Written Testimony
House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Bioresearch Labs and Inactivation of Dangerous Pathogens

Statement of

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Thank you, Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee. I am Dr. Daniel M. Sosin, Deputy Director and Chief Medical Officer with the Office of Public Health Preparedness and Response (OPHPR) at the Centers for Disease Control and Prevention (CDC). From November 2015 through August 2016, I served as Acting Director of OPHPR's Division of Select Agents and Toxins (DSAT). I appreciate the Subcommittee's continued interest in improving oversight of work with select agents and toxins to ensure that this important work is done in as safe and secure a manner as possible.

CDC's highest priority is to save lives and protect people. Scientific research in laboratories plays a critical role in accomplishing this goal and is an important part of our nation's defense against naturally occurring diseases and bioterrorism. The research done on biological select agents and toxins leads to discoveries that can save lives and help protect the American people. However, the nature of scientific laboratory work means that some risk is always present. Our goal is to reduce that risk to the maximum extent possible.

Today I am going to speak with you about CDC's role and responsibilities in implementing the Federal Select Agent Program (FSAP), including our extensive efforts over the past year to strengthen oversight of Government, academic, and private laboratories across the United States that work with select agents and toxins. This includes efforts to address challenges associated with inactivation, which is essential to conducting potentially life-saving research in areas such as detection of select agents, diagnoses of those who may have been exposed, and development of vaccines and of antidotes to mitigate the effects of possible exposure. The work of FSAP helps ensure that this critical research in laboratories across the country involving potentially dangerous and deadly pathogens is conducted as safely and securely as possible. Toward that end, FSAP recognizes and is in the process of addressing the need for improvements to the program. FSAP concurs with recent Government Accountability

Office (GAO) recommendations and is taking steps to improve oversight of inactivation and other work with select agents and toxins.

Background on the Federal Select Agent Program

The regulation of select agents and toxins is a shared Federal responsibility involving the Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the Department of Justice (DOJ). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) authorizes HHS to regulate the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety. This authority has been delegated to CDC. USDA was given similar authority to regulate select agents and toxins that pose a severe threat to animal and plant health and/or animal and plant products. DOJ is responsible for conducting a security risk assessment of entities and individuals prior to their possession, use, or transfer of select agents or toxins. This oversight helps prevent access to these pathogens by terrorists or others who may wish to misuse them.

FSAP promotes laboratory biosafety and biosecurity through: (1) developing, implementing, and enforcing the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331); (2) providing guidance to the regulated community; and (3) inspecting facilities that work with select agents. Entities must undergo a rigorous registration process and obtain approval before they can work with select agents and toxins. At the end of 2015, 291 entities--including academic, non-Federal government, Federal Government, and private laboratories--were registered with FSAP to possess a select agent or toxin. The majority of entities (251) were registered with CDC as the lead Agency. The program currently regulates 66 select agents and toxins. This list is reviewed at least every two years to determine if agents or toxins need to be added to or deleted from the list. Key regulatory functions and activities of the FSAP include:

- Maintaining a national database that enables the U.S. Government to be aware of entities and individuals authorized to work with select agents. This registry serves several functions, including allowing FSAP to proactively reach out to entities in advance of natural disasters or other events to ensure all select agents and toxins are properly secured;
- Ensuring appropriate measures are in place at each registered entity to prevent unauthorized access to, or theft, loss, or release of, select agents and toxins;
- Receiving reports of theft, loss, or release and following up with each entity to ensure that proper actions are taken and appropriate authorities notified, and to help the entity identify ways to prevent similar incidents from happening in the future;
- Taking appropriate enforcement actions in an instance of theft, loss, or release, or when deficiencies in biosafety or biosecurity measures are identified in an inspection, to address the risk and increase compliance with regulations in the future; and
- Serving as a resource on the regulations by providing guidance to those working with select agents and toxins, interpreting the regulations to help entities meet the requirements, and conducting training and outreach to increase knowledge of and compliance with the regulations.

Inactivation

Over the course of the last few years, several high-profile laboratory incidents involving select agents and toxins have occurred at Federally-regulated laboratories. As the Subcommittee is aware, some of these incidents involved inactivation at federal laboratories, including the incomplete inactivation of *Bacillus anthracis* at a CDC laboratory in 2014, potentially exposing CDC employees to live spores, as well as the May 2015 discovery by the Department of Defense (DoD) that one of its laboratories had inadvertently sent live *Bacillus anthracis* to almost 200 laboratories worldwide over the course of 12 years. FSAP worked with DoD, private laboratories, state health officials, and the Federal Bureau of Investigation to investigate all laboratories known to have received this material. FSAP's

investigations of these and other incidents yielded important insights into the challenges presented by inactivation and informed FSAP's ongoing efforts to improve the regulatory oversight of this challenging but important procedure.

The multiple episodes of inactivation failures raised questions concerning the adequacy of some inactivation and validation protocols for spore-forming bacteria. On June 2, 2015, to prevent inadvertent exposure, FSAP requested a moratorium on the use and transfer of inactivated *B. anthracis* for entities that produced and shipped inactivated B. *anthracis* to other laboratories until safer and more effective procedures regarding inactivated B. *anthracis* could be developed based on interagency scientific discussion and further research into the matter. In December 2015, FSAP issued a policy statement regarding the inactivation of *B. anthracis*, and then a revised policy statement in June 2016 that addressed feedback from subject matter experts and the regulated community.

Additionally, CDC is expecting to publish a Final Rule later this year which will address and increase oversight of inactivation. CDC's January 2016 Notice of Proposed Rule Making (NPRM) included proposed requirements to increase oversight of the inactivation of select agents, mandating registered entities use validated inactivation methods, conduct confirmatory testing before declaring a select agent "non-viable," and maintain records to facilitate tracing materials if inactivation failure is identified. During the public comment period, CDC received extensive comments on the NPRM. CDC is in the process of addressing these comments and making appropriate changes to the proposed rule. FSAP also is developing guidance to assist the regulated community in implementing the new regulatory requirements. This guidance will be significantly more detailed than previous guidance on the topic. In support of the more rigorous requirements around inactivation of biological select agents and toxins, FSAP is prepared to support the training needs for both inspectors and the regulated community. The development of this guidance aligns with GAO's recommendations to create comprehensive and consistent guidance for development, validation and implementation of inactivation protocols and better

records associated with transfer of this material. Much more work is needed on this topic, including issues that go beyond FSAP alone which will have to continue to be addressed together with the broader scientific and policy communities.

Strengthening FSAP

Following a number of high-profile laboratory incidents in 2014 and 2015, the federal government convened multiple groups to find ways to strengthen the oversight of select agents and toxins. FSAP is well underway in putting into action the recommendations derived from these efforts.

In the summer of 2015, CDC Director Dr. Tom Frieden ordered an internal 90-day review of CDC's Division of Select Agents and Toxins (DSAT) to examine the CDC-administered component of FSAP and make recommendations to improve the program. In October 2015, CDC released the full report, including recommendations in three main areas –inspections, incident reporting, and transparency and public understanding.

At the same time, Federal Departments and Agencies agreed to identify ways to strengthen policies and practices both at laboratories regulated under the FSAP and at other laboratories working with dangerous pathogens. As a result, the Report of the Federal Experts Security Advisory Panel (FESAP) provided recommendations on optimizing biosafety, biosecurity, oversight, inventory management, and control of biological select agents and toxins as well as on actions and regulatory changes to improve biosafety and biosecurity. Additionally, the Fast Track Action Committee Report on Select Agent Regulations (FTAC-SAR) provided recommendations informed by external stakeholder input. In collaboration with other Departments and Agencies, FSAP now is in the process of implementing these recommendations which will lead to program changes and improvements, many of which also are responsive to recommendations in GAO's report.

Since the release of the reports and recommendations, CDC has made significant program improvements in four key areas: inspections, customer service, incident response, and transparency and engagement. Following CDC's 90-Day internal review and the White House reports, CDC published an online resource called Progress Towards Change.[1] The website provides ongoing updates on CDC's progress towards implementing improvements recommended in the reviews. Below are examples of steps CDC is taking to address recommendations.

Improving Inspections

CDC has taken a number of important steps to improve the inspection process, relating to both the conduct of facility inspections and promoting greater consistency and clarity in the reporting of inspection findings back to the regulated entities. Key examples of our work in this area include:

- To improve the quality and consistency of FSAP inspections, FSAP identified violations that require greater judgment by inspectors and inspection teams and established an inspector training plan to address knowledge gaps and increase standardization. The establishment of this training program will support efforts to provide registered entities with clearer and more consistent information.
- To better understand and anticipate laboratory procedures and activities that are most strongly and most often associated with poor outcomes, FSAP is conducting analyses of data on inspection findings and risk in order to improve understanding of trends and associations between the two.

Improving Customer Service

FSAP efforts to more effectively support the entities working with select agents and toxins include:

[1] http://www.cdc.gov/phpr/dsat/review_initiatives.htm

- Establishing in December 2015 a formal mechanism for issuing, publicizing, and accepting entities' requests for FSAP to answer questions regarding the select agent regulations.
- Providing additional training and guidance to the select agent community, including by:
    - Establishing a training program for entities' Responsible Officials to increase education and build community. The first multiday training will be held in December 2016;
    - Establishing and updating guidance for entities on biosafety and security plan development to provide additional details and clarity on what is needed to comply with select agent regulations and increase biosafety and biosecurity measures; and
    - Developing guidance on inactivation which includes information on method development and validation, as well as safety margins; and
- Developing a new electronic information system that will increase efficiency, accuracy, and speed of interactions between the program and regulated entities and provide vital feedback for quality improvement.

Improving Incident Response

FSAP's efforts to improve our collective ability to respond to incidents when they occur include:

- Increasing outreach to state health authorities regarding incidents involving risk to workers or the community.
- Improving entity incident reporting and data collection by updating the APHIS/CDC Form 3, which is the form used to report thefts, losses, or release of select agents and toxins. The proposed new form will increase the utility of incident reports regarding the risk of reported theft, loss, and release incidents, and will allow FSAP to collect a greater level of detail on each reported event in a more consistent fashion. It will also provide the ability to clearly identify when an incomplete inactivation takes place, addressing one of GAO's

recommendations. FSAP expects that the new form (currently in draft) will ask users to indicate whether a release occurred because of a failed inactivation.

Improving Transparency and Engagement

FSAP is committed to transparency and increasing engagement with–and among–entities that work with select agents and toxins. For example:

- FSAP created a set of examples that categorize inspection violations along a spectrum of severity. This will help to ensure that enforcement actions are appropriate and consistent given the severity of the violation, and will increase compliance among the regulated community by providing more precise and transparent information on how performance and violations are graded. Instances of inactivation are included in this document. This effort helps address GAO's recommendations to develop and implement consistent criteria for enforcement actions.
- Additionally, CDC/DSAT now identifies inspection findings as low, moderate, or high severity, and, as part of a pilot project, CDC plans to generate inspection report cards that summarize the entity's regulatory departures and show its performance relative to other entities. This comparative analysis will also improve the targeting of FSAP oversight efforts.
- FSAP established an independent forum through ABSA International consisting of an online discussion forum, in-person workshop, and webinars to encourage routine peer-to-peer sharing regarding best practices among those working with select agents and toxins.

Conclusion

Many of the actions being undertaken to implement recommendations of the FESAP, FTAC-SAR and CDC reports also address recommendations raised in the GAO report. As noted above, CDC is in the process of developing a detailed guidance document for inactivation; APHIS and CDC have proposed changes to the form used by entities to report the theft, loss, or release of a select agent or

toxin to provide for clear identification of, among other things, incidents involving incomplete activation; and FSAP is creating a set of examples that categorize inspection violations along a spectrum of severity, which will help to ensure enforcement actions are consistent and appropriate given the severity of the violation.

FSAP is committed to continued improvement in oversight of laboratories that handle select agents and toxins. Many of the changes recommended can and will be made through FSAP. Other potential changes involve broader issues and will require additional partners—beyond FSAP—to address. We have and will continue to work diligently and thoughtfully with all of our federal partners and others who share in our commitment to protect Americans from biological threats. We look forward to the Committee's continued input as we continue to improve the system for oversight of research involving select agents and toxins.

Thank you for the opportunity to testify. I would be glad to answer to any questions you may have.