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The Honorable Margaret A. Hamburg, Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20933

Dear Commissioner Hamburg:

The recent outbreak of Fungal Meningitis has raised serious concerns about the reach and oversight of compounding pharmacy practices around the nation. I appreciate the FDA's swift action with the Centers for Disease Control and our state governments to investigate the specifics of the situation, including whether the New England Compounding Center was in violation of FDA's existing regulatory guidance issued in 2002 concerning compounding practices. In order to make certain that Congress is responsive to the FDA's findings; I would appreciate the agency's recommendations for improvements in the future.

This tragic incident calls for stronger oversight, more exacting standards and stricter enforcement of consumer and patient protections related to compounding pharmacies. The New England Compounding Center was licensed at the state level, in all fifty states around the nation. Further, the drug in question, a preservative-free methylprednisolone acetate injection, was shipped to twenty-three states at last count. Such actions call into question whether the New England Compounding Center crossed the line into drug manufacturing, and further, if similar practices are underway more broadly.

Clear guidelines have been drawn by both FDA and Congress, first in 1992 and later under section 503A as added by the FDA Modernization Act of 1997, and still again in FDA's own compliance guidance in 2002 that require certain conditions be met in order to compound prescription drugs. Standards under section 503A of FDAMA specifically include that the drug provider compounding the drug is only exempted from new drug approval requirements is the drug is, among other conditions, not "compound regularly or in inordinate amounts … or any drug products that are essentially copies of a commercially available drug product" and further that a drug may only be compounded if such a drug product is not one identified by the Secretary as "presenting demonstrable difficulties for compounding that reasonable demonstrate an adverse effect on the safety or effectiveness of that drug product." Congress intended this section to draw the line between compounding in response to individual patient needs, and drug manufacturing, which would require the necessary inspection and approval by the FDA. Both of these stated requirements alone draw into question New England Compounding Center's adherence to the intent of federal law, which was upheld in those states in the Fifth Circuit of the United States, some of which received contaminated substances.

Further, the framework established under section 503A of FDAMA providing for such exemptions in accordance with certain requirements was not upheld for those states in the Ninth Circuit, which FDA applies to the rest of the nation, including Massachusetts, the location of the New England Compounding Center. However, the agency, in accordance with the intent of Congress, has preserved the ability for compounding pharmacists to practice in response to individual patient needs, and has clearly set forth compliance guidance, issued in 2002, which outlines the criteria the agency continues to use in exercising enforcement against compounding practices. These criteria were violated in this tragic incident, and this calls into question the extent and occurrence of similar violations around the nation.

I would appreciate further information on what actions the agency specifically plans to take, including whether additional guidance will be provided regarding what drug products must not be compounded due to safety restrictions, and whether the agency will update compounding guidance to states. I would also like information regarding FDA's enforcement authority to intervene in situations where the agency feels a company may be violating compounding restrictions. Finally, in your response, please include how shipments from compounding centers across state lines are treated, including what guidelines the agency uses to determine whether such shipments qualify as drug manufacturing or as allowable compounding. I remain particularly concerned that compounding, which is intended for individual patient special needs, may have grown more broadly in some instances, into widespread and multi-state distribution.

The recent outbreak of dangerous, potentially deadly disease indicates a clear and present need for stronger accountability and oversight. Stricter scrutiny by the FDA could help prevent contamination of medicines – apparently the cause of this 23 state crisis – produced by such compounding pharmacies. Their relative immunity from standards of safety and effectiveness seems anomalous and unacceptable. The FDA's authority should be extended if necessary to make and enforce stronger standards that protect the public and assure quality.

Thank you again for the agency's hard work to investigate this matter, and I look forward to working with you further to better assure the safety of compounded drugs across our nation.

Sincerely,

Richard Blumenthal