

Written Testimony of Dr. Robert P. Kadlec
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Committee
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Chairman Morelle and Ranking Member Burgess thank you for the privilege and opportunity to appear before you today. I am appearing as a private citizen and not in my capacity as a Senate professional staffer. As the former Assistant Secretary of Preparedness and Response at the start of the pandemic, I lived, breathed and bled the experience. I certainly want to acknowledge the incredible work, service and sacrifice of the federal, state, local, tribal and territorial civil servants and professionals from the private health sectors that served as the backbone of the past and current pandemic response. The whole-of-nation response has been vital to the preserving our society and lives saved. I also want to commend you and your colleagues for your strategic vision and foresight in having this Subcommittee consider budgetary approaches that Congress could take to prepare the country for the next pandemic.

I am fortunate to know an individual, Senator Richard Burr, who shares your urgency and necessity to learn from the successes and mistakes of the COVID response to better prepare for the next pandemic. I am convinced because of your collective commitments to future congressional action that we as a government and nation can be better prepared to mitigate the unnecessary loss of life, economic impacts and societal disruptions that another pandemic would bring.

A Context for Future Preparedness

The risk of focusing exclusively on the current crisis to define future preparedness will hopefully be a lesson learned from this pandemic. Before COVID, our pandemic preparedness was exclusively focused on influenza. The precedence of previous influenza pandemics resulted in a form of target fixation: excluding from consideration other potential pandemic pathogens like coronaviruses, Hendra (e.g. Nipah) and other viruses. It would be a similar mistake to exclude other potentially catastrophic events that could have a national impact on public health and health care provision. For example, a large scale chemical, biological, radiological or nuclear (CBRN) cyber- or critical infrastructure attacks on the homeland would have severe effects on Americans health and welfare.

The 2021 US State Department Arms Control compliance report raised concern about the compliance of China, Iran, North Korea and Russia adherence with the Biological Weapons Convention (BWC). Our limited preparedness and faulty response to COVID could only validate and encourage them and potentially others about the utility of biological agents against the United States. We have witnessed a number of state sponsored targeted killings using advanced chemical and radiological agents. We also watched these adversarial nations to develop advanced hypersonic missiles that could deliver unconventional warheads against our homeland.

We have also witnessed the occurrence of large scale cyberattacks on health care systems. The United Kingdom's National Health System and several US health care systems were adversely effected by ransomware attacks. These attacks emanated from both state sponsors and criminal

elements. Such effects does not exclude incidents caused by disturbed individuals. My 2020 Christmas Day holiday was interrupted by a deliberate detonation of a vehicle borne improvised explosive device in Nashville that killed the perpetrator. The explosion severely damaged a critical telecommunications facility. The interruption of telephone and internet services impacted three major regional health care systems and 911 call service across several states.

You cannot dismiss the risk of major weather events either. Early in my tenure, we were confronted by three consecutive major hurricanes, Harvey, Irma and Maria. The December 2021 deadly tornadoes that effected 8 states is a more recent example. The challenges and documented incidents I encountered during my ASPR tenure, including a novel coronavirus pandemic, could be considered the new normal. I would also suggest they should be considered the likely future we must be prepared for.

Three Policy Imperatives for Future Whole of Nation Preparedness

These potential challenges require the same “whole of nation” response we saw attempted with varying success during this pandemic. It is apparent that the successes achieved during COVID required collaboration between the federal state, local, tribal and territorial governments, the private sector, academia and the general public. Nowhere was that most effective than during Operation Warp Speed. The Warp Speed approach for medical countermeasure development, if effectively applied, could have improved our efforts in disease surveillance, testing, supply chain management and health care provision. The core elements of Warp Speed can be described by three elements.

1. **Promoting Strong, Effective Leadership and Coordination.** There is a need for clear and effective leadership emanating from the White House and HHS working with FEMA to promote better all-hazard preparedness and operational response coordination across federal interagency, state and local governments, academia and the private sector.
2. **Strengthening Public-Private Partnerships.** Much progress has been made in creating public private partnerships with a variety of entities in the U.S. health care enterprise. Notably, Operation Warp Speed (OWS) defied the pundits and the odds by creating vaccines and therapeutics in record time. OWS was built on a public-private partnership created by BARDA, which leveraged pre-existing relationships between the federal government, the private sector, and academia.

Similar partnerships were created with manufactures, suppliers and distributors in the medical supply chain. They were created with entities in diagnostics through partnerships with testing developers, companies and a variety of health care providers, health care systems, and retail pharmacies. Besides enabling the advancement of specific lines of effort addressing the pandemic, the information provided, created a transformational data set as part of *HHS Protect*. These partnerships, however, are still nascent and need to be preserved, improved upon and made enduring for the next public health emergency.

3. **Capacity, and Capability Improvements, Innovation and Exercises.** Health care systems must expand their limited surge capacity, and there is a need to better coordinate and rapidly surge

personnel and staffed medical beds to meet future contingencies. Capacity must also reflect specialized capabilities that may be needed in future public health emergencies.

There were significant pre-pandemic capabilities that provided significant yet insufficient levels of capacity. The National Emerging Special Pathogens Training and Education Center and the 10 Regional Ebola and Special Pathogen Treatment Centers managed and supported care of highly infectious patients. Prior to the pandemic they provided specialized training to affiliated hospitals and health care systems. The National Disaster Medical System effectively coordinated with participating civilian health care systems and the Department of Defense and the Veteran Affairs health system. The coordination maximized the limited capabilities and capacity that DoD and VA could offer supported by the NDMS Disaster Medical Assistance Teams.

There is also an opportunity and imperative to leverage innovation to expand medical preparedness and response capacity and capabilities, including those of the Strategic National Stockpile and the medical countermeasures enterprise.

Understanding our capabilities and capacities has come through painful experiences such as COVID. According to a July 2021 [CRS report](#), there were no National Level Exercises (a term FEMA utilized that is scenario playing among the interagency, often in partnership with states and localities). The only pandemic exercise was a TOPOFF exercise conducted by HHS known as Crimson Contagion (looking at a pandemic influenza event with state, local, tribal, and territorial partners). Crimson Contagion was one exercise I was particularly adamant about having as there hadn't been a pandemic related exercise since the 2009 pandemic. Such exercises help to identify critical assumptions, shortfalls, and provide rubrics for timely response. While the bureaucratic process behind these exercises takes many months to reach consensus through After-Action Reports, it takes even longer to inform the policy and budget processes to address the identified challenges.

In the case of Crimson Contagion, we identified many challenges, including the importance of financial access in a timely measure. Given my previous role, I didn't await the drawn-out processes to perhaps inform changes years down the road. Following a hot wash (immediate debrief), I instructed staff to immediately attempt to integrate Congressional staff into the shortfalls that may hinder such a response. In fact, barely over a month later, they hosted several dozen staff to relive the exercise and tour a Strategic National Stockpile facility. These bipartisan and bicameral staff expressed their thoughts in the roundtable format where they primarily honed on concerns about the speed by which Congress could appropriate funds necessary to address that theoretical pandemic and how vulnerable to disruption and just-in-time the supply chain was.

Potential Budget Principles to Prepare for Future Pandemics

There are several historical and contemporary budget approaches that worked and didn't work. There some prospective ideas that are innovative and I think would work improve future pandemic preparedness. Whatever approach taken must be evaluated on the basis of

responsiveness to the health security threat contemplated, and ensure congressional accountability and sustainability.

The Project BioShield Act that was created by Congress in 2004 after the events of 911 was an effective tool. It created a ten year advanced appropriation to incentivize the development and procurement of CBRN medical countermeasures that did not have a commercial market. The program was successful but the Special Reserve Fund created by the legislation was not replenished when the original ten year appropriation ended. Advanced appropriations could be useful in developing potential pandemic medical and antimicrobial countermeasures. The dilemma becomes renewing such advanced appropriations and the potential that Congress may later choose not to do so. The original BioShield concept called for obligatory nondiscretionary funding.

The second potential budgetary approach could be adopting a similar funding mechanism represented by FEMA's Disaster Relief Fund (DRF) to create a Health Security Emergency Fund. This is a concept also supported by the Bipartisan Policy Center.

Congress periodically replenishes the FEMA DRF in response to large natural disasters. While the DRF can provide access to such funds for public health emergencies it is usually available later than Congressional supplemental funding. DRF allocations are subject to reimbursement of mission assignments. This approach is not conducive to large-scale pharmacologic research and development, material stockpiling, or related spending necessary to health security emergencies.

The frequency of health security events is not annual. Were Congress to establish careful guardrails to limit expenditures to true health security threats and provide an annual appropriation into a Health Security Emergency Fund (HSEF), a response that bridges the gap from potential pandemic threat emergency to true pandemic could be addressed.

The guardrails needed to define temporal health security threats include:

- Existential health security threats can and should be addressed by agencies through the normal
- Appropriations and Authorizing processes.
- Consistent and timely obligation reporting to key Congressional Committees would help Congress to more accurately forecast threat potential and related authority or financial needs. Such oversight also helps to ensure guardrail compliance.
- Given medical and public health expertise, such a fund should reside at a cross-cutting level within the agency with principal responsibilities, HHS. While interagency partnership should be encouraged in an advisory manner, it should not be a hindrance to the rapid decision-making necessary for such actions.

Upon fund maturation, a required set aside for health security-specific NLEs should occur on a rotating basis to encompass the major threat areas of pandemic, large scale CBRN incidents, and national health care disruptions (cyber or supply chain).

This iterative cycle of health-specific threats would provide for the bureaucratic processes to play out and to inform the policy and budgetary processes. Such a cycle also permits officials to see if recommendations hold up across the threat spectrum or the relative degree of insularity. Key hot wash highlights and eventual After-Action Reports should be provided to key Congressional Committees along with interpretive debriefs.

What didn't work particularly for ASPR was periodic pandemic or disaster supplemental funding to sustain improvements in preparedness. Disaster and pandemic supplemental funding were significant enablers of preparedness but when the funds from that funding (e.g. influenza, and ebola) ran out, ASPR's ability to sustain programmatic funding for pandemic influenza countermeasure development and training of our NDMS Disaster Medical Assistance Teams were jeopardized for example. When I arrived at ASPR, our NDMS teams had not received any sustainment or specialized training for several years. Fortunately, because of the hurricane supplemental funding after Harvey, Irma and Maria, we were able to fund highly infectious disease training of our NDMS personnel before the pandemic.

The Coronavirus Aid Relief Economic Security (CARES) Act worked but the delay in securing the funding through the supplemental process slowed our ability to respond. Delays impacted our ability to procure personal protective equipment at a time when those with cash in hand were buying the available limited PPE supplies. It also delayed our ability to contract with pharmaceutical companies for the development of COVID related vaccines, therapeutics and diagnostics. Congress was and remains generous in allocating funds for pandemic response. The benefit of these dollars, however, is greater in lower amounts before the crisis or outbreak happens. The ounces of prevention and preparedness are greater than the pounds of response.

I am strongly supportive of some prospective budget ideas whose time has come. I think the notion of designating preparedness funding exempt from budget caps is an excellent idea. I understand members of this Committee are supportive of the idea of put forth by the Bipartisan Policy Center. The concept Biodefense Interagency Operations creates a permanent budget designation for programs deemed highest priority to prevent, detect, and address infectious disease threats outside annual 302(a) allocations, and outside overall budget limitations. I think this would be an indispensable addition and tool for future pandemics and other potential catastrophic health security threats too.

Finally a new mechanism specific to the Strategic National Stockpile has also been proposed. Permitting the creation of a working capital fund specifically for the SNS is viewed as a potentially beneficial authority to ensure the long term sustainability of certain dual-use commercial products such as personal protective equipment (PPE). Permitting the ASPR and SNS to rotate stock before expiry could save the government and American taxpayer significant funds that could be reused for pandemic preparedness. It could be a tool that could enable better preparedness not only at the federal level but the opportunity to procure PPE and other medical supplies jointly non-federal partners (e.g. state, local tribal and territorial governments).