Hearing of the Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives

"Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events"

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Statement for the Record

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Summary

Our experience with COVID-19 proved that even a single, difficult to control disease can produce devastating consequences for the world. As we identify lessons from this event, the government must improve upon our national ability to respond to future biological events, and develop the means to attribute the origin of, and responsibility for, those events. Despite the potential involvement of many federal departments and agencies in attribution activities, the Nation lacks a plan and apparatus for determining how and why biological events began.

In 2015, the Commission released our foundational report, *A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts*, containing 33 recommendations and 87 associated action items for national biodefense. That report included recommendations pertaining to (among other topics) biological attribution, laboratory biosecurity, biological intelligence, and bioforensics – all activities vital to ascertaining the origin of a biological event. In 2022, the Commission also released, *The Athena Agenda: Advancing the Apollo Program for Biodefense.* That report included recommendations that could help inform pandemic origin investigations, for ubiquitous genetic sequencing, minimally and non-invasive infection detection, massively multiplexed detection capabilities, digital pathogen surveillance, a national public health data system, national pathogen surveillance and forecasting, comprehensive laboratory biosafety and biosecurity, and technologies to deter and prevent biological attacks.

Statement

Chairman Griffith, Ranking Member Castor, and other Members of the Committee, thank you for your invitation to provide the perspective of the Bipartisan Commission on Biodefense during today's hearing, "Challenges and Opportunities to Investigating the Origins of Pandemics and Other Biological Events." I am honored to talk with you today about federal biological attribution and other activities that comprise these sorts of investigations. My name is Asha M. George, DrPH, and I am the Executive Director of the Bipartisan Commission on Biodefense.

The Commission is co-chaired by former Senator Joe Lieberman and former Secretary of Homeland Security, Governor Tom Ridge; with former Senate Majority Leader Tom Daschle, former Secretary of Health and Human Services, and Representative Donna Shalala; former Representative Fred Upton (a longtime leader of the Committee on Energy and Commerce); former Representative Susan Brooks; former Representative Jim Greenwood (who also chaired this subcommittee); and former Commissioner of the Food and Drug Administration Peggy Hamburg serving as Commissioners. The Commissioners and I have addressed national, homeland, and public health security in various capacities for decades. Although we have left our previous positions, we remain committed to public service and the public health, safety, and security of our Nation.

In 2015, the Commission released our foundational report, *A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts*, containing 33 recommendations and 87 associated action items for eliminating what we identified as serious capability gaps in national biodefense. In the seven years since we released that report, Congress and the Administrations have addressed many of our recommendations, including the creation of a National Biodefense

Strategy (Recommendation 3). We appreciate the original iteration of the Strategy released by the Trump Administration in 2018 and the more recent October 2022 refresh released by the Biden Administration. We eagerly await the Strategy's comprehensive implementation by the federal government. The Office of Management and Budget addressed another Commission recommendation last month when it released the first biodefense budgetary crosscut assessment (Recommendation 4 from the *National Blueprint for Biodefense*) which examined biodefense spending across the federal government. Both accomplishments are the result of Congressional direction – the National Defense Authorization Act for Fiscal Year 2017 (Public Law 114-328) required the creation of the National Biodefense Strategy, and the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283) established the requirement for an annual biodefense budgetary crosscut analysis. Other Commission recommendations have been taken up by a variety of legislative vehicles, including the Farm Bill, the Intelligence Authorization Act, and the Pandemic and All-Hazards Preparedness and Advance Innovation Act. Congressional oversight plays a critical role in ensuring continued high prioritization of these and other biodefense activities.

Despite this progress, the novel coronavirus 2019 (COVID-19) demonstrated that the Nation remains at catastrophic risk of another biological event. Later this year, our Commission will release the second edition of our *National Blueprint for Biodefense*. Drawing from lessons learned from the pandemic, and biodefense successes and challenges since 2015, the updated report and its recommendations will offer a roadmap for continued efforts by the Legislative Branch and Executive Branch to address national biodefense.

COVID-19 proved that a single, difficult to control disease can still produce devastating consequences for the world. As we identify lessons from this event to carry forward, the government must not only improve the ability to respond to future biological events, but also develop the means to better attribute origin of, and responsibility for, those events. The anthrax events of 2001, laboratory accidents across the country and the world, and various pandemics (e.g., H1N1, Ebola, H5N1, MERS) time and again revealed our lack of coordination and capability to comprehend the origins of biological events fully. At the outset of an investigation, decisionmakers will have difficulty understanding whether a pathogen is intentionally introduced, accidentally released, or naturally occurring, further emphasizing the importance of determining the source. Unfortunately, there is no formal apparatus in place to assist leaders in making decisions to address biological crimes, terrorism, warfare, accidents, and naturally occurring events.

First, we must explain what we mean by attribution, as the term covers a number of activities. Biological attribution is the process of identifying an instigating biological agent, where it came from, and – if a biological attack or an accidental release is involved – who might have created and/or disseminated the agent. An attribution apparatus must incorporate diverse activities, across many federal departments and agencies. The nature of those investigations can vary depending on the entities involved. For instance, law enforcement will take a different approach than public health. If we can determine that a biological attack has occurred, not only must we attribute crimes, terrorism, and warfare to particular perpetrators, we must also correctly identify the pathogens and their sources, whether or they are naturally occurring.

Leaders in the White House and throughout the federal government need the best information possible to make far-reaching, globally significant decisions about how to respond to biological crises. The implications of imposing sanctions and embargoes, cutting off diplomatic relations, competing with other countries for scarce resources, and declaring war are too important to leave to a loose set of occasional federal players and policies. This is especially true considering the United States strategy for deterring biological attacks includes possibly responding with nuclear weapons. Although the Department of State, the Department of Defense, the Department of Justice, and other federal departments and agencies possess responsibilities for attribution, there is no structure in place dedicated to directing and coordinating activities to determine the cause of particular biological events, and to provide that information in a usable form to the White House decision-making apparatus.

The law enforcement and public health communities have clear responsibilities for the investigations that fall under their respective domains. The intelligence, defense, and scientific communities also have important roles to play. Representatives from these and other groups must align and support one another's investigations. This must occur despite differences in information sharing norms and requirements among these communities, and there being no one entity in charge for the purposes of attribution. Compounding this challenge is the occasional addition of other communities (e.g., agriculture, commerce, homeland security, wildlife) as well as classification issues that may result in some duplication of effort. The need for close coordination and collaboration is clear, but arrangements among these communities have yet to be formalized for this purpose.

The Department of Homeland Security (DHS) National Biodefense Analysis and Countermeasures Center, located at Fort Detrick in Frederick, Maryland, currently houses the National Bioforensics Analysis Center (NBFAC). The NBFAC conducts biological forensic technical analyses in support of investigations into the use (or suspected use) of biological attacks. The Federal Bureau of Investigation (FBI) is the sole user of the NBFAC. Other federal entities partner with the FBI on their investigations into biological events, choosing to enable the FBI to retain control of their specimens, rather than working directly with the DHS.

The Commission has long advocated for a cohesive national biological attribution capability. Recommendation 9 from our 2015 *National Blueprint for Biodefense* called for strengthening federal support for biological attribution. We determined at the time that the Nation had not yet fully established attribution capability and that there was no formal federal biological attribution apparatus. That recommendation remains as relevant today in 2023 as it did in 2015. We revisited attribution in our 2021 report *Biodefense in Crisis: Immediate Action Needed to Address National Vulnerabilities*, where we further recommended that the Secretary of State, the Secretary of Defense, the Secretary of Homeland Security, the Attorney General, and the Director of National Intelligence jointly develop, plan for, and establish a national biological attribution apparatus to inform decision-making. The Commission continues to believe the federal government must do more to attribute biological events. We recommend that Congress require the establishment of a federal interagency working group to develop a national biological attribution apparatus, with clearly defined roles, responsibilities, and requirements, as well as milestones for adjudicating attribution information and informing decisions following any biological event with national security implications.

Coordinated biological intelligence activities must inform biological attribution. Recommendation 6 from our *National Blueprint for Biodefense* called for establishing a National Intelligence Manager for Biological Threats at the Office of the Director of National Intelligence to coordinate and prioritize biological intelligence activities throughout the Intelligence Community. Congress has taken decisive action on this recommendation recently. As part of Fiscal Year 2022 appropriations, legislators changed the name of the National Counterproliferation Center to the National Counterproliferation and Biosecurity Center, and more importantly, designated the Center's director as the biodefense lead within the Office of the Director of National Intelligence. We hope this development is an important step towards clarifying biological intelligence priorities and informing national biological attribution activities.

As we discuss investigating the origins of pandemics and other biological threats, we must, of course, consider laboratory biosecurity and biosafety, as pandemics could arise from accidental exposures in, and leaks from, laboratories. The primary federal program to prevent the misuse of pathogens and toxins is the Federal Select Agent Program (FSAP), administered jointly by the Department of Agriculture and the Centers for Disease Control and Prevention (CDC). While this program functions somewhat as an impediment to would-be attackers, the regulatory regime of the FSAP does not fully address pathogen safety and security, in that it does not address how to prevent and deal with human error, how to ensure standards for safety and security awareness are met, and how to be more transparent within statutory confines about lapses and problems with the system. Information, knowledge, and equipment to produce pathogens *de novo* (known as synthetic biology) have become increasingly available in the years since the FSAP was established. With every passing day, the FSAP risks becoming increasingly irrelevant as

advances in synthetic biology could enable someone to take a benign pathogen not on the list, and turn it into something horrific. Therefore, restriction of access to pathogens already secured in laboratories has decreased impact today. It is time for a complete review followed by a comprehensive overhaul.

Furthermore, pathogens are not the only problems. Non-pathogens (e.g., bioregulators, small peptides) could also be used in biological weapons but fall outside of the current regulatory regime. FSAP regulations can also reach burdensome levels that make the scientific workforce resistant to conducting much needed biomedical research, and provide minimal or no enhancement of biosafety or biosecurity. FSAP regulations also fail to recognize the reality of select agents presenting in animal diagnostic samples, and the nature of the work that veterinary diagnostic laboratories must, therefore, do to keep the Nation and its animals safe and healthy. Policymakers must address discrepancies in the purpose of the FSAP, rationale for its regulations, and criteria for determining which agents are added or removed from the list; barriers to full implementation of the FSAP; the value of a dynamic, characteristic-based approach for restricted agents and toxins versus the current, static list-based approach; challenges associated with inspections; whether federal and private investments in biodefense are maximized; and how to implement a restorative (rather than punitive) process for addressing difficulties. A different approach to identifying problems and implementing solutions is needed.

Congress recognized the need to review laboratory security and biological research when it authorized the National Science Advisory Board for Biosecurity (NSABB) as part of the recent Consolidated Appropriations Act, Fiscal Year 2023 (Public Law 117-328). Recommendation 32 of our *National Blueprint for Biodefense* recommended that the NSABB engage in a

comprehensive assessment of the FSAP. With statutory authorization newly in-hand, the NSABB should execute such an assessment, with an evaluation of all pertinent strategies, laws, and guidance related to the FSAP, identification of key drivers of safety and security lapses, and identification of regulatory burdens that stifle research and innovation. Based on this review, NSABB should present actionable recommendations to Congress, the Secretary of Health and Human Services, and the Secretary of Agriculture. Ultimately, the Administration should pursue a complete overhaul of the Select Agent Program. The focus of any overhaul to the program should be less about whether we can secure stocks of pathogens, and more about whether we can control the proliferation of information, predict the nature of the changing biological threat, and ingrain a culture of security awareness within the biomedical research community. The Commission also recommended in its report, *The Athena Agenda: Advancing the Apollo Program for Biodefense,* that the Secretary of Health and Human Services, in partnership with Secretary of Defense and the Secretary of Energy, request that the NSABB assess: (1) the potential for innovation in laboratory biosafety; (2) potential outcomes of those innovations; and (3) current goals for next-generation technology in laboratory biosafety. The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, should conduct an annual review of laboratory biosafety capabilities and challenges.

The Commission included recommendations in its *Athena Agenda* about ubiquitous genetic sequencing, minimally and non-invasive infection detection, massively multiplexed detection capabilities, digital pathogen surveillance, a national public health data system, national pathogen surveillance and forecasting, comprehensive laboratory biosafety and biosecurity, and technologies to deter and prevent biological attacks. All of these could provide valuable contributions to investigations into the origins of pandemics. The Commission makes the

following recommendations regarding these topics. Further details can be found in its *Athena Agenda*:

- Increase US sequencing capability and capacity. Congress should amend the 21st Century Cures Act (P.L. 114-255) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Energy, and Secretary of Agriculture to develop a plan to increase pathogen agnostic metagenomic sequencing capability and capacity in the near- and long-term. The plan should: (1) identify where sequencing capability and capacity currently lie in public sector laboratories, academic and research center laboratories, and other laboratory networks; (2) articulate how to identify sequencing capability and capacity in private sector laboratories; (3) provide an estimate of funding needed to expand capability and capacity in these laboratories; (4) explore the use of financial incentives to collect more samples in healthcare and wastewater settings; (5) set standards for the quality of information that should accompany each sample; (6) describe coordination with international partners to further sequencing development; and (7) describe how to achieve ubiquitous sequencing in the next five years. The Secretary of Health and Human Services, Secretary of Defense, and Secretary of Agriculture should deliver this plan to Congress within one year of enactment.
- Identify the need for portable sequencing capabilities. The Secretary of Health and Human Services should, in coordination with the Secretary of Defense, Secretary of Agriculture, and Secretary of Homeland Security, identify portable sequencing end-users and the sequencing capabilities they need in the federal government; states, localities, tribes, and territories (SLTT); healthcare settings; and ports-of-entry. The Secretary should take no longer than 180 days to identify these needs.

- Develop affordable portable sequencing. The Secretary of Health and Human Services should, in coordination with the Secretary of Defense and Secretary of Agriculture, develop a research and development plan that can make fielding portable sequencing in non-laboratory settings more affordable. The plan should (1) identify research efforts to produce portable sequencing devices in the public and private sectors; (2) address the miniaturization of these devices; (3) decrease or eliminate the reagents needed by these devices; and (4) address the integration of sequencing with microfluidics, on-chip sample preparation, and advances in bioinformatics. The Secretary should take no longer than one year to produce this plan.
- Further develop the ability to detect infections with minimally- and non-invasive methods. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, Secretary of Defense, and Secretary of Agriculture to (1) identify ongoing public and private sector research and development of minimally- and non-invasive infection detection technologies; (2) determine their potential for, and challenges with, utilization; (3) develop a funding plan to advance research and development in this arena; (4) identify the data sets and integration and analytics systems needed to draw rapid conclusions from these technologies; and (5) implement newly developed advanced technologies and methods of detection within three years from enactment.
- Advance massively multiplexed detection capabilities. Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283) to direct the Secretary of Defense, in coordination with the Secretary of Health and Human Services and Secretary of Homeland Security, to develop and advance massively multiplexed detection capabilities. They should (1) assess ongoing research

and development of massively multiplexed detection capabilities across the public and private sectors; (2) identify candidate technologies with the most beneficial performance characteristics for clinical applications, environmental monitoring, detection of novel pathogens by looking for conserved regions, identification of host-based biomarkers, and orthogonal detection mechanisms; (3) develop a five-year plan for funding research and development of such technologies in the public and private sectors; (4) submit an annual progress report to Congress detailing progress, current capabilities, and future directions for research and development; and (5) implement these technologies and methods within five years of enactment.

- Invest in digital pathogen surveillance. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Agriculture, Secretary of the Interior, and Secretary of Veterans Affairs to: (1) identify end-user needs for digital pathogen surveillance systems; (2) define clear performance requirements for the private sector; (3) provide incentives for the private sector to advance capabilities; (4) establish public-private partnerships with industry entities that have demonstrated pathogen surveillance capabilities; and (5) strengthen ongoing digital pathogen surveillance efforts throughout the government.
- Improve data interoperability to enhance information sharing. Congress should amend the Public Health Service Act (P.L. 78 -410) to direct the Secretary of Health and Human Services, Secretary of Defense, Secretary of Agriculture, Secretary of the Interior, and Secretary of Veterans Affairs, in coordination with the Director of National Intelligence, to develop a pathogen data interoperability plan to enhance information sharing among federal departments and agencies, the Intelligence Community, industry, academia, and nongovernmental organizations. This plan should: (1) describe the

structure of an information sharing network among these entities; (2) include data reporting standards to ensure interoperability; (3) consider the potential effects of cyberattacks and mis- and disinformation on these systems; and (4) implement this plan within one year of enactment.

- Establish a National Public Health Data System. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, Secretary of Agriculture, Secretary of Homeland Security, and Secretary of Veterans Affairs, to establish a national public health data system that expands on current data modernization efforts. They should: (1) identify all relevant and available federal, SLTT, and private sector data streams; (2) determine and build the federal and SLTT technological capabilities needed to sustain the system over time; (3) ensure ease of data entry by including end-users in the development and beta-testing process; (4) de-identify personal data and protect privacy; (5) compile and integrate relevant data streams no later than two years after enactment; (6) ensure that the System will support timely and transparent access by the public; (7) provide funding and technical support to SLTT to enable them to contribute to this system; and (8) establish the system no later than three years after enactment.
- Integrate data within the National Public Health Data System. The Secretary of Health and Human Services should develop a plan to integrate data in the National Public Health Data System, (1) describing how information will flow and how federal, SLTT, academic, and healthcare entities will gather data; and (2) setting data reporting and collection standards to ensure interoperability.
- Secure data and ensure data integrity for the National Public Health Data System. The Secretary of Health and Human Services should, in coordination with the Secretary of

Homeland Security, develop a data security and integrity plan for the National Public Health Data System, (1) describing how HHS and DHS will secure and defend the System against cyberattacks; and (2) addressing how HHS and DHS will prevent and respond to the introduction of mis- or disinformation into the System.

- Authorize the Center for Forecasting and Outbreak Analytics. Congress should amend the Public Health Service Act (P.L. 78-410) to authorize the Center for Forecasting and Outbreak Analytics.
- Assess biosurveillance capabilities across the federal government. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, Secretary of Agriculture, and Secretary of Homeland Security, and in collaboration with the national laboratories and the private sector, to (1) assess biosurveillance capabilities and relevant data streams across the government to incorporate into the Center for Forecasting and Outbreak Analytics; (2) develop effective algorithms that produce accurate forecasts for the Center; (3) request an annual review by the National Laboratories and National Academies of Sciences to help identify problems, challenges, and potential improvements, and provide technical assistance to the federal government; (4) develop an interoperability strategy for integrating data into the Center; and (5) develop plans to ensure data interoperability and integration, provide data security and integrity, prevent and respond to cyberattacks on the Center, and prevent and respond to the introduction of mis- or disinformation into the Center's data streams.
- Review adequacy of biosafety and biosecurity standards, practices, and oversight to identify gaps, needs, and upgraded approaches. The Secretary of Health and Human Services, in partnership with the Department of Defense and Department of Energy,

should request the NSABB to assess: (1) the potential for innovation in laboratory biosafety; (2) potential outcomes of those innovations; and (3) current goals for next-generation technology in laboratory biosafety. The Secretary should take no longer than 180 days to complete this assessment.

- Address laboratory biosafety and biosecurity challenges. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, to conduct an annual review of laboratory biosafety capabilities and challenges. The Secretary of Health and Human Services should direct the Director of the Centers for Disease Control and Prevention to (1) conduct this review in coordination with at least one representative from each BSL-4 laboratory in the country; (2) identify potential innovations and policies to improve laboratory biosafety; (3) articulate ongoing challenges in laboratory biosafety, especially with regard to accident prevention, accident reporting, and needed funding for accident detection; and (4) provide goals and milestones for implementing improvements. The Secretary of Health and Human Services should complete and submit the first review within 180 days of enactment.
- Develop and support implementation of a strategy to screen DNA synthesis providers and users. Congress should amend the National Science and Technology Policy, Organization, and Priorities Act of 1976 (P.L. 94-282) to direct the Director of the Office of Science and Technology Policy to develop an updated screening framework with requirements for providers and users of synthetic biology services that meet or exceed those of the current gene sequence and customer screening best practices. Congress should amend the Public Health Service Act (P.L. 78-410) to direct the Secretary of

Health and Human Services, in coordination with the Secretary of Commerce, to implement the framework.

- Require entities to purchase genetic material from verified vendors. Congress should amend the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (P.L. 116-283), the Public Health Service Act (P.L. 78-410), the Homeland Security Act (Public Law 107-296), the Agriculture Improvement Act of 2018 (P.L. 115-334), and the National Science Foundation Act of 1950 (P.L. 81-507) to require any entity receiving a federal grant or engaging in a cooperative agreement related to synthesizing DNA and RNA to purchase their materials from vendors that follow gene sequence and customer screening best practices to minimize risk and that address gene synthesis screening, customer screening, record keeping, order refusal and reporting, and regulatory compliance.

This concludes my written remarks. The Bipartisan Commission on Biodefense appreciates the Subcommittee's interest in examining and strengthening federal biodefense activities to better address future biological threats. While this subject is complicated, biological attribution is also achievable and something Congress can accomplish before the next pandemic or other biological event affecting national security occurs. I would also like to take this opportunity to thank Hudson Institute, which serves as our fiscal sponsor, and all the organizations that support our efforts financially and otherwise. With this testimony, I am submitting four of the Commission's reports (*A National Blueprint for Biodefense, Biodefense in Crisis, The Apollo Program for Biodefense,* and *The Athena Agenda*). Thank you again for inviting me to testify today. I look forward to answering your questions and working with you to defend the Nation against biological threats.