

**Opening Statement of the Honorable Joe Pitts
Subcommittee on Health
Hearing on “Examining Drug Compounding”
May 23, 2013**

(As Prepared for Delivery)

The purpose of today’s hearing is to hear from FDA and health care experts regarding the history and importance of drug compounding to patients and the current regulation of compounding on the federal and state levels.

As we are all aware, in the summer and fall of 2012, a Massachusetts company, the New England Compounding Center (NECC), shipped over 17,000 vials of an injectable steroid solution from three contaminated lots to health care facilities across the country.

After receiving injections of NECC’s contaminated steroid, over 50 people died from complications associated with fungal meningitis. Further, almost 700 others were stricken with meningitis or other persistent fungal infections.

The outbreak ranks as one of the worst public health crises associated with contaminated drugs in the history of the United States.

This committee began an investigation into the matter, and on October 9, a bipartisan committee letter was sent to FDA, requesting details surrounding the outbreak and the prevention of future outbreaks.

On October 17, the committee sent a letter to FDA asking for all documents related to the outbreak, including internal memoranda and communications with NECC.

The Oversight and Investigations Subcommittee held a hearing on November 14, 2012, where Dr. Margaret Hamburg testified, examining whether the meningitis outbreak could have been prevented.

Two days later, on November 16, the committee sent yet another letter to FDA stating that the agency had not provided any of the internal communications or memoranda in response to the October 17 letter.

It was not until March 21, 2013 – over five months after the original request and after being threatened with the possibility of a subpoena – that FDA fully complied with the committee’s document request.

It should be noted that the Massachusetts Department of Public Health (MDPH) had fully complied with the committee’s document request – turning over thousands of pages of documents related to its interactions with NECC – before the November hearing took place.

On April 16, 2013, the Oversight and Investigations Subcommittee held another hearing entitled “A Continuing Investigation into the Fungal Meningitis Outbreak: Could It Have Been Prevented?” and released a 43-page report on its investigation into the NECC tragedy.

The report stated that FDA had been aware of potential problems at NECC since 2002.

During her testimony at the November hearing, Dr. Hamburg repeatedly expressed uncertainty about FDA’s authority over compounding pharmacies, partially due to conflicting opinions on the matter issued by two different Circuit Courts of Appeals in 2009.

This uncertainty, however, has not stopped FDA from engaging in multiple enforcement activities against compounding pharmacies engaged in practices similar to those of NECC's since the outbreak took place.

This year alone, FDA has announced recalls from compounding pharmacies in Augusta, GA, and Lake Mary and St. Petersburg, FL.

In addition, the FDA in October 2012 was prepared to issue new guidance related to compounding enforcement under its authority under Section 503. Since the outbreak, however, the FDA has called for new authority that creates a new category of compounding manufacturers.

From what I understand, there are concerns that creating this new category could undermine drug safety by lowering standards and also weaken intellectual property protection.

I would like to thank Dr. Woodcock for appearing before us today to explain her understanding of FDA's authority over compounding pharmacies and what actions the agency is taking to ensure that future outbreaks can be prevented.

I would also thank our other witnesses for sharing their expertise on compounding and its importance to patients.

###