THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

November 28, 2012

Michael A. Carome, M.D.
Sidney M. Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, DC 20009

Dear Drs. Carome and Wolfe,

Thank you for your letter concerning the current outbreak of fungal meningitis related to epidural injections of contaminated methylprednisolone acetate (MPA) produced at the New England Compounding Center (NECC). This outbreak has had devastating effects on individuals and families across the country, and I want to assure you that it is a top priority for the Department of Health and Human Services. Just last week we delivered to Congress a proposed framework to provide the Food and Drug Administration (FDA) with the tools it needs to help ensure an outbreak like this never happens again.

We have also worked aggressively in response to this outbreak to protect the public health. Through the collaborative efforts of the Centers for Disease Control and Prevention (CDC) and FDA, the Department of Health and Human Services is responding to this outbreak using a range of scientific and enforcement tools. Both FDA and CDC have taken actions to protect the public from potentially contaminated or otherwise adulterated compounded drug products. As CDC's team of epidemiologists and investigators pursued the case in regard to patient exposure and clinical outcomes, FDA investigated distribution of possibly tainted products, performed laboratory evaluations to confirm contamination, and worked with the Massachusetts Board of Registration in Pharmacy to inspect the NECC facility.

As you are probably aware, NECC initiated a voluntary recall, first for the suspected contaminated vials, then for all their products, and the State of Massachusetts Board of Registration in Pharmacy has secured a voluntary surrender of NECC's pharmacy license.

It is evident that the legal landscape is complex, and FDA's authority in this area is limited and ambiguous. We are certain that the best way to protect the public health in this area going forward is to clarify the legal framework for regulating pharmacy compounding. At the same time, we recognize that enhanced communication and collaboration with state departments of health and pharmacy boards is a crucial stop gap measure. To that end, FDA has invited every state to a day-long meeting in December. Thank you again for your letter, and we look forward to working constructively with you and other stakeholders moving forward.

Sincerely,

Kathleen Sebelius

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