Opening Statement of the Honorable Fred Upton
Subcommittee on Oversight and Investigations
Hearing on The Fungal Meningitis Outbreak: Could It Have Been Prevented?
November 14, 2012
(As Prepared for Delivery)

When we first began this investigation just over a month ago, we knew people were sick and we knew people had died and were dying due to contaminated medicine made by the New England Compounding Center. One of my own constituents, a grandmother from Cass County, Michigan, sadly lost her life to the contaminated drugs.

The loss of innocent lives is tragic enough. But, what makes this tragedy worse is the fact that it seems these deaths and illnesses could have been prevented. The NECC was not unknown to its regulators. It was not operating under the shadow of darkness. The NECC plant is about a thirty-minute drive from the FDA's New England District Office. The FDA and NECC's state regulator, the Massachusetts Board of Pharmacy, had inspected NECC's facilities multiple times since the company opened its doors in 1998. FDA even issued a Warning Letter to the NECC in 2006. The Massachusetts Board of Pharmacy entered into a consent agreement with the company that same year. I was stunned and angered to learn that an inspection of the NECC by the FDA and the Mass Board over 10 years ago identified contamination in the very same drug at issue in the current outbreak. The reason for that inspection? Patients had been hospitalized with meningitis-like symptoms. Ten years later, we are in the midst of an unthinkable, worst-case scenario - the body count is growing by the day - and hundreds have fallen ill. This is simply inexcusable.

Today, we will hear from the Massachusetts Department of Public Health and the FDA about their history with the NECC and why they treated the company the way they did. Why did state and federal regulators feel confident that this company could make drugs safely, after repeatedly finding that the company's drugs were contaminated back in 2002? After observing multiple violations of the Food, Drug, and Cosmetic Act leading up to FDA's 2006 Warning Letter, why did the agency fail to conduct a single follow-up inspection?

The committee expects the cooperation of the FDA, the Massachusetts Board, and the company as we try to uncover the facts so as to ensure this never happens again. Thirty-two innocent Americans have died during this outbreak and the public deserves to know what went wrong. I thank Dr. Smith and Dr. Hamburg for agreeing to testify today. The Massachusetts Board, in particular, has provided thousands of pages of documents relating to the NECC. I thank you, Dr. Smith, for making yourself and your staff available to the committee staff as we investigate this outbreak. I wish I could say the same about the FDA. Commissioner Hamburg, the FDA still has not provided key timeline information requested by the committee over a month ago. The FDA has not provided its communications relating to the NECC. FDA needs to focus on protecting public health by cooperating with its authorizing committee. I want a firm timetable today from you on when you will produce your documents and the rest of the requested information. The sooner FDA cooperates, the sooner we can determine what went wrong and ensure we never endure a deadly outbreak like this one.

Mrs. Lovelace, I want to thank you for your testimony today during this very difficult time - we all are deeply saddened for your loss.

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