

Testimony of

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“Preparing for and Responding to Future Public Health Security Threats”

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Summary of Testimony

PAHPA has a strong bipartisan history of Congress working together to address our nation's changing health security threat landscape and protect the American people. The last three PAHPA bills all showed major recurring themes: they all adjusted to the changing threat landscape, focused on challenges identified since the prior bill, and considerably strengthened our nation's health security with each reauthorization.

The first bill laid the groundwork for national pandemic and emergency preparedness in response to accidental and deliberate threats, while the second bill ironed out many of the details from the first bill and provided agencies with more flexibility to achieve their missions. The third bill highlighted the importance of innovation for medical countermeasures, working with local authorities, and taking a broad perspective regarding health security as an aspect of national security. The 21st Century Cures Act and the PREVENT Pandemics Act both include provisions relevant to PAHPA reauthorization that sought to increase innovation and strengthen our nation's pandemic preparedness strategy in response to lessons learned from the COVID-19 pandemic.

Since the last reauthorization, we've learned many new lessons from the COVID-19 pandemic. Among the most critical lessons: the need to be able to make medicines, vaccines, and diagnostics more rapidly and to scale their production and distribution; the vital importance of better preparing the healthcare and public health systems; the key roles our federal agencies play in response to this kind of pandemic and the need for them to be highly capable; and the great significance of the work being done to prevent future pandemics.

Introduction

Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the Committee, it is my pleasure to appear before you today to discuss this year's reauthorization of the Pandemic and All-Hazards Preparedness Act, also known as PAHPA.

My name is Tom Inglesby. I am Director of the Johns Hopkins Center for Health Security and Professor in the Department of Environmental Health and Engineering in the Johns Hopkins Bloomberg School of Public Health, with a Joint Appointment in the Johns Hopkins School of Medicine. The opinions expressed herein are my own and do not necessarily reflect the views of Johns Hopkins University.

For 25 years, our Center's mission has been to protect people's health from major epidemics and disasters and build resilience to those challenges. Our Center is a network of scholars in science, medicine, public health, law, social sciences, economics, and national security who conduct independent research to examine how scientific and technological innovations can strengthen health security. We also founded the Capitol Hill Steering Committee on Pandemic Preparedness and Health Security in 2020, in collaboration with Members of the House and Senate, as well as former Administration officials, as an educational forum to discuss new topics, technologies, and ideas that can improve domestic health security now and in the future.

Today, I was asked to provide comments on the history of PAHPA—its original intent, how it changed during prior reauthorizations, and how the COVID-19 pandemic may inform its 2023 reauthorization.

As you know, this is the first PAHPA reauthorization since the global COVID-19 pandemic, and it should be heavily informed by our nation's experience over the last three years. At the same

time, Congress must also look forward and ensure the broader national health security threat environment—including deliberate, accidental, and natural threats—is informing its work. For this purpose, I encourage the Committee to coordinate a dedicated, closed briefing for Members on the current threat environment.

The last three PAHPA bills all showed a major recurring theme: they adjusted to the changing threat landscape and strengthened our nation’s health security with each reauthorization. The first bill laid the groundwork for national pandemic and emergency preparedness and response in response to accidental and deliberate threats that were the impetus for the bill; the second bill ironed out some of the details from the first bill and provided agencies with more flexibility to achieve their missions; and the third bill highlighted the importance of innovation for medical countermeasures, working with local authorities, and taking a broader perspective regarding health security as an aspect of national security. Since the last reauthorization, we’ve learned many new lessons from the COVID-19 pandemic. Among the most critical lessons: the need to be able to make medicines, vaccines, and diagnostics more rapidly and to scale their production and distribution; the vital importance of better preparing the healthcare and public health systems; the key roles our federal agencies play in response to this kind of pandemic and the need for them to be highly capable; and the great significance of the work being done to prevent future pandemics.

I will now summarize key provisions of the last three PAHPA bills and then turn to lessons from the COVID-19 pandemic that could be used to inform this year’s reauthorization.

2006: The Pandemic and All-Hazards Preparedness Act (Public Law 109-417)

From the beginning, the health security threat landscape has been a driving force behind PAHPA. The first bipartisan Pandemic and All-Hazards Preparedness Act was passed by the 109th Congress in December 2006, and President George W. Bush signed it into law later that month. The 109th Congress started in January 2005, three and a half years after the 9/11 terrorist and anthrax letter attacks of 2001, which focused the nation's attention on the threat of biological weapons. Later that year, the country faced two additional naturally occurring public health emergencies. First, Category 5 Hurricane Katrina battered the Gulf Coast, claimed more than 1,800 lives, and ranked as the costliest natural disaster in U.S. history. Second, a sharp rise in human H5N1 avian influenza cases raised the possibility of a larger, more deadly H5N1 epidemic.

In 2005, the Senate established a dedicated Subcommittee on Bioterrorism and Public Health Preparedness within the Senate Committee on Health, Education, Labor and Pensions (HELP), led by Senators Richard Burr and Ted Kennedy. This Subcommittee led the exhaustive process to develop the legislation that became PAHPA. In the House, the process included bipartisan leaders within your Committee, namely Representatives Mike Rogers and Anna G. Eshoo.

I testified¹ before the Senate Subcommittee on issues including the federal medical response and the development of stronger public-private partnerships on this work. The resulting bill did four main things:

¹ Inglesby T. Senate Subcommittee on Bioterrorism and Public Health Preparedness Roundtable on All Hazards Medical Preparedness and Response. Comments from Thomas Inglesby, MD, Deputy Director and COO, Center for Biosecurity of UPMC. Published April 5, 2006. Accessed May 8, 2023, <https://www.help.senate.gov/imo/media/doc/Inglesby.pdf>.

1. Put someone in charge. Local, state, and federal public health and medical responses to Hurricane Katrina were inadequate and uncoordinated; respective roles and responsibilities were ill-defined. The White House performed an after-action report that concluded that the Department of Health and Human Services (HHS) should lead a unified and strengthened public health and medical command for federal disaster response, something that I also argued for at that time in my testimony. PAHPA designated the Secretary of HHS as the lead official for public health and medical responses to public health emergencies and created the Assistant Secretary for Preparedness and Response—or ASPR—to coordinate these activities and create a National Health Security Strategy every four years.
2. Expedited the development of medical countermeasures. PAHPA established the Biomedical Advanced Research and Development Authority (BARDA) to partner with biopharmaceutical companies to bridge the so-called “valley of death” in late-stage development of the diagnostics, vaccines, and therapeutics needed to protect Americans from deliberate or natural health security threats. It was recognized that many experimental but promising medical countermeasures were failing in later stages of development due in part to lack of advanced research and development funding. Our Center was a strong proponent of creating BARDA and talked with product developers to understand what was needed to get companies interested in developing needed medical countermeasures. We found that even with Project BioShield² in place, the process of medical countermeasure development typically took a decade, which is too long to

² Project BioShield was originally authorized by the Project BioShield Act of 2004 (P.L. 108-276) and focuses on medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats to national security.

combat an emerging threat. PAHPA also allowed Project BioShield funds to be used for milestone-based payments to help product sponsors get through advanced development.

3. Strengthened state and local public health security across the country. PAHPA reauthorized funding for state and local public health preparedness from the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) cooperative agreements. This funding had been originally authorized in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). PAHPA also required establishment of overarching preparedness goals and essential public health security functions to set uniform standards of preparedness from state to state. It also required building on state and local situational awareness capabilities to establish a near real-time nationwide public health situational awareness network.
4. Enhanced medical surge response. PAHPA moved the National Disaster Medical System (NDMS) from the Department of Homeland Security (DHS) back to HHS. It also reauthorized ASPR's Hospital Preparedness Program (HPP), established a process for registering and organizing volunteers, improved training and support for volunteers, and promoted the use of mobile medical assets and alternative federal facilities (such as Department of Veterans Affairs assets) to increase surge capacity during an emergency. Our Center advocated for NDMS to be moved back to HHS and helped develop the initial guidance for the HPP program.

2013: The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA)
(Public Law 113-5)

The first bipartisan PAHPA reauthorization was signed into law in 2013. The final bill was sponsored by Representatives Mike Rogers, Anna G. Eshoo, Michael Burgess, Gene Green,

Frank Pallone, and Henry Waxman. In the Senate, a bipartisan companion bill was sponsored by Senators Richard Burr, Tom Harkin, Mike Enzi, Bob Casey, Barbara Mikulski, Lamar Alexander, Joe Lieberman, Susan Collins, Kay Hagan, and Pat Roberts. In addition to reauthorizing the main programs from the first PAHPA bill, some of the key provisions in PAHPRA included:

1. Enabling more flexible public health response and adding greater emphasis on at-risk individuals. To mount a faster response to public health emergencies locally, PAHPRA authorized federally funded personnel to be temporarily reassigned to support emergency responses at the state, tribal, and local levels. It also added a greater focus on meeting the needs of at-risk individuals, such as children and elderly and disabled people, into various preparedness and response programs, a priority that my colleagues and I were committed to and were engaging with ASPR on at that time.
2. Renewing the Strategic National Stockpile and Project BioShield. PAHPRA reauthorized the Strategic National Stockpile (SNS) and required an annual review of the contents of the Stockpile be submitted to Congress. Our Center worked with the DHS to evaluate how the SNS contents matched up with various risk scenarios, helped the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) understand how the stockpile matched the terrorism risk, and briefed CDC—the managers of the SNS at that time—on the results of our work. The bill also reauthorized Project BioShield, since its original 10-year advance appropriation had expired.

3. Streamlining the FDA regulatory process. PAHPRA added to the Food and Drug Administration (FDA) authorities to support medical countermeasure development and use, for example by authorizing product manufacturers to work with FDA to create regulatory management plans and allowing FDA to authorize use of unapproved products in advance of a public health emergency.
4. Requiring a medical countermeasures strategy, implementation plan, and five-year budget. The bill required ASPR to develop and update annually a five-year budget plan based on medical countermeasures priorities to give Congress greater visibility into the expected needs of the relevant medical countermeasures program.

2019: The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) (Public Law 116-22)

The second bipartisan PAHPA reauthorization passed in June 2019. It was sponsored by Senators Richard Burr, Bob Casey, Lamar Alexander, and Patty Murray. The House companion bill was sponsored by Representatives Anna G. Eshoo and Susan Brooks, and 6 bipartisan co-sponsors. Again I testified³, and discussed public health threats the country faced at the time, healthcare system preparedness, public health preparedness, medical countermeasure development, potential pandemic pathogen research, and the global health security agenda.

New features added in PAHPAIA included:

1. Codifying the PHEMCE, which is a federal interagency workgroup led by ASPR and includes CDC, FDA, the National Institutes of Health (NIH), the Department of Defense

³ Inglesby T. United States Senate Committee on Health, Education, Labor and Pensions. Facing 21st Century Public Health Threats: Our Nation's Preparedness and Response Capabilities. Testimony of Tom Inglesby, MD, Director, Center for Health Security, Johns Hopkins Bloomberg School of Public Health. Published January 23, 2018. Accessed May 8, 2023, <http://www.help.senate.gov/imo/media/doc/Inglesby1.pdf>.

(DOD), the Department of Veterans Affairs (VA), DHS, and the Department of Agriculture (USDA). In October 2018, the Secretary of HHS administratively moved management of the SNS from CDC to ASPR to link it with the medical countermeasures advanced research and development activities at BARDA and medical response elements like NDMS. By codifying the PHEMCE, Congress aimed to ensure CDC and other agencies would continue to have a role in making decisions on medical countermeasures priorities.

2. Expanding and strengthening authority for the HHS Public Health Emergency Fund.

This allowed the fund to be used before a formal emergency declaration. I testified at that time that the fund should be appropriated in a way that allowed immediately substantial resource mobilization to facilitate rapid response to new infectious disease crises.

Unfortunately, this fund has not yet received appropriations from Congress.

3. Enhancing regional healthcare response capabilities and adding new advisory committees. PAHPAIA required ASPR to create guidelines for regional healthcare response and reauthorized grants to build readiness. My testimony called for some healthcare facilities to have more regional healthcare responsibilities, which was required of ASPR in the law, and these guidelines were in that spirit. It also established the National Advisory Committee on Seniors and Disasters and the National Advisory Committee on Individuals with Disabilities and Disasters and reauthorized the National Advisory Committee on Children and Disasters.

4. Emphasizing the broader national security threat environment. PAHPAIA required ASPR to coordinate with relevant federal intelligence agencies to maintain a current assessment of national security threats, as I recommended in my testimony. It also required HHS to

develop a strategy to address cybersecurity threats to national health security, and to report on the implementation of the recommendations of the Federal Experts Security Advisory Panel with respect to biological agents and toxins that pose a threat to public health.

Other Legislation Relevant to PAHPA Reauthorization

There are two other laws that are important to consider in this process: The 21st Century Cures Act and the PREVENT Pandemics Act.

The bipartisan **21st Century Cures Act (Public Law 114-255)**, signed into law in December 2016, added a couple important tools to the medical countermeasures toolbelt. First, it created the Medical Countermeasures Priority Review Voucher (PRV) program for material threat medical countermeasures, which was authorized through 2023. Second, it authorized BARDA to partner with a private, nonprofit entity that can use venture capital practices and methods to invest in companies developing promising, innovative medical countermeasures. This has been implemented as part of the BARDA Ventures program by their Division of Research, Innovation and Ventures (DRIVE). This authority also expires in 2023.

The PREVENT Pandemics Act was signed into law with the 2023 omnibus appropriations in December 2022. Among other things, it: created a new White House Office of Pandemic Preparedness and Response Policy, which has yet to receive funding; supported advancements in genomic sequencing for improved biosurveillance; authorized BARDA to fund warm-base domestic manufacturing surge capacity and capabilities for medical countermeasures; authorized the Advanced Research Projects Agency for Health (ARPA-H) at NIH; and required Senate

confirmation of future CDC Directors as well as created an Advisory Committee to the Director of CDC.

2023 PAHPA Reauthorization

Lastly, I will provide some overarching thoughts on how the COVID-19 pandemic can inform the 2023 PAHPA reauthorization and build on this long legislative history of bipartisan progress.

First, this PAHPA legislation has evolved as our understanding of different biological and other threats has evolved. It reflects lessons learned over 15 years of policymaking and on-the-ground experience on these issues. Its evolution has been a truly bipartisan effort. Preparedness for biological threats and for responding to national health emergencies is something that should be a priority for all of us, and fortunately it has consistently been one for a bipartisan group of legislators. I am very hopeful that this crucial precedent will continue here.

Turning to COVID, let me offer a few lessons that I take from our national and global experience with this pandemic. Here are things that we should make high priorities:

1. **Make vaccines and medicines faster.** Great acceleration was accomplished with Operation Warp Speed, but we need to take advantage of technology, innovation, and momentum to drive timelines to be faster. Every week of progress in developing a vaccine faster will save countless lives, prevent huge financial losses, and lessen societal disruption.
2. **Position our healthcare system to respond rapidly—with no warning—to the next pandemic.** That means providing our healthcare workforce with the tools they need—personal protective equipment, financial coverage to prevent and treat people sick with pandemic disease, and data systems that help state and federal leaders understand when

hospitals are nearing or over capacity. It also means being able to better address social inequities in access to care, problems that were only worsened during COVID.

3. **Be ready to scale up diagnostics so that Americans can get them easily and quickly across the country.** Without diagnostic testing readily available, we don't know who is sick and needs to be isolated and treated, where things are getting better or worse, or which groups are most badly affected by the disease. We should prepare to have abundant diagnostics available at no cost right from the start of a new epidemic.
4. **Ensure our response agencies in HHS are strong and can move rapidly.** This includes ASPR and CDC, and making sure they have the ability to quickly hire the right emergency workforce and the capacity to contract immediately with companies that need to be part of the response. They need the authorities and budget flexibility to do what the public and policymakers expect them to be able to do. I am very glad that ASPR has become an operating division, a move that will make it stronger and faster. I'm hopeful that CDC will get the support it needs to become stronger and faster in the wake of the pandemic. Just as I testified during the original PAHPA bill that HHS should lead a unified and strengthened public health and medical command for federal disaster response, I believed then and continue to believe that CDC should lead in technical, scientific, and laboratory responses to outbreaks and epidemics.
5. **Build more capacity in state and local health.** In addition to strengthening federal agencies, we need to make sure public health agencies at state and local levels have the support they need to lead disease control efforts on the ground level across the country. They are in critical positions to advise elected officials, communicate with the public,

interpret changing conditions and data, and run the operations needed to mitigate and end epidemics.

6. **Do all we can to prevent these events from happening.** That includes strong early warning systems and a broad commitment to international sharing of data about new pandemic events. It includes good animal husbandry practices to make sure we do not increase the risk of spillover. It also should encompass stronger oversight over genome sequencing to prevent the synthesis of the world's most dangerous viruses, and codes of scientific conduct that will help dissuade scientists from irresponsible work. It includes stronger attribution science and planning to make sure we are better prepared to identify the source of future pandemics.

In closing, as past epidemics have impacted the evolution of PAHPA over the years, the lessons of COVID also shine a light on the types of challenges that this reauthorization should take on. We need to take the time we have now before a new epidemic arises to fix the problems before us. If we do this, we will make the country far safer from future pandemics and will be better able to protect all Americans from future biological threats.

Thank you again for the opportunity to testify, and I look forward to answering any questions you may have.