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ONE HUNDRED TWELFTH 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

October 12, 2012

Mr. James D. Coffey
Director
Massachusetts Board of Registration in Pharmacy
239 Causeway St. 5th Floor, Suite 500
Boston, MA 02114

Dear Mr. Coffey:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is examining the facts surrounding the recent outbreak of fungal meningitis linked to a contaminated injectable steroid compounded and distributed by the New England Compounding Center (NECC) in Framingham, Massachusetts.

As of October 11, 2012, fourteen people have died and at least 170 people have been sickened across the nation. The Centers for Disease Control (CDC) confirmed that the number of cases may rise in coming weeks given that up to 14,000 patients have been injected with the drug product at issue.

On September 23, 2004, investigators from the U.S. Food and Drug Administration (FDA) and the Massachusetts Board of Registration in Pharmacy (Board of Pharmacy) inspected the NECC. The inspection was completed on January 19, 2005. On December 4, 2006, FDA sent the NECC a warning letter detailing significant violations witnessed by the investigators.[1] Included in the list of violations was the NECC's manipulation of a sterile injectable product, which caused FDA to be concerned about potential microbial contamination. In addition to the significant public health concerns that were observed, this particular inspection called into question whether the NECC was operating as a traditional compounding pharmacy or a drug manufacturer that produced, marketed, and distributed drug products, not linked to prescriptions for identified patients, on a commercial scale.

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[1] Warning Letter from Gail Costello, Dist. Dir., New England Dist. Office, U.S. Food and Drug Admin., to Barry J. Cadden, Dir. of Pharmacy and Owner, New England Compounding Center (Dec. 4, 2006), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076196.htm.

The Committee is investigating whether any remedial measures were taken after this inspection and why the NECC was able to continue operating in this manner more than six years after the fact. We are also being briefed by the FDA, CDC and others that may provide insight into the details surrounding the ongoing meningitis outbreak and discuss what measures need to be taken to ensure an incident like this never happens again.

To assist the Committee in better understanding the NECC's operations, as well any actions taken by the Board of Pharmacy to address potential violations, we ask that you make arrangements with Committee staff to schedule a briefing on these matters to occur no later than October 19, 2012. In advance of this briefing, please provide the Committee with the following documents:

1. All inspection reports and records in the possession of the Board of Pharmacy related to any facilities owned or operated by NECC or Ameridose.

2. All communications between or among or between the Board of Pharmacy, the NECC, Ameridose, and/or the FDA related to such inspections.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions considering this request, please contact John Stone with the Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Henry A. Waxman
Ranking Member

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

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Chairman
Subcommittee on Health

Frank Pallone, Jr
Ranking Member
Subcommittee on Health

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Vice Chairman
Subcommittee on Health