

**Opening Statement of the Honorable Fred Upton
Subcommittee on Health
Hearing on “Reforming the Drug Compounding Regulatory Framework”
July 16, 2013**

(As Prepared for Delivery)

This legislative hearing is the product of the thorough, thoughtful, and bipartisan investigation that the committee launched in the wake of last fall’s tragic meningitis outbreak. We were deliberate in our efforts as we wanted to know what went wrong and why before the committee acted legislatively. Sadly, Michigan has been hit hardest by the outbreak – according to CDC data last updated July 1, 2013, 264 of the 749 illnesses caused by the outbreak were in Michigan and we have endured 17 of the 61 fatalities, including three from my own district.

During our committee’s investigation, under the leadership of Oversight and Investigations Subcommittee Chairman Tim Murphy, we found that the meningitis outbreak and the loss of innocent lives could have been prevented. The New England Compounding Center was operating in an unacceptable and unlawful manner for years. Yet, it took this outbreak and its tragic consequences for the Food and Drug Administration (FDA) to act. Although the facts demonstrate that the FDA had the authority to regulate the bad actors who harmed patients with unsafe products, we believe that clarifying FDA’s regulatory authority in this area through legislation is a prudent step toward improving the safety of all Americans.

In May, this subcommittee held a hearing on the drug compounding industry to understand its evolution and the current role it plays in our health care system. We learned that compounding is an integral part of our health care system that helps patients receive the treatments necessary for their unique medical needs. As we look to legislate in this area, we want to ensure that patients can continue to receive compounded drugs that are safe. I believe that everyone here today shares that goal.

We also want to ensure that bad actors can no longer use the good name of pharmacies to hide activity that is essentially large-scale drug manufacturing. The FDA gold standard for approval should give patients the assurance that the drugs they use are safe and effective. Activities akin to large-scale manufacturing must be regulated as such in order to uphold the integrity of our nation’s drug supply.

Our hearing today is a result of thorough and collaborative investigative and policy work. While all of the bills before us today include ideas that we should consider carefully, I would like to thank Morgan Griffith for his dedication and leadership throughout both the committee’s investigative and legislative process. The Griffith discussion draft before us today includes key provisions that serve the important goals of clarifying FDA’s authority and protecting the role of traditional compounding. As we continue to work in a bipartisan manner, it is my belief that we will find common ground to advance legislation that achieves these goals.

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