Opening Statement of Rep. Diana DeGette
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing on
"How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse"

AS PREPARED FOR DELIVERY

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Mr. Chairman, I'm glad the subcommittee has convened again to consider this subject.

As you know, this is not a new subject for me.

In the early 2000's, I had the opportunity to visit a level 3 CDC laboratory in Fort Collins, Colorado. I was dismayed to see vector-borne agents being stored in a modular unit behind the lab with what was plainly a lack of consideration for safety and security concerns.

More recently, we have seen a series of safety lapses at facilities managing dangerous pathogens such as live anthrax; the mishandling of life-threatening diseases such as Ebola; and, most recently, last November's discovery that a lab had accidently shipped a toxic form of ricin to a FEMA training center multiple times between 2011 and 2016.

These and other incidents prompted the subcommittee to hold multiple hearings over the past decade to examine what changes are needed to the Federal Select Agent Program. As our repeated work in this area shows, this program is still not where it needs to be.

The Select Agent Program has the vital task of ensuring that critical biodefense research proceeds without posing any danger to the health and safety of American citizens.

To achieve this goal, the Centers for Disease Control and the Animal and Plant Inspection Service, also known as APHIS, which jointly oversee the Select Agent Program, must ensure that it exercises adequate and appropriate oversight over all laboratories that handle dangerous pathogens and toxins.

Unfortunately, were are even today left with the question of whether oversight of the Select Agent Program by both the CDC and APHIS is sufficient to guarantee that high containment labs are safely managing pathogens.

We must continue to remind ourselves that that these pathogens have to be handled with the utmost safety and security -- and that there is no room for error. The pathogens used in this program could be extremely dangerous if they fell into the wrong hands or if infection spread to the general public. Any amount of uncertainty in this area is unacceptable.

I again welcome GAO's presence here today to discuss their most recent report on the Select Agent Program's oversight of dangerous pathogens. I am concerned about many of the findings of the report, in particular GAO's observation that the Select Agent Program still may not be applying the most effective approach to oversight of the laboratories that handle these pathogens.

For example, GAO had concluded that, quote, "the program's reviews may not target the highest-risk activities, in part because it has not formally assessed which activities pose the highest risk." According to GAO's report, Select Agent Program inspectors may focus on biosecurity concerns at laboratories, such as measures to deter theft, to the exclusion of biosafety concerns like how to safely handle pathogens.

Both safety and security are essential concerns in the management of dangerous substances. Indeed, the most recent incidents have involved accidental releases and transfers of pathogens and toxins, rather than theft. But it is crucial that inspections take both these concerns into account to prevent further incidents like those we have recently witnessed.

I also want assurances that certain components of the CDC and APHIS are adequately staffed to oversee the Select Agent Program. For example, according to GAO's report, a shortage of inspectors has delayed the issuance of a substantial number of post-inspection reports. If this is true, then some laboratories are allowing poor practices to continue for a longer period than is necessary.

GAO's report also states that APHIS inspectors reported that they sometimes lack the necessary knowledge to inspect CDC laboratories, and must rely on CDC employees to assist them. In a high risk field such as biodefense research, it is unacceptable for any employees to lack adequate technical expertise. We need to know why, after so much oversight of this program, this problem persists.

Finally, GAO's audit has again underscored the need for the Select Agent Program to operate independently, and that it has not assessed the risks posed by its current oversight structure which lacks independence.

As a practical matter, this means that inspectors employed by CDC are sometimes responsible for inspecting CDC laboratories, and APHIS inspectors sometimes inspect APHIS laboratories. This is unacceptable.

This lack of independence may lead to less rigorous oversight than a program of this nature demands. I believe we should explore what measures should be considered to address this possible inspection flaw.

In conclusion, I am pleased that GAO has continued its work on behalf of this Committee examine safety and oversight issues involving the Select Agent Program.

I look forward to hearing from GAO about some of the possible solutions they believe might address some of the issues they have revealed in this latest audit.

I also look forward to hearing from both APHIS and the CDC. The CDC in particular has a long history of working closely with this Committee and does critically-important work to keep the global community safe from all types of biological threats.

Thank you to all of our witnesses for being here today, and I yield back the balance of my time.