United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

July 11, 2014

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

As members of the Senate Health, Education, Labor, and Pensions (HELP) Committee, we are writing with concerns and questions about three separate and deeply troubling incidents in which samples of select agents, highly dangerous pathogens, were reportedly improperly handled, stored, or transferred by Federal laboratories at the Department of Health and Human Services (HHS). The discovery of smallpox vials on the National Institutes of Health (NIH) Bethesda, Maryland, campus, in addition to the Centers for Disease Control and Prevention (CDC) anthrax incident last month and today's report of earlier cross-contamination of highly pathogenic influenza samples that were transferred to a laboratory at the United States Department of Agriculture (USDA) necessitates a serious and careful review of HHS's policies, procedures, and actions with respect to the appropriate handling of select agents and other serious pathogens.

First, on Thursday, June 19th, we learned that bioterrorism researchers at CDC discovered that on June 6th they had mistakenly sent live anthrax specimens to two labs at lower biosafety levels at the agency, instead of what they thought were deactivated, and therefore less serious, samples. Members of this Committee wrote a letter to CDC Director Dr. Tom Frieden on June 23rd asking for more information on that incident. Today we were notified of steps CDC is taking in the wake of this incident, and we look forward to closely examining CDC's findings and plans for addressing this issue.

Next, on Tuesday, July 8th, we were notified that NIH employees discovered vials labeled "variola" in an unused portion of a storage room at a Food and Drug Administration (FDA) laboratory on the NIH campus. This discovery raises serious concerns about how and why these vials came to be located in the laboratory, reportedly for decades, as well as the potential safety and security threats posed to staff at the NIH campus and to the general public by the presence of samples of such a serious Tier 1 select agent. It is our understanding that this laboratory was transferred from the NIH to the FDA in 1972 in conjunction with the transfer of authority for regulating biologic products. The discovery of the presence of smallpox vials was made on July 1, 2014, and the Division of Select Agents and Toxins at the CDC was notified and the vials

were secured in a CDC-registered select agent laboratory in Bethesda. On July 7, in coordination with federal and local law enforcement agencies, the vials were transported to CDC's high-containment laboratory in Atlanta, Georgia, where the presence of variola virus DNA was confirmed. We understand that CDC is conducting further tests to determine whether the samples are viable, after which they will be destroyed. The World Health Organization (WHO) was notified of the discovery pursuant to international agreements, and, should further testing reveal that viable smallpox is present, will also be invited to witness the destruction of the smallpox materials.

Finally, today we became aware that in May a CDC laboratory transferred an influenza sample to a laboratory at the USDA that was contaminated with H5N1, a highly virulent strain of avian influenza. Furthermore, we learned that proper reporting protocols were not followed in the wake of that incident.

We understand that there are investigations underway to ascertain exactly how the smallpox samples were originally prepared and came to be stored and held at that specific laboratory, as well as to establish the process that resulted in the transfer of a contaminated pathogen sample to a USDA laboratory from a CDC laboratory. We look forward to reviewing the full reports and findings once these investigations are complete. In the interim, we have several questions to which we would appreciate your prompt and detailed response.

1) CDC's Select Agent Program plays a critical role in ensuring the safety and security of select agent research and handling, such as with smallpox, anthrax, and avian influenza virus, as a comprehensive approach to ensuring the safety of the American people. Please explain what actions the CDC's Select Agent Program plans to take to review current program policies and procedures with respect to the identification, transfer, and possession of select agents in light of the recent developments, including any steps identified as necessary to improve biosafety and security at the CDC laboratories.

2) Please provide a timeline of the events and circumstances that led to the discovery of the smallpox samples and their transport and subsequent testing at the high-containment laboratory in Atlanta, with as much detail as is available.

3) Please provide a detailed overview of the actions you and the agencies within your department are taking in response to the smallpox discovery, including any plans for a broader inventory of HHS' laboratories. If the Department does not intend to carry out such an inventory please explain when the last such inventory occurred and why the Department does not believe another such inventory is necessary in light of the recent unexpected smallpox samples.

4) Please provide a list of which agencies will be involved in the smallpox investigation and the role they will play to determine how the samples were prepared and stored at the laboratory.

5) Other unlabeled and ambiguously labeled vials were found along with those labeled as variola. Have the contents of those vials been tested and identified? Please identify any

additional select agents or other pathogens found in the unlabeled and ambiguously labeled vials and corresponding actions taken.

6) In what condition were the smallpox vials discovered? Is there evidence that any of the vials labeled variola or otherwise were breached? If yes, please describe the manner of such breach and the response to ensure the safety and security of the vials.

7) What were the exact events that led to the transfer of a sample contaminated with H5N1 to a USDA laboratory from a CDC laboratory? What was the timeline of reporting this incident within HHS and USDA, between agencies, and to officials outside of the agencies?

We look forward to a continued dialogue with you to ensure that our nation's laboratories engaged in research to protect public health remain safe and secure. Should your staff have any questions, please have them reach out to Andi Fristedt in Chairman Harkin's office at 202-224-7675 or Melissa Pfaff in Ranking Member Alexander's office at 202-224-6770.

Sincerely,

Tom Harkin
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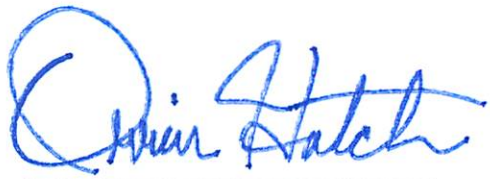

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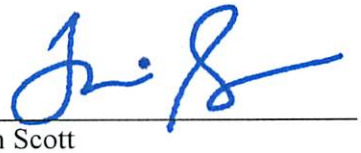

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