Opening Statement of Rep. Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Hearing on "Bioresearch Labs and Inactivation of Dangerous Pathogens"
September 27, 2016

AS PREPARED FOR DELIVERY

Thank you, Mr. Chairman.

This hearing offers the Subcommittee a valuable opportunity to check in on the progress that the Federal Select Agent Program has made in improving practices and procedures at high-containment laboratories. These places handle pathogens that have the potential to pose a severe threat to public health and safety. .

Our specific focus today is whether we have the proper scientific understanding and processes to ensure that pathogens are inactivated before shipping or releasing them.

This issue gained public attention last year when it revealed that the Army's Dugway Proving Ground had been inadvertently shipping live anthrax to labs across the world for years.

Researchers must inactivate pathogens for a variety of reasons. For example, federal agencies, universities, and others inactivate disease causing agents so that vaccine development and diagnostic testing can occur in lower safety-level labs. This work is crucial for promoting medical advancements and bolstering public health preparedness. It is a critical part of this Committee's bipartisan efforts to accelerate the pace of cures and medical breakthroughs.

However, as valuable as this research may be, it can also be very dangerous. All of the agencies here today share the responsibility of

making certain that harmful pathogens are being handled without posing undue risks to the public.

I know that we all have taken the inactivation events we are talking about today very seriously. All the agencies before us have been implementing reforms to ensure that past mistakes are not repeated. We're all eager to hear about those efforts.

But we also want to understand what more needs to be done to address this possible risk to public health.

We have a witness from the GAO with us today to testify about the oversight of high-containment laboratories. GAO's most recent report focuses on inactivation procedures at these labs.

GAO researchers have identified a number of issues related to the reporting and referral of incidents involving incomplete inactivation. For example, they found the total number of incidents of incorrect inactivation is unknown. They found that the Select Agent Program failed to identify at least 11 inactivation incidents in the last twelve years. They also found the Select Agent Program did not consistently refer inactivation incidents to HHS or USDA for further investigation and enforcement.

These findings underscore the need for further coordination, clarity, and guidance within the Select Agent Program. The report offers recommendations to the CDC, NIH, and APHIS [AY-fis], particularly regarding how to regulate the possession, use, and transfer of these pathogens.

I am particularly interested in hearing from each of our witnesses about their plans to implement the GAO's recommendations.

Mr. Chairman, I am also eager to learn about the scientific gaps that still exist regarding inactivation processes for pathogens. High-

containment labs across the government have still not adopted a uniform approach to inactivation of dangerous pathogens, which increases the risk that incomplete inactivation occurs.

We must get this right.

Research on select agents and other harmful pathogens is a critical national security endeavor. However, the process of working with these pathogens must minimize all possible risk. If something goes wrong in this program, there could be disastrous consequences.

We are fortunate that no one in the United States has been injured from exposure to select agents in the number of incidents in the past few years. However, our good fortune does not diminish the threat that the mishandling of these pathogens poses to the health and welfare of millions of Americans. At the end of the day, I need to be able to tell my constituents that the hundreds of laboratories around the country that handle these pathogens – including the CDC's facility in Fort Collins that sits just outside my district – are doing so safely and with care.

I know the agencies represented before us today understand what is at stake here. We have seen promising efforts to investigate incidents, conduct government-wide reviews, and implement recommendations. And we know that institutional and cultural changes take time..

I look forward to working with all parties before us today to make this program safer, mishaps less common, and accountability more robust.

I thank the Chairman and I yield back.