

**U.S. Senate Committee on Health, Education, Labor, and Pensions Hearing
COVID-19: Lessons Learned to Prepare for the Next Pandemic
June 23, 2020**

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Written Testimony

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 overreaction, 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 decision-making 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 build up 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 NGOs as more reliable options 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% 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% 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%.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.

¹ See 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>.

² See 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>.

³ See 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.

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.

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.