U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

September 15, 2015

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Subject: Laboratory Safety Issues – GAO Responses to Questions for the Record

This letter notifies you of our enclosed responses to questions for the record, following the July 28, 2015 hearing, "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax." We are pleased to be able to provide you with the requested information. If you or your staff have any questions about our responses, please contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov, John Neumann at (202) 512-3841 or neumannj@gao.gov, or Timothy M. Persons at (202) 512-6412 or personst@gao.gov.

Marcia Crosse
Director, Health Care

John Neumann
Director, Natural Resources and Environment

Timothy M. Persons
Chief Scientist

Enclosure

The Honorable Susan Brooks

1. **This event shows us that we need to not only solve these problems from a managerial level, but be prepared to respond appropriately if these do fall into the wrong hands.**
    a. **Absent a strong commitment from the federal government to partner with the private sector on MCM development and procurement, do you believe the federal government is capable of acquiring the MCMs needed to protect the United States against threats like anthrax, smallpox, or Ebola?**

Department of Health and Human Services (HHS)

Since 2004, Congress has authorized over $8 billion for developing and procuring medical countermeasures for chemical, biological, radiological, and nuclear threats—including for anthrax, smallpox, and Ebola—for the civilian population. HHS leads federal efforts to oversee the development and procurement of medical countermeasures for the civilian population and works in coordination with other federal departments to do so.

- The Project BioShield Act of 2004 authorized the appropriation of approximately $5.6 billion from fiscal year 2004 through fiscal year 2013 for the Project BioShield Special Reserve Fund, and funds totaling this amount were appropriated. The act helped to create a government countermeasure market by authorizing the government to commit to making the Special Reserve Fund available to purchase certain medical countermeasures from the private sector, including those countermeasures that may not be approved, cleared, or licensed by the Food and Drug Administration. Project BioShield funds may be used to award contracts to private sector researchers and developers for the purposes of procuring medical countermeasures.[1]
- In 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) authorized an additional $2.8 billion to be available from fiscal year 2014 through fiscal year 2018 for countermeasure procurement, and Congress has appropriated $255 million in each of fiscal years 2014 and 2015. PAHPRA also explicitly allows Project BioShield countermeasure procurement contracts to include costs for countermeasure development.
- The Consolidated and Further Continuing Appropriations Act, 2015 appropriated additional funds to HHS, including for the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health, to support the development and procurement of medical countermeasures for Ebola.

We previously reported on some challenges that the federal government faces in developing and procuring medical countermeasures, such as the high failure rate in research and development and difficulties meeting regulatory requirements.[2] Despite these challenges, HHS

[1]HHS's Biomedical Advanced Research and Development Authority, created in 2006, oversees and supports advanced development and procurement of some medical countermeasures from the private sector into the Strategic National Stockpile—the national repository for medications, medical supplies, and equipment for use in a public health emergency.

[2]See GAO, Public Health Preparedness: Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents, GAO-11-567T (Washington, D.C.: Apr. 13, 2011).

has made progress in developing and procuring some medical countermeasures and continues to fund medical countermeasure development and procurement in partnership with the private sector. In December 2013, we reported that HHS spent approximately $3.6 billion in contracts with the private sector for advanced research, development, and procurement of medical countermeasures from fiscal year 2010 through fiscal year 2013.[3] Of this amount, HHS spent 30 percent for countermeasures against influenza, 20 percent for smallpox countermeasures, and 19 percent for anthrax countermeasures. Our December 2013 report provides additional information regarding HHS's spending on advanced research, development, and procurement of these medical countermeasures for this period.

Department of Defense (DOD)

While HHS leads federal efforts to develop and procure medical countermeasures for the civilian population, DOD is responsible for research, development, and procurement of medical countermeasures to prevent or mitigate the health effects of biological agents and naturally-occurring diseases on armed forces personnel. From fiscal years 2001 through 2013, DOD budgeted about $4.3 billion for developing and procuring medical countermeasures against biological threats.[4] DOD also coordinates with HHS on efforts to develop, acquire, and jointly stockpile medical countermeasures needed for both civilians and armed forces personnel, as appropriate.

United States Department of Agriculture (USDA)

In other efforts, Homeland Security Presidential Directive 9 directed the Secretary of Agriculture to develop a stockpile with resources to respond to the most damaging animal diseases affecting human health and the economy, including highly pathogenic avian influenza. The Secretary assigned this responsibility to USDA's Animal and Plant Health Inspection Service (APHIS). From 2006 through 2010, APHIS allocated approximately $33 million to develop the National Veterinary Stockpile and acquire critical resources to combat animal disease threats, including vaccines, diagnostic test kits, personal protective equipment, animal handling equipment, and antiviral medication.[5]

---

[3]See GAO, *National Preparedness: HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates*, GAO-14-90 (Washington, D.C.: Dec. 27, 2013).

[4]See GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization* GAO-14-442 (Washington, D.C.: May 15, 2014).

[5]See GAO, *Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture*, GAO-11-652 (Washington, D.C.: Aug. 19, 2011).

The Honorable Richard Hudson

1. Please provide a summary of the existing tools that CDC has that would allow it to better oversee and take corrective actions against labs that commit violations.

Under the federal select agent program, CDC and APHIS have oversight of entities (including federal agencies and private institutions) and individuals that possess, use, or transfer select agents.[6] As part of that oversight, CDC and APHIS maintain a list of select agents and toxins, which they are to review and update at least biennially. Generally, entities working with these select agents must register with CDC or APHIS and renew their registration every 3 years. CDC or APHIS may conduct an on-site inspection before issuing a new certificate of registration or renewing an existing registration. CDC and APHIS may also conduct interim inspections, such as annual inspections, to assess compliance with select agent regulations. To assist entities with compliance with the select agent regulations, CDC and APHIS make various resources, including guidance documents, frequently asked questions, and webinars, available through the select agent website (http://www.selectagents.gov).

CDC and APHIS have the authority to deny, suspend, or revoke registration to use, possess, or transfer select agents and toxins if an entity or individual is in violation of the program's requirements. Additionally, any violations of the select agent regulation provisions may be subject to a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of an entity. Individuals in violation of the select agent regulations may also be subject to criminal fines, imprisonment, or both.

In addition to its oversight tools under the federal select agent program, CDC has also taken steps to improve oversight of its own laboratories—including both its select-agent registered and non-select agent-registered high-containment laboratories—following the 2014 incidents involving incomplete inactivation of and potential exposures to research samples of anthrax, avian influenza, and Ebola virus. In 2014 and 2015, CDC convened workgroups to review the agency's laboratory safety procedures and protocols and conduct internal and external reviews of these incidents, which resulted in recommendations for improving laboratory safety. CDC has begun to implement these recommendations to improve laboratory safety practices and procedures across the agency, with the stated goal of increasing CDC's culture of safety. These ongoing efforts include:

- Establishing a new leadership position that will report to the CDC Director to provide agency-wide leadership and accountability for laboratory science, safety, and quality;
- Continuing engagement with an external Laboratory Safety Workgroup to enhance best practices in laboratory safety and quality within CDC;
- Expanding biosafety training at CDC;
- Revamping and implementing new and enhanced procedures for prompt reporting of laboratory incidents to CDC leadership and staff;
- Rolling out a new electronic specimen inventory management system;

[6]The federal select agent program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products.

- Enhancing procedures for custodianship of specimens with new entrance and exit processes for laboratory staff;
- Convening a Laboratory Safety Review Board to conduct safety reviews of laboratory protocols for work in biosafety level 3 (BSL-3) and BSL-4 laboratories; and
- Expanding external accreditation for CDC laboratories.

In our testimony before the subcommittee on July 28, 2015, we provided our preliminary observations on CDC's efforts to implement workgroup recommendations and address some weaknesses in the agency's management of its own laboratories.[7] The testimony also highlighted our prior recommendations for improving federal oversight of high-containment laboratories, including the need for a single federal oversight entity. As we conduct our ongoing review of federal management of biological agents in high-containment laboratories, we will continue to assess CDC's progress in implementing workgroup recommendations.

[7]See GAO, *High-Containment Laboratories: Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses*, GAO-15-792T (Washington, D.C.: July 28, 2015).