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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 17, 2012

Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

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 contaminated injectable steroids compounded and distributed by the New England Compounding Center (NECC) in Framingham, Massachusetts and the adequacy of FDA's oversight of this firm.

As of today, the Centers for Disease Control and Prevention (CDC) has confirmed that fifteen people have died and over two hundred people have been sickened in fifteen states after receiving tainted injections from the NECC. While the previously reported cases of meningitis have been linked with one type of sterile injectable product, two other products made at the NECC have now been potentially associated with serious infections.

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 of the Food, Drug, and Cosmetic Act (FDCA) 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 "especially concerned about potential microbial contamination."[2] In addition to the significant public health concerns related to the observed activities, this inspection called into question whether the NECC was operating as a traditional compounding pharmacy or on a commercial scale as a drug

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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.

[2] *Id.* at 3.

manufacturer that produced, marketed, and distributed drug products that were not linked to prescriptions for identified patients.

FDA's warning letter informed NECC that "[f]ailure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure and injunction against you and your firm."[3] During initial discussions with Committee staff on October 12, 2012, FDA officials said that the NECC responded about a month after the warning letter assuring regulators that the firm was in compliance with good compounding practices. At the time of this briefing, FDA officials could not confirm whether any subsequent inspections were conducted to validate that the FDCA violations were corrected.

During the briefing, FDA committed to providing the Committee with additional details regarding past interactions with the NECC. In order for the Committee to fully understand the history of FDA's oversight of the NECC and knowledge of its operations, please provide the Committee with the following documents by no later than October 31, 2012:

1. All inspection reports and records in the possession of the FDA referring or relating to any facilities owned or operated by the NECC and/or Ameridose, since January 1, 2004;

2. All documents containing communications between or among the FDA; the Massachusetts Board of Registration in Pharmacy or other state entities; any third-party inspectors; and the NECC and/or Ameridose, referring or relating to the NECC and/or Ameridose, since January 1, 2004.

3. All documents relating to briefings with individuals in the Office of the Commissioner about the NECC and/or pharmacy compounding, including background information, legal memoranda, and attachments, since January 1, 2004.

Given the risk to public health posed by this outbreak, the Committee expects the FDA to comply with this request promptly. 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

[3] *Id.* at 4.

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Subcommittee on Oversight and Investigations

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