



Preparing for the Next Pandemic

A WHITE PAPER

By: Senator Lamar Alexander of Tennessee
Chairman
U.S. Senate Committee on Health,
Education, Labor and Pensions



What the United States has learned from
the past twenty years of public health preparedness
and response and how it can better prepare for future
pandemics

Foreword by former **U.S. Senate Majority Leader Bill Frist**

PREPARING FOR THE NEXT PANDEMIC

Foreword (Bill Frist, M.D.): On December 8, 2005, at the National Press Club, I said that a viral pandemic was no longer a question of if, but a question of when. I recommended a simple 6 point public health prescription to minimize the blow — communication, surveillance, antivirals, vaccines, research, stockpile/surge capacity.

Over the past twenty years, the U.S. has faced outbreaks of H1N1, Ebola, Zika, and Sudden Acute Respiratory Syndrome (SARS) and responded to the threat of bioterrorism, including during the 2001 anthrax attacks. Several steps were taken after each of these events to better prepare us for future threats. Project BioShield, the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Innovation in Advanced Development and Manufacturing, improvements to our public health systems, and the position of Assistant Secretary for Preparedness and Response were all created based on lessons learned from previous events. As a result of these steps and the hard work of public health officials, the majority of outbreaks we experienced over the past 20 years did not become pandemics. However, COVID-19 has tested our current preparedness and response capabilities in ways they had never been tested before.

We now have an obligation to learn from this experience and take decisive steps to better prepare for the future. My duty as a former elected official, and as a doctor, is to ensure we begin today to take specific actions to prepare for the next pandemic. Because — like all previous pandemics — COVID-19 too will shift from center stage. The public will have had their fill. The danger will seem removed.

Senator William Frist, M.D. is a cardiothoracic surgeon and former Majority Leader of the United States Senate. Senator Frist represented Tennessee in the Senate from 1994-2006 and holds the distinction of becoming the first practicing physician to serve in the Senate since 1928. While in the Senate, Senator Frist was heavily involved in passing landmark legislation, including the 2003 Medicare Modernization Act and the President's Emergency Plan for AIDS Relief (PEPFAR). He began serving as Majority Leader in 2003.

EXECUTIVE SUMMARY

According to the *New York Times* on March 1, “Much about the coronavirus remains unclear and it is far from certain that the outbreak will reach severe proportions in the United States or affect many regions at once. 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.”¹

Even the experts underestimated the ease of transmission and the ability of this novel coronavirus to spread without symptoms. We continue to learn more about the science and trajectory of this disease that is changing the response on a daily basis. In the midst of responding to COVID-19, the United States Congress should take stock now of what parts of the local, state, and federal response worked, what could work better and how, and be prepared to pass legislation this year to better prepare for the next pandemic, which will surely come.

During the past 20 years, four Presidents and several Congresses 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 received many reports from presidential administrations, Offices of Inspectors General, the Government Accountability Office, and outside experts throughout those 20 years warning that the U.S. needed to address the following issues: 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 health care and public health workforce; better distribution of medical supplies; and 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 faced workforce shortages and training needs, inadequate stockpiles, and funding challenges. In some instances, overreliance on inflexible federal funding contributed to these problems.

Looking at lessons learned from the COVID-19 crisis, many of the challenges 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.

¹ <https://www.nytimes.com/2020/02/29/health/coronavirus-preparation-united-states.html>

RECOMMENDATIONS:

Congress should work with federal departments and agencies, states, and the private sector to address these specific issues and newly identified gaps:

1. **Tests, Treatments, and Vaccines** – Accelerate Research and Development
2. **Disease Surveillance** – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases
3. **Stockpiles, Distribution, and Surges** – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution
4. **Public Health Capabilities** – Improve State and Local Capacity to Respond
5. **Who Is on the Flagpole?** – Improve Coordination of Federal Agencies During a Public Health Emergency

REQUEST FOR INPUT:

The five recommendations outlined above, along with a series of questions at the end of this white paper, are intended to elicit recommendations that Congress can consider and act on **this year**. I am inviting comments, responses, and any additional recommendations for the Senate Committee on Health, Education, Labor and Pensions to consider. This feedback will be shared with my colleagues, both Democrat and Republicans.

In this internet age, attention spans are short. Even with an event as significant as COVID-19, memories fade and attention moves quickly to the next crisis. That makes it imperative that Congress act on needed changes **this year** in order to better prepare for the next pandemic.

Please submit responses to PANDEMICPREPAREDNESS@HELP.SENATE.GOV by 5PM ET on June 26.

INTRODUCTION

After each public health emergency over the past two decades, the country has identified lessons learned and taken steps to be better prepared for the next one. During the past 15 years, the Department of Health and Human Services has distributed \$18 billion to state and hospital preparedness systems, and has awarded an additional \$3 billion to states and hospitals to respond to specific disease threats.² To be well prepared for the next pandemic, Congress should do even more to strengthen and support public health preparedness at all levels of government – local, state, tribal, territorial, and federal.

In the United States, state and local governments lead the public health system. The spread of infectious disease and effective methods to prevent the spread vary by community. State and local officials know what works best in their communities – what works best in New York City may be much different than what works in rural Tennessee.

Still, the federal government plays an important role.

Only the federal government can fund research at the scale necessary to create tests, treatments, and vaccines for a pandemic, coordinate the distribution of supplies and information at the national level, and provide states with the level of funding they need to respond to an unforeseen crisis. The federal government is also responsible for helping to stabilize the economy and work with foreign countries associated with a global event.

² <https://www.gao.gov/products/GAO-18-362>

SUMMARY OF PAST FEDERAL GOVERNMENT EFFORTS TO PREPARE FOR A PANDEMIC

1995 – The Centers for Disease Control and Prevention (CDC) established the Epidemiology and Laboratory Capacity program to help improve the ability of states to detect and track infectious diseases. The program provides funding through cooperative agreements to states, certain localities, and territories to support surveillance systems, modernize laboratories, and improve information networks at local and state levels. This program was later codified in the Patient Protection and Affordable Care Act (PL 111-148).

1996 – Congress authorized the Department of Health and Human Services (HHS) to establish and maintain a list of pathogens of concern and required registration of facilities in the U.S. shipping those pathogens (PL 104-132).

“...we have got to have in place the systems to detect as early as possible the presence of these agents, and we have tried to continue to strengthen our technology for doing that and to also be prepared to respond with appropriate reagents and agents to combat—whether we are dealing with biological or chemical agents, we have to be prepared with the resources or agents, if you will, the counter-agents, to deal with them.”

– Dr. David Satcher, U.S. Surgeon General, Senate Subcommittee on Public Health and Safety of the Committee on Labor and Human Resources, “Global Health: United States Response to Infectious Diseases” March 2, 1998

1998 – Congress began appropriating funding to CDC to stockpile pharmaceuticals using general authorities in the Public Health Service Act (PL 105-277).

1999 – A Government Accountability Office report found, “Surveillance and testing for important emerging infectious diseases are not comprehensive in all states, leaving gaps in the nation’s infectious diseases surveillance network.”³ The report cited the need to better integrate data systems and help states build systems that link with local and private surveillance partners, and noted

that while state surveillance and laboratory testing programs are extensive, they did not all identify every significant emerging infectious disease.

In response, CDC established the Laboratory Response Network, which has expanded since 1999. The Laboratory Response Network is a network of laboratories now comprised of CDC, Department of Agriculture, the Food and Drug Administration (FDA), Department of Defense, Department of Homeland Security, Department of Energy, and other federal partners, as well as state and local public health labs. Starting in FY1999, the CDC also awarded grants to states and some metropolitan health departments to enhance state and local laboratory capacity and develop and maintain the Health Alert Network, which is an electronic communications network connecting public health stakeholders.

³ <https://www.gao.gov/products/HEHS-99-26>

2000 – The Public Health Improvement Act (PL 106-505) was signed into law amid growing concerns about bioterror attacks and the continued threat of emerging infectious diseases, like West Nile Virus and hantavirus. The law improved federal, state, and local public health capacity to detect and respond to significant public health threats by:

- authorizing CDC to award state and local public health department core capacity grants, creating a new demonstration program to improve detection of pathogens likely to be used in a bioterrorist attack, and supporting the development of plans and measures to respond to the attacks and the training of personnel;
- requiring CDC to provide support to state health departments on infectious diseases upon request;
- authorizing the improvement of laboratories and other CDC infrastructure to enhance capacity to detect and respond effectively to public health threats, including major outbreaks of an infectious disease.

The Public Health Improvement Act provided key HHS authorities, including the Secretary's authority to declare a public health emergency and ability to support response activities through the Public Health Emergency Fund.

2002 – After the 9/11 terrorist attacks and the anthrax attacks in 2001, Congress took several steps and appropriated significant funding to HHS to strengthen state and local preparedness. CDC distributed funding to states through a Public Health Preparedness and Response for Bioterrorism cooperative agreement, and the Health Resources and Services Administration distributed funds to hospitals through the National Bioterrorism Hospital Preparedness Program.⁴

“...we identified more than 20 federal departments and agencies as having a role in preparing for or responding to the public health and medical consequences of a bioterrorist attack. These agencies are participating in a variety of activities, from improving the detection of biological agents to developing a national stockpile of pharmaceuticals to treat victims of disasters.”

– Janet Heinrich, Director for Health Financing and Public Health in the Government Accountability Office, testimony before Senate Committee on Health, Education, Labor, and Pensions, October 2001

Later that year, in June 2002, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (often referred to as the “Bioterrorism Act,” PL 107-188). This law laid the foundation for the current U.S. preparedness and response structure, authorizing state preparedness grants to help states prepare for and respond to public health emergencies, and also established community and hospital preparedness partnerships.

The Bioterrorism Act codified the National Disaster Medical System to enhance medical surge capacity. Originally established in 1984, this partnership between multiple federal

⁴ Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the United States Act, Pub. L. No. 107-117, 115 Stat. 2230, 2314 (2002), and the Departments of Labor, Health and Human Services and Education, and Related Agencies Appropriations Act of Fiscal Year 2002, Pub. L. No. 107-116, 115 Stat. 2186, 2198.

agencies, state and local governments, and the private sector supplements local surge capacity to provide medical assistance for mass casualties in disasters or public health emergencies at the request of states.⁵

The Bioterrorism Act also codified the Strategic National Stockpile “to provide for the emergency health security of the United States...in the event of a bioterrorist attack or other public health emergency.”⁶

In addition, the Bioterrorism Act:

- pushed regulatory science forward by facilitating the use of animal models to support countermeasure development
- required HHS to establish what is now called the “Emergency System for Advance Registration of Volunteer Health Professionals” to verify licenses and credentials of doctors and nurses who volunteer in advance to provide health care in a public health emergency, with the goal of expediting the verification process, and the number of health professionals available to help during a public health emergency
- authorized grants for training and education of health professionals
- supported education of health care personnel on recognizing and responding to potential bioweapons and other public health threats
- gave HHS the authority to waive certain Medicare or Medicaid requirements during national emergencies to provide flexibility for hospitals and states to respond to a public health emergency
- authorized improvements to public health surveillance and reporting capabilities, which led to the creation of the National Syndromic Surveillance Program⁷, and CDC laboratory facilities related detecting potential public health emergency
- required HHS to periodically review new and emerging technologies designed to improve or enhance the ability to conduct public health surveillance
- improved federal government coordination

The Bioterrorism Act improved federal coordination by creating the Assistant Secretary of Public Health Emergency Preparedness. The conference report for the law stated, “...there is a need to increase coordination of the Department of Health and Human Services’ efforts in responding to bioterrorism and other public health emergencies, and thus has provided for the creation of an Assistant Secretary for Public Health Emergency Preparedness.”⁸ This Assistant Secretary position was tasked with coordinating between HHS and other departments, states, and local governments on bioterrorism and public health emergencies, as well as managing the National Disaster Medical System.

The balance of roles and responsibilities within the federal government shifted with the passage of the Homeland Security Act (PL 107-296) in November 2002, which transferred key public health emergency programs, including the Strategic National Stockpile and the

⁵ <https://www.crs.gov/Reports/pdf/RL31263?source=search&guid=02693bdc7608440091a61e684f04ef03&index=3>

⁶ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188.

⁷ <https://www.cdc.gov/nssp/overview.html>

⁸ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Conference Report 107-481 to accompany HR 3448, May 21, 2002.

National Disaster Medical System, from HHS to the newly formed Department of Homeland Security. CDC continued to manage the day-to-day operations of the stockpile while it was at the Department of Homeland Security.⁹

While many of these functions were later moved back to HHS, the Metropolitan Medical Response System remained at the Department of Homeland Security and is no longer federally funded. The Department of Homeland Security continues to have authority to deploy assets in the Strategic National Stockpile.

2003 – The Department of Homeland Security established the BioWatch program to provide early warning of a bioterrorist attack in major metropolitan areas in the United States to help officials plan a rapid response.

Major Congressional Actions in Response to Public Health Emergencies over the last 20 years

- 8 laws to accelerate research and development of tests, treatments, and vaccines
- 5 laws to strengthen public health capabilities
- 6 laws to improve the ability to detect, identify, model, and track emerging infectious diseases
- 7 laws to rebuild and improve stockpiles and federal coordination of distribution
- 7 laws to clarify federal coordination

The National Institute of Allergy and Infectious Diseases was assigned lead responsibility for civilian biodefense research, with a focus on basic research, genomics research, expansion of research infrastructure, and development of diagnostics, therapies, and vaccines to protect Americans against potential bioterror attacks. However, challenges remained engaging private industry because the economics of creating products for such threats are unattractive—they are expensive to develop and get approved by FDA and, once they are approved, will hopefully be rarely needed, if ever.

To incentivize private industry to partner with the federal government, Congress advance appropriated \$5.593 billion in the Department of Homeland Security Appropriations Act for Fiscal Year 2004 (PL 108-90) for the Project BioShield Special Reserve Fund for medical countermeasures against bioterror attacks, to remain available through 2013.

2004 – Congress passed the Project BioShield Act of 2004 (PL 108-276) to support the development of medical countermeasures. The Project BioShield Act transferred the Strategic National Stockpile back to HHS and supported the stockpile by authorizing the Special Reserve Fund to facilitate the procurement of medical countermeasures for specific health threats. The new law also gave HHS the authority to issue emergency use authorizations and required coordination between HHS, Department of Homeland Security, and Department of Defense and elimination of unnecessary duplication of effort.

Also, in 2004, the National Institutes of Health (NIH) expanded Regional Centers of Excellence for Biodefense and Emerging Infectious Disease Research to advance research on biodefense and emerging infectious diseases, improve training for researchers and

⁹ Congressional Record of Senate Hearing 108-126, “Federal Biodefense Readiness,” held by the Health, Education, Labor and Pensions Committee on July 24, 2003, p. 35.

other personnel, and further capacity for testing and validating vaccine, therapeutic, and diagnostic concepts.¹⁰

2005 – Congress enacted the Public Readiness and Emergency Preparedness Act (“PREP Act,” PL 109-148). The PREP Act further incentivized coordination with the private sector by allowing the Secretary of HHS to provide liability protection 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.

In 2005, Hurricanes Katrina and Rita devastated the Gulf Coast, destroying hospitals and public health infrastructure. Several hospitals were entirely destroyed, others could not operate, and most health clinics and facilities were closed.¹¹ The Strategic National Stockpile responded to requests from Louisiana and Mississippi for medical supplies—deploying 3,500 beds, more than 275,000 vaccines for tetanus, hepatitis, and childhood vaccines, such as measles, mumps, and rubella, and chicken pox.¹²

Additionally, H5N1 avian influenza emerged as a potential novel infectious disease threat.

2006 – In December 2006, following Hurricanes Katrina and Rita, Congress passed the Pandemic and All-Hazards Preparedness Act (“PAHPA,” PL 109-417), which recognized the need for public health preparedness to address naturally occurring public health emergencies in addition to deliberate bioterror attacks.

The Pandemic and All-Hazards Preparedness Act:

- required drills and exercises be conducted to ensure operational readiness for a public health emergencies
- updated the Hospital Preparedness Program, including provisions to improve hospital preparedness and medical surge capacity to meet increased health care demands during a public health emergency
- required the Secretary of HHS, in consultation with the Federal Communications Commission, to inventory telehealth initiatives and identify ways to enhance telehealth for emergency responses
- authorized loan repayment programs to encourage service by medical professionals in areas at risk for a public health emergency
- established the Medical Reserve Corps, a network of community-based volunteer units that train to respond in a public health emergency
- transferred the National Disaster Medical System back to HHS
- gave the Secretary of HHS the authority to purchase mobile hospitals
- directed the Secretary of HHS to enter into agreements with other departments to use federal medical facilities to supplement civilian capacity as necessary
- established a training program for all-hazards public health and medical care
- expanded the Epidemic Intelligence Service

¹⁰ <https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-04-018.html>

¹¹ <https://georgewbush-whitehouse.archives.gov/reports/katrina-lessons-learned/chapter5.html>

¹² <https://www.phe.gov/about/sns/Pages/responses.aspx>

- established Centers for Public Health Preparedness to assist with training and technical assistance
- required HHS, in collaboration with state, local, and tribal public health officials, to establish a near real-time electronic nationwide public health situational awareness capability
- authorized grants for states to work with hospitals, clinical laboratories, universities, or a poison control center to improve disease detection
- codified the National Health Security Strategy as a responsibility of the Secretary of HHS to advance specific goals related to the integration of public health and medical capabilities, improving public health security, medical system preparedness, meeting the needs of at-risk individuals, coordination between federal, state, local, and tribal planning, preparedness, and response activities, and continuity of operations during an emergency.

Assistant Secretary for Preparedness and Response

The Pandemic and All-Hazards Preparedness Act also codified the Secretary of HHS as the lead federal agency for the public health and medical components of responses to emergencies under the National Response Plan (now called the National Response Framework). The law required the Secretary of HHS to establish interagency agreements with the Secretaries of Veterans Affairs, Transportation, Defense, and Homeland Security. Those agreements sought to outline roles and relationships of the departments, and clarified that the Secretary of HHS shall assume operational control of emergency public health and medical response, as necessary, in the event of an emergency.

“...this section [102 of PAHPA] consolidates public health and medical authorities, responsibilities and resources under the Assistant Secretary for Preparedness and Response (ASPR). It is the committee's view that aligning these functions under a single individual achieves unity of command and control under a clearly identified authority.”

Senate Report 109-319

The position of Assistant Secretary of Public Health Emergency Preparedness was also renamed the Assistant Secretary for Preparedness and Response and given additional authorities. The role was expanded from the coordinator position to also assuming specific medical preparedness and response capabilities and responsibilities and standing up the Biomedical Advanced Research and Development Authority.

Biomedical Advanced Research and Development Authority (BARDA)

The Pandemic and All-Hazards Preparedness Act established BARDA to support the advanced research and development of diagnostics, drugs, and medical devices to address public health threats. Congress gave BARDA relatively broad latitude to support advanced research and development activities, including “activities to facilitate manufacture of the

product at a commercial scale.”¹³ Additionally, the new law allowed BARDA to help companies work with the FDA and provide technical advice. Since its inception in 2006, BARDA has helped more than 50 tests, treatments, and vaccines receive either initial FDA approval or a new indication.¹⁴

2007 – The National Institute of Allergy and Infectious Diseases created the Centers of Excellence for Influenza Research and Surveillance. The centers played a key role in testing the vaccine for the 2009 H1N1 pandemic.

2009 – CDC and the Department of Defense detected H1N1 in 2009, and CDC used a pre-existing system of public health surveillance platforms to report illness, hospitalizations, and deaths related to H1N1. In response to the H1N1 pandemic, the Strategic National Stockpile and BARDA deployed and distributed over 2,100 regimens of Peramivir, more than 85 million N95 respirators, and over 19 million units of personal protective equipment. According to the Congressional Research Service, states had, at one point, a stockpile of medical reserves, many of which were created or funded as part of the H1N1 flu pandemic response in 2009. While the pandemic did not fully stress the nation’s surge capacity, there were many important lessons learned.

2013 – Many of the lessons learned from the 2009 H1N1 pandemic response were included in the bipartisan Pandemic and All-Hazards Preparedness Reauthorization Act (PL 113-5), which was signed into law on March 13, 2013.

The Pandemic and All-Hazards Preparedness Reauthorization Act:

- improved several federal, state, and local biosurveillance and situational awareness networking and capacity programs
- reauthorized the vaccine tracking and distribution program used to track vaccines and improve distribution in a pandemic
- reauthorized programs to support medical surge capacity, including the Emergency System for Advance Registration of Health Professional Volunteers and the Medical Reserve Corps
- directed HHS to coordinate, as appropriate, with the Office of the National Coordinator for Health Information Technology
- updated and reauthorized the Public Health Emergency Program and Hospital Preparedness Programs, emphasizing partnerships between public and private sectors and the need for national collaboration
- called on the National Biodefense Science Board to provide guidance regarding biosurveillance modernization and enhancement.

The 2013 law also further clarified that the Assistant Secretary for Preparedness and Response is the lead for medical and public health responses in emergencies, is required to coordinate with the Department of Homeland Security to minimize duplication of efforts, and work with the Departments of Homeland Security and Defense and others to conduct

¹³ Pandemic and All-Hazards Preparedness Act, Section 401.

¹⁴ <https://www.phe.gov/ASPRBlog/pages/BlogArticlePage.aspx?PostID=362>

drills and exercises to identify, inform, and address gaps in preparedness. The law required Assistant Secretary for Preparedness and Response to submit an annual Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation plan to Congress to coordinate federal efforts to support the research and development of diagnostics, treatments, and vaccines for biological and other threats.

The 2013 law also continued to encourage research, development, and manufacturing of medical countermeasures by:

- reauthorizing the Special Reserve Fund at \$2.8 billion
- providing more flexibility for BARDA to support later stage research
- coordination of research, development, procurement, and planning across the federal government
- expanding the FDA's ability to consider special protocols, such as relying on efficacy data derived from animal models
- required the Secretary of HHS to issue final guidance related to the Animal Rule
- established a formal process for communications between FDA and developers of medical countermeasures, including written regulatory management plans.

2014 – An outbreak of Ebola virus disease in West Africa required a concerted response by the international community, with the CDC providing a leadership role in the response after receiving requests for assistance from affected countries, in coordination with the State Department and Department of Defense. Despite exit screening efforts from those countries, an individual with Ebola traveled to the U.S. from Liberia, triggering intensive contact tracing efforts to determine those who were potentially exposed.¹⁵ This incident emphasized the need for preparedness at the hospital, local, and state level, as the case was initially missed by hospital staff in Texas.

Unanticipated challenges emerged during the response to Ebola, such as the need to address biological waste disposal, improve coordination with different sectors, such as the transportation sector, and establish specialized treatment facilities and provider training, including on the appropriate use of personal protective equipment.

In response to some of these challenges, HHS established through supplemental appropriations, the National Ebola Training and Education Center¹⁶, which provides enhanced training for providers and hospitals in recognizing and handling patients exposed to Ebola and other special pathogens, and the Regional Ebola Treatment Network,¹⁷ a tiered system that enables hospitals around the country to triage and treat patients with Ebola and other special pathogens. These are now called the National Emerging Special Pathogens Training and Education Center and Regional Treatment Network for Ebola and Other Special Pathogens, respectively.

¹⁵ <https://www.cdc.gov/media/releases/2014/s930-ebola-confirmed-case.html#:~:text=The%20Centers%20for%20Disease%20Control,to%20Dallas%2C%20Texas%20from%20Liberia.>

¹⁶ <https://netec.org/>

¹⁷ <https://www.phe.gov/Preparedness/planning/hpp/Pages/hpp-pathogens.aspx>

2015 – Outbreaks of Zika virus disease, a mosquito-borne illness, occurred with widespread transmission in Puerto Rico and the US Virgin Islands, with limited local transmission in Florida and Texas. With no vaccines or treatments for Zika virus disease, CDC worked with state and local officials to launch a mosquito control program to contain the virus in an effort to stop further spread and prevent it from becoming endemic, while also trying to learn more about the virus and risks associated with it, including birth defects and adverse neurological outcomes. In addition, the Strategic National Stockpile, in response to a botulism outbreak, deployed 50 doses of botulism antitoxin to treat patients confirmed to have botulism, a severe and potentially fatal neuroparalytic illness.¹⁸

2016 – The 21st Century Cures Act (PL 114-255) took steps to further incentivize research and development of diagnostics, drugs, and medical devices. It established a priority review voucher program for security countermeasures and clarified certain BARDA authorities. 21st Century Cures also authorized a Medical Countermeasure Innovation Partner, which is intended to be a non-federal entity to foster and accelerate the development and innovation of medical countermeasures.

2019 – The most recent reauthorization of federal public health and medical preparedness and response authorities, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PL 116-22), built on lessons learned from Ebola, Zika, and other public health emergencies.

Signed into law in 2019, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act:

- updated programs to improve planning and flexibility for states, territories, and local governments, and hospitals
- prioritized grants to enhance regional coordination among health care facilities
- improved medical surge capacity by:
 - encouraging states to allow for licensure of medical professionals to enable them to provide care across states lines during a public health emergency more easily
 - directing the Secretary of HHS to improve the use of Emergency System for Advance Registration of Volunteer Health Professionals
 - clarifying that members of the Emergency System for Advance Registration of Volunteer Health Professionals and the Medical Reserve Corps are covered under the liability laws of the state where the public health emergency is
 - improving the ability to preposition National Disaster Medical System teams
 - providing hiring authorities needed to improve recruitment of health care emergency responders
- required HHS to improve CDC’s biosurveillance capabilities to advance public health situational awareness, including by authorizing the Secretary of HHS to appoint up to 30 specialists at the CDC with expertise in capabilities related to biosurveillance, such as experts in informatics and data analytics
- reauthorized Epidemiology and Laboratory Capacity cooperative agreements

¹⁸ <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6429a6.htm>

- required an annual threat-based report to ensure appropriate oversight of the decisions made by the Strategic National Stockpile
- clarified that the Strategic National Stockpile should consider using private health care infrastructure and manufacturing capacity for necessary products.

The new law also gave the Assistant Secretary for Preparedness and Response new roles and responsibilities, including direction to develop guidelines to inform regional systems of hospitals and health care facilities regarding treatment of patients in public health emergencies and improve surge capacity.

Other Emergency Response Authorities

Historically, public health emergencies tend to be limited either by their duration or to a particular region of the country, whereas a pandemic is widespread and typically spreads through communities and states concurrently. While the Secretary of HHS does have some tools to coordinate larger responses like that required in a pandemic, Congress has enacted additional laws to address several types of national emergencies. In addition to the National Emergencies Act of 1976, which provides general procedures for presidential emergency declarations, the most relevant authority is the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (“Stafford Act,” PL 100-707).

The Stafford Act allows the president to declare both major disasters and emergencies and provides broad authority to coordinate federal activities, provide financial assistance, and provide support at the state and local levels. While the term “major disaster” is strictly defined in statute, the definition of an “emergency” provides the president with latitude to declare an emergency either because the situation is the primary responsibility of the federal government, or upon the request of a governor in a situation where federal support is needed to supplement state and local response capabilities. Although the Stafford Act primarily addresses presidential authorities and actions, certain authorities are specifically tied to the Federal Emergency Management Agency (FEMA) Administrator, and the Post-Katrina Emergency Management Reform Act of 2006 (PL 109-295) required the Administrator to assist the president in executing the responsibilities of the Stafford Act.

Distinct from the Stafford Act, FEMA is required by statute to lead national response planning efforts, which are currently known collectively as the National Response Framework.¹⁹ The National Response Framework establishes the overarching strategy and structure for disaster and emergency responses.

The current National Response Framework, published in 2019, includes 15 distinct emergency support functions, which represent core functions that must be carried out to stabilize communities after an emergency. The emergency support functions are associated with essential sectors such as transportation, energy, and health care. For federally supported responses, the National Response Framework relies on a lead federal agency to coordinate all response activities and other federal agencies designated in the National

¹⁹ 6 U.S.C. 314(a)(6).

Response Framework to serve as individual emergency support function coordinators. Emergency Support Function #8 is the public health and medical response support function, which is led by HHS.

While FEMA typically serves as the lead federal agency under the National Response Framework, President Obama in 2016 issued Presidential Policy Directive 44: Enhancing Domestic Incident Response (PPD-44), which allows other agencies to serve as the lead agency for certain responses that may be outside the scope of FEMA's usual mission, such as a pandemic.²⁰ The lead agency may receive support from FEMA in executing its responsibilities. Existing federal pandemic planning documents rely on the PPD-44 policy, including FEMA's "Biological Incident Annex" to the National Response Framework's interagency operational plans.²¹

FUNDING FOR PUBLIC HEALTH PREPAREDNESS AND RESPONSE

Over the past two decades funding for state, local, and hospital preparedness programs has had ups and downs, with surges as a result of major public health emergencies or threats, such as H1N1, Ebola, Zika, and COVID-19, but declines in some programs, such as the Hospital Preparedness Program.

According to the Government Accountability Office, from 2002 through 2017, HHS distributed \$21.2 billion to states and other jurisdictions to carry out public health preparedness and response activities through three primary programs.²² \$18 billion was made available through annual appropriations, and \$3 billion was provided by supplemental appropriations to respond to infectious disease threats, including the H1N1 influenza pandemic and Ebola and Zika outbreaks.

According to an Association of State and Territorial Health Officials report of 2016 survey results, states vary widely in their reliance on federal funding, though "80 percent of states receive more than 40 percent of their funds from federal sources. In 2015, [state health agencies] received an average of \$280 million in federal funding. States ranged from a minimum of \$26 million, to receiving a maximum of \$1.8 billion in federal funding."²³ The Public Health Emergency Preparedness cooperative agreements and the Hospital Preparedness Program both require grant recipients to maintain expenditures for preparedness at levels equal to their average expenditures over the preceding two year period.

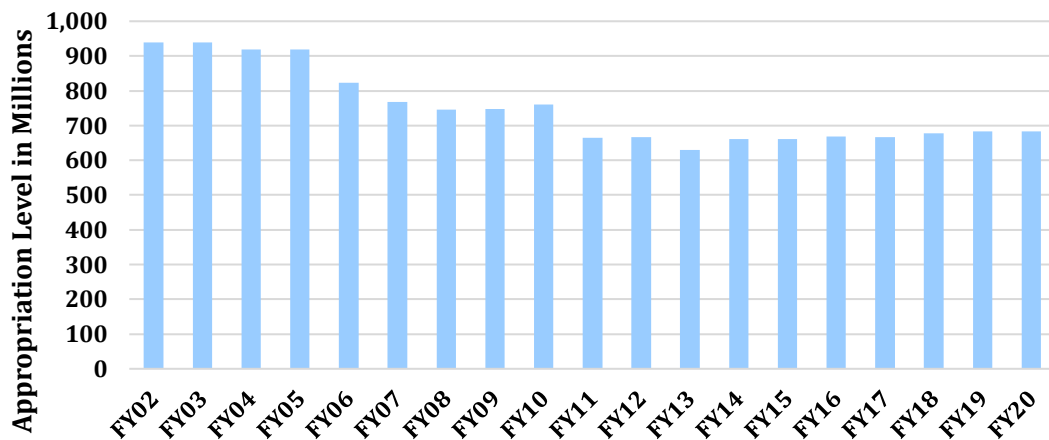
²⁰ "Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans," Federal Emergency Management Agency, U.S. Department of Homeland Security, January 2017.

²¹ Ibid

²² <https://www.gao.gov/products/GAO-18-362>

²³ <https://www.astho.org/Profile/Volume-Four/2016-ASTHO-Profile-of-State-and-Territorial-Public-Health/>

Funding History for Public Health Emergency Preparedness Cooperative Agreement



Sources: Compiled by CRS from annual CDC congressional budget justifications, <http://dhhs.gov/asfr/ob/docbudget/>, and text of relevant public laws.

Note: Amounts do not include supplemental appropriations for specific public health emergency responses.

States have also looked at ways to better leverage existing resources. The Association of State and Territorial Health Officials report also indicated that about 25 percent of state health departments share resources, generally for preparedness and response (67%) and epidemiology and surveillance (52%), which have been increasing since the Association of State and Territorial Health Officials began collecting this data. The report indicated this “may reflect growing recognition of the importance of mutual aid agreements between states and incentives inserted in cooperative agreement objectives.”²⁴ However, despite increased resource sharing, the report also indicated that infectious disease and all-hazards preparedness and response decreased as agency priorities between the 2010 and 2016 surveys.²⁵

With regard to research and development funding, National Institute of Allergy and Infectious Diseases, the lead for early stage and applied biodefense research, approximately \$3.7 billion in funding for fiscal year (FY) 2003 and \$5.9 billion for FY2020.^{26,27} In FY2018, the National Institute of Allergy and Infectious Diseases distributed 38.9 percent of its funds to support biodefense and emerging infectious diseases research, a slight increase over the 37.6 percent allocated to such research in FY2017.^{28,29}

²⁴ <https://www.astho.org/Profile/Volume-Four/2016-ASTHO-Profile-of-State-and-Territorial-Public-Health/>

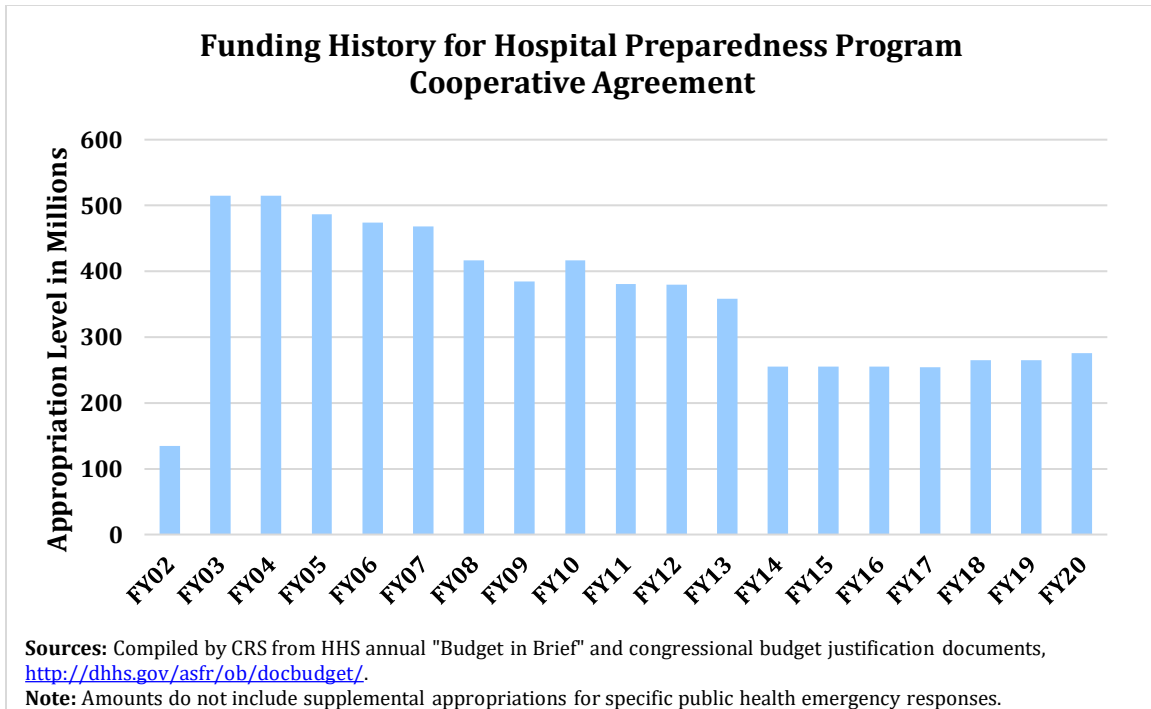
²⁵ <https://www.astho.org/Profile/Volume-Four/2016-ASTHO-Profile-of-State-and-Territorial-Public-Health/>

²⁶ [https://officeofbudget.od.nih.gov/pdfs/FY19/Approp%20History%20by%20IC%20FY%202000%20-%20FY%202019%20\(V3\).pdf](https://officeofbudget.od.nih.gov/pdfs/FY19/Approp%20History%20by%20IC%20FY%202000%20-%20FY%202019%20(V3).pdf)

²⁷ <https://www.appropriations.senate.gov/imo/media/doc/LaborHHS%202020.pdf>

²⁸ <https://www.niaid.nih.gov/sites/default/files/FY2018FactBook.pdf>

²⁹ <https://www.niaid.nih.gov/sites/default/files/FY2017FactBook.pdf>



Aside from early spikes in funding for research and development of medical countermeasures, funding has largely remained level since the expiration of the \$5.6 billion, 10-year advanced appropriation for the Project BioShield Special Reserve Fund in 2013. Although some of the funds from the advanced appropriation were redirected to support specific advanced research and development activities through subsequent appropriations laws, the existence of the advanced appropriation provided certainty to private sector stakeholders, and some have advocated for another advanced appropriation or other mechanism to provide reliable and consistent funding.

Following concerns over avian influenza in 2006, Congress began providing specific funding for pandemic influenza preparedness. With this funding, BARDA has supported the development of new treatments and next-generation platforms for pandemic flu vaccines that can also be used for seasonal flu. Additionally, as concern grew over a lack of domestic manufacturing capacity for vaccines, a large portion of the funding for flu vaccines has gone to support the Centers for Innovation in Advanced Development and Manufacturing.

After years of work, in 2012, three federal contracts were awarded totaling nearly \$400 million to Emergent Biosolutions, Novartis, and Texas A&M University System to establish advanced development and manufacturing centers in Maryland, North Carolina, and Texas, respectively.³⁰ In 2016, the Department of Defense also opened its own facility in Florida in partnership with a company called Nanotherapeutics, now known as Ology Bioservices.³¹ The concept behind the advanced development and manufacturing centers is that the

³⁰https://www.medicalcountermeasures.gov/media/8862/aspa_0420_20120615_aspr_pr_countermeasures_fact_sheet_combined508.pdf

³¹ <https://www.jpeocbrnd.osd.mil/news/news-story/2016/12/20/us-dod-expand-medical-countermeasure>

federal government will support the construction of new facilities that can be quickly repurposed to serve as additional manufacturing capacity for biological products in the event of a pandemic.

In some cases, the private partners involved in the advanced development and manufacturing program have changed, which may be a reflection of the business challenges associated with operating an advanced development and manufacturing facility. In 2015, Novartis sold the Holly Springs, North Carolina facility to Seqirus, a flu vaccine manufacturer who uses cell culture technology. Seqirus dramatically expanded the facility to produce its seasonal flu vaccine.³² Texas A&M created Kalon Biotherapeutics to carry out some of the functions of its advanced development and manufacturing facility, and in 2015, Kalon was acquired by Fujifilm Diosynth Biotechnologies Texas, which operates the facility as part of its contract manufacturing business.³³

Funding for Critical Public Health and Preparedness Programs and Agencies

- Public Health Emergency Preparedness Cooperative Agreements: The Public Health Emergency Preparedness cooperative agreement program received \$940 million funding in FY2002. Funding for the program dropped below \$900 million for the first time in FY2006. Public Health Emergency Preparedness cooperative agreement received \$683 million in annual appropriations for FY2020.
- Hospital Preparedness Program Cooperative Agreements: The Hospital Preparedness Program cooperative agreement was initially funded at \$135 million for FY2002 and was increased to \$515 million in FY2003. Hospital Preparedness Program cooperative agreement received \$276 million in annual appropriations for FY2020.
- Epidemiology and Laboratory Capacity Cooperative Agreements: CDC awarded approximately \$78 million to states and other jurisdictions for the Epidemiology and Laboratory cooperative agreements in FY2002.³⁴ In FY2019, CDC awarded approximately \$231 million to states and other jurisdictions.³⁵ The program is currently funded using both annual appropriations and mandatory funding from the Prevention and Public Health Fund.
- BARDA: Following its creation in 2006, BARDA received \$113.9 million in annual appropriations for FY2007. BARDA received \$561.7 million in annual appropriations for FY2020.
- Project BioShield: In FY2004, Project BioShield received a 10-year advanced appropriation of \$5.593 billion. Since the expiration of the advanced appropriation in 2013, Project BioShield has been funded through annual appropriations. Project BioShield received \$735 million in annual appropriations for FY2020.
- Strategic National Stockpile: Initially funded with \$51 million through appropriations for FY1999, the stockpile currently received \$705 million in annual appropriations for FY2020.

³² <https://www.fiercepharma.com/vaccines/seqirus-to-spend-140m-add-120-jobs-nc-flu-vaccine-plant-expansion>

³³ <https://brazosvalleyedc.org/mitbv-fujifilm-diosynth>

³⁴ <https://www.gao.gov/assets/700/691976.pdf>

³⁵ <https://www.cdc.gov/budget/documents/fy2021/FY-2021-CDC-congressional-justification.pdf>

REVIEWING LEGISLATION AND FUNDING

Over the past two decades, the Government Accountability Office, private sector experts, and multiple presidential administrations have repeatedly warned that gaps remain in United States preparedness and that states and the federal government are not fully equipped to respond to a major public health threat or emergency.

Specific Public Health Emergency Responses

After the outbreak of SARS in 2003, the Government Accountability Office reported in February 2004 that, “Although states have further developed many important aspects of public health preparedness, since April 2003, no state is fully prepared to respond to a major public health threat. States have improved their disease surveillance systems, laboratory capacity, communication capacity, and workforce needed to respond to public health threats, but gaps in each remain. Moreover, regional planning between states is lacking, and many states lack surge capacity—the capacity to evaluate, diagnose, and treat large numbers of patients that would present during a public health emergency. Although states are developing plans for receiving and distributing medical supplies and material for mass vaccinations from the Strategic National Stockpile in the event of a public health emergency, most of these plans are not yet finalized.”³⁶

The White House’s report on lessons learned after Hurricane Katrina in 2005 included many recommendations, including that “HHS should lead a unified and strengthened public health and medical command for Federal disaster response.”³⁷ The report also recommended that “HHS should ensure coordination and oversight of emergency, bioterrorism, and ongoing public health preparedness needs. In a public health emergency, the Secretary of HHS should have the integrated support of the public health and public health emergency preparedness programs. Within HHS, two Staff Division and seven Operating Division Assistant Secretary level positions oversee some aspect of public health programs, many of which have overlapping functions in an emergency response. The Secretary of HHS should review this issue and determine how best to ensure the integration of all relevant HHS information and functions during a public health emergency.”

In February of 2009, the Government Accountability Office released a report, “Influenza Pandemic: Sustaining Focus on the Nation’s Planning and Preparedness Efforts.” The report found that, although plans had been made and exercises had occurred, gaps remained on both the federal and state levels. GAO determined that additional action was needed to address capacity needs to respond to and recover from an influenza pandemic, such as identifying additional treatment space, and acquiring and distributing medical countermeasures, such as antivirals and vaccines, and other necessary supplies.³⁸

³⁶<https://www.gao.gov/products/GAO-04-458T>

³⁷ <https://georgewbush-whitehouse.archives.gov/reports/katrina-lessons-learned/appendix-a.html>

³⁸ <https://www.gao.gov/products/GAO-09-334>

The Government Accountability Office also noted the challenges in preparing for a medical surge in a mass casualty event like a pandemic versus a discrete event, like a hurricane, given the widespread nature of it. The report cited a National Governors Association report that “states would likely be unwilling to share scarce resources or deploy personnel into a location where the disease is active and thus expose individuals to a high-risk environment.”³⁹

The 2009 H1N1 pandemic illustrated many of the same issues seen with the COVID-19 response today. An after-action report reflected that the high volume of and increased demand for surveillance data created difficulties in communicating about the data.⁴⁰ Data was also reported across seven different time zones for the U.S. states and territories, which affected timeliness. HHS found that national-level surveillance information was not specific enough to keep pace with changes in the illness or hospitalizations at the community level or to meet the needs of local responders. The after action report noted the need to increase state and local capacity.⁴¹

The response to Zika in 2018 provides insight into gaps in testing capability. The Government Accountability Office reported in 2019 that the 16 tests for Zika that were authorized by the FDA during the outbreak “varied in their ability to detect the virus and provide accurate results.”⁴² The report also concluded that manufacturers faced challenges in accessing clinical samples, and users of the novel tests encountered challenges in determining the most accurate test to use and obtaining the equipment required to run the tests. The report determined that CDC and FDA did not follow some of their communication guidance about providing information to more easily compare performance across tests.

Bipartisan Commission on Biodefense

One of the largest recent efforts to assess the nation’s biodefense posture has been the Bipartisan Commission on Biodefense, formerly known as the Blue Ribbon Panel. In 2015, the Commission published its first report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. The report addresses a wide range of areas in which to improve biodefense, including fundamental observations on the need to support intragovernmental coordination through institutional structures, priority setting, and budgeting.

The Commission also noted that despite a large number of federal policies addressing issues related to biodefense, the federal government lacked clear direction because these policies had not been consolidated and distilled to identify a comprehensive set of priorities. The report states, “The lack of a comprehensive, cohesive, and regularly updated strategy has resulted in disorganization and confusion, particularly as Administrations change and the institutional knowledge associated with them is lost. Biodefense planning

³⁹ <https://www.gao.gov/assets/290/286548.pdf>

⁴⁰ <https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>

⁴¹ <https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>

⁴² <https://www.gao.gov/products/GAO-17-445>

has become driven by agencies with requirements that may or may not meaningfully contribute to national biodefense. A single, comprehensive, and harmonized strategy to pull these myriad documents together is lacking.”⁴³

In response to the Commission’s recommendation, in 2016, Congress required the Secretaries of Defense, Health and Human Services, Homeland Security, and Agriculture to jointly develop a national biodefense strategy and implementation plan as part of the National Defense Authorization Act for Fiscal Year 2017 (PL 114-328).

In September 2018, President Trump issued the National Biodefense Strategy and National Security Presidential Memorandum 14, which outlines the process of implementing the Strategy and complying with the Congressional mandate. Day-to-day coordination of development and implementation was assigned to the Secretary of HHS, acting through the Assistant Secretary for Preparedness and Response, with oversight from the National Security Council.⁴⁴ Departments and agencies experienced significant difficulties in meeting the deadlines established and capturing a government-wide picture of capabilities, gaps, and future needs.

“The President should retain flexibility to address biodefense at the White House in whatever way he or she chooses. However, such flexibility should not continue to result in the absence of a concentrated and continuous effort across Administrations. Further, if the White House takes charge or is expected to take charge of every significant biological event, then this responsibility should be institutionalized...The primary goal of centralization is to place the coordination and oversight responsibility in a location that will have sufficient authority regardless of personalities or party in power, and in a position with the ability to make executive decisions. The Vice President possesses these attributes.”

A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts, Bipartisan Commission on Biodefense, October 2015

In a February 2020 report assessing implementation of the strategy, the Government Accountability Office found multiple challenges to the development and implementation of a federal government wide National Biodefense Strategy, including:

- a lack of planning and guidance to support a whole of federal government approach;
- a need for guidance and methods to meaningfully analyze the data regarding existing federal biodefense programs and activities; and
- a need to clarify the decision-making processes, roles, and responsibilities.⁴⁵

The experience to date with the National Biodefense Strategy illustrates that creating a holistic strategy faces significant challenges related to leadership, coordination, and prioritization of these efforts.

⁴³ *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, Bipartisan Commission on Biodefense, October 2015, p. 13.

⁴⁴ *Presidential Memorandum on the Support for Biodefense*, September 18, 2018.

⁴⁵ *National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation*, U.S. Government Accountability Office, February 19, 2020, pp. 19-20.

Crimson Contagion

The Crimson Contagion Functional Exercise Series was led by HHS over the past two years and culminated in a national, full-scale exercise in August 2019.

The scenario for Crimson Contagion envisioned a highly transmissible strain of H7N9 avian influenza that spilled over into humans and was first detected in people around the world who had recently been to China with a tour group. The outbreak developed into a pandemic, and HHS served as the lead federal agency, with support from FEMA to coordinate non-public health and medical activities in the U.S.

The Crimson Contagion After-Action Report notes several challenges that have also become evident during the COVID-19 response:

- First, the report notes that the global supply chain for necessary medical supplies would not be sufficient to meet global demand during a pandemic.
- Second, the report highlights that HHS did not have the mechanisms in place to direct other departments and agencies during a nationwide response without the support of FEMA and does not have sufficient resources to finance such a response without supplemental appropriations from Congress, despite the existence of potential tools like the Public Health Emergency Fund.
- Third, the report notes that existing executive branch policies do not sufficiently articulate and differentiate the roles and responsibilities of both the Assistant Secretary for Preparedness and Response and FEMA as co-leads of the federal response and other agencies, such as CDC. This resulted in duplication of effort and, in some cases, conflicting information.⁴⁶

COVID-19 also exposes key differences and challenges that were unanticipated, for example, Crimson Contagion did not contemplate a scenario in which a Stafford Act declaration would be made for a pandemic because there was no precedent for doing so, and issues like supply of sedative drugs to intubate patients were not foreseen.

State Readiness

The Ready or Not 2020 report issued by the Trust for America's Health on February 5, 2020, placed 25 states and the District of Columbia in the high preparedness performance category, stating that they had met ten indicators. These indicators include areas such as incident management, cross-sector collaboration, health security surveillance like six to eight weeks of testing capacity, and public health funding goals.⁴⁷ However, it is clear that many states were not ready for an event like COVID-19.

⁴⁶ "Crimson Contagion Functional Exercise After-Action Report," Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, January 2020.

⁴⁷ <https://www.tfah.org/wp-content/uploads/2020/01/2020ReadyOrNotFINAL.pdf>

COVID-19: LESSONS LEARNED SO FAR & INITIAL RECOMMENDATIONS

For decades, public health officials have warned that the next infectious disease that could start a pandemic is just an airplane ride away. With COVID-19, that fear was realized, and the widespread, simultaneous wave of a new virus created a strain on resources as public health officials at all levels of government sought to learn more about the virus while also trying to contain it. Federal and state officials initially implemented screenings at airports, halted travel, and implemented social distancing to slow the spread of the virus and prevent the health care system from getting overwhelmed. A number of issues have been identified in the response that should be addressed by Congress this year.

1. Tests, Treatments, and Vaccines – Accelerate Research and Development

ISSUE 1.1: COVID-19 has continued to demonstrate the need for domestic manufacturing capacity of medical countermeasures. In the case of a high-value medical countermeasure such as a vaccine, it is imperative that the U.S. maintain access to that product, which is most easily achieved by encouraging manufacturers of such products to operate in the U.S. While the advanced development and manufacturing program is one model for addressing this issue, the program has faced some challenges. Additionally, the current facilities can only be used to manufacture biological products and not small molecule drugs. Questions remain around how to most effectively achieve and maintain domestic vaccine manufacturing capacity.

RECOMMENDATION 1.1: Congress and the administration should identify and implement public-private manufacturing models to improve and maintain sustainable domestic vaccine manufacturing capacity and capabilities. One approach has been the advanced development manufacturing program.

ISSUE 1.2: NIH has leveraged existing research infrastructure and also created new public-private partnerships, in coordination with BARDA, FDA, and other agencies. The Infectious Diseases Clinical Research Consortium, established in 2019 by the National Institute of Allergy and Infectious Diseases to conduct Phase 1-4 vaccine and treatment trials, has been used to rapidly enroll volunteers for COVID-19 vaccine and treatment trials.

RECOMMENDATION 1.2: Congress and the administration should continue to support NIH research and its academic partnerships, which have provided key infrastructure to rapidly pivot to COVID-19 research and clinical trials.

ISSUE 1.3: The emergence of COVID-19 has triggered an unprecedented level of private sector engagement in medical countermeasure development. The NIH's ACTIV partnership to coordinate and prioritize vaccine and therapeutic development for COVID-19, its RADx initiative to fast track and rapidly scale up new diagnostic test to detect COVID-19, and the administration's Operation Warp Speed to rapidly accelerate development and manufacture of products that show promise prior to knowing whether they are effective in humans, underscore the federal role in the development of medical countermeasures. As part of the 21st Century Cures Act, Congress authorized BARDA to establish a Medical Countermeasure Innovation Partner to carry out such partnerships and activities; however there have been challenges in leveraging this authority to develop this partnership.

RECOMMENDATION 1.3: Congress and the administration must work together to implement the Medical Countermeasure Innovation Partner program so tests, treatments, and vaccines can quickly be identified, researched, and developed for the next pandemic.

ISSUE 1.4: New infectious diseases present challenges for public health officials, as they are learning about the disease while also managing the response. Having systems and procedures in place to quickly adapt to the situation provides an advantage. When COVID-19 emerged, CDC worked with the Council of State and Territorial Epidemiologists to develop a case definition and begin tracking cases in the U.S. CDC adapted its existing surveillance systems and networks to track cases and hospitalizations due to the virus.

But, as with H1N1, the initial response to COVID-19 was hindered by limited testing capacity. An HHS retrospective review of the H1N1 pandemic response found that, "...diagnostic tests for accurately detecting influenza, especially for confirming 2009 H1N1, were not accessible and led to frustration within the clinical community due to their lack of availability. The low sensitivity of commercially available rapid antigen detection tests led to misdiagnosis and under-treatment of people with 2009 H1N1 influenza."⁴⁸

It is the responsibility of the CDC will quickly identify or develop a reliable test to diagnose a new virus. Instead of using the diagnostic test offered by the World Health Organization for COVID-19, CDC developed its own diagnostic test for SARS-CoV-2 that states could use to identify cases of COVID-19, for which FDA issued an emergency use authorization on February 4. On February 6, CDC began shipping test kits to state public health laboratories, but problems with contamination in and manufacturing of CDC's initial diagnostic test kits distributed to states delayed implementation of more widespread testing. On February 18, CDC reminded hospitals that any tests for SARS-COV-2, including laboratory developed tests, are required to be cleared or authorized by the FDA for emergency use.⁴⁹ At that time, CDC's test was the only diagnostic test that had been issued an emergency use authorization. On February 26, CDC announced it was continuing to work to resolve the

⁴⁸ <https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>

⁴⁹ https://www.cdc.gov/csels/dls/locs/2020/reminder_covid-19_diagnostic_testing.html

initial issues with its diagnostic test kits that it distributed to states, and that only 12 states were able to run the CDC test.⁵⁰ These early missteps resulted in important time lost to develop adequate testing capacity in the early phase of the pandemic.

Diagnostic tests need to be as accurate as possible. It is the responsibility of FDA to ensure the reliability of such tests during a public health emergency. As demand for diagnostic testing capacity continued to mount, on February 29, FDA issued guidance granting more flexibility in issuing emergency use authorizations for diagnostic tests, which allowed the private sector to step in and commercial and academic labs to develop such tests and ramp up testing capacity. On March 16, FDA updated their guidance to allow states to take responsibility for COVID-19 test developed by laboratories in their respective states.⁵¹

Global and nationwide demand for reagents and testing supplies limited testing capacity as well, as did a requirement that positive tests performed by state labs be sent back and verified by CDC. These factors, as well as the types of tests that have been available, resulted in limited testing supplies initially and delays in patients receiving test results.

RECOMMENDATION 1.4: Engage and partner with the private sector early to develop diagnostic tests, ensure flexibility to develop and use laboratory-developed tests in a public health emergency, and ensure that the stockpile is better prepared to address diagnostic needs.

2. Disease Surveillance – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases

ISSUE 2.1: Another key lesson reaffirmed in this pandemic is that infectious diseases can affect certain populations differently and responses must be adjusted accordingly. Certain groups at higher risk for serious illness from COVID-19 have emerged, including those 65 and older and people with certain underlying medical conditions, including diabetes, liver disease, chronic lung disease or moderate to severe asthma, heart conditions, etc. Data has also shown that COVID-19 has had a disproportionate impact on minority populations.^{52,53} It is important to study the underlying reasons for this disproportionate impact in order to inform interventions at the state and local levels. CDC has cited factors such as densely populated areas, multigenerational households, neighborhoods further from grocery stores and medical facilities, employment in essential industries, lack of paid sick leave, and underlying health conditions and access to care as likely contributing to disproportionate impact on minority populations.⁵⁴

⁵⁰ <https://www.cdc.gov/media/releases/2020/t0225-cdc-telebriefing-covid-19.html>

⁵¹ <https://www.fda.gov/media/135659/download>

⁵² <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>

⁵³ https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm?s_cid=mm6915e3_w

⁵⁴ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>

Additionally, on May 4, New York City issued a health notice, as cases of a multisystem inflammatory syndrome were identified in New York, for which some tested positive for the presence of COVID-19 antibodies.⁵⁵ On May 14, CDC issued an advisory through the Health Alert Network with a case definition for multisystem inflammatory syndrome in children, which is believed to be associated with COVID-19, and a recommendation that health professionals report cases to their state and local health departments.⁵⁶ This development illustrates the need to maintain flexibility and adapt at all levels of the response as our knowledge of this emerging threat continues to evolve.

RECOMMENDATION 2.1: Ensure timely communication between health professionals, states, the CDC, and the public, as appropriate, of case data and information regarding how emerging infectious diseases affect populations, including who is at higher risk for severe disease and death, to help inform state and local response and address any potential disproportionate impact on minority populations.

ISSUE 2.2: Initially, the case definition and testing for COVID-19 was focused on travel history. As with the 2009 H1N1 virus, the case definition was adjusted as knowledge of COVID-19 increased. However, as a recent *New York Times* article pointed out, “After an initial round of tests, the agency imposed restrictive testing standards. When doctors in Washington State and elsewhere forwarded the names of about 650 people in January who might have been infected -- they had contact with a confirmed patient, had been admitted to a hospital, or had other risk factors – the CDC agreed to test only 256. That group consisted primarily of people traveling from Wuhan and their contacts.”⁵⁷

An important question to consider for future pandemics is how the use of case definitions for surveillance impacts clinical care. For example, would cases without a travel history have been caught sooner and care altered if that criteria was removed earlier?

RECOMMENDATION 2.2: CDC, states, and health professionals should work together to identify barriers to earlier identification of cases, including whether case definitions and testing recommendations were overly narrow for too long.

ISSUE 2.3: The ability of CDC officials to provide accurate contact information to state and local health officials on American passengers to follow-up with them on self-quarantine and monitor whether anyone became ill was hampered by incomplete contact information

⁵⁵ <https://www1.nyc.gov/assets/doh/downloads/pdf/han/alert/2020/covid-19-pediatric-multi-system-inflammatory-syndrome.pdf>

⁵⁶ <https://emergency.cdc.gov/han/2020/han00432.asp>

⁵⁷ <https://www.nytimes.com/2020/06/03/us/cdc-coronavirus.html?action=click&module=Top%20Stories&pgtype=Homepage>

on passengers and communications systems issues. According to the New York Times, “...the effort was frustrated as the CDC’s decades-old notification system delivered information collected at the airports that was riddled with duplicative records, bad phone numbers and incomplete addresses.”⁵⁸ Starting in 2005 after SARS, and several times thereafter, CDC attempted rulemaking to update quarantine regulations to access airline passenger manifests so CDC could follow up with state and local health departments in the event of exposure to a certain infectious diseases.⁵⁹ In 2017, a final rule went into effect requiring airlines to report passenger contact information to CDC to the extent the data was available when requested by the Director in order to respond to a possible exposure to an infectious disease.⁶⁰ On February 12, 2020, HHS published an interim final rule allowing contact information on passengers and crew arriving from other countries to be collected. This rule will remain in effect until two incubation periods after the last known case of COVID-19 or the Secretary of HHS determines the rule can be lifted.⁶¹

RECOMMENDATION 2.3: The Departments of Health and Human Services, Homeland Security, and Transportation should coordinate to improve access to passenger contact information by appropriate public health officials to inform public health responses to infectious diseases, like measles and COVID-19, with necessary privacy protections in place. CDC should, in coordination with state health officials, review and improve the systems used to communicate such information to states.

ISSUE 2.4: Reporting delays and incomplete data challenged state health departments and CDC alike. The delays and incomplete reporting of COVID-19 cases led many news outlets and policy makers to use alternative sources, such as the Johns Hopkins University’s Center for Systems Science and Engineering COVID-19 Dashboard to get information about the number of reported cases, deaths, and recovered individuals, as well as those tested.

In FY2020, Congress provided \$50 million to CDC in annual appropriations to support internal improvements as part of its public health data systems modernization initiative.⁶² Congress appropriated an additional \$500 million to support improved public health data systems as part of the CARES Act (PL 116-136). However, Congress also enacted new reporting mandates contrary to existing reporting practices and laws in the middle of the crisis. These new conflicting reporting requirements created confusion and duplicative reporting among laboratories and states at a critical time in the response. Given states primary responsibility for public health, states should improve the timeliness,

⁵⁸ <https://www.nytimes.com/2020/06/03/us/cdc-coronavirus.html?action=click&module=Top%20Stories&pgtype=Homepage>

⁵⁹ <https://www.cdc.gov/washington/testimony/2007/t20070606.htm>

⁶⁰ <https://www.federalregister.gov/documents/2017/01/19/2017-00615/control-of-communicable-diseases>

⁶¹ <https://www.federalregister.gov/documents/2020/02/12/2020-02731/control-of-communicable-diseases-foreign-quarantine>

⁶² <https://www.cdc.gov/budget/documents/fy2021/FY-2021-CDC-congressional-justification.pdf>

completeness, and capacity for infectious diseases case reporting, and voluntarily share appropriate information with the Centers for Disease Control and Prevention.

Outdated technology at the local, state, and federal levels is a barrier to implementing the near-real time biosurveillance system that is necessary to detect, identify, and model emerging infectious diseases. Improving public health data systems at the state and local levels, as well as at CDC, is needed to support an effective biosurveillance system in the future. The Public Health Data Systems Modernization Act, which is included in Lower Health Care Costs Act, is one way to ensure the foundation required to modernize our nation's biosurveillance systems is in place.

RECOMMENDATION 2.4: Congress should pass the Public Health Data Systems Modernization Act, included in the Lower Health Care Costs Act, to modernize our nation's biosurveillance systems.

3. Stockpiles, Distribution, and Surges – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution

ISSUE 3.1: It is critical that the United States better leverage the private and commercial sectors to get the right supplies, at the right time, to the right place. Manufacturers and distributors have expertise in supplying demand and getting products where they are needed in a timely way. To further improve our preparedness, several laws have encouraged public-private partnerships for the research, development, and manufacturing of medical countermeasures. Most recently, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act modified provisions to clarify that the Strategic National Stockpile should consider leveraging private health care infrastructure and manufacturing capacity for products and supplies needed for the stockpile.

This type of public-private partnership would improve our readiness capabilities by providing excess medical supplies quickly and as needed during the next pandemic or public health emergency, and reduce our reliance on foreign manufacturers or “just in time” manufacturing supply chain practices.

RECOMMENDATION 3.1: Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.

ISSUE 3.2: During the COVID-19 response, many states relied on the federal Strategic National Stockpile to provide the needed medical supplies, such as ventilators, masks, gowns, and other personal protective equipment. Some of these medical supplies are commonly used in medical settings such as hospitals and doctors’ offices, and are supplied through commercial contracts using a “just in time” manufacturing and distribution system,

As a result, manufacturers and distributors of medical supplies had little to no excess capacity to meet increased demand, and existing supply chains could not provide sufficient levels of personal protective equipment or testing supplies. When the demand for these commonly used ancillary medical products increased sharply, manufacturers did not have the capacity to convert existing production lines or ramp up new production quickly enough to meet the demand. Some manufacturers also relied on foreign sources of material or foreign manufacturing, which increased the amount of time to produce and transport products to the U.S. Additionally, the global demand for these medical supplies increased sharply, further straining the supply chain.

Many health care providers and states experienced confusing and inconsistent direction about how to access the federal reserve of medical supplies. Procuring personal protective equipment became a crisis of its own. A breakdown in federal, state and local public health and hospital partnerships hampered mass distribution and administration of medical supplies and tests. In the early stages of the COVID-19 response, many states and local public health departments and hospitals were simply unable to purchase personal protective equipment and testing supplies.⁶³

RECOMMENDATION 3.2: States should establish distribution plans and procedures to better inform and communicate with health care providers that request supplies. The Strategic National Stockpile should provide states, territories, and tribes with guidance on best practices to coordinate and distribute medical supplies, including procedures to request resources from the federal stockpile.

ISSUE 3.3: At the beginning of 2020, as COVID-19 was becoming a global threat, the Strategic National Stockpile had 42 million masks, including 12 million N95 masks, and 17,000 ventilators. While the Strategic National Stockpile was not intended to stockpile the full amount needed to respond to a pandemic, the health care supply needs for the initial phases of the COVID-19 response far exceeded the federal reserve of medical supplies in the Strategic National Stockpile.⁶⁴

⁶³ <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns-during-covid-19-pandemic>

⁶⁴ <https://www.newsweek.com/alex-azar-coronavirus-masks-30-million-have-need-30-million-fight-america-senate-committee-1489058>

To prepare for an expected wave in the fall and the next pandemic, the country will need more appropriate supplies of products such as masks, gloves, and other PPE, ventilators, and ancillary medical supplies, such as needles, testing supplies, and bandages. Congress provided the Strategic National Stockpile with new authorities as part of the CARES Act to specifically ensure the federal stockpile is able to purchase personal protective equipment and ancillary medical supplies.

Congress must also exercise more oversight of the Strategic National Stockpile. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act, signed into law in 2019, required an annual threat-based report to ensure appropriate oversight of the procurement decisions made by the Strategic National Stockpile, including decisions informed by the Public Health Emergency Medical Countermeasure Enterprise. This report will be an important oversight tool to ensure that the decisions made to purchase certain products will strengthen the Strategic National Stockpile and the nation's ability to respond to the needs of states during a public health emergency.

RECOMMENDATION 3.3: Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.

ISSUE 3.4: The RADx, ACTIV, and Operation Warp Speed initiatives are intended to produce medical countermeasures, or a combination of countermeasures, to address the spread of COVID-19. It is critical that as soon as a test, treatment, or vaccine is available, it is distributed to the right place as quickly as possible. This requires a plan for appropriate distribution based on existing and projected need.

Early attempts at distributing novel medical countermeasures during COVID-19 have demonstrated a need for further improvement, including advanced planning. On April 29, the NIH announced positive clinical trial results for remdesivir improving patient recovery from advanced COVID-19 infection.⁶⁵ On May 1, FDA issued an emergency use authorization for the use of remdesivir, an investigational drug, in hospitalized COVID-19 patients.⁶⁶ Gilead Sciences, the drug's manufacturer, made an initial donation of 607,000 vials of the drug to HHS to distribute for use around the country under the EUA.⁶⁷ However, initial shipments of remdesivir did not begin until May 5, and there was confusion among many states and health care facilities regarding the distribution strategy and expected

⁶⁵ <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19>

⁶⁶ <https://www.fda.gov/media/137564/download>

⁶⁷ <https://www.hhs.gov/about/news/2020/05/09/hhs-ships-first-doses-of-donated-remdesivir-for-hospitalized-patients-with-covid-19.html>

receipt of product.⁶⁸ On May 9, HHS announced a new distribution strategy under which HHS would distribute vials of remdesivir to each state and territory based on the number of hospitalized patients, however the allotments also included states and territories that do not have COVID-19 cases and have limited travel.⁶⁹ States and territories were responsible for allocating the drug within their jurisdiction.

RECOMMENDATION 3.4: The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.

ISSUE 3.5: As widespread social distancing measures were put in place so that hospitals would not be overwhelmed with the surge of patients and to preserve supplies, state supplies quickly dwindled, and federal supplies of personal protective equipment and ventilators in the Strategic National Stockpile became smaller and smaller as states looked to the federal government to provide much needed supplies. The unprecedented spread of the virus to every corner of the country exhausted the federal stockpile, state resources, and exposed supply chain issues.

These supply chain challenges created shortages of needed supplies, including ventilators, masks and other personal protective equipment, swabs, reagents, and other material needed to perform diagnostic tests. Manufacturers outside the medical industry, such as Ford,⁷⁰ stepped in to manufacture personal protective equipment and testing supplies and ventilators. Small businesses also began producing medical supplies or component parts for medical devices, such as masks and face shields. The FDA also took steps to authorize or recommend alternative types of testing supplies, such as swabs and reagents.⁷¹ The FDA also provided guidance for 3D printing medical devices and products.⁷²

The federal government took a number of steps to increase necessary supplies, at the same time states were also acquiring supplies. On March 21, HHS announced a contract with five manufacturers to produce 600 million N95 respirators over the next year and a half for approximately \$440 million.^{73,74}

⁶⁸ <https://www.npr.org/sections/health-shots/2020/05/14/855663819/remdesivir-distribution-causes-confusion-leaves-some-hospitals-empty-handed>

⁶⁹ <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/remdesivir.aspx>

⁷⁰ <https://media.ford.com/content/fordmedia/feu/en/news/2020/04/30/ford-is-making-face-masks-and-face-shields-to-enable-employees-a.html>

⁷¹ <https://www.statnews.com/2020/04/16/fda-changes-coronavirus-testing-swabs/>

⁷² <https://www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices>

⁷³ <https://www.phe.gov/emergency/events/COVID19/SNS/Pages/procurement.aspx>

⁷⁴ <https://news.bloomberglaw.com/health-law-and-business/honeywell-draeger-among-manufacturers-in-line-to-produce-masks>

On April 2, 2020, President Trump invoked the Defense Production Act (DPA) to expand the U.S.'s health care surge capacity and capability to respond to COVID-19.⁷⁵ The DPA allows the U.S. federal government to enter into contracts with manufacturers that have the capacity and ability to produce medical resources, such as personal protective equipment and ventilators, needed to combat and defend against the spread of COVID-19.

In April, HHS announced partnerships with nine manufacturing companies, including General Motors, Philips, and General Electric to produce almost 30,000 ventilators by June 2020, and 130,000 ventilators by the end of 2020.

Congress provided the Strategic National Stockpile with \$16 billion in the CARES Act (PL 116-136) to purchase and distribute personal protective equipment, testing supplies, treatments, and vaccines to diagnose, treat, or prevent COVID-19. Additionally, Congress provided \$25 billion as part of the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139) for response activities and testing capacity, including for active infection and prior exposure, testing equipment and supplies, personnel to conduct testing, contact tracing, and personal protective equipment to protect such personnel.

RECOMMENDATION 3.5: Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.

ISSUE 3.6: While HHS is the lead federal agency during a public health emergency response, on March 13, 2020, President Trump declared a national emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act. This action allowed FEMA to provide support to HHS, including supporting the acquisition and distribution of supplies to states, territories, local governments, tribal governments, and private non-profit organizations.

RECOMMENDATION 3.6: Better leverage the support provided by FEMA and their emergency management experience and assets by improving a coordinated process between HHS and FEMA to more rapidly distribute supplies to states, health care providers, and other entities on the front lines, while utilizing HHS expertise with respect to public health and medical care and medical supplies.

⁷⁵ <https://www.whitehouse.gov/presidential-actions/memorandum-order-defense-production-act-regarding-3m-company/>

4. Public Health Capabilities – Improve State and Local Capacity to Respond

ISSUE 4.1: In preparing for and managing the surge of COVID-19 patients, many states issued stay-at-home or safer-at-home orders. Health care seeking behavior changed, as did recommendations on seeking routine health care services. Many doctors implemented or expanded telehealth opportunities for their patients or opportunities for vaccination, but recent findings from an analysis of vaccination rates in Michigan found that vaccinations have declined in most children two and under.⁷⁶ This phenomenon has also occurred in other states.

RECOMMENDATION 4.1: Get Americans back to their routine health care safely, and develop better plans for the future so that doctors and hospitals can continue to provide health care services and outpatient treatment during a pandemic.

ISSUE 4.2: Many state health professional licensing boards moved to quickly allow health care providers in good standing in another state to practice in their state. The Centers for Medicare and Medicaid Services waived regulations so that hospitals, doctors, and nurses could focus on providing care to those who need it and not worry about paperwork. Telehealth became an option for many patients and health care providers alike where it was not before, reducing the number of patients in clinics and emergency departments.

RECOMMENDATION 4.2: Ensure that the United States does not lose the gains made in telehealth.

ISSUE 4.3: Contact tracing is a critical public health tool that has been used in measles outbreaks, the Ebola outbreaks, and others. The Council for State and Territorial Epidemiologists 2017 Epidemiology Capacity Assessment workforce report indicated that the number of epidemiologists increased 22% between 2013 and 2017 to 3,370, but that an additional 1,200 epidemiologists were needed to reach full capacity.⁷⁷ Further, the report notes, “In 2017, more than three quarters of health department epidemiology funds were provided by the federal government, with an average of 20% provided by the states. Heavy reliance on federal funds reduces flexibility, adds to insecurity in the workplace, and may affect the ability to cover core functions.”⁷⁸

States are beginning to scale up their contact tracing capacity, with a goal of interrupting chains of transmission by tracking down the contacts of people found to have COVID-19. Congress has provided \$13.5 billion to states and territories in response to COVID-19 which can be used to expand contact tracing.

⁷⁶ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6920e1.htm>

⁷⁷ https://cdn.ymaws.com/www.cste.org/resource/resmgr/eca/2017_ECA_Report_Web_final.pdf

⁷⁸ https://cdn.ymaws.com/www.cste.org/resource/resmgr/eca/2017_ECA_Report_Web_final.pdf

RECOMMENDATION 4.3: States need to maintain the capacity to trace contacts for emerging infectious diseases, and have programs in place to surge that capacity if necessary.

ISSUE 4.4: HHS quickly distributed funding to states through existing cooperative agreements. Congress appropriated emergency supplemental funding in the Coronavirus Preparedness and Response Supplemental Appropriations Act (PL 116-123) on March 6, and on March 11, HHS distributed more than \$560 million to states, localities, territories, and tribes.⁷⁹ On March 23, \$100 million was distributed to health care systems, including to Hospital Preparedness cooperative agreement recipients, and on April 23, \$631 million was distributed through the Epidemiology and Laboratory Capacity Grants to states.⁸⁰ Prior to this, the public health response for COVID-19 was primarily supported by \$105 million from the CDC Infectious Diseases Rapid Response Reserve Fund and transfers among HHS programs of \$136 million.⁸¹ The ability to get funding to states quickly was an improvement over the H1N1 response, where an after action report found that, “Federal and state mechanisms for obtaining and distributing public health emergency funds to state and local governments were burdensome. In particular, the requirement of multiple separate applications with separate guidelines for each state to obtain Public Health Emergency Response grants, and the time required for federal approval of the applications, affected states’ capacity to respond effectively.”⁸²

RECOMMENDATION 4.4: Remove red tape and allow states to use Public Health Emergency Preparedness and Hospital Preparedness Program funds to respond to a public health emergency and report back to HHS on how they were used, rather than having to wait for written approval from Washington.

5. Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency

ISSUE 5.1: Various laws over the past two decades have attempted to provide clear lines of responsibility for federal officials in dealing with public health emergencies. The Assistant Secretary for Preparedness and Response, who has the responsibility for coordinating the

⁷⁹ <https://www.hhs.gov/about/news/2020/03/11/cdc-to-award-over-560-million-to-state-local-jurisdictions-in-support-of-covid-19-response.html>

⁸⁰ <https://www.hhs.gov/about/news/2020/03/24/hhs-provides-100-million-to-help-us-healthcare-systems-prepare-for-covid-19-patients.html> <https://www.hhs.gov/about/news/2020/04/23/hhs-announces-cares-act-funding-distribution-to-states-and-localities-in-support-of-covid-19-response.html>

⁸¹ <https://www.crs.gov/Reports/IN11253?source=search&guid=adf4fc6105c2473fa4f6562739e65ced&index=4>

⁸² <https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>

public health response, has not taken on the role intended by Congress in the response to COVID-19.

The federal response to COVID-19 was elevated to the White House with the creation of the Coronavirus Task Force, which is now overseen by the Vice President, on January 29.⁸³ The Task Force provides strategic direction and coordination, as well as, in some cases, operational decision-making.⁸⁴

In addition, following President Trump's March 13 emergency declaration under the Stafford Act, the White House enlisted FEMA to lead tactical response efforts in coordination with HHS. Following this shift in leadership, FEMA stood up a whole-of-government coordination structure within the context of the National Response Framework.⁸⁵ The structure includes operational task forces on testing, the medical supply chain, countermeasures, and health care resilience, which are each led by senior staff from across FEMA, HHS, and the Defense Logistics Agency. The structure also relies on support from FEMA's National Response Coordination Center and HHS counterparts to conduct modeling and data analysis, policy and planning, and asset deployment.

Through the FEMA structure and in addition to it, agencies across the federal government contributed to the COVID-19 response and supplemented HHS and FEMA capabilities. For example, leadership from the Department of Defense was enlisted in March to lead the Supply Chain Stabilization Task Force, which has been responsible for purchasing medical supplies and working with commercial distributors to allocate and distribute those resources to the states. The Supply Chain Task Force and its member agencies have also been coordinating efforts to implement President Trump's orders to utilize authorities under Title I of the Defense Production Act.⁸⁶

Additionally, supercomputing and other capabilities of the Department of Energy's national laboratories are being leveraged to support scientific discovery for COVID-19.⁸⁷ Early in the response, the Department of State led efforts to repatriate Americans from China and other areas abroad, which was supported by the Assistant Secretary for Preparedness and Response and CDC to manage patient care and quarantine throughout the process.

While every president is going to manage a crisis differently based on the personnel they bring with them into government, it is Congress' responsibility to provide a foundational structure that administration after administration can build on instead of creating a new structure with each new emergency. The laws that Congress passed do not seem to have anticipated fully the scope of a pandemic such as COVID-19 and the need for a whole-of-government approach. Presidents have acted where necessary. President Bush established the Homeland Security Council, which facilitated much of the public health preparedness

⁸³ <https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/>

⁸⁴ <https://www.nytimes.com/2020/05/05/us/jared-kushner-fema-coronavirus.html>

⁸⁵ Unified Coordination Group at the National Response Coordination Center Organizational Chart, April 3, 2020.

⁸⁶ <https://www.fema.gov/news-release/2020/04/14/applying-defense-production-act>

⁸⁷ <https://www.ornl.gov/news/ornl-fight-against-covid-19>

policy development during his administration. President Obama appointed Ron Klain to serve as the White House Ebola Response Coordinator. President Trump has relied heavily on Vice President Pence and Ambassador Deborah Birx.

RECOMMENDATION 5.1: Congress must clarify who is in charge and has the ability and authority to keep a continued focus on preparedness for pandemics and other major public health threats when other priorities may seem more pressing, and improve how federal agencies will coordinate during a pandemic. These roles and responsibilities must also be clearly communicated to states and local governments so they can include this information in their own preparedness planning.

ISSUE 5.2: Crimson Contagion was the first national exercise of its kind for a pandemic scenario since the passage of many of the preparedness laws that Congress has enacted since 2000. In contrast, the federal government routinely exercises its natural disaster response processes through both simulated exercises and real-world responses.

RECOMMENDATION 5.2: A key lesson from Crimson Contagion and COVID-19 is that plans and systems cannot be improved upon if they are not practiced. More training is needed, as well as more opportunities to exercise plans and processes nationwide.

QUESTIONS

In addition to these recommendations, there may be other steps Congress should take to help federal, state and local officials be better prepared for the next pandemic. To achieve these goals, please send any comments on the recommendations above, any responses to questions below, or additional recommendations to

PANDEMICPREPAREDNESS@HELP.SENATE.GOV no later than 5PM ET on June 26, 2020.

Tests, Treatments, and Vaccines – Accelerate Research and Development

1. What incentives can the federal government offer to the private sector to encourage development of more medical countermeasures with no commercial market?
2. Should the federal government create government-owned-contractor-operated facilities to solve supply chain and manufacturing challenges?
3. What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?
4. How can the federal, state, and private sector work together to more effectively distribute and administer treatments and vaccines?
5. How can the United States build manufacturing systems that can rapidly respond to new threats, whether naturally occurring or manmade?
6. What is the appropriate federal role in supporting the manufacturing of medical countermeasures, especially vaccines?
7. How can Congress and HHS make sure CDC and FDA are working more closely with the private sector on diagnostic tests to detect emerging diseases?
8. How can the United States better leverage public-private partnerships, industry, and academic institutions?
9. What the lessons learned from the current fast tracking of tests, treatments, and vaccines to make them available even more rapidly?
10. Are additional or more predictable liability protections needed to incentivize manufacturers of medical products that are not approved or cleared by the FDA for use during a certain emergency to scale up manufacturing capacity?

Disease Surveillance – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases

1. What other barriers, in addition to limited testing capacity, and insufficient and outdated technology, make it difficult to detect and conduct public health surveillance of emerging infectious diseases?
2. What appropriate role can innovative technologies play to improve public health surveillance?
3. What privacy protections should accompany new technology? Would these technologies be utilized and maintained by HIPAA-covered entities or others?
4. Has our focus in medical countermeasure development been too much on the known threats, such as anthrax and smallpox, to the detriment of emerging threats

like coronaviruses, including COVID-19, SARS and Middle East Respiratory Syndrome?

5. How can emerging infectious disease modeling be improved?
6. How can the private sector innovations to support and modernize federal and state surveillance be better leveraged?

Stockpiles, Distribution, and Surges – Rebuild and Maintain State and Federal Stockpiles and Improve Medical Supply Surge Capacity and Distribution

1. How can the Strategic National Stockpile be better managed and how can Congress increase oversight and accountability?
2. How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?
3. What steps should be taken to ensure that health care providers and first responders have the supplies they need, such as personal protective equipment?
4. As states and hospitals establish or build their own stockpiles, how will they know what supplies to stockpile? What guidance should the federal government provide on what medical supplies are appropriate?
5. Could states and hospital systems establish their own vendor managed inventory programs with manufacturers and distributors? Should the federal government or states contribute to such hospital stockpiles?

Public Health Capabilities – Improve State and Local Capacity to Respond

1. What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?
2. What changes can be made to Public Health Emergency Preparedness and Hospital Preparedness Program to help states prepare and respond more quickly?
3. How can the federal government ensure all states are adequately prepared without infringing on states' rights and recognizing states have primary responsibility for response?
4. How should the federal government ensure agencies like CDC maintain an appropriate mission focus on infectious diseases in the periods between emergencies to strengthen readiness to respond when a new threat arises?

Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency

1. Is the Assistant Secretary for Preparedness and Response the right position to coordinate a whole-of-government response to a pandemic?
2. What is the appropriate role for HHS and how can FEMA be better integrated into a nationwide pandemic response?
3. Whose job is it to coordinate supply lines so that personal protective equipment, ancillary supplies, and medicines are available and delivered to where they are needed when they are needed?

4. What is the right balance between specific and limited statutory authority and more flexibility for federal preparedness and response programs?
5. Have well-intended requirements and directives created too much bureaucracy and slowed federal response?
6. How can federal departments and agencies more effectively work together to respond to public health emergencies?