

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

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

July 31, 2015

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

Dear Dr. Collins:

Pursuant to Rules X and XI of the U.S. House of Representatives, the committee is investigating management concerns with the NIH Clinical Center Pharmaceutical Development Section (PDS).

On June 4, 2015, the NIH Clinical Center suspended operations of its Pharmaceutical Development Section after the discovery of serious manufacturing problems and lack of compliance with standard operating procedures. This followed an inspection conducted by the FDA from May 19-29, 2015, which found a series of deficiencies in the PDS physical facility. In addition, two vials of albumin, used for administration of the drug interleukin in experimental studies, were found to have fungal contamination. Hundreds of participants in 46 studies were potentially affected by the contamination, and six patients were administered drugs from vials made from the contaminated batch. The severity of the deficiencies, the disruption of ongoing studies, and the resulting suspension of PDS operations raise serious questions about the management of the NIH PDS for the last several years.

The current PDS facility was opened in 2010. FDA officials have told committee staff that the NIH PDS facility was not inspected prior to May 2015, nor was FDA required to inspect the PDS facility. However, a May 1, 2010 article in the American Journal of Health-System Pharmacy (AJHP) quoted the NIH Clinical Center Director as saying that “the new PDS area will be fully GMP-compliant and subject to inspection by FDA.”

To assist the committee’s inquiry, please provide the following documents and information by August 14, 2015:

1. The names of all consultants used to advise NIH on the construction of the current NIH Clinical Center Pharmaceutical Development Section.

2. All documents related to reports in 2009 or 2010 provided to the NIH on whether the NIH PDS facility could meet cGMP (current Good Manufacturing Practices) standards.
3. All documents related to any inspections (including the May 2015 inspection conducted by the FDA) of the PDS since January 1, 2010, and all documents related to the 2012 visit by the FDA staff exploring the possibility of a training audit at the PDS.
4. The name and qualifications of the cGMP consultant referenced in the NIH Interim Correction Plan. Please also provide any reports that the NIH provided to the cGMP consultant.
5. All documents related to any internal review or audits of PDS since January 1, 2010.
6. All documents related to any concerns with sterility in PDS operations since January 1, 2010. Please list the names and qualifications of the individuals on the NIH PDS staff involved in ensuring the sterility of drugs from the PDS since May 2010.
7. All documents to or from PDS Section Chief George Grimes, Jr., relating to PDS sterility issues and/or cGMP compliance, the adequacy of staffing levels at PDS, and/or use of overtime to ensure adequate staffing since January 1, 2015.
8. All documents to or from PDS Director Robert DeChristofaro relating to PDS sterility issues and/or cGMP compliance, the adequacy of staffing levels at PDS, and/or use of overtime to ensure adequate staffing since January 1, 2015.
9. All documents from the Office of NIH Director and/or the Office of NIH Clinical Center Director related to the performance of Robert DeChristofaro and/or George Grimes, Jr., since May 1, 2015.
10. For each of the 46 studies disrupted in light of the FDA's findings, please list the alternative source for the drug previously provided by PDS, and the date the drug from that alternative source became available.
11. List of expenditures (amounts of expenditures, nature of the contract, and names of contractors) for all contracts related to PDS since January 1, 2010.

Please also respond to the following questions by August 14, 2015:

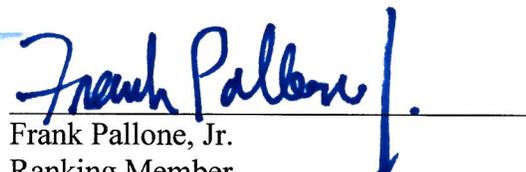
1. How many patients were affected by the suspension of clinical trials as a result of the sterility problems at the PDS?
2. How many of these patients are at the NIH Clinical Center?
3. Are any of these patients located outside of the U.S.?

4. Have any of these patients died? Have any of these patients suffered other complications and/or been hospitalized? If so, how many?
5. Were any of the patients transferred to other studies? If so, how many?
6. Did any of the 46 studies have to be completely restarted? If so, how many? And how many patients were affected?

Your prompt assistance is appreciated. An attachment to this letter provides additional information on how to respond to the committee's request. If you have any questions, please contact Alan Slobodin of the majority committee staff at (202) 225-2927 and Una Lee of the minority committee staff at (202) 225-3641.

Sincerely,

  
Fred Upton  
Chairman

  
Frank Pallone, Jr.  
Ranking Member

  
Tim Murphy  
Chairman  
Subcommittee on Oversight  
and Investigations

  
Diana DeGette  
Ranking Member  
Subcommittee on Oversight  
and Investigations

Attachment