Testimony
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
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Oversight of Select Agents by the Centers for Disease Control and Prevention

Statement of
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Good morning Chairman Stupak, Ranking Member Whitfield and members of the Subcommittee. I am Dr. Richard Besser, Director of the Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER) at the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services. Accompanying me today are Dr. Rob Weyant, Director of the Division of Select Agents and Toxins in COTPER, and Dr. Casey Chosewood, Director of the CDC Office of Health and Safety. On behalf of CDC, I am pleased to be here today to discuss how CDC oversees select agents in the Nation's laboratories.

To further scientific knowledge about biological agents and toxins and develop countermeasures against them, our academic, commercial, and government institutions conduct research on these potentially harmful agents. We recognize that such research increases the risks of accidental or intentional release of these agents. To mitigate this risk, Congress authorized the federal government to oversee labs that work with select agents—which include such things as *Bacillus anthracis* (which causes anthrax), *Yersinia pestis* (which causes plague), and Variola major virus (which causes smallpox). The creation of this program has given our nation an important tool to help minimize the inherent risks that accompany work with select agents.

The regulation of select agents is a shared federal responsibility involving HHS, the Department of Agriculture (USDA), and the Department of Justice (DOJ). Congress gave HHS the authority to regulate the possession, use, and transfer of biological agents and toxins (select agents) that could pose a severe threat to public health and

safety. The Secretary of HHS has delegated this authority to CDC. Congress gave USDA similar authority to regulate select agents that pose a severe threat to animal and plant health and/or animal and plant products. DOJ is responsible for conducting background checks, called security risk assessments, of any entities and individuals that want to work with select agents. By regulating the possession, use, and transfer of select agents, HHS, USDA, and DOJ contribute to the Nation's overall terrorism deterrence strategy.

My testimony will focus on CDC's role in the regulation of select agents. I will describe the history of the CDC Select Agent Program, CDC's role in oversight of select agent laboratories, our collaboration with other federal partners, the key components of the CDC regulatory program, key program accomplishments, and our future plans for enhancing the program.

Establishing Oversight over Select Agents: A Brief History

No program for oversight of select agents existed in the United States prior to 1996. In 1996, Congress passed the Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132; signed April 24, 1996). With the regulations that went into effect in April 1997 (42 CFR 72.6), the Secretary of HHS established a list of biological agents that have the potential to pose a severe threat to public health and safety. The Secretary also established procedures for the transfer of these biological agents. The CDC Select Agent Program has been in place since 1996. The program was originally located

within CDC's Office of Health and Safety and is now located within CDC/COTPER's Division of Select Agents and Toxins.

In 2001, Congress expanded the scope of the program by restricting the shipping, possession, and receipt of select agents by passing the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act); (P.L. 107-56; signed Oct. 26, 2001). The USA PATRIOT Act created a provision related to select agents requiring that no restricted person shall transfer (i.e., ship, possess, or receive) a select agent.

In 2002, Congress significantly strengthened oversight of select agents with the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"); (P.L. 107-188; signed June 12, 2002). The Bioterrorism Act strengthened the regulatory authorities of HHS under Sec. 511 of the Antiterrorism and Effective Death Penalty Act of 1996 and granted comparable regulatory authorities to USDA for select agents that present a severe threat to animal or plant health, and/or animal or plant products. It also required coordination and concurrence between HHS and USDA on program activities (e.g., development of regulations, reporting forms, approval of changes to regulated laboratories' registrations, etc.) for select agents regulated by both agencies.

The Bioterrorism Act has been implemented through a series of regulations. HHS published an interim final rule—the "Possession, Use, and Transfer of Select Agents

and Toxins" Interim Final Rule (42 CFR 73, 9 CFR 121, and 7 CFR 331) (effective on February 7, 2003)—which implemented the pertinent provisions of the Bioterrorism Act. A subsequent Final Rule became effective on April 18, 2005. On October 20, 2005, HHS established an Interim Final Rule adding reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to the HHS select agent list. These regulations are hereafter referred to as the "select agent regulations".

Role of the Select Agent Program in Oversight of Laboratories

Not All Laboratories Handle Select Agents

Whereas HHS and USDA have authority to regulate any laboratories that possess, use, or transfer select agents, not all laboratories work with select agents. Therefore, not all laboratories are regulated under the provisions of the select agent regulations. For instance, human immunodeficiency virus (HIV) and *Mycobacterium tuberculosis* are not select agents and any laboratories working with these agents are not required to register with either HHS or USDA.

All five currently operational Biosafety Level (BSL) 4 laboratories in the United States are select agent registered entities. (Any organization that has received a certificate of registration through either the HHS or USDA Select Agent Program is referred to as a "registered entity".)

Federal Government Guidance to Biological Laboratories and Related Requirements

Though only a subset of laboratories is regulated by the federal government under the provisions of the select agent regulations, the federal government does provide biological safety guidance to the entire laboratory community. The *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (4th edition is available in print; 5th edition is available at http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm) , produced by CDC and the National Institutes of Health (NIH), is a nationally and internationally recognized source that provides safety guidance to laboratories that work with infectious agents. The BMBL provides recommendations for safely working with a variety of human pathogens and describes standard and special microbiological practices, safety equipment, and facilities (constituting Biosafety Levels 1-4). In the BMBL, there are agent summary statements that provide recommendations for the appropriate biosafety safety level to work with these agents. The BMBL also is offered as a guide and reference in the construction of new laboratory facilities and in the renovation of existing facilities.

CDC references the BMBL in the select agent regulations and requires select agent registered entities to comply with the BMBL guidelines or equivalent standards. Specifically, the select agent regulations state that the entity should consider the BMBL, NIH's Recombinant DNA Guidelines, and the Occupational Safety and Health Administration's regulations on handling toxins (29 CFR 1910.1200, 29 CFR 1910.1450) in developing and implementing a written biosafety plan that is commensurate with the risk of the select agent, given its intended use. If the Select Agent Program determines

that the entity's biosafety and containment procedures are not sufficient to contain the select agent, then the program can cite the entity for non-compliance.

Collaboration with Other Federal Partners

The CDC Select Agent Program works closely with both USDA and DOJ to implement the select agent regulations. USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the possession, use, and transfer of select agents that pose a severe threat to animal or plant health and/or animal or plant products. For select agents that pose a threat to both humans and animals or animal products, these select agents are regulated by both CDC and APHIS and are called "overlap agents". To limit the burden on registered entities, CDC and APHIS worked closely with the Office of Management and Budget to promulgate regulations with identical requirements and analogous language and to create one set of registration and reporting forms to be used by both agencies. These actions helped standardize communication and interpretation of the regulations among CDC, APHIS, and the regulated community.

To minimize the burden on entities that possess, use, or transfer select agents, a single point of contact with either CDC or APHIS was established. This single point of contact in the "lead agency" is responsible for coordinating all activities and communications with respect to the entity's registration, including coordination with both the non-lead agency (APHIS or CDC) and with DOJ. CDC and APHIS collaborate daily on select agent activities such as the development of select agent policies, resolution of common issues associated with the entity's registration (such as reviewing the required plans),

conducting joint inspections, developing standard operating procedures and entity guidance documents, and providing concurrences to entities' amendments. We also collaborate on longer-term projects to improve the implementation of the select agent regulations, such as the establishment of a national select agent website (www.selectagents.gov) and development and deployment of a single shared database (the National Select Agent Registry).

CDC also works closely with DOJ's Criminal Justice Information Service (CJIS). CJIS conducts security risk assessments of all individuals and entities that request to possess, use, or transfer select agents. As of September 25, 2007, 14,868 individuals have received access approval from CDC to work with select agents, based on the results of the CJIS security risk assessments. CDC also provides information to DOJ's Federal Bureau of Investigation (FBI) for ongoing criminal investigations related to select agents.

Oversight of Select Agents: The CDC Regulatory Program

CDC exerts a strong oversight role by evaluating and inspecting registered entities, in addition to providing guidance and training to registered entities.

An important tenet of the CDC Select Agent Program is that it treats all registered entities the same—whether that lab is a commercial lab, state or local public health lab, or a federal lab (including CDC and Department of Defense labs). The Select Agent Program uses standard checklists to inspect all labs, has the same requirements of all

labs, and uses the same standards when referring any lab to the HHS Office of Inspector General (HHS-OIG) for possible violations of the regulations.

CDC's Approach to Inspection of Entities

Laboratory inspections are the primary means by which CDC confirms compliance with the select agent regulations. Routine inspections are conducted every three years. Additional inspections are conducted any time that an entity requests a significant change to its select agent registration. Such changes may include the addition of a new facility, addition of a new agent, or the initiation of a new procedure. Other inspections that are performed include follow-up inspections based on observations from audits performed by federal partners and investigations that may have involved biosafety or security concerns that could affect public health and safety.

CDC's protocol for routine inspections consists of an extensive review of laboratory safety and security as it relates to the possession, use, and transfer of select agents. CDC uses specific checklists to guide its inspections (the checklists can be found at www.selectagents.gov). These checklists have been developed from the select agent regulations and nationally recognized safety standards. The information entered on the checklists is derived from inspectors' observations of the physical safety and security components of the facility, an examination of the documentation available, and from interviews with laboratory personnel. These findings are conveyed to the institution in an inspection report. Entities must respond within a specified timeframe to the deficiencies noted in the inspection report and provide documentation of how they have

resolved those deficiencies. In circumstances where the deficiencies are serious and CDC wants to confirm in person that the deficiencies have been corrected, a verification site visit is performed.

When CDC identifies deficiencies and possible violations of the select agent regulations, several types of enforcement actions can occur:

- Administrative actions: CDC can decide to suspend or revoke a registered entity's certificate of registration (a suspension can be for all work at a registered entity or be specific to particular agents or particular types of experiments). Also, CDC can deny an entity's application to possess, use, or transfer select agents;
- Referral to HHS-OIG: CDC can refer possible violations of the select agent regulations to HHS-OIG. HHS-OIG can levy civil monetary penalties (up to $250,000 for an individual for each violation and up to $500,000 for an entity for each violation) or recommend criminal enforcement (imprisonment for up to five years, a fine, or both).
- Referral to FBI: CDC can refer possible violations involving criminal negligence or a suspicious activity or person to the FBI for further investigation.

As of September 25, 2007, CDC has referred 37 entities to HHS-OIG for violation of the select agent regulations (such as for unauthorized transfers and entities that are not registered with the Select Agent Program in possession of select agents). HHS-OIG has levied $837,000 in civil monetary penalties against ten (10) of the entities. For

further information, please see the HHS-OIG website (http://oig.hhs.gov). HHS has not referred to DOJ any violations of the select agent regulations for criminal prosecution.

Technical Assistance and Guidance Provided to Strengthen the Program

While enforcing the select agent regulations is the CDC Select Agent Program's primary responsibility, the program also promotes laboratory safety and security by providing technical assistance and guidance to registered entities. Some of the technical assistance that CDC provides to registered entities includes having a primary point of contact assigned to each entity, development of frequently asked questions that are posted on the program website, and technical presentations at various conferences. The CDC Select Agent Program in collaboration with APHIS provides assistance and guidance to help the entire regulated community operate as safely and securely as possible.

Some examples of the assistance that the CDC and APHIS Select Agent Programs have recently provided to the regulated community include:

- As mentioned previously, CDC and APHIS released a security guidance document to registered entities.
- CDC and APHIS released inspection checklists to assist registered entities in complying with the security, incident response, training, and recordkeeping requirements of the select agent regulations.

- CDC is further educating the entities about the regulations and the inspection process. It recently completed two training videos that explain the facility inspection process to the regulated community.

In addition, CDC has proactively worked with registered entities in advance of hurricanes to ensure that all select agents are properly secured. For example, prior to the landfall of Hurricane Katrina in 2005, CDC contacted 11 registered entities located in Louisiana, Mississippi, and Alabama. CDC collected information regarding the entities' plans to safeguard select agents during and after the storm and informed the entities that CDC stood ready to expedite the emergency transfer of select agents should the need arise. CDC has taken similar action in 2006 and 2007 in anticipation of other hurricanes and predictable natural disasters (such as floods) that could affect public health and safety, to minimize risk and any impact on public health and safety.

Program Activities and Results

Accomplishments to Date

Since the publication of the select agent interim final rule in 2003 (followed by the final rule in 2005), CDC in collaboration with our federal partners has (as of September 25, 2007):

- Conducted 607 inspections to ensure that appropriate security and safety measures are in place to deter the theft, loss, or release of select agents;
- Authorized 2,199 requests to transfer select agents; and

- Granted access approvals to 14,868 individuals to work with select agents, following a security risk assessment by CJIS.

Reports of Theft, Loss, and Release

CDC investigates all reports of theft, loss, or release of select agents to ensure that the public's health and safety are protected. It is important for the public to know that after careful investigation, no incidents reported at select agent laboratories were considered to be a public health threat. From 2003 until September 25, 2007, there have been one hundred five (105) incidents reported to CDC through the Select Agent Program's theft, loss, and release reporting system. As a result of follow-up investigations conducted by HHS, USDA, and the FBI regarding these reports, it was determined that there were:

- No confirmed losses of a select agent;
- No confirmed thefts of a select agent; and
- Three (3) confirmed releases of a select agent which were identified by illnesses in five (5) lab workers that had occurred as a result of working with these agents.

Even in the best of laboratories, which follow all biosafety guidelines, accidents like a broken test tube or a needle stick can still occur, and we can expect that we will continue to receive reports of possible losses and releases of select agents. However, we believe we should always strive to eliminate all incidents. Appropriately contained and managed laboratories have multiple systems in place to ensure biosafety and have robust occupational health services in place to quickly mitigate the effect of any laboratory incident. We also believe that the security requirements put in place by the

select agent regulations will continue to mitigate the possibility of a theft of a select agent.

Moving Forward with Enhancing the Select Agent Program

The CDC Select Agent Program has accomplished much since the program began, but we are always looking for ways to improve. The Select Agent Program is a young program and it will continue to build upon its successes and learn from its challenges. CDC is committed to continuous program improvement to fulfill its mission.

Lessons Learned

Investigations of select agent registered entities have taught CDC some important lessons:

- We need improvements in our inspection process. Some of the improvements under consideration include:
    - Expand the scope of interviews to include more types of laboratory workers during inspections, to better assess the implementation of policies and the quality of training;
    - Examine more closely the implementation of biosafety, security, and incident response plans;
    - Review a broader array of documents during our inspections, such as biosafety committee meeting minutes and occupational health records, to identify problems that may go unreported by registered entities; and

    - Assess the composition of our inspection teams, the frequency of our inspections, and whether we need to apply a prioritization system to how often we inspect labs.
- We need improvements in our verification process. Whereas before we relied primarily upon documentation from entities to confirm that deficiencies were corrected, we plan to conduct more verification site visits.
- We need to provide additional outreach and training to the regulated community, including additional outreach and training to Responsible Officials and creation of additional guidance documents related to biosafety, incident response, record-keeping, and theft, loss, and release.

The CDC Select Agent Program also must address the challenge of how the select agent regulations apply to emerging technologies, such as synthetic genomics and nanotechnology. With technology advancing at a rapid pace, CDC and its federal partners need to constantly review the select agent regulations and our implementation of the regulations to ensure that we can respond to new threats and vulnerabilities.

External Review of the CDC Select Agent Program

In the coming year, CDC will commission an external peer review of the CDC Select Agent Program. The external group conducting the review will actively solicit the input of stakeholders and the general public.

In addition to this external peer review, HHS-OIG is conducting an audit of CDC's management of its select agent program. We look forward to receiving the findings from that audit in 2008 and plan to carefully consider and implement HHS-OIG's recommendations.

Conclusion

The select agent programs at CDC and APHIS, working in concert with DOJ, have greatly enhanced the nation's oversight of dangerous biological agents and toxins. Because of the efforts of the individuals in these programs, there is improved awareness of biosafety and biosecurity throughout the select agent community. The select agent regulations have helped ensure that research with select agents is conducted as safely and securely as possible. CDC and its federal partners have accomplished much in the few years since the publication of the select agent regulations, but we must remain vigilant in ensuring laboratory safety and security. We will continue to enforce the regulations and provide technical assistance and guidance to the regulated community to ensure that the public's health and safety are protected.

CDC greatly appreciates the support of this Subcommittee and the rest of the Congress in supporting its activities. We look forward to continuing our work with you on these important issues. Thank you for the opportunity to share this information with you. I am happy to answer any questions.