

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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May 18, 2016

The Honorable Francis Collins, M.D., Ph.D.  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Collins:

The Committee appreciates the NIH's participation at the Subcommittee on Oversight and Investigation's April 20, 2016 hearing on the safety of the nation's bioresearch labs. We are following up about the extent of the NIH's commitment to laboratory safety.

Laboratory safety and security should be one of the highest priorities for federal departments and agencies. The Department of Health and Human Services, through the leadership of the Secretary and the various agency leaders, has taken the initial steps to address this key priority by establishing the appropriate offices such as the Office of Laboratory Science and Safety at both CDC and FDA and the Division for Occupational Health and Safety at the NIH. Given the importance of this critical mission area, these appropriate offices at CDC, FDA and NIH should have adequate resources, a direct report to the Agency head, and be operated and funded independently of other program management activities.

With regard to resources, we note that the CDC has established the Office of the Associate Director for Laboratory Science and Safety (OADLSS). This office has a budget of \$14.5 million for FY 2016 and will have 41 full-time employees once hiring actions are completed.<sup>1</sup> To date, 34 positions have been filled.<sup>2</sup> On paper, NIH's resources appear to be adequate. The NIH reported that the Division of Occupational Health and Safety (DOHS) budget is \$20.8 million, with \$15 million focused on laboratory safety, 47 FTEs and 158 contractors currently supporting the division.<sup>3</sup> NIH did not report other staff and resources that should be counted toward NIH's lab safety efforts.

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<sup>1</sup> CDC staff e-mail to Committee staff, April 15, 2016.

<sup>2</sup> *Id.*

<sup>3</sup> NIH staff email to Committee staff, April 20, 2016.

However, the organization of NIH's laboratory safety management function raises questions about whether NIH's use of these resources is economical and could be made more effective. DOHS is the central authority in support of most of the laboratory safety programs at the NIH, but the committee's investigation into circumstances of the discovery of smallpox vials revealed that the National Cancer Institute (NCI) at Frederick reported to NCI management and not to DOHS with respect to its laboratory safety activities and policies. Indeed, NCI-Frederick has a stronger safety policy with regard to cold storage rooms than the approach recently promoted by DOHS, and NCI-Frederick should be commended for its clear communication of this policy. That said, we question why the laboratory safety approach at NIH is not completely centralized, and why laboratory safety standards are not uniform and consistent. As noted by the External Laboratory Safety Workgroup (ELSW) of the CDC Director's Advisory Committee in its recommendations to the FDA:

Good laboratory safety programs usually employ aspects of a centralized program. This centralized approach promotes the establishment of institutional expectations in the realm of lab/research safety that are consistent across the Agency. Centralized programmatic elements provide opportunities for shared best practices and lessons learned. Finally, centralized programs provide economies of scale and can provide infrastructure (e.g. shared databases, IT elements that promote visibility, efficiency and economical use of staff and other resources.

With regard to reporting structure, in its July 15, 2015 recommendations to the FDA, the ELSW recommended: "What is important is that this leader must be cognizant of the health and safety status of staff and must have the ability to report directly to the Commissioner on these matters in a timely way." We note that the CDC's Associate Director for Laboratory Science and Safety reports directly to the Director of the CDC. However, in contrast, the Director of NIH DOHS reports to the Director of the Office of Research Services who serves as the Designated Agency Safety and Health official. The Director of ORS reports to the Deputy Director for Management who reports to the NIH Director. For biosafety incidents, the Director of DOHS notifies the Director of ORS who notifies the Deputy Director for Management who notifies the Principal Deputy Director who notifies the NIH Director.<sup>4</sup> Given the ELSW recommendation and the CDC reporting structure, the NIH should strongly consider centralizing authority for laboratory safety with one designated official who is a direct report to the NIH Director.

In addition to the above, these offices should be appropriately funded and staffed to execute critical tasks such as: implementation of appropriate policies and procedures, conducting annual inspections to monitor laboratory safety and security practices, facility inspections for safety and ensuring its compliance for generating good laboratory products and data, providing appropriate training, implementation of a robust reporting and inventory system, applied research to generate data and critical information to enhance laboratory safety and security, foster a culture of safety etc. to fulfill this critical mission. Laboratory science and safety practices should be ranked as the highest priority to the agency prior to conducting or engaging in any laboratory science and research work.

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<sup>4</sup> *Id.*

Given the critical importance of this mission and to ensure the safety of the NIH's laboratory scientists and securing hazardous biological agents and toxins, the funding associated with the operations of these offices (Office of Laboratory Science and Safety at both CDC and FDA and the DOHS at the NIH) and associated programs should come from a direct source and not through competing resources with other agency missions or priorities. According to the July 17, 2015 recommendations to the FDA from the External Laboratory Safety Workgroup (ELSW) of the CDC Director's Advisory Committee, "Funding for this function should not be drawn from Center's budgets but rather from a central source."

We would appreciate your responses to the following by June 1, 2016:

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?
2. Does the NIH agree with the ESLW 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 NIH plan to implement this recommendation?
3. Does NIH agree with the ESLW recommendation that the source of funding should be independent from other NIH institutes, centers or offices? If so, will the NIH commit to independent funding for the office responsible for laboratory safety?
4. In accordance with the ESLW recommendation, will the NIH commit to having the Director of Lab Safety report directly to the Director of the NIH?
5. Will the NIH commit to producing to 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 smallpox vials discovered in July 2014?
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?

We look forward to working with you and supporting your efforts to improve laboratory safety at the NIH. Your cooperation is appreciated.

Sincerely,



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Fred Upton  
Chairman



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Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations

Letter to The Honorable Francis Collins, M.D., Ph.D.  
Page 4

cc: The Honorable Frank J. Pallone, Jr., Ranking Member

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