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Statement for the Record

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Introduction.

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 of public health and biodefense professionals at Texas A&M University.

I will offer insights from my role as a public servant that spanned 26 years of active-duty military service and another ten years in the career senior executive service. During my military career, I had the opportunity to serve in leadership roles, primarily in military medical research & development at the United States Army Medical Research and Materiel Command. I am a former Deputy Commander and Commander of the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). That was followed by senior 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 a former, and the first, Principal Deputy Assistant Security for Preparedness and Response where I led many of the initial activities that transformed the former Office of Public Health Emergency Preparedness into the Office of the Assistant Secretary for Preparedness and Response (ASPR) after enactment of the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006.

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

I do not have to tell you how difficult the pandemic and all-hazards mission is today. You are aware of the challenges, complex decisions, and trade-offs that must be made. There will always be new authorizations needed, appropriations requests, and budget allocations competing for the many health security demands and shifting priorities within the Department of Health and Human Services and across the vast federal interagency crisis response enterprise. One of the biggest uncertainties through the years has been, “Who is in charge,” or

more appropriately, “What is the right leadership structure” that will enable effective coordination and maximal utilization of available resources across the vast federal interagency.

The Administration for Strategic Preparedness and Response (ASPR) has been elevated to an Operating Division within the Department of Health and Human Services. This elevation is long overdue. ASPR has significant operational responsibility that includes leading and managing the advanced medical countermeasures enterprise, Strategic National Stockpile, National Disaster Medical System, the Hospital Preparedness Program, health care system resiliency for disasters, and other operational responsibilities. ASPR has been, and will continue to be, a focal point for pandemic and all-hazards preparedness within the department for medical and public health preparedness and response, as well as oversight of a few unique biosecurity science policies. ASPR should also continue to have pivotal role as the Secretary’s senior advisor in the federal interagency and with the National Security Council.

Threat Landscape**.** The ASPR’s mission and leadership roles are extremely complex. They must be prepared and have the right tools to confront an ever-expanding list of potentially catastrophic threats, whether natural, accidental, or deliberate. The threats we face range from terrorism, chemical, biological, radiological, nuclear, cyber, natural disasters (i.e., earthquakes, hurricanes, critical infrastructure failure), climate change, pandemics, and others.

We have also been thrust into a new dangerous era of global power rivalry where economic conflict, war, and even the threat of adversarial nation state use of nuclear, chemical, and biological weapons cannot be discounted (Haines, 2023).

We are in an era of unprecedented danger.

In January 2023, the United Nations Secretary General, Antonio Guterres, announced that the world is only 90 seconds away from midnight (apocalypse) on the Doomsday Clock, the closest to global catastrophe the clock has ever been, even during the height of the Cold War (Mecklin, 2023).

The Doomsday Clock was created by The Bulletin of the Atomic Scientist in 1947 after World War II and the unleashing of nuclear weapons. The Clock has become a universally recognized indicator of the world's vulnerability to global catastrophe caused by human-caused threats.

Although the war in Ukraine had a major influence on the clocks forward movement, biological threats, whether natural, accidental, or deliberate in origin were a significant contributor. Specifically, climate change, emerging zoonotic infectious diseases, and dual use emerging technology research in the biological sciences without adequate biosafety/biosecurity controls worldwide are pushing us toward the cliff of disaster (Bulletin, 2023).

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 devastating consequences.

Pandemic preparedness professionals sounded the alarm about the dangers we would face over the last twenty years since highly pathogenic H5N1 viruses first caused sporadic human disease and deaths from close contact to infected poultry 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, Nipah virus, Hendra virus, and others. Almost all serious outbreaks have been zoonotic viruses, transmitting 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.

Today, I am more concerned than ever about the risks from all biological threats, whether natural, intentional, or accidental in origin – that could affect humans, animals, and plants, as well as our economy and social fabric.

You may call my comment an alarmist statement because the pandemic has been declared over.

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 pathogens to achieve their goals. Finally, the probability of an accidental laboratory release is increasing due to several factors (Haines, 2023).

It is interesting to note that in many ways, the experience of COVID-19 has increased biological risks by 1) Motivating new actors who witnessed many countries' vulnerability to biological threats; 2) Stimulating the expansion of new high containment laboratories worldwide; and 3) Enhancing new investments advancing biotechnologies that could have dual use potential.

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

This is not a hypothetical debate.

That is why careful thought is needed as Congress considers this once-every-five-years reauthorization of the Pandemic and All-Hazards Preparedness Act.

We must get this right, even if it takes more time than anticipated. The reauthorization process should not be rushed.

Evolving Hard Lessons Learned. With that dire warning and despite many acknowledged failures that accrued during the COVID-19 response, it is also important to note that we were more prepared before COVID-19 than critics will acknowledge. Lessons learned from successes and failures have accrued over the last twenty years that should be considered during your deliberations to reauthorize the Pandemic and All-Hazards Preparedness Act.

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, appropriated new funds, and reorganized government structures 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 pandemic and all-hazards preparedness and response enterprise.

We were much better prepared for the emergence of SARS-CoV-2 than we would have been without the long-term support of Congress and the work of many dedicated career professionals. This includes career professionals within the Department of Health and Human Services and across the entire the U.S. government interagency. But most importantly, it was the thousands of professionals and volunteers 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 will go down in history as a tremendous success, but it would not have been possible without prior commitment to investments in advanced medical countermeasures research, development, and manufacturing technologies, as well as regulatory science. Congressional appropriations and new authorities, including the first (PAHPA) starting in 2006 through Congress' most recent reauthorization in 2019 were essential ingredients to success.

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

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 or all-hazards crisis. This will require focused attention that optimizes available resources during the preparedness phase. A flexible 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 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. When a similar failure in the context of national intelligence impeded our efforts to prevent the 9/11 attacks, Congress acted swiftly to create a new National Director of Intelligence to fully integrate and align the federal interagency strategies, budgets, and priorities. We need a similar approach now to truly ensure national preparedness against pandemics and other potential catastrophes.

It is also unfortunate that Congress and the Administration have not authorized a COVID-19 bi-partisan commission to take stock of lessons learned, like the 9/11 Commission, to enable incorporation of recommendations into this year's reauthorization of PAHPA.

Regardless, Operation Warp Speed provides lessons learned and is an exceptional bright spot in a sea of many COVID-19 response failures. This PAHPA legislation is a fitting home to consolidate and explicitly embed these lessons into our institutions.

Leadership and an effective leadership structure between the Departments of Health and Human Services and Defense were success enablers. The Health and Defense Secretaries took charge, established a strict chain of command, empowered their subordinates, and put in place procedures that would protect the integrity of Operation Warp Speed so they could do their job. Congress also provided the necessary appropriations.

In addition to Operation Warp Speed lessons learned, I participated in two other best-practice examples during my government career that demonstrated an effective interagency coordination process is possible. I will describe these two examples to highlight attributes that were needed to successfully manage the seams between the fragmented federal bureaucracy, at least temporarily.

The first was a medical countermeasure steering subcommittee under the joint National Security Council (NSC) / Office of Science and Technology Policy (OSTP), National Science and Technology Council for Weapons of Mass Destruction that was established in response to the Anthrax letter attacks. 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 the Departments of Defense, Health and Human Services, and Homeland Security that garnered interagency ownership and accountability through a coalition of the willing and able. This policy coordination structure preceded passage of the Project BioShield Act allowing

vaccine procurement actions to proceed immediately after appropriations were provided by Congress.

The National Security Science and Technology Medical Countermeasures steering committee was replaced by the Public Health Emergency Medical Countermeasures 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. Even before I departed ASPR in 2010, 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 Administration for Strategic Preparedness and Response (ASPR).

Providing additional legislative authority for PHEMCE should be considered in the Pandemic and All-Hazards Preparedness Act reauthorization. It is an established coordinating structure and should be maintained and strengthened.

The second and most effective interagency best-practice was the H5N1 Pandemic Influenza National Strategy and Implementation Plan, that spanned 2005 through 2009. This strategy provided the vision and priorities linked to an emergency supplemental appropriation from Congress while implementation plans supplied discipline and focus. Together, they harnessed the vast federal, state, territorial, tribal, private sector, NGO, and university preparedness and

response enterprise. Other than Operation Warp Speed, I believe the H5N1 strategy and implementation plan overcame the inherent fragmented interagency and national biodefense structure better than any effort before or since that time. 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 approved cell-based new influenza vaccines.

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

The key ingredient for success was an effective leadership coordination structure, a sharp vision and strategy, comprehensive implementation plan, and dedicated resources with appropriations from Congress.

The implementation plan and strong leadership drove progress with metrics toward positive outcomes. There were over 300 action items with lead and supporting roles identified for department/agencies, private sector, and other non-government organizations. Public – public

and public – private partnerships ranged from public health, medical countermeasures (vaccines, antiviral therapeutics, and diagnostics), hospitals and health care systems, 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, the President, and Congress.

Frankly, some departments felt the detailed implementation plan with accountability for meeting milestones was White House micromanagement that superseded department/agency authorities, and it did at times. In the future, leadership coordination from the White House must also be accomplished in a manner that optimizes use of available resources without impeding effective implementation and management of programs at department/agency levels.

But the guiding vision with focused implementation action items enabled an otherwise fragmented national preparedness 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 (Biomedical Advanced Research and

Development Authority) was able to get every major influenza vaccine maker under a surge manufacturing contract and producing vaccines in a matter of weeks.

These and other lesson learned were applied to Operation Warp Speed, where joint Health and Defense leaders 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, Operation Warp Speed 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.

University research institutions are also well positioned to engage in public-private partnerships to explore and develop advanced manufacturing and new regulatory science capabilities, as well as supply chain resilience. By collaborating instead of competing with one another, these institutions could partner with industry, BARDA, and other funding organizations to move

quickly while providing hands-on, high-quality workforce training – domestically and internationally.

A clear failure during the COVID-19 pandemic response was dependency on critical medical and health care commodities from foreign supply chains. Building medical supply chain resiliency will rely on data and situational awareness across supply chain raw materials to distribution, as well as on-shoring and near-shoring manufacturing capabilities and capacities.

When facing a public health crisis, we cannot afford to learn on the job and we must have control towers to enable complete situational awareness to not only respond, but to anticipate urgent requirements to support SLTT (State, Local, Tribal, and Territorial) authorities and private sector stakeholders in the health care and medical countermeasure sectors.

Together, we must move at the speed of science to prepare and respond to emergencies of all types.

Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).

Fortunately, COVID-19 response lessons learned are starting to be enacted in Congressional legislation, such as the PREVENT Pandemics Act. It will be important for this PAHPA reauthorization to build upon the foundation of the PREVENT Pandemics Act and address legislative policy gaps.

Importantly, the 2022 PREVENT Pandemics Act provides authority for the administration to establish a White House Office of Pandemic Preparedness and Response Policy. This is an important development. If implemented well, it could address interagency policy coordination and related issues that will transcend Administrations. However, it remains unclear how the administration plans to implement this authority and consolidate existing policies, strategies, and priorities, such as Pandemic Preparedness, Global Health Security, and Biodefense. Until the office is fully stood up and operational, it will remain uncertain how much practical authority the new office will have, particularly coordinating resources during the annual budget process with other departments and agencies. This Congress may need to empower and steer this new office towards establishing a more unified and coordinated policy and budget approach to interagency biosecurity and all-hazards preparedness in the reauthorization of the Pandemic and All-Hazards Preparedness Act.

The 2022 National Biodefense Strategy also calls for strengthening national attribution capacity for natural and unnatural infectious disease outbreaks. The strategy places leadership with the Department of Health and Human Services and the Federal Bureau of Investigation with support from the Departments of Interior, Agriculture, Energy, Homeland Security, State, The Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Intelligence Community. The range of agencies and disciplines involved will require strong interagency coordination and leadership.

The complexity of 21st century biological threats will challenge our ability to distinguish natural from unnatural sources, at least initially. Thus, the starting assumptions of any suspicious infectious disease outbreak domestically or internationally should include the possibilities of natural or unnatural origins until proven otherwise, requiring much closer coordination between public health, law enforcement, diplomatic, science agencies, and the intelligence community. But biological attribution is not highlighted as a specific priority in the PREVENT Pandemics Act.

Congressional action is warranted to provide oversight, or additional legislation, if necessary, to ensure the new White House Office of Pandemic Preparedness and Response Policy is implemented in a manner that provides effective interagency governance, coordination, and leadership for the entire interagency biodefense, global health security, and pandemic preparedness and response enterprise, domestically and internationally. This must also include oversight to ensure that the administration implements innovative programs required to establish capacities and policies for biological attribution to ensure effective governance and coordination mechanisms are put in place to optimize the investigative authorities, expertise, and laboratory capabilities of relevant agencies to determine the source of infectious disease outbreaks rapidly.

Although there are many other gaps that require attention, at least these two must be closed in the Pandemic and All-Hazards Preparedness Act scheduled to be reauthorized in 2023.

Recommendations. First, it is important to note that ASPR was established to: 1) Coordinate and lead the federal medical and public health preparedness and response to pandemic & all-hazard threats; 2) Support state, local, and tribal authorities, private sector, and other NGOs; 3) Establish effective public – private partnerships to ***develop and deliver*** health security medical countermeasures; and 4) Support hospitals and health care systems resiliency during crisis.

Those attributes have not changed. What has changed is our understanding of how to implement new policies, strategies, and operational plans to achieve the desired end state against expanding and complex 21st century threats. You must also consider how to reauthorize PAHPA in the context that ASPR has become an Operating Division with expanded responsibilities.

Although there are many other recommendations that the Committee must consider, time only allows me to focus on the following four priority recommendations for now, and then only at a strategic level.

Enhance Support for State, Local, Tribal, and Territorial (SLTT) Authorities and the private sector.

Congress must consider what ASPR needs to continue building out a federal capacity required to optimally support SLTT partners. The Committee should address what ASPR needs to integrate more effectively with SLTT authorities, the private sector, universities, and other non-

government organizations. ASPR must build resilience at state and local levels by better integration during the inter-crisis period.

This means building the capacity to embed ASPR staff within SLTT agencies and to participate in regional, state, and local preparedness exercises. This must include closer alignment with FEMA (Federal Emergency Management Agency) regional offices, state emergency management authorities, and expansion of regional disaster healthcare response system pilot sites.

Near-Real Time Situational Awareness, Supply Chain, Health Systems, and Medical Countermeasures Resiliency.

Congress must introduce measures that address gaps in situational awareness not only to enable supply chain resiliency but improve pandemic early warning, healthcare capacity, and medical countermeasures development. During the heigh of the pandemic response, ASPR over several months created a Supply Chain Control Tower to provide near real-time supply chain situational awareness. This enabled ASPR to anticipate the needs of SLTT partners, hospitals, and the health care system. It also allowed ASPR to triage resources for SLTT partners more effectively when resources were most scarce. It will be critical for PAHPA to address this Supply Chain Control Tower capacity by encouraging a “warm base,” surge-able situational awareness and supply chain resiliency capability that can be activated immediately at the outset of the next health security crisis.

Through its Industrial Base Management & Supply Chain Program Office, ASPR must partner with manufacturers and distributors to establish reliable medical stockpile at baseline, and importantly, incentivize on-shoring and near-shoring industrial base medial supply chain manufacturing capabilities, capacities, and resiliency. And just as critically, ASPR must partner with the private sector and universities on next-generation supply chain technologies to ensure the United States does not continue to play "catch up" in the future. ASPR also needs additional acquisition authorities to enable more effective and timely response to health emergencies.

Leadership.

The most important recommendation centers around leadership and effective coordination, to include institutionalizing successes and remedying failures from the COVID-19 pandemic.

When facing public health crises, national disasters, terrorist attacks, and other national emergencies, Congress and the Federal Government have historically restructured our federal crisis response departments and agencies with the objective of creating a more unified and coordinated response. I commend the previous Congress and many of the Members and staff in this room today for taking a major step toward achieving these goals for U.S biosecurity through authorization of the White House Office of Pandemic Preparedness and Response Policy. In this Congress, anything this Committee does that delivers more effective interagency cooperation will be significant. The undisputed greatest success of the COVID-19 response, Operation Warp Speed, was none other than a successful interagency partnership that

succeeded despite – not because of – the existing interagency structures for cooperation and coordination.

Our federal biosecurity and pandemic response structure lacks an integrated, central authority that can streamline, consolidate, and provide priority direction over diverse policy and budgetary initiatives, while also enabling decentralized execution of responsibilities and optimizing use of available resources. Such a structure should not only enhance communication and cooperation but also provide long-term strategic oversight and direction. I would propose, therefore, that the Committee consider how it might augment the mandate and reach of the new White House Office of Pandemic Preparedness and Response Policy. Expanding and consolidating the coordination of policy, priorities, and budget requirements for pandemic preparedness, global health security, and biodefense must be considered for PAHPA reauthorization.

There are several case studies to consider, and I would suggest the Committee consider the authorities of the Office of National Drug Control Policy. Created in 1989 to coordinate and oversee federal anti-drug initiatives from the White House, the Office of National Drug Control Policy as you know works to improve interagency coordination, federal - state coordination, and to advise the President on management and budget of policies and programs under its purview. The establishment of the White House Office of Pandemic Preparedness and Response takes an enormous step at meeting the elusive goal of a coordinated federal pandemic preparedness policy structure that can operate effectively to coordinate decentralized

operations during a national emergency. It may be instructive to examine whether the office would benefit from additional authorities at analogous offices at the White House level.

Our security landscape has evolved, and it is imperative that our institutional structures evolve to meet these new challenges head-on. The elevation and expansion of the White House Pandemic Response Office is not just a necessary step; it is a strategic move toward strengthening our national pandemic preparedness and biosecurity.

For example, a critical current gap in our preparedness structure is the lack of an integrated medical countermeasure development program between the numerous federal agencies that have funding and initiatives in this area. Each agency is pursuing its own priorities – seemingly quite narrow ones – that often do not align with their sister agencies or provide any clear roadmap for producing a comprehensive national arsenal of needed countermeasures. Not only does this create untenable gaps in our preparedness, but it makes it increasingly challenging for private or academic sector entities to efficiently identify the right government partners for particular technologies and to effectively pursue a full development program.

This interagency integration need is distinct but complementary to the role of ASPR, which must also be reinforced in this historic reauthorization of the Pandemic and All-Hazards Preparedness Act. ASPR should continue to advise the Secretary of HHS on pandemic preparedness and response policy as ASPR continues its coordination and leadership role in medical and public health preparedness and response to all-hazards. In this legislation, it will be important to remember ASPR's operational all-hazards responsibilities, which includes but is not limited to biological events. Good federal plans are prerequisites, but all responses

orchestrated by the federal government require state, local, tribal, and territorial collaboration to be effective. They are on the front line.

This should also include collaboration with the private sector and NGOs. The relationships ASPR has developed since its inception make it well-positioned to deliver on SLTT needs and on public – private partnerships for the development of new medical countermeasures or advanced personal protective equipment, as well as supply chain and health care systems resiliency during crises which I am sure my other panelists will discuss in greater detail.

ASPR has tools – BARDA, the Strategic National Stockpile, the Office of Industrial Base Management and Supply Chain, National Disaster Medical System, and the Hospital Preparedness Program – but does ASPR have sufficient authorities to lead and integrate these activities to better support others?

As the former Principal Deputy Assistant Secretary for Preparedness and Response, I am confident these components belong together under ASPR, and that they are each better served in this structure.

With these constituent parts working together under a newly elevated ASPR, now an Operating Division within the Department of Health and Human Services, you have the chance to solidify the department-wide leadership role of ASPR, along with its own operational responsibilities, that will be key to a future pandemic response using what we have learned about implementation of federal strategies.

Biosafety and Biosecurity.

ASPR has an oversight role for unique biosecurity science policies, such as DNA sequencing guidelines and Dual Use Research of Concern policies. For example, ASPR chairs the Department of Health and Human Services Potential Pandemic Pathogen Care and Oversight Committee (P3CO) that provides additional pre-funding review of research proposals identified by the National Institutes of Health that may generate enhanced potential pandemic pathogens (ePPP).

As you put together PAHPA, I would like to direct the Committee's attention to the 12 findings and recommendations in the National Science Advisory Board for Biosecurity's (NSABB) 2023 report regarding dual use research of concern and enhanced potential pathogen research, which was released in March 2023. Although I am a member and chaired the Board, my comments in this testimony are my own and do not represent the Board, the National Institutes of Health, nor any other organization.

The report's recommendations reflect input from stakeholders across the life sciences research community, scientific publishing community, government funding agencies, national security experts, and some comments from the public. I feel strongly that these recommendations should be implemented by the federal government with a sense of urgency, and that implementation must be properly resourced.

I am not alone in recommending urgent action. The American Society for Microbiology (ASM) commented, “We are pleased to see that ASM’s recommendations were incorporated into the NSABB report, and we urge swift implementation of the recommended changes by the federal agencies engaged in this work (ASM, 2023).

Congress can play a role in supporting the implementation of these thoughtful dual use and enhanced potential pandemic pathogen research recommendations and monitoring the implementation progress through your oversight role.

I want to emphasize my confidence that the United States can adopt these new biosafety and biosecurity policies, which again are specifically about DURC (Dual Use Research of Concern) and ePPP research, without impeding life sciences innovation or the speed with which we can develop new pandemic preparedness tools and countermeasures. Effectively implementing the recommendations as intended will require proper resourcing, both financial and technical.

It is essential that Members of Congress and our federal agencies, especially those in life science that lack security awareness and a security culture, obtain an accurate picture of the threat landscape (Haines, 2023).

We also face a growing risk from unintentional laboratory accidents with pandemic potential due to the global expansion of high containment laboratories and ready access to advanced dual use technologies and expertise worldwide. As the former commander of a high

containment laboratory, I cannot emphasize enough the need to prioritize and properly fund laboratory biosafety and biosecurity. That means funding biosafety and supporting ongoing operations and maintenance, as well as resources to develop, train, and hire skilled biosafety professionals and high containment building engineers. There are many universities and research institutions who have worked to build exemplary biosafety practices. However, instead of having to compete against expanding overhead requirements and indirect costs at intuitional levels, biosafety should be funded directly. Congress can support the sharing of best practices and enhancement of institutional responsibility by treating biosafety as a distinct and valuable operational component that each institution must be able to resource and staff by requiring line-item budget support from federal and other funding agencies.

Federal guidelines and regulations governing research with potentially dangerous pathogens and select agents should encourage maximal transparency with the public about laboratory operations, and high containment laboratory directors should work closely with their local communities to maintain public trust about the importance of their research and their commitment to laboratory biosafety and biosecurity.

It is our shared responsibility to reduce the risk of deadly accidents, especially when the United States is viewed around the world as a model for the biosafety and biosecurity practices. This is particularly important after the pandemic because we know there are many new high containment laboratories planned or under construction worldwide.

Congress must also provide appropriate oversight to ensure the Administration, and future Administrations, take a more active diplomatic approach to promote and galvanize international initiatives needed to harmonize biosafety and biosecurity controls and standards worldwide. This is long overdue.

These recommendations are especially important and essential for those institutions, both public and private, that conduct dual use research with enhanced potential pandemic pathogens, or ePPPs – domestically and internationally.

Conclusion. As the Committee works through the many issues it will shape in this reauthorization of the Pandemic All-Hazards Preparedness Act, it will be important to prepare not only for risks like SARS-CoV-2, but also for new emerging infectious diseases with properties that could obviate preparedness efforts which are based only on our latest response to this latest pandemic virus.

As the Office of Director of National Intelligence 2023 Annual Threat Assessment plainly states, "Rapid advances in dual-use technology, including bioinformatics, synthetic biology, nanotechnology, and genomic editing, could enable development of novel biological weapons that complicate detection, attribution, and treatment" (Haines, 2023).

Many policy recommendations will be applicable across multiple pathogens and threats, but some will be inadequate if we do not consider the other families of potential pandemic

pathogens and other potentially catastrophic all-hazards threats. The rate of new zoonotic disease emergence has only increased, and perhaps more worryingly the tools of biotechnology and pathogen engineering grow more powerful and more accessible for good and for bad every single year. We cannot base pandemic preparedness efforts, biosecurity, and oversight of dual use emerging biotechnology on the assumption that things cannot be worse than COVID-19. To do so would be to miss the lessons of history and to miss an opportunity to better prepare for the complex threats we face today.

We have entered an extremely dangerous era. There is one thing we can be assured of in the future. We will be surprised. We must avoid fighting the last war, and we must avoid complacency.

You have the historic opportunity with reauthorization of the Pandemic and All-Hazards Preparedness Act to boldly reimagine the national all-hazards preparedness enterprise. We must fill critical gaps in that scheme to better support state, local, tribal, territorial authorities, as well as the private sector, universities, and other non-government organizations. Our goal must be focused on mitigating the risk of pandemics and all-hazard threats for Americans and for the world.

Thank you for the opportunity to appear before the United States House of Representatives Energy and Commerce Committee hearing on Reauthorization of the Pandemic and All-Hazards Preparedness Act.

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