



**Testimony before the
Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce
U.S. House of Representatives**

**Review of Department of Defense
Anthrax Shipments**

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Thank you, Mr. Chairman, 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 at the Centers for Disease Control and Prevention (CDC). The Committee on Energy and Commerce has played an instrumental role in ensuring that CDC and other components of the Department of Health and Human Services (HHS) have the needed authorities to prepare for, respond to, and recover from threats to the nation's health -- whether they are the result of terrorism or naturally occurring events -- and to appropriately address biosafety and biosecurity. I appreciate the Committee's continued leadership on these important issues and the opportunity to appear before you to discuss CDC's role in the investigation of and response to the inadvertent shipments of live anthrax from a laboratory at the Department of Defense (DoD) Dugway Proving Ground (Dugway) in Utah.

As CDC's Incident Manager for this response, I oversaw all aspects of CDC's involvement. Today I am going to talk with you about CDC's investigation under the authority of the Federal Select Agent Program (FSAP), and about other aspects of CDC's response in its traditional role of protecting peoples' health. I also want to mention briefly the FSAP's contributions to efforts over the past year to strengthen safety and security around Federal select agent laboratories in the United States, and participation in ongoing comprehensive reviews of FSAP and biosafety more generally, led by the White House.

CDC's Highest Priority is to Save Lives and Protect People

CDC's commitment to saving lives and protecting people applies to all aspects of our work, including responding to health threats, and -- with the U.S. Department of Agriculture -- jointly regulating laboratories that work with select agents.

CDC responded to shipments of live anthrax from Dugway to achieve several goals:

- Ensure that people were safe, by working with state health departments to identify potentially exposed workers, assess their health risk, and offer treatment when appropriate;
- Develop recommendations for effective decontamination of laboratories, in collaboration with the Environmental Protection Agency (EPA);
- Secure the samples of live anthrax inadvertently sent to many places not approved to have anthrax or any select agent, to prevent any further potential exposures; and
- Importantly, to understand what happened so that we can take additional steps to prevent this from happening again.

On May 22, 2015, after being advised by a laboratory that live anthrax was detected in a sample from Dugway that was supposed to have been inactivated, CDC initiated outreach to what has amounted to 183 domestic laboratories (164 of which are not DoD labs) to track 575 shipments of presumed inactivated anthrax material (that turned out to include live anthrax) coming from Dugway. (There were an additional nine labs in seven foreign countries that received lots from Dugway, making for a total of 192 labs that received hot lots, but CDC's outreach was only to

domestic labs). In the last two months, CDC has reached out to each laboratory to identify potential exposure to this material within the past year – with most outreach coming within hours of learning that the laboratory might hold incompletely inactivated material. If a potential exposure was encountered, CDC doctors and scientists, in collaboration with state health departments, assessed workers and the laboratory environment for any possible aerosol spore exposure (inhalation anthrax is considered to be the most deadly form of anthrax). CDC laboratory scientists tested samples shipped from Dugway to confirm our understanding of low concentrations of spores in the positive results, and CDC environmental microbiologists and hygienists worked with EPA to develop recommendations for decontamination of the laboratories to allow them to be back up and running again and ensure the safety of the people that work there.

CDC assessed the risk to workers in all 164 domestic civilian laboratories that received the live DoD anthrax specimens, and only eight individuals, working in three different civilian laboratories, were identified as potentially exposed. (DoD managed assessment and follow-up of additional individuals who worked in DoD labs). Out of an abundance of caution, given that our assessment concluded low exposure and disease risk, post-exposure prophylaxis was recommended for these eight individuals. Of those eight, two began but later discontinued post-exposure prophylaxis. The other six individuals will have completed their 60-day post-exposure prophylaxis regimen of antibiotics and vaccine by July 27. As of submitting this testimony, none have experienced complications. In fact, in over more than a decade (since 2004) of working in laboratories with these presumed inactivated

samples from Dugway, no laboratory researcher has been diagnosed with anthrax infection.

CDC and EPA have supported all seven states where laboratory decontamination has been recommended, and supported all states to effectively decontaminate these laboratories.

On May 24, in its role under the Federal Select Agent Program, CDC's Division of Select Agents and Toxins (DSAT) sent email to DoD officials (Dugway) advising to them to stop further production and shipment of anthrax samples. Dugway stopped further production and shipment of anthrax samples. Using the National Select Agent Registry database maintained by the Federal Select Agent Program, CDC identified six additional institutions in the United States, including two additional DoD facilities, that produce and ship inactivated anthrax spores or vegetative cells for research purposes. CDC requested that each of the six additional institutions also agree to a moratorium on the use and shipping of the materials pending further evaluation of the methods for killing anthrax spores and validating that the spores have been killed. All six of these institutions also agreed to honor the moratorium.

On May 26 – 28, DSAT conducted an on-site investigation of Dugway. Based on our investigation into the incident, CDC has determined that inactivation procedures used at Dugway failed to kill the anthrax spores, and its validation methods to confirm the success of the inactivation procedures (sterility testing) failed to detect growth of the live material prior to Dugway sending out the presumed inactivated material. CDC's investigation has not identified any similar problems at any of the other six institutions.

However, CDC will maintain the moratorium on use and transfers of these materials to lower biosafety level laboratories until more well-defined standards for inactivation and sterility testing have been identified.

CDC's DSAT gained new insights in three areas that will lead to stronger safeguards to prevent a similar incident from occurring. Until we finalize these safeguards, the moratorium on the production, use and shipment of inactivated anthrax spore preparations will remain in place.

First, the requirements for inactivation procedures require more oversight to increase assurance that the procedure is successful. Of necessity, there are several different methods of inactivating anthrax, depending on the type of study being conducted. These methods include heat, gaseous sterilization, non-gaseous chemical sterilization, and radiation (such as gamma irradiation, the process used by Dugway). For example, if the inactivated material will be used to measure the performance of a diagnostic test (as DoD was doing when preparing its *B. anthracis* samples), then radiation would be an appropriate method because the procedure neutralizes/kills the cells without altering their structure. For these types of experiments, chemical sterilization would not be appropriate because the cell structure would be altered, and would not be detected with a simple diagnostic test that is looking for intact cells. We are actively considering improvements to inactivation requirements to ensure procedures are successful and to enhance oversight.

Second, there is uncertainty about whether Dugway failed to conduct proper inactivation and sterility testing or, alternatively, whether there is something previously

unrecognized about anthrax spores recovering from irradiation damage. Additional studies could help us understand whether spores that do not grow immediately after irradiation will grow at a later time or if something about the method inhibits growth until further processed, such as by dilution. Increasing the rigor of sterility testing and the frequency of testing will further protect against inadvertently sending live anthrax spores.

Third, better record keeping and record systems are needed for inactivated agents to ensure that we can quickly and efficiently contact those who receive these materials. CDC has convened a working group of experts to further examine the first two areas (inactivation and sterility testing) to inform recommendations for the methods that are used. To address the third area, CDC is working with our partner at the U.S. Department of Agriculture to update the select agent requirements to strengthen those pertaining to record keeping for inactivated select agents.

In summary, CDC reacted promptly to the incident at Dugway. CDC's response included the proactive steps to contain and reduce potential risk by: issuing a call for a moratorium on transfer and use of the inactivated anthrax samples; assessing worker exposures and initiating prophylactic treatment when indicated; closing laboratories where exposures may have occurred until they could be cleaned; securing and ensuring the disposal of all Dugway production lots; and testing of inactivated materials made by other facilities to ensure that the problem was isolated to Dugway.

CDC's Role in the Federal Select Agent Program

Laboratory research is a critical component in our defense against naturally-occurring disease and bioterrorism, and the scientists who work with these organisms are dedicated to protecting Americans through improving the ways we detect and respond to health threats from infectious disease and from agents that have the potential to pose severe threats to health. All research on select agents and toxins has some risk, and our goal is to minimize that risk. We are committed to do all we can to protect workers and the communities around them while encouraging and supporting scientific advancement.

Understanding *Bacillus anthracis*, the bacteria that causes anthrax, is critical in protecting the health security of the American people. As the nation experienced in October 2001 (when letters containing anthrax were mailed, killed five people, and sickened 17 people), this organism can be used as a weapon. Research with anthrax is needed to create new tests for rapid identification and to develop vaccines, drugs, and therapeutics that can save lives of those infected. It should be noted that the DoD laboratory was working as part of a DoD effort to develop a field-based test to identify biological threats in the environment.

The regulation of select agents and toxins is a shared federal responsibility involving the HHS, USDA, and the Department of Justice (DOJ). Through the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), Congress gave HHS the responsibility and authority 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 (i.e., select agents and toxins). The authority has

been delegated 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 electronic database checks of any entities and individuals that want to possess, use, or transfer select agents. By regulating the possession, use, and transfer of select agents, HHS, USDA, and DOJ -- otherwise known as the “Federal Select Agent Program” -- contribute to the Nation’s overall terrorism deterrence strategy.

The Federal Select Agent Program promotes laboratory biosafety and biosecurity by developing, implementing, and enforcing the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR 331), providing guidance to the regulated community, and inspecting facilities that work with select agents. Since 2003, CDC has focused effort on reducing the risks for thefts, losses, and releases of select agents through monitoring of facilities and enforcement of regulations. Since implementing the select agent regulations, the Federal Select Agent Program has provided:

- A comprehensive, real-time database containing information on all entities possessing select agents, including the location of the agents, the individuals who work with them, and the associated activities;
- Standard safety and security regulatory requirements for all entities working with select agents, including the development and execution of site-specific security, biosafety, and incident response plans, which are supported by training programs and annual drills or exercises;
- A national system for reporting the theft, loss, or release of select agents;

- An electronic database check for all individuals accessing select agents, performed by the Federal Bureau of Investigation (FBI), to determine whether they are “restricted persons”;
- A system to provide eligible state emergency preparedness and response planners with information on facilities registered for select agents within their jurisdictions;
- A surveillance system to track the identification of select agents by front line laboratories;
- A confidential system for reporting safety and security concerns regarding select agents;
- A tracking mechanism to monitor shipments containing select agents and ensure that senders and recipients are adequately registered for select agents (the actual shipment of the select agent is done under Department of Transportation regulations); and
- An outreach and training program that includes a library of over 14 guidance documents and a collection of answers to 75 frequently asked questions, an inspection video, a security risk assessment tool and a training webinar series that has educated over 2000 participants. This information is available on the Federal Select Agent Program website, and we log over 25,000 visits each month.

One characteristic of CDC’s stewardship of the Federal Select Agent Program is a commitment to continuous improvement. CDC works with its federal partners within

HHS, and at USDA, DOJ, the Department of Homeland Security, and DoD to ensure that the list of select agents reflects those agents of greatest risk to public health or agriculture through misuse. Since the establishment of the Federal Select Agent Program in 2003, the list of select agents and toxins has been updated on four occasions, including adding four new agents to the list (e.g., reconstructed 1918 Influenza virus) and removing twenty-three agents and toxins. The biosafety, security, and incident response requirements of the select agent regulations have been refined over the years with advice from many stakeholders within and outside the government including the Federal Experts Security Advisory Panel, the National Science Advisory Board for Biosecurity, the Office of Public Health Preparedness and Response Board of Scientific Counselors, the Intragovernmental Select Agents and Toxins Technical Advisory Committee, the Government Accountability Office (GAO), HHS's Office of Inspector General (OIG), and the public through our rulemaking process. In addition, the CDC component of the Federal Select Agent Program has received recommendations from reviews of the program by GAO, the HHS OIG, and the Homeland Security Institute. These reviews have led to revisions to the select agent regulations to include Tier 1 (a subset of regulated select agents that are deemed to pose the greatest threat) requirements such as personnel reliability, updates to our guidance regarding incident reporting, coordination of inspections with federal partners, and tracking shipments of select agents. The Federal Select Agent Program has also made improvements in accordance with White House directives through Executive Orders 13486 and 13546. In executing these Orders, the Federal Select Agent Program revised regulations to concentrate our resources on a reduced list of the

highest agents of concern and focus additional security requirements (e.g., enhanced physical security standards, suitability assessments of lab workers before they can work with Tier 1 agents, and ongoing monitoring of personnel suitability for those with access to agents or toxins on the Tier 1 list) on Tier 1 select agents, those that have the greatest risk for deliberate misuse and the most significant potential for mass casualties, or devastating effects on the economy or critical infrastructure.

Although much work has been done to enhance the effectiveness of CDC's regulatory oversight of select agents and toxins, more work remains to be done. In the wake of recent incidents, the Federal Select Agent Program has revised the inspection process and now places more emphasis on observing the implementation of the biosafety plan (i.e., are they doing what they said they are doing) and whether they doing it correctly (e.g., observing employees donning and doffing of personal protective equipment. In response to the biosafety and biosecurity incidents last summer, CDC's FSAP program supported other U.S. departments and agencies in their laboratory sweeps as part of the Safety Stand-Down urged by the White House, by providing information on what to do if they find a BSAT in unregistered space, and working with labs that reported findings to us to secure the materials and then either transfer or destroy them on site.

For nearly 70 years, CDC has been a leader in scientific research and practice committed to protecting the American people and keeping Americans healthy, safe, and secure. The CDC Director, Dr. Thomas Frieden, recently ordered a review of CDC's

Federal Select Agent Program to identify additional areas where procedures and regulations can be improved to increase our effectiveness while balancing the requirements on those in the research community. In addition, the FSAP program is actively participating in an ongoing review led by the White House of recommendations to enhance biosafety and biosecurity in the United States. We stand ready to address recommendations from that process when they are released.

Where improvements can be made to better the program, we will make them. Where there is disagreement on the best path forward, we will contribute our scientific and programmatic expertise to the debate. We will work diligently and thoughtfully with all of our federal partners and anyone sharing our commitment to protect Americans from biological threats. We welcome the Committee's input as we undertake this important review, and we look forward to continuing to work with you to achieve our shared goal of enhancing the nation's oversight of the safety and security of select agents.