United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

October 25, 2012

Mr. Barry Cadden
Director and President
New England Compounding Center
Manager, Ameridose, LLC
Manager, Alaunus, LLC
697 Waverly Street
Framingham, MA 01701

Mr. Gregory Conigliaro
Director, Vice-President, Treasurer, and Secretary
New England Compounding Center
Manager, Ameridose, LLC
Manager, Alaunus, LLC
697 Waverly Street
Framingham, MA 01701

Dear Mr. Cadden and Mr. Conigliaro:

We are seriously concerned about the current public health crisis involving hundreds of cases of fungal meningitis and other types of infections that has been linked to drugs produced by the New England Compounding Center (NECC). We are writing to request information that will enable us to better understand how one or more drugs compounded by NECC became contaminated with fungi before distribution throughout the country.

As of October 23, 2012, at least 308 patients have become ill throughout the country, and 23 have died as a result of the contamination. 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.

In addition, our ongoing investigation into this matter has revealed that NECC was previously the subject of multiple complaints to state and federal regulators. These complaints necessitated the Food and Drug Administration (FDA) and Massachusetts Department of Public Health, Board of Registration in Pharmacy (Board) to investigate and take enforcement actions against NECC. These enforcement activities in turn highlighted ongoing concerns regarding NECC's ability to safely produce sterile injectable products as well as additional potential violations of both state and federal law.

In order to allow us to better understand the circumstances that led to the current outbreak, as well as NECC's corporate structure, affiliations, business practices, history, and interactions with both FDA and the Board, please provide the following information no later than Wednesday October 31, 2012.

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

1) A detailed description of the ownership structure and leadership of each company from 1998 to present, together with a description of any shared ownership, any family relationships between the owners and executives of the three companies, together with an explanation of how the three companies have or have not shared facilities, suppliers, employees, equipment and services. Have any of the owners, managers, or directors of the three companies served as an owner, manager, or director of any other compounding pharmacy?
2) A list of the states where each company is licensed and a copy of the most recent licenses. With regard to the Massachusetts licenses, please also provide a copy of each application for licensure, including applications for relocation or expansion, and a copy of any official correspondence related to those applications.
3) Audited financial statements showing the total sales revenue of each company from 1998 to present.
4) A copy of all complaints and reports of adverse events regarding drugs produced by each company, together with a copy of all related correspondence with federal or state regulatory bodies, including the FDA and the Board.
5) A copy of all communications with the FDA and the Board from 2002 to the present.
6) A copy of all communications from customers and clients relating to concerns about the quality, sterility or safe manufacture of drugs products.
7) A copy of any communications with customers or clients regarding the provision of patient specific prescriptions in the context of ordering or purchasing drug products.

With regard to NECC, please provide:

8) A timeline of all federal and state regulatory inquiries into complaints or adverse event reports regarding products compounded by NECC.

9) A copy of the 2006 consent decree entered into between NECC and the Commonwealth of Massachusetts and any additional consent decrees, assurance letters, attestations, or other documents produced in response to state or federal regulatory inquiries.

10) A copy of NECC's procedures for ensuring the quality and sterility of products compounded by the company.

11) A detailed description of the work performed by the independent investigator/auditor in connection with NECC's 2006 consent decree with the Commonwealth of Massachusetts, including how the investigator/auditor was selected. Please indicate if an independent evaluator was used by any of the three companies, at any time outside of the pendency of the consent decree, to verify or ensure the sterility and quality of its compounded drugs. If so, please provide the frequency, types of products evaluated, and names of the lab or labs performing the evaluation.

12) A list of every drug compounded by NECC between from January 1, 2012 and present. Please include the lot numbers, the number of doses or units in each lot, the states in which the drugs in each lot were sold, and the individual prescription received for each dose or unit.

13) An explanation of why NECC was not licensed as a manufacturer under the Federal Food Drug and Cosmetic Act, given the scope and national scale of its drug production and distribution.

14) A copy of all internal documents regarding the outbreak of fungal infections as a result of these contaminated lots. If you are asserting a clause of privilege or confidentiality regarding this request, please specify the nature of the document and the clause.

15) Any and all additional documents that you think are relevant to this investigation.

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