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U.S. Department of Homeland Security
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Before the Senate Committee on the Judiciary,
Subcommittee on Terrorism and Homeland Security.

The Role of the Department of Homeland Security's Science and Technology Directorate in Strengthening Security and Oversight at Biological Research Laboratories.

Chairman Cardin, Ranking Member Kyl, distinguished Senators, thank you for the opportunity to talk about the good work being done today at the Department of Homeland Security (DHS) related to biosecurity. It is a pleasure to be back in the U.S. Senate, where I started my professional life.

By way of introduction, allow me to explain briefly my role at DHS. I was appointed by the Deputy Secretary to be the Department's Compliance Assurance Program Manager. I am an attorney in the Office of the General Counsel, who supports the Science and Technology Directorate. I manage an office with 14 staff and a FY 2009 budget of approximately $2.8 million, and I oversee compliance efforts for all aspects of the Science and Technology Directorate's $800 million research and development program, including biological safety and security.

The main role of DHS's compliance program in biosecurity is to provide an objective and independent review of all ongoing DHS programs in the life sciences. This rigorous three-pronged review process includes several mutually reinforcing components; the review verifies arms control treaty compliance and regulatory compliance (select agent and toxin security, biosafety, and animal care and use); it further includes classification review.

The process is intended to be a complete programmatic life cycle review; treaty compliance is ensured both at a program's inception and when significant changes are proposed; regulatory compliance is checked throughout the life of project execution; and information generated by the program is continually reviewed for national security concerns. The Department's compliance office includes inspectors who are Ph.D. microbiologists, biosafety experts, animal care and use experts, and experts in national security classification, all supported by a strong professional staff. We have the necessary training to physically inspect Biological Select Agent and Toxin holdings in high containment laboratories.

The cornerstone of the process is the Department's Compliance Review Group, which oversees arms control treaty compliance.

ARMS CONTROL TREATY COMPLIANCE

DHS has a major role in implementing the national biodefense strategy, and it must ensure that its programs comply with all international treaty agreements, including the Biological Weapons Convention and the Chemical Weapons Convention. To accomplish this, DHS has implemented a comprehensive framework for treaty compliance review and certification of all biological and chemical defense projects.

The Compliance Review Group is comprised of the Deputy Secretary, the Under Secretary for Science and Technology, the General Counsel, and the Assistant Secretary for Policy. As a discretionary matter of standing practice, the Deputy Secretary has also included the Under Secretary for Intelligence and Analysis and the Assistant Secretary for Health Affairs. All biological research conducted by the Department must be determined by the Compliance Review Group to be compliant with U.S. law and our international obligations.

The bulk of the work of the Compliance Review Group revolves around the Biological Weapons Convention. Specifically, the sponsors of each research project must affirmatively demonstrate that:

- the project is clearly for prophylactic, protective or other peaceful purpose; and
- the types and quantities of agents or toxins used in the project are consistent with and justified for the intended prophylactic, protective or other peaceful purpose.

In generating compliance assessments for the Compliance Review Group, projects fall within one of three categories:

Category 1: The project, as presented, does not raise any compliance concern.

- The project does not involve "Research of Concern," as identified by the National Science Advisory Board for Biosecurity, other dual-use issues, or types or quantities of agent that reasonably could raise concerns.
- 368 Category 1 projects have been approved by the Compliance Review Group to date.

Category 2: The project, as presented, might reasonably raise the perception of a compliance issue, but does not involve National Science Advisory Board for Biosecurity "Research of Concern."

- The project has dual use elements, for example, the research may involve aerosols of specific agents are known to have been weaponized by adversaries in the past.
- The project will generate data on threat characterization and specific vulnerabilities.
- 18 Category 2 projects have been approved by the Compliance Review Group to date.

Category 3: The project, as presented, might reasonably raise the perception of a compliance issue and likely does involve National Science Advisory Board for Biosecurity "Research of Concern."

- The project will generate data on threat characterization and specific vulnerabilities.

- 22 Category 3 projects have been approved by the Compliance Review Group to date.

I want to stress that all DHS biological research must go through a comprehensive review and are ultimately signed off on by the Compliance Review Group.

REGULATORY COMPLIANCE

DHS has established a regulatory compliance program to facilitate Department-wide implementation of and compliance with DHS policies for biosafety, select agent and toxin security, and the care and use of animals in research. It is important to remember that DHS is not a regulatory authority for laboratories; we are a funding agency. DHS's select agent and toxin research is subject to regulatory control by the Centers for Disease Control and Prevention (CDC) and the Department of Agriculture Animal and Plant Health Inspection Service. At DHS, we conduct significant additional oversight because of unique sensitivities related to biodefense research, as distinct from conventional public health research, and a desire to ensure complete transparency for senior management of the department about all ongoing biodefense efforts.

The regulatory compliance program is significantly driven by our treaty compliance efforts. Laboratories conducting Category 2 or 3 projects are subject to an on-site inspection. Other laboratories are visited because we have some indication that there may be problems with non-compliance.

Of the 42 laboratories that are or have recently been working on DHS-funded biological research, we have conducted 23 on-site inspections, covering numerous government, university, private, and not-for-profit laboratories. Once the National Biodefense Analysis and Countermeasures Center at Fort Detrick becomes operational, we will also exercise compliance oversight over that facility.

Importantly, in 2008, we began doing document-based compliance reviews for laboratories conducting lower-priority research. We have completed seven document-based reviews, with five more in progress. This process is quite important for us. DHS requires providers to make available the documentation required by their regulatory agencies. This allows us to verify, for example, that laboratory staff have the appropriate FBI clearances to work with select agents, that training is up to date, and that record-keeping practices are kept to the required standard. Where document-based reviews provide evidence of non-compliance, laboratories are prioritized for onsite inspections.

I want to emphasize that the purpose of compliance inspections is to ensure DHS-funded work is being conducted in a legal and safe manner as well as to assist our providers in remaining compliant with legal requirements. DHS' regulatory compliance inspections identify and address compliance issues with the potential to impact DHS-sponsored programs, and I follow up with detailed guidance to performing organizations on approaches to enhance institutional programs for biosafety and biosecurity. My goal is to correct problems, not to bring scientific endeavors to a halt, barring substantial non-compliance findings. We aspire to eliminate non-compliance so as to help our providers anticipate and address problems proactively with regulatory authorities, and ensure the smooth functioning of the Department's research programs.

CLASSIFICATION REVIEW

To assist the Under Secretary in exercising Original Classification Authority, the Science and Technology Directorate established the Classification Review Panel, which I co-chair with the Directorate's Director of Security.

DHS has a significant priority in maintaining openness in life science research, but the nature of biodefense threat characterization studies requires that some elements remain classified to protect the public from harm. The Classification Review Panel co-chairs are responsible for ensuring all Science and Technology Directorate programs have, and are appropriately applying, classification guidance approved by the Under Secretary in his or his or her role as Original Classification Authority.

CONCLUSION

In conclusion, DHS has an exceptionally effective record of strengthening biological safety and security in DHS funded laboratories. In rare cases of substantial regulatory non-compliance, DHS has twice issued stop work orders with providers and worked with CDC to address laboratory-wide non-compliance that goes beyond the scope of the DHS-funded work. In one case, the facility lost the ability to work with select agents, and in the other, the facility was placed on a significant performance improvement plan by the CDC. I am particularly proud of this record, because it conclusively demonstrates the value of DHS's efforts in compliance.

Thank you for your attention, and I'd be pleased to answer any questions you may have.