

**Opening Statement of the Honorable Joe Pitts**  
**Subcommittee on Health**  
**Hearing on “Reforming the Drug Compounding Regulatory Framework”**  
**June 16, 2013**

*(As Prepared for Delivery)*

As we all know, 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, and 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.

Shortly after the contamination came to light, the committee began an investigation into the matter, requesting documents from the Food and Drug Administration (FDA) and the Massachusetts Department of Public Health; examining whether the outbreak could have prevented and reviewing existing federal and state regulatory authority over compounding pharmacies acting as manufacturers.

Both this subcommittee and the Oversight and Investigations Subcommittee have held multiple hearings on the issues surrounding compounded drugs.

Today’s witnesses are here to discuss three legislative proposals released since the outbreak, including a discussion draft authored by my colleague Morgan Griffith.

The Griffith draft includes targeted provisions that both clarify FDA’s authority as it relates to Section 503 of the Food, Drug, and Cosmetic Act while ensuring that traditional compounding remains within the purview of state boards of pharmacy.

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