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Statement for the Record
Attribution for Natural and Unnatural Emerging Infectious Diseases of Unknown Origin

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Chairman Griffith, Ranking Member Castor, and distinguished members of the Committee, I am honored to appear before you today for this important hearing, "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events."

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 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 (USAMRIID). 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 or employers.

Background: The Wuhan Municipal Health Commission, China, reported a cluster of pneumonia cases of unknown etiology in Wuhan, Hubei Province on December 31, 2019. The new illness was subsequently described as COVID-19 caused by the SARS-CoV-2 virus. The first infections and cases of COVID -19 occurred much earlier, likely sometime in the fall of 2019.

The first viral genomic sequence that became available outside China was posted online on January 11, 2020. Since then, viral genomic sequencing capacity has rapidly expanded worldwide, allowing scientists to track the spread of emerging phylogenetic lineages and variants in near-real time. SARS-COV-2 viral isolates have been sequenced more than 14 million times. This enormous, accruing genomic data over the course of an outbreak, epidemic, or pandemic has never been available before. This has provided incredible new capabilities for genomic surveillance and future sequencing capacities needed for pandemic investigations for attribution. COVID-19 will not be our last pandemic or major infectious disease outbreak with regional or global impact.

But today, unfortunately, more than three years later, we still do not know when, where, and the pathway for how a bat virus emerged to become a respiratory pathogen capable of sustained human-to-human and atypical asymptomatic transmission. This has been subject to intense and acrimonious scientific debate. The two-prevailing hypotheses are 1) natural zoonotic emergence or 2) unnatural, accidental research-associated infections. Both are plausible. Definitive evidence conclusively substantiating either hypothesis attributing the pandemic's source remains elusive.

My testimony today will avoid entering the debate about the origin of SARS-CoV-2. However, we must learn from COVID-19 and work to identify, understand, and fix gaps in our ability to investigate and attribute a natural or unnatural emerging infectious disease outbreak wherever it occurs worldwide.

Before COVID-19, naturally emerging and reemerging infectious disease outbreaks and the rise of infectious diseases due to drug resistance were occurring with alarming increased frequency. Examples included SARS1, Ebola, MERS-CoV, Zika, pandemic potential influenza viruses, multi-drug resistant tuberculosis, and others. Globalization of travel and trade, urbanization, wildlife and food-animal close contacts, failing states, and other anthropogenic factors have created the perfect storm triggering public health, animal health, and security risks for the global community. The impact on individual and collective health, as well as animal health, should have been clear. Preparedness authorities and scholars were aware of the growing risks from transboundary infectious diseases, many zoonotic, and the significant economic, humanitarian, and global security implications.

In addition to natural biological threats, ready access to advanced technologies, expansion of high containment laboratories worldwide, and availability of dangerous pathogens were simultaneously increasing the potential for unnatural accidental or deliberate outbreaks with grave consequences.

Just weeks before SARS-CoV-2 emerged in Wuhan, the World Bank and World Health Organization forewarned in their 2019 World at Risk Report about the growing risk of a viral pandemic that could occur through accidental laboratory escape or intentional release after being engineered in a laboratory (WorldBank, 2019).

Despite these warnings and preparedness investments, global capacities, and international agreements necessary to prevent, detect, respond, and rapidly attribute unknown emerging infectious disease threats, whether natural or unnatural in origin remains woefully inadequate.

Public health authorities are on the front line to investigate and attribute emerging disease outbreaks and are most familiar with known diseases of natural origin. Infectious disease outbreak investigations are a core competency of epidemiology and public health. Epidemiological investigations follow protocols to establish a case definition, case confirmation, and rate of background of disease to find new cases. This is followed by collecting data to build descriptive epidemiological characteristics, generate hypotheses, test hypotheses, and propose an analysis of alternatives to attribute the source. Investigations are geared to identify the source of ongoing outbreaks and prevent additional cases. Even when an outbreak is over, a thorough epidemiologic and environmental investigation and analysis enhances knowledge of a given disease to prevent future outbreaks.

Epidemiological investigative methods are a proven strategy to identify and attribute natural disease outbreaks, and traditional epidemiology works well in the United States and many other nations worldwide. But many low-middle-income countries (LMIC) lack sufficient capabilities and capacities to detect, investigate, and rapidly attribute emerging infectious diseases. LMICs on the African continent and Southeast Asia are also disease hot spots for emerging and reemerging pathogens with regional epidemic or pandemic potential.

The World Health Organization (WHO) has existing mechanisms to assist member states in investigating naturally occurring infectious disease outbreaks, and the International Health Regulations (IHR) are legally binding requirements for member states to detect and rapidly report health security threats that could impact other countries. The United Nations Secretary-General has procedures to investigate alleged deliberate use of biological weapons under the Biological Weapons and Toxins Convention (BWC).

These international mechanisms and agreements to aid member states can be effective, provided member states fully cooperate with the WHO to investigate outbreaks with potential that could rapidly spread regionally or globally. However, there have been many instances where member states, especially middle- and high-income nations, fail to cooperate fully. Unfortunately, institutional capability and capacity-building initiatives for LMICs have not achieved IHR required compliance goals. Even IHR compliant middle and high-income countries that have a sufficient laboratory, diagnostic, and reporting infrastructure, enforcement of the IHR is limited when member states fail to timely report health threats that constitute a public health emergency of international concern. Finally, allegations of non-compliance with the Biological Weapons Convention are rarely met with a willingness by a member state to be investigated.

These and other inherent limitations of multilateral organizations and agreements are amplified during periods geopolitical tension. For example, for unknown reasons, the Communist Chinese Party imposed gag orders on their scientists that prevented sharing scientific data on SARS-CoV-

2 origins and reporting knowledge of human-to-human transmission without government approval starting as early as January 2020.

In additional to strong geopolitical forces at play, professional culture, experience, and human nature are also contributing factors, especially for recognizing the potential for an unnatural outbreak source. For example, public health professionals who are on the front line of infectious disease outbreak investigations are not trained in security. Public health scientists reflexively consider natural sources in their investigative hypothesis, and rarely consider an outbreak could have unnatural origins, nor investigate with forensic rigor needed for law enforcement or national command authorities. This is not a criticism but just the nature of public health education, culture, and experience.

There are four unnatural outbreak examples that I will briefly review in chronological order of occurrence that have some aspects of geopolitical tension and professional culture inclinations as past precedents. I will also include one natural outbreak as a past precedent. Lessons observed from past precedent examples should be considered when future requirements are considered to rapidly attribute outbreaks with pandemic potential.

1977 Russian Flu**:** A novel H1N1 influenza virus strain emerged in 1977 and quickly spread worldwide. Scientists soon determined that the strain was not novel and had previously circulated globally as a decedent of the 1918 influenza pandemic, but disappeared from circulation in the early 1950's. The strain mysteriously reappeared in East Asia near the border of China and the Soviet Union in 1977 as though it had been frozen in time.

The global influenza epidemic, or pandemic, was known as the Russian Flu. The disease had an unusual presentation and the viral strain had unique characteristics consistent with an attenuated vaccine strain. Disease was restricted largely to people under ~21 years of age and impacted military academies, military recruits, and schools the hardest.

Some scientists and public health officials became suspicious that unnatural research associated incident was a possible origin because of the unusual characteristics of this reemergent viral strain. But Soviet and Chinese scientists denied their laboratories had the pandemic virus.

Western governments and scientists soon dropped the laboratory origin claim for geopolitical reasons to avoid additional Cold War tensions and proposed alternative natural etiologies. Western government and public health authorities did not want to risk compromising the World Health Organization's (WHO) Global Influenza Surveillance Network that needed Soviet and Chinese government cooperation (Furmanski, 2014).

Evidence to definitively support H1N1 a/USSR natural emergence was never found. But twenty-seven years later in 2004, a preeminent, senior Chinese virologist confided with his United States colleague that the 1977 Russian Flu's origin was unnatural research associated origin. The exact details remain elusive, but the accidental release is thought by most scholars to be associated with influenza vaccine clinical trials (Palese, 2004) (Furmanski, 2014) (Basu, 2021) (Gronvall, 2015).

1979 Sverdlovsk Anthrax Accident (USSR): An unusual anthrax epidemic was reported in the secret city Sverdlovsk, Union of Soviet Socialists Republics in 1979. The few news accounts that leaked out of the secret city estimated over a thousand deaths due to an accident at an alleged biological weapons facility. These news accounts could not be verified due to heightened tensions between the United States and the Soviet Union during the Cold War. For over a decade, the Soviet Union military ran a successful deception and denial campaign asserting the epidemic was natural intestinal anthrax disease due to consumption of contaminated meat. The U.S. Central Intelligence Agency suspected the outbreak was tied to an illicit biological weapons facility and biological weapons program in violation of the Biological Weapons Convention (BWC). A prominent geneticist and arms control scientists from Harvard University, Matthew Meselson supported the Soviet Union's claim as plausible (Wade, 1994). Actions were not taken to invoke BWC provisions of this suspected violation. The Soviet Union, the United Kingdom (U.K.), and the United States (U.S.) were among the initial twenty-two member states joining the convention. The BWC went into force just four years earlier in 1975 that likely restrained the use of diplomatic force.

It was not until Soviet Union defectors debriefed U.K. and U.S. intelligence agencies in 1992 that western suspicions were confirmed. Inhalation anthrax caused the epidemic due an accidental biocontainment breach from a military biological weapons facility that was part of a large biological weapons program. A subsequent scientific investigation in 1994 led by Meselson provided an epidemiologic characterization of the outbreak, and documented at least 66 deaths, with many more possible (Matthew Methelson, 1994).

1984 Food borne illness in Dalles Oregon: The Rajneesh cult succeeded with the first documented bioterror incident in the United States in 1984. Their motivation was to influence county elections in Dalles Oregon by contaminating salad bars at restaurants with S. Typhimurium on several occasions before the election.

A community wide outbreak of salmonellosis resulted; at least 751 cases with 45 requiring hospitalizations were documented in a county that typically reports fewer than five cases per year. Although bioterrorism was considered a possibility when the outbreak was being investigated by public health officials, it was considered unlikely despite the obvious epidemiological presentation.

The source of the outbreak became known only after a disavowed cult member confessed the incident was deliberate over a year later. The FBI was called into investigate and found a vial of S. Typhimurium identical to the outbreak strain in a clinical laboratory on the cult's compound. Other members of the cult subsequently admitted to the bioterror crime. Confessions coupled to microbial forensics attributed the outbreak to an unnatural deliberate outbreak. Without the initial confession by the disavowed cult member, law enforcement may never have discovered this bioterror incident.

2001 anthrax letter attacks: Letters containing dried anthrax spores were mailed in the aftermath of the terrorist attacks of September 11, 2001, in New York City, Florida, and Washington, DC. The letter attacks marked the first significant act of bioterrorism in the United States and highlighted our vulnerability to a rapid onset infectious disease outbreak from biological threats, whether intentional, accidental, or natural in origin.

Of note, the first case presented with inhalational anthrax that is exceedingly rare. Public health officials initially attributed the outbreak to natural origin despite this rarity and in the aftermath of the tragic events of September 11, 2001. It was only after other cases presented and mailed letters were discovered containing anthrax spores that the reality of an unnatural bioterror attack set-in. We also seemed hopeless to prevent more attacks.

When the FBI started to investigate a potential domestic source, laboratory scientists denied the spores came from their lab, and argued the anthrax could have been acquired from several places, including from nature. However, as soon as genomic sequencing revealed the *Bacillus anthracis* from the letters were from the Ames strain, it became clear the spores were descended from the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). Deflection turned to disbelief, but it could not be denied. After this revelation, most, including me were more determined than ever to help the FBI find the perpetrator and to take actions to prevent a reoccurrence.

That attack was one of the easiest bioterror attacks to confront, yet the impact was far reaching and severely challenged public health and law enforcement. The attack had international ramification as anthrax spore contaminated mail was discovered at United States' embassy postal facilities across the globe. As bad as it was, it could have been much worse had the pathogen been a contagious agent, resistant to antibiotics, an unknown pathogen, or delivered in a covert widespread aerosol attack across multiple jurisdictions.

As it was, the anthrax letters shut down government buildings for months, wreaked havoc on the Postal Service, reduced business productivity, cost the nation more than one billion dollars, and tragically, took five lives and sickened seventeen more. More than 30,000 people required post-exposure antibiotics.

Many still recall frightening moments experienced during that time, particularly those who were potentially exposed to anthrax spores. The first batch of letters were post marked on September 18, 2001, exactly one week following the terrorist's attacks of September 11th, and greatly elevated already heightened public anxiety and fear. This event also forever changed our notions of laboratory biosecurity, biosafety, and personal reliability for work in high containment laboratories and led to the emerging science of microbial forensics for attribution.

Outbreak investigations to support law enforcement also identified the need for dedicated and specialized high containment laboratories with cleared scientists to conduct investigations. Those capabilities were not available at the start of the Amerithrax investigation.

2002 – 2003 SARS1 Global Epidemic: Clinical cases presenting with an atypical pneumonia of unknown origin began in November 2002 in Guangdong province in southern China. Because of delayed reporting by Chinese government authorities, the international community did not become aware of multiple ongoing outbreaks until February 2003. Atypical pneumonia was subsequently identified to be associated with a novel coronavirus called, severe acute respiratory syndrome (SARS). International collaborations and data sharing began soon after this revelation. In the Guangdong province region, exotic wildlife cuisine was popular and legal. A reported 10,000 palm civets were consumed daily (Ma, 2002) (Pan, 2004). Diagnostic, genomic and serologic forensic evidence was found within 6 months that showed that SARS1 made multiple zoonotic jumps from multiple animals at several different locations indicating the virus was circulating and enzootic in animals for some time before causing human infections. Some zoonotic jumps led to "dead-end" human infections while the virus continued to evolve becoming fit to humans, characteristic of the gradual, natural evolution of zoonotic spillovers (Cheng VC, 2007). The virus finally adapted to humans enabling human-to-human transmission that led to 774 deaths worldwide before the outbreak was contained.

Summary of past precedents: Key past precedent themes characteristic of unnatural infectious disease outbreaks is apparent from these examples. These characteristics are prominent in autocratic regimes but are not limited to autocratic regimes. Regardless, these behavioral characteristics can hinder investigation and rapid attribution of natural and unnatural outbreaks. Institutional, autocratic regime, and cultural themes include, 1) Inherent weakness in multilateral organizations, like the WHO and the United Nations; 2) Denial; 3) Deflection; 4) Obfuscation; and 5) Disbelief; and 6) lack security culture and training in forensic rigor.

On the other hand, the SARS1 outbreak was attributed within six months as zoonotic spillover from palm civets as an intermediate animal host. Horseshoe bats were subsequently determined as a likely reservoir host for SARS-related coronaviruses. There was also strong international collaboration between Chinese scientists, the WHO, and the international community at that time to attribute the source to palm civets and mount effective control measures worldwide.

***Discussion*.** Naturally occurring biological threats pose a grave risk to our health and national security. Globalization, population growth, urbanization and other factors are creating a perfect storm for the emergence of high-consequence infectious diseases with pandemic potential.

But the threat of unnatural outbreaks with pandemic potential is growing too. Research with dangerous pathogens in high containment laboratories using advanced technologies are enabling unprecedented scientific achievements around the world to benefit society. But those same research technologies and information essential for public health preparedness and biodefense could intentionally be misapplied by malevolent actors or lead to unnatural accidental biocontainment breaches through inexperienced staff or inadequately maintained laboratories – *the dual use research of concern threat.*

It is important to note that almost all life science research with pathogens performed in high containment laboratories can be accomplished safely and securely if all staff strictly adheres to biosafety and biosecurity guidelines and best practices. Laboratory and institutional level leadership are essential to instill a culture throughout the lab of accountability, responsibility, and ethical values that enables and promotes transparency to report even the smallest of human errors or potential biocontainment breaches.

For the first time, many are realizing the scope, breathe, and risks of the expansion of high containment laboratories worldwide. Concerns about high containment laboratory expansion are coupled to advancing, readily available technologies with uneven international laboratory safety and security standards. International guidelines and codes of conduct; effective international oversight institutions and leadership; and international governance standards and controls for risky research that could generate potential pandemic pathogens and dual use research are virtually absent.

Fortunately, we have one of the most comprehensive bio-risk management frameworks to govern and oversee life science research in high containment laboratories performed in the United States, but it is not perfect (Young, 2016) (Blake, 2020).

But outbreaks worldwide are unavoidable regardless of source. Global capabilities and capacities are needed to rapidly detect, attribute, and prevent outbreaks from becoming epidemics or a pandemic.

In the United States, the CDC, state, and local public health authorities have an exemplary record investigating and rapidly attributing routine, natural disease outbreaks and foodborne illnesses. But as was described with past precedent incidents, public health authorities do not reflexively consider the potential for an unnatural origin of a disease outbreak.

After the 2001 anthrax letter attacks, the follow-on FBI Amerithrax investigation applied the emerging science of microbial forensics with newly cleared scientists, and along with traditional investigative procedures, ultimately attributed the attack to a lone U.S. scientist from USAMRIID in 2008. Unfortunately, the scientists committed suicide before the FBI indicted him, so the case was never tried in court.

The lessons learned through that investigation led the United States to establish unique capabilities and capacities to rapidly investigate and attribute unnatural, deliberate use of pathogens to meet a forensic standard required by law enforcement and national command authorities. A central component of the capability was design and construction of a unique high containment laboratory, the National Biodefense and Analysis Countermeasures Center (NBACC) that began operations in 2008. I played a major role arguing for the appropriations for this laboratory and served as the first NBACC director while we rented a Biosafety 3 Laboratory suite within USAMRIID starting in 2003 to support the FBI, Intelligence Community, and other stakeholders.

NBACC is dependent upon receiving samples for analysis from law enforcement, intelligence, and public health through strict cold chain procedures so access to materiel and pathogens to test may be dependent upon the willingness of other nations to support an international investigation. Regardless, I cannot overstate the importance of having dedicated, core laboratory capabilities and cleared scientists that are focused on microbial forensics to support attribution for national command authorities. It is not a part-time job, or other duties as assigned function.

Attribution to determine who is responsible for an unnatural deliberate or blatant negligence that leads to an unnatural outbreak with epidemic or pandemic potential is essential to hold those responsible accountable for their actions, prevent future attacks, and serve as a deterrent. Attribution and the supporting microbial forensic sciences are also important to exonerate – and rule out - suspected perpetrators or negligent actions. Attribution with forensic rigor for natural outbreaks that lead to epidemics, or a pandemic is equally important as gross negligence could be a factor that should be considered. For example, was the source due to a natural zoonotic spillover from illegal, inhumane wildlife or endangered species animal trade?

Investigation and rapid attribution of international outbreaks are more difficult depending upon the source country and geopolitical factors.

The first question to ask, what multilateral organization should have responsibility and authority to conduct a credible investigation with forensic rigor that could be subject to independent verification to attribute the source of a pandemic, whether natural or unnatural?

The World Health Organization (WHO) is the specialized health agency within the United Nations whose mission is to promote human health globally and provide technical assistance to 194 member states. The WHO played a leading role in the past with control and eradication of other infectious diseases, such as smallpox. But does the WHO have a recent demonstrated track record to lead international investigations to attribute the source of pandemics? Alternatively, have member states blocked WHO's ability to lead international investigations?

In the early days of the COVID-19 outbreak and before a pandemic was declared, two WHO-China joint missions were conducted in January and February 2020 to gain a better understanding of the epidemiological characteristics, early response efforts, and preparedness strategies to contain the virus. There were no microbial forensic investigations contemplated nor conducted by these delegations.

In reaction to increasing public pressure, the Chinese government agreed to host a Joint WHO-China Study from January 14th to February 10th one year later in 2021. The objective of that mission was the analysis of potential natural zoonotic sources of SARS-CoV-2 and the search for intermediate hosts of this virus. Investigation of an unnatural source was not permitted in the negotiated terms of reference.

The March 2021 report from the Joint WHO – China delegation was widely criticized due to the lack of firm data supporting the conclusions presented, and conflicts of interest by some delegation members. The WHO Director-General did not embrace the report's findings and he made it clear both hypotheses must be investigated whether that turns out to be natural or unnatural origin.

Protocols under the Biological Weapons Convention (BWC) and the United Nation's Secretary-General's Mechanism (UNSGM) have frameworks to investigation allegations of treaty non-compliance and have been considered in the past for both unnatural and natural outbreaks. However, the BWC has no verification mechanism and thus no real provision to rapidly conduct a forensic investigation for attribution. Further, a naturally occurring infectious disease outbreak is not a matter for the BWC.

The experience with COVID-19 and previous outbreaks with international impacts confirm there are currently no international agreements or guidelines that provide authority for forensic investigations of a pandemic, whether natural or unnatural in origin.

Looking to the future, we must continue multilateral diplomatic efforts to support an effective WHO with agreements by all member states to establish a multidisciplinary task force free of conflicts of interests for outbreak investigation and attribution missions. This proposed task force must be able to conduct professional, objective, and transparent pandemic investigations for attribution with forensic rigor that allows for independent verification. The implementation of such a task force that would include member nations with multidisciplinary expertise and experts from the country of interest with agreed upon procedures will be a difficult diplomatic negotiation. There is no promise for success.

The 74th session of the World Health Assembly in May 2021 approved a Special Session to consider a comprehensive international pandemic treaty for prevention, preparedness, and response. Negotiations are ongoing with the next negotiating session scheduled for February 2023. The proposed international pandemic treaty could strengthen the role of the WHO across a spectrum of important activities, including vaccine, therapeutic, and diagnostic access; data and information sharing; intellectual property; laboratory biosafety; animal and land-use management; health care inequities; preparedness financing, and other components important for pandemic preparedness worldwide. The United States has been circumspect regarding a formal treaty, but publicly supports revisions to the International Health Regulations and strengthening governance of the WHO. International negotiations by member states will likely come down to binding versus non-binding resolutions; concerns around national sovereignty; and what is best for individual member state's national interest. These are essential considerations for the United States. Congress and the Administration should work together to find areas of agreement important to support the proposed pandemic treaty but must steadfastly protect vital interests essential to the United States.

Reservations about an international pandemic treaty are warranted, but we must not walk away from our leadership responsibilities in this matter with the WHO and like-minded member states. We must continue to actively engage and help lead negotiations. Health security and pandemic preparedness diplomacy are a marathon, not a sprint.

Continued international scientific collaboration and development are also essential but how we do such collaboration is equally important.

Despite current geopolitical tensions and critics of scientific collaboration with Chinese scientists, we must consider the importance of maintaining open lines of communication between United States public health authorities and Chinese public health scientists. Naturally occurring infectious diseases will continue to emerge in China and throughout Southeast Asia. Effective international scientific collaborations may provide early warnings for emerging infectious disease outbreaks with pandemic potential. For this reason, we must find a venue to re-establish effective scientific dialogue. For example, research is needed to underpin the establishment of international bio-risk management and biosafety standards. This would be a productive investment for future joint U.S - China scientific collaborations. Better understandings of viral ecology are needed too, but unnecessarily dangerous research must be avoided.

The administration must also accelerate strategies to work with international partners to implement a long-standing need for an international bio-risk management framework. This is urgently needed to assure that research with dangerous pathogens is safe, secure, and built upon an ethical foundation worldwide to decrease the possibility of unnatural, accidental or deliberate pandemics. Harmonized international bio-risk management standards will require effective international collaborations, agreements, and harmonized national legislative regimes appropriate to the life sciences. International agreements must include emphasis on scientific leadership at the laboratory and institutional level. It is necessary to build a culture of accountability and responsibility from the ground up. Promoting and supporting effective leadership at the laboratory level and mentoring next generation scientists are essential to provide effective biosafety and biosecurity assurances to mitigate risks. Leadership and a culture of safe, secure, and responsible science cannot be legislated. It requires leadership and mentorship at institutional levels.

Science and medicine are universal languages at the professional level, even during periods of turbulent geopolitical tension. International collaboration and science diplomacy will help nurture a culture of accountability and responsibility with next generation scientists. Science diplomacy through smart collaborations with responsible university institutions must be a component of a long-term U.S. foreign affairs strategy. Twining of responsible universities in the United States with universities in other countries must become an integral component of international collaboration, science diplomacy, early warning, and attribution for future outbreaks with pandemic potential.

A central component of this approach must include a targeted One Health international development approach that provides aid to LMICs to build basic public health and veterinary institutional capacities. Enhanced One Health capacities and core competencies will strengthen

International Health Regulation compliance. Higher education has an essential role too through global educational outreach to build the ethical foundation for next generation scientists.

Establishing capabilities to facilitate investigations and rapid attribution of outbreaks with pandemic potential will require multiple approaches from policy, international diplomacy, to new technologies.

Stand-off biosurveillance technologies, genomics, diagnostics, satellite imagery, artificial intelligence, health security data management, and reporting systems to name a few are needed. Fortunately, technology solutions are readily available today that were not available previously. The challenge is the political will to target investments that will make a difference.

The biggest challenge to improving our ability investigate and attribute the source of pandemics and other biological threats reside in overcoming geopolitical forces and the behavior characteristic described with the past precedent examples in my testimony. Because of the severe consequences and international nature of pandemic and other biological threats, source attribution requires transparent and objective investigations with forensic rigor supported by scientific findings devoid of conflict of interests with independent verification, whether the offending pathogen emerged naturally or unnaturally. It comes down to individual member state's willingness to act in good faith to support transparent and objective international inquiry. Behavior characteristics that are typically associated with autocratic regimes such as deflection, denial, obfuscation, and non-cooperation are difficult to overcome.

Currently, the WHO is beholden to strong member states that elect not to cooperate with transparent international outbreak investigations and/or International Health Regulations. The Scowcroft Institute of International Affairs at The Texas A&M University's Bush School of Government and Public Service recognized this limitation and previously made a number of recommendations to strengthen the role of the WHO Director General. One recommendation proposed to change organizational lines of authority between regional directors and the Director General to partially mitigate this limitation (Andrew Natsios, 2017). Our recommendations should be reconsidered as a component to help overcome organizational challenges and limitations inherent in the WHO structure.

Detection and attribution must also be tied to response mechanisms, such as rapid diagnostics, vaccine, and therapeutic surge development and manufacture. Congress has an historic opportunity this year through the reauthorization of the Pandemic Preparedness and All Hazards Innovation Reauthorization Act to ensure that the marketplace for medical countermeasures incentivizes the research and investment needed to counter future biological threats. Now is the time to realize a well-resourced and modernized Strategic National Stockpile (SNS). Now is the time to reflect on and learn from OWS's immense successes in quickly accelerating regulatory and manufacturing hurdles. And now is the time to invest in the domestic industrial base, including domestic Active Pharmaceutical Ingredients (API), in order to achieve the goal of manufacturing a new vaccine within 100 days of a future emergency. The country must have a sound infrastructure of warm base manufacturing alongside surge capacity when pharmaceutical interventions are needed. All of this can and must be done with public-private collaboration, enabling, and ensuring equitable access for all Americans.

In closing, I want to state that above all, the nation is counting on strong biodefense and health security leadership and a national leadership structure that ties together components in the National Security Council and Office of Science and Technology Policy. Strong leadership is essential to drive effective coordination, collaboration, communication, and innovation across the vast United States government interagency, as well as with state, local, tribal governments, the private sector, universities, other non-government organizations, and with strategic international partners.

Thank you for the opportunity to appear before you and share my experiences on this important national security topic.

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