

**COVID-19: LESSONS LEARNED TO
PREPARE FOR THE NEXT PANDEMIC**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING COVID-19, FOCUSING ON LESSONS LEARNED TO PREPARE
FOR THE NEXT PANDEMIC

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JUNE 23, 2020
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Tuesday, June 23, 2020

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

The Committee met, pursuant to notice, at 10:03 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Burr, Collins, Cassidy, Roberts, Murkowski, Romney, Braun, Murray, Baldwin, Murphy, Warren, Kain, Hassan, Smith, Jones, and Rosen.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The Committee on Health, Education, Labor, and Pensions will please come to order. First, the usual administrative matters. This is a little like the theater announcements that we used to receive. We are getting used to those. We follow the advice of the attending physician and the Sergeant-at-Arms who have consulted with all the right people. We are seated at least six feet apart. That means there is no room for the public or the media here, but the media is participating, we hope, and we hope the public is as well. www.help.senate.gov is our website.

Our witnesses are participating by video conference, which is a real change for the U.S. Senate and in some ways a very welcomed one because I think it makes it possible for us to be able to attract witnesses who have very busy schedules on the same day such as today. Some Senators are participating by video conference.

Senators may remove their masks since we are 6 feet apart. I am grateful to the Rules Committee, the Sergeant-at-Arms, the Press Gallery, the Architect of the Capitol, the Capitol Police, our Committee staffs, and Chung Shek and Evan Griffis for all their hard work to help keep us safe. Senator Murray and I will each have an opening statement and then we'll turn to our witnesses who we thank very much for being with us today.

Each witness, we would ask that you summarize your remarks in five minutes, which will allow more time for the large number of Senators who we expect to participate to present their testimony. We will have one round of questions for a five minute round.

Less than four months ago, on March 1, the coronavirus situation was about this. At the end of February, there were 79,000 cases around the world. Only 14 in the United States, except for 39 who had been brought home from overseas with the virus. By March

the 2nd, there were two deaths in the United States. By March the 3rd, when we had a hearing, there were six deaths. And on March the 1st, on Sunday in the New York Times on the front page it said this, that most experts were far from certain that this virus would carry to all parts of the United States, and that with its top-notch scientists, “modern hospitals and sprawling public health infrastructure, most experts agree the United States is among the countries best prepared to prevent or manage such an epidemic.”

Well, even six weeks after the first virus was found in the United States, even the experts underestimated the ease of transmission and the ability of this coronavirus to spread without symptoms. These qualities made the virus, in the words of Dr. Fauci, “my worst nightmare.” In the period of four months, he said, it has devastated the world. This Committee is holding this hearing today because even with an event as significant as COVID-19, memories fade and attention moves quickly to the next crisis. While the Nation is in the midst of responding to COVID-19, the U.S. Congress should take stock now of what parts of the local, state, and Federal response to this crisis worked, what could work better and how, and be prepared to pass legislation this year to be better prepared for the next pandemic which will surely come.

On June 9, I released a white paper outlining five recommendations for Congress to prepare Americans for the next pandemic. They were these. No. 1, tests, treatments and vaccines. Accelerate research and development. No. 2, disease surveillance. Expand our ability to detect, identify, model, and track emerging infectious diseases.

No. 3, stock piles, distributions, and surges. Rebuild and maintain Federal and state stockpiles, and improve medical supply surge capacity and distribution. No. 4, public health capabilities. Improve state and local public health capabilities. And finally, who is on the flagpole, who is in charge. Improve coordination of Federal agencies during a public health emergency. I have invited comments and responses in any additional recommendations for the Senate Committee on Health, Education, Labor, and Pensions to consider. I will share this feedback with my colleagues, both on the Democratic and the Republican side.

This is not a new subject for any of the witnesses that we have today. 15 years ago the then Majority Leader of the U.S. Senate Bill Frist said in a speech at the National Press Club that a viral pandemic is no longer a question of, if but a question of when. He recommended what he calls a six-point public health prescription to minimize the blow, communications, surveillance, antivirals, vaccines, research, stockpile surge capacity. Senator Frist is one of our witnesses today and I am including in the record two of his speeches.

Our next witness, Dr. Joneigh Khaldun serves as Chief Medical Executive and Chief Deputy Director for the Michigan Department of Health and Human Services, where she has worked to coordinate the state’s response to COVID-19. Our third witness is Dr. Julie Gerberding, who served as Director of The Centers for Disease Control and Prevention under President George W. Bush. She helped lead preparedness efforts on the response to SARS, West

Nile Virus, H5N1 Avian Influenza, and the rise of multi-drug resistant bacteria like MRSA.

Another witness is Governor Michael Leavitt. He was Governor of Utah. He was Secretary of Health and Human Services and an Administrator of the EPA under George W. Bush. Following the emergence of H5N1 Avian Flu, Governor Leavitt increasingly focused his efforts on pandemic preparedness. As Secretary in 2007 he said this 13 years ago, everything we do before a pandemic will seem alarmist, everything we do after a pandemic will seem inadequate. That is the dilemma we face, but it should not stop us from doing what we can do to prepare. Congress has passed legislation to prepare for pandemics before.

During the last 20 years, four Presidents, Clinton, Bush, Obama, Trump, and several Congresses have enacted nine significant laws to help local, state, and Federal Governments, as well as hospitals and health care providers, to prepare for a public health emergency including a pandemic. Congress provided over \$18 billion to States and Hospital Preparedness Systems over the last 15 years to help them prepare as well.

In writing those laws, Congress considered many reports from Presidential commissions, offices of Inspectors General, the Government Accountability Office, and outside experts. The reports contained all sorts of warnings that the United States needed to address the following familiar issues, familiar by now, better methods to quickly develop tests, treatments, and vaccines, and scale-up manufacturing capacity, better systems to quickly identify emerging infectious diseases, more training for the health care and public health workforces, better distribution of medical supplies, better systems to share information within and among states and between states and the Federal Government. Many reports also warned that while states play the lead role in a public health response, many states didn't have enough trained doctors, nurses, and healthcare professionals, had inadequate stock piles, and struggled with funding challenges.

In some instances, over-reliance on inflexible Federal funding contributed to these problems. Looking at lessons learned from the COVID crisis thus far, many of the challenges that Congress has worked to address during the last 20 years still remain. Additionally, COVID-19 has exposed some gaps that had not been previously identified. These include unanticipated shortages of testing supplies and sedative drugs which are necessary to use ventilators for COVID-19 patients.

Memories fade, attention moves quickly to the next crisis. Four months ago, five months ago we were in the midst of the impeachment of a President. Today, that seems like ancient Roman history. That makes it imperative that Congress act on needed changes this year in order to better prepare for the next pandemic. I look forward to hearing from our witnesses and I would also appreciate the feedback we are receiving on the white paper. I will set a deadline for June 26 on that feedback so the Committee has time to consider it and to draft and pass legislation this year.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman, and I also want to thank all of our witnesses for joining us today. And of course thank our staff for wrangling the technology to make this hearing possible. I said before, we need to understand fully and exactly everything that has gone wrong in our response to COVID-19. Why and how we work to make sure we are never in this situation again. But I want to be absolutely clear from the start, reflecting on how we prepare for the next crisis is no substitute for responding to the crisis at hand, which has infected over 2 million people in our country, killed over a 120,000, and which continues to spread.

Unfortunately, the White House is pretending this pandemic is over. President Trump has said it is fading even as several states see record case increases. Vice president Pence wrote an op-ed saying we are winning the fight and there isn't a second wave while experts like Dr. Fauci warn we aren't even through the first wave yet. Admiral Giroir has stepped down from his role leading testing efforts without being replaced, and President Trump is calling for less testing, even though we don't have anything close to the testing and tracing capacity we need to safely reopen our communities. It is not just officials in the White House who are sticking their heads in the sand.

Leader McConnell and some Republicans have suggested there is less urgency to take further action since we gained some 2.5 million jobs after losing more than 20 million jobs. You know, as a former preschool teacher, I can tell you even some of our younger students know that map doesn't add up. So I hope we don't just spend our time today talking about how to avoid mistakes in the next pandemic, but instead address the mistakes this administration is still making during this one and the ones they are at risk of repeating as the response to COVID-19 continues. One lesson we have already learned, this crisis is no great equalizer, but rather a force which perpetuates and deepens the injustices that black communities, latino communities, tribal communities, people with disabilities, and so many others face.

We have known for decades that our healthcare system treats some communities much worse than others, especially communities of color. Those disparities are caused by a long history of systemic racism and underfunding, and those in charge have a responsibility to acknowledge the problem and do everything they can to close that gap. This administration has not taken that responsibility seriously. At best, they turned a blind eye to the problem. At worst, they seem determined to make it worse as we have seen in the administration's irresponsible rule to allow discrimination in health care.

We have also seen once again how desperately we need a national universal paid sick leave policy so workers can stay home and do what is best for their health and for public health without fear of losing their job or their paycheck. And we have learned how important it is the Department of Labor's Occupational, Safety and Health Administration is. They need to stop dragging their feet and finally make clear safety isn't optional by immediately issuing an

emergency temporary standard. There are also several lessons We need to apply regarding vaccines.

We cannot allow the Trump administration to bungle this like they have so much else. This pandemic will not end until we have a vaccine that is safe, effective, that we can widely produce and equitably distribute and that is free and accessible to everyone. So when it comes to developing a vaccine, we don't just need a fast process, we need a thorough, transparent, and science driven one. We need to know the process is free of political interest influence, especially after the hydroxychloroquine debacle. And the final COVID-19 vaccine or vaccines truly meet the gold standard families have relied on for so long, which is why the administration needs to commit now to being fully transparent about the vaccine development and review process and about the data that is ultimately used to evaluate safety and effectiveness.

We also need the administration to detail how it will produce and distribute vaccines everywhere to everyone. Even the incomplete data we currently have shown black, latino and tribal communities are disproportionately impacted by COVID-19 and have significantly less access to testing than white communities. This is an injustice that we cannot repeat when it comes to vaccines nor can we afford to repeat delays like those the Trump administration caused by refusing to take responsibility for resolving coordination problems in the national supply chain.

Instead, the Trump administration must work now to draft and release a comprehensive COVID-19 vaccine plan, the type of comprehensive plan we still haven't gotten on testing. One that addresses all of these questions and other barriers, like how do we fight misinformation and vaccine hesitancy? How do we strengthen our immunization infrastructure to ensure it is ready to meet this unprecedented challenge? How do we build global partnerships in this effort, instead of turning our back on the rest of the world, which not only betrays our American values but also puts people here at home directly in harm's way.

Mr. Chairman, these are not questions we need to answer before the next pandemic starts, they are questions we have to answer before the current pandemic can end. I look forward to hearing our witnesses perspectives on all of these urgent issues today, and Mr. Chairman I hope in the future, very near future, this Committee will also be able to get the perspectives of several important members of this administration we have not heard from yet, Secretary Azar, Secretary Scalia, and Secretary DeVos.

It is clear we have a lot more work to do to respond to this pandemic and I urge our Republican colleagues to come back to the table so we can work on this together because the challenges our Nation is grappling with right now, the public health crisis of COVID-19, the economic crisis this pandemic has set in motion, and of course the persistent systemic inequities driven by racism that this crisis has only exasperated are urgent. Our Nation cannot keep waiting. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray. Each witness will—I would ask you to summarize your statement in five minutes so we will have more time for questions. I welcome our witnesses. It is a distinguished panel. We look forward to hearing from each of

you. It is my privilege to introduce the first one. Senator Bill Frist, with whom I served and many of us served. He represented Tennessee for two terms in the Senate. He was the Majority Leader of the U.S. Senate. He served on this Committee in the U.S. Senate. He is a heart and lung transplant surgeon by training. First practicing physician to serve in the Senate since 1928.

He now serves on several boards including the Robert Wood Johnson Foundation. He is senior fellow at the bipartisan policy center and chairman and founder of Health Nashville. In 2005, and I am sure he will talk about this, he gave many speeches on the inevitability of a global pandemic and the importance of preparedness. I have submitted two of those speeches to the record during this Committee's May 7th hearing.

Next, after Dr. Frist, we will hear from Dr. Joneigh Khaldun. Dr. Khaldun serves as the Chief Executive and Chief Deputy Director for Health of the Michigan Department of Health and Human Services. In this position she oversees the Population Health Medical Services, Aging and Adult Services, and Behavioral Health and Developmental Disabilities Administration for the State of Michigan. Dr. Khaldun has extensive experience in state and local Governments. Prior to her current role, she served as Director and Health Officer for the Detroit Health Department. She is a practicing emergency medicine physician.

Our third witness is Dr. Julie Gerberding. She is Executive Vice President and Chief Patient Officer at Merck & Company, and serves as a Co-Chair of the Commission on Strengthening American Health Security at the Center for Strategic and International Studies. Dr. Gerberding served as the Director of the Centers for Disease Control, the CDC, from 2002 to 2009.

Under her leadership CDC coordinated preparedness efforts and responses to several public health threats including SARS, West Nile Virus and Avian Flu. She played a key role in the CDC response to Anthrax attacks in 2001. Senator Romney will introduce our final witness, Governor Mike Leavitt.

Senator ROMNEY. Thank you. Mr. Chairman. I am happy to introduce my friend Mike Leavitt. Mike is actually the one who is most responsible for freeing me from the golden chains of the private sector. He got me to leave my position at Bain Capital and to come out help run the Olympic Winter Games of 2002 in Salt Lake City. As such, he was my boss. He was the Governor of the State of Utah at the time and we became since then dear friends. He also was kind enough when I was running for President to lead my transition team.

I am not sure I would have been a great president, but I would have had a great administration because he put together an extraordinary team and laid out a pathway to help our Country in numerous ways. Mike Leavitt, as you also have indicated, was a three-term Governor of Utah in the Bush administration. He served as Administrator of the EPA and then for several years as a Secretary of Health and Human Services.

One of his priorities was to focus on pandemic preparation. He secured some \$7 billion in funding with the Administration—through the Administration and Congress to prepare for pandemics. Since leaving Government, he has founded a firm called

Leavitt Partners. It is the premier healthcare consulting firm in the country, with hundreds of employees under his management as well as a private equity firm that he has built. It set an extraordinary record and he continues to contribute to our Country, my friend Mike Leavitt.

The CHAIRMAN. Thank you, Senator Romney. Now we will begin with Senator Frist. Welcome, Senator Frist, back to your old Committee.

**STATEMENT OF WILLIAM FRIST, M.D., FORMER U.S. SENATE
MAJORITY LEADER, NASHVILLE, TN**

Dr. FRIST. Good morning, Chairman Alexander and the Ranking Member Murray, Members of the Committee. And it is great to be back to the halls in the Senate even if only remotely and to see so many old friends and colleagues. I do want to commend the Committee for placing a focus now on preparing for the inevitable biological and infectious diseases that absolutely will come in the future. As you mentioned, in December 8th of 2005 at the National Press Club, I said in the very same speech I gave, in this body 15 years ago and repeatedly all across the country, I said a viral pandemic is no longer a question of if but a question of when.

I even said it would come from China at the time. Grounded deeply in my own experiences as a physician in the Senate, being in China with a Senate delegation during the SARS pandemic in 2003, personally treating HIV, AIDS patients, responding to the Anthrax attacks, it was crystal clear then we were woefully unprepared for what was to inevitably come. In those talks, I proposed a specific six-point plan called a Manhattan Project of the 21st century to prepare the Nation. And during my time in the Senate, we laid the foundation with the Bioterrorism Act of 2002, Project Bio-shield 2004, the PREP Act 2005, the Pandemic and All-Hazards Preparedness Act of 2006, and subsequently, as you have outlined in your white paper, we have done more but this was not enough nor will it be enough.

A little bit disappointingly, most of what I recommended in 2005 remains undone. So for my recommendations, I use the exact same six categories I used then. No. 1, communication. We have got to clarify who is in charge in an emerging pandemic. Only then will we be consistent and be coordinated. The Federal response must be led at the National Security Council level to facilitate this whole of Government approach. CDC, the trained and experienced experts, should regain its position as the Nation's apolitical voice of public health.

No. 2, surveillance. We must modernize our real-time domestic and international surveillance and threat detection system. This pandemic has laid bare our inability at the Federal level to track outbreaks with testing and reporting across the country. We must engage globally, diplomatically and economically.

An outbreak anywhere in the world is a risk everywhere. It is a risk to every community in America. The ability of developing nations to detect, track and contain a novel virus will be inextricably tied to their capacity of their public health infrastructure, which is vitally dependent on U.S. support. Categories three and four were agents and vaccines, and as in 2005, we have a dangerously inad-

equate vaccine manufacturing base here within the United States. We must establish public, private partnerships with industry that are and can be sustained. For our supply chains including testing and vaccine development, the Federal Government must be re-engineered to serve as a sort of control tower function.

No. 5, I said then and now research and development. In my words in 2005, I called for massive R&D investment to create a biologically based Manhattan Project to help better defend us against naturally occurring, like we are seeing now, or accidental or intentional bioterror threats, including infectious disease. Categories of stockpiling and surge capacity were No. 6. The Federal Government should take the lead role serving as overlaying central repository paired with a well-structured surveillance system that would accurately track outbreaks to ensure that supplies are responsibly and appropriately distributed where the risk is greatest.

In telemedicine, with which this Committee has dealt, I echo Chairman Alexander's recommendations that we, "ensure the United States does not lose the gains made in telehealth." We must make permanent the majority of regulatory changes, with some modifications, in order to unleash this revolutionary power of virtual care delivery in America. I want to quickly touch on two other important areas, public health funding and vulnerable populations.

For the funding, observing closely for the past 25 years, I conclude like our armed services defense, we must have predictable, consistent base funding for our public health security programs. Yes, health security is National Security so let's treat it as such. That is why I joined. Dr. Tom Friedman and others to advocate for the creation of a specific new health defense operations budget designation. This discretionary approach, with exempt from spending caps, a small number of critical pre-existing health security funding lines.

Lastly, this whole concept of vulnerable populations of health equity, any pandemic preparedness response needs to comprehensively consider how to protect and care for the most valuable here at home and globally. And real quickly, I encourage the Committee to underscore this vital connection between the health of the world's most vulnerable and the security of Americans here at home, especially as you soon consider global access to immunization. Members of the Committee, thank you for having me here today. The work you are doing now will literally save lives in the future.

[The prepared statement of Dr. Frist follows:]

PREPARED STATEMENT OF BILL FRIST

Good morning Chairman Alexander, Ranking Member Murray, and Members of the Senate Health, Education, Labor, and Pensions Committee. Thank you for inviting me to testify at today's hearing, "COVID-19: Lessons Learned to Prepare for the Next Pandemic." It is great to be back in the halls of the U.S. Senate—even if only remotely—and to see so many old friends and colleagues.

I want to commend Chairman Alexander and Ranking Member Murray for placing a focus *now* on preparing for the biological and infectious diseases threats of the future. For too long, we have lurched from one public health crisis to another—retroactively appropriating emergency funds and so avoiding a large-scale pandemic through a great deal of American ingenuity and, sometimes, an even greater dose of good luck. But with COVID-19, our luck has run out.

In 2005, in a series of speeches I predicted a global pandemic arising from China and proposed a six-part plan to prepare the Nation focused on: 1. Communication; 2. Surveillance; 3. Antiviral Agents; 4. Vaccines; 5. Research and Development; and 6. Stockpiling and Surge Capacity.

On June 5, 2005 at Harvard University, I called for and outlined a greater than “Manhattan Project” for the 21st Century with “no less than the creation, with war-like concentration, of the ability to detect, identify and model any emerging or newly emerging infection, natural or otherwise; for the ability to engineer the immunization and cure, and to manufacture, distribute and administer whatever may be required to get it done and to get it done in time. For some years to come, this should be the chief work of the Nation, for the good reason that failing to make it so would be to risk the life of the Nation.”

On December 8, 2005 at the National Press Club, I said, “A viral pandemic is no longer a question of if, but a question of when. We know—depending upon the virulence of the strain that strikes and our capacity to respond—that the ensuing death toll could be devastating.”

My reasoning then for recommending a bold, comprehensive preparedness plan was first and foremost, to protect human life. But my second, as captured in my December speech’s title: “Pandemic: The Economy’s Silent Killer,” was to preserve economic stability when a pandemic inevitably came. I had the Congressional Budget Office study the impact of a severe pandemic on our economy, and they estimated a 5 percent reduction in GDP. Tracking almost exactly, the International Monetary Fund’s World Economic Outlook released in April estimated a 5.9 percent decline in U.S. GDP for 2020—over a trillion dollars in losses.

I share this not because my remarks were prescient of what was to come 15 years later, but as Majority Leader of the Senate, I failed to sufficiently make the case, and truly comprehensive pandemic preparedness legislation never passed. I had seen SARS firsthand on the ground (with a Senate delegation) in China in 2003, personally treated patients suffering the ravages of HIV/AIDS in Sub-Saharan Africa and here at home in my medical practice, lived through and helped navigate our response to the 2001 Anthrax attack on the U.S. Senate and our postal workers, and at the time of this 2005 proposal, shared global concerns about the deadly H5N1 avian influenza. But now that we all are living through what once was a predicted threat, my hope is the smart work of this Committee and others, combined with the will of the people, will make these needed changes a reality. I can assure you that new, more deadly viruses will raise their heads in the future. It’s biology. They know no borders. And they kill.

But we are not starting from scratch. As Senator Alexander’s recent White Paper, “Preparing for the Next Pandemic,” clearly outlines, Congress has not wholly ignored this threat. Indeed, during my time in the Senate and as Senate Majority Leader, we enacted:

- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act,” PL 107–188)
- The Project BioShield Act of 2004 (PL 108–276)
- The Public Readiness and Emergency Preparedness Act of 2005 (“PREP Act,” PL 109–148)
- The Pandemic and All-Hazards Preparedness Act of 2006 (PL 109–417)

But these and all the well-intended legislation that followed failed to protect us. While 9/11 and the Anthrax attacks were a wakeup call, and while our Nation’s leaders did respond and put in place funding and new important public health authorities, we didn’t fully prepare for a pandemic—a simultaneous nationwide, indeed a worldwide, assault on every one of our citizens, our underfunded public health infrastructure, and our economy. We took some important steps and in many ways, the basic foundations from which we need to respond to a pandemic are in place. Now, we need to establish a clear chain of command coupled with a more systematized, coordinated response structure and power it with robust, sustained financial resources to enable our public health leaders to keep Americans safe.

Most of what I recommended in 2005 in those speeches delivered around the country and in this body remains undone today, thus I outline my recommendations along the exact same six categories.

1. Communication

As I said then, “Number one is communicating with the public.” To allay irrational fear, communication—of accurate, reliable, consistent information—must be the bedrock of every public policy response.

From the outset of the COVID-19 crisis and continuing today, we have had mixed and contradictory messages on the severity of the outbreak, the differing roles of Federal, state and local government, the availability of tests, potential treatments, the appropriateness of masks, and timelines and approaches for reopening. This has unquestionably led to unnecessary viral spread, duplication of efforts, gaps in response, and loss of life. It’s fixable.

First, we must clarify who is in charge in a pandemic. The current response structure is broken. The Federal response should be led at the National Security Council level to facilitate a “whole of government approach”, re-establishing the NSC’S Directorate for Global Health Security and Biodefense. The NSC should set out guidelines and ensure seamless coordination between and among departments, with regular and consistent pressure testing.

Second, the CDC should regain its position as the Nation’s apolitical voice of public health. The CDC has 20,000 health professionals who dedicate their lives to protecting Americans. The National Center for Immunization and Respiratory Disease has more than 700 FTE staff who are experts in this area. They have spent decades working on the public health control of respiratory viruses. This Administration has sidelined the entire agency from their role in briefing the public, which has had a chilling effect on the information that could leave the agency and reach the public. CDC guidance has had to go through dozens of levels of review which in many cases took weeks instead of days. This led to confusion and uninformed improvisation at the state and local levels without strong Federal leadership.

Third, we must make sure what is said at the Federal level coordinates and integrates well with the more regional needs, abilities and resources of state and local municipalities. This can be accomplished in part by strengthening the relationship between CDC and the Association of State and Territorial Health Officials (ASTHO). In times of infectious disease outbreak or pandemic, predetermined, clearly delineated emergency channels of communication, authority and action should immediately be implemented.

2. Surveillance

Every moment counts. The sooner we detect, identify, and contain a viral threat, the better the health and economic prognosis will be. This pandemic has laid bare our inability, at the Federal level, to detect and track outbreaks across the country, and provide real-time, consistently formatted data to states and localities that can help them understand the threat, and in turn inform Federal and regional allocation of supplies and personnel. Compared to 2005, the tracking tools are much more sophisticated. But, just like then, we have waited until *after* an outbreak to develop and deploy much of this technology. Valuable time is lost as the virus aggressively continues to exponentially infect the world. Here we must think global to protect the safety and security of our families in our neighborhoods.

That’s why we need a real-time domestic and international threat detection system. Some experts have recommended a new epidemic forecasting center similar to the National Hurricane Center, which would function as a government-academic partnership to help guide decisions from National Strategic Stockpile needs and disbursements, to informing travel restriction decisions as novel viruses emerge, to providing states and localities real-time information to guide their public safety decisions in an outbreak.

While not necessarily intuitive, a huge part of effective infectious disease surveillance is maintaining Federal support of global health. The next zoonotic disease transmitted from animals to humans will likely come out of Asia or Africa. The ability of developing nations to detect, track and contain a novel virus will be inextricably tied to the capacity of their own public health infrastructure, something that is vitally dependent on U.S. support. And their willingness to mutually share that critical infectious disease surveillance information and allow our scientists to reliably participate in its interpretation will depend on the integrity and trust of our diplomatic relationships.

Our national health, when it comes to recurrent deadly viruses and pandemics, depends on global health.

We typically commit about 1 percent of Federal resources to international assistance, but in our COVID-19 emergency packages, only one-tenth of 1 percent of

funds have gone to help low-and middle-income countries in their COVID fight. We must recognize containing COVID globally is essential to halting its spread in the U.S., particularly as we begin to reopen our country for travel and business. (Indeed, New Zealand had just announced the eradication of COVID-19 when two infected U.K. travelers potentially reintroduced the virus, coming in contact with as many as 320 people.) To ensure a comprehensive Federal approach to global health security, Congress's fractured global health jurisdiction (which spans at least 10 different committee and subcommittee structures across both chambers) should be rectified by the establishment of separate bipartisan special committees or formal working groups that provide a coordinating, overarching vision for the regular committees of jurisdiction.

The White House Office of Management and Budget should establish a senior staff role to ensure consistency of health security funding and management decisions across all agencies and accounts—domestic and international—as the George W. Bush administration did effectively.

We cannot close our borders until a vaccine is developed and all 300 million Americans are inoculated. Nor can we completely shut down our economy and livelihoods. So, while protecting our own people is first and foremost, supporting global response efforts are essential to keeping Americans safe.

Viruses are indifferent to a country's borders. Surveillance must be global as well as domestic.

3. & 4. Antiviral Agents and Vaccines

The development of a COVID-19 vaccine has quickly become the Holy Grail, and after record genome sequencing, our private sector is tackling this challenge with unprecedented innovation and remarkable speed.

(In my personal opinion, I believe that the rapidly developing *treatments* of COVID-19 via anti-viral agents, monoclonal antibodies, and convalescent serum, coming this late summer and fall, will have the most dramatic impact on re-opening our economy, equal to or possibly more so than the long-awaited vaccine.)

But had we invested years ago in speeding up the “bug-to-drug” development timeframe for the vaccines, it's possible this record timeline could have been halved. To that end, I strongly agree with Chairman Alexander's assessment that, “Only the Federal Government can fund research at the scale necessary to create tests, treatments, and vaccines for a pandemic . . .” It will take partnerships.

What was true in 2005 is still true today: we have a dangerously inadequate vaccine manufacturing base in the United States. This must be rectified. Bottom-line: there's so little profit and so much uncertainty in vaccine manufacturing today. We must establish longstanding public-private partnerships with industry that are sustained and are not at risk of disappearing with each Appropriations cycle. We cannot expect the private sector to independently invest billions of dollars developing antivirals and vaccines for novel viruses that we hope we'll never need to use. That's not a sustainable business model.

One approach that should be considered here is a model adopted recently by Civica Rx—an innovative, new nonprofit pharmaceutical entity that partners with health systems, insurers, and the Federal Government to prevent generic drug shortages by establishing stable supply chains, expanding domestic manufacturing, and entering into long-term supply contracts. Though its success is yet to be fully demonstrated, the model of shared responsibility among all stakeholders might be considered with drug and vaccine development and distribution.

We should also consider options like the continuous manufacturing provisions in Senator Blackburn's Securing America's Medicine Cabinet Act, which would strengthen our ability to more quickly manufacture certain drugs at a lower cost and with better quality controls.

Beyond investing in the science to create future treatments and vaccines for unknown threats, it is imperative that we act now to address the very real challenge we are about to face when a vaccine is developed. The same supply chain shortages and equity issues we witnessed with personal protective equipment (PPE) and testing components are about to be magnified when every nation in the world is simultaneously seeking the vaccine and the components needed to package and administer it, to protect their people.

The Federal Government should serve a “control tower” function to address these inevitable, pending domestic supply chain issues. It must clarify which agency will be responsible for this vital function, boldly prepare them for it, and then give that agency the full authority and resources to act.

Additionally, we must recognize when it comes to competing global interests, it is not a zero-sum situation. Today, exactly as we said in 2005, we simply do not have the domestic manufacturing capacity in this country necessary to cover our own needs. The greater the capacity to produce a vaccine globally, the better off we are. Access must be addressed proactively before it is a politically explosive as well as economically and ethically catastrophic.

While the World Health Organization Access to COVID-19 Tools (ACT) Accelerator has little chance of really corralling every player to share “equitably” before meeting their own needs, participation or cooperation now will at least be the point on which countries will judge one another. China will exploit the hole in U.S. engagement in at least two ways: providing products and access directly to countries and by pressing the idea that the global rules-based, capital system is the cause of any vaccine access failure. We should consider constructive ways to engage globally to counter this narrative, including participating in the Coalition for Epidemic Preparedness Innovations.

5. Research and Development

I previously called for a massive R&D investment to create a “Manhattan Project for the 21st Century” to help us better defend against naturally occurring, accidental, and intentional threats—including infectious diseases. We must make long-term, multi-year investments here.

For example, Project BioShield when it was enacted in 2004 was intentionally an advance ten-year appropriation, established to allow the government to guarantee a market for chemical, biological, radiological, and nuclear (CBRN) medical countermeasures. But since 2014, there hasn’t been an advance appropriation, and instead it is reliant on the annual appropriations cycle. That doesn’t send a powerful message to the private sector.

A meaningful investment here could, for example, go toward standing up public-private partnerships to ensure robust and timely diagnostic testing development to avoid repeating the test development mistakes of this spring.

6. Stockpiling & Surge Capacity

This is unequivocally an area where we fell short. There was unnecessary confusion about Federal, state, and even hospital-level responsibilities in procuring PPE and testing supplies, which led to hoarding, drove up market prices, and pitted states and even hospitals against one another. And most importantly, our failure here put the lives of our frontline workers at risk. We would never ask our soldiers to go into battle without armor, and we should never send our healthcare first responders into a pandemic without PPE and other vital supplies.

It is easy to point the finger, but the reality is our National Strategic Stockpile—its contents, relationships between state and Federal, its distribution policy—has been neglected over the course of multiple administrations. States and health systems should make a good faith effort to create their own stockpiles, but realistically we must acknowledge that competing, short-term, state budget priorities will always win out over long-term preparedness planning. The Federal Government must take the lead role here, serving as a central repository. Ideally, paired with a well-structured domestic and global surveillance and wisely managed distribution system, our Nation could appropriately fortify our stockpile at early signs of a threat, and also accurately and sensitively track outbreaks to ensure supplies are rapidly distributed to those in greatest need. Stockpile resources should be stored regionally, with a transparent and operationally capable plan for distribution to local municipalities.

In strengthening our Strategic National Stockpile framework, the Federal Government should stand up capabilities to map supply chain data—including where it is and how much there is (a Federal registry). Ideally, we would onshore some of these manufacturing capabilities, and for others preplan resilient measures to convert existing factories to supplies that may be needed. These will require Federal incentive or partnership to keep domestic production lines at the ready.

Additionally, there needs to be more coordination between BARDA and the Stockpile. We need a resilient system that involves more ongoing input from experts on what is needed for the future, so we can strategically invest and fortify the Stockpile for the next, most probable threat, not the last one. Furthermore, both BARDA and the Stockpile would benefit from more financial resources.

Being prepared also means training first responders, and ensuring a civilian volunteer corps to step in and help handle the surge. It means allocating adequate surge facilities—vaccination sites, treatment centers, laboratories, and morgues. I

have specifically advocated for funding for an expanded contact tracing workforce and voluntary self-isolation facilities, if needed utilizing vacant hotels, with Andy Slavitt, Scott Gottlieb and other public health leaders, recognizing that our ability to immediately trace and self-isolate at the sign of illness are of utmost importance today to public safety as we reopen. The current pandemic will rapidly accelerate tracking and tracing technology for the future, and it will improve with time though it's still just a bit too early in its development, practical application and general acceptance.

The recommendations within each of these six categories are by no means exhaustive, and I know my colleagues on this panel will have much to add. A few additional areas I want to touch on are: (1) Public health funding; (2) Vulnerable populations and health equity; (3) Virtual care, and (4) Establishing a Coronavirus Commission.

Public Health Funding

In just a few short months, we already spent more in the four COVID response packages than we have on the Iraq War.

Researchers estimate that there is a \$34 per capita gap between what is needed to assure the conditions that populations are healthy and our Nation's current public health investment—approximately a \$10 billion deficit. It is time we look at public health as part of our Nation's defense.

Last month, I joined with Dr. Tom Frieden, former Senator Tom Daschle, Dr. Tom Ingelsby and others to advocate for the creation of a Health Defense Operations budget designation.

Health Defense Operations—HDO—provides an increased, sustained, predictable base funding for public health security programs that prevent, detect, and respond to outbreaks like COVID or pandemic influenza.

Congress is to be commended for the quick response to COVID-19 by providing critical emergency supplemental funding during the pandemic. But this funding in response to emergencies will not sufficiently protect us for the future. Supplemental appropriations are by their nature temporary. Future health and economic security can best be protected by changing the way we allocate funds to protect us all from health threats. We have all seen the limitations that caps and sequestrations cause for discretionary funding. We have seen that even mandatory funding doesn't ensure stable support as those funds are often siphoned off during calm periods when outbreaks are out of the news.

We propose a new approach for specific public health programs that are critical to prevent, detect, and respond to health threats. We call this the Health Defense Operations (HDO) budget designation, and it would exempt critical health protection funding lines at the CDC, NIH, FDA the office of the Assistant Secretary for Preparedness and Response from the spending caps so our public health agencies can protect us.

Specifically, Health Defense Operations programs will:

- be exempted from the Budget Control Act budget caps
- not be sequesterable for the length of the fiscal year
- and be required to submit bypass budgets (Program—> Agency—> Congress) ensuring there is an unvarnished look at preparedness needs.

This does not exempt these identified programs from the appropriations process, but rather exempts them from budget mechanisms that have eaten away at public health. We propose an \$11 billion annual increase in funding for specific funding lines at CDC, NIH, FDA and ASPR, a comparatively small investment compared to prior COVID supplementals and our annual defense budget.

The detailed recommendations I have outlined require a dependable, consistent funding source, and the Health Defense Operations budget designation can create a thoughtful cross-agency approach to funding diverse needs over time.

An alternative approach would be to establish a Public Health Infrastructure Fund that would provide a mandatory stream of resources to states and localities to build public health capabilities while ensuring accountability. Ultimately, our public health infrastructure, as has become apparent to all over the past four months, has been woefully underfunded for years and we need a new budgetary approach to combat funding shortfalls.

While I recognize that the HELP Committee does not appropriate these funds, robust public health infrastructure funding will be necessary if we are serious about effectively preparing for the inevitable next pandemic with incumbent loss of life.

Vulnerable Populations and Health Equity

The greatest strains of a pandemic fall on particular demographics because of specific economic, or social or health status. With COVID-19, we continue to see a disproportionate burden of illness and death among racial and ethnic minority groups. These populations disproportionately work in front-line jobs that prevent them from staying home, are more likely to be uninsured or underinsured, live in densely populated areas and in multi-generational homes that make it harder to isolate when sick, rely on public transportation, and have serious underlying medical conditions. Any pandemic preparedness response needs to comprehensively consider how to protect and care for the most vulnerable. I recommend:

- States and the Federal Government collect and share data on confirmed cases by race, ethnicity, disability and income to understand what populations are being hit hardest and why;
- States, in consultation with Federal health agencies, establish protocols for intensifying testing in the highest risk settings and among the highest risk individuals to ensure early detection paired with contact tracing;
- States and Federal health agencies include representatives from communities of color and other marginalized groups to inform and shape pandemic response decisions.

We are living through a singular time in our Nation's history, and our preparedness policies should seek to end the barriers to health and well-being for communities of color, with the goal of health equity.

Virtual Care

Necessity is the mother of all invention, and the explosion of telehealth and virtual care has been one of the most constructive advances to emerge from this crisis. I want to echo Chairman Alexander's recommendation that we "Ensure that the United States does not lose the gains made in telehealth." The gains for the patient include convenience, affordability, and rapid access to quality care that is needed. The field of virtual health care, delivered from a remote location by text, phone or video has been accelerated by five years or more. And patients and the country will benefit in a transformative way.

I am heavily involved in virtual care, beginning with my days 30 years ago taking care of over a hundred transplant patients remotely. Today I serve on the board of two virtual health care companies, Teladoc Health (physical and mental health) and Smile Direct Club (dental health). Teladoc Health delivers care via telemedicine in 175 countries and in more than 40 languages, partnering with employers, hospitals, and health systems. I have seen firsthand how our recent policy changes at the Federal and state levels have in an overwhelmingly positive way unleashed private sector innovation—stepping in to address care gaps created by the pandemic's stay at home orders.

To continue this progress, I recommend:

1. **Allow telehealth access regardless of patient and provider location:** Congress must act to modernize 1834(m) by removing the geographic and originating site restrictions. By doing this, all Medicare patients can access care outside of specific geographic locations and outside specific brick-and-mortar facilities.
2. **Allow HHS to determine appropriate telehealth services and providers:** Congress should give the Secretary of HHS the ability to expand the list of eligible telehealth practitioners and ensure the Secretary has the authority to determine eligible telehealth services. Additionally, Congress should make permanent the 80 new telehealth services that can be reimbursed by Medicare.
3. **Allow federally Qualified Health Centers and Rural Health Clinics to offer telehealth after COVID:** 1834(m) limits the types of "distant sites" for a provider to use telehealth. The law does not allow FQHCs or RHCs, critical safety net providers, to be reimbursed as distant sites. The CARES Act changed this during the pandemic, but action must be taken to ensure FQHCs and RHCs can reach their patients via telehealth and receive appropriate reimbursement for their services.

While the Administration has done a good job, there is a risk that broad telehealth deployment if not carefully designed could actually replicate barriers in place in the traditional health system that produce disparities. One glaring example is a bias in some of the new authorities that have been authorized for two-way video communications. We should treat all forms of communications equally, as long as doctors are able to meet the same standards of care. If we discriminate against telephone (without video) users, for example, we will leave behind rural communities without access to broadband as well as minority and other lower-income populations that may not have more expensive smart phones with two-way video capabilities. I urge CMS to continue to allow patient choice and physician discretion when it comes to technology post COVID. And as we move forward, we need to ensure that patient privacy and security are protected.

Additionally, we have learned that in order to deploy vast networks of physicians to where they are needed, we must have a mechanism to address state physician licensure. Many states did that by waivers of various kinds, but it was a steep learning curve with no consistency.

Finally, while I believe the majority of regulatory changes made to advance telehealth and virtual care during COVID should be made permanent, parity in payment is one that should be revisited following the crisis. Undoubtedly it was a needed change to motivate physician engagement and participation, but since some of the overhead costs are eliminated in virtual transactions, it will likely make sense to reimburse closer to 70 to 80 percent of in-person visits. Reimbursement parity laws completely remove telehealth savings to the patient.

Coronavirus Commission

In closing, I have one final recommendation. After September 11, 2001, we recognized that our country faced a new threat that required a new approach to our national defense. Without a doubt, the massive disruption caused by the COVID-19 pandemic makes clear we need to recalibrate again. A deadlier virus will cause devastation on an even more frightening scale.

To further examine what parts of the local, state, and Federal response worked, and what could work better and how, we should form the coronavirus equivalent of the **9/11 Commission**. We must do everything in our power to make sure our imperfect response is not repeated. It's a matter of saving lives.

Thank you Chairman Alexander, Ranking Member Murray, and Members of the Committee for having me here today. The work you are doing now will literally save lives in the future—thank you for your tireless commitment to improving health in the spirit of bipartisanship.

[SUMMARY STATEMENT OF BILL FRIST]

In 2005, in a series of speeches I predicted a global pandemic arising from China and proposed a six-part plan to prepare the Nation focused on: 1. Communication; 2. Surveillance; 3. Antiviral Agents; 4. Vaccines; 5. Research and Development; and 6. Stockpiling & Surge Capacity. Much of what I recommended in 2005 remains true today.

1. Communication

- We must clarify who is in charge in a pandemic. The Federal response should be led at the National Security Council level to facilitate a whole of government approach.
- The CDC should regain its position as the Nation's apolitical voice of public health.
- We must make sure what is said at the Federal level coordinates and integrates well with the more regional needs, abilities and resources of state and local municipalities.

2. Surveillance

- This pandemic has laid bare our inability, at the Federal level, to track outbreaks across the country, and provide real-time data to states and localities. That's why we need a real-time domestic and international threat detection system.

3. & 4. Antiviral Agents and Vaccines

- We have a dangerously inadequate vaccine manufacturing base in this country. We must establish public-private partnerships that are sustained and are not at risk of disappearing with each appropriations cycle.
- Furthermore, the Federal Government should serve in a “control tower” function now to address pending supply chain issues for when a vaccine is developed.

5. Research and Development

- I previously called for a massive R&D investment to create a “Manhattan Project for the 21st Century” to help us better defend against naturally occurring, accidental, and intentional threats—including infectious diseases. We must make long-term, multi-year investments here.

6. Stockpiling & Surge Capacity

- The Federal Government should take the lead role, serving as a central repository. Ideally, paired with a well-structured domestic and global surveillance system, our Nation could fortify our stockpile at early signs of a threat, and also accurately track outbreaks to ensure supplies are distributed to those in greatest need. Stockpile resources should be stored regionally, with a transparent and operationally capable plan for distribution to local municipalities.
- Being prepared also means training first responders, and ensuring a civilian volunteer corps to step in and help handle the surge.

Public Health Funding: Last month, I joined with Dr. Tom Frieden, former Senator Tom Daschle, Dr. Tom Ingelsby and others to advocate for the creation of a Health Defense Operations budget designation to provide an increased, sustained, predictable base funding for public health security programs. It would exempt critical health protection funding lines at the CDC, NIH, FDA, and ASPR from spending caps so our public health agencies can protect us.

The CHAIRMAN. Thank you, Dr. Frist.
Dr. Khaldun, welcome.

STATEMENT OF JONEIGH S. KHALDUN, M.D., MPH, FACEP, CHIEF MEDICAL EXECUTIVE AND CHIEF DEPUTY DIRECTOR FOR HEALTH, MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, LANSING, MI

Dr. KHALDUN. Yes. Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to speak with you today about Michigan’s response to COVID–19 and how we can prepare for future pandemics. COVID–19 has infected at least 61,000 and killed over 5,800 adults and children in Michigan. At our peak in April we identified over 1,500 cases and there have been 180 deaths each day. Due to the decisive and necessary actions of our Governor Gretchen Whitmer, as well as the sound judgment of our residents and the work of our local Health Departments, those numbers have declined by more than 80 percent. But let me be clear, this is not the time for victory laps.

COVID–19 is still very present in Michigan and across the country. We simply cannot let our guard down on COVID–19. More than ever, leaders must be laser focused on protecting our communities and addressing the inadequacies in our public health infrastructure. So the greatest tragedy of this pandemic is how it has ravaged communities of color. Michigan was one of the first states to release COVID–19 data by race and ethnicity. In Michigan, just 14 percent of our population is African-American and they represent 31 percent of COVID–19 cases and 40 percent of deaths. This is not unique to Michigan.

Racial and ethnic minorities are disproportionately being inspected by and dying from COVID-19 across the country. These disparities cannot be explained by genetics. They exist because of institutional and structural racism that has deprived communities of color of adequate resources and opportunities for prosperity and optimal health. Indeed, racism is a public health crisis that must be met with urgency, funding, elimination of policies that perpetuate health inequities. If we truly care about the health of every individual in this country, we must ensure that there is equitable access to testing, treatment and vaccines for COVID-19 at no cost.

We also need consistent and accurate messaging from the highest levels of the Federal Government. As a practicing emergency medicine physician and public health leader, I rely on swift, scientifically sound guidance from our Nation's leaders during the crisis. We need accurate and clear messaging from the White House about the true threat of the disease, how and when to get a test, and the importance of wearing masks and social distancing. Next, we must develop and implement a national testing strategy infrastructure.

As a country, we did not expand access to COVID-19 testing at the rate needed to identify cases quickly with tragic consequences. Michigan has now built a testing network of nearly 70 labs and 250 testing sites and we conduct about 14,000 test per day with the capacity to do more. I am grateful for the support of our Federal partners, but we still struggle with the limited number and types of supplies we receive from HHS and FEMA. To fill in the gap, we work non-stop to procure testing materials from the private market but supply constraints remain a limiting factor.

A national procurement and testing strategy would have prevented state and local Governments from competing with each other and avoid one of the most outrageous realities of this pandemic, turning people away who should have been tested. Finally, we must invest in public health infrastructure at the Federal, state and local level. More than 25 percent of local public health physicians have been eliminated in recent years and Federal spending on public health and prevention is minimal and declining. These cuts hinder our ability to adequately respond to public health threats. I have experienced this firsthand.

In my former role as Detroit's Health Commissioner, I lead the city's response to the largest hepatitis A outbreak in modern history, pulling a limited staff away from other critical public health work to quickly ramp up vaccination infrastructure. As Michigan's Chief Medical Executive, I scrambled to respond to the state's outbreak of Eastern equine encephalitis, a mosquito borne illness that infected and killed a record number of people and animals. Simultaneously, I had to pull together a team within weeks to respond to a mysterious vaping related illness without any additional funding or staff.

My experience with COVID-19, unfortunately, is no different. Since March, we have had to take extraordinary measures to build data systems, armies of contact tracers, and set up testing infrastructure. To ensure the U.S. can adequately respond to this crisis and the next, we need long-term investments in our public health departments and programs. Now is not the time to celebrate or to turn our focus away from COVID-19. If anything, we must get

more aggressive, more aggressive in addressing health inequities, expanding testing and contact tracing, and ensuring our public health infrastructure is strong. Thank you for the opportunity to share Michigan's experience today.

[The prepared statement of Dr. Khaldun follows:]

PREPARED STATEMENT OF JONEIGH S. KHALDUN

Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to speak with you today about Michigan's response to COVID-19, what steps need to be taken to protect the public health from this devastating disease, and how we can prepare for future pandemics.

COVID-19 continues to ravage communities across the country, and Michigan has not been spared. Michigan identified its first two cases of COVID-19 on March 10, 2020, the same day that our Governor, Gretchen Whitmer, declared a state of emergency. By April 1, 2020, Michigan had identified 9,334 confirmed cases and 334 deaths from the disease. Governor Whitmer has taken a series of appropriate and decisive actions to protect the health of Michigan residents, including restricting gatherings and travel unless they were necessary to sustain or protect life, limiting healthcare activities that were not time-sensitive, and aggressively building up testing and contact tracing to contain the disease.

As of June 20, 2020, Michigan had 61,084 confirmed cases, and 5,843 deaths due to COVID-19. It has tragically killed people of all ages in our state, from as young as 5 up to 107. While our road has not been easy, we have made progress. Due to the Governor's actions, the sound judgment of most of our businesses and residents, and the work of our local health departments, Michigan has seen a significant decline in cases and deaths over the past several weeks. Our hospital systems, particularly those in southeast Michigan who were hit hardest during this pandemic, are now stable in bed availability, supply of personal protective equipment (PPE), and resources available to take care of their sickest patients. As of last week, Michigan was one of four states in the country on track to contain the disease, according to the public health experts at Covid Act Now.¹

Because of this, Michigan is cautiously reopening the economy with robust safety protocols in place.² But let me be clear: this is not the time for victory laps. COVID-19 is still very present in Michigan and we continue to respond to outbreaks across our state. There is no vaccine and much of the population has likely not been infected, meaning most people are not immune to the disease. There is no FDA-approved antiviral treatment. And many states are still seeing increasing numbers of cases. In Michigan, I am preparing for the real possibility of a resurgence of cases in the fall during influenza season, which would be devastating for the health of our residents and could stretch our hospital capacity once more.

For these reasons, we cannot let our guard down now on COVID-19. The COVID-19 pandemic is not over. As we move forward with fighting this disease, Federal, state, and local leaders must be laser-focused on protecting our communities from COVID-19 and addressing the inadequacies in our public health infrastructure.

Health Inequities

The greatest tragedy of this pandemic is how it has ravaged communities of color. Michigan was one of the first states to release data on cases and deaths by race and ethnicity. In Michigan, a state where just 14 percent of the population is African American, 31 percent of COVID-19 cases, and 40 percent of deaths, are African American. Governor Whitmer swiftly responded to this information by establishing the Michigan Coronavirus Task Force on Racial Disparities, chaired by Michigan's Lieutenant Governor Garlin Gilchrist.³ I have the pleasure of serving on this task force alongside several other community, academic, and government leaders, and the task force has moved swiftly to identify causes and promote solutions to address these inequities.

The racial disparities in the effects of COVID-19 are not unique to Michigan. African Americans, Hispanics, and other racial and ethnic minorities across the country

¹ <https://covidactnow.org/?s=53768>.

² *MI Safe Start Plan*, May 7, 2020.

³ *Executive Order 2020-55*.

are disproportionately being infected by and dying from COVID-19.⁴ This is no surprise. Health disparities and inequities have plagued this country since its inception. To be clear, these disparities cannot be explained by genetics. Instead, the disparities exist because of institutional and structural *racism* that has deprived communities of color of adequate resources and opportunities for prosperity and optimal health. Indeed, racism is a public health crisis that must be met with urgency, funding, and the elimination of policies that perpetuate health inequities: policies like redlining, lack of investment in schools, and both implicit and explicit bias in the healthcare system.

These policies have caused communities of color to be more likely to live in poverty, have inadequate housing, have poor access to healthcare, and work in lower paying jobs.⁵ This means that due to the nature of their employment, people of color have disproportionately been deemed “essential” during the COVID-19 pandemic, needing to leave their homes and interact with the public instead of having the privilege of safely working from home while maintaining health and other fringe benefits. Homelessness, multi-generational households, or unsafe living conditions make it difficult to effectively self-isolate and quarantine, allowing COVID-19 to rapidly spread. People of color are also more likely to have underlying health conditions that are often undiagnosed or poorly treated, putting them at higher risk of being severely affected and dying from COVID-19.

Strategies to fight COVID-19 and future pandemics must focus on eliminating barriers in access to healthcare. No one should worry about paying out of pocket for testing or treatment of COVID-19. Everyone should have access to health insurance, and our healthcare safety net which cares for the most vulnerable must be adequately funded. Vaccine distribution strategies should be data-driven and focus on those who are at highest risk of severe disease, with clear guidance in place to ensure communities of color have equitable access. Strategies should be employed that embed testing and vaccination distribution in communities—not only in doctor’s offices or hospitals. The strong partnerships that state and local health departments have cultivated with communities over the years should be leveraged to address ongoing challenges with access to care. These partnerships will also be critical to overcoming the mistrust of the healthcare system that often exists in communities of color, fueled by historical inequities in treatment.⁶

We also have to ensure access to adequate housing. Housing policy is health policy. In the short term that means safe places where people who have COVID-19 can self-isolate and longer term making sure people have access to affordable, healthy housing in safe neighborhoods.

Finally, we must address implicit and explicit bias in our healthcare system. Research has shown that, once care is accessed, both implicit and explicit bias by healthcare providers contributes to health care disparities.⁷ One of the factors associated with implicit bias is how we are socialized. We all have implicit biases but often do not realize that they exist—assumptions about individuals and groups can cause medical providers to not use a patient’s individual circumstances or objective data to guide clinical management. Explicit biases include those that are more explicitly racist, that may also not be fully recognized. This bias is known to impact health outcomes in communities of color and COVID-19 is no different. Implicit bias training should be a mandatory part of all health professional training, and medical schools and residency training programs should accelerate efforts to increase diversity in their classes.

⁴Garg S, Kim L, Whitaker M, et al. Hospitalization Rates and Characteristics of Patients Hospitalized with Laboratory-Confirmed Coronavirus Disease 2019—COVID-NET, 14 States, March 1–30, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:458–464. DOI: <http://dx.doi.org/10.15585/mmwr.mm6915e3>.

⁵US Bureau of Labor Statistics, Report 1082, Labor force characteristics by race and ethnicity, 2018. October 2019. <https://www.bls.gov/opub/reports/race-and-ethnicity/2018/home.htm>.

⁶Armstrong, K et al. Distrust of the Healthcare System and Self-Reported Health in the Unites States. *J Gen Intern Med.* 2006 Apr; 21(4): 292–297. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1484714/>.

⁷Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care; Smedley BD, Stith AY, Nelson AR, editors. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Washington (DC): National Academies Press (US); 2003. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK220358/>.

Consistent and Accurate Messaging

I have the utmost respect for my colleagues at the U.S. Centers for Disease Control and Prevention (CDC), and I have been grateful for their support since we first began building up Michigan's response to COVID-19 in January 2020. However, we have been challenged by the lack of consistent, science-based strategy and messaging from the White House. I am a practicing emergency medicine physician and have had the honor of serving as Baltimore's Chief Medical Officer, Detroit's Health Commissioner, and now as Michigan's Chief Medical Executive. As frontline clinicians and public health leaders, we rely on swift, scientifically sound guidance and messaging from our Nation's leaders and Federal public health experts during a crisis. This has not been the case since the beginning of this outbreak, with inconsistent and inaccurate messaging from the White House about the true threat of the disease and potential treatments. There should be a clear, accurate, and consistent message at the national level alerting people to the risks of the disease, how and when to get a test, the importance of contact tracing, and basic public health messaging relaying the benefits of wearing masks and practicing social distancing. As with previous outbreaks such as Ebola, or H1N1, we must make sure our Nation's top public health leaders are the face of this pandemic and are given full authority to swiftly implement the most scientifically sound practices and to communicate this information to the public.

National Testing Strategy and Infrastructure

As a country, we did not expand access to COVID-19 testing quickly enough. In the early stages of the pandemic in Michigan, individuals had to meet strict criteria, including having severe symptoms, or a clear history of travel to an impacted country, to access testing. Once they met that strict criteria and were tested by a healthcare professional, state and local public health leaders had to subsequently arrange for packaging and shipment of the patient's sample to the CDC lab, where the CDC then prioritized which samples were run. By early February, Michigan was working through the process to be able to run samples in our state laboratory, but that process was then halted as the CDC had to work through unexpected inconsistencies in the testing platform.

By the end of February, Michigan's public health laboratory was the only laboratory in Michigan able to perform COVID-19 testing. On March 10, 2020, when Michigan confirmed its first case of COVID-19, our laboratory only had enough supplies to run a few hundred tests a day for a few days. Weeks of delays and restrictions in testing meant we were not able to identify cases at the level and speed needed—with tragic consequences—as there were likely hundreds, if not thousands of cases in Michigan well before they were identified by testing.

Since that time, through painstaking work, Michigan has built a testing system that now conducts about 14,000 tests per day. We are working toward a goal of 30,000 tests a day, or about 2 percent of Michigan's population per week, in line with recommendations of national public health experts. Nearly 70 laboratories in the state have validated testing for COVID-19, and about 250 test sites are currently operating. With this expanded capacity, Michigan has broadened testing criteria significantly, and we are focused on testing anyone who has symptoms, may have been exposed, or is most vulnerable to disease. The assistance of Michigan's National Guard and funding from the Paycheck Protection Program and Healthcare Enhancement (PPHCE) Act as well as the Coronavirus Aid, Relief and Economic Security (CARES) Act have been vital supports in the state's testing strategy.

I have greatly appreciated the support we've received from our Federal partners including, but not limited to those at the U.S. Department of Health and Human Services (HHS), the CDC, the Assistant Secretary for Preparedness and Response (ASPR), and the Federal Emergency Management Agency (FEMA). They have consistently answered our calls and Michigan is now regularly receiving testing supplies. However, we still struggle with the lack of detail provided on the timing, quantity, and type of supplies coming to the state, and often the supplies we receive are not compatible with the laboratory systems that exist in the state. This makes planning and coordination challenging.

Early identification of cases and testing should have been an early priority at the Federal level. When it was clear in other countries that the disease could rapidly spread, the U.S. should have swiftly established a national testing strategy and set up clear testing criteria and infrastructure for state and local governments to easily obtain testing supplies. Instead, state and local governments were left to compete for limited supplies and people who likely had the disease were turned away from testing, resulting in the disease spreading like wildfire in our communities. Even

today, Michigan is unable to meet its testing goal of 30,000 tests per day. Laboratories still struggle with a fragmented and inconsistent supply of test kits and laboratory reagents. Our hospital laboratories frequently run low on reagents and are still only able to test the sickest patients. Going forward, the Federal Government should institute a national supply chain strategy to resolve bottlenecks that no state alone can address—and ensure an ample supply of test kits and reagents.

Invest in Public Health Infrastructure at the Federal, State, and Local Levels

In its 1988 report, “The Future of Public Health”, the Institute of Medicine expressed concern that, “this nation has lost sight of its public health goals and has allowed the system of public health activities to fall into disarray.”⁸ Despite this grave warning, our public health systems continue to struggle for the support and funding needed to ensure there is a robust, versatile, and flexible system available to protect and promote the health and well-being of our residents. Public health departments across the country are continuously asked to do more, with less. Between 2008 and 2017, more than 56,000 local public health positions were eliminated, which accounts for almost 25 percent of the workforce.⁹

Nationally, less than three percent of the annual \$3.6 billion spent on health is dedicated to public health and prevention, and this proportion has been decreasing since 2000.¹⁰ Funding from the CDC for public health preparedness and response has been cut by over half in the past decade.¹¹ In fiscal year 2016, Michigan’s per capita state funding from the CDC was \$18.80 compared to the national average of \$21.31.¹² This places Michigan 43rd in CDC funding.¹³ These cuts have had a significant impact on our ability to adequately fund and respond to public health threats.

I have experienced this first-hand. As Detroit’s Health Commissioner, I led the city’s response to the largest Hepatitis A outbreak in modern history, pulling my limited staff and funding away from other critical public health work to quickly set up pop-up clinics, and worked with federally Qualified Health Centers and hospitals to make sure patients were appropriately screened and those at highest risk were vaccinated. In my role as Michigan’s Chief Medical Executive, last year I had to quickly respond to the state’s worst outbreak of Eastern Equine Encephalitis (EEE) ever recorded. This debilitating mosquito-borne illness infected many and ultimately killed six people and dozens of animals across the state. I had to scramble to set up a surveillance and mitigation strategy coordinated across 45 local health departments in a matter of weeks.

My experience with COVID-19 is no different. Since March 2020, our state and local health departments have had to take aggressive and extraordinary measures to expand contact tracing infrastructure—the bread and butter of any communicable disease response. We set up a new technological infrastructure that enables more effective management of contacts. We built our own contact tracing army—over 10,000 Michiganders have volunteered to be contact tracers, approximately 500 are deployed today, and we are moving quickly to hire surge staffing embedded in local health departments, using funds from the PPPHCE Act and the CARES Act.

But the ability to respond to crises like these should be built into the public health system, not jerry-rigged as a global pandemic spreads like wildfire. We should not have to rely on volunteers or take staff away from other critical public health work to respond to emerging public health threats. Lack of ongoing investment in technology, surveillance, and staffing infrastructure means that state and local health departments are constantly improvising and building these systems *during* a response, resulting in dangerous delays in understanding disease spread

⁸Institute of Medicine 1988. *The Future of Public Health*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/1091>.

⁹Trust for America’s Health. *What we are learning from COVID-19 about being prepared for a public health emergency*. Issue Brief, May 2020. Accessed 18 June 2020 <file:///C:/Users/HUDsonn2/Downloads/TFAH2020CovidResponseBriefFnl.pdf>.

¹⁰Trust for America’s Health. *The Impact of Chronic Underfunding on America’s Public Health System: Trends, Risks, and Recommendations*, 2020. Accessed 17 June 2020 <https://www.tfa.org/report-details/publichealthfunding2020/>.

¹¹Ibid.

¹²Citizens Research Council of Michigan. *An Ounce of Prevention: What Public Health Means for Michigan*. Report 403, August 2018. Accessed 17 June 2020 <https://cremich.org/wp-content/uploads/rpt403-public-health-2.pdf>.

¹³Citizens Research Council of Michigan. *An Ounce of Prevention: What Public Health Means for Michigan*. Report 403, August 2018. Accessed 17 June 2020 <https://cremich.org/wp-content/uploads/rpt403-public-health-2.pdf>.

and swiftly controlling it. To ensure the U.S. can continue to respond to COVID-19, safely reopen and sustain our economy, and respond to the next emerging threat, we need long-term investments in our public health departments and programs.

Public health experts have been gloomily warning of our lack of preparedness for a global infectious disease pandemic for years. Unfortunately, COVID-19 has turned those warnings into a real-life public health nightmare, killing over 120,000 people in the U.S. and leaving under-resourced public health departments scrambling to provide a coordinated and robust response. It has further unveiled the tragic injustice of racial inequality in our society. But it is not too late to save the lives of hundreds of thousands more. We have an opportunity to make the next chapter in this crisis a success story brought about by strong Federal leadership making serious and sustained investments in public health infrastructure.

Now is not the time to celebrate or turn our focus away from COVID-19. We must still aggressively fight this pandemic and if we do not redouble our efforts many more people will unnecessarily die. As a country we must urgently address health inequities, expand testing and contact tracing, and make sure our public health infrastructure is strong. We must remain vigilant, hopeful, and committed to protecting the public's health.

Thank you for the opportunity to share Michigan's experience.

[SUMMARY STATEMENT OF JONEIGH S. KHALDUN]

COVID-19 has and continues to ravage communities across the country. As of June 20, 2020, Michigan had 61,084 confirmed COVID-19 cases and 5,843 deaths. While we have made tremendous progress in slowing the spread of this disease in Michigan, we recognize that now is not the time for victory laps. COVID-19 is still very present in Michigan and we continue to respond to outbreaks across our state. Nationally, this destructive virus has killed over 120,000 people so far with no end in sight and has left under resourced public health departments scrambling to provide a coordinated and robust response in the absence of Federal leadership. It has also further unveiled the tragic injustice of racial inequality in our society. But it is not too late. With strong Federal leadership and strategic policy, we have the opportunity to turn this crisis around and prevent additional suffering and death.

Health Inequities

Across the country, communities of color are disproportionately being infected by and dying from COVID-19. For example, despite making up only 14 percent of Michigan's total population, African Americans represent 31 percent of COVID-19 cases and 40 percent of deaths. This cannot be explained by genetics and has everything to do with institutional and structural racism that has consistently left communities of color without adequate resources and opportunities for prosperity and optimal health. Strategies to fight COVID-19 and future pandemics must focus on eliminating policies that perpetuate inequities and should ensure equitable access to health care, vaccines, education, employment, and housing.

Consistent and Accurate Messaging

Since the beginning of the COVID-19 outbreak, Michigan has been challenged by the lack of a consistent, science-based Federal strategy and message about the true threat of the disease, mitigation strategies, and potential treatments. A clear, accurate, and consistent message is needed at the national level alerting people to the risks of the disease, how and when to get a test, the importance of contact tracing, and basic public health messaging relaying the benefits of wearing masks and practicing social distancing.

National Testing Strategy and Infrastructure

As a country, we were not prepared for COVID-19. We did not have the testing capabilities, testing supplies, or personal protective equipment needed to adequately respond. Governments and hospitals have had to compete for resources, often against the Federal Government. Combined with delayed and sometimes unusable supplies from our Federal partners, this created unneeded uncertainty in an already difficult situation. While things have improved, many of these issues continue to be a concern. We need a national strategy and leadership to ensure a smooth supply chain that makes sure the right supplies are arriving when and where needed.

Public Health Investment

Nationally, less than three percent of the annual \$3.6 billion spent on health is dedicated to public health and prevention, and this proportion has been decreasing since 2000. COVID-19 has shown the problems with this disinvestment. To ensure the U.S. can continue to respond to COVID-19 as well as the next emerging threat, we need to invest long-term in our public health departments and programs.

The CHAIRMAN. Thank you, Dr. Khaldun.
Dr. Gerberding, welcome.

STATEMENT JULIE L. GERBERDING, M.D., MPH, EXECUTIVE VICE PRESIDENT AND CHIEF PATIENT OFFICE, MERCK & CO., INC., CO-CHAIR, CSIS COMMISSION ON STRENGTHENING AMERICA'S HEALTH SECURITY, KENILWORTH, NJ

Dr. GERBERDING. It has been a long time since I have testified in front of the HELP Committee and it is good to be back, but I also thank you for your incredible leadership and all you do to protect the health of Americans. There is a lot of media claiming that this pandemic is the pandemic of a century, but I agree with Dr. Frist. I think this pandemic is the harbinger of things to come.

While we focus on how we can mitigate its harm right now, we do have to peer into the future and accelerate our preparedness efforts and really take seriously this time what needs to be done to truly create a health security agenda for America. Now, I would like to just start with what we know for sure because we are still in a learning phase here. We know for sure this virus is incredibly transmissible. We know it causes great harm, serious morbidity and mortality especially among vulnerable people, and we know that it is going to continue to spread for many months to come.

We are nowhere near the end of the mitigation phase of this crisis. We also know that shelter in place and quarantine can be successful in slowing down transmission, but that comes at a tremendous price to individuals and families as well as economies and global macroeconomic forces simply because it shuts down business and people don't have livelihoods and the economies don't have a base. Now, what don't we know? We don't know what we need to know about the virus, its interaction with the host, and how it is going to evolve over time. We don't know really how to calibrate our balance between opening our societies and resuming some important business functions and at the same time continuing social distance so that we can slow down spread. We don't know to what extent daycare, schools, and colleges contribute to community transmission and transmission of this virus to other more vulnerable people in society.

Last but not least, we don't know if we can stop this pandemic with a vaccine. So let's talk a little bit about vaccine. If we want to end a pandemic, we are going to need a vaccine that is feasible and produced at large scale. We need a vaccine that ideally is successful in a single dose and we need a vaccine that we can reasonably predict will likely be effective and safe.

Let me talk about why this is a stern taskmaster, the science of vaccinology in the context of COVID-19. First, with respect to efficacy. We need a vaccine that produces effective immunity, neutralizing the virus, preventing infection even among vulnerable, older

or immunosuppressed people, and we need a vaccine that is durable so that protection lasts beyond a few weeks or months. And finally, of course, ideally, we would like to have a vaccine that is robust if the virus does change or evolve over time. But as high a bar as efficacy sets, we also need a higher bar for safety because we are going to be using this vaccine in some of the most healthy people as well as some of the most vulnerable people, including children and potentially even infants.

We must not sacrifice safety for the sake of speed and I think that is going to be a very important component of our communication about the vaccine opportunity because people need to trust that the vaccine will be safe. We already have concerns that myths and lies about the safety of the products that are in progress are a deterrent to people's willingness to step up and accept immunization.

While I am cautiously optimistic about the prospects for a vaccine, we are a long way from being able to promise the delivery date or the characteristics of what I suspect will be several vaccines that will have different effectiveness in different populations. So, Senator Frist outlined an incredible historic list of the six things that we need to do for future pandemics. That has been echoed in your white paper, Senator Alexander. It has been presented in various forms by the bipartisan Blue Ribbon panel, by the CSS Commission that you referenced earlier, as well as many after-action reports filing ongoing outbreaks during my tenure at CDC.

All of these perspectives have some common themes, and first and foremost is the theme of sustained National leadership at the level of the National Security Council. But I want to highlight one other theme that Senator First brought up and that is the critical importance of sustained, long-term budgetary investment, ending the cycle of complacency in crises that we have been in for so many years and instead creating a budget process for our Nation's preparedness, and particularly for the CDC, which you characterized as an independent scientific organization that needs to function in an apolitical environment.

We need to make sure that we find a budget mechanism that allows the sustained funding to not be subject to budget caps and not be something that gets involved in horse-trading when the budget balancing process rolls around every year. That alone would help us secure an ongoing progressive investment in preemptive preparedness that truly will change the game for Americans. So thank you for allowing me to testify and I look forward to your questions.

[The prepared statement of Dr. Gerberding follows:]

PREPARED STATEMENT OF JULIE L. GERBERDING

Chairman Alexander, Ranking Member Murray, and other Members of the Committee, thank you for the opportunity to appear today. Reviewing the lessons learned from COVID-19 and other past pandemics and preparing for the next pandemic is critical. Unfortunately, we can't expect this pandemic to be a "once in a century" event; it is a sobering harbinger of things to come. Thank you for your leadership in this critical area.

Experts have predicted for years that a pandemic of this magnitude would occur, and significant progress has been made over the last decade in increasing our capabilities and readiness. Now that we are in the midst of the experience, while we must focus on the immediate task at hand, we can already see some of the

vulnerabilities in our system that need to be addressed for the future. We must increase our posture of readiness for future infectious disease threats, with science, capability, and capacity in the U.S. and across the globe. We must ensure there is a robust market for innovation and continue collaboration, partnership, and strategic investments across the public-private continuum.

As one of the very few companies that have continued to invest in both vaccines and anti-infective medicines, at Merck we know we have a special responsibility to help advance both vaccine and antiviral therapies as part of our overall COVID-19 response. We have been fully committed to developing an effective response to the COVID-19 pandemic since it was first recognized, and we know that success will require global collaboration among countries, companies, and other key stakeholders. Despite the unprecedented, rapid collaboration and investment from the biopharmaceutical industry, we will continue to have more lives lost to COVID-19.

The development of a new vaccine is complex, time intensive, and carries no guarantees. It is estimated that only six percent of vaccine candidates get to the finish line and that is why only a small number of companies have continued to operate in this space.

Manufacturing and distributing a vaccine under normal circumstances is exceedingly complex, requiring hundreds of steps, thousands of complex tests, all validated to ensure that every single vial has the identical high quality and safety. When we think about what will be needed to address the pandemic, we are talking about orders of magnitude beyond what we as an industry are currently doing and which truly exceeds the current global capacity.

In order to meet this need, we must all appreciate that the biopharmaceutical collaborators are working at risk. In other words, we are making considerable investments in key elements such as manufacturing capacity before we typically would, before we know whether we even have a successful product—in many cases building a factory before we have fully developed the process at a smaller scale. As a result, we have to think carefully about how these decisions will impact other development programs and allocation of investments, including considering the inevitable opportunity costs.

In the short-term, we can expect many more months of ongoing transmission risk, with many people at risk. This will be further complicated as we expect influenza season to confound the impact of COVID-19 on communities and health systems. Sheltering in place and social distancing have proven effective mechanism to slow the transmission of the virus and protect the health care capacity; however, it comes at a huge price. The economic, individual/family, and community hardships are real. At the same time, communities with less social distancing are beginning to demonstrate more transmission.

I believe we need to find the right evidence-based balance between sufficient social distancing, including masks and avoidance of crowds, with prudent steps to resume business activities and more normal activities of daily life. This is imperative.

We also need to address escalating levels of misinformation related to the pandemic and the public and individual health impact of future vaccines. We are continuously seeing dissemination of information that is inaccurate and/or misguided. This can be quite dangerous as it leads to questioning the safety and efficacy of vaccines, which we know are critical to containing this pandemic and preventing future ones. We have seen the erosion of trust in governments and health care workers, who will be conducting vaccination programs. Ultimately this misinformation and mistrust can lead to a troubling reduction in people choosing to receive vaccines.

The current pandemic has only further emphasized the value of vaccines in preventing illnesses. We know that it is better to prevent an illness rather than treat it, but we are now living a stark example of that principle. As we look forward to a time when new vaccines and treatments are widely available, we must do more to ensure the adequate funding of prevention and immunization infrastructure in our health system more broadly. As this pandemic has shown very clearly, these are critical for health protection but also for national and economic security.

Testing protocols for future pandemics will also be critical. The 6 key priorities for testing are as follows:

1. Test people with symptoms for diagnosis;
2. Test people exposed to known/suspected cases;
3. Test people in “hotspots” where transmission is increasing;
4. Routinely test people in locations known to be or likely to be high risk (nursing homes, health care settings, prisons, meat packing plants, etc.);

5. Test to understand patterns of transmission risk and improve policy decisions (e.g., in daycares, schools, campuses, etc.; using antibody testing)—this is the essence of public health surveillance;
6. Deprioritize other “general” testing to unlog the system, especially until the reliability of tests improves.

Accelerating and enhancing health care surge capacity planning is also essential. This includes a multitude of critical activities, such as:

1. Conducting a thorough supply chain assessment to understand and address vulnerabilities;
2. Examining how to best strengthen the Strategic National Stockpile performance to be the most effective and efficient during a pandemic (e.g., consider expansion of personal productive equipment, ventilators, and other durable medical equipment);
3. Augmenting supplies of antibiotics, intravenous fluids, and other medicines to sustain critical care;
4. Formalizing augmented health care workforce contingency plans (credentials across states, retirees, volunteers, Department of Defense) and updating training;
5. Institutionalizing telehealth and payment reforms; planning for needed in-person primary care, maternal health, mental health, substance abuse, and dental care clinics;
6. Creating an interoperable pandemic health data network (instead of local and state stand-alone networks);
7. Engaging and incentivizing the private sector in planning efforts;
8. Exercising and improving plans with accountability from partners to follow through on lessons learned.

As we look forward, it is important to understand the key lessons that can and should be applied to help us better prepare for and respond to future pandemics. Vaccine development is complex and carries no guarantees; for this reason, we need to support the pursuit of multiple approaches.

While the first step is clearly finding the one or more effective vaccines, we can't underestimate the challenges of successfully deploying those vaccines. The complexity of the situation on the ground and challenges faced by vaccinators in the Democratic Republic of Congo (DRC) with our Ebola vaccine have been unparalleled. The scope and scale of the vaccine distribution, delivery, and administration challenges for COVID-19 will be significantly greater and will require unprecedented partnerships amongst manufacturers, supply chain and logistics professionals, governments, community leaders, health care workers, and individual citizens.

Key lessons we learned through our experience with Ebola that we can leverage moving forward include:

1. Public-private partnerships can be very powerful and effective, but also exceptionally complex and resource intensive. Bringing a diverse set of collaborators together requires trust and an “eyes wide open” effort with clear roles, expectations, and accountability defined for each collaborator.
2. Regulatory requirements and regulatory-manufacturing interplays are highly complex, requiring approval of both the product and the manufacturing process at each manufacturing facility for licensure. Accounting for these complexities requires more standardization and rightsizing specifically for preparedness goals, as well as better pre-work and harmonization when moving forward.
3. Numerous non-regulatory policies, such as trade, GMO, and BSL requirements can act as barriers to the free flow of raw materials and other component parts needed for vaccine manufacturing and quality testing. If these can be identified in advance, manufacturers and government officials can work actively to address them before they result in manufacturing delays.

Preparing for tomorrow's pandemic requires a new health security doctrine. For the past two years, I have co-chaired with former Senator Kelly Ayotte the Center for Strategic International Studies (CSIS) Commission on Strengthening America's Health Security. Senators Murray and Young are part of the Commission. Other congressional Members include: Representatives Bera, Brooks, Cole, and Eshoo, in addition to several security experts. In November 2019, the Commission released the *Ending the Cycle of Crisis and Complacency* report. The report lays out several

key steps that the Administration and Congress should take to create a sustainable basis for strengthening the health security of Americans.

We began the Commission's work with a simple understanding: health security is national security, in a world that is increasingly dangerous and interdependent.

Biological threats—outbreaks from natural, intentional, and accidental causes—are occurring more often and at the same time, the world is increasingly insecure, violent and disordered, and it is exactly in these danger zones where an increasing number of biological outbreaks occur.

Globalization and the rise of international trade and travel mean that an outbreak in a disordered setting with a compromised health system can quickly become a pandemic, threatening the United States and the rest of the world. Policymakers increasingly recognize these threats can undermine the social, economic, and political security of nations.

Unfortunately, this recognition occurs when a health crisis strikes—COVID-19, measles, MERS, Zika, dengue, Ebola, pandemic flu—and U.S. policymakers rush to allocate resources in response. Yet all too often, when the crisis fades and public attention subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold.

That realization led us to conclude: the U.S. Government needs to break the cycle of crisis and complacency and replace it with a doctrine that can guarantee continuous prevention, protection, and resilience. The Commission advocates for a package of strategic, affordable actions to advance U.S. health security.

First and foremost, we recommend permanent health security leadership as a central pillar of the National Security Council (NSC) by a credentialed and qualified expert.

Second, we need to invest directly and consistently, over the next decade, in the capacities of low-income countries. The best approach to protect the American people is to stop outbreaks at the source. The Global Health Security Agenda has a proven track record in building health systems and health security preparedness in low-and middle-income countries, financed through a \$1 billion Ebola emergency supplemental funding. We recommend sustaining that success, not disrupting or curtailing it.

Create a new non-discretionary budget authority that assures sustainable investments independent of budget caps or the necessity of annual budget trade-offs.

We recommend that the U.S. Government expand DTRA's geographic authorities to operate in all continents where health security threats exist. Furthermore, support for military overseas infectious research laboratories should be sustained. DOD biological research and development programs often focus on diseases not studied in other venues and result in medical countermeasures that would otherwise be delayed or not developed at all.

Congress should require national, state, and local governments to conduct regular preparedness exercises with updates to Congress on strengths and identified gaps in capacity.

The Commission also advocates that the U.S. Government strengthen and adapt programs and capacities to deliver health services in fragile settings that meet the special needs of acutely vulnerable populations, elderly, women, and children.

It is also important to prioritize a "one health" research agenda, including significantly augmenting research to understand the intersection of human, animal, and ecosystem factors that promote the emergence and spread of infectious diseases and how to reduce and contain these threats. This would include expanding the investment in animal and environmental health surveillance for infectious diseases, modernizing global public health infectious diseases data systems and tools, and seeking predictive insights and preemptive interventions, not just counter-measures and emergency response capabilities.

The last area of priority concern is to plan strategically, with strong private-sector partners, to support targeted investments that will accelerate the development of new technologies for epidemic preparedness and response. We assert that the U.S. Government should directly invest in the Coalition for Epidemic Preparedness Innovations, or CEPI, an international alliance that finances and coordinates the development of new vaccines to prevent and contain epidemics.

Again, thank you for the opportunity to testify in front of you today, and it is my sincere hope that we can work closely together to advance the U.S. health security agenda, so we are better prepared for the next pandemic.

[SUMMARY STATEMENT OF JULIE L. GERBERDING]

We must increase our posture of readiness for future infectious disease threats, with science, capability, and capacity in the U.S. and across the globe. We must ensure there is a robust market for innovation and continue collaboration, partnership, and strategic investments across the public-private continuum.

Unfortunately, recognition of the health security vulnerabilities tends to occur when a crisis strikes—COVID-19, measles, MERS, Zika, dengue, Ebola, pandemic flu—and U.S. policymakers rush to allocate resources in response. All too often, when the crisis fades and public attention subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold.

The U.S. Government should examine package of strategic actions to advance U.S. health security:

- Permanent health security leadership as a central pillar of the National Security Council (NSC) by a credentialed and qualified expert.
- Invest directly and consistently, over the next decade, in the capacities of low-income countries.
- Create a new non-discretionary budget authority that assures sustainable investments independent of budget caps or the necessity of annual budget trade-offs.
- Expand DTRA's geographic authorities to operate in all continents where health security threats exist. Sustain support for military overseas infectious research laboratories.
- Congress should require national, state, and local governments to conduct regular preparedness exercises with updates to Congress on strengths and identified gaps in capacity.
- U.S. Government must strengthen and adapt programs and capacities to deliver health services in fragile settings that meet the special needs of acutely vulnerable populations, elderly, women, and children.
- Prioritize a "one health" research agenda, including significantly augmenting research to understand the intersection of human, animal, and ecosystem factors that promote the emergence and spread of infectious diseases and how to reduce and contain these threats.
- Support targeted investments that will accelerate the development of new technologies for epidemic preparedness and response.

It is also essential to accelerate and enhance health care surge capacity planning, including:

- Conducting a thorough supply chain assessment to understand and address vulnerabilities.
- Examining how to best strengthen the Strategic National Stockpile performance to be the most effective and efficient during a pandemic.
- Augmenting supplies of antibiotics, intravenous fluids, and other medicines to sustain critical care.
- Formalizing augmented health care workforce contingency plans (credentials across states, retirees, volunteers, Department of Defense) and updating training.
- Institutionalizing telehealth and payment reforms; planning for needed in-person primary care, maternal health, mental health, substance abuse, and dental care clinics.
- Creating an interoperable pandemic health data network (instead of local and state stand-alone networks).
- Engaging and incentivizing the private sector in planning efforts.
- Exercising and improving plans with accountability from partners to follow through on lessons learned.

The CHAIRMAN. Thank you, Dr. Gerberding.
Welcome, Governor Leavitt.

**STATEMENT OF GOVERNOR MICHAEL O. LEAVITT, FORMER
U.S. SECRETARY OF HEALTH AND HUMAN SERVICES, SALT
LAKE CITY, UT**

Mr. LEAVITT. Thank you, Chairman Alexander, and Ranking Member Murray, and the Members of the Committee. A special thank you to Senator Romney for that generous introduction. Only months into my service at the Department of Health and Human Services, Dr. Gerberding and I participated in an emergency briefing on the H5N1 Avian Influenza. We were told it was a virus with pandemic potential.

The next morning a colleague of mine entered my office carrying a book. The book was entitled "The Great Influenza: A History of the Pandemic of 1918" written by John Berry. As he handed it to me, he delivered a message. It was, you need to understand this. He was right, not just for me, but for all of us. As I read the book and several others, as I saw briefings and learned from others, it quickly became evident to me that ultimately a pandemic would occur. And that is true today. We have it but we will have another and we need to be prepared. And at that point in time our country was unprepared. As the H5N1 continued to spread, as you indicated earlier Mr. Chairman, Congress was alerted and appropriated \$7.4 billion. Several Members of this Committee will remember that well.

Over the next three years, we undertook an aggressive effort to heighten our Nation's readiness for a pandemic. We sought to develop vaccine manufacturing inside the territorial boundaries of the United States. We wrote the national pandemic response plan. Congress passed legislation that has become a foundation of that plan, the PREP Act of 2005, Pandemic All-Hazards and Preparedness Act of 2006.

Those two bills, when added to Project Bioshield, which was passed in 2004, contain many of the legislative authorities that have been actually used in recent months. 54 pandemic summits were held in partnership with the Governors of each state and territory. There were three messages that were delivered at those summits, all three still critical even in the midst of a pandemic and certainly in the future. The first was just a reminder that pandemics happen. They are a biologic fact and a certainty. Pandemics occur, and when they do they obviously bring death and suffering and sweeping change.

The dilemma is that they happen far enough apart that we forget, as people have made the point already. The second message was that pandemics happen and every generation has to prepare on their own or they will be complacent as well. And finally, everyone needs a pandemic plan. States need a plan, local Governments need a plan, businesses, churches, schools, hospitals, because a pandemic is different than any other disaster that we deal with. It is intensely local.

In a terrorist event like 9/11 or a natural disaster like Katrina, the Federal Government's response is to call on unaffected states to send people and equipment to the disaster area. In a pandemic, those resources are to a large degree unavailable because they are needed at home. The message is clear that any state or any community that fails to plan thinking that somehow the Federal Gov-

ernment will ride to its rescue will be tragically mistaken, not because the Federal Government lacks the will, not because it lacks the wallet, but because the Federal response plan is based on focusing primarily on localized disasters.

Gratefully, the H5N1 Avian Influenza did not become a pandemic but the process has taught us a lot and the lessons we need to learn are still true today. I will just highlight four. First, the need to clarify roles between states and national Governments in advance. Second, having a vaccine is critical, but it is only the beginning. While we have manufacturing capability, fill, finish and distribution priorities will inevitably be a problem and they still need planning.

Third, providing situational awareness is a critical role of the Federal Government and principally CDC. The disease gathering—information gathering capability of the Federal Government needs investments and it needs modernization. And last, I will echo what my colleagues have said, pandemic preparation requires investment every year. Mr. Chairman, I look forward to our conversation.

[The prepared statement of Mr. Leavitt follows:]

PREPARED STATEMENT OF GOVERNOR MICHAEL O. LEAVITT

Good Morning, Chairman Alexander, Ranking Member Murray, and Committee Members.

Thank you for the invitation to appear before the HELP Committee again and for accommodating my remote participation.

The topic of this hearing is of great importance to me personally and to the Nation. I am pleased that this Committee has the foresight to recognize that even while we are still in the midst of responding to COVID-19, now is, in fact, the right moment to be capturing the lessons we are learning through this public health emergency, so we haven't long forgotten them by the next one and to be looking ahead to how to prepare for the next pandemic.

Before we turn to talk about the future, I want to acknowledge the significant losses we've experienced across this country over the past several months. For the families that have lost loved ones, I convey my greatest sympathies to you. For those who have felt the economic pain of job or income loss, I hope you are soon on the path to recovery. And to the heroes in the public and private sectors who have helped us respond to this emergency and keep essential businesses open to serve our communities, I thank you for your efforts. This pandemic has affected us all in profound and different ways, which is why we must learn from what we are experiencing today and take steps to set ourselves up for the best possible outcomes in the future.

The Foundation of Preparedness is Laid Long Before an Emergency

Shortly after becoming Secretary of the U.S. Department of Health and Human Services, the H5N1 avian influenza appeared to have pandemic potential. With support from President George W. Bush and Congress, my colleagues and I initiated an aggressive pandemic planning process. Part of our efforts involved energizing local and state preparedness by holding pandemic summits in 54 states and territories. These summits were full-throated efforts to sound the alarm and remind states and local communities that pandemics happen. When they do, there are no other natural or manmade disasters that can compare to their disruption. It was also an attempt to assure states understood that because the pandemic would unfold across the country at the same time, states and local communities also needed to prepare.

The experience reminded me that pandemic planning is made even more difficult because anything you do to prepare in advance of a pandemic seems like an over-reaction, and anything you say sounds alarmist. But after a pandemic starts, anything you have done to prepare seems inadequate.

We are, as a Nation, understandably focused right now on mitigating the health and economic harm caused by COVID-19. However, while we focus on the pandemic in front of us, we can't miss this opportunity to reflect on the lessons of COVID-

19 and apply those lessons, so we are more prepared for the next pandemic or public health emergency. Unfortunately, time is of the essence since the next pandemic event might be the second wave of COVID-19 this fall.

As Chairman Alexander points out in his white paper, “Preparing for the Next Pandemic,” action often only comes in response to a threat. That is human nature. It can be challenging to focus citizens and policymakers on public health preparedness when they are focused on other pressing issues of daily life. If a snake isn’t at your ankle, then you aren’t thinking about it.

The terrorist attacks on the United States on September 11, 2001, and the subsequent anthrax attacks ushered in a period of heightened awareness that homeland security and domestic preparedness are just as crucial to the Nation’s safety as foreign policy and a combat-ready military. In the subsequent five years alone, Congress passed, and the President signed into law, the Bioterrorism Act (2002), Project BioShield (2004), the Public Readiness and Emergency Preparedness Act or “PREP Act” (2005), and the Pandemic All-Hazards and Preparedness Act (2006). Collectively, these laws provided necessary tools that have been deployed in the years since, and some specifically in response to COVID-19, including;

- Preparedness grants to help states and health care providers prepare for and respond to public health emergencies;
- Authority for HHS to waive certain Medicare or Medicaid requirements during national emergencies to provide flexibility for hospitals and states to respond to a public health emergency;
- Establishment of a multi-year Special Reserve Fund and authority for HHS to enter contracts to procure medical countermeasures before they are approved;
- The Hospital Preparedness Program, which helps hospitals buy tangible resources like ventilators, mobile medical units, and pharmaceutical caches;
- Authority to the FDA to issue emergency use authorizations, which allow the use of medical countermeasures before FDA approval;
- Liability protections for companies, health care providers, and others involved in the distribution and administration of medical countermeasures in a public health emergency, except in cases of willful misconduct;
- The Covered Countermeasures Process Fund to compensate eligible individuals who suffer injuries as a direct result of a countermeasure administered or used under a PREP Act declaration.
- Establishing the Secretary of HHS as the lead Federal authority for the public health and medical components of responses to emergencies under the National Response Framework;
- Creating the position now known as the Assistant Secretary of Public Health Emergency Preparedness (ASPR) to coordinate HHS efforts to prepare for, respond to, and recover from disasters and public health emergencies; and
- Creating the Biomedical Advanced Research and Development Authority (BARDA) to fund the advanced research and development of medical countermeasures.

Cooperation by Federal and State Governments is Key to Response

It is my perception that Members of this Committee, in general terms, share an aspiration for the United States to be prepared to prevent, mitigate, respond, and recover from a public health emergency, whether deliberate, accidental, or natural. I also sense there is consensus that both the states and the Federal Government have an essential role in that effort. So, the age-old dilemma of how to divide responsibility between state governments and the Federal Government seems to be very much at play.

Having served as a Governor and a Cabinet Officer, I have come to understand that both the states and the Federal Government have different capabilities and roles to play. I dealt with this dynamic regularly because both the Department of Health and Human Services and the EPA had important missions and were heavily dependent on state partnerships to carry them out.

On matters related to public health emergencies, I view the Federal Government as excelling in two areas. First, the Federal Government collects and distributes money. While public health is a core function of states, the Federal Government is

a significant supporter of this state-based infrastructure. Second, the Federal Government provides leadership, support, and coordination to the states and local agencies that are the front lines of any response. As a practical matter, however, the Federal Government is challenged to execute uniformly across the entirety of this vast, diverse nation, and thus roles should be assigned with care. With those limitations, the Federal Government is highly dependent on states to meet emergency response needs.

I saw this very clearly when Hurricane Katrina struck in 2005. Our Department's role was to aid victims after their evacuation or rescue. I quickly understood that the Federal Government's emergency response system is in no small measure the aggregation of multiples state emergency response capacities operating under Federal coordination. Emergency response was done differently in Arkansas than in Texas or Florida. But each in their way, the states got it done. If we had insisted on absolute uniformity, the effort would have failed.

Shortly after Hurricane Katrina, we were required to prepare the Nation for a potential pandemic influenza. Once again, it became evident that the Nation's public health capacity was the aggregation of state and local public health organizations, acting with Federal coordination. Each state deployed its assets. Were some better than others? Yes. But the Federal Government simply does not and should not have sufficient capacity to deploy everywhere.

All disasters are local. When it is a hurricane or flood, particular areas of the country become the focus. While the response is led at the local level, the Federal Government is needed, as noted above, to step in to provide funding as well as leadership and coordination in some cases. But a pandemic imposes a unique strain on our system of response since the emergency is happening on such a wide scale all at once and requires resources and coordination in different magnitudes of scale. Because of this, pandemic preparedness requires special preparation and attention, and so I offer up five recommendations for your consideration.

Define the Division of Duties Between States and the Federal Government in Advance

Because of the Federal Government's involvement in many state domains, it should not surprise anyone that states have expectations that the Federal Government comes to the rescue, even in areas that are clearly state responsibilities. In a pandemic, there are times when the Federal Government cannot come to the rescue. Not because the Federal Government lacks a will or the wallet, but because many of the resources they would typically call on belong to the states. In a natural disaster like Hurricane Katrina, Federal emergency managers call other states and pay them to deploy their emergency response assets to the disaster area. In a pandemic, state resources are not deployable because they are needed at home.

In the current pandemic, at times there was confusion by some on matters such as the purposes of the Strategic National Stockpile (SNS), the procurement of personal protective equipment (PPE), and who had the authority to make public health decisions. In the middle of a pandemic, emergency finger-pointing is unproductive and costly. Roles and responsibilities must be communicated clearly before an emergency occurs to encourage swift decisionmaking and response.

In my view, there are some duties only the Federal Government can accomplish. For example:

- Support the research, development, and manufacture of vaccines and medical countermeasures, and approve safe and effective products;
- The stabilization of the economy through fiscal and monetary policy;
- Managing relationships with other countries;
- Supplementing states and local governments with emergency funding;
- Creating situational awareness by collecting data and research from the states and giving it a big picture perspective;
- Providing general guidance and assurance to the American people; and
- Interstate and intercontinental transportation.

There are also duties better handled by states and local authorities. Most of the state duties are execution-oriented. For example:

- Managing public health functions such as inspection, data collection, workforce;
- Making risk framework decisions (e.g., Red, Orange, Yellow, Green) in various areas;

- Management of health care delivery capacity;
- Communicating local conditions and guidance;
- Regulation of health care delivery;
- Conducting testing and contact tracing; and
- Public health enforcement.

The Federal Government Must Ensure and Maintain Domestic Capacity to Manufacture Vaccines for the Entire U.S. Population Within Six Months of the Emergence of a Virus With Pandemic Potential

Due to the unparalleled impact that a pandemic has on the health, economy, and security of the entire country, the Federal Government must ensure the capacity to domestically manufacture enough vaccines to protect all Americans. A pandemic virus does not stay within state lines. Just as the Federal Government must prepare to deploy military assets such as the Army Corps of Engineers when the U.S. homeland is attacked or devastated by a natural disaster, it must also prepare to develop and deploy life-saving countermeasures and vaccines. This understanding led President George W. Bush to make domestic vaccine manufacturing capacity a key pillar of the National Strategy for Pandemic Influenza.

Unlike seasonal vaccines or routine immunizations, there is no commercial market for most medical countermeasures outside of a public health emergency. No state alone, or even a group of states, can create and sustain such demand. Only the Federal Government has the financial and practical capacity to lead this effort.

Over the last two decades, Congress has taken steps to de-risk vaccine research and development by funding pre-clinical, clinical, and advanced research, giving the Federal Government authority and dedicated funding to procure countermeasures, and establishing liability protections.

On November 1, 2005, President George W. Bush requested \$7.1 billion in emergency funding for pandemic influenza preparedness activities, of which \$6.7 billion was for implementing the HHS Pandemic Influenza Plan. Over the next year, \$5.6 billion of that request was funded by Congress and allocated to HHS. In June 2007, HHS used some of these funds to retrofit existing domestic manufacturing facilities of U.S.-licensed biologics for pandemic influenza vaccine production. Over the years, additional funding has gone to support the Centers for Innovation in Advanced Development and Manufacturing (CIADM) to build warm base manufacturing capacity through both new and converted facilities.

These investments must be sustained over time, and unfortunately, they were not. As a result, we do not have the robust, warm base capacity we need for this and future pandemics. After initial Federal construction support, manufacturers bore the full cost and risk of maintaining these facilities. Several of the facilities were eventually sold and used to produce seasonal vaccines or as contract manufacturing facilities. They may eventually be made available for COVID-19 vaccine manufacturing.

HHS has announced contracts with manufacturers to buildup domestic manufacturing capacity for both COVID-19 vaccines and therapeutics using funds recently appropriated by Congress. This is the right move, and I'm glad to see it's being done. But we need to take a longer-range view and not wait until a pandemic has already hit our shores before making these kinds of investments. This approach should be a centerpiece of a long-term preparedness strategy.

There are several things that the Federal Government can do to increase and sustain domestic vaccine manufacturing capacity, including:

- *Support the research, development, and domestic manufacturing of seasonal influenza vaccines.* Domestic seasonal influenza vaccine platform technologies and manufacturing facilities are the foundation of domestic pandemic vaccine capacity. Increased domestic seasonal flu vaccine infrastructure investments can be leveraged to produce pandemic vaccines with similar scientific and platform technology profiles. The Federal Government can further support the U.S. domestic seasonal flu vaccine market through tax incentives, reimbursement strategies, research, development, and procurement contracts, and other public-private partnerships.
- *Utilize a federally Facilitated Vaccine Portfolio Strategy.* A successful pandemic vaccine strategy is not "one shot, and you're done." Once a virus with pandemic potential is identified, the Federal Government must utilize a portfolio strategy to support parallel research, development, and

manufacturing of multiple vaccine candidates. To execute this strategy, the Federal Government must have access to pre-designated domestic manufacturing facilities for each type of vaccine candidate technology (such as Messenger RNA (mRNA), cell, or egg-based) in multiple regions of the country. The Federal Government can expand beyond the current CIADM program by:

- Funding the warm base maintenance required to keep domestic vaccine manufacturing facilities, their personnel, and their technology up-to-date and pandemic-ready;
 - Entering into cost and risk-sharing agreements with commercial and academic partners to co-manage domestic vaccine manufacturing facilities;
 - Identify and pre-certify non-traditional contract manufacturing facilities, such as animal vaccine and agricultural biotech facilities, which can quickly convert to a vaccine or vaccine-component manufacturing facility in the event of a pandemic. Participating facilities could receive additional compensation for operating losses from forgoing manufacturing of their traditional business lines.
- *Leveraging Federal Contracting Authorities in New Ways.* While the Federal Government must ensure domestic vaccine manufacturing capacity, it cannot do it without the cooperation and innovation of the private sector. Most government contracts to support medical countermeasures are quite simple. The Federal Government gives money to one company for the research, development, or procurement of a specific medical countermeasure with demonstrated safety and efficacy for delivery on a particular schedule. Producing a nationwide supply of domestically manufactured pandemic vaccines requires the support of more complex business relationships. For example, the government may have several options for vaccine components, manufacturing facilities, and fill and finish capabilities. They need the flexibility to “mix and match” as science and needs evolve. If a vaccine manufacturer’s vaccine candidate fails in clinical trials, there must be an ability to use that same manufacturer’s facility, and perhaps even their personnel and supply chain to produce vaccines from other manufacturers with successful vaccine candidates. HHS can use their Other Transactions Authority (OTA), a widely used mechanism by other agencies, to enter into contracts with a consortium of companies to spread risk over several different vaccine candidates.¹ Other useful authorities exist under DOD programs with similar interests.
 - *Recruiting Federal Employees with Vaccine Manufacturing and Procurement Experience.* Every day of my tenure as Secretary of Health and Human Services, I was impressed by the knowledge, expertise, and commitment to health and public service of the HHS staff. They each bring valuable expertise to their roles. One area that needs additional focus is ensuring that the team tasked with managing and executing the Federal domestic vaccine enterprise have technical experience in vaccine manufacturing and procurement. A further area of required expertise is familiarity with flexible and complex contracting and procurement authorities that may involve other departments and sophisticated performance metrics.
 - *Understand That the U.S. Isn’t the Only Vaccine Game in Town.* With the increase in global partnerships to develop vaccines for use overseas, U.S. vaccine manufacturers have several potential government and non-government partners to choose to do business with. One executive from a COVID-19 vaccine manufacturer stated that they did not seek Federal funding because “Our focus was to move as quickly as possible, and we really didn’t want to . . . spend a month negotiating with the U.S. Government.”² The domestic vaccine supply of the United States is put at risk when U.S. vaccine manufacturers begin to see contracts to manufacture vaccines for foreign countries and global NGO’s as more reliable options

¹See generally, “Rapid Medical Countermeasure Response to Infectious Diseases: Enabling Sustainable Capabilities Through Ongoing Public-and Private-Sector Partnerships: Workshop Summary (2016.)” available at <https://www.nap.edu/catalog/21809/rapid-medical-countermeasure-response-to-infectious-diseases-enabling-sustainable-capabilities>.

²See generally, “BIO: What’s the ROI on a COVID-19 vaccine? We have no idea, says Pfizer.” by Arlene Weintraub, FiercePharma, June 11, 2020. Available at <https://www.fiercepharma.com/pharma/bio-what-s-roi-a-covid-19-vaccine-we-have-no-idea-says-pfizer>.

than partnering with the Federal Government. The U.S. Government needs to be a consistent, efficient, and transparent contracting partner.

We Need Modern Day Data Collection and Aggregation to Guide Our Response

Detailed and accurate data is essential for the Federal Government to coordinate and states to execute a response to a public health emergency. The lack of an established process to share near real-time data electronically leads to duplicative, time-consuming processes at CDC and other Federal health agencies, to aggregate and organize data already stored electronically at the state, local, tribal, and territorial levels.

There are currently two major types of datasets tracking the COVID-19 outbreak: a Federal dataset run by the CDC, and state-based data sets. A recent survey showed substantial differences between state and Federal data on COVID-19 testing. According to the survey,

- 28 states and the District of Columbia's test numbers reported by the CDC fall within 10 percent of the total test numbers reported by the states and only a few match precisely;
- 22 states' test numbers reported by the CDC fall outside the 10 percent range—and some of the discrepancies are very large; and
- 13 states' total test numbers reported by the CDC diverge from state reporting by more than 25 percent.³

Some of this confusion comes from conflicting reporting requirements for laboratories and states, while a critical element is the lack of interoperable software capacity to collect and aggregate test results.

While Congress appropriated \$500 million to support improved public health data systems as part of the recent CARES Act (PL 116-136), money alone will not solve the problem. HHS should work with the private sector to acquire the software capacity to collect and aggregate test results submitted by state and local public health agencies but coordinated and maintained by the CDC. HHS should give guidance and technical support to the states so they can each collect and submit their data in a manner compatible with CDC's, to establish the near-real-time biosurveillance system that is necessary to detect, identify, and model emerging infectious diseases.

Better data faster means a better public health response. It also allows Federal and state governments to quickly predict how a disease will impact different populations and help identify high-risk individuals and communities that need additional interventions.

We Should Modernize and Sustain Our Public Health Infrastructure

The public health function of our state and local governments is being tested in many ways through the current public health emergency, and it is clear that it is in desperate need of modernization. In part, this is due to budget pressure at the state level to prioritize Medicaid spending or other health priorities over investments in public health. Public health is often a forgotten function of government, working quietly behind the scenes and not drawing attention to the part it plays when things are going well. But the COVID-19 pandemic has thrust public health into the spotlight, and it is now getting the attention it warrants.

The CARES Act included funding to make essential upgrades to our public health infrastructure, and I hope that this funding is used wisely to help states and local agencies make long-term improvements. I believe that upfront investments in public health modernization at the state and local level save the Federal Government money over time. For example, if state and local public health agencies maintained the capacity to trace contacts for emerging infectious diseases and surge that capacity as necessary, Congress wouldn't need to come up with such large emergency supplemental appropriations to respond to every emergency. With a strong foundation of well-trained personnel, IT infrastructure, and surge capacity steadily funded, it wouldn't be as great of a strain to respond to a pandemic or any other health emergency.

³See generally, "Assessment of the CDC's New COVID-19 Data Reporting" The COVID Tracking Project, May 18, 2020. Available at <https://covidtracking.com/documents/CDC-Report-CTP.pdf>.

This is not just an issue for governments. Right now, many employees of large and small businesses alike are having their livelihoods threatened by the economic impact of COVID-19. There can be no real economic recovery until we have public health risk mitigated. This connection between public health and financial well-being provides strong incentives for employers and the business community to step up in new ways to partner with and support state and local public health agencies.

Preparedness Needs to Have the Same Urgency as Response

Finally, one of the goals of preparedness should be to identify potential threats and responses before they happen. Preparedness exercises must be done regularly at the Federal, state, and local government levels, as well as by the private sector, communities, and families. In many places, these exercises are a standard practice already, and I think that they should become more widespread, more frequent, and should focus on known and unknown threats. One of the things we did at our business was develop a continuity of operations contingency plan for a pandemic or economic downturn. We didn't know if either or both would happen, but when they did it allowed us to transition to remote work and take other quick measures to mitigate the impact of COVID-19 on our clients and employees. Similarly, I reached out to family members and encouraged them to develop preparedness plans.

Right now, it feels a bit like we are walking out onto an icy lake. We're not sure how thick the ice is. So, you walk a few feet, stop, and pause, and get a sense of whether you feel comfortable or not, whether you hear cracking sounds. If you do, you move back, but if you don't, then you move forward. And that's where we are as a country. We have seen individuals and institutions scramble over the last few months to develop risk frameworks to guide public health and economic decisions—essentially frameworks for how we safely walk across the icy lake. These are the “Red, Orange, Yellow, Green” and “Phase 1, Phase 2, Phase 3” decisions that Governors and Mayors must make. After the pandemic, these officials should be encouraged to preserve these risk frameworks so they can build on them in future emergencies. The specific details of any given plan may need to change, but the mindset of thinking in advance and gaming out a response should not.

Conclusion

Thank you for the opportunity to address this Committee. I agree with Chairman Alexander that now is the time not just to respond, but to prepare. This pandemic is not over. New cases are still rising in some locations, and others that have seen a decrease may have a second wave in the fall or next year. That means we still have time to prepare for what this disease may bring and for future public health emergencies. As the Committee looks at different policy recommendations, I remind you to consider how the Federal, state, and local governments, as well as the private sector, communities, and individuals, can all play a role. We are “all in this together” in pandemic response and recovery but must now extend this mentality to preparedness as well.

I look forward to answering any questions you have.

[SUMMARY STATEMENT OF MICHAEL O. LEAVITT]

This pandemic has affected us all in profound and different ways, which is why we must learn from what we are experiencing today and take steps to set ourselves up for the best possible outcomes in the future.

All disasters are local. When it is a hurricane or flood, particular areas of the country become the focus. While the response is led at the local level, the Federal Government is needed to step in to provide funding as well as leadership and coordination in some cases. But a pandemic imposes a unique strain on our system of response since the emergency is happening on such a wide scale all at once and requires resources and coordination in different magnitudes of scale. Because of this, pandemic preparedness requires special preparation and attention, and so I offer up five recommendations for your consideration.

1. Define the Division of Duties Between States and the Federal Government in Advance.

There are some duties only the Federal Government can accomplish:

- Support the research, development, and manufacture of vaccines and medical countermeasures, and approve safe and effective products;
- The stabilization of the economy through fiscal and monetary policy;

- Managing relationships with other countries;
- Supplementing states and local governments with emergency funding;
- Creating situational awareness by collecting data and research from the states and giving it a big picture perspective;
- Providing general guidance and assurance to the American people; and
- Interstate and intercontinental transportation.

There are some duties better handled by states and local authorities:

- Managing public health functions such as inspection, data collection, workforce;
- Making risk framework decisions (e.g., Red, Orange, Yellow, Green) in various areas;
- Management of health care delivery capacity;
- Communicating local conditions and guidance;
- Regulation of health care delivery;
- Conducting testing and contact tracing; and
- Public health enforcement.

2. The Federal Government Must Ensure and Maintain Domestic Capacity to Manufacture Vaccines for the Entire U.S. Population Within Six Months of the Emergence of a Virus with Pandemic Potential.

3. We Need Modern Day Data Collection and Aggregation to Guide Our Response.

4. We Should Modernize and Sustain Our Public Health Infrastructure.

5. Preparedness Needs to Have the Same Urgency as Response.

The CHAIRMAN. Thank you, Governor Leavitt. And thanks to each of you. We will now begin a five-minute round of questions. I would ask the Senators and the witnesses to try to observe the five-minute limit. We have a lot of Senators who want to talk to these very distinguished witnesses. I will begin.

When we are through, I am going to ask each of the witnesses to answer this question, if you were the king or the queen and you could do two or—let's say three things to be ready for the next pandemic, what would those three things be? Now, Dr. Frist I only have five minutes, but let me start with you with this question. Someone might ask, why are you taking time in the midst of this pandemic to talk about planning for the next one? How would you answer that question?

Dr. FRIST. Yes, I think the points are made. We need to end this pandemic. But, we don't know even when a second surge is going to come. So as much as we can do to prepare that infrastructure and the structure itself for the next pandemic, the next emerging threat, it will apply to what we are doing now.

The sense of urgency is simply that we have identified pretty quickly in the last several months the needs that are out there, which we have talked about in this hearing thus far, and now is the time to go ahead in a parallel fashion, pass legislation, and I would add things like the telehealth hearing that you had the other day, good things you can do now which will make either a second surge preparation more adequate or another pandemic which will occur more tolerable in the future.

The CHAIRMAN. Thank you. And as each of you said, memories are short and we will move on to the next issue if we don't deal with this one now. Now, let me go to Dr. Gerberding and Governor Leavitt first. Let's talk about manufacturing. Let me drill down on

that a little bit. We dealt with manufacturing before. We built three manufacturing plants.

Today, we have 10, 12, 14 of vaccines that are racing toward trying to produce several hundred million doses by early 2021. Ideally, what sort of manufacturing capacity should the Federal Government have on hand, ready to produce these doses and to distribute them properly? Can we just rely on the private sector to do that or should we have our own manufacturing plants? I thought we did that with three manufacturing plants. Are they adequate? What happened, Governor Leavitt?

Mr. LEAVITT. As time has gone on and the urgency has diminished, we have seen the ongoing funding of those, particularly in the area of maintenance and keeping them warm—we invested and I think properly invested in partnerships to enhance it. What I think we did not do adequately as a country over the course of time is maintain them in a way that they were warm and could be stood up quickly. I will also mention that we have a big challenge in being able to fill and finish and distribute that infrastructure.

Yes, the private sector can in fact be very important in that process because that infrastructure exists, but planning how it will be distributed, who will get it first, etc. is a big need and it is one that will need to deal with, to Senator Murray's point, even now. So if we have time, and I know that the Department is likely working on this, but that is a critical need.

The CHAIRMAN. Dr. Gerberding, you have seen it from both sides, the Government and now the private sector. Should we build manufacturing plants or pay for the private sector to build manufacturing plants for the future, or can we remodel those we now have? What should we do? What is a smart strategy in manufacturing for the Federal Government?

Dr. GERBERDING. One thing Senator to point out about the manufacturing that has been built in these partnerships is that was primarily targeting influenza, and influenza vaccine is a dual-purpose vaccine because of course we have seasonal flu every year and the idea would be they can call upon those seasonal flu operations to flex in the case of a pandemic as we did in 2009 when we were experiencing H1N1 pandemic. Broadly speaking, the few large manufacturers of vaccines that are still in business are nearly at capacity just to create the vaccines that we need for day-to-day purposes and immunizing our population against known threats.

We clearly need an emergency capacity buildup. And in my view that is best done in private, public partnerships. We may get to a point, as we experiment with these 130 products that are in various stages of development for this pandemic, where we understand the concept of a platform approach, meaning that we can repurpose a given facility easily for the next problem that comes along and that we don't have to go back to ground zero and build a new each time a new and unfamiliar need for vaccine arises.

I think a partnership model works best and we must not remove the incentives for the biopharmaceutical industry to continue to innovate. It is that innovation that has gotten this far this fast in this particular pandemic, but at the same time we can't invest at scale for 130 candidates. We have to make choices. And that is where the NIH—

The CHAIRMAN. My time is up and I want to respect the five-minute limit as interesting as the comments may be. Thank you.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. Thank you to all of our witnesses. Really appreciate your testimony today. Dr. Khaldun, the United States COVID-19 response has failed to keep black and latino families, Indian tribes, and other people of color healthy and safe. Disproportionately high numbers of people of color are becoming seriously ill or dying from COVID-19.

This tragic reality is driven in part by long-standing systemic racism and underinvestment in communities of color, which have contributed to significant health disparities, but it is also a result of this administration's failure to take these disparities seriously and devote attention and resources to the communities most in need of assistance. I am going to ask you today, what can we do to address the immediate impact of the pandemic on communities of color?

Dr. KHALDUN. Thank you, Senator Murray, for that question. So we in the state of Michigan have identified these disparities very, very early. The Governor actually announced quickly a task force to really understand why these disparities exist and then to develop specific recommendations for how we address them. So some of the things that we have done is making sure that testing is accessible in minority communities.

We actually worked with the communities to bring testing to places where they normally wouldn't have access to care. We have also eliminated costs for a lot of our testing sites so you don't have to worry about it if you don't have insurance or even if you don't have a primary care doctor. A lot of our sites in Michigan for testing, you don't have to have a doctor's order in order to be able to get a test done.

Then we have to think about all of the people who have been deemed essential during this pandemic and been coming out of their homes to have to work and how we can protect them. So making sure they are not allowed to lose their jobs and that they get supports at home so that they can be able to be as safe as possible.

Senator MURRAY. Thank you. Obviously, we have to work on this. We can't ignore it as we have been doing and I think this is a really important point we need to think about not just for today, but moving forward, so thank you. Dr. Gerberding, we have a very robust system for evaluating vaccines.

Unfortunately, we have seen some concerning polling already suggesting some Americans would not be willing to get a COVID-19 vaccine. So the time to build that confidence is right now and a number of experts are expressing concern that President Trump's vaccine acceleration process known as Operation Warp Speed could undermined confidence in COVID-19 vaccine, particularly, if the public perceives that a vaccine was rushed out for political reasons or without rigorous review. What specific commitments should the administration make right now to build public confidence in a vaccine?

Dr. GERBERDING. There are two things that I would recommend, one is transparency about exactly what the safety assessments are and that involves the participation of the ACIP at the CDC, the

FDA, and several of the other scientific organizations that have an oversight of that. The second thing that I would propose is that the safety be monitored by the National Academy of Medicine.

This is something that has happened many years over the arc of childhood immunizations and when I for example had responsibility for administering the smallpox vaccination program for First Responders, it was the National Academy of Medicine that monitored the safety of that program and helped us identify very early that there was a safety signal. So I think involving the scientific community, credible experts, apolitical and orientation is really going to be a very important part of building this trust.

Senator MURRAY. Okay. And a comprehensive plan, I would assume you would agree?

Dr. GERBERDING. Absolutely. Yes, absolutely.

Senator MURRAY. Senator Frist, good to see you again. You have repeatedly emphasized the importance of strong public health funding and argued that insufficient public health investments have met state and local public health departments are responding to COVID-19 with, “one hand tied behind their backs” and you have argued for the creation of a \$4.5 billion mandatory annual investment in public health infrastructure. I think this is something that is critically important and I want to ask you, if we were to create such a fund, how do you predict the U.S.’s response to the next infectious disease outbreak would look different than what we currently have?

Dr. FRIST. Well, I think all or many of the panelists have empathized this importance of the sustained funding and the public health infrastructure fund is one option to do that, one that I do support.

A strong public health system can quickly alert us to problems. You can build resilient communities that are healthy and socially connected. It creates a reserve capacity to respond to an emergency of any kind which is why I co-authored that op-ed with Senator Daschle and the FDA Commissioner Andrew Von Eschenbach in support of what was a \$4.5 billion public health infrastructure fund. It is really interesting.

We have not consistently provided the type of funding this needed to build an ongoing strong public health system. If you look back at the Great Recession, frontline state and local health departments have lost more than 56,000 positions due to funding cuts. These are the people we need whether for contact tracing or epidemiology. They have been lost now over the last about 10 years.

Strong predictable investments from the Federal Government will ensure that public health departments here on the ground, in your community are fully staffed and resourced and able to handle the needs of today’s demand for things like the contact tracing force.

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

The CHAIRMAN. Thank you, Senator Murray. Senator Burr is next and for 17 years he has been busy writing many of the laws we are talking about today.

Senator Burr.

Senator BURR. Chairman, thank you. Thank you for that recognition. Senator Frist, Secretary Leavitt, Dr. Gerberding, Dr.

Khaldun, welcome. We value the ability to pick your brain on this. I think this is probably the most important period in this pandemic it is when we begin to do the after action review and figure out what worked, what didn't work, what needs to be changed, and it is important that Congress go through this process.

When we moved the last PAHPA reauthorization bill out of this Committee, I reminded my colleagues at that time, this was by no means the finish line and much work remained for us to be better prepared. Dr. Gerberding, you were in a unique situation at CDC and now in the private sector, but in your testimony, you advocate for a greater use of public-private partnerships. During our last HELP Committee hearing on the pandemic, I urged the CDC to put these types of collaborations in place so that we could leverage innovative technology companies and our ability to detect, to identify, and detract threats including emergency infectious disease.

Given your experience at the helm at the CDC, why was the agency so ill-equipped to put these types of agreements in place before the pandemic and what would you recommend to CDC going forward as it relates to public, private partnerships?

Dr. GERBERDING. Thank you, Senator. And I must say I don't know what the CDC was or was not doing in collaboration with private sector partners. Just seeing it from the outside looking in, there has been a tradition of recognizing the importance of the private sector when I was there. We had desks in the Emergency Operation Center for a number of private-sector entities that we recognized as important in the supply and stockpiling logistics and testing, etc.

But I will also say that there are some complexities of working with the private sector and Government. And I just go back to what Governor Leavitt said in the context of planning for influenza pandemic where we recognized that the Federal Government has a critical role but we had learned then and what I think we are seeing now is that the private sector is powerful, and leveraging that power and those resources is essential to being able to scale a national response.

Senator BURR. Well, I thank you for that. I think that the deficiency was most evident in testing and the inability for CDC to reach out to the private sector. Thank goodness PAHPA reauthorization allowed greater expansion of authorities by the directorate FDA to use emergency use authorizations to set up these public-private partnerships, and we have probably more capacity than is being utilized in testing nationwide today. One of the areas where efficiencies can be gained in vaccine manufacturing and production is through the use of platform technology, Dr. Gerberding.

For example, Merck licensed the Ebola vaccine platforms being used to develop coronavirus vaccine. How can we enhance the coordination between innovators, BARDA, FDA to ensure that these platforms against these threats is as efficient as possible when the need arises? In other words, how do we keep these platforms as an approved entity and we only do the clinical proof on what we are trying to treat off the platforms?

Dr. GERBERDING. I think BARDA is well on its way to being able to accomplish that. I think CEPI is another model, the Coalition for Epidemic Preparedness Innovation. But what needs to happen is

not necessarily having a focus on efficiency. We need to have a broader expectation that will invest in a lot of things that won't pan out. If we aim for efficiency, we are going to be slow and miss the boat. We need to be prepared to experiment, to try a broader array of things, and I continue to think that BARDA is critical to the coordination of all of that.

Senator BURR. Thank you for that, Dr. Gerberding. This question is to my good friend, Mike Leavitt and Bill Frist. We did what I thought was revolutionary at the time with the investment in three flex manufacturing facilities for vaccines. And the testimony has been correct that they were designed for the annual influenza or some variation, at the time H1N1, H5N1, and they are very difficult to program over and surge in front of that vaccine for coronavirus. Can both of you give us what you think this Committee should do legislatively to encourage the creation of some type of multi-manufacturing facilities that can be utilized when the Federal Government feels a national need?

Mr. LEAVITT. I will respond quickly. First, just annual appropriation, supporting it when there is not a crisis is the first thing that has to happen because it is keeping facilities warm and keeping access to them during those periods that makes it possible when there is a need.

Senator BURR. Senator Frist.

Dr. FRIST. Yes, and Senator Burr, again, thank you. I just 17, 18 years ago I remember all the nights in the majority leader office as you helped put together BARDA so thanks for that. You know, I think it is going to come down a little bit to what Senator Murray asked about increased funding and how we do it. I am on record as supporting a mandatory appropriation about \$4.5 billion fund but also I mentioned my testimony the HD, which is an annual appropriation which really comes to what Governor Leavitt talked about.

An annual appropriation in a sort of an advanced category would allow you to fund it to BARDA individually, to NIH individually, discretionary funding, and to the NIH all three, but it would be annual and it would be annual appropriations with oversight by the U.S. Senate, by the Congress itself. That does have the advantage of this timeliness of incorporating science, what is needed at a particular time and guarantees that funding in a sustained way. So I would also encourage looking at that because that immediacy of what is needed to years from now is going to be very different as we just saw with flu vaccine manufacturing versus the current manufacturing.

It is going to have to be flexible and it is going to have to be nibble, and you might consider, even though it is not directly in your Committee, that sort of annual appropriation oversight be able to support the type of public-private partnerships in this area of manufacturing.

Senator BURR. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Burr. Senator Casey is next and he too has been very involved being the principal Democratic co-sponsor of the last reauthorization of the PAHPA bill, I believe.

Senator Casey.

Senator CASEY. Mr. Chairman, thank you very much. And thank you for noting that, and I am grateful for the testimony of our witnesses and the wisdom and experience they bring to bear on these issues for this hearing. I wanted to start with Dr. Khaldun regarding what you have seen in a lot of what is in your testimony with regard to the challenges faced in the state of Michigan like so many other states. I know that Detroit, obviously one of the hardest hit cities in the country, just like all major cities, like Philadelphia have been hit, especially in the black community and that is true in so many of our urban areas.

I know that in your testimony, I guess when you compare the percent of the population of African-Americans in Michigan, about 14 percent but 40 percent of the deaths and more than 30 percent of the cases. In our state the death number, percent might be a little lower, but it far outstrips the percent of the population. We have had to date at least 1,368 deaths of black Pennsylvanians from COVID-19. So I have two questions, the first one is, how have the social determinants of health impacted people's ability to protect themselves and their families from the virus and from the COVID-19 disease?

Dr. KHALDUN. Well, thank you, Senator Casey. So absolutely, when you talk about the health disparities that we are seeing not just in Michigan, but across the country, those social determinants of health, so housing, transportation access to healthcare, poverty, those are things that we believe are really contributing to the disparities in COVID-19 as they contribute to other health disparities.

Again, people who are of color are more likely to live in poverty. They have been more deemed as essential workers coming out of their house instead of being able to safely work from home, needing to take public transportation, living in crowded or perhaps unsafe living conditions making them more likely to spread COVID-19. So those are some of the things that we have seen in Michigan that we believe are contributing to the disparities.

Senator CASEY. I guess as well some, many I should say, African Americans are the ones who are on the frontlines and often the very front of the front line. Is that correct?

Dr. KHALDUN. Yes, that is correct, Senator Casey. So again going back to the fact that people of color are more likely to live in poverty and therefore more likely to have those lower wage jobs, some of our grocery store workers, bus drivers, those types of jobs. And those are the exact people that when across the country we had stay home or stay safe orders, a lot of those people were unable to stay at home. They had to come out and I believe that contributed to the disparities and the disparate numbers of deaths that we have seen.

Senator CASEY. Thank you, doctor. The second question I have is, we know that public health is driven at a very much a state and local level. But obviously this pandemic has reminded us that all levels of Government need the help of the Federal Government. And I guess when you step back and look at where we have been, what parts of the response so far do you believe require coordination and the convening power of the Federal Government?

Dr. KHALDUN. Yes, so I think that very early on, and first let me actually start by saying I really appreciate the support of my Federal colleagues at the CDC who since January has been really supportive of us at the state and local level in Michigan. But I do think that we should have had, as I said in my testimony, a more urgent testing response in our communities.

Early on in my state labs, we were preparing in January actually to be able to perform the test, but we ran into delays and I am sure that in Michigan because of those delays, there were people who weren't tested and the disease was spreading before we even knew it. So I believe that a coordinated strategy at the Federal level would have helped us in that way. Also with PPE, we had to fight other states and even local Governments in being able to get access to PPE and it really delayed us and I think exposed many more people to the virus in Michigan.

Senator CASEY. Finally, Dr. Gerberding, I want to thank you for your help in Pennsylvania helping our citizens and our state to better understand what we have been up against and am particularly grateful for that. I guess in the 30 seconds we have, you spoken about an immunization infrastructure. Could you fill in for us, I know your testimony spoke to this, the kind of the who, what, when, where, the mechanics of that, who should be involved and what role the Federal Government should play?

Dr. GERBERDING [continuing]. Are just beginning to improve that for adolescents and adults but it is fragile and I think one of the most important things that is not getting enough attention right now is the fact that distributing this vaccine, even in the United States, is going to be incredibly challenging, making the decision about who goes first, how to allocate doses as they become available, and how to sustain that atmosphere of trust and willingness to step forward and receive it.

The infrastructure for that is going to be local and that means that we need to support our local and State health officials in getting ready to make those really hard decisions and implement that really macro-program.

Senator CASEY. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Casey.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. Dr. Frist, it is great to see you again. We have missed you. One of the lessons from the COVID pandemic is that our country is far too dependent on foreign manufacturing of drugs, diagnostics, and medical supplies. For example, about 80 percent of the basic components used in medicines, the active pharmaceutical ingredients, are coming from China and India for our U.S. market. The exact dependence remains unknown since there is no API registry. Well, what happened is just about the time that the COVID-19 epidemic hit the United States, India stopped exporting 26 APIs and finished drugs.

The CARES Act includes portions of legislation that I introduced with Senator Tina Smith, the Meds Act, that includes greater reporting requirements on the sources of APIs as well as redundancy plants and tended to deal with shortages, but are there specific incentives that the Senate should consider specifically to encourage

domestic manufacturing, including perhaps tax incentives or greater investment in FDA's emerging technology program?

Dr. FRIST. Thank you, Senator Collins. I think this whole coordination of procurement is huge and in the Committee's white paper, you talked about coordination, procurement as being a very clear and important Federal responsibility. As you pointed out, we have been inadequately prepared here. We have seen it day in and day out and we can do so much more to establish this resilient domestic right here at home manufacturing lines, detracting of supply chains, ensuring a robust support of the national strategic stockpile.

The incentives will have to be financial. The real problem in these public, private, or the real challenge in these public, private partnerships is this lack of continued funding over time to adjust to the market, where on the private sector, they will be generous and they will be patriotic but at the end of the day, they do need to report fiscal responsibility. So we have to step in and whether it is with direct tax credits, whether it is with a funding stream by an artificial market that is set up over time, we do have to keep a revenue stream out there that is dependable, it is sustainable, and that is long term, and that is flexible because it will change year to year in terms of what those manufacturing, the specific manufacturing needs are.

As for the testing itself, the tests are remarkable right now between the public-private partnerships and the private sector moving ahead and is being revolutionized before eyes in a very quick fashion. Now, it came too late. It came too late but now there is an encouraging more and more of that with some sort of financial incentive.

Senator COLLINS. Thank you. Dr. Gerberding, last month the Aging Committee held a hearing on the impact of the coronavirus on older adults living in nursing homes. And that hearing reaffirmed my belief that a baseline test for all residents and staff, not just those that are symptomatic, is necessary to prevent outbreaks. COVID-19's impact on long-term care settings directly intersects with the stark racial disparities we are seeing, and unfortunately, remarkably Maine has the Nation's worst COVID-19 racial disparity.

Many of the worst outbreaks that have occurred in Maine are in nursing homes and the CDC reports that some 40 percent of those health care workers that have tested positive were identified as black or African Americans. As a former director of the CDC, what do you recommend as the best way for Congress to help address this racial disparity among those that are the frontline workers in our nursing homes?

Dr. GERBERDING. Thank you, Senator. Obviously we need to test symptomatic people and their context but to me the third most important reason to test are the people who are working in these known high-risk environments and clearly nursing homes are among those at the top of that list. Those are intrinsic hot spots and we need to test often and test everyone who comes and goes from those centers until such time that we can demonstrate that transmission has been contained.

I can't say enough about how critical it is to not overlook the most vulnerable people and that includes the elderly people but also those who are vulnerable on the basis of underlying conditions and often that tracks with the racial and ethnic disparities that you are alluding to. It is a very difficult challenge. The solution to it is multifactorial.

It really is a reflection of the social determinants of health as much as anything else and that is a long answer, and I know I have a short period of time, but the first step is to make the measurement clear and transparent so that we all have to stare it in the face and recognize that we are not successful until we deal with that challenge.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you, Senator Collins.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman, having trouble with my mute button here.

The CHAIRMAN. You are on now.

Senator BALDWIN. Great. Thank you. So I wanted to start by just reflecting that every Member of this Committee would love to be able to turn the page on the current pandemic and start planning for the next one, but the cases of COVID-19 and hospitalizations continue to rise and we can't divert our attention from the ongoing crisis. And I think it is very clear that the administration has not yet learned a critical lesson particularly about worker safety. Without enforceable worker safety standards, workers and their families are needlessly put at greater risk when they go back to work.

Guidelines from the CDC have not been enough, and yet the Occupational Safety and Health Administration has failed to move forward with mandatory and meaningful rules for employers. In response to disturbing widespread reports of safety concerns leading to preventable illnesses and deaths, I introduced the COVID-19 Every Worker Protection Act. This bill would require OSHA frankly to do its job and to issue an emergency temporary standard that establishes a legal obligation of all workplaces to implement infectious disease exposure control plans that would keep workers safe during the COVID-19 pandemic.

Dr. Khaldun, do you believe that giving employers clear and mandatory rules through an emergency temporary standard would help improve our public health response by protecting workers, their families, and their communities during a pandemic? And correlated with that, why is a focus on worker safety particularly important for communities of color and others who have been disproportionately impacted by COVID-19?

Dr. KHALDUN. Thank you, Senator. So, absolutely. The health and safety of our frontline workers has been incredibly important. I think it is really unfortunate that a lot of our frontline workers have been infected by or even died from COVID-19. In the state of Michigan, our Governor did issue an executive order that established robust protections for our workers so that is incredibly important. It goes back to these social determinants of health and the fact that communities of color are more likely to live in poverty and have these lower wage jobs. So again, they have had to come out

of their homes instead of being at home during this pandemic, so it is incredibly important.

The CHAIRMAN. Senator Baldwin, we have lost your signal and we will wait just a moment. See if we can regain it. If not, we will go back to you—why don't we move on to Senator Cassidy and then we will come back to Senator Baldwin, let her reclaim her time when ever she regains her internet signal.

Senator Cassidy.

Senator CASSIDY. Thank you all for being here. I appreciate your service in the midst of an epidemic. I have got questions to begin with, with Mr. Leavitt and Dr. Gerberding. Let's kind of reflect on your past history, if you will.

Dr. Gerberding, all of you are recommending lots more money for the Centers for Disease Control and public health, mandatory spending almost most of you. If you are not saying that specifically, it seems as if you wish it to be mandatory. There is a lot of folks out there that feel as if the CDC has not responded to the challenge with the money that they have been given and before significant more dollars are given, would like to see some sort of recommendations for reform. So some of the criticisms made, which I have made some of them by the way, whether it is right to make them are not, a little bit slow to the mark, laborious contracting with lots of red tape, a loss of focus, afraid to take bold action, and they misjudged terribly the rapidity by which the virus would spread throughout our community.

Now, if we are going to ask to give them another \$4 or \$5 billion and more and more and more, I think it is fair to say, is there reform that could be instituted, that you are just not putting more money into a system which is inherently not working well, but rather more money in system which is streamlined so that it can work better? What are your thoughts on that, may I ask?

Dr. GERBERDING. You know, I have known the CDC for a long time before and after I worked there and I can say that the scientists who are there are national treasures and the scientists who are there leading this pandemic are the same scientist that were there when I dealt with SARS. So I don't think it's a deterioration of the science or the scientific capability of the agency.

I do think the scale of this response would test any public health agency as it has around the world, but I also do think that modernization is a word that really needs to be the framework for considering where do we go from here. One of the things that I would acknowledge, and maybe Governor Leavitt would like comment, is that when we did extensive rehearsal for influenza pandemic preparedness, again involving some of the very same people, we rehearsed everything except one thing, we didn't rehearse testing because in influenza you don't rely on the test to make the diagnosis and make the decisions. So the whole apparatus necessary to scale test to 300 million people was not something that we practiced and we made—

Senator CASSIDY. Let me ask, and I can concede that although it seems as if there could have been—because I understand in different times people were concerned about bubonic plague and other kind of exotic infectious diseases coming in, so it seems that testing could have been imagined as an issue, but there has so far not

been a plan I have seen to actually go beyond mitigation into actual suppression. And so we have communities that have moved beyond litigation that should be in suppression, but again, we don't see the plan for that. So what would be your response to that?

Dr. GERBERDING. Well, I am not sure I could agree with you on the we have ended the mitigation phase and are into recovery. This virus is still not—

Senator CASSIDY. I am not speaking nationwide. I am speaking particular communities.

Dr. GERBERDING. But in every community the vast majority of people remain susceptible so they are only one visitor when travel away from exposure.

Senator CASSIDY. Which is why you need the suppression, I guess. Let me go to you, Dr. Leavitt—Mr. Leavitt, I am sorry. The defenders of the CDC said it actually put good stuff out there, but there is a review process that squashes it, and yes, they actually have thought ideas that would say Montana you are so low, we can move to a suppression strategy, but they float it, it gets killed.

Now, I look at the interaction between CDC and HHS and the White House as a black box, but someone told me that the Congress should demand recommendations without review. Meaning that we get the recommendations for those, what that means, I didn't. That we get the recommendations unvarnished, not if you will kind of looked at through the political lens or through the lens of that which the administration wished to have. It is the pure scientists that Dr. Gerberding just kind bragged on. What are your thoughts on that?

Mr. LEAVITT. I am inclined to believe that Congress getting the facts in an unvarnished way is a good thing and that good ideas will be held up under scrutiny. I will point out that there are times when even within a Department or the Government there are conflicting missions. Testing is a good example. CDC had the mission of being able to get testing out quickly. FDA, it was about being accurate. Sometimes accurate and quick don't align, and in a situation like that, in an emergency situation that occurred. I too agree with.

Dr. Gerberding, CDC is a treasure not just in the United States, but around the world in dealing with disease around the world. If you look at international organizations and lift up the hood, you will see at the heart of that are the scientists in CDC, and I know you are not intending to diminish that but it is—in an emergency, it is easy to be critical in an emergency. The reality is they need support.

Senator CASSIDY. I accept that but I think with Dr. Gerberding said about modernization, if we don't have modernization, it is going to be difficult to get people to support the more financially. I yield back.

Mr. LEAVITT. I totally agree with that, particularly in the data infrastructure. Our data infrastructure, the ability to collect data from the states in an almost real-time, be able to create situational awareness, that is one of the fundamental important duties of the Federal Government in a pandemic situation is to provide situational awareness.

Senator CASSIDY. Thank you.

The CHAIRMAN. Senator Cassidy.
Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman. Thank you to all of our witnesses. Senator Cassidy knows the high regard in which I hold him and he is not wrong that there needs to be reform at the CDC going forward and admission of the ways in which they didn't measure up. But let's just be a hundred percent clear here, the CDC is trying to do good work here. They are sending out regular guidance on the importance, for instance, of wearing masks as maybe the most evidence based method of preventing the spread of this disease.

The President of the United States refuses to wear a mask. His top advisors refuse to wear masks. He says it is an attack on him politically for people to wear masks. The CDC develops guidance for individual industries and businesses to reopen. The White House then prevents that guidance from being dispensed to states because the White House doesn't want to take responsibility for the decisions made to reopen the country.

I think the CDC needs to do some hard looking internally, but I also think that they have been prevented from doing the best work they could by this administration, this President. I appreciate the focus of this hearing moving forward, but any good fire department that has a house on fire and a house next door that is in danger of catching on fire does both, they put out the fire at the house that is engulfed in flames and they try to do work next door to prevent the next house from catching fire. We are not doing both in the Senate right now. We are holding a hearing on getting ready for the next pandemic and we are not taking up any legislation this work period in order to address the existing pandemic.

I want to frankly direct some of my questions to our witnesses with respect to what we could be doing now, which I think also probably is part of the conversation about what to do moving forward. Dr. Gerberding, you referenced how important it was for us to join the international vaccine effort, CEPI. The Coalition for Epidemic Preparedness Innovations is a multinational public, private sector collaboration to develop a vaccine for COVID-19.

It is also working on other vaccines as well. I agree with you. We should join CEPI as a mechanism to get ready for the next pandemic but we should join CEPI right now, correct? There is no reason to wait, especially given that they are doing most of their work as we speak on a vaccine for COVID-19.

Dr. GERBERDING. I completely agree with you, Senator.

Senator MURPHY. Just underscore why that is important. Why is it important for us to be in CEPI right now as they develop a COVID-19 vaccine?

Dr. GERBERDING. Well, CEPI is already funding many of the biopharmaceutical entities that are working on vaccines. So they have already reviewed and invested, but they also are positioned uniquely right now on a global basis to help adjudicate the allocation and the planning for how we are going to solve this global problem because we are not safe until everyone is safe.

That means we have to be thinking about vaccine in the billions of doses not in the hundreds of millions of doses. So right now CEPI is probably the leading organization, together with many

other partners, to provide the credibility and the scientific oversight to try to make sure we do that right.

Senator MURPHY. It is pandemic response malpractice for the United States not to be part of CEPI. All of our allies, all of our friends are part of this organization. And while we hope that it is our funding and our domestic programs that develop a vaccine, if it is a CEPI partner develops the vaccine, we want to be at that table. That is something we can do right now.

Dr. Khaldun, we talked a little bit about supply chain and what we do moving forward to try to prevent the problems that happened this time around. But in my state, the supply chain crisis isn't history, it is present. We still can't get PPE at our nursing homes. I was just at a hospital testing site last week and they don't have enough cartridges to be able to do their quick turnaround tests. I just want to be clear, Dr. Khaldun, the supply chain crisis isn't fixed is it?

Dr. KHALDUN. That is correct. We still in our state have lab capacity to be able to do at least twice as many labs as we are doing now, but we are limited by the number of swabs and reagents. So that is absolutely still a challenge.

Senator MURPHY. I think this discussion is really important. I have argued from the beginning that you can't wait for the next pandemic to hit us in order to get ready, but we have not beat this pandemic. On Sunday, there were one 183,000 new cases reported globally. That was the highest number of cases on any single day since the beginning of this pandemic. And that was Sunday.

It was Sunday and we are going to break for a very nice July 4th recess for Members of Congress who still have jobs, who are largely still healthy without having passed any legislation to try to help states, help local, public health districts address an epidemic that is still present. We need to be able to do both and my worry, Mr. Chairman, is that we are not at least during this work period. Thanks for the opportunity to ask questions.

The CHAIRMAN. Thank you, Senator Murphy.

Senator Roberts.

Senator ROBERTS. Thank you, Mr. Chairman. And thanks to all of the witnesses. I would like to thank Chairman Alexander, Senator Burr for working with me over the years to help address this issue, particularly during our work on something called Pandemic All-Hazardous Preparedness Act and response to the COVID-19 pandemic. We are making progress and in March Congress passed the CARES Act which included the Priorities Zoonotic Animal Drug Provision or PZAD. Everything has to be an acronym. This provides a pathway at FDA for expedited approval of animal drugs that have the potential to prevent or treat a zoonotic or vector-borne disease.

This isn't new, Mr. Chairman. It isn't as if the dogs haven't been barking about this back in the day when I had the privilege of being chairman of the Emerging Threats Committee on the Armed Services Committee. We were in charge of the Nunn-Lugar Program and we were allowed into secret cities in Russia at that particular time. Obviously, we are not now. But there was one that I visited called Obokensk. It is about 60 miles north of Moscow and

it was there that we had a whole range of scientists and I saw warehouses full of pathogens. It was stunning. It was shocking.

Everything from Ebola to Smallpox where there was no preparedness or no treatment, but the big one was hoof and mouth disease and these scientists were trying to weaponize these pathogens for an attack on a Nation's food supply. Well now we have seen that with COVID-19. Not exactly with regards to the livestock that we have but we have seen it in the packing houses and what it does to the food supply chain. So, and back at that particular time when Bill Frist was our Majority Leader, he was also our doctor with regards to every Senator.

Bill, I still want to thank you for what you did for me with one malady that I was suffering from. Bill had no patience for patients that were a little reluctant and so he took me by the arm, arched me into the cloakroom, got Dr. Cameron on the line up at Johns Hopkins and made an appointment for me, not the next day but the following Monday at 7 o'clock in the morning.

I then had the wonderful experience of enjoying 10 days of my life at Johns Hopkins. The view was nice in terms of Baltimore, but I didn't particularly want to end my days there which was not the case. Bill, thanks for everything that you have done for me and for a lot of Senators. The question I have is what are we doing now? One thing I want to point out, we have the National Bio Agriculture Facility, the replacement for Plum Island, at a level 4 lab at Kansas State University. It is a Consortium with other land-grant schools.

Again, we are making some progress. That facility will be open in 2022, but it is open right now doing some work and additional work at Kansas State. Now, the question I have is, we used to have exercises and I know of three. The first one, I played the role of the President. We had a hoof and mouth disease outbreak. Started in Texas. By the time Oklahoma figured out, it was in North Dakota. All of our exports stopped. Our entire food supply chain stopped. We had to euthanize millions of head of cattle. It was something we never experienced before. I know that leaves two others.

I am not sure we are doing that today and I don't know why we are not now. Now, we have a wonderful exercise with COVID-19, it just happens to be real. Senator Frist I am going to ask you this question. What can we do, and this is for all the witnesses, to continue facilitating coordination between public health and agriculture sectors and improving our surveillance in these areas before we have an outbreak? Dr. Frist, please.

Dr. FRIST. You know, it is—one of the things that these pandemics bring out is a reason I was able in 2005 to be so certain that we would have an infection and I mentioned, I predicted it coming out of China or it could have come out of these congested areas in Africa, is this integration, this assimilation between human and animal. And if you look at the layout for the future, almost certainly the next virus will emerge through this chain of anergenic shifts and drifts to come between animals coming to humans. I didn't first appreciate it.

But in 2001 when Anthrax hit our Capitol and about a third of Senate was moved out of their offices for a year, this symbiotic re-

lationship and this focused understanding, this important understanding of the veterinary world with human health and I would also add with environmental health. It is all one health.

We in our own ways are very isolated and insular and thinking silos. The only way to bring people together, to expand their thinking, their diversity of thinking in real time are these exercises in each should be built into every administration. It should be done on an annual basis. And from that we will be able to predict in almost exponential type thinking things like this need for testing, which we have missed in the past.

Senator ROBERTS. I appreciate it. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Roberts.

Senator WARREN.

Senator WARREN. Thank you, Mr. Chairman. No, I have to be honest. I am puzzled by the topic of today's hearing which asks us to start preparing for "the next pandemic." The next pandemic. What about the pandemic that is going on right now. You know, the last time I checked the U.S. was still fighting coronavirus and losing. Cases are rising rapidly over 20 states and hundreds of people are dying every single day. In Massachusetts, we learned first-hand just what happens when the Federal Government isn't prepared for a pandemic.

Back in March, we asked the Federal Government for medical supplies. Weeks later, only a fraction of those supplies had arrived and the Federal Government was reportedly seizing shipments that were headed our way. Now, even as the cases have come down, supply chain problems persist. Doctors in Milton are using construction goggles as PPE and Massachusetts General Hospital told the Boston Globe that its supply chain was, "fragile." If we don't apply the hard lessons learned in Massachusetts, states like Florida and Texas and Arizona where cases are now rising are going to pay the price.

Dr. Khaldun, Michigan has also experienced some of these supply chain problems. Since March, the Federal Government has implemented systemic ways to try to ensure that states with rising COVID caseloads will have all the masks and gowns and testing kits and other supplies that they need. Is that right? Is that what has actually happened in Michigan?

Dr. KHALDUN. I am grateful and thank you, Senator, for that question. I am grateful for the support of my colleagues at HHS and FEMA. They have been regularly sending us supplies. But quite frankly, they have not been enough. Some of the supplies that we have received have been expired. And so we still are working aggressively to try to make sure we have enough PPE for now and the potential second wave that we will probably see in Michigan come the fall.

Senator WARREN. Yes, it sounds like the very clear supply chain lessons that were learned by the states that were hit hard early on are just simply not being applied even though we are now more than three months into fighting this virus. So here is another one to focus on. As Massachusetts fought to reduce the spread of COVID-19, it developed a robust contact tracing program that is now the model for the Nation.

Experts agree that contact tracing is essential to successfully contained coronavirus. So Dr. Khaldun, Michigan has also invested in contact tracing and tracking information, and 500 Michiganders, as I understand it, are already working on tracking these infections, but the state could use more support. So let me just ask you, do you need more resources for this work and do you think that we should have a nationwide contact tracing program to help states that are dealing with COVID-19 cases?

Dr. KHALDUN. Absolutely, Senator. So, yes, absolutely. I think we should have a Federal strategy for contact tracing. We have over 10,000 Michiganders who have volunteered to do this contact tracing, more than 500 of them are already deployed. We have additional paid staff throughout the state. What has been a hodgepodge of local, state and Federal Governments trying to support this. Some more support would actually be welcomed from the Federal level.

Senator WARREN. Well, I think—it is important for all of us to hear your voice on this. I appreciate it, Dr. Khaldun. You know we are nowhere near close to a national contact tracing program. The House has passed key provisions of the contact tracing legislation that I introduced with Congressman Levin from Michigan, but Republicans in the Senate have refused to provide states with the funds they need to trace coronavirus infections. So let's have one more turn of this.

Let's talk about who is going to be hit the hardest if we don't learn the lessons of the past few months. In Massachusetts, we already know data. Data show that black and Hispanic people in the commonwealth are three times more likely than white people to contract COVID-19. So, Dr. Khaldun, if the Federal Government fails to right the wrongs of its early response to COVID-19, how will its failure impact people of color and other vulnerable communities that are at risk for the coronavirus infection?

Dr. KHALDUN. I think if we don't aggressively address those social determinants of health, so adequate housing, making sure people have access to health care, no out-of-pocket costs for testing, absolutely. African-American communities, latino communities, our tribal communities are going to be the ones that are hit the hardest so it is something that is very concerning for me.

Senator WARREN. Well, thank you very much, Dr. Khaldun. And thank you for your work. You know, there is going to be a time and place to take the lessons from this pandemic and apply them to the next one.

But right now as COVID-19 cases top 2.3 million nationwide, our country can't look at the coronavirus pandemic as if it is an event from the past. 120,000 Americans are already dead and more are dying every day. We must expand contact tracing. We must secure our supply chain. We must protect communities of color and we must stop pretending that this pandemic is over. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren. We will go to Senator Murkowski, I believe, and then we will go back to Senator Baldwin. Let her reclaim her time when we lost internet contact with her.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. I so appreciate this hearing. I happen to think it is very timely and I am not one that thinks that we are beyond this pandemic we are in the midst of it. But even while we are in the midst of an active pandemic, it is important to not only understand where we have been but where we are going.

Governor Leavitt, I really appreciate the comment that you made in 2007 while serving as Secretary and you have repeated some of it in your opening testimony, everything we do before a pandemic will seem alarmist, everything we do after a pandemic will seem inadequate. This is the dilemma we face, but it shouldn't stop us from doing what we can to prepare and prepare every day for what we really don't know.

Back home in Alaska, we have heard from our state officials and just from Alaskans around the state, what are the priorities as we are dealing with the here and now. It is still supplies and manufacturing, making sure that we have what it is that we need. Testing capacity continues to be a challenge, but we have been aggressive with that which I credit our state teams with but worrying about supplies.

Consistent messaging, no different in Alaska than what we are seeing around the country. Levels of confusion, though when you are having mitigation strategies that are perhaps conflicting, that causes an issue of distrust from the public and we need to pay attention to that. But the one that I want to speak to and have questions about is the public health IT infrastructure. Our state reports that IT infrastructure for contact tracing is still lacking. What we are using is Excel spreadsheets and faxes as our main tool for their contact tracing efforts. We have 761 cases as of this morning. Over 250 of those are active. Our teams have been working and staying on top of it but the article in the newspaper just yesterday is we are close to being maxed out.

As we are thinking about that and recognizing that there are several proposals out there for a national contact tracing, TTSI, that the contact tracing, diagnostic testing, supported isolation, and the need to suppress or mitigate. So the question that I would have is, is whether or not we need to have a national contact tracing program or do you believe that we can focus our attention on bolstering the funding and the capacity of public health departments at the state and locality level.

Because as I talk to Alaskans, they are saying, we think we have this. We want this support, financial support, but we don't know that we want a national program. So I would—I guess I would ask you, Dr. Frist and you Governor Leavitt for your views on that role with contact tracing because I think going forward this is going to be a key aspect to how we can stay on top of what we are dealing with. Your thoughts.

Dr. FRIST. Thank you, and just to prefix what I am saying, I think our second pandemic may come in about three months and that is why I do think it is important to do exactly what we are doing. Learn very quickly and then probably can but right now and then an after-action review will I am sure occur next year or two years or three years. On the contact tracing workforce, there has been a whole bunch of estimates out there as to what is needed.

We know it is the most effective action at this standpoint and the workforce does operate under state and local management, even if it is a Federal program and it needs to expand to help control COVID-19. We have to. All of these studies have concluded that we must expand it. It is about 180,000 people that are needed and can states do that? Probably not because states have had their public health infrastructure underfunded at the state and local level.

A lot of them don't even have epidemiologist to the local communities much less contact tracers. And so I think we have to go out for Federal support this time around, maybe not next time around, until we have an effective vaccine that is on the market. If we see new cases, we are going to have to increase it.

Massachusetts has done a great job. They hired and trained applicants quickly, got them out there. So Dr. Gottlieb and I and Andy Slavitt have proposed for this pandemic a Federal workforce, federally funded, and then allocation of that funding to the state so they can get it up and running today and we have that on record—

Senator MURKOWSKI. Thank you, Dr. Frist.

Mr. LEAVITT. Senator, I believe that a national strategy is required. It will require some local execution. Let me be deliberate about that. Clearly, we will need to have national funding to support this in the way that Senator Frist has articulated. Second, there has to be a national system that local input feeds into where standards are used and how data is collected so it can be rolled up quickly.

There are components of local execution that are required but there is a clear need for national funding on this pandemic, as I agree with Senator Frist, public health has been malnourished over the course of the last almost 40 years, and we need to buildup that infrastructure. We can have a national system but it will require some execution by the local level, but ought to be done according to a set of national standards.

Senator MURKOWSKI. Thank you. Thank you both.

The CHAIRMAN. Thank you, Senator Murkowski.

Now, we will go back to Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman, and I apologize for the interruption in internet service, but I am glad to be back with the panel. My first question, of course, related to urging OSHA to issue an emergency temporary standard that would be enforceable and mandatory as workplace reopen. And I think especially about schools that are preparing to start in-person classes again, K through 12 and higher education and their needs. But I want to move to the companion issue of these shortages that we have been seeing in the very things that would likely be contained in an emergency temporary standard that OSHA should promulgate.

Just as the administration has failed to issue these enforceable standards to protect workers, they have also failed to provide the leadership needed to take decisive action. For example, ramping up production of testing and testing supplies, other needed equipment, PPE here in the United States. Some have touched on this already, but it is why I introduced with Senator Murphy the Medical Supply Transparency and Delivery Act.

What it does is unlock full authority of the Defense Production Act to increase the production of critical supplies including PPE as well as the supplies needed for testing. So Dr. Khaldun, I directed my first question to you and I will follow-up also with you. Can you describe how shortages of testing supplies or PPE have hindered your state's efforts to respond to the current pandemic?

Dr. KHALDUN. Yes. So, as I said earlier Senator, in the beginning we had to delay testing in our state even when our state lab was able to do tests initially. We could only do a few hundred and then there were very strict criteria at the beginning were only the sickest could actually get access to a test while the disease spread in our state.

We still have, for example, our hospital labs. They are still only able to test the sickest patients because they have challenges with reagents and a lot of our community testing sites also still have challenges with reagents and testing swabs. Again, I am grateful for what we have received, but often when we receive supplies from the Federal Government, they actually don't match up with that what our labs are actually able to run so we can't even use them. So it is still absolutely a concern.

Senator BALDWIN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Baldwin. Sorry that we lost you there for a while. But thank you for sticking with us. Senator Romney.

Excuse me, Senator, Kaine.

Senator KAINE. Thank you, Mr. Chairman. Thanks to the witnesses, especially to Secretary Leavitt. When I was Governor of Virginia, we were dealing with H1N1 and then Secretary was a great partner with the administration. I associate myself with comments of all my colleagues that we got a current challenge, we have to plan for the future one. Just the magnitude of the current challenge, last week in the United States the number of new COVID-19 cases increased by 25 percent over the previous week. And that shows that the current challenge is getting worse not better, but we do have to plan for the future.

One of the things I want to do is take advantage of this experience to talk about the future. So first topic to the witnesses, every pandemic would likely be a little bit different but it seems like there is a template that the successful nations have used to deal with COVID-19. And the template is aggressive early testing and contact tracing to find those who are ill, the isolation of people who have COVID-19, and immediate treatment of those folks.

Do you agree that those four elements early testing, contact tracing, isolation, treatment should be a template that we should prepare to use in future pandemics?

Mr. LEAVITT. I will respond Senator Kaine. Those are—what we have collectively come to know as social distancing measures. They are they constitute the only medical intervention that we have absent a pandemic—or absent a vaccine, excuse me. And the reality is that is likely to be the case in any pandemic situation. We will be without a vaccine for a time. So that is a fundamental. It is a public health basic. What we do have to remember is that any medical intervention has side effects and this has side effects.

If I were to take pain medication, for example, I would be told you can't use this too long and you can't use too much of it or you are going to have other problems develop. We are obviously trying to find the balance now in this medical intervention that we have used, absent having no vaccine.

The answer is yes, but there is going to be a limit to which we can use them as a practical matter without having the side effects of the economy that we have experienced, the side effects of the social logic damage that is becoming more evident.

Senator KAINE. You have anticipated my next question, Secretary Leavitt. The side effects on the economy. I was having this conversation with Chairman Rich in the Foreign Relations Committee last week because we had a similar hearing about the global aspects of the pandemic. And he pointed out that the aggressive testing and contact tracing, some nations, some cultures accepted maybe a little bit better than would be accepted here. We were talking about South Korea.

I responded and I said that is true, it might be hard for people here to accept contact tracing but because South Korea did that early they didn't then have to use the heavy hand of Government to shut the economy down. South Korea's unemployment rate has gone up by about 1 percent. Because they isolated sick people, they didn't have to do the large economic shutdown that the United States had to. So the basic measures we talked about are not only good public health measures, they are also measures to protect the economy.

I want to move to one element of these basics and that is testing. I am very concerned about this and you have all talked about it, particularly Dr. Khaldun, the difficulty of doing testing and mission because of an adequate supplies and mixed messaging. Over the weekend, the President said he had instructed his administration to slow down testing because he thinks increased cases is bad.

I am going to be clear about this, increasing number of cases is bad, increasing deaths is bad, increasing hospitalizations is bad, but the idea that you would slow down testing because you didn't want to find out if people are sick is just grotesque. The Chairman, the Ranking Member of the Committee, Senator Murray and Senator Schumer, wrote a letter to Secretary Azar that I would like to introduce for the record, Mr. Chairman, if I could.

The CHAIRMAN. So ordered.

[The information referred to can be found on page 69 in Additional Material.]

Senator KAINE. Pointing out that \$14 billion that has been provided by Congress for testing has yet to be obligated by the Administration. I am deeply worried that there is a bias against testing because we don't want to know bad news. I have been puzzled, we are in the fifth month of the pandemic, why hasn't the Administration issued national guidance about how many tests we should do. The website of the CDC, instructions to colleges doesn't even mention the word testing and I believe there is either a fear of finding out how bad this is or a desire to not be held accountable for falling short of testing guidelines.

As I conclude, I will just point out, we heard from Admiral Giroir a month ago, May 12, and we sort of had to drag out of him, what

would be an appropriate national testing goal for the beginning September when schools are going back in and he said 40 to 50 million tests a month, which is 1.3 to 1.7 million tests a day. At that time in May 12 we were doing between 300,000 and 400,000 tests a day. Now more than a month later we are at 500,000 test a day.

If Admiral Giroir is right and we have to do between 1.3 and 1.7 million tests today in September and many experts say it is higher, I have grave doubt about whether this administration is going to enable our country to do that if we are only at 500,000 on June 23. With that, thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chairman, and thank you to all of the witnesses for being here today. As I looked at your bios, I am realizing that the combined years of public service sitting before us is extraordinary and I thank you all for your service. There will be time for thorough review of everything that went wrong with the Administration's response to the current pandemic.

Our Nation can better prepare for future pandemics by reversing cuts to public health and preparedness funding, re-engaging with international partners, and ensuring that key Federal positions are occupied by qualified staff. However, we are in the middle of a pandemic now. COVID-19 continues to spread quickly through the United States even as many European nations have gotten their outbreaks under control. America has 4 percent of the world's population yet 25 percent of the overall deaths from this endemic and 20 percent of new daily cases being reported.

In my home state, the toll in our nursing homes continues to be extraordinary, 80 percent of the deaths in New Hampshire have been in long-term care facilities. Our primary focus must be on strengthening the Federal response to the current pandemic that is still raging across our country.

I want to start with a couple of questions to Dr. Khaldun. Dr. Khaldun, in the early stages of the pandemic Michigan's per capita testing for COVID-19 was below the national average. Since then, you have been able to not only ramp up testing and become one of the few states that have an infection rate of less than 1 percent among those being tested.

What specific steps were critical to addressing those initial challenges in your state and what Federal support is needed to help other states replicate your approach by expanding testing capacity, improving demographic data collection from testing sites, and using that data to quickly respond to potential outbreaks?

Dr. KHALDUN. Thank you for that question, Governor. It has certainly been a massive effort and response not only from our state and local health departments but our procurement team in the state, our Michigan National Guard. There are many, many people who have contributed to us being able to respond, going from just a few hundred tests today to now about 14,000 a day. We have focused on how after we bring in testing into communities.

Working with community partners. We have made sure that when we do our contact tracing, we have updated and have to do again, building the plane while we are flying it, updating our con-

tact tracing platforms so that we can effectively isolate, understand who has potentially been exposed and isolate them as quickly as possible.

Again, it has been a massive effort but I would not say that we are necessarily winning in Michigan. We are still seeing outbreaks across the state and we continue to work hard to expand testing.

Senator HASSAN. Well, that is helpful. Are there particular things you think the Federal Government can do?

Dr. KHALDUN. Yes, I again I have been really pleased that we have been working with our Federal partners on testing supplies, but often we don't know when those testing supplies are going to come, and when they come with their less than what we expected to get or they are not even useful. So we need really a clear strategy from the Federal Government on supplies, when we will get them, so that we can actually plan on the state and local level for how we will get those supplies out.

Senator HASSAN. Well, thank you. I also wanted to follow-up with you on another issue. In April, you wrote a letter to clinicians across Michigan highlighting the fact that African American residents comprise 40 percent of COVID-19 deaths statewide despite making up only 14 percent of the state's population.

This is a disparity that you have talked about a little bit today and it is a disparity we have seen across the Nation during this pandemic and in overall health care and outcomes. What types of dedicated investments from Congress are needed to give state and local Governments across the country the support they need to improve health and wellness in communities of color and work toward eliminating these health disparities during the pandemic and beyond?

Dr. KHALDUN. We really have to focus upstream and talk about those social determinants of health. So housing policy is health policy. We have to make sure communities of color who are disproportionately living in poverty have access to healthy and safe housing. Making sure they have access to health insurance and expanding Medicaid across the country would be important.

No one should have to pay out-of-pocket costs for testing or treatment or a vaccine. And to make sure there is equitable distribution across this communities to make sure that we are addressing disparities. I also talked about implicit and explicit highest in our health care system. Again, many people, it has been well documented that these disparities exist, that is why I sent the letter as well.

Senator HASSAN. Thank you very much and thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hassen.

Senator Smith.

Senator SMITH. Thank you, Mr. Chairman and Ranking Member Murray, and to all of you for being here today. I want to start by associating myself with the comments of my colleagues who made on the really important point that we have so much work right now to address the existing pandemic that we are dealing with and living through right now. And I especially am concerned about how COVID-19 is exacerbating existing health disparities and the systemic racism that is literally deadly for black and Hispanic and na-

tive communities in my state and all around the country. But here is one example that really shows what this means in real life.

Recently an obstetrician in Minnesota shared a story about a black Minnesotan a Liberian immigrant, a pregnant woman who went to the emergency room because she thought she had complications with her pregnancy related to COVID-19. So she goes to the emergency room and not once, not twice, not three times, but four times. The first three times she is turned away because even though she is COVID positive, it was determined that she wasn't sick enough to be admitted to the hospital. Two days later, she returns for a fourth time and she is so sick that an emergency cesarean is performed in a last-ditch effort to save her and her child and they both died. She wasn't believed and she died.

Now, implicit bias healthcare is kind of a policy wonkish term, but this is what it means when bias and racism and disparity kills people. I know that we have talked a lot about what this disparity means when it comes to COVID, but Dr. Khaldun, I want to ask you this question. What can we do so that black women are not turned away from getting the health care that they need when it comes to COVID?

Of course, I have to acknowledge that we know that maternal mortality rates for African American women in our country are three or four times higher than they are for white women even without the complexities of COVID. What can we do to address that problem?

Dr. KHALDUN That is right. We experience that disparity when it comes to maternal and infant mortality in the state of Michigan. Even an African-American baby is twice as likely to die before its first birthday than a white baby and in the state and some of the things that we can do is really make sure that, I believe that we should have mandatory implicit bias training for all health professionals students.

I think that our health professional schools should all work to expand diversity in their students. I also think, and this is some of the work we are working on with our partners in Michigan, we have to make sure that those best practices when it comes to hemorrhage bundles and just the top quality care for OB care really implemented across hospitals, even those hospitals that take care of the most impoverished women, we have to make sure there are high standards set and that everyone has access to equitable care.

Senator SMITH. Thank you for that. I agree with you on that. I think that those are the kinds of things we need to do all of the work we need to do to diversify our health care system. And also make sure that we have community based care available for women and that would be I would think would be the same when it comes to COVID. Let me ask you this question, Dr. Khaldun. What should we be doing better in order to make sure that our public health messages are reaching communities of color and are relevant and appropriate for black and brown latino communities, indigenous communities who are a very important part of our, my work here in Minnesota also.

For messaging, those community partnerships are incredibly important. That is some of the work we have done here in Michigan. Again, with our coronavirus racial disparities task force, we are

working very closely with community members to make sure that the messages that we are putting out are resonating and that we use those community like those trusted community leaders to get accurate messaging out into the community. Those partnerships are critical. We can't do this alone and we shouldn't be only doing it from a state and local Government perspective.

Senator SMITH. Right. I think that is so right and it brings me to my last point here, which is that in order for that to work, those community organizations and need to have capacity and local public health agencies need to have capacity. And I know that you worked at the local level as well at the state level.

Right now in Congress, we are having a debate about how urgent it is that we get emergency resources to state and local Governments right now in order to help make sure that this response happens. And so could you just answer briefly, I just have a second left, on how important it is you think from where you sit that we get that state and local aid to Governments right now as we are dealing with this epidemic.

Dr. KHALDUN. That is right. Our state and local Governments absolutely have been underfunded for her decades, especially our local health departments. They often don't have even one epidemiologist. So funding at the state and local level are incredibly important for COVID-19 and other critical public health work.

Senator SMITH. I think it is why so many of us supporting the Heroes Act funding to get emergency aid to state and local Governments. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Smith. Senator Jones. We will go back to Senator Jones. Senator Rosen.

Senator JONES. I am sorry. I had problems with the mute button. Mr. Chairman, can I go forward?

The CHAIRMAN. Okay, we will go to Senator Jones.

Senator JONES. Thank you. Thank you, Mr. Chairman. I really appreciate this hearing and I hope we have more to be honest with you. I don't think this is a topic that can be handled in just one hearing and I hope our other committees in the Senate will likewise have hearings on their respective jurisdictions about lessons learned from this pandemic. I would like to first go to my Northern neighbor, Tennessee neighbor, Senator Frist and talk a little bit more about manufacturing. I know Senator Alexander asked about it.

Senator Collins, Senator Murphy mentioned it as well. But the focus I want to talk about is really on PPE, masks, gowns, those kind of things. We have—I really—it seems to me that we have had not only a shortage now, we are going to continue to have a shortage in the future. We have got to rebuild our national stockpile, but also keep that replenished as our stockpile ages. We have seen in Alabama supplies sent from the national stockpile that were 10 years past expiration dates, that were rotted. So it seems to me that one of the things that we can do is try to incentivize, and you mentioned that in your testimony.

I have a bill pending called the Build Healthcare Equipment and In America Act to try to give those tax incentives to companies to either repurpose existing facilities, stand up new facilities, and also

give some help or infrastructure such as broadband in areas that might not have it.

In addition to the tax incentives, I was caught by your statement that we have got to help with markets, long-term markets, maybe even I can't remember the exact phrase, might have been artificial markets. So in addition to the tax incentives like I have got in my bill, what can we do to create those markets? Because I just think we are going to be, even when we are out of this pandemic, we are going to be living in a new world in which more masks, more gowns, more shields are going to be needed for businesses, schools, and healthcare workers going forward. So, how can we do that in addition to the incentives?

Dr. FRIST. Thank you. We deal in pandemics, remember virus occur. They don't all become pandemics. So when we talk about pandemics, we were talking about something that explodes and then it goes around the country to multiple places. That is the global emphasis of if there is an outbreak anywhere, it is important here. The markets does come in part to stockpiling but in addition it extends this whole concept of what we are dealing with is a rare but certain event, a rare but certain event.

The rarity is hard for Congress to deal with because of the attention span of Congress, having spent a lot of time in the room that you are in, and that is where it is important to have timelines that are 10 years or 15 years. Markets tend to look day-to-day and therefore this will artificial market means that we have to have some side, sort, of the tax credits could do it, but some sort of public funding that will guarantee a market over that 10, 15 year period when that certain event, that certain pandemic will occur. Your higher point is on the stockpiling and it too, and the CDC we talked about modernization which I agree with, but we also need to modernize the stockpile.

There is still a lot of debate. Is it a Federal responsibility or do we push it upon the states? States, because they have to balance their budgets, are not—because of the immediate demands of the constituents, is not going to be able to do it. So the stockpiles need to be not just implemented at one point in time, but they, just like we have to have these exercises every year, have to be looked at year to year as to the current threats or risks that are being determined by our communities of science, those scientist at the CDC.

If we do that, we can have regional stockpiles coordinated with an overlay at the Federal Government, with great coordination, better coordination, going back to Governor Leavitt's plans with the states is to the immediacy of what needs to be in that stockpile and then the markets design around that. The Federal Government itself can't go out and build these factories. It has got to have to be people who are in the business who can change with science, change with the time, change with the biology in real-time.

Senator JONES. Great. Thank you, Senator, I appreciate that. Governor Leavitt, let me ask you real quick in my remaining seconds here, I completely agree that we need to do more investing in public health, but in your testimony you mentioned that Medicaid funding crowds out state budgets for public health funding and I would like for you to just explain briefly what you mean by that. Are you suggesting that we should cut Medicaid and that would

help public health funding because it seems to me in my state more Medicaid is better for public health than less.

Mr. LEAVITT. Senator, let me just say that public health generally has been starved for resources for probably 30 or 40 years and the budgets have just continued to go down. There is a direct correlation, it is just a fact, I am not making—drawing the causation. I am just saying there is correlation here that Medicaid budgets have dramatically gone up.

When I was first Governor I think Medicaid was 6 percent of the budget. It would probably be 20 percent in the state that I was Governor now. Public health as a percentage of that is gone down. We have just undernourished it and I am worried about that. I don't think that every—it is a local function. It is a state function. Right now it is being driven and funded primarily by Federal dollars. I think that is not a good idea in the long term. So I am just advocating that states need to be to pay attention to their public health infrastructure as well.

Senator JONES. Right. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Jones.

Senator Rosen.

Senator ROSEN. Well, good morning everyone and thank you, Mr. Chairman for bringing this important hearing and of course Ranking Member as well and everyone on the panel for all of your work in the past and your comments about how we can plan for not just a global pandemic but all those smaller kinds of crises that we may have that we have to plan for you even if they are regional.

I do believe that it is really important to keep up with research in order to understand this virus because scientists around the globe are frantically working to gain a better understanding of COVID-19. How the virus specifically attacks a patient's immune system, what treatments work, how to best prevent infection. To make sure we do not have gaps in research and information in how the virus impacts a wide range of patients, I introduced along with Senator Rubio the Ensuring Understanding of COVID-19 to Protect Public Health Act.

This bipartisan bill would direct the NIH to conduct a longitudinal study of patients that includes diversity among gender, race, ethnicity, geography, and age, and many other things. We are looking at both the short-term and long-term impacts along with interventions.

This would be reported publicly on a regular basis so that all researchers and public health officials have the latest information. So Dr. Khaldun, as a public health official directly dealing with the current pandemic, what challenges have you faced in getting comprehensive information about the latest research on COVID-19, and could you please speak to how not having robust data available hurts not only ongoing research but patient care?

Dr. KHALDUN. Yes. So we all are learning about this virus. Obviously, it is a new virus. So we are all learning how it responds in the human body and who is the most impacted, but absolutely it would be great to have more research to look at the disparities and why those disparities exist, to look at how it even impacts children. We are seeing this mysterious disease in children as well. So abso-

lutely the research and the data would be incredibly important to advancing this response.

Senator ROSEN. Building on that, what recommendations would you have for us, maybe in Congress or others, how can we make it easier for doctors and public health officials to get this comprehensive data? Updates are coming in rapidly. I want to avoid, what—I really want to avoid these gaps that we seem to be having in the data between states and counties and cities, etc., etc.

Dr. KHALDUN. Yes, I think we need uniform surveillance and data systems across the country. We at the state, we have our own data system, the locals often are doing their own, and then we have kind of a hodgepodge of ways that we get data to the CDC and we have recently updated that.

We absolutely need more data. It would be great to have, I would say, more coordination and updating when the CDC does come out with guidance or research to make sure that our state and local Governments get that as quickly as possible. Some more coordination and better surveillance will be important.

Senator ROSEN. From the CDC?

Dr. KHALDUN. The CDC.

Senator ROSEN. Thank you. I want to move on and talk a little bit about telehealth. Of course last week we had a great hearing on telehealth. It showed how vital this tool is for caring for patients not only during the pandemic but also after. So of course along with many of my colleagues, we support continuing the flexibilities for telehealth reimbursement that we have allowed through Medicare through the passage of the CARES Act, and I want to tell you I think it has been fantastic in Nevada. We have a model health company that will send a paramedic or a nurse to a patient's home and use telehealth to connect with the physician to treat the patient.

They do a history and physical, they take the vital signs, they may do blood work right there, and then can speak with the physician. If the situation is more serious, they can get the patient to a hospital or to a follow-up kind of an urgent care situation. So again, Dr. Khaldun, from your experience during this pandemic, how do you think that telehealth has really improved patient outcome and people's ability to receive care?

Dr. KHALDUN. Telehealth has been incredibly important to maintaining our health care system during this response, and I actually hope that we don't go backward, that we continue to use the lessons we have learned with this response as we move forward. We have expanded access in our state to telemedicine and telephonic visits, including authorization for teledentistry, OT, PT, speech therapy as well.

It has been incredibly helpful with our health care system, and I hope we learn from those lessons.

Senator ROSEN. I hope we do too. Thank you. I appreciate you being here today.

The CHAIRMAN. Thank you, Senator Rosen. If the witnesses will stay with us another 10 minutes, we will conclude the hearing. Senator Murray, do you have closing remarks?

Senator MURRAY. Well, thank you, Mr. Chairman. You know, I just have to say COVID-19 has killed more than 120,000 people in

the country and sickened more than 2 million. None of us would have said that 4 months ago. And we just have to just say this is stunning. I mean, especially when I heard Vice President Pence last week, “our whole of America approach has been a success and the Nation’s response to COVID–19 is a cause for celebration.”

I mean, we are in a pandemic that has just stunned this Nation and we should not be ignoring that or talking nonchalantly about it. I will ask Dr. Khaldun to just comment, based on your experience in Michigan, would you characterize the Federal Government’s response as a cause for celebration? Is it time to declare mission accomplished?

Dr. KHALDUN. Absolutely not, Senator. We are in the middle of a pandemic. We are still seeing outbreaks across the country and increasing cases. So we definitely should not be celebrating right now.

Senator MURRAY. Yes, and I don’t think so either. So Mr. Chairman, thank you for this hearing. I really do appreciate all of our witnesses for taking the time to join us today and share your expertise. While it is clear we still have a lot of work to do to prepare for the next pandemic, it is even more apparent to me that there is a lot more that has to be done right now to respond to this one, because despite what we heard from the White House, this crisis is far from over.

Several states are seeing record setting new case counts. There are many steps that we need to be taking as soon as possible to fight COVID–19. We need to increase testing not decrease it like we continue to hear President Trump suggest. We need to take steps to pave the way for a safe, effective vaccine that is free and accessible nationwide. And we need to take steps to address the harmful health disparities that are being compounded by this crisis.

Of course we have to address racial injustice not just in health care but in so many other ways as well. So as we continue to focus on that, I would like to ask consent to submit for the record an outline of health equity principles from the Robert Wood Johnson foundation, Mr. Chairman.

The CHAIRMAN. So ordered.

[The information referred to can be found on page 75 in Additional Material.]

Senator MURRAY. I really hope we continue to talk about this and build on this conversation today not just with future hearings and discussions but we need to take, Congress needs to take, immediate action so our country can deal with the crisis at hand. Thank you.

The CHAIRMAN. Thank you, Senator Murray. And thanks for your cooperation and that of your staff in scheduling the hearing. In a moment, I am going to ask each of our four witnesses if they can summarize in about 60 seconds the top three things they would do now to prepare for the next pandemic if they were the king or the queen of the United States, but first, let me make a couple of comments. Several of my colleagues have wondered why in the middle of a pandemic we would be thinking about how to prepare for the next one.

Well, I think Senator Frist made that argument very eloquent, as eloquently as did other witnesses. It is because our experience has been, we haven't been able to adequately take the steps that we need to take to prepare for the next pandemic if we wait till the current one is over. Over the last 20 years, we have had four Presidents, two Republicans, two Democrats, several Congresses earnestly working on this subject. They have passed nine different major laws.

I mentioned what those were before, but it was after Anthrax and after SARS and after the flu pandemic and after Ebola, the attention of Congress on difficult issues was on other matters. The same thing happened in the states where hospitals and states allowed their stockpiles to be diminished because other matters demanded more budgetary considerations. So I would ask my colleagues, when do you think would be a better time to ask the U.S. Congress, for example, to build a manufacturing plant for vaccines that we for many years might not even use. Probably during this pandemic is the best time to get the attention of the Congress for such a use.

Or when would be a better time to accelerate research for testing and treatments, if we can think of ways that would speed and accelerate those testing and treatment for the next pandemic? Or when will be a better time to do the appropriate funding for the Centers for Disease Control to do data surveillance? Or when would be a better time to look at our stockpiles and our Hospital surges than while we are in the midst of them? When would it be a better time to talk about strengthening funding for state and local public health departments, which Governor Leavitt said have been going downhill for 40 years in terms of funding? Well if we haven't been able to do it for 40 years, why not try doing it in the midst of a pandemic. When would be a better time to consider who ought to be on the flagpole?

It is not going to be easy to accept the recommendation of Dr. Gerberding and the commission that recommended putting someone in the NSC in charge or to improve coordination of Federal agencies in other ways. And when would be a better time to do what is probably the most difficult recommendation that many of you have made which is create a funding stream that is automatic, that is mandatory at a time when the Federal Government has such a big deficit.

The reason we are doing this today is because we are in the midst of these problems and our eyes will be clearer on what the solutions may be and our wills will be better and we have an notoriously poor record of short memories when it comes to doing everything we need to do. We have tried but we have not obviously done some of the things that we need to do. So in my view, and I think in the view of at least several of the witnesses and many others, now is the time to do those few things that we know must be done for the next pandemic while our attention is focused on these matters.

A couple of other comments before I ask our witnesses for their concluding remarks, one was I appreciate Dr. Gerberding's comment about asking the National Academy of Medicine to become involved in transparency for the vaccines. I think that is a very good

idea. And that is what they are for. And I think their opinion about the safety of a vaccine would go a long way toward dispelling any worries about it. And the other comment I want to make was on contact tracing. Of course contact tracing is essential and of course Federal funding is essential but we have already done the Federal funding.

I mean Congress gave states \$150 billion, all of which could be spent on contact tracing. In addition to that, that was a month ago. And then in addition to that, Congress gave states another \$11 billion as part of a \$25 billion testing package that was expressly for the purpose of contact funding if the state chose to use it that way. We specifically decided not to tell states to use it that way but they could use it that way.

That is plenty of money to hire all the contact tracers that you need. I mean according to one estimate by professional firm, an average salary for a contact tracer might be \$37,000. And if that were the case, the cost of a 100,000 would be \$3.7 billion, a lot less than the \$11 billion that was specifically allocated to states for the purpose of hiring contact tracers if they chose to use it.

Senator Blunt, who is the Chairman of the Appropriations Committee for Health and I wrote a letter to CDC asking to make that clear to Governors that they have that money and many states have not spent their \$150 billion that we gave them earlier. This is an allowable expense there.

Yes, we need Federal funding for contact tracing. Yes, they are important. Yes, it might be 100,000, 150,000, 180,000 but we have already appropriated that money and states ought to use it and many already are now. To conclude the hearing, let me ask the four witnesses, even though they have already said this in their testimony, if they were in charge and they could do three things this year to get ready for the next pandemic, what would those three things be? Senator Frist, maybe begin with you.

Dr. FRIST. Thank you, Mr. Chairman. The pandemic is growing around the world. And as I said, a break anywhere is a risk everywhere so we got to think globally. We need to test more. Continue to focus on the vulnerable populations as we talked about here and around the world. I too endorse Senator Murray's underlining of the Robert Wood Johnson Foundation principles.

My three things are No. 1, we need to establish to invest in long-term partnerships. Age and partner with the private sector to develop the diagnostic tests and treatments, vaccinations. No. 2, put in place a budget mechanism to ensure public health funding does not disintegrate when memory of this pandemic fades.

I mentioned the health defense operations budget in my prepared statement. And No. 3, telehealth. It works. It allows social distancing and clinical care to be delivered. And for the future, it is convenient. It is affordable. And for the future of health, it will be transforming.

The CHAIRMAN. Thank you, Dr. Frist.

Dr. Khaldun.

Dr. KHALDUN. Thank you, Chairman, for the opportunity to speak today. The three things I would focus on are one, disparities, two, surveillance, testing, and tracing, and isolation. And then, funding of state and local health departments. When we talk about

disparities, we have to talk about housing. Everyone should have access to affordable and healthy housing. We have to invest in communities of color, so education and jobs, access to healthcare we have to focus on, so funding for the health care safety net, our federally qualified health centers who provide this care in these communities. We have to buildup, as has already been talked about, the testing capabilities, the contact tracing capabilities.

We are grateful for the funding that we received in the State of Michigan but it also needs to be long-term funding and not just come up when we have an emergency. And then finally, we must invest in long-term infrastructure in our state and public health departments.

As has been said before, many of them only have one epidemiologist or no epidemiologist, and we are always building these responses on the fly. This needs to be something that is long term as far as funding for state and local health departments. Thank you.

The CHAIRMAN. Thank you.

Dr. Gerberding.

Dr. GERBERDING. Thank you. I certainly support what Senator Frist said and stand by the recommendations of the CSIS report as well. I will emphasize three things one is a national vaccine plan that includes not only the science and the development and the manufacturing piece in collaboration with the private sector, but also the allocation, uptake, and monitoring piece because we know this is in our future and we are not ready for it yet.

The second thing I would say is that we are coming into a high probability of jointness of ongoing COVID in the context of influenza, and we need to exercise health care surge under that scenario. Again, including the supply chain and the private sector in that process so that we can understand how to create more robust supply and hopefully really improve immunization rates for influenza this season at a time when we need it now more than ever.

The last thing I would just re-emphasize is the importance of the budgetary authority that allows for sustained investment not just at the Federal level and CDC, but through our state and local health departments. You can't plan for preparedness in one year cycles any more than you can plan for the Department of Defense to be prepared for that kind of security in a one-year timeframe. We need long-term, sustained, progressive accountability and measures for progress. Thank you.

The CHAIRMAN. Thank you.

Governor Leavitt.

Mr. LEAVITT. Unless you think I cannot count, I am going to give you four. The first is to advance in clarity on the division of labor between state and Federal Government and the pandemic. States need to be with that, armed with a clear understanding of their role and the Federal Government, its role. Second, rejuvenating the public health infrastructure, as others have stated, is not only important in a time of pandemic but in the health system where working toward value of the social determinants of health will play a dual role and an important role, and will have ongoing benefit in both in and out of a pandemic. Third the HHS, CDC data modernization.

It is a critical piece of infrastructure that needs to be put in place in advance. We should be working on it now. It can be valuable in three months from now as well as in three years from now. and finally, again the echo, annual appropriation on emergency management not just episodic funding.

The CHAIRMAN. Thank you, Governor Leavitt. Thanks to each of our four witnesses. As I listened to the priorities, I am reminded again, most of those recommendations will help with the current pandemic, all will help with the future pandemic, and in my opinion, they will all be easier to pass and turn into law during this current pandemic than they will be if we wait a year or two and try to compete with other priorities of the moment.

The hearing record will remain open for 10 days. Members may submit additional information for the record if they would like. I have also invited comments and responses and any additional recommendations in response to my white paper preparing for the next pandemic for our Committee to consider. I will fully share those recommendations that I receive with my colleagues, both Democrat and Republican. The deadline for submitting those comments is 5 p.m. this Friday, June 26. Comments may be sent to pandemic preparedness at help.senate.gov.

[The information referred to can be found on page 69]

The CHAIRMAN. This is our fourth hearing this month on the COVID-19 pandemic. We have had one on going back to school, one on going back to college, we have had one on telehealth, we have had this one, and then we will meet again at 10 a.m. on next Tuesday, June 30th for an update on progress toward safely getting back to work and back to school and our witnesses will be Dr. Fauci, Dr. Hahn, Admiral Giroir and Dr. Redfield. Thanks again to our distinguished panel of witnesses, to the Senators who participated, to the staff who helped put this together. The Committee will stand adjourned.

ADDITIONAL MATERIAL

LETTERS OF SUPPORT

UNITED STATES SENATE

June 21, 2020

The Hon. ALEX AZAR, *Secretary*
U.S. Department of Health and Human Services,
200 Independence Avenue,
Washington, DC.

DEAR SECRETARY AZAR:

We write to express concern regarding the distribution of funds Congress allocated for COVID-19 testing and contact tracing, including for providing testing to the uninsured. Congress provided more than \$25 billion to increase testing and contact tracing capacity¹ and \$2 billion to provide free COVID-19 testing for the uninsured by paying providers' claims for tests and associated items and services (such as, office or emergency room visits needed to get an order for or to administer a test).^{2,3} While it has been months since these funds were first appropriated, the Administration has failed to disburse significant amounts of this funding, leaving communities without the resources they need to address the significant challenges presented by the virus. The United States is at a critical juncture in its fight

¹<https://www.Congress.gov/bill/116th-congress/house-bill/266/text>.

²<https://www.Congress.gov/bill/116th-congress/house-bill/6201/text>.

³<https://www.Congress.gov/bill/116th-congress/house-bill/266/text>.

against COVID-19, and now is the time for an aggressive and fast response. This Administration will put our country at grave risk if it tries to declare an early victory, leave lifesaving work undone, and leave resources our communities desperately need sitting untouched.

Regarding funding for ramping up testing and contact tracing capacity, the Administration has full discretion to spend, as it sees fit, more than \$8 billion of the \$25 billion provided by Congress. With COVID-19 cases spiking in numerous states, the Administration has not released a plan to distribute this funding. It is critical that the Administration disburse the \$8 billion immediately with an emphasis on addressing two major unmet needs: contact tracing and collecting data on COVID-19 racial and ethnic disparities.

The country's current contact tracing workforce is inadequate to deal with the new spike in COVID-19 cases. Leading public health groups say state and local governments need \$7.6 billion to quickly scale up contact tracing, including \$4.8 billion to hire at least 100,000 contact tracers.⁴ Meanwhile, other experts believe the country needs closer to 300,000 contact tracers. A bipartisan group of experts proposed last month that \$46.6 billion is needed to contain the spread of COVID-19—including \$12 billion for expansion of the contact tracing workforce.⁵

Dr. Scott Gottlieb, who served as Commissioner of the Food and Drug Administration under President Trump, said recently that, "Right now, we haven't been able to trace [spread of the virus] back to the source because we don't have all that track and trace work in place. And so that's a challenge for public health officials."⁶ Yet despite this urgent need, the Centers for Disease Control and Prevention (CDC) has not even awarded nearly \$4 billion in funding at its disposal that could be used for public health surveillance, and state, local, tribal and territorial surveillance and contact tracing efforts.

Additionally, the effort to gather COVID-19 data on race and ethnicity is woefully inadequate. Recent reports found that 52 percent of reported cases are missing information on race or ethnicity, preventing public health officials from knowing where to target interventions in communities of color.⁷ Even with these low reporting frequencies, the data we do have indicates that the disparities are vast. By its own admission, the Trump administration must change its approach to this issue. CDC Director Robert Redfield acknowledged that the Administration's paltry initial report to Congress on demographic data fell short, saying that "I want to apologize for the inadequacy of our response."⁸ Brett Giroir, HHS Assistant Secretary for Health and former coronavirus testing czar, said "We're flying blind until this comes in. We can't develop a national strategy to reach the underserved, or know how well we're doing, until we have the data that shows us if we're reaching them or not."⁹ Communities of color ravaged by COVID-19 cannot afford to wait any longer for a better approach.

Regarding funding to provide free testing for the uninsured, to date, media reports note that "only \$10.8 million, or 0.5 percent of the \$2 billion Congress set aside to help providers pay for COVID-19 testing for uninsured patients, has been approved to be paid during the first two weeks of the program's operation." Recent news reports note that slow distribution of these funds may be caused by technical flaws with the portal for submitting claims, a lack of awareness about the availability of the funds, and coding issues. No patient should avoid seeking medical care because they are worried they cannot afford it—especially in the midst of a pandemic, in which reluctance to seek care because of cost endangers the health of others. Congress appropriated these funds in large part because we know that patients often forego recommended tests and treatments because of cost.¹¹ The need for these funds is made even more acute by the Trump administration's sabotage of our

⁴ <https://www.naccho.org/uploads/full-width-images/Joint-Public-Health-Contact-Tracing-Workforce-Request-4.30.20-FINAL.pdf>.

⁵ <https://apps.npr.org/documents/document.html?id=6877567-Bipartisan-Public-Health-Leaders-Letter-on>.

⁶ <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2020/06/15/the-health-202-u-s-isn-t-ready-for-the-contact-tracing-it-needs-to-stem-the-coronavirus/5ee6528b602ff12947e8c0d7/>.

⁷ <https://www.politico.com/news/2020/06/14/missing-data-veils-coronavirus-damage-to-minority-communities-316198>.

⁸ <https://www.politico.com/news/2020/06/04/coronavirus-robert-redfield-racial-disparity-cdc-301223>.

⁹ <https://www.politico.com/news/2020/06/14/missing-data-veils-coronavirus-damage-to-minority-communities-316198>.

¹¹ <https://www.norc.org/PDFs/WHI%20Healthcare%20Costs%20Coverage%20and%20Policy/WHI%20Healthcare%20Costs%20Coverage%20and%20Policy%20Issue%20Brief.pdf>.

health care system, leaving increasing numbers of Americans uninsured. Even before the pandemic began, the U.S. Census Bureau reported that the number of Americans without health insurance rose by about 2 million in 2018. Even the number of uninsured children increased.¹²

The pandemic has exacerbated this trend. After the start of the pandemic, the Kaiser Family Foundation estimates that as many as 27 million people may have lost employer-sponsored insurance between March 1 and May 2, many of whom may be eligible for an automatic special enrollment period.¹³ Further, the Trump administration has refused to open a national special enrollment period to make it easier for patients and families to sign up for comprehensive coverage, while continuing to promote “junk” short-term plans that are allowed to discriminate against people with pre-existing conditions and are not required to cover the essential health benefits, like prescription drugs.

This funding is also important to addressing health disparities. As of 2018, non-elderly Black, Hispanic, American Indian and Alaska Native, and Native Hawaiian people and Pacific Islanders are more likely to be uninsured than white people.¹⁴ This lack of access to care is one factor that contributes to the worse health outcomes experienced by communities of color with respect to COVID-19.¹⁵

Funding to cover the cost of testing for the uninsured is also critical to support health care providers. The American Hospital Association estimates that, over a 4-month period from March 1 to June 30, hospitals will experience \$202.6 billion in losses. The rise in the uninsured population contributed to a 13 percent increase in bad debt and charity care in March of this year compared to the prior year.¹⁶

We call on you to immediately disburse the remainder of the \$25 billion in funds to ramp up testing and contact tracing capacity, as well as to make sure providers are aware of and able to easily access the \$2 billion that Congress appropriated to provide testing for the uninsured. Thank you for your urgent attention to this matter.

Sincerely,

CHARLES E. SCHUMER,
UNITED STATES SENATOR.
PATTY MURRAY,
UNITED STATES SENATOR.

STATEMENT FROM THE AMERICAN SOCIETY FOR MICROBIOLOGY

June 23, 2020

On behalf of our 30,000 members in the United States and around the world, the American Society for Microbiology (ASM) thanks Chairman Lamar Alexander, Ranking Member Patty Murray, and Members of the Senate Health, Education, Labor, and Pensions (HELP) Committee for holding this hearing to review lessons learned from past global infectious disease outbreaks and the current COVID-19 pandemic, and to discuss how we can better prepare for future pandemics. We also wish to express our appreciation to the Chairman for issuing a white paper on this subject with a call for comments. This is an important first step to ensuring a better response in the future, and ASM looks forward to providing more specific comments to the Committee.

As soon as the public health emergency subsides, Congress and the Administration must initiate a high-level, broad-based, comprehensive and scientific review of the COVID-19 response through either a Federal commission or a qualified, non-partisan entity such as the National Academies of Science, Engineering, and Medicine. This process should also be forward-looking and make cross-cutting recommendations on how the United States can better prepare for future public health emergencies, including funding needs and policy changes. By fully understanding what went well and what did not during this most recent pandemic, we can help thwart, or at the very least minimize, the effects of the next pandemic.

¹² <https://khn.org/news/number-of-americans-without-insurance-rises-in-2018/>.

¹³ <https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/>.

¹⁴ <https://www.kff.org/disparities-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-the-aca-2010-2018/>.

¹⁵ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>.

¹⁶ <https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due#:~:text=Discussion,of%20%2450.7%20billion%20%20month.>

Attached is a stakeholder letter dated March 30, 2020 spearheaded by ASM and signed by 38 additional national and international organizations, calling for a science-based review. ASM believes a high-level, comprehensive pandemic response review should make recommendations to do the following:

- Ensure global collaboration and open lines of communication with our international partners;
- More rapidly scale up laboratory testing capacity in order to get tests to those who need them;
- Ensure a steady supply chain of materials to labs and hospitals to mitigate shortages;
- Clearly and effectively communicate practical, science-based information and guidance to stakeholder entities and to the public; and
- Reduce patient access barriers so that all who need testing can get testing.

The current crisis has brought to light a number of barriers, challenges and shortcomings in our ability to respond to a public health emergency. Some of these were the results of “real-time” decisionmaking, while others exposed systemic breakdowns, chronic underfunding, and a lack of resources that were years—if not decades—in the making. These cut across multiple agencies and span levels of government from Federal, to state, to local authorities.

While ASM members in clinical laboratories have the most immediate connection to the current crisis, our members work in several areas that will be critical to a long-term strategy to head off future pandemics. These include conducting basic biomedical research, vaccine development, and service delivery in clinical laboratory settings.

ASM stands ready to work with you to help improve the systems we have in place today and to develop the solutions that will help address tomorrow’s challenges.

ASM reiterates our commitment to assisting the Committee, its Members, the Congress, the White House Coronavirus Task Force and the agencies as the U.S. continues to respond to the COVID-19 pandemic. More information from ASM on nCov2019: <https://asm.org/Press-Releases/2020/COVID-19-Resources>.

The American Society for Microbiology is one of the largest professional societies dedicated to the life sciences and is composed of 30,000 scientists and health practitioners. ASM’s mission is to promote and advance the microbial sciences.

ASM advances the microbial sciences through conferences, publications, certifications and educational opportunities. It enhances laboratory capacity around the globe through training and resources. It provides a network for scientists in academia, industry and clinical settings. Additionally, ASM promotes a deeper understanding of the microbial sciences to diverse audiences.

March 30, 2020.

The Hon. RICHARD SHELBY, *Chairman*
Committee on Appropriations,
U.S. Senate,
Washington, DC.

The Hon. PATRICK LEAHY, *Vice Chairman*
Committee on Appropriations,
U.S. Senate,
Washington, DC.

The Hon. ROY BLUNT, *Chairman*
Subcommittee on Labor, HHS, Education,
Committee on Appropriations,
U.S. Senate,
Washington, DC.

The Hon. PATTY MURRAY, *Ranking Member*
Subcommittee on Labor, HHS, Education,
Committee on Appropriations,
U.S. Senate,
Washington, DC.

DEAR CHAIRMAN SHELBY, VICE CHAIRMAN LEAHY, CHAIRMAN BLUNT AND RANKING MEMBER MURRAY:

We, the undersigned organizations representing millions of individuals working to address the unprecedented challenges SARS-COV-2 has presented to our society, our healthcare system, and our economy, are committed to working with Congress

and the Administration to address the pressing needs associated with the novel coronavirus (SARS-COV-2) and COVID-19.

We are writing to request that, as soon as the immediate public health emergency subsides, Congress and the Administration initiate a high-level, comprehensive review of the COVID-19 response through either a Federal commission or a qualified, nonpartisan entity such as the National Academies of Science, Engineering, and Medicine. This process should also be forward-looking and make cross-cutting recommendations on how the United States can better prepare for future public health emergencies, including funding needs and policy changes. By fully understanding what went well and what did not during this most recent pandemic, we can help thwart, or at the very least minimize, the effects of the next pandemic.

Specifically, such a review should recommend the most effective ways to:

- Ensure coordination and collaboration across and amongst Federal agencies and with state and local authorities;
- Clearly and effectively communicate practical, science-based information and guidance to stakeholder entities and to the public;
- Build public health capacity, including at the local, state and tribal health department levels;
- Rapidly scale up laboratory testing capacity in order to get tests to those who need them;
- Ensure a steady supply chain of materials to labs, clinics, hospitals and workplaces to mitigate shortages;
- Protect the most vulnerable in our communities by reducing patient access barriers to testing and health care services; and,
- Facilitate global collaboration to ensure that responses are based on real-time, accurate information.

The current crisis has brought to light a number of barriers, challenges and shortcomings in our ability to handle a public health emergency. Some of these were the results of “real-time” decisionmaking, while others exposed systemic breakdowns that were years—if not decades—in the making. These cut across multiple agencies and span levels of government from Federal, to state, to local authorities.

While public health professionals, health departments, clinical laboratories, clinics and hospitals have the most immediate connection to the current crisis, a comprehensive, well-planned approach will be critical to a long-term strategy to head off future pandemics. A comprehensive approach includes medical research and development, social, behavioral and economic considerations, corporate partners to ensure product and service delivery, small businesses, universities and research institutions, as well as healthcare professions.

We stand ready to work with you to help improve the systems we have in place today, and to develop the solutions that will help address tomorrow's challenges.

Sincerely,

1,000 DAYS
AABB
AMERICAN ACADEMY OF PEDIATRICS
AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY
AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE
AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY
AMERICAN ASSOCIATION OF IMMUNOLOGISTS
AMERICAN INSTITUTE FOR MEDICAL AND BIOLOGICAL ENGINEERING
AMERICAN PUBLIC HEALTH ASSOCIATION
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
AMERICAN SOCIETY FOR MICROBIOLOGY
AMERICAN SOCIETY FOR NUTRITION
AMERICAN SOCIETY FOR PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS
AMERICAN SOCIETY FOR VIROLOGY
AMERICAN SOCIETY OF HEMATOLOGY
AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE
ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY
ASSOCIATION OF AMERICAN CANCER INSTITUTES
ASSOCIATION OF AMERICAN UNIVERSITIES
ASSOCIATION OF MATERNAL & CHILD HEALTH PROGRAMS
ASSOCIATION OF POPULATION CENTERS
ASSOCIATION OF PUBLIC HEALTH LABORATORIES
ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES
BIOPHYSICAL SOCIETY
COALITION FOR THE LIFE SCIENCES
FEDERATION OF ASSOCIATIONS IN BEHAVIORAL & BRAIN SCIENCES
FOUNDATION FOR VACCINE RESEARCH
GLOBAL HEALTH TECHNOLOGIES COALITION
INFECTIOUS DISEASES SOCIETY OF AMERICA
NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS
NATIONAL SAFETY COUNCIL
OSA, THE OPTICAL SOCIETY
POPULATION ASSOCIATION OF AMERICA
RESEARCH!AMERICA
SOCIETY OF INFECTIOUS DISEASES PHARMACISTS
SUSAN G. KOMEN
THE SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA
TRUST FOR AMERICA'S HEALTH
VACCINATE YOUR FAMILY

Health Equity Principles for State and Local Leaders in Responding to, Reopening, and Recovering from COVID-19



Overview

COVID-19 has unleashed a dual threat to health equity in the United States: a pandemic that has sickened millions and killed tens of thousands and counting, and an economic downturn that has resulted in tens of millions of people losing jobs—the highest numbers since the Great Depression. The COVID pandemic underscores that:

- Our health is inextricably linked to that of our neighbors, family members, child- and adult-care providers, co-workers, school teachers, delivery service people, grocery store clerks, factory workers, and first responders, among others;
- Our current health care, public health, and economic systems do not adequately or equitably protect our well-being as a nation; and
- Every community is experiencing harm, though certain groups are suffering disproportionately, including people of color, workers with low incomes, and people living in places that were already struggling financially before the economic downturn.

For communities and their residents to recover fully and fairly, state and local leaders should consider the following **health equity principles** in designing and implementing their responses. These principles are not a detailed public health guide for responding to the pandemic or reopening the economy, but rather a compass that continually points leaders toward an equitable and lasting recovery.

1

Collect, analyze, and report data disaggregated by age, race, ethnicity, gender, disability, neighborhood, and other sociodemographic characteristics.

Pandemics and **economic recessions** exacerbate disparities that ultimately hurt us all. Therefore, state and local leaders cannot design equitable response and recovery strategies without monitoring COVID's impacts among socially and economically marginalized groups.¹ Data disaggregation should follow **best practices** and extend not only to public health data on COVID cases, hospitalizations, and fatalities, but also to: measures of **access**

¹ People of color (African-Americans, Latinos, Asian-Americans, American Indians, Alaska Natives, and Native Hawaiians and other Pacific Islanders), women, people living in congregate settings such as nursing homes and jails, people with physical and intellectual disabilities, LGBTQ+ people, immigrants, and people with limited English proficiency.

"Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care."

[What Is Health Equity? And What Difference Does a Definition Make?](#)

Robert Wood Johnson Foundation, 2017

Health Equity Principles

1. Collect, analyze and report disaggregated data.
2. Include those who are most affected in decisions, and benchmark progress based on their outcomes.
3. Establish and empower teams dedicated to racial equity.
4. Proactively fill policy gaps while advocating for more federal support.
5. Invest in public health, health care and social infrastructure.

to testing, treatment, personal protective equipment (PPE), and safe places to isolate when sick; receipt of social and economic supports; and the downstream consequences of COVID on well-being, ranging from housing instability to food insecurity. Geographic identifiers would allow leaders and the public to understand the interplay between place and social factors, as [counties with large black populations](#) account for more than half of all COVID deaths, and [rural communities](#) and [post-industrial cities](#) generally fare worse in economic downturns. Legal mandates for data disaggregation are proliferating, but [11 states](#) are still not reporting COVID deaths by race; 16 are not reporting by gender; and 26 are not reporting based on congregate living status (e.g., nursing homes, jails). Only three are reporting testing data by race and ethnicity. While states and cities can do more, the federal government should also support data disaggregation through funding and national standards.

2

Include in decision-making the people most affected by health and economic challenges, and benchmark progress based on their outcomes.

Our communities are [stronger, more stable, and more prosperous](#) when every person, including the most disadvantaged residents, is healthy and financially secure. Throughout the response and recovery, state and local leaders should ask: *Are we making sure that people facing the greatest risks have access to PPE, testing and treatment, stable housing, and a way to support their families? And, are we creating ways for residents—particularly those hardest hit—to meaningfully participate in and shape the government's recovery strategy?*

Accordingly, policymakers should create space for leaders from these communities to be at decision-making tables and should regularly consult with community-based organizations that can identify barriers to accessing health and social services, lift up grassroots solutions, and disseminate public health guidance in culturally and linguistically appropriate ways. For example, they could recommend trusted, accessible locations for new testing sites and advise on how to diversify the pool of [contact tracers](#), who will be crucial to tamping down the spread of infection in reopened communities. They could also collaborate with government leaders to ensure that all people who are infected with coronavirus (or exposed to someone infected) have a safe, secure, and acceptable place to isolate or quarantine for 14 days. Key partners could include community health centers, small business associations, community organizing groups, and workers' rights organizations, among others. Ultimately, state and local leaders should measure the success of their response based not only on total death counts and aggregate economic impacts but also on the health and social outcomes of the most marginalized.

Are we making sure that people facing the greatest risks have access to PPE, testing and treatment, stable housing, and a way to support their families?

3 Establish and empower teams dedicated to promoting racial equity in response and recovery efforts.

Race or ethnicity should not determine anyone's opportunity for good health or social well-being, but, as COVID has shown, we are far from this goal. People of color are more likely to be [front-line workers](#), to live in dense or overcrowded housing, to lack health insurance, and to experience chronic diseases linked to unhealthy environments and [structural racism](#). Therefore, state and local leaders should empower dedicated teams to address COVID-related racial disparities, as several leaders, [Republican](#) and [Democrat](#), have already done. To be effective, these entities should: include leaders of color from community, corporate, academic, and philanthropic sectors; be integrated as key members of the broader public health and economic recovery efforts; and be accountable to the public. These teams should foster collaboration between state, local, and tribal governments to assist Native communities; anticipate and mitigate negative consequences of current response strategies, such as [bias in enforcement of public health guidelines](#); address racial discrimination within the health care system; and ensure access to [tailored mental health services](#) for people of color and immigrants who are experiencing added trauma, stigma, and fear. Ultimately, [resources matter](#). State and local leaders must ensure that critical health and social supports are distributed fairly, proportionate to need, and free of undue restrictions to meet the needs of all groups, including black, Latino, Asian, and Indigenous communities.

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4 Proactively identify and address existing policy gaps while advocating for further federal support.

The Congressional response to COVID has been historic in its scope and speed, but significant gaps remain. Additional federal resources are needed for a broad range of health and social services, along with [fiscal relief](#) for states and communities facing historically large budget deficits due to COVID. Despite these challenges, state and local leaders must still find ways to take targeted policy actions. The following questions can help guide their response.

Who is left out?

Inclusion of all populations will strengthen the public health response and lessen the pandemic's economic fallout for all of society, but federal actions to date have not included all who have been severely harmed by the pandemic. As a result, many [states](#) and [communities](#) have sought to fill gaps in [eviction](#) protections and [paid sick and caregiving leave](#). Others are extending support to undocumented immigrants and mixed-status families through [public-private partnerships](#), faith-based charities, and [community-led mutual aid systems](#). Vital health care providers, including safety net hospitals and Indian Health Service facilities, have also been [disadvantaged](#) and need targeted support.

Will protections last long enough?

Many programs, such as expanded Medicaid funding, are tied to the federal declaration of a public health emergency, which will likely end before the economic crisis does. Other

policies, like enhanced unemployment insurance and mortgage relief, are set to expire on arbitrary dates. And still others, such as stimulus checks, were one-time payments. Instead, policy extensions should be tied to the extent of COVID infection in a state or community (or its anticipated spread) and/or to broader economic measures such as unemployment. This is particularly important as communities will likely experience reopenings and closings over the next six to 12 months as COVID reemerges.

Have programs that meet urgent needs been fully and fairly implemented?

All existing federal resources should be used in a time of great need. For example, [additional states should adopt](#) provisions that would allow families with school-age children to receive added [Supplemental Nutrition Assistance Program](#) (SNAP) benefits, and more communities need [innovative solutions](#) to provide meals to young children who relied on schools or child care providers for breakfast and lunch. States should also revise eligibility, enrollment, and recertification processes that [deter Medicaid use](#) by children, pregnant women, and lawfully residing immigrants.

5

Invest in strengthening public health, health care, and social infrastructure to foster resilience.

Health, public health, and social infrastructure are critical for recovery and for our survival of the next pandemic, severe weather event, or economic downturn. A comprehensive public health system is the first line of [defense](#) for rural, tribal, and urban communities. While a [sizable federal reinvestment in public health is needed](#), states and communities must also reverse steady cuts to the public health workforce and laboratory and data systems. Everyone in this country should have [paid sick and family leave](#) to care for themselves and loved ones; comprehensive health insurance to ensure access to care when sick and to protect against medical debt; and jobs and social supports that enable families to meet their basic needs and invest in the future. As [millions are projected to lose employer-sponsored health insurance](#), Medicaid expansion becomes increasingly vital for its [proven ability](#) to boost health, reduce disparities, and provide a strong return on investment. In the longer term, policies such as [earned income tax credits](#) and [wage increases for low-wage workers](#) can help secure economic opportunity and health for all. Finally, states and communities should invest in [affordable, accessible high-speed internet](#), which is crucial to ensuring that everyone—not just the most privileged among us—is informed, connected to schools and jobs, and engaged civically.

Everyone in this country should have paid sick and family leave ... comprehensive health insurance ... and jobs and social supports that enable families to meet their basic needs and invest in the future.

Conclusion

These principles can guide our nation toward an equitable response and recovery and help sow the seeds of long-term, transformative change. States and cities have begun imagining and, in some cases, advancing toward this vision, putting a down payment on a fair and just future in which health equity is a reality. Returning to the ways things were is not an option.

A Storm for Which We Were Unprepared

Bill Frist, M.D.
The American Mind
Essay—04.13.2020

Senator Bill Frist saw it coming years ago.

*Senator **William Frist**, M.D. is a nationally acclaimed heart and lung transplant surgeon and the former Majority Leader of the U.S. Senate. In 2005, during his tenure in Congress, he delivered the Marshall J. Seidman Lecture for the Department of Health Care Policy at Harvard University. In this strikingly prescient speech, he foretells the possibility of a viciously deadly pandemic and calls for action to defend against that eventuality on a vast scale. Though his warnings went unheeded, we are honored to publish his words now as part of our **ongoing efforts** to understand and counteract COVID-19 and its effects.*

I am a physician and a surgeon who by accident of fate finds himself in the halls of power at a time of dangers for his country and the world, the most compelling of which are exactly those a physician is trained to recognize and fight. To me it seems no more natural to be a United States Senator, and in my case the majority leader of the Senate, than it did to Harry Truman, who spent so many hard and unambitious years as a farmer and then found himself in such a place and at such a time as he did. And, like him, as someone who comes from the outside, and for whom the perquisites of power appear strange and irrelevant, I have asked myself what my purpose is as a public servant, what my obligations are, and what high precedents I should follow.

After some thought, I have determined my purpose, I know my duty and obligations, the precedents to honor, and why—neither history nor life itself being empty of example. Just as a surgeon must follow a purely objective course and a general must look at war with a cold and steady eye, a statesman must operate as if the world were free of emotion. And yet, to rise properly to the occasion, the surgeon must have the deepest compassion for his patient, the general must have the heart of an infantryman, and the statesman must know at every moment that the cost of his decisions is borne, often painfully, by the sovereign population he serves—all as if the world were nothing but emotion. The difficulty in this is what Churchill called the “continual stress of soul,” the rack upon which the adherents of these professions, if they meet their obligations well, will of necessity be broken.

In balancing objectivity with emotion, the practical with the moral, the smooth operation of power with its homely and human effects, one is driven to consider first things and elemental purposes, and this consideration makes clear that the guiding star of statesmanship is not aggrandizement of the state or the furtherance of a philosophy or ideology, and neither glory nor ambition nor accumulation of territory or riches. Rather, the guiding star must be the fact of human mortality, and the first purpose of a public official a simple watch upon the walls. We are charged above all with assuring the survival of the Nation and protecting the lives of those whom we serve and who have put us in our place, entrusting us with this gravest of responsibilities.

Whether leading a small nomadic band, captaining a ship, or at the head of a huge industrial nation, the task is the same. It is not merely that which can be accomplished with sword and shield, but, rather, the exercise of courage, sacrifice, and judgment, in the preservation of the life of a nation in its people as families and individuals. And as if by design, this task becomes in its execution a principle that unites the powerless and powerful in an unimpeachable equality.

Clear and Present Danger

In times of peace and prosperity, whole nations sometimes willfully forget that we are mortal, and the forgetfulness then can rule beyond its natural life even in the face of war and pestilence, when by all accounts the star of mortality shines in air cleared of the luminous distractions of peace.

Like everyone else, politicians tend to look away from danger, to hope for the best, and pray that disaster will not arrive on their watch even as they sleep through it. This is so much a part of human nature that it often goes unchallenged. But we will not be able to sleep through what is likely coming soon—a front of unchecked and virulent epidemics, the potential of which should rise above your every other concern. For what the world now faces it has not seen even in the most harrowing episodes of the Middle Ages or the great wars of the last century. And not only are we unprepared for rampant epidemics, we have not taken sufficient note of the fact

that though individually each might be devastating, they are susceptible of either purposeful or accidental combination, in which case they could be devastating almost beyond imagination.

The history of pathogens advances in parallel with and is no more static than our own, with which it is always intertwined, even if at times invisibly. Sometimes it rushes forward with great speed and breathtaking evolutionary vigor, and sometimes it rests in slow backwaters. When, in 1967, the U.S. Surgeon General declared that we had won the war on infectious diseases, we thought the slack water would last forever. But that war had never ended other than in wishful thinking.

Even now we accept as normal, because it is normal, that more than a quarter of all deaths—fifteen million each year—are due to infectious diseases. Three million children die every year of malaria and diarrheal diseases alone, one child every 10 seconds. As sobering as this may be, we have been nonetheless in a quiescent stage of the mutability of pathogens, a hiatus from which they are now poised to break out. When viral diseases evolve normally—such as in the typical course of the human influenza virus undergoing small changes in its antigenicity and killing an average of 500,000 people annually throughout the world—it is called an *antigenic drift*. When they emerge with the immense power derivative of a jump from animal to human hosts followed by mutation and/or recombination with a human virus, as in the influenza pandemic of 1918–1919, in which 500 million people were infected and 50 million died, including half a million in the United States, it is called an *antigenic shift*.

To have believed with the Surgeon General forty years ago that the great advances of biological science were capable of permanently suppressing infectious disease was to have been unaware that these triumphs were appropriate only to one phase in the life of a continually evolving enemy whose natural rate of evolution and adaptation is far greater than our own. Shifts are the result of random, fortuitous, and unavoidable changes. Human population increase, concentration, and spread, intensification of animal husbandry, and greater wealth in developing countries bring animals both wild and domestic into closer contact with ever-larger numbers of people. War, economic catastrophe, and natural disasters subdue active measures of public health. The unprecedented use of antibiotics builds unprecedented resistance. Travel, trade, and climate change bring into contact disparate types and strains of disease. And as a consequence of all this, microbes evolve, mutate, and find new lives in new hosts.

The annual toll of infectious diseases worldwide—including four million from respiratory infections, three million from HIV/AIDS, and two million from waterborne diseases such as cholera—is a continuing and intolerable holocaust that, while sparing no class, strikes hardest at the weak, the impoverished, and the young. But this is just a beginning, in that the evidence strongly suggests that we are at the threshold of a major shift in the antigenicity of not merely one but several categories of pathogens, for never have we observed among them such variety, richness, opportunities for combination, and alacrity to combine and mutate. HIV, variant Creutzfeldt-Jakob disease (mad cow), avian influenzas such as H5N1, and SARS are merely the advance patrols of a great army forming out of sight, the lightning that however silent and distant gives rise to the dread of an approaching storm—a storm for which we are entirely unprepared. How can that be? How can the richest country in the world, with its great institutions, experts, and learned commissions, have failed to make adequate preparation—when preparation is all—for epidemics with the potential of killing off large segments of its population?

Precedent and Presage

To see what lies on the horizon one need only look to the relatively recent past. I have a photograph of an emergency hospital in Kansas during the 1918 influenza pandemic. People lie miserably on cots in an enormous barn-like room with beams of sunlight streaming through high windows. It seems more crowded than the main floor of Grand Central Station at five o'clock on a weekday. In this one room several hundred people are in the throes of distress. Think of 2,000 such rooms filled with a crush of men, women, and children—500,000 in all—and imagine that the shafts of sunlight that illuminate them for us almost a century later are the last light they will ever see. Then bury them. That is what happened.

How would a nation so greatly moved and touched by the 3,000 dead of September 11th react to half a million dead? In 1918–1919 the mortality rate was only 10 percent, which seems merciful in comparison to the near 100 percent rate common to hemorrhagic fevers. Nor is influenza nearly as infectious as, for example,

smallpox. How, then, would a nation greatly moved and touched by 3,000 dead, react to five or fifty million dead?

Smallpox is just one of many threats. During the cold war, the Soviet Union, which stockpiled 5,000 tons annually of biowarfare-engineered anthrax resistant to 16 antibiotics, also produced massive amounts of weaponized smallpox virus just as universal immunization had come to a halt. As a result of conditions prevalent during the dissolution of the USSR, it is impossible to rule out that quantities of this or other deliberately manufactured pathogens such as anthrax, pneumonic plague, tularemia, etc. may find or may have found their ways into the possession of terrorists such as bin Laden and al-Zarqawi. Although the United States has put up enough—questionable—smallpox vaccine for the entire population, it has neither the means of distribution nor the immunized personnel to administer it in a generalized outbreak, nor the certainty that the vaccine would be relevant to a specific weaponized strain of the virus. Ring vaccination would be useless if the pathogen were released at many sites simultaneously, and in such a circumstance hospitals and the now nonexistent auxiliary means of relief would be quickly overwhelmed.

Panic, suffering, and the spread of the disease would intensify as—because people were dead, sick, or afraid—the economy ceased to function, electrical power flickered out, and food and medical supplies failed to move. Over months or perhaps years, scores of millions might perish, with whole families dying in their houses and no one to memorialize them or remove their corpses. Almost without doubt, the epidemic would spread to the rest of the world, for in biological warfare an attack upon one country is an attack upon all. Every vestige of modernity would be overturned. The continual and illusory flirtation with immortality that is a hallmark of scientific civilization would shatter, and we would find ourselves looking back upon even the most difficult times of the last century as a golden age. Despite the common wisdom, humanity has not moved beyond this kind of scenario. Of late it has moved unnecessarily and gratuitously toward it.

Any number of unknown viruses for which at present there is neither immunization nor cure are at this moment cooking in Asia and Africa, where they arise in hotbeds of densely intermingled human and animal populations. We are in unexplored territory. Economic and environmental changes in Asia have forced wilderness-deprived waterfowl to alight to feed amid farm animals in newly dense populations due to recently acquired wealth and dietary expectations, in a culture in which live poultry is brought to market. The reassortment of viral DNA as a result of this mingling is so frenzied that it is only a matter of time until the emergence of a virus unequalled in transmissibility and virulence. The epidemiological calculus of flu is notoriously volatile due to the unknowns of rapid reassortment. We do know now, however, that the incidence of H5N1 has been underestimated, that North Korea may be at the cusp of an Avian Flu crisis, and that we are woefully underprepared even for a virus that we can foresee, much less for one that we cannot.

No such viruses have yet reached critical mass or leapt from the channels imposed by their inherent limitations, environmental obstacles, and deliberate actions to contain them. But the evidence I have seen, the patterns of history, and new facts such as rapid, voluminous, and essential travel and trade; the decline of staffed hospital beds; and a now heavily urbanized and suburbanized American population dependent as never before upon easily disrupted networks of services and supply, lead me to believe that—especially because vaccines, if they could be devised, would not be available en masse until six to nine months after the outbreak of a pandemic—the imminence of such viruses might result in the immensely high death tolls to which I have alluded.

It is true that none of these viruses has yet spread geometrically—instantly and irrevocably overcoming health care systems and pulling us backward across thresholds of darkness that we long have believed we would never cross again. And yet this they might do—either entirely on their own or as a result of intentional human intervention. No intelligence agency, no matter how obsessively and repeatedly rearranged, and no military, no matter how powerful and dedicated, can assure that a few technicians of middling skill using a few thousand dollars' worth of readily available equipment in a small and apparently innocuous setting cannot mount a first-order biological attack. It is possible, for example, to unite the prairie-fire infectiousness of smallpox with the almost absolute fatality of Ebola fever. It is possible simply and inexpensively to synthesize virulent pathogens from scratch, or to engineer and manufacture *prions* that, introduced undetected over time into a nation's food supply, would after a long delay afflict virtually the entire population with a terrible and uniformly fatal disease. Unfortunately, the permutations are so various that the research establishment as now constituted cannot set up lines of investigation to anticipate even a small proportion of them. Never have we had to fight such

a battle, to protect so many people against so many threats that are so silent and so lethal.

But is it reasonable to assume that anyone might resort to biological warfare? Indeed it is. Al-Qaida has declared that, "We have the right to kill four million Americans—two million of them children . . . [and] it is our right to fight them with chemical and biological weapons." In *Al-Istiqlal*, the weekly of Islamic Jihad, we read that "it is the duty of Muslims to act in any possible way to acquire weapons of mass destruction, starting with nuclear weapons and ending with chemical and biological weapons." It is hardly necessary, however, to rely upon stated intent. One need only weigh the logic of terrorism, its evolution, its absolutist convictions, and the evidence in documents and materials found in terrorist redoubts.

Those who equate terrorism with its targets and take false comfort in attributing to the terrorist the moral status and restraint of his victim should consider that for more than half a century at least eight countries have possessed a collective arsenal of, at times, not only scores of thousands of nuclear warheads but the virtually ineluctable means of delivering them. Still, apart from the first and only use of nuclear weapons, in every trying condition, in crisis and in war, in victory and in defeat, not one has been detonated except in test. Who would gamble that if the terrorist enemy possessed even a single nuclear charge, he would fail to devote all his resources to its detonation in the midst of the maximum number of innocents? And though not as initially dramatic as a nuclear blast, biological warfare is potentially far more destructive than the kind of nuclear attack feasible at the operational level of the terrorist, and biological war is itself distressingly easy to wage.

Rising to Meet the Day

I ask again how it is that nowhere is anyone prepared either for naturally occurring epidemics of newly emergent diseases or those that are deliberately induced? It would take whole encyclopedias to dwell on what has not been done and the inadequacy of what little has been done, but a hint may be accurately conveyed by the fact that the Nation's largest biocontaminant unit with fully adequate quarantine and negative air is a ten-bed facility in Omaha, or by the absurdity of a recent announcement from the Washington Hospital Center that in "implementing plans for handling *any* disaster that might *effect* our capital," and "to deal with the *worst* in biological, chemical, and natural disasters," it has built, "a multi-use, 20-bed ready room" (emphasis mine).

We may have built a 20-bed ready room, but there is on the horizon a silent wave that is coming at the world, and, if we do nothing, it will sweep over us invincibly. My duties as physician and public official having fused, I propose that we take the measure of this threat and make preparations to engage it with the force and knowledge adequate to throw it back wherever and however it may strike. It need not be invincible and we need not fall to our knees before it. Means adequate to the success of a defensive plan are present in great profusion. Whereas the approaching biological shift is gathering force like a massing army, providence has massed an army to meet it. Having themselves expanded geometrically, the life sciences have come to the threshold of a great age, and to cross it they need only encouragement and a signal from the body politic to put their resources in play.

We are not without weapons in this war. They are present in the stupendous material and intellectual wealth of the civilized world, which, despite current divisions of action and opinion, has everything to lose in common. They are present in the approximately \$30 trillion per annum combined gross national products of just NATO and Japan. They are present in the great stores of science and technology amassed over thousands of years of civilization; in the many hundreds of universities, advanced research institutions, and hospitals; in the private sector's ruthless focus, which, though frequently condemned for its lack of humanity, may yet be the instrument that saves humanity. They are present in the special temperament and brilliance of individual scientists; in the magnificent light that comes of the surprising and ingenious application of new technologies; and in the vigor, intelligence, and decency of free and unoppressed peoples.

The nature of the threat being mortal and reaction to it heretofore irresponsible and inadequate, I propose—entirely without prejudice to the necessity and absent the diminution of the means to disrupt, defeat, and confound the aggressor by force of arms—an immense and unprecedented effort. I see not an initiative on the scale of the Manhattan Project, but one that would dwarf the Manhattan Project; not the creation of a giant, multi-billion dollar research institution, but the creation of a score of them; not merely the funding of individual lines of inquiry, but of richly supported fundamental research, a supreme effort in hope of universal application;

not the fractional augmentation of medical education but its doubling or tripling; not a wan expansion of emergency hospital capacity, but its expansion, as is necessary and appropriate, by orders of magnitude; not to tame or punish the private sector, but to unleash it especially upon this task; not the creation of a forest of bureaucratic organization charts and the repetition of a hundred million Latinate words in a hundred million meetings that substitute for action, but action itself, unadorned by excuse or delay; not the incremental improvement of stockpiles and means of distribution, but the creation of great and secure stores and networks, with every needed building, laboratory, airplane, truck, and vaccination station, no excuses, no exceptions, everywhere, and for everyone.

I call for no less than the creation, with war-like concentration, of the ability to detect, identify, and model any emerging or newly emerging infection, natural or otherwise; for the ability to engineer the immunization and cure, and to manufacture, distribute, and administer whatever may be required to get it done and to get it done in time. For some years to come, this should be the chief work of the Nation, for the good reason that failing to make it so would be to risk the life of the Nation.

It could be very costly, yes, but it is the kind of thing that, once accomplished, is done. And it is the kind of thing that calls out to be done, and that, if not done, will indict us forever in the eyes of history. In diverting a portion of our vast resources to protect nothing less than our lives, the lives of our children, and the life of our civilization, many benefits other than survival would follow in train, not least the satisfaction of having done right. If the process of scientific discovery proceeds as usually it does, diversions of money, energy, and effort into the construction of a vast public and private research and medical system capable of intercepting and defeating the worst natural or terroristic epidemics would very likely bring as well a magnificent offshoot—understanding diseases that we do not now understand and finding the cures for diseases that we cannot now cure. If the laws of supply and demand have not been repealed—and they have not—the heretofore unequaled abundance of medical goods and services would contribute to solving the problems of financing health care—and it would do so the old-fashioned way, by paying for it. And, as always, disciplined and decisive action in facing an emergency can, even in the short run, compensate for its costs—by adding to the economy both a potent principle of organization, and a stimulus like war but war's opposite in effect, which would power the productive life of the country into new fields, transforming the information age with unexpected rapidity into the biotechnical age that is to come—and all this, if the Nation can be properly inspired in its own defense and protection, perhaps just in time.

Rest for a moment what may be your astonishment at the scale of the initiative I have proposed, and allow a conservative Republican from Tennessee, who is by nature skeptical of government action, to affirm the root conservative principle that if the life of the Nation is potentially at risk no effort should be judged too ambitious, no price too high to pay, no division too wide to breach.

We have built great cities, dams, and aqueducts. We have built the interstate highway system, bridges, canals, fleets, armies, and a world of structures the cost of which defies expression. We have decided upon going to the moon and then done so in a few short years. Can we not, then, build this thing, and take these steps, to protect our lives and the lives of our children, to evade mass death and alleviate the greatest suffering that man has ever known, that comes to all classes, all races, all ages? Have we been so blinded and confused that we cannot see the single most important challenge before us, and the single greatest opportunity?

I am aware that what is now required has not been asked since the eighth of December, 1941. And I am aware of the difficulties. But I know as well that however much it may be shunted aside by the ordinary and the profane, a deep understanding of mortality, second to none, is present in the people—who are not superficial, who are not to be dismissed, and from whom an almost miraculous collective wisdom has arisen whenever it has been needed. It arose at the time of the American Founding, to create a republican democracy despite the militant opposition of the world's greatest empire. It arose when the premise of the founding, that all men are created equal, was turned into reality even though to do so meant the bloodiest war in the Nation's history. It arose in the world wars and the cold war, when the Nation fought and persevered for a century, with patience, devotion, and generosity, not merely for the sake of its narrow interests—which some could not even see—but out of principle. I believe that despite their imperfection the sinews of the American people are intact, and I believe that the sinews of our allies and their great civilizations are intact as well.

America on the Front Lines

Especially since September 11th, awareness of mass biological warfare has been at the edge of the popular imagination, but seems to have escaped political will. Blind and chattering elites have dismissed the concerns of the public, or failed to hear them, as if there were a set of facts, a certitude of result, or some infallible wisdom with which to support this dismissal. But no such facts exist and the certitude of those who would discount the danger is just a pose spun from thin air. Failure to foresee, to prepare for, and to forestall bioterrorism and a biological shift is a failure of statesmanship that, until remedies are found and action taken, is also a personal failure for everyone in a high and responsible position—even the highest, especially the highest, including the president, and including me. In this regard the people are ahead of their leaders and possessed of more common sense. They know, quite frankly, that we are as vulnerable as hell, and that no one is really doing anything about it.

The persistent inaction is especially gratuitous in light of the fact that the magnitude of the issue should have the power to heal many a breach and cross many an ideological chasm. For those who hold that attention to moral questions is illusory and impractical, and for those who protest that devotion solely to practical matters is amoral, here is the urgent fusion of both, that cannot be dismissed as either, even if until now it has been perceived and neglected as if it were neither. As in crises of times past, left and right, modernists and traditionalists, the old world and the new, can agree that the protection and preservation of human life on a massive scale is the one goal in their philosophies that will enable their every other principle to seek its every other action.

Conservative predilection and purely empirical observation lead me to believe that what I have proposed, though universal in effect, cannot be brought to fruition as a universal scheme. The World Health Organization is essential, but it works best as an expression of the power and resolution of nations. For the Nation is yet the highest level of effective organization, and, paradoxical as it may seem, a worldwide defense against biological catastrophe would be strongest were it erected at the national level, in a loose confederation with unavoidable duplications but with, nonetheless, the organic development among countries of an efficient division of labor.

In this the United States is as blessed as it has been since its beginnings. We are the wealthiest, freest, and most scientifically advanced of all societies, the first republican democracy, the first modern state. And although we have suffered criticism of late and to no small degree because of our awkwardness as a young nation, we have been willing since our Founding and are willing still to pursue certain ideals. Though not infrequently condemned from the precincts of cynicism, America has mostly left cynics in its wake, sometimes after saving them from floods that they themselves have unleashed.

Do not discount America or dismiss its resolution. Our imperfections are accompanied by fine qualities and beliefs of which we will never be ashamed and from which we have no intention of recoiling. We believe in government with the consent of the governed, and in the sanctity of the individual. We have as a nation by and large rejected a mechanistic view of human nature in favor of a belief in the soul and the grace it may be granted. (If there is no soul, what is the basis of human equality in law or morals, given that we are unequal in all other ways?) This belief to which we hold firm is descended from our founding, which occurred at a time of miraculous poise in human history when science and reason were in uncontradictory balance with faith; when in America the freshest optimism the world has ever known was tempered by a view of human nature unsurpassed in its clarity and caution.

Lest this seem too abstract, consider that when we found ourselves in violation of our elemental principles we suffered through many years of fratricidal warfare to put them right. Both sides fought with inimitable courage, and the side—of which I am a son—that was reduced to waste and ash, rose from its ruins to fight a greater battle, a battle with itself, finally to embrace the principles it had opposed.

From the blood of my fathers and in my blood itself I have not merely a vision of ruin, waste, and ash, but the certain knowledge, a vivid memory that has of late been refreshed and confirmed. This is not the last time you will hear from me, but today I have tried to impress upon you the urgency I feel in the matter of the immediate destiny not only of America but of the world, for pandemics know neither borders, nor race, nor who is rich nor who is poor, they know only what is human, and it is this that they strike, casting aside the vain definitions that otherwise divide us.

It is my pre-eminent obligation as a public servant and my sacred duty as a physician to ask you to support the essence of my proposal. In respect of human mortality, for the sake of your own families and children, for the honor and satisfaction of doing right, and to sweep away the inexcusable prevarication that has accumulated since the great shock of September 11th, I bid you join in this declaration. May God preserve us all, and may our actions and foresight make us worthy of His preservation.

REMARKS AS PREPARED FOR MAJORITY LEADER BILL FRIST, M.D.

PANDEMIC: THE ECONOMY'S SILENT KILLER

NATIONAL PRESS CLUB

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Introduction

Imagine a cigarette carelessly flung on the edge of a scorched and brittle forest. Un-extinguished, the cigarette smolders in the leaves until it catches flame. The winds blow in, sparks are carried afar, the thirsty limbs ignite. A forest fire is born.

When the elements are aligned, the path of a global pandemic is similar.

Think of a fast-moving, highly contagious disease that wipes out 50 million people. Half a million in the U.S. The killer pandemic claims more victims in 24 weeks, than HIV-AIDS has claimed in 24 years.

In the United States—the most developed nation in the world—bodies pile up in the streets. There aren't enough morticians to bury the dead. Nor are there enough doctors and nurses to tend to the sick.

Normal life stops. The churches close, the schools shutter. Communications and transportation grind to a halt.

The public succumbs to hysteria and panic. Police protection fails. Order decays. Productivity dives.

Sounds like science fiction, doesn't it? But what if I told you, it already happened? What if I told you it was the pandemic flu that swept across America and around the globe in 1918?

Or if I told you that this glimpse into the past *might just* be a preview to our future?

A viral pandemic is no longer a question of if, but a question of when.

We know—depending upon the virulence of the strain that strikes and our capacity to respond—that the ensuing death toll could be devastating.

In recent weeks, the growing death toll of the avian flu and the mounting drumbeat of discussion have placed the virus under the microscope of the public eye. Yet—like all stories—it too will shift from center stage. The public will have had their fill. The danger will seem removed.

But while the story may recede from the cover of *Newsweek* or the centerfold of *Time*, I know that a threat that strikes at our very mortality—as this does—must not recede to the backdrop of public concern.

As a physician, a heart surgeon, my life has centered on mortality—the preservation of life.

Similarly, as public officials, the mortality of mankind should be our first, and if necessary, only concern. Measured against everything we consider from day to day—budgeting, taxes, judges, pensions—your mortality, the care and protection of human life, is the most fundamental responsibility entrusted to us.

Which is why we will not look away from what may come.

Today I ask you to walk forward with me to a future where an avian pandemic strikes. (It's almost Christmas ... think of the Ghost of Christmas Future.) As we look to that future, let's zero in on a critically important aspect that has received almost no focus to date—the pandemic's impact on our economy.

"When a pandemic strikes, exactly how devastating will the economic fallout be?"

That is the question I'll answer today.

But before we fast-forward to the future, let's quickly rewind.

"Exactly what is this avian influenza?"

The year is 1997. The place, Hong Kong.

The culprit: the H5N1 strain of the avian flu, a highly contagious virus *primarily* affecting wild waterfowl. The birds are a natural breeding ground for the virus—they can carry the virus without symptoms, spreading it far and wide.

In 1997 the dynamics shift. The virus that has affected only animals so far spreads to 18 people in Hong Kong. A third of them die.

By slaughtering the region's entire poultry stock—1.5 million birds—Hong Kong authorities quickly stem the spread of disease.

But to scientists and public health officials, it is the first shot heard round the world. The Hong Kong outbreak signaled that the H5N1 strain had satisfied two of three prerequisites for a pandemic:

1st: the H5N1 strain was a novel type of virus, to which no human being has any pre-existing immunity.

2nd: The virus could reproduce in humans and cause serious illness.

The only remaining requirement—not yet fulfilled—is human-to-human transmission.

For the final element to fall into place, it will require little more than the shuffling of a few genes between the animal and human forms of a virus (—a phenomenon known as an antigenic shift.)

The resulting mix will be totally unfamiliar to the human immune system which normally fights infections—meaning that human beings will have no natural immunity to it. More alarming, the right mix of genes could allow for sustained human-to-human transmission: an avian pandemic would launch to life.

Since the 1997 outbreak, the avian flu has progressively and relentlessly spread across 16 countries. From Hong Kong, the virus has stretched its tentacles into Thailand, South Korea, Vietnam, Japan, Cambodia, Laos, Indonesia, China, Malaysia, Russia, Kazakhstan, Mongolia, Turkey, Romania, and Croatia—infesting 135 humans, and killing 69 (in five countries—Cambodia, China, Indonesia, Thailand, Vietnam).¹

With each outbreak, the signs are increasingly clear that a pandemic is looming.

1st: it's found a permanent ecologic niche among domestic ducks in rural Asia.

2nd: it's increased the range of species it can infect—moving to cats and tigers.

3rd: it's grown more robust, rendering itself resistant to 1 of 2 types of anti-flu drugs.

4th: it's shown the ability to mutate rapidly, with the propensity to acquire new genes.

Last, it's demonstrated that it can infect humans directly.

With each person that the virus infects, the more likely it is that genetic re-assortment will occur, and a pandemic will arise.

Possible Pandemic Scenarios

A second fundamental question: "How severe will that pandemic be?"

To forecast the economic impact, it's a question we must answer.

The most frequently cited, deadliest pandemic in recent history was the 1918–1919 Spanish influenza.

The flu infected between a quarter and a third of all Americans, and killed half a million (2–3 percent of those infected). Worldwide, 40 to 50 million people died.

Unlike the seasonal flu, the 1918 influenza preyed on and killed a younger, healthier demographic, the most productive segment of our population—as opposed to the elderly, the weak, and the very young. In the United States, the pandemic was so acute that the average lifespan was shaved-off by 10 years.

¹From 2003 to present. Deaths have occurred in Cambodia, China, Vietnam, Thailand, and Indonesia.

“So, will an avian pandemic today be *more severe or less severe* than the 1918 avian flu?”

We don’t know.

Scientists who believe that the coming pandemic will be LESS severe cite the dramatic 20th century advances in science and medicine. We have far more sophisticated tools for surveillance, the ability to design vaccines, and better treatment options like antibiotics for secondary bacterial infections.

Those who believe that we’re MORE vulnerable today argue (perhaps even more persuasively) that the world is much more densely populated which facilitates rapid spread. They cite that the population is comprised of a higher proportion of elderly; that our dependence on just-in-time delivery systems would wreak greater disruption; and last that a million people living today with preexisting compromised immune systems (by cancer therapy) means a more susceptible host.

This line of reasoning—that a pandemic would be worse—is compounded by the fact that the world today is so tightly interconnected through travel, trade, and on-line communication—a factor that could greatly amplify the spread of fear, panic, and even the virus itself.

Whatever the outcome, this latter argument speaks to an undeniable truth. When facing the prospect of a modern pandemic, no longer are we battling the rapidly spreading virus alone, but the repercussions of disease in a world where everything is interdependent.

“But,” you say, “1918 is a long time ago.”

“Is there a modern example of a viral outbreak that we can learn from?”

And the answer is yes—the 2003 outbreak of the SARS virus.

SARS is our Best Benchmark

SARS, though not a pandemic, demonstrated—for the first time ever—the profound sensitivity of the modern global economy to a contagious, spreading, infectious disease.

The SARS virus infected only 8,000, and killed just 774 (remember the annual seasonal flu kills 30,000 in America every year). BUT what we learned was that the global reaction to this newly emerged virus was *disproportionately greater* than the actual virulence of the disease.²

From an economic standpoint, SARS taught us that when a modern pandemic emerges, it will generate two waves of reaction.

The first economic wave leads to the INDIRECT costs to the economy. It will be propelled by fear, confusion and misunderstanding, and a lack of confidence in the authorities’ ability to respond.

- In the early stages of the SARS outbreak, fear and uncertainty led to a dramatic 30–80 percent decline in tourism in East Asia in the spring of 2003. GDP fell by an astounding 2 percent in the second quarter.
- In Hong Kong, airline passenger arrivals dropped by two-thirds in April 2003. (as compared to the month before). Retail sales fell 8.5 percent for the quarter.
- Foreign direct investment in Asia plummeted.
- And in Canada—where fewer than 500 people were infected—the country suffered more than \$1 billion in economic losses.³

The second economic wave is caused by the DIRECT impact of the disease. It represents the hit the economy takes from hospitalizations, deaths, lost productivity, and a consequent slowdown in the flow of goods and services. In SARS, these DIRECT economic losses—from the medical treatment costs and lost productivity—accounted for only 1–2 percent of the \$30–50 billion in total damages.⁴

SARS taught us that the indirect impacts—from fear, misunderstanding, and a lack of confidence in a community’s (or a nation’s) ability to respond—must be addressed when forecasting the economic impact of a pandemic.

CDC Study

“What current economic studies have looked at the impact of a modern avian pandemic on the US economy?”

²Economic Risks Associated with an Influenza Epidemic, Bio-Era.

³Economic Risks Associated with an Influenza Epidemic, Bio-Era.

⁴Economic Risks Associated with an Influenza Epidemic, Bio-Era.

The data are very limited.

The most cited—and until today—the most recent study is the 1999 report by the CDC (Centers for Disease Control and Prevention). The study, however,—conducted 4 years before the SARS outbreak—was incomplete. It measured only the DIRECT medical and health costs to the economy: hospitalizations, outpatient visits, and deaths.

Assuming an attack rate of 15–35 percent, the CDC predicted that:

- 38–89 million people would become clinically ill;
 - 18–42 million would require outpatient care;
 - 314,000–734,000 people would be hospitalized; and
 - 89,000–207,000 people would die.
- Their conclusion: The estimated cost to the U.S. economy would be a 1 to 2 percent drop in GDP (\$71-\$166 billion loss in 1995 dollars).

Projected Economic Effects

But that’s just the DIRECT costs.

“What would the TOTAL economic impact be?”

To shed light on that answer, I asked my economic advisers, the Congressional Budget Office, to provide a comprehensive analysis of the economic impact of a pandemic on the U.S. economy.

Our CBO study looked at two scenarios—a severe pandemic (much like the 1918 pandemic) and a mild pandemic. For a severe scenario, the CBO assumed a 2.5 percent case fatality rate, and for a mild scenario they assumed a 0.1 percent case fatality rate.

I will focus my remarks on the severe scenario:

- 30 percent of the population is infected (90 million Americans)
- 2 million people die.

CBO assumed that:

- The pandemic would last for 3 months.
- And 30 percent of the workforce would become ill and miss 3 weeks of work

The supply side economic impacts would include:

- A shrinking of the labor force due to illness and the death of 1 million labor force participants;
- A disruption of the supply chain due to shutdowns in transportation; and
- A shortage of health care personnel and quality medical care for flu-and non flu-related illnesses.

The supply side impacts can be roughly correlated to direct losses—from lost productivity, illness, and death.

CBO concluded that these supply side impacts would cause the Nation’s GDP to decline by a full 3 percent in the year the pandemic occurs.

And then there is the demand side of the equation.

The impacts to demand would also be astounding:

- Voluntary quarantining would reduce turnout at restaurants, shopping malls, sporting events, churches and schools.
- Demand would fall by 80 percent in entertainment, arts, recreation, restaurants, and lodging (for 3 months).
- Retail trade would fall by 25 percent.
- The demand for medical and hospital services would surge.
- And, a fear of travel, coupled with government-imposed restrictions, would lead to a dramatic decline in domestic and international travel.

These demand-side impacts can be roughly characterized as indirect economic losses, (and they reflect the public’s fear, misunderstanding, and lack of confidence in authority). CBO concluded that these indirect losses would cause the Nation’s economy to fall by an additional 2 percent!

Thus, together, the supply and demand impacts would result in a 5 percent reduction in GDP.

This is a \$675 billion hit (in 2006 dollars) to the U.S. economy.

These are huge numbers. This scenario suggests that a severe influenza pandemic would have an impact on the U.S. economy that is slightly larger than the typical recession experienced since World War II. On average those recessions lowered real GDP 4.7 percent.

(The CBO study also reports results for a milder pandemic of the 1957 and 1968 variety. The analysis found that the impact on the economy would be a 1.5 percent drop in GDP—1 percent on the supply side and 0.5 percent on the demand side.)

Similar to what the SARS experience brought to light, the CBO scenarios suggest that fear, misunderstanding, and a lack of confidence and trust in authority may have almost as much impact on the economy as the direct toll of sickness and death.

Public Health Prescription

A \$675 billion hit to the economy is—without question—a grim prognosis. But our hands are not tied. In fact, the policy implications become crystal clear. By immediately outlining and implementing a specific policy prescription, we can minimize not only the direct economic effects of a pandemic, but perhaps more significant, greatly reduce the costly indirect effects of panic, fear and paralysis.

There are 6 steps we must take.

1. Communication

Number #1 is communicating with the public.

To allay irrational fear, communication must be the bedrock of every public policy response. Communication—of accurate, reliable, consistent information—isn't an option—it is the antidote—the vaccine for irrational fear. (Think Katrina.)

Failing to effectively communicate with the public—both before and during the pandemic—would be analogous to having a fire escape plan for your home, but neglecting to share the plan with your family. You don't want your family jumping out the window when there's a ladder under the bed. To minimize losses, you not only create an emergency plan, you tell people about it—again and again and again..

Prior to the pandemic—today—we must organize a communications structure with representatives from public health, law enforcement, military, and government to serve as the liaison to the public. It must be grounded in trust and reliability. During an outbreak, the communications structure should update the public every 6–8 hours on what they need to know—educating them on symptoms, cases, deaths, outbreak locations, and when and where to find care.

2. Surveillance

Second is surveillance. Remember the forest fire? We must stomp on the sparks before they ignite. The sooner we detect, identify and contain avian flu—in animals and in humans—the better the economic prognosis will be. That's why we need a real-time international threat detection system. And that's why I've proposed \$1 billion to build it. By developing rapid testing technology, by training more epidemiologists, by enhancing our global partnerships, and by helping developing nations compensate farmers for livestock culled we can contain the flames before they spread.

3. Antiviral Agents

Third are antiviral agents. Antiviral agents (and believe it or not there are only two) are the only front-line therapeutic tool we currently have to treat the avian flu, and slow its spread. But the bad news is, our current supply is inadequate. Today we have 4.3 million courses of Tamiflu stockpiled. That's enough to treat less than 2 percent of the U.S. population. We must increase that number to provide Tamiflu for at least 25 percent of the population. A five-day course of Tamiflu for 75 million Americans would cost approximately \$1.35 billion—a tiny fraction of the economic impact of a full-blown pandemic.

4. Vaccines

Vaccines are our best line of defense—for prevention. Yet, unfortunately, until we identify the strain—which we can do only when sustained human-to-human transmission occurs—we cannot begin to produce a targeted, fully effective vaccine. With our current grossly inadequate vaccine manufacturing capacity, it could take as long as a whole year to achieve “bug to drug”—that's the window of time between first identifying the specific strain and manufacturing a vaccine available for distribution. In a time of pandemic, that's an unacceptable wait.

We have a dangerously inadequate vaccine manufacturing base in this country. Why? Bottom-line: there's so little profit and so much uncertainty in vaccine manufacturing today.

30 years ago there were 24 vaccine manufacturers. Today there are only 5 . . . and only 1 on U.S. soil (Sanofi Pasteur).

In the United States we have 18,000 (not millions) doses of a test vaccine stockpiled, and 22 million more on order—enough to treat 11 million people—clearly far less than we need.

How do we grow our manufacturing base?

- We can immediately begin by increasing the annual market for the seasonal flu vaccine. The most we've ever sold in a year is 83 million doses, but by recommending that a larger percentage of the population receive the annual vaccine, we can increase the demand for vaccines and incentivize manufacturers to enter the market.
- We should target tax credits to increase manufacturing capacity, streamline regulations, and offer balanced, sensible liability protection for manufacturers to make these life-saving emergency medicines.
- Together these will lay the groundwork for a quicker “bug-to-drug” time-frame.

5. Research and Development

5th is research and development.

Vaccines and antivirals our best tools for the present. But research is our best hope for the future. We must harness the best minds in academia, and in the public and private sectors. We need to bring them together to form a “Manhattan Project for the 21st Century” which can help us better defend against naturally occurring, accidental, and intentional threats—including infectious diseases.

One example is targeted research for a cell-based flu vaccine. By investing in cell-based manufacturing technology, rather than relying on antiquated egg-based technology, the window for bug to drug can be cut from a year to less than 6 months. With tens of thousands of people dying every week, every moment counts. (When tens of thousands of people are dying every week, every moment will count . . . ?)

6. Stockpiling & Surge Capacity

6th, we need to stockpile and prepare for surge capacity.

If identification and vaccine manufacture represents the “bug-to-drug” portion of the equation, stockpiling of medicine and surge capacity represents the “drug-to-person” side—that is, to respond with medical treatment.

Our current health infrastructure simply and unequivocally lacks the capacity to respond effectively to a severe pandemic. We don't have the number of hospital beds, ventilators, health care personnel, morticians, vaccines, antivirals, or communication networks we need. All would be overwhelmed.

Being prepared means training first responders, and ensuring a civilian volunteer corps to step in and help handle the surge. It means allocating adequate surge facilities—vaccination sites, treatment centers, laboratories, and morgues. Has your community done so?

Our goal should be building a stockpile of antiviral agents for 75 million people, and putting in place a specific plan to deliver them. As soon as an effective vaccine is available, we must begin stockpiling, with the objective of having 300 million vaccinations—enough for every American.

Conclusion

We know that a pandemic influenza is no longer a question of if, when.

While there is no way to predict *when* an avian pandemic will occur, what we CAN predict, what we DO know, is the cost of being under-prepared.

The study I report on today sends a strong message.

A \$675 billion potential hit to our economy—almost half of which is brought on by factors which CAN be eliminated by planning—gives us every reason to act now with a prescription, and immediately implement the course of action. Now is the time to act.

The six-point prescription is simple—communication, surveillance, antivirals, vaccines, research, stockpile/surge capacity. We have the intellect, the ingenuity, the tools, the knowledge to minimize the blow.

Science and technology afford us the power to allay the direct effects. Sound public policy—grounded in communication and information—renders us the ability to ease the indirect effects.

My duty as an elected official, and as a doctor, is to ensure that we begin filling that prescription today. Our economy, our Country, our lives depend on it.

[Whereupon, at 12:39 p.m., the hearing was adjourned.]

