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ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

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November 16, 2012

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

Dear Commissioner Hamburg:

During your testimony before the Subcommittee on Oversight and Investigations on November 14, 2012, at the hearing entitled "The Fungal Meningitis Outbreak: Could It Have Been Prevented?" you asked that the Committee enact legislation to address perceived gaps in the ability of the Food and Drug Administration (FDA) to adequately protect the public from contaminated compounded products. Your request is a serious and important one, and we stand ready to work with you on identifying any such gaps, as well as better understanding whether existing authorities were used to their full capability.

In order to effectively and responsibly address the question of clarifying or enhancing FDA's authority over compounding pharmacies, the Committee must identify what happened at the New England Compounding Center (NECC), and why FDA did not use its authority to take enforcement action against NECC until October 2012, after the meningitis outbreak. Your agency has not provided any internal communications or memoranda in response to the Committee's bipartisan request letter of October 17, 2012. We need these documents to identify any possible weaknesses in FDA's regulatory system that can be immediately corrected administratively or legislatively. Without gaining insight into whether FDA used its existing authority effectively, providing clearer or additional authority to FDA may not solve the actual, underlying problem.

Since 2002, FDA has initiated several inspections of NECC based on serious adverse events associated with contaminated drug products. In fact, one of these inspections was based on FDA learning that patients had been hospitalized with meningitis-like symptoms after receiving tainted injections of methylprednisolone acetate, the same product at issue in the current meningitis crisis. In 2003, FDA convened a meeting with officials from the Massachusetts Board of Pharmacy in order to discuss a joint strategy for achieving safe compounding practices at the firm. FDA emphasized the potential for serious public health

consequences if NECC's compounding practices, in particular those relating to sterile products, were not improved. What was FDA's role in developing and implementing this joint strategy? Was the agency confident that NECC's problems were adequately addressed? On what basis did FDA reach that conclusion?

In addition to these inspections and underlying deficiencies, FDA initiated another inspection of NECC in September 2004. Pursuant to violations observed during this inspection or otherwise brought to the attention of the agency, FDA issued a Warning Letter to NECC in December 2006. In this letter, FDA noted that it was aware of the firm's marketing and distribution of drug products to health care providers across the country without patient-specific prescriptions. It also noted the agency's concerns about NECC's manipulation of sterile injectables and the potential for microbial contamination associated with such practices. FDA asserted that failure to promptly correct these deviations could result in additional regulatory action, including seizure or injunction against the firm. Two years later, in October 2008, FDA reiterated that it could seize NECC products or issue an injunction against the firm and stated that the agency would follow up to ensure that NECC had implemented corrective measures at a future inspection. Did FDA believe it had the authority to take the actions it threatened in the 2006 Warning Letter? Why did FDA not conduct any follow-up inspections? Did FDA even check in with State regulators to ensure that NECC was not continuing to jeopardize public health?

These are just a few of the key events and decisions the Committee has questions about. The Massachusetts Board of Pharmacy has provided the Committee with thousands of internal emails referring or relating to NECC. FDA has provided the Committee with zero. In fact, when asked by Committee staff on November 6, 2012, FDA staff stated that they had not even begun to search for responsive emails.

This Committee has a long history of thoroughly and deliberatively investigating problems and offering solutions. We cannot and will not be in a position to do so in this instance until we have a full accounting of FDA's past actions and decisions relating to NECC and the reasoning behind them. Time is of the essence.

We need the FDA to be fully cooperative and prompt in its response so the Committee can immediately address your request for clearer and/or additional authority.

Please provide all documents responsive to the Committee's October 17, 2012, letter, including all internal emails, by no later than November 30, 2012. This is one month past the initial deadline. Further, as was requested by Committee staff on October 12, please provide the Committee with an accurate and comprehensive timeline of FDA's interactions with NECC since 2002.

As it was made apparent during the November 14 hearing that such actions and decisions were influenced by larger policy considerations and related judiciary matters, we also request that you provide the Committee with all memoranda and briefing materials produced by or for FDA staff referring or relating to FDA's authority over compounded drugs and compounding facilities since 2002. This should include all memoranda and briefing materials referring or

relating to FDA's enforcement discretion. These documents should also be provided no later than November 30, 2012.

If you have any questions, please contact Karen Christian or John Stone with the Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

Joseph R. Pitts
Chairman
Subcommittee on Health

Joe Barton
Chairman Emeritus

Michael C. Burgess
Vice Chairman
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cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Frank Pallone, Jr., Ranking Member
Subcommittee on Health