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BIODEFENSE

The Nation Faces Long-Standing Challenges Related to Defending Against Biological Threats

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Chairman Lynch, Ranking Member Hice, and Members of the Subcommittee:

I am pleased to be here today to discuss our work on long-standing biodefense challenges. Catastrophic biological events have the potential to cause loss of life and sustained damage to the economy, societal stability, and global security. Among those biological threats is the unpredictable nature of naturally-occurring disease, which could affect human and animal health and agricultural security. Further, while the revolution in biotechnology presents opportunities to advance the life sciences, that same technology in the wrong hands could be used to create crippling biological weapons. For example, according to the Blue Ribbon Study Panel on Biodefense, nonstate actors such as terrorist organizations, domestic militia groups, and "lone wolves" have both the interest and capacity to develop biological weapons.[1] Thus, the scientific community must safeguard the biological agents it uses to assess threats and must protect laboratory workers and the population at large from the intentional or accidental release of dangerous pathogens during the pursuit of more knowledge about them.

The biological threat landscape is vast and requires a multidisciplinary approach. The biodefense enterprise is the whole combination of systems at every level of government and the private sector that contribute to protecting the nation and its citizens from potentially catastrophic effects of a biological event. It is composed of a complex collection of federal, state, local, tribal, territorial, and private resources, programs, and initiatives designed for different purposes and dedicated to mitigating various risks, both natural and intentional. We have reported that complex interagency and intergovernmental efforts can benefit from developing a national strategy. In addition, we reported that interagency and intergovernmental activities can benefit from the leadership of a single entity with sufficient time, responsibility, authority, and resources needed to provide assurance that the federal programs are well coordinated, and that gaps and duplication in capabilities are avoided. Recognizing the fragmentation and the need for an integrated strategy to address biodefense challenges, in March 2011 we reported that reducing fragmentation in the biodefense enterprise could provide confidence that the nation is prepared to prevent, detect, and respond to biological

[1]*A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. Bipartisan Report of the Blue Ribbon Study Panel on Biodefense (Washington, D.C.: Hudson Institute, October 2015).

attacks with potentially devastating consequences in terms of loss of life, economic damage, and decreased national security.[2] At that time, we reported that while some high-level biodefense strategies have been developed, there was no broad, integrated national strategy that encompassed all stakeholders with biodefense responsibilities to guide the systematic identification of risk; assess resources needed to address those risks; and prioritize and allocate investment across the biodefense enterprise. Since that time, others, including the Congress, have also called for the development of a national biodefense strategy.[3]

In September 2018, in response to a statutory requirement in the National Defense Authorization Act For Fiscal Year 2017, the White House released the National Biodefense Strategy and National Security Presidential Memorandum-14 (NSPM-14), which establishes a governance structure to guide the strategy's implementation.[4] Part of the governance structure includes the creation of a Biodefense Steering Committee chaired by the Secretary of Health and Human Services. The other members of the Committee include the Attorney General, the Secretaries from the Departments of State, Defense (DOD), Agriculture (USDA), Veterans Affairs (VA), Homeland Security (DHS), and the Administrator of the Environmental Protection Agency (EPA). The steering committee is responsible for monitoring and coordinating the implementation of the Strategy. The National Defense Authorization Act also included a provision for us to review the strategy, and we have ongoing work in this area.

We reported on a wide range of biodefense-related issues in which we have examined the threat of biological terrorism and specific surveillance programs and activities aimed to identify emerging infectious diseases carried out by multiple federal departments and agencies. Since 2009, we have identified broad, cross-cutting issues in leadership, coordination,

[2]GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue,* GAO-11-318SP (Washington, D.C.: Mar 1, 2011).

[3]The National Defense Authorization Act for Fiscal Year 2017 also called for the development of a national biodefense strategy. Pub. L. No. 114-328, §1086, 130 Stat. 2000, 2423 (2016) (codified at 6 U.S.C. § 104).

[4]Pub. L. No. 114-328, §1086(e), 130 Stat. at 2424 (codified at 6 U.S.C. § 104(e)).

and collaboration that arise from working across the complex interagency, intergovernmental, and intersectoral biodefense enterprise.[5]

As such, this statement describes a range of ongoing challenges to building and maintaining the nation's biodefense, as well as the new National Biodefense Strategy which is intended to help address them. These include challenges related to (1) threat determination, (2) situational awareness and data integration, (3) biodetection technologies, (4) biological laboratory safety and security, and (5) emerging infectious disease surveillance. The statement is based on our prior work issued from December 2009 through March 2019 on various biological threats and biodefense efforts, and selected updates related to our 2015 work on DHS's BioWatch Program.[6]

To conduct our prior work, we reviewed reports from the bipartisan Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Center), relevant presidential directives, laws, regulations, policies, strategic plans, and other reports; surveyed states; and interviewed federal, state, and industry officials, among others. Selected updates were obtained in the course of follow-up on prior recommendations from 2015. More information on our scope and methodology can be found in each of the reports cited throughout this

[5]GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing*, GAO-10-171 (Washington, D.C.: Dec. 18, 2009); GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader*, GAO-10-645 (Washington, D.C.: June 30, 2010); GAO, *Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy*, GAO-12-55 (Washington, D.C.: Oct. 31, 2011); GAO, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810 (Washington, D.C.: Sept. 10, 2012); GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry*, GAO-13-424 (Washington, D.C.: May 21, 2013), which discusses the Department of Agriculture's efforts to better detect and control new or reemerging diseases in animals; GAO, *Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center*, GAO-15-793 (Washington, D.C.: Sept. 24, 2015); GAO, *Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established*, GAO-16-99 (Washington, D.C.: Oct. 23, 2015). GAO, *Biodefense: The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance,* GAO-16-547T (Washington, D.C.: Apr. 14, 2016). GAO, Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks GAO-17-445, (Washington, D.C.: May 23, 2017).

[6]GAO-16-99. DHS's BioWatch program aims to provide early indication of an aerosolized biological weapon attack.

statement. The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Nation Faces Ongoing Challenges Across the Biodefense Enterprise

Our past work has identified five key challenges related to the nation's ability to detect and respond to biological events that transcend what any one agency can address on its own. They include: (1) enterprise-wide threat determination, (2) situational awareness and data integration, (3) biodetection technologies, (4) biological laboratory safety and security, and (5) emerging infectious disease surveillance. The complexity and fragmentation of roles and responsibilities across numerous federal and nonfederal entities presents challenges to ensuring efficiency and effectiveness across the entire biodefense enterprise. In September 2018, the White House issued the National Biodefense Strategy and through NSPM-14 established a governance structure to guide its implementation. The activities and responsibilities assigned to the interagency governance body by the strategy and NSPM-14 may create new opportunities to make progress on these longstanding and complex issues. However, because implementation of the Strategy and NSPM-14 are in early stages, it remains to be seen how or to what extent they are able to do so. We have ongoing work assessing the strategy and early efforts to implement it. We plan to report in fall 2019.

Enterprise-Wide Threat Determination Needed to Help Leverage Resources and Inform Resource Tradeoffs

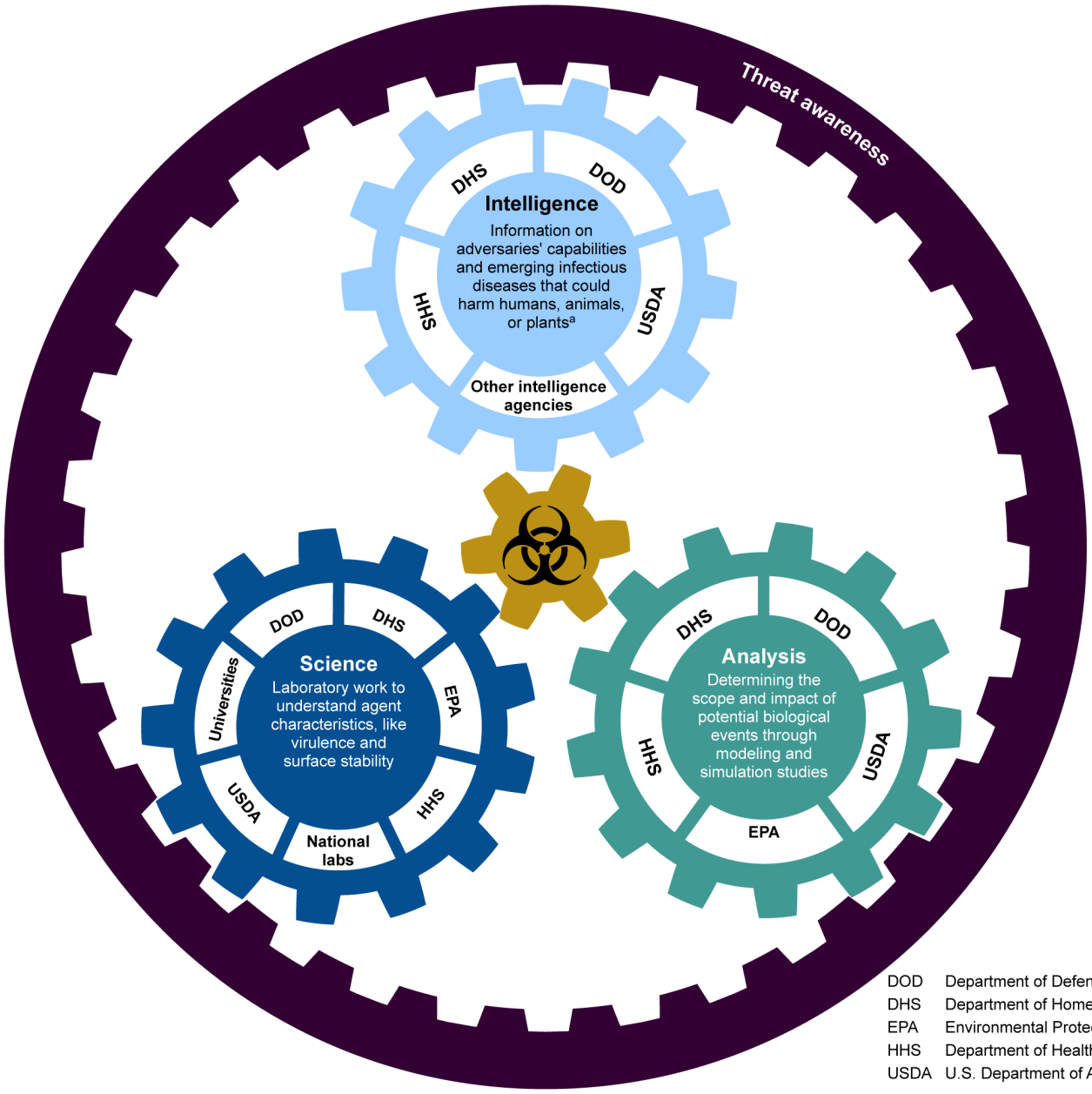
We reported in October 2017 that opportunities remain to enhance threat awareness across the entire biodefense enterprise, leverage shared resources, and inform budgetary tradeoffs among various threats and agency programs.[7] As depicted in figure 1, we reported in October 2017 that key biodefense agencies, including DHS, DOD, HHS, USDA, and EPA, rely on intelligence and global surveillance information, scientific study of disease agent characteristics, and analysis to better understand threats and help make decisions about biodefense investments.[8] These activities are often conducted to support the agencies' mission or to understand a specific threat.[9]

[7]*GAO, Biodefense: Federal Efforts to Develop Biological Threat Awareness,* GAO-18-155 (Washington, D.C.: Oct. 11, 2017). We did not make recommendations in this report, because we saw the development of a national strategy, which was required by law at that time, created an opportunity to institutionalize mechanisms to help the nation make the best use of limited biodefense resources, to include broader shared threat awareness to inform opportunities to leverage resources.

[8]Ibid.

[9]An example of a specific threat awareness activity: DHS's Bioterrorism Risk Assessment is a dedicated effort to identify and assess the risk of biological events that stem from nonstate actors intentionally seeking to harm U.S. interests using biological agents. By design, it is focused on the consequences and likelihood of terrorist events threatening human health, and, there is no similar comprehensive mechanism in place that integrates threat awareness information for all potentially destabilizing biological threats.

Figure 1: Three Components of Threat Awareness

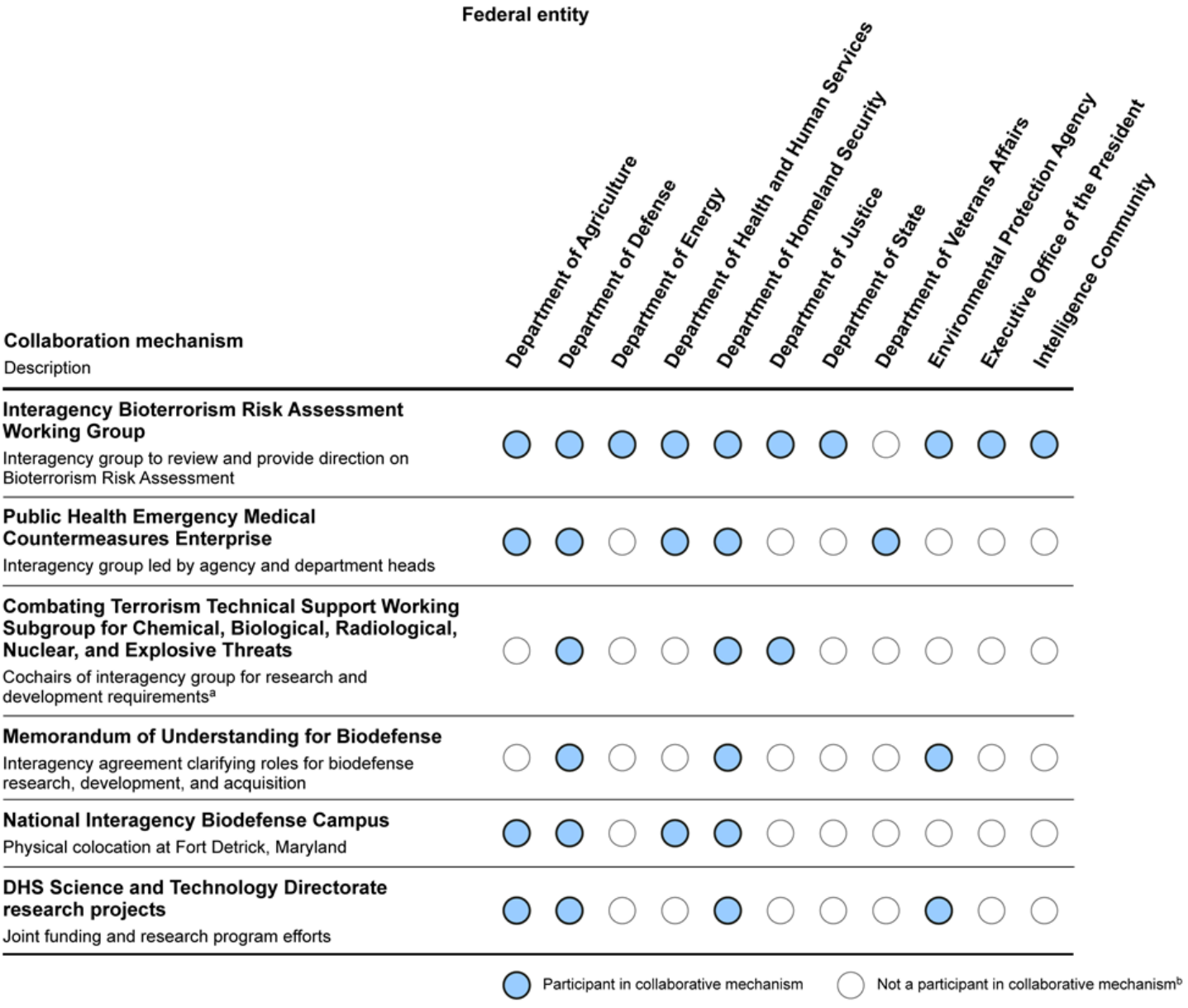


Source: GAO analysis of agency information. | GAO-19-635T

[a]Epidemic intelligence on naturally-occurring global disease events—performed by agencies like HHS and USDA—relies on the analysis of open source global disease surveillance information. This is a separate function and mission from the information collection activities by the Intelligence Community on adversaries' capabilities to cause harm using a biological weapon.

Additionally, to facilitate collaboration among government partners, federal agencies with key roles in biodefense share biological threat information through many different mechanisms including interagency bodies, working groups at the agency and executive level, formalized agreements, colocation, joint projects and funding efforts, and shared expertise (see figure 2).

Figure 2: Examples of Collaboration Mechanisms for Biodefense and Threat Awareness



Source: GAO analysis of agency information. | GAO-19-635T

[a]Subgroup members include senior representatives from the White House and 17 federal entities as well as state and local agencies.

[b]For illustrative purposes only. Nonparticipation is not intended to denote a deficiency.

The collaborative mechanisms in which the key agencies in our October 2017 review participated may facilitate information sharing in support of specific federal activities and in individual programs, or in response to specific biological events after they begin to unfold. However, as we reported in October 2017, there was no existing mechanism that could leverage threat awareness information to direct resources and set budgetary priorities across all agencies for biodefense. The nation faces many biological threats, including naturally occurring diseases that affect human, animal, and plant health, and biological weapons used by state or nonstate actors. Without a mechanism that is able to assess the relative risk from biological threats across all sources and domains, the nation may be limited in its ability to prioritize resources, defenses, and countermeasures against the most pressing threats.

The Strategy and NSPM-14 outline requirements for participating agencies that lay the ground work for a more systematic, cross-government examination of existing programs. The effort offers the potential for the nation to progress toward more integrated and enterprise-wide threat awareness and to use that information to identify opportunities to leverage resources, but this will take time and entails a change in the way participating agencies have traditionally operated. Because implementation of the strategy is in its early stages, it is too soon to assess how, if at all, it might address this challenge.

Ongoing Challenges to Fulfill Enhanced Situational Awareness and Data Integration Requirements

We have reported that DHS's National Biosurveillance Integration Center (NBIC), which was created to integrate data across the federal government with the aim of enhancing detection and situational awareness of biological events, has suffered from long-standing issues related to its clarity of purpose. In 2009, we reported that some of NBIC's partners were not convinced of the value that working with NBIC provided because NBIC's mission was not clearly articulated. We also reported that NBIC was not fully equipped to carry out its mission because it lacked key resources—data and personnel—from its partner agencies, which may have been at least partially the result of collaboration challenges it faced.[10] In the 2009 report, we recommended that NBIC develop a strategy for addressing barriers to collaboration and develop accountability mechanisms to monitor these efforts. DHS agreed, and in

[10]GAO, Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing, GAO-10-171 (Washington, D.C.: Dec. 18, 2009).

August 2012 NBIC issued the NBIC Strategic Plan, to provide its strategic vision, clarify the center's mission and purpose, and articulate the value that NBIC seeks to provide to its partners, among other things.[11] In September 2015, we reported that despite NBIC's efforts to collaborate with interagency partners to create and issue a strategic plan that would clarify its mission and efforts, a variety of challenges remained.[12] We identified options for policy or structural changes that could help a federal data integrator like NBIC better fulfill its mission, given the complexity and difficulty inherent in achieving truly integrated situational awareness that makes new meaning out of disparate data, but we did not make specific recommendations.

The National Biodefense Strategy identified biosurveillance data integration among several information sharing activities that need to be enhanced. Interagency attention to the goals, opportunities, and challenges of enterprise-wide data integration offers the potential for the nation to better define what kind of integrated situational awareness is possible, what it will take to effectively and efficiently achieve it, and what value it has. However, it remains to be seen how or whether the interagency efforts to implement the Strategy will be able to address ongoing situational awareness and data integration challenges.

Challenges Determining Optimal Biodetection Technology Solutions

BioWatch

Since 2012, we have reported that DHS has faced challenges in clearly justifying the need for the BioWatch program and its ability to reliably address that need (to detect aerosolized biological attacks).[13] In September 2012, we found that DHS approved a next-generation BioWatch acquisition in October 2009 without fully developing knowledge that would help ensure sound investment decision making and pursuit of optimal solutions. We recommended that before continuing the

[11]See U.S. Department of Homeland Security, *National Biosurveillance Integration Center Strategic Plan*, Washington, D.C.: Aug. 2012.

[12]GAO, *Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center*, GAO-15-793 (Washington, D.C.: Sept. 24, 2015).

[13]GAO-12-810.

acquisition, DHS reevaluate the mission need and possible alternatives based on cost-benefit and risk information. DHS concurred and in April 2014, canceled the acquisition because an alternatives analysis did not confirm an overwhelming benefit to justify the cost. DHS continues to rely on the currently-deployed BioWatch system for early detection of an aerosolized biological attack, but in 2015 we found that DHS lacked reliable information about the current system's technical capabilities to detect a biological attack, in part because DHS had not developed technical performance requirements for the system.[14] We reported in September 2015 that DHS commissioned tests of the current system's technical performance characteristics, but without performance requirements, DHS could not interpret the test results and draw conclusions about the system's ability to detect attacks.

At the time of our report in October 2015, DHS was considering upgrades to the Gen-2 system, but we recommended that DHS not pursue upgrades until it establishes technical performance requirements to meet a clearly defined operational objective and assesses the system against these performance requirements. DHS concurred and reported it was working to address the recommendation. DHS has since begun to aquire a different type of biodetection system, BioDetection 21 (or BD21), intended to replace BioWatch. BD21 is currently in a pilot phase; therefore we cannot yet determine how it will be implemented in the future or what decisions DHS will ultimately make regarding the existing BioWatch system.

Multiplex Point-of-Care Technologies

In August 2017, we reported that from a homeland security and public health perspective, threats of bioterrorism, such as anthrax attacks, and high-profile disease outbreaks, such as Ebola and emerging viruses like dengue, chikungunya, and Zika, highlight the continued need for diagnostic tests that provide early detection and warning about biological threats to humans.[15] Multiplex point-of-care technologies 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.[16] Multiplex point-of-

[14]GAO-16-99.

[15]GAO, *Medical Devices: Capabilities and Challenges of Technologies To Enable Rapid Diagnoses of Infectious Diseases,* GAO-17-347 (Washington, D.C.: Aug. 14, 2017).

[16]One run means that the user prepares and inserts one sample into the device and later receives an output with results of tests for more than one human infectious disease. Within the device, multiple tests may be run in parallel or sequence.

care technologies can be used for diagnosing different diseases, including more common diseases such as influenza, emerging infectious diseases, or diseases caused by select agents in minutes to a few hours.

We further reported that, while potential benefits of these technologies include more appropriate use of antibiotics and improved ability to limit the spread of disease, among others, developers and users disagreed on the strength of evidence showing the extent of multiplex point-of-care technologies' improvement on patient outcomes and identified the need for more clinical studies to establish the benefits of these technologies. Additionally, implementation challenges include lack of familiarity with such technologies, cost considerations, false positive results for rare diseases, and the challenges related to the regulatory review process for developers to get approval or clearance to market their technologies.[17]

The National Biodefense Strategy and its interagency governing leadership offer the potential for the nation to better define the role of detection technologies in a layered national biodefense capability to help those that pursue these technologies better articulate the mission needs and align requirements and concepts of operation accordingly. Because implementation of the strategy is in its early stages, it remains to be seen how or whether the interagency will be able engage on this issue in a way that helps to drive informed investment tradeoff decisions about technology alternatives.

Continued Oversight Needed to Enhance Biological Laboratory Safety and Security

Addressing Safety Lapses at Laboratories

We—along with Congress and various federal committees—have, for many years, identified challenges and areas for improvement related to the safety, security, and oversight of high-containment laboratories. These laboratories conduct research on hazardous pathogens—such as the Ebola virus and the bacteria that causes anthrax—and toxins that may pose a serious threat to humans, animals, or plants. In 2008 and

[17]We did not make recommendations as part of this work. The focus of our technology assessments is to provide foresight on key technologies and the policy implications for the federal government.

2009, we found a proliferation of high-containment laboratories across the United States, with the number of such laboratories in the government, academic, and private sectors increasing since 2001.[18] We recommended that the National Security Advisor name an entity charged with government-wide strategic evaluation of high-containment laboratories. National Security Staff disagreed with this recommendation. After reporting on these issues again in 2013, the Office of Science and Technology Policy implemented this recommendation.[19] In January 2013, we also found that, for the subset of these laboratories subject to federal oversight, the oversight was duplicative, fragmented, and dependent on self-policing.[20] We recommended that HHS's Centers for Disease Control and Prevention and USDA's Animal and Plant Health Inspection Service work with DHS and DOD to coordinate inspections and ensure consistent application of inspection standards; the departments generally agreed with our recommendations and noted various actions they had already taken, or planned to take, to coordinate inspection efforts, such as conducting joint inspections.

More recently, in response to reported lapses in laboratory safety at HHS and DOD in 2014 and 2015, we examined how federal departments oversee their high-containment laboratories. In March 2016, we found that most of the 8 departments and 15 agencies that we reviewed had policies that were not comprehensive or were not up to date.[21] Also, while the departments and agencies we reviewed primarily used inspections to oversee their high-containment laboratories, some of them were not routinely reporting inspection results, laboratory incidents, and other oversight activities to senior officials. We made 33 recommendations in total, including that departments develop and update policies to include missing elements and ensure that oversight activity results are reported to

[18]GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009) and *High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T (Washington, D.C.: Oct. 4, 2007).

[19]*High-Containment Laboratories: Assessment of the Nation's Need is Missing*, GAO-13-466R (Washington, D.C.: Feb. 25, 2013)

[20]GAO, *Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program*, GAO-13-154 (Washington, D.C.: Jan. 31, 2013), GAO-09-574, and GAO-08-108T.

[21]GAO, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, GAO-16-305 (Washington, D.C.: Mar. 21, 2016).

senior officials. To date, 12 of the 33 recommendations have been implemented—including updating policies and reporting requirements. We continue to monitor agency progress in implementing the 21 that remain open.

In response to several incidents involving the shipment of improperly inactivated pathogens, in August 2016 we reported on issues related to the inactivation of pathogens in high-containment laboratories and found that both the science and the federal guidance around pathogen inactivation are limited and inconsistently implemented.[22] Additionally, we found that federal officials did not know how many incomplete inactivation incidents have occurred because laboratories do not have to identify them in incident reports, and are only required to report incidents involving certain pathogens. We made 11 recommendations to HHS and USDA that they improve the oversight of inactivation by revising reporting forms, improving guidance for development and validation of inactivation protocols, and developing consistent criteria for enforcement of incidents involving incomplete inactivation. To date, 6 of the 11 recommendations have been addressed and we continue to monitor the 5 that remain open.[23]

Safety lapses continued to occur at laboratories in the United States that conduct research on hazardous pathogens, raising concern about the efficacy of federal oversight. In October 2017, we found that the Federal Select Agent Program—jointly managed by HHS and USDA—oversees laboratories' handling of certain hazardous pathogens known as select agents, but the program does not fully meet all key elements of effective oversight.[24] For example, the Federal Select Agent Program was not independent from all laboratories it oversees, and it had not assessed risks posed by its current structure or the effectiveness of its mechanisms to reduce organizational conflicts of interest. We made 11

[22]GAO, *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*, GAO-16-642 (Washington, D.C.: Aug. 30, 2016) and GAO, *High-Containment Laboratories: Actions Needed to Mitigate Risk of Potential Exposure and Release of Dangerous Pathogens*, GAO-16-871T (Washington, D.C.: Sept. 23, 2016).

[23]For example, HHS and USDA updated reporting forms to include incomplete inactivation as a type of incident and issued updated regulations and guidance that included clear definitions of inactivation and a validated inactivation procedure.

[24]GAO, *High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, GAO-18-145 (Washington, D.C.: Oct. 19, 2017).

recommendations for the Federal Select Agent Program, including to (1) assess risks from its current structure and the effectiveness of its mechanisms to reduce conflicts of interest and address risks as needed, (2) assess the risk of activities it oversees and target reviews to high-risk activities, and (3) develop a joint workforce plan; to-date, 5 of 11 recommendations have been addressed and we continue to monitor the progress for the 6 that remain open.

DOD's Biosafety and Biosecurity Program

In September 2018 we found that DOD had made progress by taking a number of actions to address the 35 recommendations from the Army's 2015 investigation report on the inadvertent shipment of live anthrax; however, DOD had not yet developed an approach to measure the effectiveness of these actions.[25] Additionally, we reported that although DOD had implemented a Biological Select Agents and Toxins Biosafety and Biosecurity Program to improve management, coordination, safety, and quality assurance, DOD had not developed a strategy and implementation plan for managing the program. Also, we found that the Army had not fully institutionalized measures to ensure that its biological test and evaluation mission remains independent from its biological research and development mission so that its test and evaluation procedures are objective and reliable. Finally, DOD had not completed a required study and evaluation of its Biological Select Agents and Toxins infrastructure that will affect the future infrastructure of the Biological Select Agents and Toxins Biosafety and Biosecurity Program. DOD officials had no estimated time frames for when DOD will complete the study and evaluation. We recommended that DOD develop an approach to assess the effectiveness of the recommendations, a strategy and implementation plan for its Biological Select Agents and Toxins Biosafety and Biosecurity Program, measures to ensure independence, and time frames to complete a study. To date, all of these recommendations remain open. In agency comments, DOD concurred with all four of our recommendations and discussed the actions the department intended to take to address them, including finalizing the development of a long-term strategy and implementation plan by September 1, 2019.

[25]In May 2015, DOD discovered that one of its laboratories (formerly called the Life Sciences Division) at Dugway Proving Ground, Utah, had inadvertently made 575 shipments of live Bacillus anthracis—the bacterium that causes anthrax—to 194 laboratories and contractors worldwide from 2004 through 2015. See GAO, *Biological Select Agents and Toxins: Actions Needed to Improve Management of DOD's Biosafety and Biosecurity Program*, GAO-18-422 (Washington, D.C.: Sept. 20, 2018).

The National Biodefense Strategy highlights the need for continuous improvement of biosafety and biosecurity for laboratories and other facilities. However, it is not yet known how, if at all, the strategy will drive interagency partners to develop additional oversight or other practices to mitigate the risk of bioincidents at high containment laboratories, because implementation of the strategy is in its early stages.

Challenges Building and Maintaining Emerging Infectious Disease Surveillance

We have reported that establishing and sustaining biosurveillance capabilities can be difficult for a myriad of reasons.[26] For example, maintaining expertise in a rapidly changing field is difficult, as is the challenge of accurately recognizing the signs and symptoms of rare or emerging diseases.[27] Additionally, we reported in October 2011 that funding targeted for specific diseases does not allow for focus on a broad range of causes of morbidity and mortality, and federal officials have said that the disease-specific nature of funding is a challenge to states' ability to invest in core biosurveillance capabilities.[28] Further, we reported in May 2018 that although the awards funded by supplemental appropriations have allowed state and local public health departments, laboratories, and hospitals to surge during a threat—for example, the H1N1influenza and Zika viruses—most of the 10 non-federal stakeholders we interviewed, as well as HHS officials said that the timing of these awards can result in challenges to carrying out preparedness and response activities during infectious disease threats.[29]

An effective medical response to a biological event depends in part on the ability of individual clinicians and other professionals to identify, accurately diagnose, and effectively treat diseases, including many that may be uncommon. For example, in May 2017, we reported that because Zika virus disease was a newly emerging disease threat in the United

[26]Biosurveillance, as defined by the July 2012 National Strategy for Biosurveillance, is the ongoing process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health, for the purpose of (1) achieving early detection and warning, (2) contributing to overall situational awareness of the health aspects of the incident, and (3) enabling better decision making at all levels.

[27]GAO-10-645.

[28]GAO-12-55.

[29]GAO, *Infectious Disease Threats: Funding and Performance of Key Preparedness and Capacity-Building Programs* GAO-18-362 (Washington, D,C., May 24, 2018).

States and relatively little was known about the virus prior to 2016, HHS and state and local public health agencies were not fully equipped with information and resources needed for a rapid response at the outset of the recent outbreaks.[30] They faced challenges establishing and implementing surveillance systems for Zika virus disease and infection and its associated health outcomes.[31] Additionally, in March 2019, we reported that USDA would likely face surveillance challenges that could delay detection of the first cases in a foot-and-mouth disease outbreak in livestock, which could have a devastating impact on our economy and trade agreements.[32] For example, foot-and-mouth disease can spread without detection as signs can be difficult to notice in some species, take up to 4 days to manifest after an animal is infected, and infection in wild animals could go undetected and continue to spread the virus.[33]

In 2011, while reporting on nonfederal biosurveillance efforts, we found state and local agriculture, public health, and wildlife departments were completely or largely dependent on federal funding for biosurveillance-related activities.[34] At that time, we also reported that the common federal approach of disease-specific funding—for example, West Nile virus—limited nonfederal efforts to develop core capabilities that could provide

[30]GAO, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks*, GAO-17-445 (Washington, D.C.: May 23, 2017).

[31]Challenges included establishing surveillance case definitions early in the outbreak when little was known about the Zika virus, timely communication of critical information that was rapidly evolving, and the lack of interoperability between surveillance systems. Lack of knowledge about the biological aspects of the virus also presented challenges for manufacturers of diagnostic tests for Zika virus. We made five recommendations to the Food and Drug Administration and the Centers for Disease Control and Prevention, including that the Centers for Disease Control and Prevention establish a transparent process for providing test manufacturers access to diagnostic tests and the Food and Drug Administration and the Centers for Disease Control and Prevention provide information to help ensure that users of diagnostic tests can compare performance. Agencies agreed with four recommendations but raised some concerns with sharing certain information. Two of the five recommendations have been implemented to date.

[32]GAO, *Foot-and-Mouth Disease: USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened* GAO-19-103 (Washington, D.C., Mar. 12, 2019).

[33]As part of this work, we made recommendations to help improve USDA's foot-and-mouth disease preparedness. USDA agreed with these recommendations, and described actions it will take to implement them.

[34]GAO-12-55.

surveillance capacity that cut across health threats and for emerging-disease threats.

According to federal, state, and local officials, early detection of potentially serious disease indications nearly always occurs first at the local level, making the personnel, training, systems, and equipment that support detection at the state and local level a cornerstone of our nation's biodefense posture.[35] In May 2018, we reported that officials from HHS told us that their grant awards funded by annual appropriations are intended to establish and strengthen emergency preparedness and capacity building, but may not fully support the need for surge capacity that states and other jurisdictions require in order to respond to an infectious disease threat.[36] We reported that during recent infectious disease threats, HHS received supplemental appropriations to respond to Zika in 2016, Ebola in 2014, and H1N1 pandemic influenza in 2009. However, as mentioned above, officials also said that the timing of these awards can result in challenges to carrying out preparedness and response activities during infectious disease threats.

HHS officials, as well as all 10 selected non-federal stakeholders, also noted in May 2018 that a funding mechanism to fund rapid response activities when additional support is needed would be beneficial and could help address timing challenges.[37] However, we reported that concerns were also raised about (1) when such a mechanism for funding infectious disease threats should be used, and (2) that any type of emergency fund should not be used to make up for a lack in investments at all levels of government for current preparedness and capacity-building activities. We did not make recommendation as part of this work. However, part of our May 2018 reporting included perspectives from various stakeholders on such a fund. Stakeholders cited six factors that may be considered for a new emergency response fund: (1) who determines when to use an emergency fund, (2) what factors would trigger the use of an emergency fund, (3) methods to determine the amount of available funding, (4) activities to fund with an emergency fund, (5), accountability for use of an emergency fund, and (6) whether an emergency fund would be specific to infectious disease threats.

[35]Ibid.

[36]GAO-18-362.

[37]Ibid.

The National Biodefense Strategy and its interagency governance structure offer the opportunity to design new approaches to identifying and building a core set of surveillance and response capabilities for emerging infectious diseases. However, it is too early into implementation to determine how effective, if at all, the new strategy will be in addressing this challenge. How and to what extent implementation of the Strategy is able to efficiently leverage and effectively sustain capacity across both nonfederal and federal stakeholders will affect how prepared the nation is to more quickly gear up for whatever challenges emerge when outbreaks of previously non-endemic diseases threaten the nation.

Thank you, Chairman Lynch, Ranking Member Hice, and Members of the Subcommittee. This concludes my prepared statement. I would be happy to respond to any question you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff has any questions concerning this testimony, please contact Christopher P. Currie at (404) 679-1875 or curriec@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals making key contributions to this statement include Kathryn Godfrey (Assistant Director), Susanna Kuebler (Analyst-In-Charge), Nick Bartine, Jeffrey Cirillo, Michele Fejfar, Eric Hauswirth, Tracey King, Dawn Locke, and Adam Vogt. Key contributors for the previous work that this testimony is based on are listed in each product.