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OF

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

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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 United States 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 & 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% reduction in GDP. Tracking almost exactly, the International Monetary Fund's World Economic Outlook released in April estimated a 5.9% 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 #1 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 one percent of federal resources to international assistance, but in our COVID-19 emergency packages, only one-tenth of one 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.

And 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 uncertainly 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 10-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 towards 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. Theses 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 have 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 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.