United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

October 25, 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:

We are deeply concerned about the recent outbreak of fungal meningitis and related infections, which has caused at least 23 deaths and sickened more than 308 individuals across the country. The outbreak, which has been linked to a compounding pharmacy in Massachusetts, has raised serious questions about the level of oversight that this entity was subject to, both by state and federal regulators. We write to request information regarding the Board's interactions with the pharmacy in question, in order to better understand the circumstances that led to the present outbreak.

As you are aware, the Centers for Disease Control and Prevention ("CDCP") has linked the fungal infection outbreak to three lots of preservative-free methylprednisolone acetate produced by New England Compounding Center ("NECC"). According to the CDCP, the three lots consisted of 17,676 products distributed to 23 states, exposing approximately 14,000 patients since May 21, 2012.

As a pharmacy licensed in the state of Massachusetts, NECC is required to comply with legal requirements administered by your agency. In following its own procedures to ensure that NECC was in compliance with the terms of its license, the Massachusetts Department of Public Health, Board of Registration in Pharmacy (Board) inspected NECC at least at least four times: when it was founded in 1998; in 2004 (jointly with the FDA), as the result of complaints received in 2002 and 2003; in 2011, when the facility was renovated and expanded; and in 2012, as the result of a complaint relating to improper storage and handling that may have impacted the potency of a drug compounded by NECC.

In addition, the Board has previously taken other actions against NECC. Based on the results of the 2004 joint inspection with FDA, the Board documented concerns with the sterility of the compounded products produced by NECC, and raised concerns regarding whether the company was meeting the requirements of its license by receiving a patient-specific prescription prior to producing a compounded drug.

These concerns led to a 2006 consent decree between the Board and NECC, which appears to be the only consent decree of its kind during the relevant period. The decree required NECC to submit to independent quality review of its products for a six month period. Moreover, in the period since 2006, NECC's owners have additionally opened co-owned drug manufacturer Ameridose, LLC (Ameridose), and distributor Alaunus, LLC (Alaunus), both of which appear to be also licensed by the Board.

These inspections and enforcement actions should have drawn attention to concerns regarding the quality and sterility of products produced by NECC, which were documented as far back as six years ago, as well as to the fact that NECC was operating a large scale drug manufacturing operation. In light of these facts, it is unclear why the company was allowed to continue producing large quantities of standardized drugs with insufficient quality protections and in the absence of individual prescriptions.

In order to better understand how large quantities of contaminated drugs were distributed throughout the country, we would appreciate if you could provide documents and information responsive to the requests below to the Committee no later than Wednesday, October 31, 2012.

1) A copy of any procedures or guidelines used in the course of inspecting compounding facilities together with a description of the inspection process. Please indicate the extent to which inspection procedures may vary based upon the production of sterile drugs, or large quantities of drugs, or drugs shipped across state lines.

2) A detailed description of the process used to determine if a compounding pharmacy is in compliance with the license requirement that the pharmacy have a patient-specific prescription for the preparation and distribution of each dose or unit of a drug.

3) All communications with the FDA regarding any Massachusetts-based compounding pharmacy between 2002 and present. Please also describe how the Board determines inspection priorities and how the Board and the FDA interact when the Board or the FDA becomes aware of a complaint or concern with regard to a particular compounding pharmacy.

4) For the period 2002 to present, please state in how many instances the Board has suspended or revoked a pharmacy license, entered into a consent decree or otherwise taken action against a pharmacy. Under what circumstances does the Board revoke a compounding pharmacy's license? What were the reasons the Board declined to revoke NECC's license in 2006?

5) With regard to NECC, Alaunus, and Ameridose, a copy of each application for licensure, including applications for relocation or expansion, and a copy of any official correspondence related to those applications.

6) A copy of all complaints and adverse reaction reports, if any, provided to your agency, and a detailed accounting of any investigative or enforcement actions taken as a result of those complaints or reports.

7) All documents relating to each inspection performed, including but not limited to all communications between the Board and officials or employees of the company being inspected, 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 does produced, all information relating to the quality of the production process, all documents containing observations and impressions of the investigators, and all preliminary and final findings of the inspections.

8) With regard to the 2004 joint FDA inspection of NECC, please specifically provide:

    a. A description of the size and scope of NECC's operations at the time of the inspection, 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; and

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

    d. The same information contained in a-c at the time of the renovation-expansion inspection of NECC in 2011.

    e. Specific evidence observed or collected during the course of the inspection that suggested NECC had exceeded its compounding authority under its state license, 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.

9) A copy of the 2006 consent decree together with all documents relating to any underlying enforcement action taken by the Board in conjunction with any issues raised during the 2004 inspection. Please also provide copies of the independent audit or analysis reports prepared by Pharmaceutical Systems Inc. or any other independent auditor or evaluator as a condition of the consent decree or at any other time.

10) Any other enforcement actions, settlements, agreements, or consent decrees entered into with NECC, Alaunus or Ameridose.

11) A copy of all internal Board documents relating to NECC from 2002 through 2012, including reports or correspondence provided to Board Members relating to the companies together with a copy of all Board minutes and transcripts relating to the companies.

12) Any other documents in your possession that you think are relevant to this inquiry.

Thank you for your prompt attention to this matter. We look forward to continuing to work together to ensure a safe and effective pharmaceutical distribution system.

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