

## **Chairman Murphy Opening Statement**

### Subcommittee on Oversight & Investigations “How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse”

This is the third time in as many years that this subcommittee has held a hearing on the Federal Select Agent Program and the Federal government’s high-containment laboratories. Each time, a panel of witnesses appears before us to testify about changes made in response to one failure or another.

Two years ago, CDC Director Tom Frieden testified about changes made at the CDC after failing to follow safety procedures potentially exposed dozens of CDC employees to anthrax. Dr. Frieden told us then that the CDC was implementing every step possible to “make sure that the problems are addressed comprehensively in order to protect our own workforce, and to strengthen the culture of safety, and to continue our work protecting Americans.”

Last year, the Deputy Assistant Secretary of Defense for Chemical and Biological Defense came before us to explain how at least 192 labs across the world received live anthrax from the Dugway Proving Ground, an Army lab in Utah. The Army undertook a comprehensive review of the incident and the Deputy Secretary told us that the Department was “committed to ensuring that this doesn’t occur again.”

Sweeping improvements and policy changes only work if the policies are effective. And, in this area, past policy reviews have not brought about the changes necessary to improve safety. For that reason, Ms. DeGette and myself, along with Chairman Upton and Ranking Member Pallone, asked the GAO to evaluate the biosafety, biosecurity, and oversight policies for the 8 departments and 15 component agencies that own and operate the Federal government’s high-containment laboratories. GAO has been issuing recommendations for years on the need for better policies and standards at high-containment labs—recommendations that have not been implemented—so the agency was well-positioned to receive our request.

GAO found that, while the departments and agencies have improved on their biosecurity policies in recent years, comprehensive policies and better oversight of the labs are still needed. High-containment laboratories, which store the most dangerous pathogens, must have tight inventory controls, rigorous training, and required incidence reporting. And agencies and departments must have strong oversight of their laboratories with accountability for those who fail to follow the policies.

While GAO has been doing its work, the Committee has been conducting its own review into the discovery of smallpox vials at the NIH in 2014. The preliminary findings of the majority staff are discussed in a supplemental memorandum released yesterday. We found a number of flash points where, if NIH or FDA had done just a little more than what their policies required, or thought outside the box just a little bit, those agencies could have discovered the smallpox vials years earlier.

For example, the NIH experienced a major event in 2011, when it learned that a researcher received an unauthorized transfer of antibiotic resistant plague specimens, and in 2012, when it discovered unregistered, antibiotic resistant anthrax, including at an FDA lab in the very same building where the smallpox was discovered two years later. The 2012 discovery was prompted by a disclosure of two investigators during a re-training exercise prompted by the 2011 discovery by the CDC's Division of Select Agents and Toxins, not by any investigative work on the part of the NIH. And the 2012 discovery resulted in the CDC putting NIH on a Performance Improvement Plan. These discoveries, including two different dangerous pathogens, should have spurred NIH and FDA to conduct a comprehensive sweep of all laboratories, and a comprehensive review of its policies, at the time. But they didn't.

When we informed NIH and FDA of our findings, we found agencies still reluctant to acknowledge the full extent of their failings. NIH did not even acknowledge its failings in how it registered into the Federal Select Agent Program a historical collection of select agent samples held in sealed envelopes unopened since 1960. NIH registered the materials without opening the envelopes. The agency did not confirm the materials inside the envelopes, or even verify that the samples were still secure. And they registered these materials not once, but twice, without opening the envelopes. When they finally did open the envelopes, they discovered 7 additional vials of one select agent then previously reported. These failures defy common sense. This is a culture of complacency, and shows that it is not enough to change the policies—we must also change the culture at NIH.

While the Department of Defense is holding 12 people accountable for the factors that led to the Dugway shipments, in contrast HHS and its agencies have not been fully accountable and transparent with the committee on disciplinary and personnel actions resulting from lab safety incidents. For example, the Committee requested documents from the CDC as part of our investigation regarding the four instances of improperly stored anthrax at NIH. Unfortunately, the CDC produced redacted documents, blacking out key information. There was no legal basis for these redactions, and CDC offered no explanation. This type of response is designed to delay and stymie Congressional oversight on behalf of the American people. When we request documents, we expect unredacted documents. If these agencies are not being forthcoming with Congress, then they are certainly not being forthcoming with the American people. For all the CDC rhetoric about transparency, redactions of key details in requested investigative documents prove otherwise. We all deserve better.

Neither NIH nor FDA ever conducted an internal review of the smallpox incident along the lines of the reviews conducted by the CDC or the DOD, deferring instead to an outside review by the CDC and FBI. I urge these agencies to initiate internal reviews of their own failings leading up to the smallpox discovery. If we've learned nothing from all of the incidents involving select agents over the years, it is that we can't find the next safety lapse if we don't go looking for it.