



The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 09 2016

Dear Mr. Chairman:

Thank you for your letter of May 18, 2016, cosigned by Mr. Murphy, Chairman of the Subcommittee on Oversight and Investigations, regarding laboratory safety and security at the Food and Drug Administration (FDA or the Agency). Laboratory safety and security is one of our highest priorities at FDA and we are fully committed to ensuring the safety of our laboratory scientists, the employees of FDA, and the surrounding community.

We appreciate the opportunity to respond to your questions, and have restated them below in bold, followed by FDA's responses.

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.

FDA's Office of Laboratory Science and Safety (OLSS) provides leadership, oversight, and coordination of laboratory policies and operations across FDA to ensure laboratory safety and security. In FY 2017, consistent with the President's Budget, OLSS will receive \$5.2 million in support to cover 13 full-time employees (FTEs) – one senior executive office director, four GS-15 level positions, five GS-14 level positions, two GS-13 level positions, and one GS-11 level position – as well as operational costs. This level of support will allow OLSS to continue to make progress on achieving FDA's goals of augmenting, consolidating, and standardizing laboratory safety and security at FDA.

2. Does FDA agree with the ELSW recommendation that the sources 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?

FDA believes that OLSS should have a dedicated level of funding to allow for proper oversight of FDA's labs. OLSS will sit in the Commissioner's Office, and will be managed and operated independently from the other Centers and Offices. FDA will work with existing funding in FY 2016 and funding received in FY 2017 to fund OLSS. FDA is working to determine the long-term resource requirements needed for this important priority.

3. In accordance with the ELSW recommendation, will the FDA commit to having the Director of Lab Safety report directly to the FDA Commissioner?

As previously shared, ensuring the safety and security of our laboratory scientists, employees, and the public at large is one of our highest priorities at FDA. To support FDA with this critical mission, FDA will realign OLSS such that the Director of OLSS will report directly to the Commissioner. OLSS will serve as the Agency's coordinator and lead for implementation of policies and procedures, centralized training, and oversight for operations of all laboratory science, safety, and security related activities. OLSS will work very closely with the Office of the Chief Scientist, the Office of Operations, the Office of Regulatory Affairs, and the other product centers and directorates across the Agency.

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 contribute to the lapse related to the unaccountable smallpox vials discovered in July 2014?

Yes. FDA is currently conducting its internal investigation into the root cause and systemic weaknesses that contributed to the lapse related to the unaccountable smallpox vials and other pathogens discovered in July 2014. This investigation is expected to be completed by Fall 2016. Upon the completion of this investigation a final report will be issued, which will be shared with the Committee.

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?

Yes. FDA is fully committed to ensuring the safety and security of our laboratory scientists and the public. FDA has already issued a Staff Manual Guide (FDA SMG 2130.8) that addresses, among other things, the reporting of select agents and toxins associated with certain discoveries or inventory discrepancies. We are also committed to revising that Staff Manual Guide to include a procedure for the safe and secure transport of select agent materials associated with a discovery or incident. OLSS is working aggressively to ensure that the appropriate policies and protocols are integrated into the SMG for the safe and secure transport of select agent material on-site at FDA and between FDA laboratories when they are discovered in locations unregistered with the Federal Select Agent Program.

If you have further questions, please contact Meghan Scott or Melissa Safford in FDA's Office of Legislation. Meghan may be reached at 301-796-4675 or Meghan.Scott@fda.hhs.gov. Melissa may be reached at 301-796-8914 or Melissa.Safford@fda.hhs.gov.

Thank you for your interest in this matter and your patience in allowing us to respond to your requests. The same letter has been sent to your cosigner.

Sincerely,

A handwritten signature in black ink, appearing to read "Dayle Cristinzio".

for Dayle Cristinzio
Acting Associate Commissioner
for Legislation

cc: The Honorable Frank J. Pallone, Jr., Ranking Member
Committee on Energy and Commerce

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