Opening Statement of the Honorable Tim Murphy
Subcommittee on Oversight and Investigations
Hearing on "Bioresearch Labs and Inactivation of Dangerous Pathogens"
September 27, 2016

(As Prepared for Delivery)

Today this Subcommittee will continue our examination of bioresearch labs and the handling of dangerous pathogens, including the 66 pathogens classified as federal "select agents." Specifically, we will focus on the inactivation of bacteria and viruses, or making dangerous organisms harmless and incapable of spreading disease while retaining characteristics for future use – including crucial biodefense research. This research allows for the development of diagnostic tests to detect emerging infectious diseases, as well as discovering vaccines and other medical countermeasures to protect us from epidemics.

First, I would like to thank the GAO for their hard work and pivotal report, as well as their participation in today's hearing. I'd like to also thank CDC, FDA, NIH and the Department of the Army for their participation today.

Disastrously, recent incidents at federal bioresearch labs have revealed lackadaisical methods used to inactivate anthrax, a deadly select agent. Such negligence continues to put human lives at risk. In 2015, the Army's Dugway Proving Ground shipped live anthrax -- thought to have been successfully killed -- to contractors, sub-contractors and private labs in all 50 states and nine foreign countries for more than a decade. The dangers presented by such a careless mistake are unacceptable. Thankfully, no one was harmed, so the Army dodged a catastrophe in this matter. However, without major overhaul of how deadly agents, like anthrax, are handled and how research is conducted, the risk of repeating this mistake is remains viable.

In 2014, this Subcommittee held a hearing on live anthrax that was shipped out – once again - thought to have been inactivated. The anthrax was shipped from a high-containment lab at CDC to another lab at CDC with a lower level of biosafety. The transfer of live anthrax potentially exposed over 80 CDC employees. An internal CDC review and USDA inspection found multiple failures: unapproved inactivation techniques were used; a virulent strain of anthrax was unnecessarily used in the research; lab staff lacked training and knowledge required to inactivate anthrax; lack of standard operating procedures for inactivation; inability to find anthrax samples; and disinfectant used for decontamination was expired. These kinds of incidents drove direct action from the White House- a stand-down was ordered in the summer of 2014.

However, and disappointingly, even with consciousness raised about lab safety, bioresearch labs persist in questionable inactivation practices today. Recently we learned that the CDC in Fort Collins, Colorado sent a shipment of Zika, Dengue, and chikungunya viruses to CDC Atlanta. The viruses were used in control panels for a trioplex diagnostic test under emergency use authority. Despite CDC Ft. Collins' knowledge that the inactivation had not been confirmed, the shipment was sent. Live viruses – including Zika – were handled and shipped across the country. CDC Ft. Collins told CDC Atlanta not to open the package until inactivation was confirmed. Ultimately, the package was not opened.

This continued problem of mistakenly shipping live anthrax and other pathogens led the Committee to make a bipartisan request to the GAO to evaluate issues related to inactivation. By coincidence, the request was made two weeks before the discovery of the massive anthrax inactivation problem at Dugway. Today, the GAO will present its findings and recommendations

on the inactivation of dangerous pathogens. Failed inactivation has been long overlooked by regulators and the research community. GAO brings us several important findings. First, the GAO found that the Federal Select Agent Program, operated by both the Departments of Health and Human Services and Agriculture, does not require laboratories to identify incidents involving failed inactivation in its reporting resulting in inconsistent and incomplete reports. From 2003 until 2015, the Select Agent Program reported 10 incidents, but GAO documented an additional 11 situations in which select agents were not effectively inactivated. Since the Select Agent Program lacks standard practices for identifying such incidents, we don't know how often they occur, or why.

The GAO also noted the need for better and more consistent follow-up when problems with inactivation are discovered. According to GAO's report, the federal select agent regulators were inconsistent in both their referrals for further investigation and in their enforcement approach. As one example, two incidents at CDC under investigation by USDA in 2014 were not referred for further investigation. The lack of consistency by select agent regulators -- CDC and USDA – leaves this Subcommittee and the public with zero confidence in regulators' ability to protect the safety of the American public.

GAO'S most alarming discovery is the fact that today, we still don't know what it takes to effectively and reliably inactivate certain select agent pathogens. In some cases, the chemical or radiological "dosing" is not actually effective; in other cases, the process for verifying the inactivation is not reliable. It is extremely troubling that after fifteen years of efforts, we still lack competency in ensuring the safety of the public from dangerous, and sometimes fatal, bacteria and viruses. This needs to be among our highest priorities for reforming the Select Agents Program.

To reiterate, it has been 15 years since we became aware of the need for an effective Select Agents Program. Clearly, there's still a lot of work to do.

I do want to commend the Army for its response to the shocking shipments of anthrax from the Dugway laboratory, and also I want to acknowledge the cooperation that we've received from both the NIH and the FDA; both have worked to identify improvements needed and to implement those changes, including creating new offices and committing additional resources.

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