vital in planning how our system of hospitals in New Orleans would respond to this crisis. It was clear that in the early fight against the pandemic, successful public health measures would be key in preventing complete collapse of the healthcare system and success on the level ofindividual hospital systems would be determined by their ability to manage a commonproblem in healthcare: hospital strain.

Managing hospital strain is vital in a healthcare system's response to COVID–19 and any future healthcare crisis.

Hospital capacity strain, defined as "excessive demand on the strength, resources, or abilities of a hospital and any resource the hospital uses to provide care (e.g. beds, nurses, physicians, equipment)", is a problem that has existed in healthcare for decades.[5] Prior to the COVID–19 pandemic, hospitals would experience strain on a smaller scale. For example, what systems are in place to respond when an emergency department is full with a large number of patients in a waiting room, how does a hospital manages mass casualty incidents, or how do we care for critically ill adults when the ICU is full and these patients have to remain in the emergency department? Hospital strain occurs much earlier than the nightmare scenarios of running out of ventilators or other vital resources and having to invoke crisis standards of care. However, prior to and during the COVID–19 pandemic,[6] hospital strain has been repeatedly associated with increased risk of poor patient outcomes. A recent study in the ***Annals of Internal Medicine*** estimates that influxes of COVID-19 patients causing excessive demand on hospital resources may have contributed to as many as 1 in 4 deaths related to COVID–19 in the United States.[7]

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[4] Grasselli G, Greco M, Zanella A, et al. Risk Factors Associated With Mortality Among Patients With COVID–19 in Intensive Care Units in Lombardy, Italy. ***Jama Intern Med***. 2020;180(10). doi:10.1001/jamainternmed.2020.3539.

[5] Eriksson CO, Stoner RC, Eden KB, Newgard CD, Guise J-M. The Association Between Hospital Capacity Strain and Inpatient Outcomes in Highly Developed Countries: A Systematic Review. ***J Gen Intern Med***. 2017;32(6):686–696. doi:10.1007/s11606–016–3936–3.

[6] Bravata DM, Perkins AJ, Myers LJ, et al. Association of Intensive Care Unit Patient Load and Demand With Mortality Rates in US Department of Veterans Affairs Hospitals During the COVID–19 Pandemic. ***Jama Netw Open***. 2021;4(1):e2034266. doi:10.1001/jamanetworkopen.2020.34266.

[7] Kadri SS, Sun J, Lawandi A, et al. Association Between Caseload Surge and COVID–19 Survival in 558 U.S. Hospitals, March to August 2020. ***Ann Intern Med***. Published online 2021. doi:10.7326/m21–1213.

As previously stated, it was clear early in the COVID–19 pandemic that hospital strain would be a vital problem for healthcare systems to manage in order to save as many lives as possible. Our response in March 2020 to decrease the impact of this strain on our hospital system and specifically our intensive care units was to "scale" critical care services. Scaling critical care services via the development of what is referred to as surge capacity has been performed for decades around the world in times of acute, brief periods of need. Guidelines on how to respond to ICU strain by creating ICU surge capacity have been published prior to the COVID–19 pandemic. These guidelines were used by many hospital systems during the COVID–19 pandemic, including ours, and provided a framework on how to create additional care teams, how to re-organize staff to accommodate more patients, recommendations on communications and triage, and other operational guidance. These guidelines are purposefully broad in recommendations so that they are applicable to any disaster or pandemic and, therefore, additional response was needed on the hospital level to address the strain unique to COVID–19: an illness that causes a large influx of critically ill adults with a high severity of illness and continues to strain the system over the course of months and now, over a year.

At University Medical Center New Orleans, we scaled critical care for COVID–19 in the following ways. First, we focused on increasing the uniformity of critical care provided by improving the application of evidence-based critical care practices to all ICU patients. Too many different ways of caring for a large number of critically ill adults would quickly extinguish the bandwidth of an ICU. Given the concern early in the pandemic of hospitals running out of ventilators or ICU beds, we used the medical evidence that has existed for decades in critical care medicine that tells us what practices to use to prevent a patient needing a ventilator, if a ventilator is needed using evidence-based practices to help the patient improve and be liberated from the ventilator as soon as possible, and uniformly applying practices known to help patients survive and no longer need an ICU bed.

Second, we scaled critical care capacity by adding more nurses, therapists, and physicians to ICUs, as recommended in guidelines, by a partnership between the LCMC Network of hospitals and the Louisiana State University and Tulane Schools of Medicine who provided additional physician support. Experienced nurses and other staff were brought in from other areas of the hospital. I cannot emphasize enough the importance of our existing and newly added ICU healthcare workers in responding to this crisis and their bravery for running toward the problem and not away. They work incredibly hard with a sense of purpose and duty, selflessly asking only how they can help their colleagues and our patients. Patients are alive today because of these heroes and institutional partnerships. These additional personnel needed quick, simple instruction on four decades of previous medical evidence of best critical care practices and how to apply this evidence to a large number of COVID–19 ICU patients. We created a number of local protocols and guidelines that were simple enough to hand to a new ICU provider and they could then easily apply best practices to their patients.

Finally, we added processes to make this uniform, evidence-based care reliable with observers ensuring a checklist of good ICU practices was occurring with each and every patient and notifying providers when items needed to be performed. With this approach, intensive care units at University Medical Center New Orleans have achieved COVID–19 survival rates as good or better than survival rates reported in the medical literature, despite high rates of medical comorbidities that portend a worsened prognosis with COVID–19.[8],[9]

Responding to hospital strain by scaling critical care services and creating surge capacity is applicable to future COVID–19 waves and any new emerging threat that has the potential to strain the healthcare system. The implementation of simple, easy to use patient care tools that increase uniformity and reliability are key when healthcare systems are stressed and may avoid the associated increase in poor patient outcomes historically associated with hospital strain.

Dissemination of early experiences and knowledge improves patient care outside of individual hospitals.

After several hospital systems in Southeast Louisiana began to experience an influx of COVID–19 patients in March 2020 and had developed their operational re-

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[8] Janz DR, Mackey S, Patel N, et al. Critically Ill Adults With Coronavirus Disease 2019 in New Orleans and Care With an Evidence-Based Protocol. ***Chest***. 2021;159(1):196–204. doi:10.1016/j.chest.2020.08.2114.

[9] Rosenthal N, Cao Z, Gundrum J, Sianis J, Safo S. Risk Factors Associated With In-Hospital Mortality in a US National Sample of Patients With COVID–19. ***Jama Netw Open***. 2020;3(12):e2029058. doi:10.1001/jamanetworkopen.2020.29058.

sponses to the subsequent strain, Dr. Alex Billioux at the time was the Assistant Secretary for the Louisiana Department of Health's Office of Public Health. Dr. Billioux recognized the extensive organizational work occurring in hospital systems in New Orleans and Baton Rouge and decided to create a task force of intensive care unit physicians and nurses that would collect the COVID–19 patient care resources developed so far in these hospitals and disseminate those current best practices to hospitals around the state. This Louisiana Department of Health COVID–19 Critical Care Task Force conducted numerous online seminars in the Spring of 2020 where we educated hospitals around Louisiana on the most current, evidence-based practices in caring for COVID–19 patients in the ICU, shared our own operational challenges and solutions, and helped other hospitals solve other challenges they were experiencing. The feedback from hospitals around the state was positive: these hospitals were commonly too busy, too overwhelmed, too understaffed to have time to develop these easy to use patient care tools or come up with operational solutions and these seminars immediately solved many of those problems. The Office of the Assistant Secretary of Health and Human Services (Preparedness and Response), learned of our early experience with COVID–19 in Louisiana and our dissemination of this experience with the Louisiana Department of Health. The Office of HHS ASPR then added our materials developed in Louisiana to the nationwide HHS ASPR COVID–19 Clinical Rounds and had representatives from our Louisiana Task Force conduct live seminars via these clinical rounds.

I personally witnessed two significant impacts during these state-and nation-wide educational seminars. First, many hospitals experiencing strain from a pandemic do not have the time or expertise to develop patient care and operational tools that are evidence-based, easy to use, and reliable. Published pandemic response guidelines from national organizations are available to all hospitals during these crises, but often hospitals need more specific help and problem solving that is not covered in general guideline statements. Hospitals responded with gratitude when we were able to share what we created with them and allowed them to spend more time in patient care at the bedside. Second, non-evidence-based practices were being disseminated frequently at the time via the internet, social media platforms, and other non-peer reviewed sources.[10] This created a great deal of confusion amongst healthcare providers early in the pandemic as to how to treat a patient with COVID-19. These state- and nation-wide educational seminars helped clarify questions from healthcare providers on which practices were supported by medical evidence and recommended by national guidelines.

Future responses to healthcare crises and pandemics need to incorporate on a national level not only the generation of guidelines by medical societies and health organizations, but also frequent, open-access educational offerings and interactive seminars where providers on the front line can share knowledge and help others solve their own operational challenges. Strained hospitals, especially critical access hospitals and hospitals in resource-limited settings, do not have the time or resources to develop their own approach to every aspect of a pandemic. Larger hospital systems can share their experiences via a national educational platform to lighten the workload of the more resource-limited hospitals and collectively decrease strain on the entire healthcare system.

A Learning Healthcare System is vital in the response to the current and future pandemics.

Early information gathering and creation of surge capacity were only the first steps in the response to the COVID–19 pandemic. The approaches described above are only a way to save lives while new preventative and treatment tools are created through scientific discovery. Even during a pandemic, "The randomized, double-blind, placebo-controlled trial with systematic and comprehensive collection of safety, biomarkers, short-and long-term survival outcomes, remains the most effective and ethical science to save lives."[11] Within weeks of COVID–19 spreading around the world, not only were healthcare systems focused on treating patients but of equal importance these systems were focusing on learning from these patients in order to save lives in the future. Randomized, controlled trials were designed and instituted in parallel with the provision of patient care, giving the world high-quality answers to questions about almost any proposed treatment for COVID–19. This

[10] Rice TW, Janz DR. In Defense of Evidence-Based Medicine for the Treatment of COVID–19 ARDS. ***Ann Am Thorac Soc***. 2020;0(ja). doi:10.1513/annalsats.202004–325ip.

[11] Singer M, Kalil A. Do not just sit there, do something but do no harm: the worrying aspects of COVID–19 experimental interventions. ***Intens Care Med***. Published online 2021:1–3. doi:10.1007/s00134–021–06460–9.

allowed the medical community to focus on what was discovered to be high-value care for COVID–19 and avoid interventions that were found to be of no benefit.

The first treatment to show robust evidence of benefit in critically ill patients with COVID–19, a steroid medication named dexamethasone, was published online in the ***New England Journal of Medicine*** on July 17, 2020 in a randomized trial of over 2,000 patients.[12] In the span of only approximately 7 months, a novel viral pathogen had been discovered, a pandemic had ensued causing high rates of critical illness, and a randomized trial of over 2,000 patients was able to be conducted and shared with the world a treatment that saves lives. Five months later on December 10, 2020, approximately 1 year since the first reports of patients infected with the novel SARS-CoV–2 pathogen, the results of a randomized trial of the BNT162b2 vaccine in over 43,000 patients was published.[13] The rapidity of these discoveries is unprecedented in the history of Medicine, is a result of the integration of clinical research into patient care via a learning healthcare system approach and is clearly lifesaving.

A learning healthcare system aims to provide high-quality healthcare to patients while also integrating in parallel clinical research infrastructure to learn from patients during their care as to how to improve medical care in the future.[14] This integration of patient care and discovery allows the medical community to "learn from what we do and do what we learn." Lives will be saved in future pandemics as hospital systems continue to integrate clinical research infrastructure into the care of patients.

Caring for the caregiver is a vital component in crisis response.

We have asked a lot of healthcare providers caring for COVID–19 patients over the past year and a half. At the beginning of the pandemic, ICU nurses, physicians, advance practice providers, respiratory therapists, pharmacists, environmental services staff, and many others ran toward the problem, not away from it. This was in the setting of many unknowns at the time about caring for COVID–19 patients, including how much of a risk this type of work would be to the health of the caregiver, how long this pandemic would last, when was more help coming, when would we see family again or have a day off, and how do we care for both critically ill patients and our loved ones at home. Healthcare workers responded to this overwhelming amount of work with a sense of purpose, meaning, and duty. People needed help, it is the nature of the healthcare worker to help them. There is not an option to run away from this problem, that is not who we are.

Since the beginning of this pandemic, it is easy to see what we have asked of the healthcare system and the people who perform the work of caring for COVID–19 patients. In Louisiana, that has been asking healthcare providers to help rescue all of us from an initial COVID–19 surge in March 2020, followed by again by a second surge in July 2020, a third in December 2020, and now the beginning of our fourth COVID–19 surge in Louisiana in July 2021. The human beings performing these jobs are being strained with every additional COVID–19 patient admitted and every additional COVID-19 surge that occurs.

There is developing evidence that we have strained the human beings providing care to patients with COVID–19 to a critical point. Even a brief review of healthcare news over the past year immediately reveals countless stories of nurses, healthcare's most precious resource and who have shouldered the heaviest load in the COVID–19 response, are leaving the profession at high rates. A recent report by Vivian Health revealed 43 percent of nurses are considering leaving the healthcare profession in 2021 and 72 percent report hospital morale has worsened over the past year. In my specialty of Critical Care Medicine, 48 percent of ICU nurses are considering leaving healthcare. The past and current COVID–19 surges and future healthcare crises will likely be characterized by running out of healthcare workers rather than running out of ventilators and stretching existing healthcare workers to an even greater degree. Expending healthcare resources on recurring COVID–19 surges and losing valuable healthcare workers from the profession will almost certainly impact all the other important goals we hope to accomplish in improving the health of the nation. How do we improve care for underserved patient populations, increase ac-

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[12] The RECOVERY Collaborative Group. Dexamethasone in Hospitalized Patients with Covid–19—Preliminary Report. ***New Engl J Med***. Published online 2020. doi:10.1056/nejmoa2021436.

[13] Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid–19 Vaccine. ***New Engl J Med***. 2020;383(27):2603–2615. doi:10.1056/nejmoa2034577.

[14] Lindsell CJ, Gatto CL, Dear ML, et al. Learning From What We Do, and Doing What We Learn: A Learning Health Care System in Action. ***Acad Med***. 2021;Publish Ahead of Print. doi:10.1097/acm.0000000000004021.

cess to care, make in-roads on decreasing cardiovascular disease and diabetes, improve outcomes for patients with cancer, and improve many other aspects of healthcare delivery when healthcare is asked repeatedly to instead focus on COVID–19 surges? How do we accomplish all these goals when so many healthcare workers leave the profession?

Studies of healthcare workers caring for COVID–19 patients have shown that the risk for the development of mental health problems may be as high as other disasters such as the September 11th attacks or Hurricane Katrina.[15] Recent research focusing on the psychological impact of COVID–19 on healthcare workers suggests that over one third of healthcare workers are experiencing anxiety or depression,[16] as many as one in four have symptoms of post-traumatic stress disorder,[17] and symptoms of burnout are experienced by over half of critical care physicians.[18] This is the state of the workforce asked to return to the COVID–19 front lines for a second, third, and now fourth wave. We will continue to confront current and future waves, which is our duty, knowing that our physical and mental health is the cost we will continually pay. Our eyes are forward, focused on saving the patients in front of us who unfortunately may pay a higher price. However, in this time when almost all this suffering may be prevented by a vaccine, we ask why is this suffering necessary and when will it end?

Conclusion

I present these lessons learned as one member of the healthcare community, eager to also learn lessons from my colleagues around the world. Experiences during this pandemic have been diverse and we need to learn from everyone's successes and failures by ongoing discussions as we are having today. Learning from the frontlines, healthcare systems responding effectively to strain, rapid dissemination of medical evidence and operational strategies, understanding that good clinical research results in better clinical care especially when these are integrated, and taking better care of the caregivers are just a few of many approaches to future crises in healthcare. Let us continue to develop the national resolve to end the current crisis by embracing the gift Medical Science has repeatedly provided to humanity for hundreds of years: vaccinations.

[SUMMARY STATEMENT OF DAVID JANZ]

Lessons Learned During the COVID–19 Pandemic and How These Lessons Apply to Future Crises in Healthcare

1. Learning in real-time from "forward positions" during a pandemic prepares locations which will soon experience similar strain in their healthcare system.

Summary: Healthcare systems first to experience a crisis can inform those about to experience a crisis.

How this applied to COVID–19: Many healthcare institutions benefited from not just the early descriptions of the disease caused by SARS-CoV–2, but also from learning what operational challenges locations experienced early in the pandemic.

How this applies to future crises: organized dissemination of operational information from forward positions in a pandemic can prepare the locations at highest risk of spread.

2. Managing hospital strain is vital in a healthcare system's response to COVID–19 and future healthcare crises.

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[15] Wright HM, Griffin BJ, Shoji K, et al. Pandemic-related mental health risk among front line personnel. ***J Psychiatr Res***. 2021;137:673–680. doi:10.1016/j.jpsychires.2020.10.045.

[16] Sun P, Wang M, Song T, et al. The Psychological Impact of COVID–19 Pandemic on Health Care Workers: A Systematic Review and Meta-Analysis. ***Front Psychol***. 2021;12:626547. doi:10.3389/fpsyg.2021.626547.

[17] d'Ettorre G, Ceccarelli G, Santinelli L, et al. Post-Traumatic Stress Symptoms in Healthcare Workers Dealing with the COVID–19 Pandemic: A Systematic Review. ***Int J Environ Res Pu***. 2021;18(2):601. doi:10.3390/ijerph18020601.

[18] Azoulay E, Waele JD, et al. Symptoms of burnout in intensive care unit specialists facing the COVID–19 outbreak. ***Ann Intensive Care***. 2020;10(1):110. doi:10.1186/s13613–020–00722–3.

Summary: Excessive demand on hospital resources, referred to as strain, has occurred for decades in healthcare, occurs much earlier than running out of a resource, and is associated with worse patient outcomes.

How this applied to COVID–19: Healthcare systems response to COVID–19 has largely been a story of how successful a system is in dealing with strain on a large scale.

How this applies to future crises: Adding healthcare personnel and effective, evidence-based patient care tools will mitigate strain in COVID–19 surges and beyond.

3. Dissemination of early experiences and knowledge improves patient care outside of individual hospitals.

Summary: Operational experiences of hospitals have historically existed in silos.

How this applied to COVID–19: The ability to disseminate solutions from our hospital system to hospitals around the country improved care of COVID–19 patients.

How this applies to future crises: Future crises should be responded to by breaking down silos around healthcare institutions so others can learn from their experiences.

4. A Learning Healthcare System is vital in crisis response.

Summary: A Learning Healthcare System emphasizes and integrates both patient care and discovery of new treatments.

How this applied to COVID–19: The rapidity of discoveries of treatments and vaccines to prevent COVID–19 is lifesaving, unprecedented, and a result of clinical research.

How this applies to future crises: Lives will be saved in future pandemics if we continue to integrate clinical research into healthcare systems.

5. Caring for the caregiver is a vital component in crisis response.

Summary: The ability for a system to respond to a healthcare crisis is largely dependent on the physical and mental health of the healthcare worker.

How this applied to COVID–19: The COVID–19 pandemic has resulted in healthcare workers experiencing increasing rates of physical and mental health problems.

How this applies to future crises: Our ability to respond to future crises or improve the health of the Nation will be limited by healthcare workers leaving the profession due to the ongoing COVID–19 pandemic.

The CHAIR. Thank you.
Ms. Cicero.

STATEMENT OF ANITA CICERO, DEPUTY DIRECTOR, CENTER FOR HEALTH SECURITY, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, BALTIMORE, MD

Ms. CICERO. Chair Murray, Ranking Member Burr, and Members of the Committee, thank you so much for the opportunity to speak with you today. I am the Deputy Director of the Johns Hopkins Center for Health Security. The opinions expressed are my own and don't necessarily reflect the views of Johns Hopkins University. For over 20 years, the mission of our Hopkins Center for Health Security has been to protect people's health from epidemics and disasters, and to ensure that communities are resilient to major challenges.

Last year, our center launched the Capitol Hill Steering Committee on Pandemic Preparedness and Health Security, and I would like to acknowledge the excellent leadership from Senators Baldwin, Burr, and Casey, three of the six Senate co-chairs of the

steering committee. For as long as I can remember, this HELP Committee has crafted and supported comprehensive bipartisan policies. Thank you for continuing that tradition today. The profound effects of the COVID–19 pandemic should galvanize this Committee and Congress broadly to do everything in your power to prevent this or worse from happening again, and to better—be better prepared if it does. Our goal should be a pandemic free future. When we take a step back and look at the big picture, and identify the lessons learned from the COVID–19 pandemic, what jumps out is the need to fundamentally shift from a largely reactive posture to a more proactive posture across the board.

In my remarks this morning, I will focus on three points where we need to shift to a more proactive stance. First, we support the $30 billion investment over the next 4 years to improve pandemic preparedness as called for in the American Jobs Plan. This would bolster our public health capabilities and biomedical preparedness to better protect Americans. Second is the need for a dedicated Disease X medical countermeasure program at BARDA. BARDA has a proven track record of partnering with private industry and developing vaccines, therapeutics, and diagnostics against a defined list of biological threat agents. However, there is no sustained funding or program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats.

While it is not possible to identify which specific virus will cause the next pandemic, we do know that certain viral families possess the kinds of attributes such as high lethality, high transmissibility, and asymptomatic spread that are likely to lead to large scale outbreaks. Because we know that viral families with these attributes can produce our next pandemic pathogen, BARDA could was sufficient and sustained resources work in partnership with companies to advance the development of innovative technologies and specific vaccine platforms that are best suited against these viral families. That way, when the next viral pathogen emerges, we would have the ability to adapt the technologies and platforms quickly, and quickly develop effective vaccines and drugs before the outbreak has a chance to spread.

A dedicated Disease X medical countermeasure initiative should be created in BARDA in coordination with NIH, DOD, and other Federal stakeholders. My final example is the need for innovation in next generation masks and respirators for medical workers, essential workers, and the public. Advances in this area are long overdue. Despite the importance and daily utility of masks, health care workers have been using basically the same surgical masks, procedure masks, and respirators that—for decades.

By incentivizing innovation, we can develop medical masks and respirators that are reusable, better fitting, and more comfortable for long stretches. The public should also have better quality masks. While it is great that you can buy a mask almost anywhere these days made of cloth, there is very little quality control. The Government could establish standards around breathability, wearability, and effectiveness of masks to ensure more reliable protection. Currently, also, most masks and respirators are either made overseas or their materials are sourced from overseas.

BARDA could provide financial support to domestic companies to scale up production, and the SNS could purchase enough to meet future needs based on a range of severe scenarios.

In conclusion, there are many more common sense, attainable things that we can do today with your vision and leadership and support to save American lives and our Nation's jobs and economy tomorrow. Thank you for inviting me to contribute and I look forward to answering any questions you may have.

[The prepared statement of Ms. Cicero follows:]

PREPARED STATEMENT OF ANITA CICERO

Chair Murray, Ranking Member Burr and distinguished Members of the Committee, thank you for the opportunity to speak with you today about the COVID–19 pandemic.

I am the Deputy Director of the Johns Hopkins Center for Health Security and a Senior Scientist in the Department of Environmental Health and Engineering at the Johns Hopkins Bloomberg School of Public Health. The opinions expressed herein are my own and do not necessarily reflect the views of the Johns Hopkins University.

For over 20 years, the mission of our Center for Health Security has been to protect people's health from epidemics and disasters and ensure that communities are resilient to major challenges. We have 30 faculty at the Center with expertise in fields including infectious disease, epidemiology, medicine, law, the social sciences, and immunology.

During the past year and a half, I have co-led our Center's policy work in response to the pandemic and our efforts to understand what the Nation should do to be better prepared for even more catastrophic pandemics in the future. Last year our Center launched the Capitol Hill Steering Committee on Pandemic Preparedness and Health Security, a bipartisan, bicameral educational initiative to provide congressional staffers and other stakeholders with information and analysis on current and future national health security priorities. I would like to acknowledge the excellent leadership of HELP Committee Members, Senators Baldwin, Burr and Casey—three of the four Senate co-chairs of the steering committee—along with Senator Cindy Hyde-Smith of Mississippi and Senators Ben Cardin and Chris Van Hollen of Maryland.

I also would like to express my appreciation for this Committee's long-standing leadership and bipartisan work to improve our Nation's pandemic preparedness and biodefense. For as long as I can remember, the HELP Committee has crafted and supported comprehensive, bipartisan policies. Thank you for continuing that tradition.

Covid–19 has done great damage to our country in terms of sickness, loss-of-life, terrible economic consequence, and job loss. And we are not in the clear yet.

The profound effects of this pandemic should galvanize Members of Congress to do everything in their power to prevent this, or worse, from happening again and to be better prepared if it does. We should aim for creating a pandemic-free future. Investing $30 billion over the next 4 years to improve pandemic preparedness, as called for in the American Jobs Plan, would get us on a more solid footing by bolstering our public health capabilities, innovation, and biomedical preparedness to better protect Americans.

When we take a step back and look at the big picture to identify important lessons learned from the COVID–19 pandemic, what jumps out is the need to fundamentally shift from being largely *reactive* to being more *proactive* across the board.

Before the next large scale outbreak occurs, we need to be more proactive in improving our situational awareness through better data collection, diagnostics, surveillance and genomic sequencing; more proactive in bringing our antiquated public health infrastructure into the 21st century; more proactive in using cutting-edge technologies to quickly develop medical countermeasures; more proactive in having a reliable supply chain and stockpile in place; more proactive in our ability to provide excellent care for patients in our health system, even during large surges; and more proactive in earning the trust of diverse communities before a pandemic so that there is greater support for outbreak response measures. We have learned the

hard way that trying to play catch up and accomplish these things in the midst of a pandemic is like swimming against a strong rip tide.

Our Johns Hopkins Center for Health Security has submitted *recommendations* to Senator Murray and Senator Burr for improving the Nation's public health and medical preparedness response programs.

In my remarks today I will focus on two of the important areas where we need to shift to a more proactive stance if we want to be better prepared for a future pandemic—one that could be more catastrophic than COVID–19. The first area is advancing biomedical preparedness and the second is improving our public health infrastructure.

I want to stress that the examples I will give of innovations in each of these areas are not futuristic, out-of-reach goals. They are achievable and realistic improvements that, with the support of Congress, can enormously advance our Nation's preparedness for future pandemics.

1. Advancing Innovation in our Biomedical Preparedness

Three ambitious but achievable goals for advancing innovation in our biomedical preparedness are: (1) establish a dedicated "Disease X" medical countermeasure program; (2) incentivize innovation in masks and respirators for health care workers and the public; and (3) prioritize development and review of at-home diagnostic technologies.

We have seen firsthand during this pandemic how powerful and lifesaving it is to have rapid and safe vaccines and therapeutics, as well as reliable diagnostics against novel infectious disease threats. The Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health & Human Services (HHS) has a proven track record of partnering with private industry and developing medical countermeasures against a defined list of biological threat agents.

However, there is no sustained funding, program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats. The U.S. should set an ambitious goal of rapidly developing medical countermeasures for novel or unknown viral threats in just a few months. Innovative technologies, outside-the-box thinking, sustainable partnerships, and game-changing science can be harnessed to meet this goal.

Disease X

The next deadly virus, or "Disease X," could be right around the corner. The U.S. will need to move even faster to develop and deploy medical countermeasures to save lives and safeguard the economy. Accordingly, a new dedicated Disease X Medical Countermeasures Initiative should be created to accelerate this process at BARDA, in coordination with DOD and other Federal stakeholders. BARDA needs sufficient and sustained Federal funding dedicated to developing medical countermeasures against future viral threats that are unknown and therefore not on the "material threat determination" list.

It is not possible to identify which specific virus will cause the next pandemic, but we do know that certain viral families possess the kinds of attributes—such as high lethality, high transmissibility, and asymptomatic spread—that are likely to lead to large scale outbreaks. Because we know that viral families with these attributes can produce our next pandemic pathogen, BARDA could, with sufficient, sustained resources, advance the development of the technologies and vaccine platforms that are best suited to use against these viral families, and support innovations that enable rapid, large-scale response. That way, when the next viral pandemic pathogen emerges, we would have the ability to quickly adapt those technologies and platforms to develop effective vaccines and other medical countermeasures before the outbreak picks up speed.

Next Generation Masks and Respirators

Just as we need to commit to developing medical countermeasures in weeks, not months or years, we should likewise increase our expectations for effective masks for medical workers, essential workers, and the public. Innovations in this area are long overdue. Medical masks and respirators for health care workers are essential pieces of personal protection equipment (PPE), especially during outbreaks of contagious respiratory pathogens. However, despite their importance and daily utility, health care workers have been using basically the same surgical masks, procedure

masks, and respirators for decades. Through incentivizing innovation, we can develop masks and respirators that are reusable, better fitting, and more comfortable for long stretches.

The public should also have better-quality masks that are certified to meet breathability, wearability, and effectiveness standards established by government. It's great that anyone can buy a cloth mask almost anywhere these days, but there is little quality control for public use masks. BARDA launched a Mask Innovation Challenge, and they should continue to foster technical advances in this area. Using new information gleaned from this challenge, BARDA could create target product profiles for new and better-quality medical respirators and public use masks.

As with other types of PPE and medical supplies, we must ensure the stability of a reliable supply chain for a range of respiratory devices. Currently, most masks and respirators are either made overseas, or their materials are sourced from overseas. Once devices meet new target product profiles established, BARDA should provide financial support if needed to domestic companies to scale up production, and the SNS should purchase enough to meet anticipated future needs based on modeling of various severe scenarios.

Although it is uncomfortable to imagine, a future viral pathogen could be even deadlier and spread more easily than SARS-CoV–2. On the most basic level, health care workers, other essential workers, and the public must have an abundant supply of masks that can protect them from infection while countermeasures are being prepared.

At-Home Diagnostics

Another area ripe for innovation are at-home diagnostics for viral threats. Limitations around access to reliable diagnostic testing have dominated much of the response to COVID–19. As outbreaks emerged in countries around the world, the US was unable to quickly deploy reliable testing tools. Looking ahead, a world in which individuals and families have access to reliable home testing for infectious disease threats is in reach if we set that as our goal. We can change the paradigm if there is enough will and commitment to do so. People already can take home HIV tests, and BARDA is currently funding advanced development of at-home diagnostics for influenza. Imagine if you could conveniently and cheaply test yourself and your family for things like strep throat, flu or a new dangerous virus. Currently, we mostly fly in the dark without knowing what kinds of viruses are infecting us or circulating in our communities.

Congressional funding, and the development and review of at-home diagnostic technologies by BARDA, FDA, and CMS should be prioritized. BARDA could increase the development of direct-to-consumer home tests for infectious diseases. FDA could help to streamline regulatory pathways for such devices. And CMS and private insurers should provide payment and reimbursement schedules for these devices to facilitate uptake. There are now some at-home COVID tests on the market, but it took us more than a year into the crisis to get there, and their pricing puts them out of reach for many people.

At-home diagnostics for infectious diseases, coupled to information technology, could have a transformative benefit for current and future pandemic response. Not only could it decrease the unnecessary use of antibiotics, but it could also greatly improve our early warning surveillance for infectious disease threats.

For these and other achievable advances in our Nation's biomedical preparedness, it is critical to have strong Federal leadership that is motivated and empowered to maintain the momentum and contribute to the success of our pandemic response efforts. In this regard, it is important to have a strong, operational, well-functioning office of the Assistant Secretary for Preparedness and Response which has the hiring and budgeting authorities it needs to respond quickly and proactively during serious health emergencies that the Nation could face.

2. Advancing Innovation in our Public Health Infrastructure

In addition to innovation in biomedical preparedness, we must support innovation in our public health capabilities at the state and local levels; they are our first line of defense against dangerous outbreaks. We also need to fully support the creation and annual funding of a National Center for Epidemic Forecasting and Outbreak Analytics.

State and Local Public Health Capacity

Because we have never sufficiently prioritized public health in the past, its infrastructure is woefully inadequate now. Some of our state and local public health agencies are still reliant on 1950's technologies—using pencil, paper, and fax machines to manage data—while the hospitals down the street from them are fully in the 21st century. There is a technological disconnect between public health and health systems that greatly hinders our ability to collect, share, and appropriately respond to actionable data during a public health crisis.

A strong public health infrastructure is not something that can be ramped up after a large-scale outbreak has already gained steam. We have certainly seen this across the board during the COVID–19 pandemic from spotty and irregular collection and reporting of COVID–19 case data to the too little/too late attempt to hire contact tracers to trace infections once there was already rampant community spread of the virus.

Although Congress has appropriated $1 billion for data modernization across the CARES Act and the American Rescue Plan, it will take years for our country's public health data infrastructure to be brought up to speed. In the meantime, we are now in a position where we are facing a new wave of Covid–19 without the data we need to make crucial decisions. We do not conduct surveillance in a way that gives us real time data about who is getting sick from which variant. Many states are moving to weekday-only or even weekly reporting of cases. Data on mild breakthrough cases of fully vaccinated people is not being collected. There is no central tracking of outbreaks in schools. These kinds of gaps make it difficult to understand how the virus is circulating in our communities.

What does a more proactive strategy for public health infrastructure look like? Given sufficient resources, people, and modern IT systems, public health agencies at the local and state levels could be seamlessly connected to health care providers and labs and collect more accurate, standardized, real-time data. We need to leave the disjointed, local reporting systems behind and develop uniform systems for reporting on testing, positive cases, hospitalizations, and deaths.

National Center for Epidemic Forecasting and Outbreak Analytics

There is $500 million in the American Rescue Plan for the National Center for Epidemic Forecasting and Outbreak Analytics, as well as data modernization. To establish this as a permanent capability, the epidemic forecasting center should be included in annual appropriations to support its ongoing mission.

I thank Congress for the investments it has already made in our data infrastructure and encourage a continued commitment to supporting our Nation's public health institutions with the authorities and funding they need to ensure we have a proper infrastructure in place for the next pandemic.

Again, I hope that my testimony has shown that there are commonsense, attainable things we can do today, with your vision, leadership, and support, to save American lives and our Nation's jobs and economy tomorrow.

Thank you for inviting me to contribute to the hearing and for your important work on pandemic preparedness. I look forward to answering any questions you may have.

[SUMMARY STATEMENT OF ANITA CICERO]

Chair Murray, Ranking Member Burr and distinguished Members of the Committee, thank you for the opportunity to speak with you. I am the Deputy Director of the Johns Hopkins Center for Health Security and a Senior Scientist in the Department of Environmental Health and Engineering at the Johns Hopkins Bloomberg School of Public Health. The opinions expressed are my own and do not necessarily reflect the views of the Johns Hopkins University.

The profound effects of the COVID–19 pandemic should galvanize Congress to do everything in its power to prevent this from happening again and to be better prepared if it does. Investing $30 billion over the next 4 years to improve pandemic preparedness, as called for in the American Jobs Plan, would bolster our public health capabilities, innovation, and biomedical preparedness to better protect Americans.

When we take a step back and look at the big picture of lessons learned from the COVID–19 pandemic, what jumps out is the need to fundamentally shift from being largely reactive to being more proactive across the board. I will focus on two of the

important areas where we need to shift to a more proactive stance if we want to be better prepared for a future pandemic that could be even more catastrophic than COVID–19. The first area is advancing biomedical preparedness and the second is improving our public health infrastructure.

1. Advancing Innovation in our Biomedical Preparedness

Three ambitious but achievable goals for advancing our biomedical preparedness are: (i) Establish a dedicated "Disease X" medical countermeasure program in BARDA to leverage platform technologies and rapidly develop medical countermeasures against those viral families that have the attributes likely to lead to future pandemics. (ii) Innovate and set quality standards for next generation masks and respirators for health care workers and the public; ensure the stability of a reliable supply chain for a range of respiratory devices; and stockpile sufficient quantities. (iii) Prioritize development, facilitate regulatory review, and find workable reimbursement and payment mechanisms for at-home infectious disease diagnostics to increase surveillance and accessibility. For these and other achievable advances in our Nation's biomedical preparedness, it is critical to have strong and operational ASPR.

2. Advancing Innovation in our Public Health Infrastructure

In addition to innovation in biomedical preparedness, we must support innovation in our public health capabilities at the state and local levels. We must bridge the technological disconnect between public health and health systems that greatly hinders our ability to collect, share, and appropriately respond to actionable data during a public health crisis. What does a more proactive strategy for public health infrastructure look like? Given sufficient resources, people, and modern IT systems, public health agencies could be seamlessly connected to health care providers and labs and collect more accurate, standardized, real-time data on testing, positive cases, hospitalizations, and deaths. We also need to fully support the creation and annual funding of the National Center for Epidemic Forecasting and Outbreak Analytics.

These recommendations are attainable with your vision, leadership, and support, to save American lives and our Nation's jobs and economy tomorrow. Thank you.

The CHAIR. Thank you. And again, thank you to all of our witnesses for being here today and for your testimony. We will now begin around a 5-minute questions for our witnesses. I again ask our colleagues, keep track of the clock and please stay within those 5 minutes. Mr. Becker, let me start with you. You do have significant experience building innovative data and laboratory infrastructure for state and local health departments.

As we have all seen over this past year and a half, complete and accurate data on cases, hospitalizations, and deaths allows us to reduce community spread and it saves lives. I want to ask you, what was the biggest initial barrier to effectively sharing COVID–19 data between public health systems, medical systems, and Federal agencies?

Mr. BECKER. Thank you for the question, Senator. I would say interoperability is the biggest challenge, but it is only the biggest by an nth degree. So interoperability with our hospital systems create a lot of workload and stress on the public health system, which is already underfunded and understaffed. And one of the issues that we have from a public health standpoint is that our systems don't talk the same language. So we are talking at each other, but not to each other and that creates confusion and especially in the pandemic.

That is the top one. But I would say just underneath that is just the scalability of the systems that exist today. These systems were built 20, 30, even some of them 40 years ago, and they are slow

and they don't adapt to today's world. One of the issues that we had, for instance, in Washington State was the electronic lab reporting system, which was designed many, many years ago, could only handle about 350,000 cases per year in the State of Washington. And that is about what we asked of it.

In the pandemic, we were asking it to do that in less than a month, and it created slow systems that couldn't respond, a frustrated workforce, and that just leads to error and the ability—the lack of ability to respond to the immediate needs of the system. So I think those were two. I took liberties with your question but thank you.

The CHAIR. That was great. Thank you so much. You know, the flood response to this pandemic caused new health inequities and exacerbated existing ones. And without improved data on race and ethnicity, it is difficult to know the extent of the impact and to adjust our response accordingly. How can we improve data collection and sharing so we can have a better understanding of the impact of the pandemic on communities of color?

Mr. BECKER. Thank you for the great question. And that is a true issue that we are going to have to deal with at all levels of state, local, and Federal Government. And we need standards for one on the collection of that data, so it is normalized across all those systems. And it sounds very simple when you talk about just collecting additional race, ethnicity, and demographic data, but it is actually quite complicated. It is complicated by the systems that don't allow for those quick changes.

But it is complicated by the way the questions need to be asked and the workforce that needs to be trained to ask them and the regional variations that happen across this country with racial and ethnic diversity. For instance, in Washington State, we have tribal Governments and there is 29 of those. And we need to get those affiliations right so we can report back to those tribal partners. And that is a lot of work for them right now to classify themselves once that data is in our system.

The CHAIR. Okay, thank you. Ms. Cicero, we have to address all the facets of our public health infrastructure while working to improve our response workforce, data, medical countermeasures to state and local capacity. We can't solve just one of these challenges, ignore all the others, and expect our system to work better the next time around. What is your top recommendation for Federal action that will allow us to comprehensively and systematically address the failures we have seen over the course of this pandemic?

Ms. CICERO. Thank you for that question, Senator. Once again, I believe it is very important to invest sufficiently in our future for long standing, sustained support for our public health infrastructure, for biomedical preparedness, for our hospitals, frontline workers. And we can do that through the $30 billion investment, or at least that is a good start, through the American Jobs Plan. And that money would be well spent so that we don't just react to this crisis and move on in that crisis complacency cycle but invest in the future in a sustained way.

The CHAIR. Thank you. I will retain the balance of my time. We have a number of Senators and a vote at 11:30 a.m. So, Senator Burr, I will turn it over to you.

Senator BURR. Thank you, Madam Chair. Mr. Becker, what if I told you that technology was available today that through video, an algorithm could determine the pulse rate, the oxygenation level, the respiration rate of individuals in the video and could predict a potential outbreak of COVID in any given geographical area 3 days before somebody presented themselves to the emergency room for a test. Would that be a plus for the surveillance network?

Mr. BECKER. Thank you, Senator. It would be an absolute plus. I mean that—real time data analytics and the ability to predict things and catch them before they spread in the community are a fantastic thing, but the challenge is operationalizing that within the current system.

Senator BURR. The challenge is incorporating that in a layered surveillance system and a culture that looks and says, no, we just need a bigger computer that processes 10 day old data faster. That is the challenge that we are in right now, is that we are not taking advantage of technology in all aspects. And we have seen it in development. We have seen it in manufacturing, but we haven't seen it in the early stages. Ms. Cicero.

Ms. CICERO. Yes. Thank you, Senator Burr. I wanted to add to that I agree with your point. And we have the ability now, if we invest and commit to it, to develop at home diagnostics for infectious diseases. People can already get HIV testing from home. I know that HHS is working on supporting companies that are developing at home influenza testing, and that should be the future. That wouldn't it be great if we could test our families for strep or for flu or for the new unknown virus and better diagnose those viruses so that we can have early warning and reduce use of antibiotics and also better protect Americans.

Senator BURR. Great point. Ms. Arthur, you said solutions like READDI at the University of North Carolina, Chapel Hill have established—have been established to fill the gaps in the early stage discovery development so that we can better be prepared when the next pandemic comes. How can early stage discovery of treatments targeting virus families better prepare us for future pandemics, and what tools do we need to succeed in that type of work?

Ms. ARTHUR. Thank you, Senator. I think this is an example of how we invest in early stage development in peacetime. It is very similar to what Anita was saying, that we should be working on leveraging novel technologies, both platform technologies for viral families as well as new antiviral mechanisms for viral families. We can do a lot of different work across these families, the coronaviruses, the flaviviruses, and have a base of knowledge and understanding of how those different technologies actually could respond if we see a novel virus in that family.

I think we learned that with SARS and MERS, with the SARS-CoV–2 outbreak, and doing a deeper analysis and a deeper set of testing of these kinds of new mechanisms could actually allow us to spring forward even faster with new products if we see a disease x that we don't know. It has to have that funding on the back that pulls those products through from early stage development through the more expensive later stage clinical trials and the manufacturing scale up. But that partnership between the agencies could do that.

Senator BURR. Let me just remind you, the shelf life of Congress funding programs is about 18 to 36 months. And then we sort of forget about it unless there is a crisis that materializes. So it is a challenge. Ms. Cicero, let me ask you a question, but before I do, let me just—you talk about the expanded jurisdiction authority of BARDA. BARDA does have the authority today to invest and develop massively in technology platforms. So even though it is not there in an increased threat list, we did add antibiotics to their portfolio.

From the standpoint of the technology platforms, it has expanded their capabilities significantly. Now, Hopkins gave the CDC a good run for their money with COVID tracking. Not only did it become a useful tool for the American people to be able to track the virus in their communities, Federal officials were also using it as a resource, and it was quoted frequently.

How can the Federal Government better partner with the private sector and academia to advance virus surveillance capabilities?

Ms. CICERO. Thank you for that question, Senator, and I agree with your stated goal early on that for CDC it should be the premier CDC in the world. It has been for years, and that needs to be our goal going forward into the future. We need to provide CDC with a sufficient resources and purpose to be able to expand, to be able to work more seamlessly with the private sector, with academia, and to invest in the kinds of systems that they need for better surveillance, to work more seamlessly with state and local public health agencies, and to be able to really have that real time data that is more actionable so that it informs the response.

Senator BURR. Madam Chair, just one last question. Dr. Janz, how was Dr. Cassidy as lecturer?

[Laughter.]

Dr. JANZ. Best diarrhea there is.

Senator BURR. Very good answer. Thank you.

[Laughter.]

The CHAIR. Thanks.

Senator Casey.

Senator CASEY. Chair Murray, thank you for calling this hearing. I want to thank you and Ranking Member Burr, and I want to get to our witnesses, we are honored you are here, and get to my questions. I did want to join so many of our colleagues in paying tribute to Mike Enzi, former Senator from Wyoming. Probably the best way to describe Mike Enzi is he was a paragon of decency in a town where that is often in short supply. Just such a good person.

It is always interesting what you remember when you hear about the passing of someone that you knew or someone that you had some familiarity with. And I got to know Mike on this Committee. But before I was on this Committee, I think it was my first year. I remember standing on the Senate floor, just one of those interactions you remember at a moment like this where our former Senate Majority Leader, Harry Reid, was standing next to me toward the back of the chamber and he made reference, and he pointed across the room and said, he said, Bob, that is Mike Enzi. He is a good man. That is all he said. And then as Harry Reid often does, he didn't say much more. But I didn't know Mike at that point in time and then got to know him a few years later on this Com-

mittee. And we are going to miss him in so many ways. And we are just so saddened that soon after leaving this chamber that he, in this legislative body, that he was taken from us.

We are thinking of him, remembering him with respect and fondness, but also, of course, thinking of his family and praying for them. So we are all going to be paying tribute to him in the next number of days. I wanted to thank the witnesses for sharing their remarkable expertise with the Committee on Pandemic Preparedness legislation, all kinds of legislation.

I appreciate the opportunity to have worked with Chair Murray in the past on these issues. And Ranking Member Burr, he was working on these issues before, just a number of years before I got to the Senate, also with Ted Kennedy, I guess, Richard, at that time, as he made reference to, Senator Enzi, Senator Kennedy working together. But I appreciate both the Chair and the Ranking Member and the work they have done, especially on previous authorizations of the so-called Pandemic All Hazards Preparedness Act. We are still grappling, of course, with the COVID–19 pandemic. And we also need to look ahead to the next public health emergency and get prepared for that. So I will start with me Ms. Arthur. I want to thank you for your testimony today and the expertise you bring. The many—and also the many times you have shared that expertise with members of our staff. I wanted to ask you to expand on what you had in your written testimony on page 13.

Just for reference, you made reference to state immunization information systems, and you describe them this way on page 13, "computerized multifaceted systems that operate in 62 jurisdictions and have the ability to maintain immunization records across the lifespan that can be used—can also be used for providing for providers, I should say, to order vaccines and maintain an accounting of inventory and it goes on from there. But I guess the basic question with regard to these information systems is what are some of the challenges they currently face?

Ms. ARTHUR. Thank you, Senator, for that question. These systems are very, very important to the core public health infrastructure of each state, and they face many different challenges. Data capture, the way that they are built. Some of them are older. Each state has their own. Some of them do not yet include or had to quickly add space for adult immunization because of the pandemic. I think what is most important, very much like Mr. Becker said, is the interoperability of systems.

Interoperability with the electronic health record, interoperability between states. Many people might live in one state and work in another. It is really important that we think of these immunizations information systems as one of the core foundations of our vaccination infrastructure.

Senator CASEY. How about, are there resources available from the Federal Government to support both as you make reference to functionality and interoperability?

Ms. ARTHUR. Absolutely there are. The CDC actually has immunization cooperative agreements with the 50 states, territories, HHS, etc. But the funding here has been stagnant for many years. And each state then apportion some, or maybe a very small amount

of their state budget to these systems. They really do need an overhaul and a clear modernization. And certainly there are several legislative bills moving that actually seek to help the states modernize their immunization information systems. We strongly support those among the vaccine companies at BIO. And thank you for your support of that as well.

Senator CASEY. Thank you.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. Thank you. Let me just follow-up right there, Ms. Arthur. You allude to it in your testimony and going back to what Chair—Ranking Member Burr said earlier. Congress gave $1 billion to CDC to upgrade information systems. And I was specifically asking last year for more money for immunization information systems and was told that billion was going out to states in order to upgrade. That is where it was targeted because I was frustrated with CDC's inability to give real time data.

Now, Mr.—so it seems as if we are advocating for dollars of which a billion has already been appropriated and we are told that is where it went. But Mr. Becker, in your testimony, you indicate that in Washington State there has been inadequate money to upgrade the immunization information system. I say that because it seems like there is a disconnect here. We gave $1 billion.

I was specifically told it is going to go to upgrade state information systems. And I am hearing from a very innovative state that you have inadequate resources to upgrade. So let me ask, did you receive money from that $1 billion that we gave CDC last year?

Mr. BECKER. Thank you, Senator. I will have to go back and find out how much Washington State actually received from the CDC. But I can tell you that whatever we received was not adequate to meet the needs of what we have faced today.

Senator CASSIDY. Now, it could be that the state used it for something else. Let's just be fair to CDC. Unless they came down with a specific instruction to spend it on immunization information systems. But it does seem, let me just ask, in your testimony, you do mention that you had a hard time keeping track, but this is exactly what information—immunization information systems are supposed to do. Why was Washington State's not adequate to do so?

Mr. BECKER. Thank you, Senator. Is this the scalability, interoperability that I mentioned in the very first part?

Senator CASSIDY. But in the interoperability, you mentioned by EHRs, but the way if a child is given a measles, mumps, rubella vaccine, the provider actually enters that. So, and we have had other states come in here and testify that their IIS was able to, is currently accepting adult immunizations on COVID. Now, I guess I am just exploring, I am not trying to accuse. I am just trying to understand why this is not the case. Why isn't it the case in Washington?

Mr. BECKER. I think it is this disparate system. So you have very big hospital systems that can invest the infrastructure to send those things seamlessly. You have private providers——

Senator CASSIDY. What I am not sure about though, if a pediatrician has any measles, mumps, rubella in that big hospital system,

clearly the mechanism occurs. I won't belabor, but it does seem—I am just not, I am just not getting a clear picture into what the problem is. We get $1 billion the CDC. Somehow it is not happening. And yet the system works for childhood immunization, but it is not working for adult. I won't belabor. Dr. Janz, I think one thing is clear. You mentioned in your testimony the need to have uniform standards of care. Fecal material is hitting the fan. And we don't have enough ICU beds—I probably used that line in my diarrhea lecture.

We don't have enough ICU beds, but then we learned that we are putting too many people on ventilators and putting on ventilators at too early a stage actually was associated with negative outcomes. How do we—I have to think that there is probably uneven uptake of that information in ICUs across the Nation. I don't know that I am just assuming. How do we establish that uniform communication of care when—how we manage a ventilator patient, to ventilate or not, really is critical in terms of both ICU utilization, but also the patient's survival?

Dr. JANZ. Yes. Thank you, Senator. It was vital for us to be able to spread evidence based medicine, how to prevent patients——

Senator CASSIDY. How did you do it?

Dr. JANZ. Via the Louisiana Department of Health and the Department of Health and Human Services. When we have conducted seminars with hospitals around the state in the Nation where they asked us, how do you solve these specific operational problems? We gave them answers.

Senator CASSIDY. Were you also able to give them like a checklist, similar——

Dr. JANZ. Yes, we shared with them all of the materials we developed on our own hospital. We stepped outside of the silo of an individual hospital system and shared all that.

Senator CASSIDY. Sorry to interrupt but I am almost out of time. And you want went nationally. Who sponsored your national outreach?

Dr. JANZ. ASPR with the Department of Health and Human Services.

Senator CASSIDY. Well hats off to ASPR for pulling that together.

Dr. JANZ. Absolutely.

Senator CASSIDY. Did you—were you able to demonstrably see that how patients were being managed kind of stayed in lockstep with best practices across the nation?

Dr. JANZ. Yes, it did catch up over time into what——

Senator CASSIDY. Over time, how long over time? A month, a week?

Dr. JANZ. Oh, in the scale of weeks. It was very quick. Hospital, the feedback I got from hospitals——

Senator CASSIDY. One more thing. We were short—I got a call from an anesthesiologist in San Francisco when things were really bad in New Orleans. He goes, we shut down elective, but COVID hadn't hit us yet. We should be shipping all our machines to you and then you ship them back when it hits us because we understood there is going to be an uneven kind of implementation. It never happened. Instead, we are scrounging to build new ventilators when they were sitting idle in many parts of our Nation. I just

say that because I do think part of what we are doing here would be to source existing resources where they are needed from one part of the Nation to another, as opposed to attempting to build from scratch a lot of machines that are very sophisticated, but then we don't need them when it is all done. So anyway, with that, I thank you all for your service and your testimony.

The CHAIR. Thank you.

Senator Smith.

Senator SMITH. Thank you, Ranking Member Murray—I mean, Chair Murray and Ranking Member Burr. I really appreciate this bipartisan hearing. I am struck—here we are today. We are at a pivotal point in the COVID–19 pandemic. There has been a 400 percent increase in new COVID cases over the past month. So what we do right now is going to determine what happens next with COVID–19. So today we are talking about lessons learned, but I feel driven to remind us that we need to learn these lessons like today and then apply them today so that we can avoid and mitigate what looks to me like being another very concerning surge. So that is in my mind as I think about where we are.

Mr. Becker, I was really struck by how you described our public data systems as decrepit. I think you are right. So many of us during this pandemic have talked about the need of following the science and the data, yet our data systems are so inadequate to the task that we have. But I want to pull in on the issue that Senator Murray raised about the issues of how the COVID–19 pandemic has really laid bare the deep inequities and disparities in our health care system as we see that communities of color are so much more likely to get sick and even to die.

I think that this disparity is caused in large part by the social determinants of health, right. By our access to housing, food security, employment, education, transportation. Some people say that these upstream, so-called upstream impacts are responsible for up to 80 percent of a patient's outcome, likely outcome.

I want to ask you about this, could you tell us what steps you think we should be taking as we think about data to help improve—how can the Federal Government work better with state and local entities on data collection related to these social determinants of health?

Mr. BECKER. Thank you, Senator. If I described our public health system as decrepit and old, I would describe that as social determinants of health system as infantile. It hasn't developed. It is in its infancy. And there are no standards across the country about how the last mile of those systems around housing and food insecurities collect data and then report it back up to the health care system or the public health system.

There needs to be an adequate investment in that technology now to create the technology of the future. And I certainly believe in honor of our Seattle Kraken, our new NHL team, that we don't need to skate to where the puck is as we work today, we need to skate to where the puck is going. And social determinants of health is where it is going from an infancy standpoint. We have a huge opportunity in front of us for that.

Senator SMITH. A huge opportunity. And I can only imagine the challenges around interoperability between data systems that tack-

le social determinants of health issues like housing and employment and integrating that with the public health system. But the opportunity to actually have an impact on population health here is really, really huge.

Dr. Janz, I am very interested in the work that you have been doing, and I am wondering if you could tell us a little bit about how health equity issues factored into the work that you did, that you are doing around scaling up critical care capacity in the hospital.

Dr. JANZ. Thank you, Senator, for that question. As I mentioned earlier, University Medical Center in New Orleans cares for a vulnerable patient population in a low income community where over 80 percent of the patients that we serve are patients of color. We aim to improve their care. And it is difficult to do when we have to deal with COVID surge after surge after surge.

When I leave here today, I will go back to New Orleans. Instead of working on improving care for these patients, improving cardiovascular care, decreasing rates of diabetes, improving access to care, things like that, instead, we will deal with how do we manage this next COVID surge. And that is predominately the majority of what we will spend their time dealing with. That means this unlevel playing field will remain unlevelled. Every time we have to spend time and resources dealing with the next COVID surge is time we have lost.

Senator SMITH. Right. Well let me—in fact, it strikes me that as we grapple with this next surge of COVID, we are going to be exacerbating health disparities as sort of people, communities of color, black and brown people fall further and further behind because of lack of access to basic care for chronic diseases that are caused by the social determinants of health that Dr. Becker and I were talking about.

I am out of time, but I just want to pause and acknowledge the powerful statements that you made about the impact of stress and your concerns about the mental health of health care providers. I think that this is a deeply concerning issue and something that we can't look away from. We need to see, and we need to address. So I am grateful for you bringing that up also.

The CHAIR. Thank you.

Senator Marshall.

Senator MARSHALL. Thank you, Madam Chair, and welcome to our witnesses as well. I want to talk about innovation for a second. And Ms. Arthur, that means I am looking at you. Certainly the lessons to be learned. I have always believed that innovation could do more to drive the cost of health care down than any legislation we can write. That innovation could impact this current pandemic and future pandemics more than any legislation we can write here if we would just get out of your way and let your people do their job.

I think a good analogy here is FMD, foot mouth disease. And we are starting to build vaccine banks. Much like the COVID virus, there are different variants of FMD, and that is one of the challenges. Is there any talk in your world of any type of vaccine banks being built?

Ms. ARTHUR. Not exactly. But I think that the companies want to work with the Government to again exploit these opportunities to work on viral families. Many companies actually do that. They

are constantly looking at the genetic sequence data for both existing pathogens of pandemic potential as well as novel pathogens when they show up in these various global databanks.

Companies are constantly exploring whether or not the products they have, be they vaccine technology or diagnostic technology or treatment technology, could work in some way against that pathogen. So I think that companies rely on the big public data banks, but they are constantly pressure testing their products in that case.

Senator MARSHALL. Would you agree with me, if you were going to try to set up these vaccine banks, knowing the origin of COVID would be very helpful. So, for instance, if it was from a bat cave and you had a collection of the eight most similar viruses, that those might be clues to help you develop future vaccines.

Ms. ARTHUR. I think it is very important to always understand the zoonotic nature of every virus, whether you know what animal it comes from, how it, animal to human transmission. All very important in understanding the epidemiology of a disease.

Senator MARSHALL. Is there much talk in your world about viral gain of function and how that would impact vaccine development?

Ms. ARTHUR. We don't talk about that very much within the industry.

Senator MARSHALL. Okay, I am going to turn to Dr. Janz just for a second. Dr. Janz, the doctors, nurses, respiratory therapist were the heroes of this pandemic. Extra shifts, working days at a time, major burnout going on. We put our lives on the line. And I say we, I spent time in an ICU treating COVID patients in an ER and certainly understand the stress that is going on there. You know, as we stand here today, and I talked to my docs back home, the biggest concern treating COVID patients isn't therapeutics and what type of respiratory therapy to give, it is a nursing shortage. Would you agree that is certainly a huge limiting factor for your docs, and just not in big hospitals, but small hospitals and across the Nation?

Dr. JANZ. Oh, I couldn't agree more, Senator. If we ever ran out of ventilators in our hospital, we would have run out of nurses 30 ventilators ago. The nursing shortage—nurses are perhaps the most vital responders to this pandemic. They have shouldered the greatest workload in responding to taking care of patients with COVID–19. And among their most precious, precious resource, we have too few of them. And we are not supporting them enough.

Senator MARSHALL. I just want to bring to the attention of the Committee that I spoke to a hospital yesterday who is trying to bring in some nurses from the Philippines, and they have worked with this agency for quite some time, but they are running into passport issues and State Department issues and they de-prioritize nurses down to forgive me the nomenclature, may be a level four. We need the State Department to go back to work to the office to get through these.

I hope that you all would join me in letters urging our State Department to help get some of these nurses from other countries in here as well. Last thing I want to talk about when it comes to doctors is I am getting lots of phone calls from doctors and they are referring—they would tell me, well we appreciate the word of thanks from Congress, but why are you trying to cut our pay?

Thanks to the budget neutrality clause in the Medicare physician fee schedule, we are going to say thanks to all these doctors by cutting their pay up to 10 percent.

I just think that is the wrong message to send to be sending to the health care heroes who have saved our lives. I am not sure if your association, your medical associations is looking into that issue or not, but certainly a lot of concern from docs back home about their pay getting cut.

Dr. JANZ. I think all health care professionals right now need help, especially our nursing colleagues who again, are shouldering the heaviest load in responding to this pandemic. And we need to think of ways to help bolster them, not things that we can take away from them or else otherwise we are not going to get out of this any time soon.

Senator MARSHALL. Thank you, Dr. Janz. Thank you, Madam Chair. I yield back.

The CHAIR. Senator Lujan.

Senator LUJAN. Thank you, Chair Murray and Ranking Member for this important hearing. Before us today, we have a distinguished panel of experts whose thoughtful approaches about how to better prepare for the next pandemic. However, as Dr. Janz notes in his testimony, non-evidence based practices were being disseminated frequently at the time via the Internet, social media platforms, and other non-peer reviewed sources. Going down the panel, yes or no, does COVID misinformation spread online undermine public health efforts? Dr. Becker—Mr. Becker?

Mr. BECKER. I would say any information that is misinformation hurts public health.

Ms. ARTHUR. Absolutely.

Senator LUJAN. Dr. Janz.

Ms. CICERO. Yes. Yes, it does.

Senator LUJAN. Mr. Becker, you also state that we must operationalize systems that capture uniform data quickly and shared across state lines rapidly. In your testimony, you state that eliminating paper based reporting is the best way to achieve that goal. How can we better equip and prepare rural providers who at times do not have access to the broadband needed to move away from paper based reporting?

Mr. BECKER. Yes, I think, Senator, you are hitting on a fundamental problem that I am really hitting at with the regional concept. Each region faces different infrastructural problems, community problems, and we need solutions that address that from the beginning of the process to the end of the process at CDC. And that is going to be different in each community, whether it is a broadband connection, whether it is the lack of resources from a workforce. And we need everyone at the table from the local, state and Federal level to help solve those problems and direct funding that can directly impact those problems.

Senator LUJAN. It is just a reminder of why the infrastructure package must have the goal of 100 percent connectivity across the country, and it would allow us to have better health outcomes as well based on your advice there, Mr. Becker. I appreciate that. Mr. Becker, Ms. Cicero in sustained investment—is sustained invest-

ment in public health infrastructure the best way to ensure that we are receiving the best on the ground data?

Mr. BECKER. Certainly sustained support has to be there for the long term. We can do a lot with the money that has been given, but it will only triage the problem. The sustained funding will get us to that next mile.

Senator LUJAN. Ms. Cicero.

Ms. CICERO. Yes, thank you, Senator. We do need that bolstering of capability around data. Right now, we don't know—we don't have a central way of tracking outbreaks in schools. We don't have real time data to let us know if when someone is infected, which variant they are infected with. We are beginning to do this. It takes a while with the funds that are appropriated to be usefully used. It takes a while to scale up those systems, but that will be very important to do going forward.

Senator LUJAN. Appreciate that. And I echo the concerns raised by Chair Murray about better data collection by race and ethnicity. Dr. Becker, you mentioned challenges faced by tribes in collecting data. How can these challenges be overcome?

Mr. BECKER. Thank you, Senator. Yes, in the State of Washington we have 29 tribal Government affiliations, and that is not represented in the data systems as we collect them. And right now what happens is our epicenters and our tribal partners go in and correct that data and accurately reflect it. But that is a labor intensive processes and we need to design a system that allows us to collect it right up front.

Senator LUJAN. My understanding is IHS is still not releasing the data they have state by state. That has also created challenges and us being able to understand where progress is made and where it is not and how we can refocus our efforts. I very much appreciate your attention and response in that area, Mr. Becker. Dr. Janz, New Mexico faces a significant health care workforce shortage. As a result, caring for the mental health of our providers is especially important. How can we better support the mental health needs of our health care workforce?

Dr. JANZ. I think we first need to engage with these frontline staff to understand what their exact needs are. I think every individual is going to have different needs, especially when they have been dealing with the stress of taking care of a high volume of COVID–19 patients. And thinking that one solution for every hospital in the country is going to meet all those needs is probably an inadequate response. We need to engage the stakeholders here, which are those frontline workers, and figure out what are their needs and how can we best develop systems to fill those needs.

For example, if one particular hospital, the nurses in that hospital and the physicians have a greater need for mental health resources, those resources should be made readily available. They should not be difficult for them to seek out and obtain those resources. If a different hospital has a different need, for example, among their workforce, then the system should be nimble enough to respond to that need.

But there needs to be response everywhere, because in this time of COVID, what happens in someone else's hospital affects my hos-

pital, affects the hospital next to it and around the country. And so if one hospital is suffering, all of them will continue to suffer.

Senator LUJAN. Appreciate that. And Chair, I do have a line of questioning around Project Echo. I will submit them into the record. As well, just very much appreciate the panelists for being here today. And with that, I yield back.

The CHAIR. Thank you.

Senator Tuberville.

Senator TUBERVILLE. Thank you, Madam Chair. Thank you for being here today. And this is for the whole group, just a short answer would be great. We spent trillions of dollars, the Federal Government has on COVID relief legislation. I am a firm believer that just throwing money sometimes is not the proper answer. What we need is people and a plan. Aside from spending more money, what would you do differently, Mr. Becker, on our next go around for whatever we have coming our way?

Mr. BECKER. Thank you, Senator. And I completely agree that just throwing money at the problem is not going to solve it. What I suggest is actually having the partners sit down at the table and help design systems that are localized to their community. And that is why I talk about having the local partners there, the state partners there, but also our Federal partners there not just as funders that send off a contract and say get it done, but to help us knock down those roadblocks and barriers that come up as you implement a plan, because the plan is never going to be what you wrote on paper when you begin with. But we don't have that Federal partnership on the other side to help knock down those roadblocks.

Senator TUBERVILLE. Thank you.

Mr. Arthur.

Ms. ARTHUR. Thank you, Senator. I would actually make sure that all the data we are getting as we are learning about the disease is very quickly disseminated to both the academic and industry sector. I think that was a place where there was some delays and particularly small and medium sized companies didn't necessarily have access quickly to the natural history data, all the different science, the outcomes which could have allowed them to move even faster in their development of products.

Senator TUBERVILLE. Thank you.

Dr. Janz.

Dr. JANZ. I would echo the statements by my colleagues in this panel. There isn't a day that we don't use data generated by public health experts to plan what we are going to do in the hospital that day, the next week, the next month, and over the next few months. Public health infrastructure and data obtained in real time from these experts has been vital in our response to the current pandemic and any future pandemic.

Senator TUBERVILLE. Thank you.

Ms. CICERO. Senator, I agree wholeheartedly with the comments that are made by my fellow panelists. So I will pick a different issue. And that is, again, I think we need to be much more proactive in getting ready. But we are not going to be able to scale up contact tracers, have lots of different therapeutics, etcetera, in the midst of a surge during a pandemic.

We have to prepare in the future to do that. I think for medical countermeasures in particular, we need a strong PHEMSE, as Ms. Arthur said, we also need a very strong ASPR that is able to be nimble and flexible and have the authorities that it needs to work quickly and deploy resources effectively in the middle of a crisis.

Senator TUBERVILLE. Thank you. This is another question for the whole group. We will start with you again, Mr. Becker. We spent $41 billion on COVID research, $41 billion. And kids are getting ready to head back to school. Are any of you all aware of any studies that we have focused on for the effectiveness of masks for kids under 12 years old? That is getting ready to be a huge topic. Mr. Becker?

Mr. BECKER. Thank you, Senator. That is outside my lane of expertise.

Senator TUBERVILLE. Okay.

Ms. ARTHUR. Me as well. I don't know of any——

Senator TUBERVILLE. Dr. Janz.

Dr. JANZ. It is also outside my line of expertise.

Ms. CICERO. Senator, thank you for that question.

Senator TUBERVILLE. Found somebody that knew something about it. Good.

Ms. CICERO. I think that opening schools and how safe our kids are in schools in the fall is on everyone's mind right now. And I am not aware of a study that focuses on the effectiveness of masks for children under 12. But again, this is an area where we shouldn't—we need to develop better masks that are reliable, that fit different kinds of faces, that are wearable all day, that kids can communicate through.

I do think that it is very reasonable in states and localities where cases are surging, and hospitalizations are beginning to fill up to maybe reimpose some mask mandates in those areas. And certainly for our kids in school, for now, it would be important that they wear those masks indoors.

Senator TUBERVILLE. I hope that what we have just gone through for the last year and a half, that if we start to wear these masks again, God forbid, heaven help us, that we would come up with a mask that everybody understands it actually works to some degree. Because you see people wearing masks that obviously they don't work. They are just wearing something put over their face. I heard very early from doctor friends of mine that said, listen, nothing but N95 really helped. Everything else is kind of shut the door. Is that your thoughts?

Ms. CICERO. Thank you, Senator. Not completely. They—I believe that wearing the cloth masks that we have had available has helped to reduce transmission, especially indoors when we know the risk of COVID transmission is much higher. And we—but we can do better. And I think that we haven't innovated in this area, and we haven't really tried hard.

I know that BARDA has recently had a massive innovation challenge. That is a good thing. I think we can do a lot more in this area to get better masks for the general public and also to be able to generate them quickly. I think when people buy masks in the CVS, they should know, first of all, they are available and second,

they are certified. And so they are effective at reducing the risk of infection.

Senator TUBERVILLE. That is a good idea, certification. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Murphy.

Senator MURPHY. Thank you very much, Madam Chair. Thank you for convening this hearing. I would have hoped for a little bit more robust answer from the panel with respect to the efficacy of masks. I mean, we have enormous amounts of pretty well reliable data telling us that this is an incredibly effective means of controlling the virus. We have to look no further than the story of influenza in 2020 to know what a difference it makes, even if you are not all wearing N95 masks. We essentially eliminated the flu over the course of the past year. Why? Because the flu is much less contagious than COVID–19.

I share my—the hopes of Senator Tuberville, that we can get to a point where we are not required to wear masks in any setting. But I think it is important to tell the American public that they work. I wanted to turn to you, Ms. Arthur, to talk to us for a second about the issue of intellectual property protections.

The United States has some of the strongest IP protections for medicine in the world. We should be proud of that because we save a lot of people's lives through the innovations that we create in the United States. But our IP protections were really never envisioned for a setting like this. They were never envisioned to provide protection in the case of a pandemic with a massive built in Government marketplace buying technology or medicines that every single American is going to need or desire.

The risk here is pretty obvious that the amount of profits that could be made by private industry in this case is potentially limitless. And the question is whether, especially as we enter a world in which we may be needing annual booster shots, essentially get potentially paid for by the US taxpayers, guaranteeing a marketplace for decades for the small number of companies that have produced the vaccine, whether we need to sort of step back and have a conversation about perhaps modifying the level of IP protection specific for these technologies.

Obviously, we have had this conversation internationally through the WTO. But make the case as to—I assume BIO is probably very protective of IP protections. So make the case as to why from a taxpayer standpoint, we shouldn't be worried about the amount of money that can be made in the out years when it comes to vaccines and boosters.

Ms. ARTHUR. Thank you, Senator, for that question. I will say yes, indeed, at BIO we are very protective of the intellectual property our companies work hard to arrive at. I think that actually you should think of these products as an investment, not just in COVID, but all the other things that these technologies will be able to do that will save lives both in the short term and the long term. And that intellectual property is the base of that ability for companies to continue to do the R&D they should do for, commercial and of course future pandemic indications.

From many of our companies, particularly small and medium sized companies, this intellectual property that they have garnered for this technology they have worked on is the foundation of the valuation of that company. I think it is extremely important to understand that moving or loosening the intellectual property protections we have in the U.S. could have a number of negative effects. It could certainly limit companies' willingness to respond to the next pandemic. I think that is extremely important to understand.

But in addition, it could actually devalue some of those companies for some of the other uses they have for that technology as investors worry about them losing the intellectual property rights. And then I think last, it could—it really does devalue the great—the great exercise—the great abilities of the U.S. Government and the U.S. as a leader in biotechnology. I do think, however, that in the future, remember that the commercial value of these products will actually lead to more competition, not less.

There are companies behind the three that have vaccines on the market now who are going to have better innovations. Maybe it is lower dosing, maybe it is less dosing, maybe higher efficacy, better safety. This actually will spur more companies to work on great vaccines and therapeutics for COVID.

Senator MURPHY. I don't know that—I appreciate the answer and I want to give you the chance to make the case, but I am not sure I agree. I think that given the exceptional nature of this moment and what it will hopefully be the exceptional historical nature of this pandemic, it is not a danger to the overall bottom line of any individual company or the industry writ large to create some special set of rules for these technologies, given the fact that we are spending trillions of dollars in a way that we don't for any other comparable disease or virus on an annual basis. So I look forward to continuing this conversation. And I appreciate the chance to talk about this. Thank you, Madam Chair.

Ms. ARTHUR. Thank you, Senator.

The CHAIR. Thank you.

Senator Scott.

Senator SCOTT. Thank you, Madam Chair. At a risk of continuing the conversation with Senator Murphy. I am prepared to ask the question. I am unwilling to ask the question, so I am going to do it anyway, Ms. Arthur. I believe that had it not been for our ability to partner with the private sector, we might not be sitting here today. I believe that if we were unable or unwilling to recognize that perhaps the greatest economic engine, the greatest engine of innovation our Nation has seen and health care doesn't come from the Government, it comes from the private sector. But if, in fact, we had not had Warp Speed partnering with the private sector, we would not be having a conversation in person in this Nation and maybe in the world, and that the death toll would be multiple times higher than it is today. Am I in the realm of possible?

Ms. ARTHUR. I firmly agree. I think what was really strong about Operation Warp Speed was the collaboration and the skills that were deployed by industry with the help and advice of Government, but really, the U.S. Government relied on what our decades of experience with experienced and small and medium manufacturers to really deploy the best of science for a really important goal. And

doing it in—I still marveling because I have been in the vaccine business 25 years. I am still marveling that we made these extremely important, efficacious and safe vaccines in a year and deployed them in 6 months. It is incredible what we have done.

Senator SCOTT. I remember sometime in April, May 2020, when I think it was NBC that said that the theory that we were going to have a vaccine within a year would take more than a miracle. It was nearly impossible to have any appreciation or expectation that somehow, some way, with all the great minds in the world working together, we could do what we have done. And so I do think we should have a longer conversation about the power of partnership and the synergy of public private-partnerships in many areas of Government. I think we could easily miss the point of why we are having this hearing and why we are able to have this hearing.

However, I have questions about virtual health and telehealth, and I will get to those prepared questions. So thank you for that. When I think about the pandemic, I don't find many silver linings at all. The death toll is devastating. The number of folks who have recovered but not fully is just mind boggling. But I do see, however, as the possibility of a silver lining is that perhaps the telehealth conversation accelerated forward five or six or 7 years. But in that silver lining, I think about in rural America or rural South Carolina, where one out of four people don't have the ability to connect because they have a flip phone, no phone or not a smartphone, 15 percent of Americans find themselves in the same category as one out of near—almost one out of four rural Americans.

The telehealth platform is so important that we probably need to spend more time investigating audio only in that telehealth delivery system with integrity in the system to make sure that we are talking to the patient if you can't see the patient. I think this platform needs greater investigation, and frankly, more resources. Thoughts on that? Let's start with you, Mr. Becker.

Mr. BECKER. Thank you, Senator. Yes, absolutely. I think telehealth has advanced because of the pandemic and there is infrastructural problems to getting it to the last mile in rural areas. When we were at public health in Harris County, we put the mobile telehealth on mobile vans and drove them out to communities of need that didn't have access. And we found community centers with extra space to set up the private room so patients can come into the community centers they were already visiting and have access to those services while they were there. So there are solutions, Senator. But I think, again, coming back to your previous—we need to work with our local partners, but also our private partners to figure out how to get that technology and those services out.

Senator SCOTT. Thank you. My last 30 seconds here. Dr. Janz, my mother has worked in the hospital for the last 47 years. And I think about all of our emergency responders who are willing to stick around and do their jobs in the face of losing their lives. And I know that the importance of PPE and obtaining the drugs that were necessary—did your hospital encounter any problems or challenges with PPE or drugs?

Dr. JANZ. Thank you, Senator. And thank you to your mother for her service over all those years. We obtained and maintained adequate supplies of PPE and medicines during the pandemic. It did require lots of work and effort, asking lots of other hospital systems around the state and country to help us out with those items. But we were able to maintain those items. And by just the generosity of our community. In spring of 2020, community members were dropping off N95 masks in the lobby of our hospital for us to use on the scale of hundreds to thousands of them a day. It took a village, but it worked.

Senator SCOTT. I will say, as my time has run out, Madam Chair, that the excellence that we have seen in America's health care system is a marvel of the world. And I think bills like my Made in America Act that would provide more reasons to bring your PPE home and your generic drugs being made here in America is a necessary component of what I consider resiliency. Our Nation needs to be more resilient when it comes to challenges. And one of the ways for us to get there is for us to work in a bipartisan fashion together to bring home some of those really important resources to our Nation. Thank you for the extra minute.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you, Chair Murray. I have long prioritized the need to prepare for a pandemic influenza and have worked with Members of this Committee and back in my House days on the Energy and Commerce Committee on that mission. And we have made progress. But I think we can build on this progress as we plan for unknown disease threats. I will soon be introducing the Disease X Act to do exactly that. Specifically the Disease X Act would provide BARDA with the additional resources needed to stand up a medical countermeasures program aimed at developing responses to unknown viral threats or disease x.

Ms. Cicero, you noted in your testimony that there are certain viral families that are more likely than others to lead to a large scale outbreak. What do we know about these viral families that are cause for concern? And why is it critical that we make an investment sooner rather than later in a disease x model?

Ms. CICERO. Thank you for that question, Senator. When we look at the characteristics of pandemic pathogens that are most likely to result in a large scale outbreak, first of all, we look at the viral families that have been known to infect humans in the past, and then those that have the kinds of characteristics like high transmissibility, high lethality, and also asymptomatic spread.

When you pair that with the fact that you don't have existing countermeasures already in the stockpile and ready to go, that is a terrible brew for the kinds of viruses that will cause a problem. And the handful of viral families that we would recommend is important to start with are things like the paramyxovirus family, which has deadly viruses in it, like Hendra and Nipah.

Surely the coronavirus family, which is SARS–1, SARS-CoV–2, as we have seen, and also MERS, the orthomyxoviridae families, which avian flu is a member of that, as well as the poxvirus family. So it is those types of families that we know could produce a member that could become a pandemic. The reason why we need to in-

vest now and not wait for the pandemic pathogen du jour to present itself is because it takes a long time to develop the kinds of platforms and technologies that will work well and could be quickly adapted into effective and safe vaccines and therapeutics and even diagnostics.

I think it is a wonderful success story that Operation Warp Speed has produced in less than a year three different vaccines that Americans are able to use. But we must remember that coronavirus research started after SARS–1 in 2003. And then there was MERS, which is also part of the coronavirus family.

That research also. So if you look back, it is almost, research since—15 years of research and over $12 billion that were invested to allow us to be able to generate these vaccines quickly. So we need to prepare in advance.

Senator BALDWIN. Thank you. Like many of you, I view this pandemic as an opportunity to reset and make us better prepared going forward. But I want to caution that we have planned before. It has been widely reported that the Obama administration left behind a pandemic playbook intended to inform the work of the incoming Administration. When I was serving on the Energy and Commerce Committee in the House, I remember working with George W. Bush administration for the pandemic influenza implementation plan.

When I look at how little of that guidance in these two documents was put to use by the previous Administration, it makes me wonder how we can reset, provide guidance moving forward, and expect that won't be gathering dust in a department somewhere around Homeland Security or HHS.

I don't know, it's not fair to ask you this, but Ms. Cicero, how can we best equip our public health preparedness infrastructure to really build on what already exists and use it, and then chart out a path to responding to future pandemics?

Ms. CICERO. Yes. Thank you for that question, Senator. And it is true that these playbooks have existed in the past. We don't think just because they weren't deployed and used and followed strictly during this pandemic that playbooks aren't useful. It is very useful. Coordination across different agencies and sectors is so difficult that kind of coordinating playbook of who is doing what, who is responsible for what is very, very important. At the same time, we can't just live by the playbook. We have seen that we have had a lot of curveballs thrown at us during this pandemic and we have to have some flexibility and nimbleness baked into the system so that we are able to pivot as necessary.

Our Center for Health Security at Hopkins over the years has done a number of tabletop pandemic exercises to test capabilities, and we would never have done something so dastardly as having a delta variant in the middle of kind of the recovery from COVID. I mean, it would just be unheard of—but that has happened to us. And so a playbook can't give us everything, but it is fundamental to be the basis of the planning.

We have seen too, even if we had followed the Obama playbook, I believe that we—our public health infrastructure is still woefully under-resourced and not quite in the 21st century. So we have to

get those capabilities so that they can be deployed according to national plans that makes sense.

Senator BALDWIN. Yes. But the fact is, we didn't use the playbook, so——

Ms. CICERO. I don't think so.

Senator BALDWIN. Alright. Thank you.

The CHAIR. Thank you.

Senator Braun.

Senator BRAUN. Thank you, Madam Chair. In observing this journey from the beginning, I would like to reflect what Senator Scott said. I think it is amazing how the private sector—I remember early on CDC, FDA kind of maybe arguing about who was going to control the dynamic. Thank goodness it went the way it did and a modern miracle that we got the vaccines done that quickly. I am more concerned about this. We got the delta variant. When you look at vaccinations, it has got to be 80, 85 percent of the world, technically.

I was in the logistics business before I got here. It seems like mission impossible, and I think we need to keep pushing to do the best we can. Begs the question, though, that this is so disproportionately affected, 1 percent or under of our population. And I would like you to each take maybe a minute or less, I would like to hear all four opinions, doesn't it make more sense to put resources into where you really go after the therapeutics to focus just—because of the numbers, where you got to focus on maybe 1 percent to have something that looks like it is already eluding vaccinations.

I think you have got to do both. But I have not heard enough conversation about putting disproportionate resources into therapies that when you do get critically ill, and especially focused on the data we have got on who does get critically ill, shouldn't we be pivoting to putting more effort and resources on therapy while doing vaccines? Start with Mr. Becker.

Mr. BECKER. Thank you, Senator. I think we are going to have to do both. And I think you have to leverage and triage what the immediate need is of the virus at the time. And that is going to require pivoting at multiple points, probably the way this virus has handled itself.

Ms. ARTHUR. Thoroughly agree. It is extremely important, Senator, that we have therapies not just that can potentially treat early stage disease, which I think we are now, but the new therapies that we see coming that could treat the more serious consequences and get you out of the hospital faster will save lives and save money as well.

Dr. JANZ. I completely agree that a combination approach is going to be vital. The ad coming out added and the therapy front, though, is remember all of the therapies developed to date to treat patients with COVID, especially critically ill adults with COVID, none of them are curative. They may save some lives, but many patients will still die, even with these new therapies that have been developed. So I don't think that only a therapeutic approach here is an answer. The preventive approach is still vital.

Ms. CICERO. Thank you, Senator. I agree with Dr. Janz. I agree that we need to do both, but we also should remember what vac-

cines are intended to do. When we talk about vaccine effectiveness, it doesn't mean effectiveness against any infection at all of the virus. Instead, it is effectiveness against clinically apparent disease.

We have seen, while cases are still rising, that as compared to last year, hospitalizations, deaths are about half of what they were before. And that really is due in large part to vaccination. But certainly we support the development of therapeutics as well because they have an important role to play.

Senator BRAUN. Then I will be more specific. Do you think that we can outmaneuver this devious virus through vaccinations only? And I know you have just said you would like a combined approach. And do you think conferred immunity from infection is an ally in the effort as well? Mr. Becker.

Mr. BECKER. Thank you, Senator. I would just say that is probably outside my lane of expertise so I will pass to my colleagues.

Ms. ARTHUR. I think that it is extremely important to actually focus on the vaccination campaign because I think it is the longest term way to protect us. The vaccines are showing that they work against the variance. And I think innovation will actually allow us to keep up majestically.

Senator BRAUN. Logistically we can actually pull that off across the world?

Ms. ARTHUR. I think we can. I think the industry, GAVI, the countries that are working hard to get—do just what we did in the U.S., get these vaccines as close to——

Senator BRAUN. My comment would be that logistically it looks like we are not even though I wish we could. Even when you look at the most kind of agile country in the world ourselves, with the difficulties we are running into, and this has nothing to do with the anti-vaccine because we are lucky we got a vaccine. It is just the mechanics of pulling it off.

Ms. ARTHUR. I agree, Senator. It is definitely complicated, but you have seen a lot of innovation in the way we are doing. And for treatments, I think what is hard is, is that some of the treatments have a very complex way of being given. So we could probably have the same logistics issue there. If we had a simple pill we could give, I agree with you that might help us save lives. But I think vaccination has an infrastructure globally where once we get the vaccines there, they can be deployed.

Dr. JANZ. I would point us toward all the pandemics and diseases of the past. Fortunately, they have been eradicated by vaccines around the world. This has been done before. This can be done again. We need to root cause analyze why it hasn't happened yet. Figure out what those reasons are, why we haven't had as much vaccine uptake, and then address those causes and attack this from that angle.

Senator BRAUN. Seems to be most of the other ones have not been that transmissible and they haven't looked like they turn into variants that quickly.

The CHAIR. Senator Braun, we have a vote called and we have got a few more Senators here. I am going to ask you if we can please wrap quickly.

Senator BRAUN. Thank you.

The CHAIR. Thank you.

Senator Rosen.

Senator ROSEN. Thank you, Chair Murray. And thank you, everyone, for being here and testifying. As Dr. Janz just said, no therapy is curative yet. I do hope that we get there, but it will take time. And so I want to talk about booster shots. We continue to work toward fully vaccinating our Country. We have to plan ahead, and we have to ensure a robust and effective system for any booster shots that might be needed in the future, particularly for some of our vulnerable populations. So, Dr. Janz, some early research is showing promise for immune compromised patient patients such as organ transplant recipients. We have increased—they need to have increased antibodies to fight COVID after a third dose possibly of the vaccine. More reporting has just recently come out about this. So has the research determined what is sufficient antibody level would be to provide protection? And is there currently a standard testing protocol for health care providers to test their patients, especially the most vulnerable, to see what those levels are, and if, in fact, they might need the booster?

Dr. JANZ. I am aware of the recent research that was published that in patients specifically solid organ transplant patients, where they—when they received a third vaccination dose, that they had almost a 50 percent increase in their antibody response. What level is protective is outside of my area of expertise.

My specific environment that I work in University Medical Center in New Orleans, which serves an underserved patient population, and patients that are immunocompromised, we need the answer to these questions to know how to take care of these patients better. And we look toward the experts in giving us those answers.

Senator ROSEN. Yes, I think it is really important for us to be able to have the scientists tell us what those levels are so we can determine the next case, and if we need a booster, when we need it.

Ms. ARTHUR. Senator, I will say that there is a lot of really great research going on as we analyze the small number or the small number of breakthrough cases to existing vaccines that will help us establish what that correlate is. They will test people, have a breakthrough, and see where their antibodies are. That data taken together allows us to see what the number is we should watch for that tells us what protection will be long term.

Senator ROSEN. Yes, that will be helpful all around the world, I think. And do you have any information, anybody on the panel for the latest research on a possibly a universal booster, so regardless of what vaccination you may have received, you can just go ahead and get a booster?

Ms. ARTHUR. There are several studies going on. There are studies going on with what we call heterozygous boosting where they are looking at if you got J&J, you get boosted with Pfizer or Moderna and other products that are right behind that are also in those studies like Novavax's product.

We will certainly see whether we can boost across the various platforms. I think, in addition, companies are looking at what we call the cross protection across new variants. And a lot of this data we are seeing on whether or not you work against delta or lambda

is part of that assessment of how these products work long term. And then some companies are looking at actually adding more virulent strains to their existing product. You may have what we call like a pan-corona vaccine in the future.

Senator ROSEN. Right. No, that is right. Thank goodness the scientists are working so fast with the modern computing. It is going to hopefully save the world. And speaking of computing and everyone going around the world, we have supply chain issues sometimes. So our domestic supply chain, I would like to talk about that and the role of non-profits. I recently introduced Expanding Access to Affordable Prescription Drugs and Medical Devices Act, because we have to do more to shore up our domestic supply chain.

Hopefully this is going to reduce drug costs and drug shortages and buildup our domestic manufacturing capacity through support of nonprofit drug and medical device organizations. So Ms. Cicero, could you talk about the impact that increased domestic supply of affordable critical drugs and devices would have in our ability to strategically plan while still going on in this pandemic, or God forbid, any future pandemics.

Ms. CICERO. Thank you, Senator Rosen. And I do not have the adequate background to talk in detail about the supply chain issues for low cost drugs versus other kinds of drugs. But I can reiterate your concern, and I agree that one of the major lessons that we have learned from this pandemic is that we did not have a resilient enough supply chain. We need to do more to bring manufacturing into the United States. We need to know where our supplies are coming from.

We need to make that more reliable so that it will be able to surge in the middle of—if some kind of public health emergency and have the supplies we need rather than losing control of that and not being able to get lifesaving drugs to people. And also PPE and other medical supplies that we need in the middle of a pandemic.

Senator ROSEN. Thank you. I appreciate all of your answers and being here today.

The CHAIR. Senator Hassan.

Senator HASSAN. Well, thank you, Madam Chair and Ranking Member Burr. Thanks to all of our panel for being here today. I want to start with a question to you, Ms. Cicero. You are very familiar with the challenges we faced during this pandemic, including the inability to manufacture and distribute essential medical supplies and personal protective equipment to health care workers. I recently introduced bipartisan legislation with Senator Cassidy to help address these challenges.

You have spoken generally about the importance of being prepared. But specifically, our bill would improve transparency into the strategic national stockpile, authorize transfers of expiring products, assist states in establishing and maintaining their own stockpiles, and incentivize domestic manufacturing.

Can you speak generally or if there are specific issues we haven't addressed yet to the importance of investing in our preparedness infrastructure, including the strategic national stockpile?

Ms. CICERO. Thank you for that question, Senator. And as Senator Burr referenced earlier, our strategic national stockpile really

was created with a bioterrorism mindset. And it is time to break out of that, not to leave that behind, have that to be included, but go beyond that. And I think that is partially what resulted in the lack of transparency now in understanding what is in the stockpile. People seem to know little bits and pieces, but a lot of it is classified. And so we should do what we can to increase the transparency.

Also I think it is appropriate to have a deep assessment of the stockpile. Do we have what we need? How do we get what we need? I agree with you that having stockpiles in states or other locations to add on, not replace, our strategic national stockpile would be a good thing.

I also think we should be thinking creatively about how to make sure all our products in the stockpile don't sit on the shelf and expire and then be thrown away. We could recycle or we can give PPE and masks, etcetera, to hospital systems to make sure they are being used and then replenish the stockpile as we go rather than holding on to it all. So, thank you for introducing that legislation. I think that would be an improvement.

Senator HASSAN. Thank you very much. Mr. Becker, the clinical lab at Dartmouth Hitchcock Medical Center in New Hampshire has been conducting COVID–19 test sequencing in partnership with public health officials. Sequencing COVID–19 test samples helps us stay ahead of potential outbreaks, which is especially important given the emergence of several variants, including the delta variant that we are dealing with right now.

The size of the sequencing data files can make data exchange between hospital systems and public health officials more difficult, which limits the ability of states to identify emerging variants in real time. What specific steps can we take now to ensure that labs and public health departments are able to quickly and efficiently exchange data in support of their efforts to track the delta variant?

Mr. BECKER. Thank you, Senator. I think having the CDC set standards and a secure system to allow that to happen like they do in other disease sets would be an initial first step that we should take.

Senator HASSAN. Thank you. And then a question for you, Ms. Arthur. Over the past year, companies have struggled to source active pharmaceutical ingredients and Americans have struggled to access essential medications. And this is really kind of a follow-up on Senator Rosen's line just now. The Federal Government has made significant investments through BARDA and the National Institutes of Health to support development of new medical countermeasures over the past year, including vaccines and therapeutics.

However, our limited domestic manufacturing of essential medications, including generics, leaves us vulnerable to potential shortages of critical drugs during future public health emergencies. What specific steps should we be taking to increase domestic manufacturing of essential medications? And how do we incentivize competition within this space in order to improve supply chain resiliency?

Ms. ARTHUR. Thank you, Senator, for the question. So I think that it is important to understand the reasons why different types of companies are no longer manufacturing in the United States. So

in the biologics space that—the companies we work with, there is actually lots of investment in footprints of manufacturing here in the U.S., although there certainly could be more, and there is many legislative actions to do that.

For essential medicines, I think we need to look at what are the different laws around the environmental impact, how do they source the chemicals that they need in the U.S., and some of—fixing some of these things could indeed encourage companies to return some of their manufacturing for essential generic medicines to the United States.

Senator HASSAN. Thank you very much. And thank you, Madam Chair and Ranking Member Burr.

The CHAIR. Thank you. Senator Burr, do you have a final comment?

Senator BURR. Just ending comments, Madam Chair. All of you highlighted BARDA, ASPR, a number of other things. 20 years ago, they didn't exist. These are new entities and thank goodness we have shown a little bit of vision at updating them every 5 years to reflect what we have learned. Ms. Cicero, the challenge with SNS is the Federal Government purchases 4 percent of PPE. The private sector purchases 96 percent of all PPE. The Federal Government probably won't buy every time China dumps.

We are going to rely on domestic manufacturing, and we are going to incentivize. We don't have the control of making the private sector buy the 96 percent. And if the N95 mask is being dumped by China, 3M, Honeywell, all those manufacturers are out. The only option is a payment for warming those facilities that will only be outstripped by Congress's memory and they will not fund it forever. So something that is sustainable is got to be what we are shooting for.

Mr. Becker, your state received $154 million in 2020 and 2021 for vaccine preparedness, which can be used to upgrade your data systems. That has nothing to do with the $1 billion that Senator Cassidy alluded to. So I would love for you to go back and look at that and see if, in fact, the state shared all of that with our public health entities. There has been a lot of criticism toward previous Administrations playbooks that weren't used. Let me just make two statements. One, Congress deserves as much criticism as any Administration out there, period. End of sentence.

It doesn't have to be that way going forward. But we do. Second, I remember vividly in Ebola when that Administration didn't use the playbook that was written, we wrote it in statute. The ASPR, Dr. Laurie was relegated over to run the hospital, domestic hospital structure, not to be in charge of this global outbreak and the coordination of treatment. That was all taken out of her hands. Every Administration has recreated the wheel and Congress 20 years ago had a vision of what we needed, and we put it in place.

The last Administration followed most of it that was in statute, so they deserve a little bit of credit for having accomplished something that none of us thought they could do. Senator Lujan talked about broadband and the need to stretch it out. I have been having that conversation up here for 20 years. I have no firm belief today that if we appropriate X amount of money that last mile, Mr. Becker, is going to get covered and that community health center is

going to be covered. But I will tell you this, if we stop focusing on putting cable in the ground and we start funding the technology that is available today, Starlink, the sister company to SpaceX, started by Elon Musk, can deliver broadband delivery anywhere in the United States today.

High speed, $50 a month average, and we don't have to put a thing in the ground. So this belief that America has to sit with or without, we can turn on the without tomorrow. It just takes Federal Government coordinating with the technologies that are out there. And Amazon is going to have a competing satellite network up in 2 years. So we are going to have two people delivering satellite direct broadcast competition. Last thing I want to say is, if there is a takeaway, if there is a headline today or tomorrow on what this hearing is about, I would suggest to it is this, if you are not vaccinated, get vaccinated.

We can work out all of the challenges that each one of you have expressed to us because we are that good. But what we can't do is we can't overcome bad decisions by people that sit at home and say, even though this benefits my children, even though this benefits my parents, this happened too fast, so I am scared of it. Boy, that is a cop out. If Americans would get vaccinated at the same rate they started when vaccines became available, yes, we would be talking about breakthrough infections—breakthrough infections, are 0.004 percent of the individuals who have been vaccinated. Infections for the population of the United States is a little over 10 percent.

Breakthroughs are just a speed bump in a parking lot compared. What does it tell us? It tells us every American owes it to everybody to get vaccinated. So my hope is that we are well on the way to doing that. Thank you, Madam Chair.

The CHAIR. Thank you, Senator Burr. Especially want to echo that last comment. That will end our hearing today. I really want to thank all of our colleagues and I especially want to thank our witnesses today, Mr. Becker, Ms. Arthur, Dr. Janz, Ms. Cicero. We learned a lot. Very thoughtful discussion and I appreciate all of your contributions.

For any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, August 10th at 5 p.m.. The hearing record will also remain open until then for Members who wish to submit additional material for the record. This Committee will next meet Tuesday, August 3rd, for an executive session. Committee stands adjourned. Thank you.

ADDITIONAL MATERIAL

II

117TH CONGRESS
1ST SESSION

S. 1543

To amend the Public Health Service Act to provide best practices on student suicide awareness and prevention training and condition State educational agencies, local educational agencies, and tribal educational agencies receiving funds under section 520A of such Act to establish and implement a school-based student suicide awareness and prevention training policy.

IN THE SENATE OF THE UNITED STATES

MAY 10, 2021

Ms. HASSAN (for herself, Ms. ERNST, Mr. BLUMENTHAL, Mrs. CAPITO, Mr. COONS, Mr. CORNYN, Mr. MARKEY, Mrs. SHAHEEN, Mr. TILLIS, Mr. MURPHY, and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to provide best practices on student suicide awareness and prevention training and condition State educational agencies, local educational agencies, and tribal educational agencies receiving funds under section 520A of such Act to establish and implement a school-based student suicide awareness and prevention training policy.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Suicide Training and Awareness Nationally Delivered for Universal Prevention Act of 2021'' or the ''STANDUP Act of 2021''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Since 2010, suicide has been the second-leading cause of death for young people ages 10 through 24. In 2019, 6,488 young people ages 10–24 died by suicide.

(2) Based on the 2019 Youth Risk Behavior Survey of the Centers for Disease Control and Prevention (in this section referred to as ''CDC''), 8.9 percent of youth in grades 9–12 reported that they made at least one suicide attempt during the 12 months before the survey.

(3) While there is no complete count of suicide attempts in the United States, CDC data suggests that for every reported death by suicide among people ages 10 through 24, approximately 33.5 young people visit a hospital for self-harm related injuries.

(4) In 2019, suicide was the tenth-leading cause of death overall in the United States, with over 47,500 people dying by suicide, and there were more than twice as many suicides in the United States as there were homicides.

(5) Youth often display warning signs and signals before harming themselves or others. Research shows that 70 percent of those who die by suicide tell someone of their plans or give another warning sign.

(6) According to the CDC, the rates of suicide among non-Hispanic American Indians and Alaska Natives were 60 percent greater than the general population in 2019 and are the highest of any racial or ethnic group in the United States. In addition, a study of CDC data from 2001 through 2015 shows that suicide rates for Black children ages 5 through 12 were roughly 2 times higher than those of similarly aged White children.

SEC. 3. STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING.

(a) IN GENERAL.—Title V of the Public Health Service Act is amended by inserting after section 520A of such Act (42 U.S.C. 290bb–32) the following:

"SEC. 520B. STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING POLICIES.

"(a) IN GENERAL.—As a condition on receipt of funds under section 520A, each State educational agency, local educational agency, and tribal educational agency that receives such funds, directly or through a State or

Indian Tribe, for activities to be performed in schools with respect to grades 6 through 12, including the Project AWARE State Education Agency Grant Program, shall—

''(1) establish and implement a school-based student suicide awareness and prevention training policy;

''(2) consult with stakeholders (including principals, teachers, parents, local tribal officials, and other school leaders) in the development of the policy under subsection (a)(1); and

''(3) collect and report information in accordance with subsection (c).

''(b) SCHOOL-BASED STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING POLICY.—A school-based student suicide awareness and prevention training policy implemented pursuant to subsection (a)—

''(1) shall be evidence-based;

''(2) shall be culturally and linguistically appropriate;

''(3) shall provide evidence-based training to students in grades 6 through 12, using school-based mental health service providers, if such providers are reasonably available, regarding—

''(A) suicide education and awareness, including warning signs for suicide and self-harm;

"(B) methods that students can use to seek help for themselves and others; and

"(C) student resources for suicide awareness and prevention;

"(4) shall provide for retraining of such students every school year;

"(5) may last for such period as the State educational agency, local educational agency, or tribal educational agency involved determines to be appropriate;

"(6) may be implemented through any delivery method, including in-person trainings, digital trainings, or train-the-trainer models; and

"(7) may include discussion of comorbidities and risk factors for suicidal ideation or self-harm, including substance misuse, sexual, or physical abuse, mental illness, and other evidence-based comorbidities or risk factors.

"(c) COLLECTION OF INFORMATION AND REPORTING.—Each State educational agency, local educational agency, and tribal educational agency that receives funds under section 520A shall, with respect to each school served by the agency, collect and report to the Secretary the following information:

"(1) The number of student trainings conducted.

"(2) The number of students trained, disaggregated by age and grade level.

"(3) The number of help-seeking reports made by students after implementation of such policy.

"(d) EVIDENCE-BASED PROGRAM LISTING.—The Secretary, in consultation with the Secretary of Education, shall make publicly available the policies established by State educational agencies, local educational agencies, and tribal educational agencies pursuant to this section and the training that is available to students and teams pursuant to such policies, including identification of whether such training is available to trainees at no cost.

"(e) IMPLEMENTATION TIMELINE.—A State educational agency, local educational agency, or tribal educational agency shall establish and begin implementation of the policies required by subsection (a)(1) not later than the beginning of the third fiscal year following the date of enactment of this section for which the agency receives funds under section 520A.

"(f) DEFINITIONS.—In this section:

"(1) The term 'evidence-based' has the meaning given to such term in section 8101 of the Elementary and Secondary Education Act of 1965.

"(2) The term 'local education agency' has the meaning given to such term in section 8101 of the Elementary and Secondary Education Act of 1965.

"(3) The term 'school-based mental health service provider' has the meaning given to such term in section 4102(6) of the Elementary and Secondary Education Act of 1965.

"(4) The term 'State educational agency' has the meaning given to such term in section 8101 of the Elementary and Secondary Education Act of 1965.

"(5) The term 'tribal educational agency' has the meaning given to such term in section 6132 of the Elementary and Secondary Education Act of 1965.

"SEC. 520B–1. BEST PRACTICES FOR STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING.

"The Secretary, acting through the Assistant Secretary, in consultation with the Secretary of Education and the Bureau of Indian Education, shall—

"(1) publish best practices for school-based student suicide awareness and prevention training, pursuant to section 520B, that are based on—

"(A) evidence-based practices; and

"(B) input from relevant Federal agencies, national organizations, Indian tribes and tribal organizations, and related stakeholders;

"(2) publish guidance, based on the best practices under paragraph (1), to provide State educational agencies, local educational agencies, and tribal educational agencies with information on student suicide awareness and prevention best practices;

"(3) disseminate such best practices to State educational agencies, local educational agencies, and tribal educational agencies; and

"(4) provide technical assistance to State educational agencies, local educational agencies, and tribal educational agencies.".

SEC. 4. EFFECTIVE DATE.

The amendments made by this Act shall only apply with respect to applications for assistance under section 520A of the Public Health Service Act (42 U.S.C. 290bb–32) that are submitted after the date of enactment of this Act.

○

Section-by-section

S.1543, the Suicide Training and Awareness Nationally Delivered for Universal Prevention Act, "STANDUP Act" of 2021

A bill to amend the Public Health Service Act to provide best practices on student suicide awareness and prevention training and condition State educational agencies, local educational agencies, and tribal educational agencies receiving funds under section 520A of such Act to establish and implement a school-based student suicide awareness and prevention training policy.

SEC 1. SHORT TITLE

This Act may be cited as the "Suicide Training and Awareness Nationally Delivered for Universal Prevention Act of 2021" or the "STANDUP Act of 2021".

SEC. 2 FINDINGS

SEC. 3. STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING.

Amends Title V of the Public Health Service Act by inserting after section 520A of such Act (42 U.S.C. 290bb–32)

SEC. 520B. STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING POLICIES.

a) General
   - Conditions the receipt of funds under Section 520A that go directly to SEAs, TEAs, and LEAs with programming in secondary schools, specifically Project AWARE.
   - Only requires the establishment of a policy for suicide awareness and prevention training for students.

b) Policy Creation
   - In the creation of this policy, educational agencies must consult with stakeholders (including principals, teachers, parents, other school leaders).

c) Reporting
   - Standard reporting on the number of student trainings conducted, the number of students trained, and the number of help-seeking reports made by students after implementation of such policy.

d) Training Requirements
   - Basic policy structure for the suicide awareness and prevention training include:
     i. shall be evidence-based;
     ii. shall be culturally and linguistically appropriate;

iii. shall provide evidence-based training to students in grades 6 through 12, in coordination with school-based mental health service providers as defined in section 4102(6) of the Elementary and Secondary Education Act of 1965, if applicable, regarding— suicide education and awareness, including warning signs of self-harm or suicidal ideation; methods that students can use to seek help for themselves and others; and student resources for suicide awareness and prevention;
iv. shall provide for retraining of such students every school year;
v. may last for such period as the State educational agency, local educational agency, or tribal educational agency involved determines to be appropriate;
vi. may be implemented through any delivery method, including in-person trainings, digital trainings, or train-the-trainer models; and
may include discussion of comorbidities and risk factors for suicidal ideation or self-harm, including substance misuse, sexual, or physical abuse, mental illness, and other evidence-based comorbidities or risk factors.

e) Evidence-Based Program Listing:
   - The Secretary of Education, shall make publicly available the policies established by SEAs, LEAs, and TEAs.

f) Implementation Timeline
   - Grantees must establish the policies for student suicide awareness and prevention trainings no later than the beginning of the third fiscal year after the agency received grant funding under Project AWARE.

g) Definitions

SEC. 520B–1. BEST PRACTICES FOR STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING.

- The HHS in coordination with the DOE must publish best practices and guidance for school-based student suicide awareness and prevention training, that are based on evidence-based practices and on input from relevant federal agencies, national organizations and related stakeholders.
- HHS and Education Secretaries make public a listing of implemented policies and trainings available pursuant to such policies (including identification of whether such training is available to trainees at no cost)

SEC. 4 EFFECTIVE DATE

Amendments made by this bill only apply to applications for assistance under PHSA Section 520A that are submitted after the date of enactment of this bill.

(h) TECHNICAL ASSISTANCE.—The Secretary may provide tech- nical assistance to grantees in carrying out this section.

(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $7,000,000 for each of fiscal years 2018 through 2022.

SEC. 520E–3. ø290bb–36c¿ NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Suicide Prevention Lifeline program (referred to in this section as the "program"), authorized under section 520A and in effect prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016.

(b) ACTIVITIES.—In maintaining the program, the activities of the Secretary shall include—

(1) coordinating a network of crisis centers across the United States for providing suicide prevention and crisis inter- vention services to individuals seeking help at any time, day or night;

(2) maintaining a suicide prevention hotline to link callers to local emergency, mental health, and social services re- sources; and

(3) consulting with the Secretary of Veterans Affairs to en- sure that veterans calling the suicide prevention hotline have access to a specialized veterans' suicide prevention hotline.

(c) PLAN.···

(1) IN GENERAL.···For purposes of maintaining the suicide prevention hotline under subsection (b)(2), the Secretary shall develop and implement a plan to ensure the provision of high-quality service.

(2) CONTENTS.···The plan required by paragraph (1) shall include the following:

(A)Quality assurance provisions, including···

(i) clearly defined and measurable performance indicators and objectives to improve the responsiveness and performance of the hotline, including at backup call centers; and

(ii) quantifiable timeframes to track the progress of the hotline in meeting such performance indicators and objectives.

(B) Standards that crisis centers and backup call centers must meet···

(i) to participate in the network under subsection (b)(1); and

(ii) to ensure that each telephone call, online chat message, and other communication received by the hotline, including at backup call centers, is answered in a timely manner by a person, consistent with the guidance established by the American Association of Suicidology or other guidance determined by the Secretary to be appropriate.

(C) Guidelines for crisis centers and backup centers to implement evidence-based practices including with respect to followup and referral to other health and social services resources.

(D) Guidelines to ensure that resources are available and distributed to individuals using the hotline who are not personally in a time of crisis but know of someone who is.

(E) Guidelines to carry out periodic testing of the hotline, including at crisis centers and backup centers, during each fiscal year to identify and correct any problems in a timely manner.

(F) Guidelines to operate in consultation with the State department of health, local governments, Indian tribes, and tribal organizations.

(3) INITIAL PLAN; UPDATES.···The Secretary shall···

(A) not later than 6 months after the date of enactment of the Suicide Preventions Lifeline Improvement Act of 2021, complete development of the initial version of the plan required by paragraph (1), begin implementation of such plan, and make such plan publicly available; and

(B) periodically thereafter, update such plan and make the updated plan publicly available.

(d) TRANSMISSION OF DATA TO CDC.···The Secretary shall formalize and strengthen agreements between the National Suicide Prevention Lifeline program and the Centers for Disease Control and Prevention to transmit any necessary epidemiological data from the program to the Centers for Disease Control and Prevention, including local call center data, to assist the Centers in suicide prevention efforts.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.···To carry out this sec- tion, there are authorized to be appropriated $113,600,000 for each of fiscal years 2022 through 2024.

(2) ALLOCATION.···OF the amount authorized to be appropriated by paragraph (1) for each of fiscal years 2022 through 2024, at least 80 percent shall be made available to crisis centers.

SEC. 520E–4. ø290bb-36d¿ TREATMENT REFERRAL ROUTING SERVICE.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Treatment Referral Routing Service (referred to in this section as the "Routing Service") to as- sist individuals and families in locating mental and substance use disorders treatment providers.

(b) ACTIVITIES OF THE SECRETARY.—To maintain the Routing Service, the activities of the Assistant Secretary shall include ad- ministering—

(1) a nationwide, telephone number providing year-round access to information that is updated on a regular basis re- garding local behavioral health providers and community- based organizations in a manner that is confidential, without requiring individuals to identify themselves, is in languages that include at least English and Spanish, and is at no cost to the individual using the Routing Service; and

(2) an Internet website to provide a searchable, online treatment services locator of behavioral health treatment pro- viders and community-based organizations, which shall include information on the name, location, contact information, and basic services provided by such providers and organizations.

(c) REMOVING PRACTITIONER CONTACT INFORMATION.—In the event that the Internet website described in subsection (b)(2) con- tains information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section

117TH CONGRESS
1ST SESSION

S. _____

To amend the Public Health Service Act to ensure the provision of high-quality service through the Suicide Prevention Lifeline, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. REED (for himself and Mr. MORAN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act to ensure the provision of high-quality service through the Suicide Prevention Lifeline, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Suicide Prevention Lifeline Improvement Act of 2021".

SEC. 2. SUICIDE PREVENTION LIFELINE.

(a) PLAN.—Section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended—

(1) by redesignating subsection (c) as subsection (e); and

(2) by inserting after subsection (b) the following:

"(c) PLAN.—

"(1) IN GENERAL.—For purposes of maintaining the suicide prevention hotline under subsection (b)(2), the Secretary shall develop and implement a plan to ensure the provision of high-quality service.

"(2) CONTENTS.—The plan required by paragraph (1) shall include the following:

"(A) Quality assurance provisions, including—

"(i) clearly defined and measurable performance indicators and objectives to improve the responsiveness and performance of the hotline, including at backup call centers; and

"(ii) quantifiable timeframes to track the progress of the hotline in meeting such performance indicators and objectives.

"(B) Standards that crisis centers and backup centers must meet—

"(i) to participate in the network under subsection (b)(1); and

"(ii) to ensure that each telephone call, online chat message, and other communication received by the hotline, including at backup call centers, is answered in a timely manner by a person, consistent with the guidance established by the American Association of Suicidology or other guidance determined by the Secretary to be appropriate.

"(C) Guidelines for crisis centers and backup centers to implement evidence-based practices including with respect to followup and referral to other health and social services resources.

"(D) Guidelines to ensure that resources are available and distributed to individuals using the hotline who are not personally in a time of crisis but know of someone who is.

"(E) Guidelines to carry out periodic testing of the hotline, including at crisis centers and backup centers, during each fiscal year to identify and correct any problems in a timely manner.

"(F) Guidelines to operate in consultation with the State department of health, local gov-

ernments, Indian tribes, and tribal organizations.

"(3) INITIAL PLAN; UPDATES.—The Secretary shall—

"(A) not later than 6 months after the date of enactment of the Suicide Prevention Lifeline Improvement Act of 2021, complete development of the initial version of the plan required by paragraph (1), begin implementation of such plan, and make such plan publicly available; and

"(B) periodically thereafter, update such plan and make the updated plan publicly available.".

(b) TRANSMISSION OF DATA TO CDC.—Section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended by inserting after subsection (c) of such section, as added by subsection (a) of this section, the following:

"(d) TRANSMISSION OF DATA TO CDC.—The Secretary shall formalize and strengthen agreements between the National Suicide Prevention Lifeline program and the Centers for Disease Control and Prevention to transmit any necessary epidemiological data from the program to the Centers for Disease Control and Prevention, including

local call center data, to assist the Centers in suicide prevention efforts.''.

(c) AUTHORIZATION OF APPROPRIATIONS.—Subsection (e) of section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended to read as follows:

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated $113,600,000 for each of fiscal years 2022 through 2024.

''(2) ALLOCATION.—Of the amount authorized to be appropriated by paragraph (1) for each of fiscal years 2022 through 2024, at least 80 percent shall be made available to crisis centers.''.

SEC. 3. PILOT PROGRAM ON INNOVATIVE TECHNOLOGIES.

(a) PILOT PROGRAM.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall carry out a pilot program to research, analyze, and employ various technologies and platforms of communication (including social media platforms, texting platforms, and email platforms) for suicide prevention in addition to the telephone and online

chat service provided by the Suicide Prevention Lifeline.

(2) AUTHORIZATION OF APPROPRIATIONS.—To carry out paragraph (1), there is authorized to be appropriated $5,000,000 for the period of fiscal years 2022 and 2023.

(b) REPORT.—Not later than 2 years after the date on which the pilot program under subsection (a) commences, the Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall submit to Congress a report on the pilot program. With respect to each platform of communication employed pursuant to the pilot program, the report shall include—

(1) a full description of the program;

(2) the number of individuals served by the program;

(3) the average wait time for each individual to receive a response;

(4) the cost of the program, including the cost per individual served; and

(5) any other information the Secretary determines appropriate.

SEC. 4. HHS STUDY AND REPORT.

Not later than 2 years after the Secretary of Health and Human Services begins implementation of the plan required by section 520E–3(c) of the Public Health Service Act, as added by section 2(a)(2) of this Act, the Secretary shall—

(1) complete a study on—

(A) the implementation of such plan, including the progress towards meeting the objectives identified pursuant to paragraph (2)(A)(i) of such section 520E–3(c) by the timeframes identified pursuant to paragraph (2)(A)(ii) of such section 520E–3(c); and

(B) in consultation with the Director of the Centers for Disease Control and Prevention, options to expand data gathering from calls to the Suicide Prevention Lifeline in order to better track aspects of usage such as repeat calls, consistent with applicable Federal and State privacy laws; and

(2) submit a report to Congress on the results of such study, including recommendations on whether additional legislation or appropriations are needed.

SEC. 5. GAO STUDY AND REPORT.

(a) IN GENERAL.—Not later than 2 years after the Secretary of Health and Human Services begins implementation of the plan required by section 520E–3(c) of the Public Health Service Act, as added by section 2(a)(2) of this Act, the Comptroller General of the United States shall—

(1) complete a study on the Suicide Prevention Lifeline; and

(2) submit a report to Congress on the results of such study.

(b) ISSUES TO BE STUDIED.—The study required by subsection (a) shall address—

(1) the feasibility of geolocating callers to direct calls to the nearest crisis center;

(2) operation shortcomings of the Suicide Prevention Lifeline;

(3) geographic coverage of each crisis call center;

(4) the call answer rate of each crisis call center;

(5) the call wait time of each crisis call center;

(6) the hours of operation of each crisis call center;

(7) funding avenues of each crisis call center;

(8) the implementation of the plan under section 520E–3(c) of the Public Health Service Act, as added by section 2(a) of this Act, including the progress towards meeting the objectives identified pursuant to paragraph (2)(A)(i) of such section 520E–3(c) by the timeframes identified pursuant to paragraph (2)(A)(ii) of such section 520E–3(c); and

(9) service to individuals requesting a foreign language speaker, including—

(A) the number of calls or chats the Lifeline receives from individuals speaking a foreign language;

(B) the capacity of the Lifeline to handle these calls or chats; and

(C) the number of crisis centers with the capacity to serve foreign language speakers, in house.

(c) RECOMMENDATIONS.—The report required by subsection (a) shall include recommendations for improving the Suicide Prevention Lifeline, including recommendations for legislative and administrative actions.

SEC. 6. DEFINITION.

In this Act, the term "Suicide Prevention Lifeline" means the suicide prevention hotline maintained pursuant

to section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c).

QUESTIONS AND ANSWERS

RESPONSES BY LES BECKER TO QUESTIONS OF SENATOR BRAUN

SENATOR BRAUN

Question 1. As we look toward future disease outbreaks, even localized ones, how important is it that hospitals be able to quickly trace contacts so we can learn how a disease is spread?

Answer 1. Case investigation and contact tracing (CICT) is the gold standard approach recommended by the Centers for Disease Control and Prevention (CDC) for investigation, mitigation, and containment of cases and outbreaks. CICT is typically conducted by the local public health disease detective staff who initially interview a case, or cases, to gather critical information to further educate the individual and inform broader public health action at workplaces, congregate settings, and the community-at-large.

While the notion is enticing to have CICT closer to patient/provider interactions, three core issues could be detrimental to community health. Those issues are (1) a duplicative workforce, (2) complications with integration of data systems, and (3) coordination and resource connections.

Duplicative workforce: While a hospital may hire staff to perform CICT, it would require a robust and flexible workforce coupled with an epidemiology workforce to ensure proper investigation considerations, data integrity, and reporting. This workforce would only cover potential cases that intersect with that particular hospital system and not necessarily all the provider clinics throughout the state that interact with potential cases. Therefore, one would still need to maintain a similar workforce at the local public health department to ensure statewide coverage. With two workforces providing similar functions, this would lead to larger coordination issues and would complicate the autonomies of local health departments prescribed by state statues in "home rule" states—especially in healthcare systems that span county lines.

Integration of data systems: With an additional workforce would also come the burden on hospitals to work with public health on universal data systems. Hospitals would need to ensure their systems can cater to the ongoing local needs but also mesh with local and state public health systems. This work is already conducted at the state level to ensure continuity between all county health departments. Adding an additional layer of hospitals to the mix will further complicate technology upgrades to these data systems. Additionally, as outbreaks and emerging diseases occur, they require rapid modification and maintenance to existing systems critical to rapid, coordinated response.

Coordination and resource connections: This workforce would need to be continually trained and aware of public health actions and resources available at the local level that is consistent with local public health. There are pre-existing and ever-evolving partnerships maintained at the local health department level to ensure current and future response lessons are learned across all settings. Partnerships and coordination are key to the day-to-day public health work. Care coordination and connection are other aspects conducted by public health. Adding another workforce that would need to maintain similar relationships and knowledge could create scenarios of inconsistent knowledge and messaging between local health departments and hospitals that could confuse a situation.

Current state and moving into the future: There is always room for improvement for better coordination between hospitals and public health. There is tremendous public health value in improving partnerships with healthcare providers. Providers are the trusted messengers and often the first responder to a potential case in an emerging situation. While notifications to public health through electronic lab reporting are instantaneous, the information a patient with potential disease receives while waiting for a test result can impact the trajectory of an outbreak. Providers can let a patient know what to expect from public health and what to do while waiting for a test result. Public health and healthcare also need to continually and rapidly identify communications and tools to be used for patient-provider interactions for emergent situations. This includes some education on the patient's role in protecting their loved ones and their community.

Question 2. At the onset of the COVID–19 pandemic, the Trump administration took swift action to expand health care accessibility across the country to meet Americans' health care needs. Through the temporary expansion of virtual medicine, our country has had the opportunity to innovate as well as collect and analyze data around the value and utilization of virtual medicine.

Qustion 2(a). A survey by the Harris Poll recently found that "87 per cent of Americans receiving telehealth services during the pandemic were satisfied with the services they received". Yet, 82 percent of participants in this study "agreed that telehealth appointments were a great option during the pandemic but doctors' visits are best in person." While increased virtual medicine flexibilities has been one silver lining of the pandemic, there are many factors—such as the real value of health care services via video or phone and the potential for fraud and abuse and duplicative services—that Congress must consider before taking legislative action.

These are some of the immense considerations that Congress is grappling with.

Question 2(i). What are the most salient lessons learned in the virtual medicine space over the pandemic, and how do you recommend Congress respond?

Answer 2(i).

1. Invest heavily in broadband access. U.S. Department of Health and Human Service's recent announcement that Health Resources and Service Administration invested $19 million will support expansion of telehealth nationwide and improve access in rural and other underserved communities;[1] however, Congress must increase investment in broadband across America. Broadband policy is critical to making telemedicine a success. One of the largest equity issues we still face as a Nation is lack of access to services due to lack of access to reliable high-speed internet. Coverage and policy changes do not help if patients cannot use the service due to structural limitations. Consumers of telehealth need high speed and unbiased access, which will allow smaller firm innovation to drive effective competition. Consumers of health care via telemedicine should not be penalized with speed reduction, data caps, or prioritized services based on which company can afford to purchase prioritization of their services.

2. Payment methods and policies must support health care practitioners. Working in a remote environment, the treating practitioner does not have direct access to ancillary health care providers (e.g. nurses, medical assistants or scribe support). This raises general productivity issues for practitioners as they must accomplish all support work for the visit, and in some cases American with Disability Act compliance issues if those staff serve as an accommodation. Some doctors anecdotally shared that productivity was lessened by telehealth in systems that did not have adequate support for the peripheral aspects of medicine.

3. Bring back the home office tax deduction. Many practitioners are operating from home for telemedicine purposes and this additional fiscal incentive could help maintain adoption.

4. Congress and U.S. Department of Health and Human Services must lift CMS restrictions on telemedicine/telehealth treatments, and make sure these coverage standards are identical in Tri-Care and Medicaid where possible. Variation in coverage standards reduces adoption by patients and practitioners and could lead to exploitation by private insurance.

5. The Office of Management and Budget (OMB) may want to more broadly consider how we assess the value and savings of telemedicine in proposed legislation. The savings, while not always direct to the encounter, are quantified for the patient in other ways such as travel, quicker access and potential referral/intervention, the prevention of critical escalation due to the frequency of basic care, reduced potential for transfer injuries, and savings to those supporting the patient.

6. Congress must consider policies to review use of artificial intelligence to reduce the potential for large scale unintended consequences and disparate outcomes. As larger data sets are gathered, due to the increase in telemedicine and expanded use in Electronic Medical Records, the application of artificial intelligence is growing. With this progression we are seeing documented results nationally showing significant unintentional bias against marginalized populations. Federal agencies must be given funding to evaluate and approve use of artificial intelligence tools in health care settings to reduce the potential for large scale unintended consequences and disparate outcomes.

7. Authority for the practitioner, housed in state law or policy, to reject the visit as not appropriate for telemedicine. In Washington State, the Washington Medical Commission has adopted a policy that explicitly stated this discretion for doctors

[1] *https://www.hhs.gov/about/news/2021/08/18/biden-harris-administration-invests-over-19-million-expand-telehealth-nationwide-improve-health-rural.html*.

and physician assistants.[2] To a large degree health system operators also adhered to that standard.

8. Respect and encourage license portability through new and existing compacts between the states. Medical doctors (allopathic and osteopathic) have what is arguably the most successful compact with 35 member states and seven more under consideration in state legislatures. This compact was heavily utilized throughout the pandemic and is considered an essential portability tool.

Question 2(ii). Does the data available support the permanent extension of certain virtual medicine services, or do we need more before we discuss permanency of pandemic virtual medicine flexibilities?

Answer 2(ii).

1. With obvious exceptions, health systems in Washington activated near total telehealth systems for the majority of patients during the early days of the pandemic. The overwhelming results show telemedicine can work for most patients, but it is not perfect. It was clear that practitioners need certain support. Those specific supports are discussed above.

2. Harris polling data. Based on health care provider complaints we have received thus far in the pandemic, some patients are simply not comfortable with telemedicine visits and will never opt for them. This is acceptable and should be allowable going forward. With that in mind, it is possible the Harris poll cited is accurate in both statistics. Polling answers are likely not mutually exclusive depending on the question asked and demographic polled. Similarly, our demographic data indicates there will be a subset of practitioners, independent of specialty area or age, that simply will not participate in telemedicine as a modality unless forced. This avoidance should also be allowable going forward.

3. Notably, we did not see increased allegations of fraud regarding telemedicine since the onset of the pandemic.

4. Reduced costs through telemedicine are frequently only experienced by the patient's side of the equation but not the practitioner or the system. Patients, and to some degree the system, benefit from earlier intervention at a basic level which reduces costs. Chronic disease management and monitoring is a classic example of this. On the practitioner side however, the savings are not significant enough to warrant a deviation from payment parity. Direct to Consumer telemedicine companies may benefit from reduced overhead, but they offer limited services to patients and are more beneficial to contract with larger systems to offer those limited services as an extension. The practitioner did not go to 75 percent of their medical school, the system is not paying for 75 percent of practitioner service, and the brick and mortar system and IT infrastructure did not cost 75 percent less to build.

Where is the reduced overhead? By paying practitioners less, there is less incentive to try a new modality and that will prevent appropriate telemedicine expansion.

5. Overall, the permanent extension of certain pandemic flexibilities is likely warranted. Many groups such as Center for Telehealth and e-Health Law (CTeL) and regional health systems have gathered data showing increased adoption by patients and practitioners. What that data supports comes down to how OMB scores the bills that establish the changes. As discussed previously, it is not always about direct savings, but downstream savings as well, which are sometimes not considered or more difficult to quantify. A reasonable approach may be to have Centers for Medicare and Medicaid Services (CMS) expand their trial and assessment of extension of virtual medicine services so relevant data may be gathered where little currently exists in those use cases where it is needed.

6. Care should be taken to harmonize making pandemic flexibilities permanent. There needs to be suitable messaging and clear understanding of what is possible by CMS or others. For example, when CMS lifted geographic restrictions on treatment of beneficiaries via telemedicine. There was significant confusion that this change only applied to reimbursement as opposed to legality of practice, which is retained by the states.

7. The most difficult part of this conversation is appropriate treatment vs. appropriate modality. This usually comes down to audio only and asynchronous or message interaction. However, certain modalities simply are not conducive to effective assessment, diagnosis, and treatment for specific conditions and use by certain professions. Again, CMS determination of effectiveness and coverage could assist in

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[2] *https://wmc.wa.gov/sites/default/files/public/documents/TelemedicineAndContinuityOfCarePOL2018-01.pdf.*

clarifying the landscape on a Federal level and many others would likely follow suit. Mandating reflective standards in Tri-Care and others could further that goal.

RESPONSES BY PHYLLIS ARTHUR TO QUESTIONS OF SENATOR BRAUN

SENATOR BRAUN

Under the direction of the Trump Administration, HHS established Operation Warp Speed, a public-private partnership that accelerated vaccine, therapeutic, and testing development, all while maintaining proper safety and efficiency standards. As devastating as the COVID pandemic has been, a positive outcome has certainly been greater efficiency in medical countermeasure innovation.

Question 1. In your testimony, you discussed the importance of public-private partnerships in facilitating efficient medical countermeasure research and development—what are the most important lessons that BIO has extracted from the pandemic in the therapeutics space?

Answer 1. Senator Braun, thank you for the thoughtful question. I want to agree with your assessment that Operation Warp Speed (OWS) was highly successful in its goal of partnering with industry to rapidly develop and distribute medical countermeasures during the pandemic. Much of that success is due to companies in the countermeasure space, large and small, stepping up and dedicating resources to combating the pandemic. It is also a credit to the design of OWS which combined the industry leadership and expertise in Dr. Slaoui's role along side General Perna and HHS's know-how and capabilities. OWS was effective at quickly identifying potential successful countermeasures, contracting with the companies, accelerating their trials, and scaling up production of the final product.

From the perspective of industry, the initial pathways for products were clear. OWS had the needed resources to "take multiple shots on goal" and support many different products and types of products in both the vaccine and therapeutics space. With OWS the NIH established the Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) program, which coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. The Administration through OWS identified there were numerous products in development, all competing for patients to participate in clinical studies. ACTIV worked to coordinate and streamline processes to make the best use of biomedical research resources and testing of preclinical and clinical compounds. It also worked to prioritize the most promising candidates and move them into clinical trials in a way that was safe and efficient. This system was successful in streamlining the development process, and the well-funded OWS was able to contract with companies and purchase products as they were finishing development.

Ultimately, OWS became a supercharged version of what many had envisioned the ASPR role to be. It was a clear leader in planning the response that drove product development and procured products from their private sector partners. OWS showed that given the resources and authority, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and industry can rally to respond to any health security threat.

As OWS went along, eventually a decision was made to focus on vaccines. Therapeutic funding and opportunities began to disappear, and that culminated in the COVID therapeutic BAA being pulled from BARDA. BIO has expressed its disappointment in that decision, and with a sizable portion of the population still unvaccinated and variants on the rise, the need for therapeutics is more important than ever. Additionally, we are now able to look at COVID with a more long-term view and see the need for a second generation of COVID products, but as of now there are limited pathways for the companies working in this space to partner with the Government. I would urge Congress to continue to invest in COVID therapeutics. Those investments will pay dividends not only by saving lives from COVID but may also better prepare us for the next pandemic.

RESPONSE BY ANITA CICERO TO QUESTIONS OF SENATOR ROSEN

SENATOR ROSEN

As we have seen, this pandemic has had a significant impact on most aspects of our medical and public health systems. As we work to strengthen our critical safety-nets and better prepare for the future, we must not overlook the importance of safeguarding our Nation's blood supply. There have been shortages throughout the

country. Just last month, an urgent call for donations went out to residents in the Las Vegas area to help with blood donation shortages so cancer patients could receive the treatment they needed.

Question 1. It's not just the volume of blood donations, but also the supplies needed and the staff who are essential both for collecting the blood donations but also managing the supply at our blood banks. Ms. Cicero what are your recommendations for how to include consideration of safeguarding our blood supply as we look at improving other critical public health infrastructure and our medical domestic supply chain? Dr. Janz, please comment if you have anything to add as well.

Answer 1. Thank you for that question, Senator Rosen. We are experiencing a blood and platelet shortage in the United States. I agree that our country needs to be able to sustain the infrastructure necessary to maintain a sufficient supply of blood donations and other essential medical services even during pandemics and other public health emergencies. It is important to understand that hospital preparedness and pandemic preparedness extend well beyond the hospital walls, into communities with other vital healthcare related facilities and services, such as blood banks. In order to minimize the disruption of services during shocks to the healthcare system, blood banks need to ensure that they have appropriate emergency staffing plans in place. Employees of blood banks, including nurses and phlebotomists, must be appropriately supported and supplied with personal protective equipment, training, and infection control practices that ensure their safety and their willingness to continue working even during times of a surge in cases. Blood banks should also join and play an active part in regional healthcare coalitions. Healthcare coalitions facilitate information sharing among participating organizations, promote situational awareness, provide a way to share resources among members, and serve as a link with regional authorities. During 'peace times', healthcare coalitions also support pandemic exercises and drills, so that members such as blood banks can pressure test their procedures and pandemic plans, including plans for successfully handling the complex logistics of managing the blood supply during infectious disease outbreaks. As we continue to digest lessons learned during the COVID–19 pandemic, it will be important to assess the role and performance of healthcare coalitions in the response. If the assessment determines that healthcare coalitions did not play a beneficial or proactive role during the COVID response, measures should be taken to address any limitations or challenges that inhibit their performance. Apart from healthcare coalitions, public health authorities should take into account the critical role that regional blood banks play and ensure that public health strategies and communications (including those related to 'stay at home' recommendations) do not inadvertently discourage donations or the provision of other daily health needs.

RESPONSES BY DAVID JANZ TO QUESTIONS OF SENATOR ROSEN, AND SENATOR BRAUN

SENATOR ROSEN

Throughout the pandemic, we have seen the important role mobile clinics have played in delivering lifesaving health care and COVID–19 vaccines to our most vulnerable patients, particularly those in rural communities. I was incredibly grateful to FEMA for sending two mobile trailers on vaccination routes across rural Nevada, where volunteer nurses and doctors were successfully able to deliver over 7,600 COVID–19 shots into arms. Allowing providers the flexibility to meet patients where they are is especially vital in our rural communities. That's why I've introduced bipartisan legislation with Senator Collins to expand access to mobile health clinics and ensure that our small and rural communities are not left behind.

Question 1. Dr. Janz, how can we use lessons learned from the COVID–19 pandemic and utilize mobile clinics on a more permanent basis going forward, to ensure patients receive regular, routine care, rather than on an emergency basis?"

Answer 1. I thank Senator Rosen for this important question and I agree that increased access to preventative healthcare is vital to improve the health of the Nation. I believe each community will have unique needs and challenges and recommend engaging community leaders to learn what these may be and which type of healthcare outreach will address these issues.

Question 2. As we have seen, this pandemic has had a significant impact on most aspects of our medical and public health systems. As we work to strengthen our critical safety-nets and better prepare for the future, we must not overlook the importance of safeguarding our Nation's blood supply. There have been shortages throughout the country. Just last month, an urgent call for donations went out to

residents in the Las Vegas area to help with blood donation shortages so cancer patients could receive the treatment they needed.

It's not just the volume of blood donations, but also the supplies needed and the staff who are essential both for collecting the blood donations but also managing the supply at our blood banks. Ms. Cicero what are your recommendations for how to include consideration of safeguarding our blood supply as we look at improving other critical public health infrastructure and our medical domestic supply chain? Dr. Janz, please comment if you have anything to add as well.

Answer 2. I thank Senator Rosen for this excellent question on a vital and limited resource. I think it is important for the Nation to take an accounting of all the potentially lifesaving but limited resources in healthcare and learn how we can bolster these resources as a response to current and future crises. The blood supply is certainly one of these resources. However, as discussed in my original testimony, the shortage of healthcare providers, including nurses, respiratory therapists, and physicians looms as a larger threat to our preparedness. An ample blood supply without a nurse to infuse the blood in a timely manner would not benefit our patients.

SENATOR BRAUN

Question 1. COVID increased attention on the safety for patients and staff in hospitals while also intensifying demands on health leaders to act more efficiently and decisively. Can technology—including faster and more accurate data collection—be the bridge between these two priorities?

Answer 1. I would like to thank Senator Braun for this important question. The backbone of a Learning Healthcare System, discussed in my original testimony, includes collecting data and disseminating these data in real-time. These data can be important to a variety of stakeholders: patients, healthcare providers, healthcare systems, and leadership in these systems. Historically, data would be collected, analyzed, and disseminated over the course of years, which resulted in very slow advances in healthcare delivery. A Learning Healthcare System aims to integrate clinical research infrastructure with the infrastructure of the hospital system to collect high-quality data and not only disseminate these data in real-time, but also have the backing of hospital leadership to make changes in patient care and hospital function. This can occur on the scale of weeks rather than years. Hospital leadership should look toward this model of integration of clinical research infrastructure into the daily function of the hospital to improve every aspect of healthcare delivery.

[Whereupon, at 12 p.m., the hearing was adjourned.]

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