OPENING STATEMENT FOR THE HONORABLE MORGAN GRIFFITH

VICE-CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

NOVEMBER 2, 2017 HEARING ON THE FEDERAL SELECT AGENT PROGRAM

Today, the Subcommittee examines the concerns over federal oversight of labs working with dangerous viruses and bacteria for research needed to protect public health and national security.

The Federal Select Agent Program ("Program") under the joint management of the CDC and the USDA's Animal and Plant Health Inspection Service was established by legislation enacted in 2002, shortly after the 9-11 attacks and the anthrax mailings. These events spurred Congress to conclude that certain dangerous pathogens such as anthrax, smallpox and plague – called select agents and toxins – required regulation of its possession, use and transfer.

The Program oversees 276 registered laboratories and almost 4,000 individuals involved with vital research into diagnostics, vaccines, and medical countermeasures that saves lives, protects American agriculture, and helps protect the safety and security of the American people. In 2016, the Program conducted 181 inspections of registered laboratories, and was notified of 177 separate incidents involving potential exposures with 998 lab workers monitored but fortunately with no illnesses developed.

Because of the importance of this work and its potential dangers, this Subcommittee has convened hearings in recent years on safety lapses in federal high-containment laboratories:

- the anthrax incident at CDC that potentially exposed more than 80 CDC workers;

- a mistaken CDC shipment of deadly bird flu to a USDA lab;

- a U.S. Army lab's mistaken shipments of live anthrax samples for a decade to almost 200 different locations in the U.S. and around the world; and

- the FDA's discovery of decades-old, undeclared and unregistered smallpox vials in a storage room that FDA had been renting from NIH and was missed by annual NIH safety inspections.

The pattern has been: incident involving handling of select agents, news stories, committee hearing, outrage, reaction, and short-term reform. Wash, rinse, repeat. The question before the Subcommittee this morning is how do we break this pattern, and instill a systematic approach toward oversight of federal select agents that improves safety and enhances public confidence.

The GAO's latest report adds urgency to this question. The GAO found that the Program did not fully meet all key elements of effective oversight. That is troubling. Select agents are dangerous materials, posing a severe threat to human or animal health. One would have assumed that the oversight program for select agents would meet at least some of the effective oversight elements found at other government oversight programs for dangerous research, such as work involving radioactive materials and nuclear weapons. That is not the case. For example, the GAO concluded that the Program is not independent. Both CDC and APHIS, the joint managers of the Program, have high-containment laboratories registered with

the Program. As a result, experts advised the GAO that the Program cannot be entirely independent as oversight of their own laboratories may represent a conflict of interest. One wonders whether or how this has impacted the Program's oversight. Two years ago, the HHS Office of Inspector General reported to the Committee that the CDC was the entity with the most referrals for Program violations.

The GAO also found that experts and laboratory representatives raised concerns that the Program's reviews did not target the highest-risk activities such as anthrax inactivation, in part because it has not formally assessed which activities pose the highest risk. Thus, lab representatives told the GAO that the Program focused on inventory controls and conducted time-consuming reviews so that nicknames such as "Rob" matched with registered names such as "Robert." On the other hand, as the Subcommittee learned at its hearing in September 2016, the incomplete inactivation of select agents (particularly anthrax) was a recurring problem in recent high-profile lab incidents. Unfortunately, the Program had not focused on the need for more specific reporting and investigation of incomplete inactivation of anthrax.

Technical expertise is another concern. Even with recent extra hires, workforce and training gaps remain.

The GAO also noted the Program did not have joint strategic planning documents to guide its oversight. It is perplexing how the CDC and APHIS operated for nearly 15 years without a joint strategic plan.

Finally, the GAO reviewed effective oversight approaches in selected foreign countries and regulatory sectors. For example, in Great Britain, oversight of laboratories that work with pathogens is under an independent government

agency focused on health and safety. Under this structure, the agency has direct access to a department head, with control over defining its own budget and staffing needs without organizational conflict of interest.

The Subcommittee will examine whether administrative responses are sufficient to help the Program meet the key elements of effective oversight. However, it is also fair to ask whether Congress has a legislative role. This Program at its inception was created in a fragmented state – a marriage of two divisions from two subcabinet agencies in different Cabinet departments. The Program was created with a security emphasis of guards/guns/gates in response to terrorist attacks. Fifteen years later, does this regulatory model for bio-research laboratories make the most sense with more concern about biosafety and the growing public health threat of emerging infectious diseases?

I welcome and thank our witnesses for appearing here today. I look forward to the testimony.