



July 28, 2016

The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your May 18, 2016 letter regarding the National Institutes of Health's (NIH) commitment to laboratory safety. I agree with you and Subcommittee Chairman Murphy that laboratory safety and security must consistently be a high priority for federal research agencies. I assure you that the NIH takes this commitment very seriously, and as Dr. Lawrence Tabak, Principal Deputy Director of NIH, outlined in his testimony before the April 20, 2016 hearing of the Subcommittee on Oversight and Investigations, we have taken and continue to take actions to preserve the public's trust by ensuring safety practices and strong leadership.

The Government Accountability Office (GAO) in its March 2016 Report entitled, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Needed," identified six policy elements that are key for managing high-containment laboratories and are consistent with federal internal control standards. In the March 2016 report, and as referenced in its April 20 testimony before the Subcommittee, the GAO found that the NIH met all six key elements for managing hazardous biological agents in high-containment laboratories, including reporting incidents to senior department officials.

I am pleased to have this opportunity to respond to your inquiry and provide you information to clarify any remaining questions concerning our lab safety practices and oversight structure. The NIH actions since 2014 illustrate our continued commitment to building and maintaining a culture of safety.

Below are responses to your specific questions:

1. What is the justification for the level of funding and staffing for the laboratory safety activities of the NIH? Does the NIH have appropriate funding and staffing for executing critical tasks associated with laboratory safety?

Response:

The NIH Division of Occupational Health and Safety (DOHS) – NIH's laboratory safety program – provides leadership and guidance in the development, promulgation, and

implementation of comprehensive occupational safety and health policies, standards, and procedures consistently across NIH Institutes and Centers (ICs). The current level of funding and staffing is appropriate to meet the safety needs of the NIH's complex research portfolio.

2. Does the NIH agree with the ELSW recommendation and the CDC approach that the safety of all NIH laboratories should be overseen by one centralized office using uniform and consistent safety standards? If yes, how does the NIH plan to implement this recommendation?

Response:

While this Extramural Lab Safety Working Group (ELSW) recommendation was directed to the CDC, the NIH supports the centralization of laboratory safety programs. In fact, the May 4, 2015, ELSW Advisory Committee to the Director report to the HHS Secretary stated that:

“The Division of Occupational Health and Safety (DOHS) is recognized across the NIH as the central authority in support and promotion of laboratory and research safety programs at the NIH.”

However, we recognize that unique situations do exist within the NIH structure that offer opportunities for further centralization. First, the National Cancer Institute's (NCI) Frederick National Laboratory for Cancer Research (FNLCR) in Frederick, Maryland, is a contractor-operated Federally Funded Research and Development Center (FFRDC). The contractor is Leidos Biomedical Research, Inc. The NCI Office of Scientific Operations serves as the NCI Project office for the Frederick National Lab Operations and Technical Support (OTS), Computer and Statistical Service, and Scientific Library contracts. Because the FNLCR is a contractor-operated FFRDC, the OTS contractor – Leidos – provides all aspects of laboratory safety and security, with significant interactions with the NIH DOHS to ensure that the operations are consistent with all HHS/NIH and other applicable requirements. In consultation with NCI management, we are exploring how and when we could modify the Leidos contract so that moving forward the safety and health portion of the contract could be overseen by a contracting officer's representative within the NIH DOHS. This would allow direct interface and collaboration between the centralized NIH safety organization – DOHS – and the contract organization. This approach will help increase our ability to ensure consistency in application and implementation of NIH safety and health policies.

Additionally, the National Institute of Environmental Health Sciences (NIEHS), located in Research Triangle Park, North Carolina, maintains an environmental, health, and safety program. To provide consistent NIH laboratory oversight, laboratory safety functions will continue to be located onsite in North Carolina, but will report to the NIH DOHS located in Bethesda, Maryland.

Accomplishing these steps will fully centralize the NIH safety and health program and ensure that uniform and consistent safety standards are applied.

3. Does NIH agree with the ELSW recommendation that the source of funding should be independent from other NIH institutes, centers, and offices? If so, will the NIH commit to independent funding for office responsibility for laboratory safety?

Response:

It is important to note that the ELSW made no such recommendation for the NIH. However, implementing the changes mentioned in question 2 will further centralize the control of funding for the NIH safety and health program by providing the DOHS with oversight of all laboratory safety budgets.

4. In accordance with ELSW recommendations, will the NIH commit to having the Director of Lab Safety report directly to the Director of NIH?

Response:

It is important to note that the ELSW made no such recommendation for the NIH. The current reporting structure at the NIH assures that incidents and important reporting matters rapidly come to the attention of the NIH Director. This is evidenced by the reporting of the smallpox incident in 2014. The ELSW found that, “[The] finding was promptly communicated to the NIH Director.” Further, the ELSW stated “This incident and the response to it are demonstrative of clear and prompt reporting of incidents and local responsibility to respond appropriately.” Nevertheless, in the interest of further streamlining the reporting structure, the NIH Director will establish a Laboratory Safety Officer (LSO) designation for an individual that directly reports to the NIH Director. The DOHS Director will be designated as the LSO. Organizationally, the DOHS will remain in the NIH’s Office of Research Services and maintain the Designated Agency Safety and Health Official reporting structure, as well. The DOHS Director maintaining both roles ensures consistency.

5. Will the NIH commit to producing the Committee a written report of its internal investigation into the root causes and systemic weaknesses that contributed to the lapse related to the unaccountable small pox vials discovered in July 2014?

Response:

Yes, the NIH will provide a written report to the Committee.

6. Will the NIH commit to issuing a written procedure for the safe transport and securing of select agent materials on-site at NIH or between NIH laboratories, such as when select agents are discovered in locations unregistered with the Federal Select Agent Program?

Response:

The NIH is committed to safeguarding select agent materials. Our agency has had established written procedures since 2006 for the safe transport and security of registered select agent materials on-site at the NIH and between NIH laboratories. The NIH has issued a separate standard operating procedure specific to the safe transport and security of select agent materials that may be discovered in locations not registered with the Federal Select Agent Program.

Thank you for your interest in supporting our efforts to ensure the highest level of laboratory safety at the NIH. A copy of this response is being sent to the co-signer of your letter.

Sincerely yours,



Francis S. Collins, M.D., Ph.D.  
Director

cc: The Honorable Diana DeGette, Ranking Member  
Subcommittee on Oversight and Investigations