DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

HOUSE ENERGY AND COMMERCE COMMITTEE

U.S. HOUSE OF REPRESENTATIVES

"HOW SECURE ARE U.S. BIORESEARCH LABS? PREVENTING THE NEXT SAFETY LAPSE."

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RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. I am Dr. Segaran Pillai, Director of the Office of Laboratory Science and Safety, within the Office of the Commissioner at the Food and Drug Administration (FDA or the Agency) within the Department of Health and Human Services (HHS). Thank you for the opportunity to appear today to discuss FDA's efforts to ensure the safety and security of our laboratories, and the people who work in them.

FDA's laboratories provide a critical role in fulfilling FDA's regulatory mission. FDA's laboratories, like all laboratories, must comply with all applicable Federal, state, and local safety requirements. To ensure this, the Agency is deeply committed to ensuring compliance with relevant laws and regulations through a combination of training, issuance of specific policies and procedures, appropriate oversight by safety officers in the Centers, and by fostering an Agency-wide culture of safety and security in our laboratories.

Upon discovery of vials of *Variola* at an FDA laboratory located on the National of Institutes of Health's (NIH) campus in July 2014, the FDA Commissioner established the Laboratory Safety Practices and Policies Workgroup (LSPPW). The LSPPW was charged with providing ongoing, structured coordination throughout the Agency and with ensuring implementation of FDA's policies, procedures, and activities for managing all potentially hazardous materials.

One of the first key actions of the LSPPW was to complete a "Clean Sweep" – a full visual audit of all storage areas and laboratories. The vast majority of FDA's roughly 670,000 vials and samples were properly stored; however, there were two instances where select agents were improperly stored in secure locations. In both cases, the Centers for Disease Control and

Prevention's (CDC) Division of Select Agents and Toxins was notified and the materials were destroyed.

The LSPPW continues to lead a careful and deliberate review of FDA's biosafety and biosecurity programs to identify and implement measures to improve laboratory safety practices across the Agency. As part of that review, and to foster a culture of safety, the Agency created a new position, the Director of the Office of Laboratory Science and Safety to provide executive leadership, oversight, and coordination of laboratory policies, practices, and operations.

I joined FDA in October 2015 to lead this newly established Office of Laboratory Science and Safety and serve as the Agency's focal point for laboratory safety and security. In my current capacity, I also serve as the Agency's senior laboratory scientific advisor to the Commissioner of Food and Drugs.

ADVISORY COMMITTEE TO THE DIRECTOR OF CDC, EXTERNAL LABORATORY SAFETY WORKGROUP

In May 2015, members of the Advisory Committee to the Director of CDC's External Laboratory Safety Workgroup (ELSW) conducted a thorough on-site review of FDA's laboratory safety policies and procedures. During this three-day visit, the workgroup met with key FDA officials to discuss the circumstances surrounding the discovery of *Variola* samples on NIH's campus, and reviewed the policy elements of biosecurity and inventory control, laboratory safety training programs, laboratory security operations, as well as compliance programs. The resulting report, released on July 2, 2015, contained eight observations that included a total of 30 recommendations. We have implemented many of those recommendations and are making

steady progress on the remaining recommendations that resulted from that review in order to build and strengthen FDA's comprehensive laboratory safety and security program.

The ELSW recommendation to augment communications throughout the Agency is a top priority. FDA is fully committed to coordinating its Agency-wide laboratory safety training, policies and practices, where feasible. In addition, FDA will continue to work diligently to centralize appropriate laboratory safety practices, including standardizing policies and procedures, and refining inventory policies and audit procedures. Another priority is to provide the communication tools necessary for staff to effectively report problems and solutions to appropriate sources and senior officials. FDA will continue to implement and improve Agency-wide communication and training programs.

CULTURE OF SAFETY AT FDA

FDA is deeply committed to fostering an Agency-wide culture of laboratory safety. To gauge the culture of safety at FDA, we held a series of 13 focus groups with laboratory staff throughout the Agency. The purpose of the focus groups was to raise safety awareness, and identify trends and risk areas. Accountability, safety culture, communication, and training were identified as critical areas by the focus groups. One of the key positive findings was that, in general, staff was not afraid of reprisal if they were to report safety issues.

FDA is in the process of establishing a robust and consistent process for communication of issues and challenges between safety officers and senior leadership. Safety professionals are at the frontline of the FDA safety program. Providing direct lines of communication to senior

leadership will ensure that issues and challenges are identified immediately, and that the root cause will be fully addressed and resolved in a timely manner.

FDA is planning additional ways to engage laboratory staff in a variety of settings, including focus groups, town-hall meetings, and other forums to provide a positive and productive outlet for employees to communicate their thoughts and ideas for improving safety and security at FDA laboratories.

An integral way to promote a culture of safety and security and ensure compliance with legal and regulatory requirements is through training. FDA is in the process of implementing a core-curriculum of biosafety and biosecurity training for all FDA personnel working in biomedical research laboratories. This cross-cutting, Agency-wide safety training program will instill and strengthen a culture of safety and compliance throughout the Agency.

FDA intends to evaluate ways to leverage external safety expertise from industry and elsewhere to bring fresh ideas to the FDA biosafety and biosecurity program.

Through the LSPPW, FDA issued a new Agency-wide inventory control and management policy for hazardous biological agents and toxins. The policy provides for implementation and use of a central electronic inventory control and management system that will allow the Agency to provide efficient oversight of all hazardous biological agents and toxins located at the Centers and Offices. This policy reaffirms FDA's commitment to a culture of security by clearly establishing the roles and responsibilities of FDA safety officers within each of the Centers for scientists, and their managers, who work with hazardous biological agents and toxins.

GAO REPORT

As I have discussed, FDA has already taken steps to enhance laboratory safety and security practices and support the culture of safety. We appreciate the GAO's recommendations as they further validate our strategic approach as we continue to develop a comprehensive and sustainable laboratory safety and security program. The recommendations in both the ELSW and GAO reports provide essential feedback for FDA as we continue to enhance our laboratory safety and security practices and policies. As recommended in the GAO's report, the Agency will continue to build upon its efforts to improve laboratory inventory control, management, and reporting processes.

The GAO reported that, as of December 2015, FDA met five of the six elements key to policies for managing hazardous biological agents in high-containment laboratories. Although FDA's current policies do not provide for laboratory incidents to be reported to senior Agency officials, incident reporting does occur within each of the FDA Centers and Offices and an analysis of the root causes is performed annually.

In addition to following the Occupational Safety and Health Administration's (OSHA) incident reporting policy, FDA policies provide for laboratory managers and principal investigators to report incidents involving significant spills and personnel exposure to hazardous biological agents and toxins to their supervisors, as well as Center or Office leadership. We are working to establish a process for these incidents to be systematically reported to me. I would then communicate these reported concerns with FDA and HHS executive leadership team as frequently and immediately as needed.

Building upon these practices, I am also working closely with FDA Center and Office safety officers to develop a more comprehensive reporting mechanism to capture laboratory accidents, incidents, near-misses, and laboratory-acquired infections. This new reporting mechanism will be implemented in the coming months, and will require all Centers and Offices to report all such events to my office. The FDA's Office of Laboratory Science and Safety will establish an official FDA-wide policy and work with the HHS Biosafety and Biosecurity Coordinating Council to determine appropriate criteria and procedures for reporting incidents to HHS leadership in a timely manner. The HHS Biosafety and Biosecurity Coordinating Council, on behalf of the Secretary, provides a high-level and formal mechanism to coordinate and collaborate on biosafety and biosecurity issues across the Department. GAO's recommendations specific to FDA are in line with current efforts to improve the culture of safety and security at the Agency and I look forward to integrating them into our overall laboratory safety and security framework.

SUPPORT OF U.S. GOVERNMENT EFFORTS TO STRENGTHEN BIOSAFETY AND BIOSECURITY

In addition to the improvements in laboratory safety at FDA, the Agency is also participating in U.S. Government (USG) efforts to strengthen biosafety and biosecurity. On October 29, 2015, the USG released two sets of recommendations as well as the implementation plans: one from the Federal Experts Security Advisory Panel (FESAP), which conducted an internal USG review of biosafety and biosecurity practices; and another from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR), which conducted an external review that focused on the effects of the select agent regulations on researchers and laboratories. Recommendations made

by both the FESAP and FTAC-SAR address the culture of responsibility, oversight, outreach and education; applied biosafety research; incident reporting; material accountability; inspection processes; and regulatory changes and guidance to improve biosafety and biosecurity. In addition, an approach was identified to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer biological select agents and toxins. The USG has developed a plan to implement the FESAP's and FTAC-SAR's recommended actions. The USG expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities.

CONCLUSION

FDA is fully committed to enhancing laboratory safety and security. Since the discovery of the vials of *Variola*, FDA's senior officials have taken direct and definitive action to improve FDA's laboratory safety and security policies, practices, and to foster a culture of safety and security across the Agency. FDA stands committed to enhancing the safety and security of both our staff and the public.

No regulation or guideline can ensure safe and secure laboratory practices unless applied to daily activities. Individuals and the organizational commitment to the culture of safety influence all aspects of safe and secure laboratory practice. This includes a willingness to report incidents and concerns, apply lessons learned, and ensure timely communication of potential risks, as well as the ability to respond to an incident judiciously. Safety in the laboratory evolves through experience and knowledge gained over time on how to recognize and minimize risk and control

hazards. As we share and apply this critical knowledge to our daily activities, we are confident that the level of risk will decrease, with the goal of reducing risk to the lowest possible level.

Thank you. I am happy to answer your questions.