United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

October 25, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

We are writing to express our serious concern regarding the current public health crisis resulting in hundreds of cases of fungal meningitis and other types of infections linked to drugs produced by the New England Compounding Center (NECC).

As of October 23, 2012, at least 308 patients have become ill throughout the country, and 23 have died. The number of cases has steadily increased over the past several weeks, and may continue to increase. The Centers for Disease Control and Prevention (CDCP) has linked the outbreak of fungal infections to three contaminated lots of preservative-free methylprednisolone acetate produced by NECC; however, there are questions as to whether other NECC products may also be contaminated. According to the CDCP, the three lots consisted of 17,676 products that were distributed to 23 states, exposing approximately 14,000 patients since May 21, 2012.

We appreciate your staff discussing the warning letter issued to NECC by the Food and Drug Administration (FDA) in 2006 and the complaints that led to the 2004 inspection of the NECC facility. However, the Committee has additional questions about how large quantities of contaminated drugs were distributed throughout the country, particularly given that the investigation has now expanded to include two additional drug companies with the same ownership as NECC, Ameridose, LLC (Ameridose), and Alaunus, LLC (Alaunus).

As we work together to understand how this tragedy happened and to prevent future incidents, we request that you provide the documents and information described below to the Committee no later than Wednesday, October 31, 2012.

1) From January 1, 2002 to present, a list of all complaints and adverse event reports FDA has received concerning compounded products. Please include whether states were notified, any enforcement actions taken, including all inspections, warning letters, injunctions or seizures executed against compounding pharmacies and how such actions were coordinated with state regulatory authorities.

2) A copy of any written procedures or guidelines for addressing complaints against or inspections of compounding pharmacies. Please include procedures for contacting and coordinating with state regulatory authorities and procedures for coordinating access to sales, distribution and prescription records, as well as whether the agency has entered into any Memoranda of Understanding with States or relevant regulating agencies regarding compounding pharmacies and compounding pharmacy inspection procedures. Also please include a copy of any written procedures or guidelines for enforcement actions, such as warning letters, seizures, or injunctions.

With regard to NECC, Alaunus, and Ameridose, please provide:

3) A copy of each complaint received regarding any product produced, manufactured, or distributed by any of the companies, and all information relating to the complaint, including if it was shared with the Massachusetts Department of Public Health or Board of Registration in Pharmacy, as well as any investigative or enforcement actions taken as a result of each complaint.

4) A copy of any adverse event report received regarding any product produced, manufactured, or distributed by any of the companies (not including any reports relating to the ongoing *Exserohilum, Cladosporium,* and *Aspergillus* fungal infections), and any actions taken in relation to any adverse reaction report.

5) A copy of all correspondence between the FDA and each of the companies as well as any correspondence with any state regulatory authorities relating to these companies.

6) All documents relating to the 2004 inspection(s) of NECC, and any additional documents from the inspections of any of the three companies, including, but not limited to, all inventories and sales records regarding the types and amounts or drugs produced, all efforts undertaken to confirm that patient-specific prescriptions had been received for each dose produced, all information relating to the quality and cleanliness of the production processes, all documents containing observations and impressions of the investigators, and all preliminary and final reports or findings of the inspections.

7) With regard to the 2004 inspection(s) of NECC please specifically provide:

   a. A description of the size and scope of NECC's operations at the time of the investigation, including how many different compounded substances the company produced during the period of the inspection;

   b. How many doses were included in each of the lots examined by investigators;

   c. The company's overall production volume during the period examined by investigators; and

   d. Specific evidence observed or collected during the course of the inspection that suggested NECC was acting as a manufacturer, including, but not limited to, any evidence that drug products were being produced without a patient-specific prescription, that NECC or its staff were soliciting hospitals or clinics or physician's office to purchase compounded drugs, or that NECC or its staff suggested to hospitals, clinics or physicians' offices that prescriptions could be submitted in names other than a patient receiving the dose.

8) All internal FDA documents since 2002 relating to NECC, Alaunus and Ameridose.

9) Any additional documents in the possession of FDA, that in the judgment of FDA, are relevant to this inquiry.

10) Please provide a timeline of actions taken in response to the recent meningitis outbreak, including what steps are needed to conclude the investigation and when the investigation will be complete.

Please contact Beth Stein at (202) 224-2931 and Nick Geale at (202) 224-9602 to arrange for production of the requested documents and information.

Sincerely,

Tom Harkin
Chairman

Michael B. Enzi
Ranking Member