

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 Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Califf:

The Committee appreciates the FDA'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 FDA'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.¹ To date, 34 positions have been filled.²

In contrast, the FDA has not yet formulated the budget request for its Office of Laboratory Safety, or the level of staffing.³ With regard to reporting structure, in its July 15,

¹ CDC staff e-mail to Committee staff, April 15, 2016.

² *Id.*

³ In a briefing with Committee staff, FDA staff indicated that FDA was envisioning 13 full-time staff in the Office of Laboratory Safety.

2015 recommendations to the FDA, the External Laboratory Safety Workgroup (ELSW) of the CDC Director's Advisory Committee 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, FDA staff reported that the Director of FDA's Office of Laboratory Safety currently reports to the Commissioner through the Office of Chief Scientist, although the reporting structure may not yet be finalized.⁴ Given the ESLW's recommendation and the example of the CDC reporting structure, the FDA's Director of Laboratory Safety should be a direct report to the Agency Lead such as the Director for CDC and NIH and the Commissioner for FDA. The Director of Laboratory Safety position should not reside within other agency offices which have competing priorities. Although this is true for CDC, FDA and NIH do not have the appropriate reporting structure at the current time.

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.

Given the critical importance of this mission and to ensure the safety of the FDA'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 Division for Occupational Health and Safety 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." However, there has been no decision from the FDA on whether funding for its Office of Laboratory Safety will be independent from other program management activities.

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

1. What level of funding and staffing for the Office of Laboratory Science and Safety will the FDA commit to for the next fiscal year budget? Please explain the justification for the level of funding and staffing.
2. Does FDA agree with the ESLW recommendation that the source of funding should be independent from other FDA centers or offices? If so, will the FDA commit to independent funding for the Office of Laboratory Safety?

⁴ FDA staff email to Committee staff, April 18, 2016.

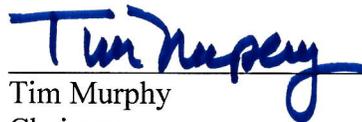
3. In accordance with the ESLW recommendation, will the FDA commit to having the Director of Lab Safety report directly to the FDA Commissioner?
4. Will the FDA commit to producing to the Committee a written report of its internal investigation into the root causes and systemic weaknesses that contributed to the lapse related to the unaccountable smallpox vials discovered in July 2014?
5. Will the FDA commit to issuing a written procedure for the safe transport and securing of select agent materials on-site at FDA or between FDA 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 FDA. Your cooperation is appreciated.

Sincerely,



Fred Upton
Chairman



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

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