Prepared Testimony of Nicole Lurie, MD, MSPH before the U.S. Senate Committee on Homeland Security and Governmental Affairs, April 14, 2021

Good morning. I am Dr. Nicole Lurie. I currently serve as strategic advisor and response lead at the Coalition for Epidemic Preparedness Innovations, an international organization focused on vaccine development to prevent epidemics and pandemics. From 2009-2017, I served as Assistant Secretary for Preparedness and Response at the US Department of Health and Human Services. In addition to preparedness activities, I was involved with responses to H1N1, MERS, Ebola and Zika outbreaks, as well as other crises that required a whole of government response. I testify here in my own capacity, representing only myself, and not the organization in which I currently work.

We have long known that a pandemic was not a matter of if, but when. Over the past thirty years, our country has made substantial investments to develop robust authorities, plans, and systems to respond in the face of contagion rapidly and nimbly. Yet, ongoing preparedness program funding cuts, and failures of leadership along with active dismantling of preparedness infrastructure by the Trump administration thwarted our ability to build on the institutional knowledge gained during the 2009 H1N1 pandemic, and to rapidly and fully leverage these investments and lessons to protect the American people when confronted with COVID-19.

I start with the premise that the role of government is to protect its people from harms, and to build resilience to those that cannot be prevented. That, by definition, involves preparing for the worst, and scaling back if the worst does not materialize. In the decades leading up to the Trump administration, that was also the posture of the US government, spanning both Republican and Democratic administrations.

What did US preparedness look like at the beginning of the COVID-19 pandemic?

Pandemic planning has been a focus in US government dating back to the 1990's. Initially, the nation's focus was largely on influenza, which remains one of our greatest pandemic risks. The Bush administration made significant contributions to preparedness when H5N1, a novel influenza virus, presented a pandemic threat. Since then, there has been substantial progress

preparing for a pandemic across federal, state, and local levels of government and in the private sector. As a country, we have developed, exercised and refined plans, created robust authorities that have enabled federal engagement in both preparedness and response, and developed nimble response systems and infrastructure. These efforts were put to the test during real-life experience with epidemics spanning the Bush and Obama administrations as well as the 2009 H1N1 pandemic, in which the Obama administration embraced and built on the pandemic preparedness investments of the Bush administration.

While none had close to the impact of COVID-19, they provided important experience and lessons, and resulted in institutional learning and iterative improvements in planning. Undoubtedly, the strength of these plans contributed to our country's success mitigating widespread domestic impacts from these events, as well as successful management, prior to 2017, of additional crises necessitating White House leadership and a whole of government response. All were successfully managed within existing authorities.

In the years leading up to COVID-19, certain federal preparedness and response capabilities were maintained and even bolstered. For example, CDC regularly exercised aspects of pandemic planning. In the year before COVID, HHS conducted a long-planned 9-month, whole of government country-level exercise regarding how to respond to a pandemic. While gaps were of course uncovered, they could be anticipated, and there was sufficient basis to know what needed to be addressed and what to expect in the event of a pandemic.

It is also well known that in response to the 2014-5 Ebola epidemic, the Obama administration reconstituted the pandemic office at the National Security Council, and that office developed a comprehensive playbook for pandemic response. The Pandemic and All Hazards Preparedness Act, PAHPA, and its subsequent reauthorizations (PAHPRA and PAHPAIA) provided broad authorities for action, improving our nations preparedness posture with each iteration. And while not a federal initiative, the Johns Hopkins Center for Biosecurity hosted a highly visible exercise in October 2019, attended by many US government officials. The exercise focused on a hypothetical, uncontrolled outbreak of a novel coronavirus (including supply chain

implications), providing practice for multiple federal officials just 2 ½ months prior to the real one starting.

The US also has decades of experience with countermeasure development, especially for influenza vaccines. Each time a novel influenza virus is detected, a risk assessment is performed to determine how far into the vaccine development process to go. This decision reflects an assessment by government experts of whether the virus is likely to be easily transmissible and its impact should such transmission occur. Sometimes it is appropriate to stop after just making a virus seed, and sometimes development goes all the way to stockpiling bulk vaccine. Until recently, countermeasure development was guided through the formal coordination process by the Public Health Emergency Medical Countermeasure Enterprise, which encompassed the major agencies with a stake in the development of countermeasures. This process was remarkably successful, leading the licensure, approval or clearance of over 50 vaccines, therapeutics or diagnostics against recognized public health threats. While it is always our hope that there will never be a need to use the countermeasures we develop, these efforts taught us the value of coordinated investment. Countermeasure development for H1N1 and Ebola also reinforced the value of starting early. We can always take an off ramp if things turn out not to be so bad—but we can't ever make up for lost time. And even off ramps leave you better prepared for the next time.

Unfortunately, a series of actions over the period leading up to the pandemic left us less ready than we otherwise might have been. Among them were the dismantling of the pandemic office at the NSC, and the degradation of the PHEMCE process, which would have been critical to an early start on countermeasures. Another example is a contract for a high-speed mask production line that was terminated without an obvious replacement. Sustaining funding for preparedness has proved challenging across all administrations. For example, from its peak in 2002, the Hospital Preparedness Program alone experienced a 50% decline over a 16-year period. The public health preparedness system tenuously persists with repeated cycles of panic and neglect, hamstringing efforts to build durable capabilities, not least a high quality, sustainable workforce. But even these actions cannot fully explain the failure of the Trump administration to act early in the pandemic. Our withdrawal from the world stage

compromised important strategic global health relationships; nonetheless, there was sufficient warning of a potential pandemic by the last week in December 2019, to warrant attention, and by mid- January, when cases were detected outside of China, the threat was very clear.

Of grave concern to me, in key federal agencies where a more assertive and robust response was needed, the approach appeared to be one of decision-making governed principally by political considerations. In addition, I believe that a climate of fear and retribution that had developed over the few years leading up to the pandemic inhibited seasoned, usually apolitical, career employees in key agencies from stepping up and speaking out about problems with the response.

All of that said, this would have been a difficult situation for anyone to manage, and the adage that even the best of plans does not survive first contact with the enemy is true. But in this case, it does not appear that the enemy—in this case, the virus-- was even acknowledged, or that a plan was activated to fight it. In other words, we lost valuable time, both time between when this virus was first noted as a likely threat in late December 2019, and the interval between the first case in the US on Jan 21, 2020, and the declaration of the public health emergency at the end of January. Other than important, early NIAID efforts to jumpstart the Moderna vaccine, for which they should be applauded, it wasn't until much later that countermeasure development started in earnest and at scale. And even when the pandemic was finally acknowledged, there was no overall plan forthcoming from the Trump administration.

Much has been made about whether or not the 'authorities' that enable the federal government to contribute to response were sufficient. These include those authorities provided for under the Public Health Service Act, which allows for the declaration of a public health emergency with HHS in charge, as well as the Stafford Act, which allows for the declaration of an emergency or major disaster with FEMA in the lead. I contend that there were sufficient authorities to act and to execute a robust, whole of government response. I say this because these authorities were exercised and proved sufficient during the 2009 H1N1 pandemic, in dealing with Ebola and other crises. There was, however, a failure to leverage the full power

that these authorities provide such a response; in short, all the authorities in the world cannot make up for the failure of leadership. The failure to fully engage and deploy the deep experience and expertise of the federal government and provide urgently needed national leadership, early and consistently, has resulted in untold numbers of deaths and chronic health problems for many who survived COVID, let alone the mental health consequences for so many-health care workers, parents, children, and those who have lost loved ones to this pandemic.

Recognizing that the retrospectoscope is a powerful instrument, here are 10 things that should have happened early on:

1) **Immediately acknowledging an infectious disease threat anywhere is a threat everywhere, convening a whole of government effort to examine the scenarios of how COVID-19 could unfold, making a plan for each**. This could have included defining situational triggers for when Stafford Act authorities to coordinate a whole of government domestic response should have been invoked.

2) **Communicating, from the top, in a clear, forthright and consistent way about the severity of the threat and need for an all-hands-on-deck response**. We all know that did not happen, and that the inconsistent communication, rampant epidemic of 'truth decay' and politicization of the response confused the public, with deadly consequences.

3) **Developing and executing a real time research agenda for dealing with the unknowns of COVID-19.** This had been a practice in past crises. While the WHO activated its R&D Blueprint to guide the global research response in February, no such coordinated effort appeared to guide a domestic research response or U.S. federal research investments. This led to delays, and lack of focus and coordination, in fully leveraging the vast capabilities of the U.S. intramural and extramural research enterprise.

4) **Strengthening surveillance and testing.** The US had warnings that the SARS-CoV-2 virus was coming before it arrived, and thankfully, astute clinicians, as well as travelers from China, alerted us to early cases. We were dealing with a new disease, with high levels of asymptomatic transmission, but relying on traditional methods of surveillance and contact tracing that required widespread availability of diagnostics. The failure of test development at CDC, coupled with the legacy of disinvestment in public health meant that neither local public health departments nor their public health labs were equipped to handle volume of required testing or contact tracing; rapid development and scaling of diagnostics, validation of diagnostic tests and laboratories to perform them, including rapid execution of partnerships to facilitate expanded testing and tracing early on, would have been in order. BARDA authorities for countermeasure development could well have been leveraged early to this end to develop and scale additional test capacity. As we know, that did not happen. Further, even in the face of electronic record companies' unprecedented collaboration to provide data, public health and health care data remained largely unlinked and underleveraged. Both for surveillance purposes, and for managing healthcare aspects of the pandemic, this has remained a huge shortcoming.

5) **Examining what resources were on hand, including what was in the Strategic National Stockpile (SNS) and determining what would be needed.** It should have been clear in the first weeks of January that there were not enough masks and PPE in the SNS, and it would have been sensible to make provisions to manage what was there and conserve its use. Emergency contracts to ramp up production of these products and to gain visibility into the supply chain were urgently needed but did not materialize. Instead, we shipped masks overseas. Without a doubt, the failure to provide adequate PPE for healthcare workers resulted in needless infections and deaths and traumatized a vital workforce. It is now estimated that 3600 healthcare workers died on the front line in the United States. It is noteworthy that severe shortages of PPE were a feature of H1N1 and Ebola epidemics; in each case, HHS was able to put together a system to gain

visibility into what was in the supply chain without compromising business relationships, supporting voluntary reallocation of resources that were double- and triple-ordered.

6) **Recognizing the rest of health-related supply chain vulnerabilities and scaling up US production where needed.** Given our dependence on offshore manufacturing of so many key health, medical and laboratory products, it would have been critical to catalog those likely to be in short supply, including essential medicines and laboratory testing equipment, and do everything possible to maintain adequate inventories. This was not done, despite knowing that these kinds of shortages, from antibiotics down to testing wells and pipette tips, had been noted in previous exercises and should not have been a surprise. Our nation's entire critical supply chain management system needs a major upgrade, including for health products.

7) P**reparing the healthcare system.** Failure to recognize the pandemic seriously at the outset meant the healthcare system was not put on alert; it lost valuable time in preparing for the enormous patient surge, in terms of staffing, equipment and supplies, policies and procedures, and coordination across communities. In the face of inadequate funding for the Hospital Preparedness Program, it was no surprise that regional healthcare coordination entities struggled with patient load balancing and distribution for as long as they did. Further, this was a new disease, and early on, HHS failed to provide an adequate mechanism to connect clinicians to one another to recognize new clinical syndromes, share treatment experiences and rapidly study promising practices.

8) **Starting countermeasure development early, as soon as the threat was detected, to include diagnostics, therapeutics and vaccines**. Fortunately, as part of its prototype pathogen approach, NIAID had been working on stabilizing the coronavirus spike protein and on developing mRNA vaccines for several years, and the Institute took critical early steps to advance this work. But BARDA was hamstrung in taking early action to develop

countermeasures, both because of the lack of a standing emerging infectious disease fund and because of administration decisions not to reprogram funds to get started. It was not until March that an emergency supplemental provided a bolus of funds for this purpose. Ultimately, Operation Warp Speed, with its funding and leadership came together and has had remarkable achievements in the vaccine development arena. But they couldn't make up for lost time either, especially with regard to diagnostics and effective therapeutics. As a point of reference, CEPI was concerned enough about the potential for a pandemic that its staff called developers working on MERS vaccines and other platform technologies even before the sequence was posted and asked them to pivot work to a new vaccine. CEPI resources pale in comparison to those of the US government; I would posit that we would be in a different place the USG had made a resource commitment and mounted a Warp Speed-like effort much earlier. You can always take an off ramp. You can't make up for lost time. A standing emerging infectious disease fund that can be used to start countermeasure development in the face of a new threat is urgently needed. Emergency supplementals simply take too long.

9) **Coordinating and providing guidance for state, local and tribal governments and health care settings.** While we live in a federalist system, we also recognize that in a public health emergency people expect to be treated similarly regardless of where they live. Big differences in policy across states or regions also confuse the public and put confidence at risk. Further, many jurisdictions don't have the expertise or resources to develop comprehensive guidance, based on best available evidence. State, local, tribal and territorial (SLTT) governments and their healthcare systems should not have been left to fend for themselves, or to have to compete with one another for scarce resources, driving up their prices. The federal government works best in strong partnership with SLTT government and their healthcare entities; this did not happen.

10) **Mobilizing private sector partners.** Private sector entities of many kinds were eager and willing to step up, and there were multiple missed opportunities to consider what was needed, and to leverage and coordinate their resources, making more rational use what existed in a fragile supply chain. Instead, multiple, poorly thought contracts, such as those for more ventilators, were executed seemingly ad hoc, often wasting taxpayer funding without producing needed products.

Looking forward

While this pandemic is far from over, it's now time to look forward, and to envision the kind of system we want for the future. This hearing provides a welcomed opportunity to move that process forward. In doing so, it is critical to remember that a good response does not happen automatically but is built on the back of strong day to day systems. I know many on this committee would like to focus on new authorities, and while some will undoubtedly be helpful, I do not believe new authorities will solve our basic problem. They simply can't substitute for leadership. Here are some of the things we need to do.

1) **Make it safer for career employees to do their jobs, including maintaining the integrity of our science agencies.** There is not an easy answer here, and the issue deserves considerable thought before jumping into a solution. There are lessons to be learned from near miss reporting at places like the FAA, other confidential, non-whistleblower reporting systems, and outside, independent monitoring entities. Understanding that some aspects of government are inherently political, we need to protect those components that should not be. Preparedness and response has traditionally been a bipartisan effort; we cannot let political interference and partisan division take our country down.

2) **Reconceptualize the organization and role for public health.** This is not a time to build back public health to the time of days gone by, but to reconceptualize it, including getting more clarity and focus on the most critical roles for CDC and its relationship to state/local health agencies; how they are organized and funded, how they gather,

analyze and report data; and how we can achieve the nation-wide ability to link and leverage public health and healthcare data while maintaining individuals' privacy and confidentiality. This will require modernizing the science and laboratory systems available to public health agencies to ensure they have the tools to act and sustainable funding to do so. It's been gratifying to see the recent down payment on next-generation genome sequencing at CDC. It will also require new surge-ready public-private partnerships with commercial and academic labs, and other kinds of workforces, and novel ways of funding public health that are results-driven. We can no longer expect public health agencies to live off the funding fumes of the last emergency.

3) **Create and maintain a standing emerging infectious disease fund at BARDA that can be activated when a threatening new disease shows up.** The cost of preparedness means paying to lean forward, because you can't make up for lost time. The sooner diagnostics are available, the sooner you can manage an outbreak. The sooner vaccines are available, the sooner you can prevent a pandemic. And, the sooner therapeutics are available, the sooner you can treat those who become ill. All of these save lives.

4) **Re-examine the SNS**. It's time to take a hard look at what the SNS is for; right now its budget is dominated by maintaining important countermeasures for bioterror threats like anthrax. While those are critically important, it crowds out other important aspects of readiness, like a supply of masks to bridge to surge manufacturing. That bridge to surge production needs to be ready for activation 'on demand'. Additionally, I believe the SNS needs to be able to monitor critical supply chains, and to maintain and procure critical health and medical material, domestically sourced to the extent possible. This includes not only essential medicines, but raw materials. The shortages of raw materials for making diagnostics, masks, vaccines and the like must not happen again.

5) **Strengthen and clarify FDA authorities**. There are a set of important issues around FDA authorities that need examination, including what should constitute criteria for an emergency use authorization, what a strong vaccine safety monitoring capability needs to encompass in the setting of widespread emergency use, aspects of clinical trial authorization, and how diagnostic test and labs are authorized. Recognizing that these are the jurisdiction of other committees, I mention them here for completeness only.

6) **Protect against cyber-threats.** While not referenced in my enumeration above, it is important to recognize that our research, our manufacturing, our supply chains are subject to near constant cyber-attacks by both state and non-state actors, and our public is subject to considerable misinformation from similar sources, contributing to the epidemic of truth decay. While dramatically increased in tempo, there was not a sufficiently aggressive posture toward these threats. Fortunately, the Biden administration has begun to address this, but more is likely needed.

Finally, remember that **preparedness requires continuous, proactive financial investment.** On "blue sky" days, it's easy to think that this isn't a priority, that the things we've already purchased or the systems we built are sufficient, and that precious resources may be better spent elsewhere. It is definitively not the case that you can build and buy 'stuff' and then you are done. Technology gets out of date, and people, our most precious resource, come and go. Some of our agencies face such stiff competition from the private sector that they cannot attract and retain the caliber of people needed to respond. Staff need to be trained, need to practice and need to be in day-to-day jobs that can provide critical surge when the situation demands it. Response depends on strong day to day systems, and those need to be built, incentivized and maintained. It seems that the public, and Congress as their voice and instrument, all too easily lose sight of the fact that preparedness is forever. We cannot afford to let our guard down. Too much is at stake. Almost 600,000 dead, and still counting…. I look forward to seeing our nation act on the hard lessons learned.