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

We convene this hearing of the Oversight and Investigations Subcommittee to examine the recent outbreak of fungal meningitis linked to contaminated products made by the New England Compounding Center, or NECC.

I want to extend my deepest condolences to everyone who has lost a loved one in this tragedy. Thirty-two people have died—including three within my district in Marion County, Florida, one of whom lived right up the street from me—and well over 400 people have been sickened, making this one of the worst public health disasters ever caused by a contaminated drug in this country.

After a tragedy like this, the first question we all ask is: could this have been prevented? After an examination of documents produced by the Massachusetts Board of Pharmacy and the U.S. Food and Drug Administration – the answer here appears to be yes.

Before this outbreak, FDA had conducted three series of inspections of NECC, each based on a separate set of allegations or events. The Massachusetts Board of Pharmacy's history with NECC is even more extensive, involving at least 12 separate complaints concerning NECC or its pharmacist, Mr. Cadden, since NECC opened in 1998. Over the course of these inspections, regulators noted the same kinds of problems at issue in the current outbreak – problems with sterility and violations of its license.

For example, back in 2002, several adverse events were reported to FDA involving patients who had received steroid injections made by the NECC. FDA followed up and inspected the company. Just six months after that inspection, patients were again hospitalized after receiving NECC injections. In what can only be seen as a warning of things to come, the patients infected in 2002 displayed meningitis-like symptoms. The product in question was the very same product connected to the current outbreak. In that case, the NECC drug was contaminated with bacteria.

After the 2002 meningitis cases, officials from FDA and the state pharmacy board met in 2003 to review NECC's conduct. During this meeting, the FDA made a prophetic statement. The FDA stated that there was "the potential for serious public health consequences if NECC's compounding practices, in particular those relating to sterile products, are not improved."

Even though FDA was clearly aware of the risks posed by NECC's compounding practices, the agency was slow to act. In fact, it took FDA four years after finding problems with NECC's sterility practices and violations of the Food Drug and Cosmetic Act to issue a Warning Letter. The company challenged the charges FDA made in the 2006 Warning Letter. It took FDA another two years to respond to the company's claims. When FDA finally responded in 2008 - six years after the agency first inspected the NECC – it directed the company to correct the violations and warned that it would follow-up with future inspections. But FDA never did. FDA didn't even follow-up after the Colorado Board of Pharmacy notified the agency in 2011 that NECC was again sending its drugs to out-of-state hospitals without first receiving patient prescriptions. FDA didn't even refer this complaint to the Massachusetts Board for follow-up. We are left to wonder what would have happened if FDA had investigated, or at least informed the Massachusetts Board of the Colorado complaint. It is possible that this outbreak very well might have been prevented.

We are joined today by Joyce Lovelace, whose husband Eddie passed away in September. Ms. Lovelace, we thank you for sharing your story with us today. I pledge that we will get to the bottom of this so we can ensure that an outbreak like this never happens again.

We are also joined by Commissioner Hamburg of the FDA and Commissioner Smith of the Massachusetts Department of Public Health. I am interested in learning whether they think this outbreak could have been prevented and whether their agencies did enough to stop it.

This committee has a long history of conducting bipartisan oversight, and this investigation is no exception. It is my sincere hope that this hearing will serve as an opportunity to determine the reasons why so that history doesn't repeat itself.

###