Hearing of the United States Senate Committee on Homeland Security and Governmental Affairs

February 17, 2022

Statement for the Record

Dr. Gerald W Parker, Jr
Associate Dean for Global One Health
College of Veterinary Medicine & Biomedical Sciences

Director, Pandemic and Biosecurity Policy Program
Scowcroft Institute of International Affairs
George H. Bush School of Government and Public Service
Texas A&M University

Chairman Peters, Ranking Member Portman, and distinguished members of the Committee, I am honored to appear before you today for this hearing entitled, "Addressing the Gaps in America's Biosecurity Preparedness."

I come before you today as an individual who has spent an entire career in biodefense, public health preparedness, and health security from research in a high containment laboratory to strategic operational and policy levels; and now mentoring our next generation at Texas A&M University. I will offer insights from my role as a public servant that spanned 26 years active-duty military service and another 10 years as in the career senior executive service. During my military career I had the opportunity to serve in leadership roles primarily in Army medical research & development at the United States Army Medical Research and Materiel Command and the United States Army Medical Research Institute of Infectious Diseases. That was followed by executive leadership roles at the Department of Homeland Security (DHS), Department of Health and Human Services (HHS), and the Department of Defense (DOD). I am now a faculty/administrator at Texas A&M University.

But today, the views and opinions I offer are my own, and not representative of past or current organizational affiliations.

I do not have to tell you how difficult the homeland security mission is today. You are aware of the challenges, difficult decisions, and trade-offs that must be made. There will always be new authorizations, appropriations requests, and budget allocations competing for the many homeland security demands and shifting priorities. The homeland security mission is extremely complex and the threats we face are constantly evolving and range from terrorism, cyber, natural disasters, and pandemics.

The COVID-19 pandemic exposed the stark reality that a novel respiratory virus can emerge anywhere and rapidly spread around the world in weeks with devasting consequences.

Pandemic preparedness professionals sounded the alarm about the dangers we would face over the last twenty years since highly pathogenic H5N1 viruses first jumped from poultry to cause sporadic human disease and deaths in 1997 (Chan, 2002). Since then, we have witnessed an alarming increase of emerging infectious disease outbreaks with epidemic and pandemic potential. Serious outbreaks have included, SARS (severe acute respiratory syndrome), MERS (middle east respiratory syndrome), Influenza viruses, Ebola viral disease, Zika, Nepah virus, Hendra virus, and others. Almost all serious outbreaks have been zoonotic viruses, jumping from animals to humans. Livestock and food producing animals were not immune to transboundary infectious diseases such as ASF (African swine fever), PEDv (porcine epidemic diarrhea virus), and FMDv (foot and mouth disease virus) that had devasting consequences to agriculture sectors and food security in impacted areas of the world.

Given current geopolitical tensions and the situation around the world, the threats from terrorism and violent extremism have become even more of an increasingly reality. Malevolent actors could deploy weapons of mass destruction against our nation, the civilian population, and our critical infrastructure. The intentional use of pathogens (viruses, toxins, or bacteria) by a terrorist organization, an inspired small terror cell, or a malevolent nation state falls into the category of a weapon of mass destruction.

Today, I am more concerned than ever about the risks from all biological threats, whether natural, intentional, or accidental – that could affect humans, animals, and plants, as well as our economy and social fabric. You may call my comment an alarmist statement because we may be near the end of the pandemic phase as we enter the endemic phase.

But COVID-19 will not be our last pandemic due to anthropogenic factors that favor emergence of potential pandemic pathogens for the foreseeable future. I am also concerned COVID-19's demoralizing experience may inspire malevolent actors to pursue and intentionally use dangerous viruses to achieve their goal. Finally, the probability of an accidental laboratory release is increasing due to a number of factors.

Just weeks before SARS-CoV-2 emerged in Wuhan, China, the Global Preparedness Monitoring Board, convened by the WHO and the World Bank, forewarned in the World at Risk Report the growing risk of a viral pandemic resulting from accidental laboratory escape or intentional release of an engineered pathogen (GPMB, 2019).

With that dire warning and despite many acknowledged failures that accrued during the COVID-19 response, we were more prepared before COVID-19 than critics will acknowledge. After the terrorist attacks in New York City and Washington, DC on September 11, 2001, and letters containing deadly anthrax spores were mailed in September and October 2001, Congress authorized new programs and appropriated new funds on a continuing basis as the threat landscape evolved and we accrued lessons learned to counter biological threats and prepare for

pandemics and all-hazards. This led to an evolving and learning pandemic and all-hazards preparedness and response enterprise. We were much better prepared than we would have been before SARS-COV-2 emerged without the long-term support of Congress and the work of many dedicated career professionals. This included career professionals at the Department of Homeland Security and across the entire the U.S. government interagency. But most importantly, it was the thousands of professionals in communities across the nation at state, local, territorial, and tribal governments, as well as those in the private sector, academia, and other non-government organizations who were on the front line serving bravely with distinction through the pandemic.

The accelerated development of safe and effective COVID vaccines through Operation Warp Speed (OWS) would not have been possible without prior Congressional appropriations and new authorities. Those enabled the executive branch to establish new and evolving programs in biodefense and public health preparedness vaccine research, development, manufacturing, and regulatory science over the last twenty years. This came with hard lessons learned by many dedicated government and industry professionals over that twenty-year journey.

However, a recent report by the Bipartisan Commission on Biodefense, "Biodefense in Crisis: Immediate Action Needed to Address Vulnerabilities" (Commission, 2021) and the stark reality of the COVID-19 response tell us that we have a long way to go. We remain dangerously vulnerable to the inevitable next biological crisis – whether natural, deliberate, or accidental.

I previously testified on biodefense before the House Committee on Energy and Commerce's Subcommittee on Oversight and Investigation and the House Committee on Homeland Security Subcommittee on Emergency Preparedness, Response, and Communications (Parker, 2016) (Parker, 2017). Today, I will reiterate a slightly modified statement I made in those past testimonies:

1. As we have so vividly experienced over the 2-year COVID-19 pandemic, biological threats are real and have potential to cause mass casualties and mass disruption to society.
2. A deliberate bioterror attack on a large urban center has potential to cause mass casualties on a scale similar to a nuclear weapon.
3. The inter-epidemic period, or time between outbreaks, requires urgent action to focus available resources on optimizing pandemic preparedness and biodefense.
4. Strong centralized leadership will be necessary to drive urgent preparedness action in the inter-epidemic period.

This statement has relevancy to the topic today regarding the DHS' current operating organization for biosecurity and the fragmented biodefense and pandemic preparedness structure across the federal government. We cannot afford to remain complacent about biological threats, nor can we afford to continue business as usual. ***Urgency, innovation, creative imagination, and leadership are more important than ever*** as we enter the post COVID-19 era.

The nation is tired of COVID-19. I am tired of COVID-19 too. But we must avoid falling into the complacency trap and the "boom and bust" emergency *preparedness* funding cycles reminiscent of past outbreaks.

Congressional emergency supplemental appropriations may flow after a crisis, but that is too late. Sustained investments and leadership attention are most needed during the inter-epidemic period to prepare for the inevitable next biological crisis.

The complexity and changing nature of threats we face today, including from biological threats, are confounded by the complexity of the vast homeland security enterprise. The homeland security enterprise extends far beyond the Department of Homeland Security (DHS). Other federal department/agencies, such as Department of Health and Human Services (HHS), Department of Agriculture (USDA), Department of Justice (DOJ), Office of the Director of National Intelligence (ODNI), and others have homeland security responsibilities, as do state, local, territorial, tribal governments, and the private sector. I also believe that families and individuals have homeland security and preparedness responsibilities, too.

Science and technology will play a vital role defending against the many threats to homeland security, especially weapons of mass destruction. By their very nature, potential weapons of mass destruction evolve rapidly, and our ability to counter new threats must evolve faster. Of the four traditional weapons of mass destruction – biological, nuclear, radiological, and chemical – biological threats are fundamentally changing in new ways that we do not completely understand yet. Malevolent actors can easily elude intelligence and law enforcement interdiction, and nation state proliferation of biological weapons defies traditional deterrence strategies.

Most recognize the bravery, dedication, and hard work by our local public health, health care providers, and emergency first responders that are on the front line in our communities across the nation to defend us against homeland security threats, including biological threats. But we must do better to equip our first responders with technologies they need to detect, counter, treat, and protect themselves against biological threats.

The science and technology enterprise is also on the front line applying their expertise and knowledge for preparedness and response in laboratories. One of the successes of the COVID-19 response was the unprecedented science and technology surge from the research enterprise. Scientists, laboratories, and manufacturers from universities, government, private sector, and other non-government organizations pivoted to provide focused attention to the highest priority requirements. The ability to harness this vast research, development, and acquisition enterprise was and continues to be of upmost importance. The unprecedented research, development, and manufacturing surge helped protect the homeland and contribute to global health security to mitigate as best we could SARS-COV-2's devasting consequences.

We must learn from the COVID-19 response and apply lessons learned to understand how we can take urgent action on the highest priorities *before* the next inevitable biological crisis. This will require focused attention that optimizes available resources during the preparedness phase. An effective and agile national enterprise approach with an effective centralized leadership structure, vision, and goals that transcends administrations is essential to overcome a fragmented federal interagency system. Without an effective leadership structure that bridges the seams in the federal bureaucracy, even the best of leaders at the national, state, and local levels will not be able to drive effective coordination, collaboration, communication, and innovation across the preparedness and response continuum.

Unfortunately, the inability to harness the fragmented structure of the federal interagency has long been recognized as a major biodefense, health security, and public health preparedness and response gap.

The 2018 National Strategy for Biodefense was the latest policy iteration that intended to provide the leadership and coordination structure to overcome this gap. Unfortunately, COVID-19 revealed the nation still lacks an effective interagency structure, other than what was put in place for Operation Warp Speed.

In fairness, SARS-COV-2 emerged before the 2018 National Biodefense Strategy could be reasonably implemented. However, the strategy assigned a single agency, HHS, to lead day-to-day actions to prepare for pandemics and biological crises. Experience should have warned the Administration and Congress that a single department/agency without a centralized dedicated biodefense leadership structure in the National Security Council (NSC) would not allow even the most experienced health security leaders to effectively galvanize focused preparedness and response actions across the fragmented interagency.

Operation Warp Speed (OWS) was an exceptional bright spot in a sea of many COVID-19 response failures. Leadership and an effective leadership structure between HHS and DOD were success enablers. The HHS and DOD Secretaries took charge, established a strict chain of command, empowered their subordinates, and put in place procedures that would protect the integrity of OWS so they could do their job. Congress also provided the necessary appropriations.

In addition to OWS lessons learned, I believe there are two other best-practice examples that demonstrated an effective interagency coordination process that largely managed the seams between the fragmented federal bureaucracy, at least temporarily.

The first was a medical countermeasure steering subcommittee under the joint NSC / Office of Science and Technology (OSTP), National Science and Technology Council for Weapons of Mass Destruction that was established in response to the Anthrax letter attacks. This steering committee was established as DHS was being created pursuant to the Homeland Security Act of 2002. This interagency coordinating structure was co-chaired by the NSC and OSTP. The co-chairs established sub-groups that formulated requirements, provided threat and risk

assessments, vaccine acquisition plans, and mass prophylaxis strategies. Sub-groups were jointly led by DOD, HHS, and DHS so there was interagency ownership and accountability. This policy coordination structure preceded passage of the Project BioShield Act, allowing immediate vaccine procurement actions to ensue after appropriations were provided by Congress.

Although this interagency coordination structure was successful during its tenure, a major shortcoming was the failure to share appropriate classified information with state and local authorities and other relevant non-government organizations that would have aided their preparedness actions. I am aware that appropriate sharing of information regarding bioterrorism threat intelligence with state and local authorities continues to be a challenge today.

The National Security Science and Technology Medical Countermeasures steering committee was replaced by the Public Health Emergency Medical Countermeasures Emergency Enterprise (PHEMCE). Over time, and after the urgency of the terrorist attacks of September 11, 2001, faded, PHEMCE became overwhelmed with its own bureaucratic weight. Many believe the PHEMCE lost an ability to be an agile decision-making body even though it remains an effective information sharing and longer-term deliberative committee within HHS, primarily between the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Food and Drug Administration (FDA), and Assistant Secretary for Preparedness and Response (ASPR).

The second and more effective interagency best-practice was the H5N1 Pandemic Influenza National Strategy and Implementation Plan, that spanned 2005 through 2009. The strategy provided the vision while implementation plans supplied discipline and focus. Together, they largely harnessed the vast federal, state, territorial, tribal, private sector, NGO, and university preparedness and repones enterprise. Other than OWS, I believe the H5N1 strategy and implementation plan overcame the inherent fragmented interagency and national biodefense structure better than any effort before that time, and since then. I will provide a brief synopsis of the strategy.

The H5N1 Pandemic Influenza National Strategy and Implementation Plan were initiated in 2005 and 2006, respectively (Bush, 2005) (Bush, 2006). The National Strategy guided preparedness and response to an influenza pandemic, with the intent of (1) slowing the spread of a pandemic to the US to provide time to take preparedness actions, like surge vaccine manufacturing; (2) limiting the domestic spread of a novel influenza viral strain once it arrived, and mitigating disease, suffering and death; and (3) sustaining infrastructure and mitigating economic and societal impact. The Administration requested and Congress approved ~$6 billion in emergency supplemental appropriations for pandemic preparedness in 2006, the first time an appropriation was made for preparation ahead of a pandemic.

A key pillar of both documents was pandemic vaccine advanced development, surge manufacturing, stockpiling, and distribution planning. The goal was to establish domestic production capacity and countermeasure stockpiles to ensure: 1) Sufficient H5N1 Influenza

vaccines for all front-line personnel and at-risk populations, including military personnel; 2) Sufficient manufacturing surge capacity to vaccinate the entire US population within six months of the emergence of a virus with pandemic potential; and 3) Advancement in regulatory science and removal of other legal barriers to the expansion of our domestic vaccine production capacity.

To achieve surge manufacturing capacity goals for pandemic readiness, the influenza vaccine industry would need to move away from their decades-old approach, culturing influenza viruses in large-scale egg production facilities, toward modern cell-based technology. Unfortunately, this proved more technically and financially difficult than anticipated. Today, nearly fifteen years later, most FDA-approved influenza vaccines still use egg-based manufacturing technology. Pandemic vaccine readiness funding only resulted in two FDA approval cell-based new influenza vaccines. One of the new influenza vaccines used recombinant sub-unit protein technology.

But preparedness efforts during that era pushed the biotechnology and vaccine industry, as well as the FDA toward vaccine technology platforms, innovative manufacturing approaches, and advances in regulatory science.

The key ingredient for success was centralized leadership, a clear vision and strategy, and a detailed implementation plan. The plan drove progress with metrics toward positive outcomes. There were over 300 action items with identified lead and supporting department/agencies, private sector, and non-government partnerships. Public – public and public – private partnerships ranged from public health, medical countermeasures (vaccines, antiviral therapeutics, and diagnostics), emergency management, critical infrastructure, transportation, agriculture, universities, schools, and many others. Accountability was built into the plan. Departments were held accountable for progress by cabinet secretaries, the President's Advisor for Homeland Security, the Vice President, POTUS, and Congress.

Frankly, some departments felt the detailed implementation plan with accountability for meeting milestones was White House micromanagement and superseded department/agency authorities, and maybe it did at times. But the guiding vision with focused implementation action items enabled an otherwise fragmented national enterprise from the federal, state, local and tribal government levels, along with our private sector and academic partners to make progress that otherwise would not have been feasible.

Progress achieved under this strategy and implementation plan also served us well in the response to the 2009 Influenza Pandemic, where BARDA was able to get every major influenza vaccine maker under a surge manufacturing contract and producing vaccines in a matter of weeks.

Lesson learned were applied to OWS, where joint HHS and DOD leadership were able to far exceed expectations and deliver COVID-19 vaccinations to the public in only eleven months after the SARS-COV-2 genomic sequence finally became publicly available. In addition to an

effective leadership and program management structure, OWS established effective and trusted public – private partnerships where government and industry project managers quickly elevated problems so government and industry leadership could quickly find solutions.

Based on these lessons learned, I believe that establishing an industry stakeholder advisory board could be beneficial to facilitate interagency coordination with the private sector on topics such as strategic portfolio management that leverages novel platform technologies for advanced development and innovative manufacturing capacities in industry and some universities, as well as innovation needed for mass prophylaxis. The engagement of this advisory board could help our response agencies do what they must do – move at the speed of science to prepare and respond to emergencies of all types.

COVID-19 response lessons learned are starting to move forward in Congress even before comprehensive after actions reviews have started. The PREVENT Pandemic working draft bill was released by the Senate Health, Education, Labor, and Pensions (HELP) Committee on February 25, 2022. Although this bill is the purview of the Senate HELP Committee, many of the draft bill's provisions have significant homeland security implications that may require coordinating legislation. In my opinion, the draft bill is a good start for discussion, but it does not create a vision for a more comprehensive approach to protecting the health and security of the nation against catastrophic biological threats. Preparedness for biological threats requires "whole of government" and "whole of nation" solutions that go beyond public health and individual Congressional committee jurisdictions.

I now want to turn my attention to some issues organic within DHS. These include DHS' current operating organization that supports biodefense, such as the Countering Weapons of Mass Destruction Office (CWMD), Office of the Chief Medical Officer (CMO), DHS' biosurveillance capabilities, and DHS Science and Technology Directorate.

I will first provide my perspectives on the Science and Technology Directorate. Despite the hard work by many and the progress since the Directorate's creation pursuant to the Homeland Security Act in 2002, I believe the Science and Technology Directorate has ceded responsibility as a lead technology coordinator for the homeland security enterprise. I believe an interagency lead role for the homeland security technology enterprise is required as originally envisioned when DHS was established - particularly for biodefense. Strong leadership for the interagency biodefense enterprise is needed now more than ever before. I urge DHS to consider evaluating the current structure of the CWMD and CMO in the context of former Secretary Michael Chertoff's Second Stage Review (2SR) and the lessons learned from OWS. However, this will require addressing the broader federal interagency fragmentation and the need for centralized and focused biodefense leadership from the National Security Council for this to be an effective change.

To provide context, I joined DHS in 2004. There was a true sense of urgency after the terrorist's attacks on September 11, 2001, the anthrax letter attacks, enactment of Project BioShield, and issuance of Homeland Presidential Directives 9 and 10. The Science and Technology Directorate

placed high priority on defense against weapons of mass destruction – including biological threats – and assumed an interagency leadership role for the homeland security enterprise. Biodefense threat, risk, and net assessments were established with the intent to drive interagency requirements and provide leadership for biodefense programs across the interagency. The National Security Council and Office of Science and Technology Policy, discussed previously, also provided effective White House level leadership that relied on DHS risk and net assessments. Initial attempts by DHS S&T to lead, coordinate, and fund, where appropriate, the broader homeland security research enterprise were initially successful. However, over time, other agencies were not receptive to being "coordinated" by DHS. That is likely why the National Biosurveillance Integration Center (NBIC) struggled to reach its potential as originally envisioned.

Today, I see a Science and Technology Directorate that is more concerned with staying in their "lane" and serving only the DHS components as more important than playing a leadership role for the interagency. I also see a broader interagency that does not place value on the DHS threat and risk assessments. From what I can discern, DHS S&T seems to have abandoned their practice of conducting interagency biodefense net assessments.

In defense of the Directorate, competing and "siloed" interagency biodefense interests are now commonplace across the federal interagency, leading to a *relative* lack of interagency coordination and inefficient use of available resources despite growing biological threats (Commission, 2015).

From my experience, I cannot overstate the importance of establishing an effective leadership and coordination structure to build bridges between the fragmented federal silos. Without this, we will continue to make preparedness progress, but incrementally at best. We will not be able to drive urgent action during the inter-epidemic period when urgent action is needed the most.

When I last came before Congress, I voiced my concerns that DHS was not giving biological threats priority consideration. I was particularly concerned that DHS may eliminate funding for research and development for animal agriculture biodefense, and that the National Biodefense and Analysis Countermeasures Center (NBACC) may be closed (Parker, 2017).

I want to take this opportunity to thank DHS and Congress for their continued support of NBACC. The concept and requirement for this unique high containment laboratory were established in 2004 as DHS' first national laboratory. The laboratory incorporated special design considerations to assure safe, secure, and responsible research with dangerous pathogens. Construction began in 2006 and was turned over to DHS to start operations in 2008. The mission of the lab is to provide the scientific basis for the characterization of biological threats and bioforensic analysis to support attribution to interdict planned malevolent biothreats or actual deliberate use. NBACC has played a key role supporting FBI law enforcement cases, including suspected bioterror criminal investigations, and resolving America's most difficult biodefense challenges. NBACC is also working with the private sector to develop defense against malevolent use of synthetic biology. More recently, the laboratory and scientific

expertise provided detailed and timely data on environmental characteristics of SARS-COV-2 that informed public health guidance.

Staying with a high containment laboratory theme, DHS, in coordination with the USDA embarked on an aggressive construction campaign to move the Plum Island Animal Disease Research Center from New York to the National Bio and Agro-Defense Facility (NBAF) on the campus of Kansas State University. Construction is now largely completed. NBAF is undergoing certification and will be operated by USDA.

DHS faithfully delivered on its promises to provide a state-of-the-art high containment BSL-3 agriculture and maximum containment BSL-4 laboratory to enable critical animal health, one health, and biodefense research for livestock, as well as operational diagnostic services for transboundary infectious diseases. I would like to take this time to thank DHS and Congress for funding both the design and construction of this facility. During the period since 2004, DHS also provided critical research and development funding for defense against agriculture bioterrorism. That funding filled critical gaps identified by USDA and other key homeland security stakeholders that otherwise would not have been funded by USDA.

USDA is also commended for increasing resources needed to assume operational ownership for NBAF. USDA is building and seeking appropriations to build a strong animal health research and diagnostics portfolio for livestock and food biosecurity. Challenges remain to ramp-up laboratory operations – especially recruiting and retaining scientists experienced working in maximum biocontainment laboratories with a focus on biodefense for animal agriculture.

NBAF is an essential component of the homeland security enterprise. DHS must remain engaged to help guide research and diagnostic requirements in support of USDA.

I have one final and important perspective to share regarding the formative years of DHS. The Science and Technology Directorate placed a priority in engaging university scientific expertise to leverage their innovative culture to solve difficult homeland security problems. That support continues today, through extramural research contracts, but more importantly through University Centers of Excellence. Some of the early centers brought focus to food security, one health zoonotic infectious diseases, and defense against transboundary infectious diseases impacting livestock and crops. Those early, successful agriculture biodefense and food security centers graduated to “emeritus” status after more than a decade of service. Unfortunately, that means the critical mass of scientific expertise from those centers had to move on to non-homeland security pursuits due to insufficient, or lack of funding for university-based agriculture biosecurity research from USDA.

Nonetheless, DHS still values University Centers of Excellence with focus areas evolving along with new homeland security priorities and challenges. For example, my university, Texas A&M University, hosts the DHS Cross Border Threat Screening and Supply Chain Defense Center of Excellence (CBTS). The CBTS center coordinates effectively with DHS and the other university centers to target priority homeland security challenges. The CBTS center also coordinates

closely with the HHS Office of Global Affairs' health attaché stationed in Mexico City supporting cross border health issues and supply chains.

In addition to the Science and Technology Directorate, CWMD and CMO have specific biodefense roles and responsibilities for DHS.

Establishment of the CMO evolved, at least in part, from Secretary Chertoff's Second Stage Review. Oversight and coordination of DHS's biodefense components were priorities for the CMO, as was recommended by the biodefense sub-task force of the Secretary's Second Stage review, which I chaired. Timing is everything as Hurricane Katrina hit with devasting consequences just as the CMO office was standing up. Early biological crises and natural disasters demonstrated the need to have an experienced physician close to the Secretary because acute and long-term impacts of natural disasters and weapons of mass destruction effect the health of the nation and the homeland security enterprise. The CMO involvement across the countering weapons of mass destruction and national disaster enterprise, and proximity within the Office of the Secretary was viewed as essential at the time.

The CWMD was established and fully authorized as an office within DHS in 2018, and the CMO missions were incorporated into the CMWD office. The CWMD mission is to lead DHS's efforts and coordinates with domestic and international partners to safeguard the U.S. against chemical, biological, radiological, and nuclear (CBRN) and health security threats. The goals of the CWMD are to (1) anticipate, identify, and assess current and emerging WMD threats; (2) strengthen detection and disruption of CBRN threats to the homeland; and (3) synchronize homeland counter-WMD and health security planning and execution.

BioWatch has been the DHS flagship biological detection system, now managed by the CWMD office. The system served a vital role when it was first deployed in response to urgent requirements. In 2003, the nation was on high alert for bioterror attacks on the homeland as the war on terror progressed after the tragic events of September 11, 2001. Unfortunately, surveillance systems to detect a deliberate aerosol release of deadly pathogens or toxins with potential for mass casualties were non-existent. The initial biological detection system deployed was eloquent in its simplicity. BioWatch leveraged existing Environmental Protection Administration air surveillance collection sites in American cities and the CDC Laboratory Response Network. BioWatch largely uses the same system construct today.

Over the years, the BioWatch Program came under justified criticism that I will not attempt to summarize in my testimony. However, I will describe a non-technical accomplishment that is rarely highlighted.

National, state, and local public health and emergency management authorities soon had to develop communication and coordination protocols as the BioWatch System began providing alerts of potentially dangerous pathogens in the environment. But there were no other indicators that a bioterror attack had occurred. While these alerts constituted a "false positive" for a bioterror attack, in reality, the system was accurately detecting low-level presence of non-

viable nucleic acid evidence indicating wildlife infections. BioWatch was teaching us about environmental microbiology in wildlife that was not anticipated when the system was deployed. Nonetheless, local authorities had to learn how to differentiate between non-threatening signals and true alerts indicating the potential of a wide-spread aerosol release of dangerous pathogens.

In coordination with public health, emergency management, and law enforcement at the national, state, and local levels, DHS established the concept of a BioWatch Actionable Result (BAR). A BAR is defined as a determination that occurs when analysis of an air filter from a BioWatch sampler indicates the confirmed presence of a target organism's nucleic acid signature. BAR protocols enabled local, state, and national authorities to become proficient in how to effectively process low confidence but potentially very high consequence information. This required effective coordination, collaboration, and communication across multiple jurisdictions that is lacking in many other areas of the public health and emergency response enterprise.

Almost all biological crisis events, whether intentional, natural, or accidental are characterized by an initial period of low confidence, but potentially very high consequence, information. The longer authorities wait to act on low confidence information that may turn out to be high consequence, more lives could be lost unnecessarily. The early days and weeks of COVID-19 were characterized by low confidence information, but that was due to lack of information sharing from ground zero of the outbreak in Wuhan, China.

Over the years, the BioWatch system made incremental, but not transformative technical improvements. Unfortunately, technology needed for operational deployment of environmental real-time detection of 21st century biological threats is lacking. As BioWatch currently stands, the program falls short of its potential. I believe we need to re-envision environmental detection and biosurveillance as we take stock of COVID-19 lessons learned and requirements needed to provide near-real time biosurveillance, detection, and data analytics.

I believe it would be in the best interest of our nation's biosecurity and biosurveillance efforts to ultimately transition the BioWatch program once there are better technology solutions. A future biological detection and biosurveillance systems should not only focus on bioterrorism attacks, but also high consequence emerging infectious diseases that could impact humans, animals, and plants.

DHS' security focus and mission locations across the vast homeland security enterprise should be a component of future national biosurveillance and detection strategies. For example, existing missions and capabilities within the infrastructure of the Transportation Security Administration (TSA) and Customs and Border Protection (CBP), in coordination with USDA's Animal and Plant Health Inspection Service (APHIS), should be incorporated into future biosurveillance strategies and technology research and development investments.

Near real time biosurveillance, data processing, and information sharing solutions are urgently needed across the homeland security enterprise, and globally. DHS has an important role to contribute to federal interagency and national efforts.

Microbial forensics is the last area of biological detection that requires highlighting. DHS, in coordination with the FBI, operates a unique capability for microbial forensics within the NBACC laboratory, previously discussed. Core microbial forensic laboratory capabilities to enable attribution – an area that DHS and FBI have the primary role – must be sustained. Their science and approach must also evolve to keep pace with the rapid pace of advances in the life sciences. NBACC is the only laboratory in the United States, and the world, that serves as a core microbial forensics research and operations center.

As stated earlier in my testimony, I am more concerned than ever about the risk of biological threats – whether from outbreaks, accidents, or attacks. This includes a need to underpin no-regret attribution decisions with a sound scientific foundation through microbial forensics. I cannot overstate the importance of having dedicated, core laboratory capabilities and scientists that are focused on microbial forensics to support attribution. It is not a part-time job, or other-duties-as-assigned function.

Microbial forensics is still, and will always be an evolving science – perhaps not well understood outside of the relatively few professionals in their field. But, prosecutors and national command authorities who will one day be thrust into the position of making no-regret attribution decisions will quickly grasp the importance of microbial forensics as essential to underpin their pending difficult decisions.

Finally, scientific and policy discussions have debated the appropriate level of investment and attention needed for biodefense and pandemic preparedness to defend against potentially catastrophic biological threats, regardless of etiology for over two decades. Some may have thought it was a hypothetical debate.

The COVID-19 pandemic exposed the stark reality that a novel respiratory virus can emerge anywhere and rapidly spread around the world in weeks with devasting consequences. It is no longer hypothetical. We must be better prepared for the next inevitable biological crisis or pandemic.

Recommendations:

1. The Committee should take necessary actions to assure a national biodefense and pandemic preparedness organizational structure with dedicated, centralized leadership is established at a senior executive White House level, and resourced. The organizational leadership structure must clarify interagency coordination processes with clearly identified lead and supporting agency roles. White House leadership and federal departments must hold lead and supporting agencies accountable toward achieving progress for preparedness goals. This will require coordination beyond traditional jurisdictional boundaries, as well as Department/Agency authorities and appropriations.

2. The Administration and Congress should take stock of Operation Warp Speed lessons learned and determine how those management best-practices can translate to a sustained biodefense and pandemic medical countermeasures enterprise as a component of the broader national enterprise in the first recommendation. Key ingredients were joint DOD and HHS leadership and ownership accountability.
3. Both recommendations 1 and 2 would benefit by establishing a board of directors that includes an empowered outside advisory board that brings together both federal, state, and local public health and emergency management leaders, along with biotechnology and other industry leaders to help guide the government agencies and advise White House leadership.
4. The Committee should ensure that the Administration develops a comprehensive biodefense pandemic preparedness strategy that is tied to a unified and transparent budget. The strategy must have a detailed implementation plan, with clearly identified lead and supporting agency roles – and support from a strong White House leadership position and staff to elevate the importance of biodefense and pandemic preparedness for homeland security as described in the first recommendation. An effective leadership structure is essential to enable good leaders to drive interagency coordination, collaboration, communication, innovation, and optimal use of available resources. The Office of Science and Technology Policy's Apollo Project and the American Pandemic Preparedness Strategy hold promise as an aspirational vision for public health and pandemic vaccine development. However, it appears the strategy was not coordinated with the interagency. DHS, USDA, and other agency contributions and requirements were not apparent in early versions. The strategy also lacks a One Health component, which is essential because potential pandemic pathogens are zoonotic. Finally, without Congressional appropriations, progress toward achieving improved preparedness will be limited.

In closing, I want to reiterate essential contributions of DHS components to the national biodefense and pandemic preparedness enterprise, whether support comes from the Office of the Secretary, CMO, CWMD, the Science and Technology Directorate, and other components. DHS brings a unique health security perspective lacking from most of the federal interagency biodefense enterprise. Finally, I cannot overstate the importance of establishing an effective coordination structure to build bridges between the fragmented federal silos with a strong leadership structure. But we must have a national structure that includes tight linkages from the federal level to state, local, tribal, private sector, university, and NGO partners. Without this, we will continue to make preparedness progress, but incrementally at best.

Thank you for the opportunity to appear before this hearing of the United States Senate Committee on Homeland Security and Governmental Affairs today.

Bibliography

Bush, G. W. (2005, November). *The National Strategy for Pandemic Influenza*. Retrieved from The Centers for Disease Control and Prevention (archived from Homeland Security Council): https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-strategy-2005.pdf

Bush, G. W. (2006, May 2006). *The National Strategy for Pandemic Infuenza: Implementation Plan*. Retrieved from The Centers for Disease Control and Prevention (archived from Homeland Security Council): https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-implementation.pdf

Chan, P. (2002, May). *Outbreak of avian influenza A(H5N1) virus infection in Hong Kong in 1997*. Retrieved from National Library of Medicine: https://pubmed.ncbi.nlm.nih.gov/11938498/

Commission. (2015, October). *A National Blueprint for Biodefense: Leaderhship and Major Reform Needed to Optimize Efforts*. Retrieved from Bipartisan Commission on Biodefense: https://biodefensecommission.org/reports/

Commission. (2021, March). *Biodefense in crisis: Immediate action needed to reduce vulnerabilities*. Retrieved from Bipartisan Commission on Biodefense: https://biodefensecommission.org/reports/biodefense-in-crisis-immediate-action-needed-to-address-national-vulnerabilities/

GPMB. (2019, September 18). *Annual report on global preparedness*. Retrieved from Global Preparedness Monitoring Board: https://www.gpmb.org/annual-reports/overview/item/2019-a-world-at-risk

Parker, G. (2016, February 12). *Hearing on "Outbreaks, attacks, and accidents: Combating Biological Threats", Subcommittee on Oversight and Investigations*. Retrieved from House Engergy & Commerce, United States House of Representatives: https://energycommerce.house.gov/committee-activity/hearings/hearing-on-outbreaks-attacks-and-accidents-combatting-biological-threats

Parker, G. (2017, November 7). *How effective is the Science and Technology Directorate? Stakeholder perspectives*. Retrieved from Emergency Preparedness, Response, and Communications Subcommittee, United States House of Representatives Homeland Security Committee: https://docs.house.gov/meetings/HM/HM12/20171107/106557/HHRG-115-HM12-Wstate-ParkerG-20171107.pdf