

June 13, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “The State of U.S. Public Health Biopreparedness: Responding to Biological Attacks, Pandemics, and Emerging Disease Outbreaks.”

The Subcommittee on Oversight and Investigations will hold a hearing on Friday, June 15, 2018, at 9:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled “The State of U.S. Public Health Bio-preparedness: Responding to Biological Attacks, Pandemics, and Emerging Disease Outbreaks.”

The purpose of this hearing is to follow up on the past biopreparedness oversight issues examined by the Subcommittee, and to receive updates from the agencies on current assessments and strategies. This hearing will also highlight the need to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA), which is due to expire at the end of September 2018.¹

I. WITNESSES

- Rick A. Bright, Ph.D., Director, Biomedical Advanced Research and Development Authority; Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services;
- Anne Schuchat, M.D. (RADM, USPHS), Principal Deputy Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services;
- Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health; and
- Denise Hinton (RADM, USPHS), Chief Scientist, U.S. Food and Drug Administration.

¹ PAHPA created and expanded programs to enhance the public health system’s capacity to monitor and respond to public health emergencies. The act expanded programs for state and local public health emergency preparedness activities and mandates the use of evidence-based benchmarks and standards to measure levels of preparedness. Ass’n of State and Territorial Health Orgs., *ASTHO Legal Preparedness Series Emergency Authority & Immunity Toolkit - Pandemic and All-Hazards Preparedness Act*, <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Authority-and-Immunity-Toolkit/Pandemic-and-All-Hazards-Preparedness-Act-Fact-Sheet/> (last visited June 11, 2018).

II. BACKGROUND

This section will outline four areas of continuing oversight interest in the area of biopreparedness: biological threats; detection and diagnostics; development and stockpiling of medical countermeasures (MCMs); and science, safety and security of laboratories in the life sciences-biodefense complex.

A. Biological Threats

Biological threats fall into three main categories: natural infectious diseases, synthetic biology/engineered pathogens, and bioterrorism. Synthetic biology could cause harm either intentionally (e.g., an engineered pathogen used in a bioterrorist attack) or accidentally (e.g., through the accidental release of dangerous agents from a lab conducting dual use research).²

In this century, the nation has witnessed the impacts of naturally occurring outbreaks such as influenza, Ebola, and SARS.³ Health authorities are currently monitoring other potential emerging infectious diseases that could cause a pandemic, such as the H7N9 influenza strain circulating in China.⁴ Further, as recently noted by Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) Robert Kadlec, “[t]errorist organizations such as ISIS and al-Qaida remain determined to attack; further ISIS has demonstrated no compunction about using chemical and other unconventional weapons in attacks overseas. State actors have already threatened our homeland with nuclear weapons and have shown the means to employ both chemical and biological weapons.”⁵

The Subcommittee explored the growing nature of these biological threats and the need for an elevated response at a hearing held on February 12, 2016.⁶

An attachment to this memorandum provided by the National Institute of Allergy and Infectious Diseases (NIAID) shows examples of emerging and re-emerging infectious diseases as of June 2018.

² GiveWell, *A conversation with George Poste on February 12, 2014*, <https://www.openphilanthropy.org/sites/default/files/Poste%202-12-14%20%28public%29.pdf> (last visited June 11, 2018). George Poste, DVM, PhD., is Director, Complex Adaptive Systems Institute, Arizona State University and an ex officio member of the Blue Ribbon Study Panel on Biodefense.

³ See *Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 115th Cong. (2018) (written testimony of Hon. Robert Kadlec, M.D., Assistant Sec’y for Preparedness and Response, U.S. Dep’t of Health & Human Services).

⁴ *Id.*

⁵ *Id.*

⁶ See *Outbreaks, Attacks, and Accidents: Combating Biological Threats Before the Subcomm. on Oversight and Investigations of the H. Comm on Energy and Commerce*, 114th Cong. (2016) Serial No. 114-117.

B. Detection and Diagnostics

Laboratory Response Network

The Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) is a network of 134 local, state and federal laboratories that can provide the laboratory infrastructure and capacity to quickly respond to public health emergencies, and incidents of biological and chemical terrorism. The network, established in 1999 and overseen by the CDC, enables rapid detection of and response to emerging infectious diseases such as Zika, Ebola and influenza, as well as select agents and toxins. All 50 states have at least one member laboratory and 85 percent of the U.S. population lives within a two-hour drive of an LRN lab.

The ability of the LRN to respond to quickly unfolding emergencies is essential and, as such, the network was designed to deploy rapid detection technology and laboratory tests (known as assays) to quickly test suspicious materials and detect the presence of biological or chemical agents in the event of a bioterrorism attack.

In August 2016, the Committee launched a bipartisan investigation about the current capabilities of the CDC LRN, and two additional information request letters followed on October 26, 2016, and February 28, 2017.⁷ These letters requested information regarding the LRN's lab capacity, funding levels, and laboratory test development.

In response to questions about funding for the network, the CDC provided documentation indicating that spending decreased over the last decade. The LRN's expenditures have gradually decreased from \$15 million in 2007 to \$9 million in 2016. Expenditures for the LRN totaled \$116.2 million during that 10-year period.⁸ The CDC has also at times received funding from other federal agencies to help support network activities. The Department of Homeland Security's Science and Technology Directorate, Department of Defense's Defense Threat Reduction Agency and its Joint Program Executive Office, and the Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) and Biomedical Research and Development Authority (BARDA) have each provided funding for LRN support over the last 10 years. Funding has varied year-to-year by agency, but the total amount the four agencies have provided to the LRN since Fiscal Year 2008 is \$21.5 million.⁹

⁷ Letter from Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce, et al. to Thomas Frieden, M.D., Dir., Centers for Disease Control and Prevention (Aug. 11, 2016) *available at* <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/letters/20160811CDC.pdf>; Letter from Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce and Hon. Tim Murphy, Chairman, H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations to Thomas Frieden, M.D., Dir., Centers for Disease Control and Prevention (Oct 26, 2016) (On file with the Committee); Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce and Hon. Tim Murphy, Chairman, H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations to Anne Schuchat, M.D., Acting Dir., Centers for Disease Control and Prevention (Feb. 28, 2017) *available at* <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/letters/20170228CDC.pdf>;

⁸ Letter from Anne Schuchat, M.D., Acting Dir., Centers for Disease Control and Prevention, to Hon. Greg Walden, H. Comm. on Energy and Commerce. (May 23, 2017) (On file with the Committee). In the letter to the Committee, the CDC represented that there may be additional funding sources for the LRN than those it had identified.

⁹ *Id.*

In response to questions on lab test development, the CDC provided information about the process by which it selects and develops new assays the LRN can use to detect for biological agents, toxins and emerging infectious diseases. The CDC has indicated that the Food and Drug Administration (FDA) has approved 510(k) clearances for four assays and issued emergency use authorization for another six assays.¹⁰ Out of a total of 45 select agents affecting humans on the current select agents and toxin list,¹¹ the CDC LRN has assays cleared by FDA under the 510(k) process for three, after nearly 20 years of the LRN program and more than \$135 million in funding during the last decade.¹²

Most recently, the CDC arranged for the evaluation and deployment of a Department of Defense Ebola Zaire assay by the LRN amid the 2014 Ebola epidemic in West Africa. After the 2015 Zika outbreak in Brazil, the CDC also began development of an LRN diagnostic for the Zika virus.¹³

Biosurveillance

Two areas of biosurveillance of interest to the Subcommittee have been BioWatch and multiplex point-of-care technologies (MPOCTs). BioWatch is an early warning system designed to detect a large-scale, covert attack that releases anthrax or other agents of bioterrorism into the air. Overseen by the Department of Homeland Security (DHS), the BioWatch program involves a system of aerosol collectors deployed in more than 30 cities, as well as laboratory facilities and personnel to analyze samples from these collectors. This program relies heavily on CDC, and the state and local public health laboratories that are members of the CDC LRN. The program aims to reduce the time required to recognize and characterize potentially catastrophic aerosolized attacks by monitoring for the presence of certain biological agents considered to pose high risk for an aerosolized attack. A committee investigation and a U.S. Government Accountability Office (GAO) report found that DHS lacked reliable information about BioWatch's technical capabilities to detect a biological attack and therefore lacks the basis for informed cost-benefit decisions about upgrades to the system.¹⁴ DHS continues to work on ways to upgrade the BioWatch system.

MPOCTs are technologies that can simultaneously test for more than one type of human infectious disease pathogen from a single patient sample (such as blood, urine, or sputum) in one run at or near the site of a patient. MPOCTs can enable rapid testing while the patient is at the doctor's office, clinic, or other testing location, including the home. From a homeland security and public health perspective, MPOCTs are of interest as an early detection tool, and can help assess the potential spread and effect of the disease in the case of dangerous pathogens. At the

¹⁰ *Id.*

¹¹ See Fed. Select Agent Program, *Select Agents and Toxins List*, <https://www.selectagents.gov/selectagentsandtoxinslist.html> (last visited June 11, 2018).

¹² Schuchat, *supra* note 8.

¹³ *Id.*

¹⁴ See *Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism Before the Subcom. on Oversight and Investigations of the H. Comm. on Energy and Commerce* 113th Cong. (2013) Serial No. 113-56; U.S. Gov't Accountability Office, *Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established*, GAO-16-99 (Oct. 2015) available at <https://www.gao.gov/assets/680/673309.pdf>.

Committee's request, the GAO conducted a technical assessment of MPOCTs.¹⁵ The GAO found that MPOCTs have a range of performance characteristics that describe, among other things, the ability of the technology to correctly identify the presence or absence of a pathogen. Developers identified several technical challenges to developing multiplex assays that can slow MPOCT development and raise costs. GAO also identified potential benefits of MPOCTs included improved patient health care and management, more appropriate use of antibiotics, improved ability to limit the spread of disease, and health care cost savings.

C. Development and Stockpiling of Medical Countermeasures

Public Health Emergency Medical Countermeasures Enterprise

In 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to coordinate federal efforts to prepare for, and respond to, public health emergencies from a MCM perspective.¹⁶

Pursuant to the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act, the PHEMCE is led by the ASPR and is comprised of senior leadership from the CDC, the NIAID at the National Institutes of Health (NIH), the FDA, the Department of Defense (DoD), the DHS, the Department of Veteran's Affairs (VA) and the Department of Agriculture (USDA).¹⁷

The PHEMCE's mission components include:¹⁸

- **Requirements Setting:** The PHEMCE is responsible for establishing requirements for MCMs based on factors such as threat and risk assessments, which are principally conducted by the DHS.
- **Early Stage Research:** The NIH is the lead federal PHEMCE agency for conducting and facilitating research into areas of public health concerns, which could ultimately lead to the development of MCMs to diagnose, treat, and prevent a wide-range of public health threats.
- **Advanced Development/Manufacturing:** The Biomedical Advanced Research and Development Authority (BARDA), within HHS' ASPR, develops MCMs for emerging public health threats and partners with industry to accelerate development and increase MCM manufacturing capacity. In the past decade, BARDA's efforts, supported by industry and government partnerships, have resulted in 35 FDA approvals for 31 unique

¹⁵ U.S. Gov't Accountability Office, *Medical Devices: Capabilities and challenges of technologies to enable rapid diagnoses of infectious diseases*, GAO-17-347 (Aug. 2017) available at <https://www.gao.gov/products/GAO-17-347>.

¹⁶ See 71 C.F.R. § 129 (2006) and U.S. Dep't of Health & Human Services, Assistant Sec'y for Preparedness and Response, *Public Health Emergency Medical Countermeasures Enterprise*, <https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx> (last visited June 11, 2018).

¹⁷ 42 U.S.C. § 300hh – 10.

¹⁸ U.S. Dep't of Health & Human Services, Assistant Sec'y for Preparedness and Response, *PHEMCE Mission Components*, <https://www.phe.gov/Preparedness/mcm/phemce/Pages/mission.aspx> (last updated Feb. 27, 2015).

MCMs for threats to the public health.¹⁹ BARDA has also supported the development of 27 MCMs against threats that have been identified by the DHS, through Project Bioshield, as being national security threats.²⁰

- **Regulatory Science Management:** The PHEMCE endeavors to ensure MCMs are safe and effective, which is generally the responsibility of the FDA.
- **Procurement / Inventory Management / Stockpiling:** The PHEMCE oversees the procurement and management of MCMs to respond to public health threats. Currently, the CDC and BARDA are the lead PHEMCE agencies for this mission component.
- **Response Planning, Policy, Guidance and Communication:** The PHEMCE, led by CDC and ASPR, coordinates federal medical response and communication strategies when faced with a public health emergency.
- **Deployment / Distribution / Dispensing / Administration:** The CDC and ASPR engage and coordinate with state and local partners to facilitate the distribution of MCMs and administration of other medical assets in times of public health emergencies.
- **Monitoring / Evaluation / Assessment:** The CDC and FDA are the principal PHEMCE agencies for monitoring the safety and performance of MCMs that have been deployed in response to public health emergencies response.

Concerns have been raised about the length of time it takes to classify a hazardous pathogen as a material threat and then approve the development of medical countermeasures. According to ASPR, it can take upwards of two years for the DHS to designate a pathogen as a material threat.²¹ For example, carfentanil, a highly potent form of fentanyl, was known as a weapon of mass destruction after Russian forces used it in the Moscow theatre against Chechen terrorists in 2002,²² but pharmaceutical-based agents, such as fentanyl, were only recently added as a material threat. ASPR would like to reduce the time it takes for the DHS to designate a material threat to 90-days or less.²³ After a pathogen is classified as a material threat, PHEMCE can approve the development of MCMs for a material threat. ASPR is currently considering other steps that could reduce the timeframe to approve countermeasure development while still maintaining an adequate level of input from all PHEMCE partners and experts, and hopes to devise a plan to reduce the MCM development timeframe by year's end.²⁴

¹⁹ Kadlec, *supra* note 3.

²⁰ *Id.*

²¹ Briefing by staff, U.S. Dep't of Health & Human Services, Assistant Sec'y for Preparedness and Response with staff, H.Comm. on Energy and Commerce, June 11, 2018.

²² See, e. g. Erika Kinetz and Maria Danilova, *Lethal chemical now used as a drug haunts theater hostages*, Associated Press, Oct. 8, 2016, <https://apnews.com/256605b7679d4a61bde9a8eac8906ea9>.

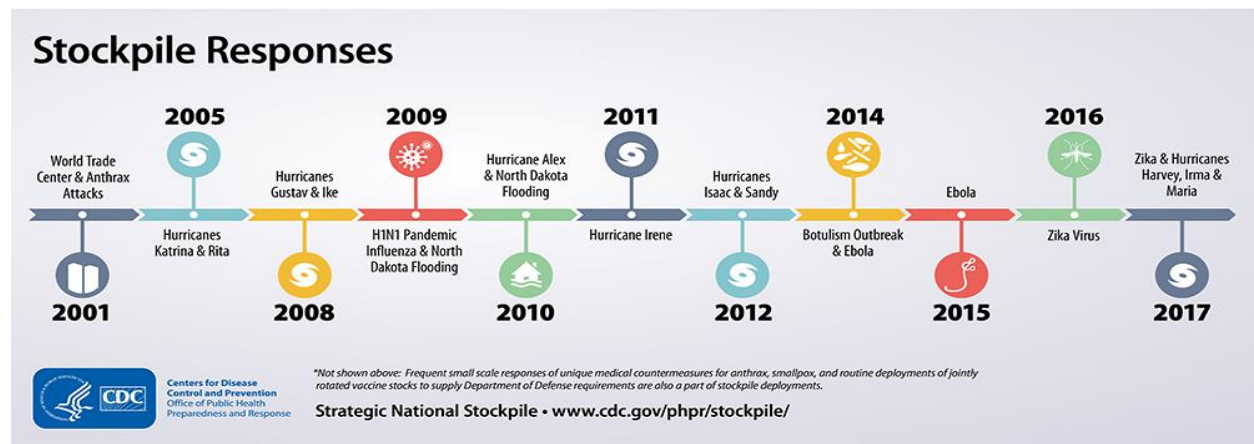
²³ Assistant Sec'y for Preparedness and Response, *supra* note 21 and E-Mail from staff, Assistant Sec'y for Preparedness to staff, H. Comm on Energy and Commerce (June 12, 2018 9:13am).

²⁴ Assistant Sec'y for Preparedness and Response, *supra* note 21.

The CDC is the primary federal agency responsible for public health surveillance, epidemiologic investigations, and public health communications. The CDC is also currently responsible for managing the Strategic National Stockpile (SNS), though the President's Fiscal Year (FY) 2019 Budget Request transfers SNS management authority from the CDC to HHS' ASPR.²⁵

The SNS is a federal repository of MCMs such as vaccines, antibiotics, and other medical supplies that are to be used in public health emergencies.²⁶ For FY 2018, the SNS received a total of \$610 million, including supplemental funding included in the omnibus spending bill passed earlier this year. Since FY 1999, the federal government has appropriated more than \$9.15 billion to the SNS, with annual SNS funding levels significantly increasing in the years following the September 11, 2001, terror attacks and 2001 anthrax attacks.²⁷

Through coordination with the PHEMCE, CDC's current responsibilities regarding the SNS include MCM procurement, shelf life analysis, and MCM replenishment. In addition, the CDC, through its Office of Public Health Preparedness and Response (OPHPR), is also responsible for the delivery of MCMs to areas that have been affected by public health emergencies. OPHPR also provides training to state and local medical personnel and public health officials on how to properly receive and distribute MCMs from the SNS in the case of a public health emergency. In 2017, OPHPR provided such training to more than 3,700 state and local personnel and led a total of 12 medical emergency simulation exercises.²⁸



Source: Centers for Disease Control and Prevention

²⁵ U.S. Dep't of Health & Human Services, Centers for Disease Control and Prevention, *Fiscal Year 2019 Justification and Estimates for Appropriation Committees*, available at <https://www.cdc.gov/budget/documents/fy2019/fy-2019-cdc-congressional-justification.pdf>.

²⁶ 42 U.S.C. § 247d-6b.

²⁷ Source: Total tabulated from tables in Congressional Research Service e-mail to staff, H. Comm. on Energy and Commerce (June 1, 2018).

²⁸ Centers for Disease Control and Prevention, *Public Health Preparedness and Response 2018 National Snapshot*, available at https://www.cdc.gov/phpr/pubs-links/2018/documents/2018_Preparedness_Report.pdf.

Over the last few years, independent audits have raised concerns over CDC's logistical management of the SNS. In June 2017, HHS' Office of Inspector General (OIG) issued a report which called into question the readiness of the CDC to effectively deploy SNS resources during a public health emergency.²⁹ In its review, OIG identified "systemic issues [that] could put at risk approximately \$7 billion of Stockpile inventory and negatively affect Stockpile readiness during a national emergency."³⁰ The OIG's conclusion was based on a review of findings from each of five SNS site audits that covered FYs 2013 and 2014, and additional information related to the value of the SNS, security, and funding.

Questions have also been raised about the SNS Division of State and Local Readiness (DSLRL), which oversees expenditures of about \$8.6 million. The DSLRL initiatives are meant to ensure that local partners have the resources and training in place to distribute and properly use products from the SNS in the event they need to be deployed. ASPR, however, has identified concerns with state and local partners' current state of readiness, specifically regarding "last mile" distribution and how quickly partners are able to distribute products on the ground after receipt from SNS.³¹ Among the concerns highlighted by ASPR is that state and local partners currently do not know what products are in the SNS and therefore do not know how to properly deploy the products.³² To improve state and local readiness, ASPR intends to bolster education and training programs so local partners and first responders have familiarity with SNS products. ASPR also intends to review assessment tools used to rank state and local partners' readiness status and to design an array of distribution models that could be implemented by local entities to improve their response plans.³³

Other issues raised regarding the CDC's management of the SNS include instances in which the CDC failed to fund the procurement of an MCM for the SNS after the MCM's development and FDA approval.³⁴ For example, there have been instances where BARDA has had to use Project Bioshield funding to procure MCMs that have been FDA-approved but were not ultimately purchased by the SNS. The reason for this was due to the fact that the government has to not only ensure that the specific MCMs remain available, but also must sustain a company since they are developing MCMs that do not have a traditional commercial market. Some of the MCMs that have been produced in this manner include: anthrax vaccine adsorbed; axibacumab; and obiltoxaximab.³⁵

Recently, members of the Blue Ribbon Study Panel on Biodefense wrote to Dr. Robert Kadlec, HHS ASPR, with a number recommendations to enhance the United States' MCM infrastructure. Included among the Panel's recommendations were proposed SNS management

²⁹ U.S. Dep't of Health & Human Services, Office of Inspector Gen., *Readiness of CDC's Strategic National Stockpile Could Be at Risk in Case of a Public Health Emergency* (A-04-16-03554) (June 2017) available at <https://oig.hhs.gov/oas/reports/region4/41603554RIB.pdf>.

³⁰ *Id.*

³¹ Assistant Sec'y for Preparedness and Response, *supra* note 21.

³² *Id.*

³³ *Id.*

³⁴ E-Mail from staff, Assistant Sec'y for Preparedness to staff, H. Comm on Energy and Commerce (June 12, 2018 4:02pm).

³⁵ *Id.*

reforms, which, according to the Panel, were precipitated by the CDC's inadequate management of the SNS.³⁶

Pursuant to the President's FY 2019 budget, the transfer of the SNS from the CDC to the ASPR will be effective October 1, 2018.³⁷ According to HHS, the benefits of moving the SNS to ASPR include that: (1) a unified command for the SNS as the reorganization will vest the MCM production and stockpiling responsibilities with a single agency; (2) ASPR's mission is more targeted than that of the CDC's, enabling it to be a better advocate for the SNS; and (3) ASPR has established relationships with state/local emergency responders, who would play a critical role in a SNS deployment.³⁸

National Pre-Pandemic Influenza Stockpile

In November 2005, the White House Homeland Security Council issued the *National Strategy for Pandemic Influenza*, designating HHS as the department to lead the nation's medical response to pandemic influenza.³⁹ According to the CDC, a pandemic influenza occurs when a new influenza A virus emerges, usually originating in animals, that is able to easily spread from person to person due to lack of effective treatments and acquired immunity.⁴⁰ The *National Strategy* also emphasized the need to ensure that the nation had an adequate MCM production capacity and stockpile to respond to potentially pandemic strains of influenza.⁴¹ The Homeland Security Council reiterated the importance of having a pre-pandemic MCM stockpile in its *National Strategy Implementation Plan*, which was released in May 2006, categorizing the pandemic threat as a national security issue.⁴²

BARDA, which was established by the Pandemic and All-Hazards Preparedness Act, is responsible for the procurement and management of the nation's pre-pandemic influenza stockpile as well as the development of influenza MCMs. BARDA is also tasked with accelerating the development and procurement of MCMs related to chemical, biological, radiological, and nuclear threats as well as threats related to emerging infectious diseases.⁴³

³⁶ Letter from the Blue Ribbon Study Panel on Biodefense to Hon. Robert Kadlec, M.D., Assistant Sec'y for Preparedness and Response, U.S. Dep't of Health & Human Services (May 15, 2018) (on file with the Committee).

³⁷ U.S. Dep't of Health & Human Services, *Fiscal Year 2019 Public Health and Social Services Emergency Fund Justification of Estimates for Appropriations Committee*, available at <https://www.hhs.gov/sites/default/files/fy-2019-phssef-cj.pdf>.

³⁸ *Id.*

³⁹ Executive Office of the President of the United States, Homeland Security Council, *National Strategy for Pandemic Influenza*, Nov. 2005 available at <https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-strategy-2005.pdf>.

⁴⁰ Centers for Disease Control and Prevention, *Influenza (Flu) Questions and Answers*, available at <https://www.cdc.gov/flu/pandemic-resources/basics/faq.html> (last updated May 15, 2017).

⁴¹ Executive Office of the President, *supra* note 39.

⁴² Executive Office of the President of the United States, Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan*, May 2006 available at <https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-implementation.pdf>.

⁴³ 42 U.S.C. § 247d-7e.

In June 2017, and at the Committee's urging,⁴⁴ HHS issued an update to its *Pandemic Influenza Plan*, which was initially published in 2005 and had been last updated in 2009.⁴⁵ In the 2017 update, HHS stated that the national pre-pandemic influenza stockpile "satisfies requirements for vaccine and adjuvants to address influenza viruses that are assessed to be the highest risk for human infection."⁴⁶ BARDA, in collaboration with other HHS agencies, utilizes CDC's Influenza Risk Assessment Tool (IRAT) to assess pandemic risks that are associated with emerging novel influenza viruses and make determinations regarding a potential update to the pre-pandemic stockpile or the development of new vaccine candidates.⁴⁷

CARB-X

CARB-X is a non-profit public-private partnership dedicated to accelerating antibacterial research to tackle the global rising threat of drug-resistant bacteria.⁴⁸ With more than \$500 million to invest between 2016 and 2021, CARB-X funds the research and development of new antibiotics, vaccines, rapid diagnostics and other life-saving products to tackle the global threat of drug-resistant bacteria. CARB-X was created in response to the U.S. government's 2015 Combating Antibiotic Resistant Bacteria (CARB) initiative, and the United Kingdom's government's call in 2016 for concerted global effort to address the growing drug-resistance public health crisis. Launched on July 28, 2016, CARB-X is a cooperative effort between BARDA and the NIAID. CARB-X is funded by BARDA and Wellcome Trust, the world's largest medical charity which is based in the U.K.

D. Science, Safety and Security of Laboratories in the Life Sciences-Biodefense Complex

Currently, there are about 1,200 high-containment laboratories in the U.S. conducting research on diagnostics and cures for highly dangerous pathogens. For more than a decade, the Subcommittee has held hearings and conducted investigations related to the Federal Select Agent Program, including on the safe handling of federal select agents and other dangerous pathogens.

Federal Select Agent Program

The Federal Select Agent Program regulates the possession, use, and transfer of biological select agents and toxins to ensure laboratory research conducted on the materials is done in a safe and secure manner. Sixty-six select agents and toxins that could potentially be

⁴⁴ See Letter from the Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, et al., to Hon. Thomas Price, M.D., Sec'y, U.S. Dep't of Health & Human Services (Apr. 20, 2017), available at <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170420HHS.pdf>.

⁴⁵ U.S. Dep't of Health and Human Services, *Pandemic Influenza Plan 2017 Update* (last visited June 7, 2018) available at <https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf>.

⁴⁶ *Id.*

⁴⁷ See Letter from Hon. Nicole Lurie, M.D., Assistant Sec'y for Preparedness and Response, U.S. Dep't of Health & Human Services to Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce (Mar. 15, 2016) available at <https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/letters/20160229HHS%20Response.pdf>.

⁴⁸ CARB-X, *About CARB-X*, <https://carb-x.org/about/overview/> (last visited June 11, 2018).

used in bioterrorist attacks – including anthrax, smallpox, and plague – are currently regulated through the program. Managed jointly by HHS and the USDA, the program provides oversight of more than 275 entities that have registered through the program in order to conduct research on the hazardous pathogens.⁴⁹

The Federal Select Agent Program was established in 1996 through the passage of the Antiterrorism and Effective Death Penalty Act. The law, passed in the aftermath of the Oklahoma City bombing, required HHS to identify a list biological agents and toxins that could threaten public health and safety and establish regulations regarding the transfer of those agents. The September 11, 2001, terrorist attacks and the 2001 anthrax mailings led to increased concern about the threat of bioterrorism attacks, and additional restrictions which banned certain individuals from transporting or receiving select agents were included in the USA Patriot Act of 2001.⁵⁰ Congress expanded the program through the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to include regulation of the transfer and the use and possession of select agents and increased safeguards and security requirements.

Concerns raised by the mishandling of dangerous pathogens prompted the Committee to request an assessment of the select agent program by the GAO. In response to the Committee's request, the GAO reviewed oversight procedures of the select agent program and issued a report in October 2017 that highlighted deficiencies in the program's capabilities.⁵¹ The report raised concerns about potential conflicts of interest as the select agent program is not independent from all the laboratories it oversees. The report also noted that the program has historically focused more on security and preventing thefts of select agents and toxins than on biological safety issues within the labs using the pathogens for research. The Subcommittee, which has held multiple hearings on the select agent program and safety lapses at federal labs, questioned USDA and CDC officials about the GAO report's conclusions and recommendations at a November 2, 2017, hearing.⁵²

Prioritizing lab science and safety

Following the 2014 incidents involving anthrax mishandling at the CDC and the smallpox discovered in storage for an FDA lab on the NIH campus, federal efforts intensified to improve the management of government labs. In particular, an external scientific working group recommended improvements to the CDC and FDA for overhauling their lab safety programs. This included the recommendation that a program director would be a single point of accountability and would have a direct reporting relationship to the head of the agency. When Stephan S. Monroe, the CDC's Associate Director for Laboratory Science and Safety (ADLSS), testified before the Subcommittee in April 2016, he said the formation of the director position

⁴⁹ Federal Select Agent Program, *About Us*, <https://www.selectagents.gov/about.html> (last visited June 11, 2018)

⁵⁰ See USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).

⁵¹ U.S. Gov't Accountability Office, *Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, GAO-18-145 (Oct. 2017) available at <https://www.gao.gov/assets/690/687868.pdf>.

⁵² See *Concerns Over Federal Select Agent Program Oversight of Dangerous Pathogens Before the Subcom. on Oversight and Investigations of the H. Comm. on Energy and Commerce 115th Cong.* (2017) available at <https://docs.house.gov/meetings/IF/IF02/20171102/106574/HHRG-115-IF02-Transcript-20171102.pdf>.

was “the most fundamental change implemented in the wake of the 2014 incidents.”⁵³ Further, Dr. Monroe noted that the fact that the ADLSS reported directly to the CDC director provided “high-level oversight and coordination of critical laboratory policies and operations” across all CDC campuses.

In response to the 2014 safety lapses,⁵⁴ the FDA’s Office of Laboratory Science and Safety (OLSS) was formed in order to provide oversight and to improve security and safety across all divisions of FDA. The formation of the office was announced in 2016 as a means to consolidate oversight responsibilities and standard policies for all FDA laboratories. In 2017, the FDA issued a strategic plan outlining the goals of the new office.

According to the OLSS strategic plan, the office’s mission is to:

- Ensure FDA’s laboratories and workplaces are operated in a safe and secure manner to protect employees, the surrounding communities, and the environment;
- Research and disseminate innovative ideas and validated methods for safe and secure laboratory practices;
- Support high-quality (i.e., accurate, reliable, and timely) FDA laboratory results; and
- Promote a culture of shared responsibility and safety.⁵⁵

Just as the ADLSS was organized to directly report to the CDC Director, the OLSS was also envisioned to directly report to the FDA Commissioner. A reorganization issued by the FDA in 2017 made the OLSS a direct report to the FDA Commissioner.⁵⁶ However, the FDA now plans to have the OLSS report to the Office of the Chief Scientist instead of directly to the Commissioner.⁵⁷

In addition, the budget and staffing for the OLSS have not been consistent. In 2016, the FDA informed the Committee that the office’s budget for FY 2017 was \$5.2 million and that it would support 13 full time employees.⁵⁸ FDA officials subsequently told Committee staff that the FY 2017 budget for OLSS was \$9 million, but that funding levels would support not just

⁵³ *Laboratory Safety at the Centers for Disease Control and Prevention Before the Subcomm. on Oversight and Investigations of the H. Comm on Energy and Commerce*, 114th Cong. (2016) (written testimony of Hon. Stephan S. Monroe, PhD., Assoc. Dir. for Laboratory Science and Safety, Centers for Disease Control and Prevention) available at <https://docs.house.gov/meetings/IF/IF02/20160420/104823/HHRG-114-IF02-Wstate-MonroeS-20160420.pdf>.

⁵⁴ Brady Dennis and Lena H. Sun, *FDA found more than smallpox vials in storage room*, WASH. POST, July 16, 2014, https://www.washingtonpost.com/national/health-science/fda-found-more-than-smallpox-vials-in-storage-room/2014/07/16/850d4b12-0d22-11e4-8341-b8072b1e7348_story.html.

⁵⁵ U.S. Food and Drug Admin., 2017-2022 Operating Model – *Office of Laboratory Science and Safety*, Updated Oct. 13, 2017, available at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/OLSS/UCM583016.pdf>.

⁵⁶ See 82 Fed. Reg. 34540 (July 25, 2017) available at <https://www.federalregister.gov/documents/2017/07/25/2017-15564/office-of-the-commissioner-statement-of-organization-functions-and-delegations-of-authority>.

⁵⁷ Briefing by staff, U.S. Dep’t of Health & Human Services, U.S. Food and Drug Admin. with staff, H. Comm. on Energy and Commerce, June 11, 2018.

⁵⁸ Letter from Dayle Cristinzio, Acting Assoc. Comm’r for Legislation, U.S. Food and Drug Admin., to Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce. (Sept. 9, 2016) (On file with the Committee).

OLSS operations (including staff and contractor support) but also the Employee Safety and Environmental Management staff that were transferred to OLSS.⁵⁹ The FDA later informed the Committee that no permanent full-time employees (FTE) were hired by OLSS in FY 2017, rather the office recruited 19 individuals through temporary detail assignments and contract support.⁶⁰ In a briefing with Committee staff, the FDA confirmed that the office's FY 2018 budget is \$5.6 million and the FY 2019 budget is \$6 million.⁶¹ The office currently employs three FTEs and three contractors. At this time, FDA has not reported the total number of FDA laboratories to the Committee staff. FDA has not yet reported to the Committee the number of audits that OLSS has conducted.

By contrast, the CDC's ADLSS office's FY 2016 budget was \$14.5 million and supported 34 FTEs.⁶² As of this month, the office had 43 FTEs with three slots vacant and oversaw audits of laboratories used by 239 teams of scientists.⁶³ The CDC recently reported to Committee staff that it had submitted a proposed reorganization to the Department that would eliminate the Associate Director's direct reporting relationship to the Director, and instead would report to a Deputy Director.⁶⁴

III. ISSUES

The following issues may be examined at the hearing:

- How timely are the PHEMCE decisions regarding biological threats being made? Can the timeliness of these decisions be improved?
- How can the number of FDA-approved assays for threat agents be increased?
- Is there adequate oversight to ensure the efficacy of MCMs in the SNS and the pre-pandemic vaccine stockpile?
- Are U.S. public health agencies implementing recommendations to improve laboratory science and safety?

⁵⁹ E-Mail from staff, U.S. Food and Drug Admin. to staff, H.Comm. on Energy and Commerce (May 17, 2017, 3:57pm) (On file with the Committee).

⁶⁰ E-mail from staff, U.S. Food and Drug Admin. to staff, H. Comm. on Energy and Commerce (Aug. 20, 2017, 12:50pm) (On file with the Committee).

⁶¹ U.S. Food and Drug Admin., *supra* note 57.

⁶² Letter from Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce and Hon. Tim Murphy, Chairman, H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations to Hon. Robert M. Califf, M.D. Comm'r, U.S. Food and Drug Admin. (May 18, 2016) (citing E-mail from staff, Centers for Disease Control and Prevention to staff, H. Comm. on Energy and Commerce (Apr. 15, 2016)) (On file with the Committee).

⁶³ Briefing by staff, U.S. Dep't of Health & Human Services, Centers for Disease Control and Prevention with staff, H. Comm. on Energy and Commerce, June 8, 2018.

⁶⁴ *Id.*

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Christopher Santini, or Andrea Noble of the Committee staff at (202) 225-2927.

Global Examples of Emerging and Re-Emerging Infectious Diseases

