

United States Senate

WASHINGTON, DC 20510

October 12, 2012

The Honorable Margaret H. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We are writing to express our deep concern about the recent outbreak of fungal meningitis in patients throughout the country, and especially in our home state of Tennessee. Our hearts go out to those who have been sickened, those who have passed away, and their families, and we are hopeful that all patients affected are identified and receive the necessary care.

We understand that the FDA has been working closely with the Centers for Disease Control and Prevention (CDC), several state health departments, and the Massachusetts Board of Pharmacy to investigate the scope and cause of this outbreak of fungal meningitis, including a thorough review of the operations of the New England Compounding Center (NECC).

It is our hope that this investigation will help us identify the root causes of the outbreak and what actions may be necessary to prevent this from happening in the future. To help us and our staff better understand this complex situation, we would appreciate you or your staff providing us with answers to the following questions:

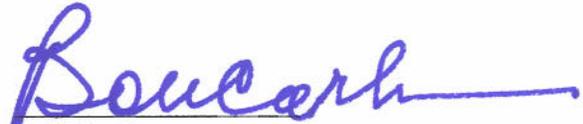
- What authority does the FDA have over compounding pharmacies under current law? To what extent does the FDA exercise this authority?
- What is the nature of the FDA's relationship with state boards of pharmacy? How does the FDA coordinate with these boards to regulate compounding pharmacies?
- How does the FDA define a compounding pharmacy? Is this definition used by the state boards of pharmacy when granting licensure?
- Has the FDA ever inspected NECC's facility? If so, what dates did such inspections occur?
- What actions have been taken since your agency sent a warning letter to NECC in December 2006? To your knowledge, what actions has the Massachusetts Board of Pharmacy taken since that letter?

We will continue to monitor the situation and anxiously await the results of your investigation and my questions. We thank you again for all of your ongoing efforts to address these infections, and we look forward to working with you to ensure the safety of patients in Tennessee and across the country.

Sincerely,



Lamar Alexander
United States Senator



Bob Corker
United States Senator