

**Opening Statement**  
**Hearing on Drug Quality and Security Act**  
**January 30, 2018**

The 2012 outbreak of Fungal Meningitis resulting from contaminated steroid injections manufactured by the New England Compounding Center (NECC) was a failure of epic proportions. Of the 753 people sickened by the outbreak, 264 call Michigan home. My home state was the hardest-hit. Nineteen out of the 64 deaths caused by this tragedy were from Michigan and three of them were constituents of mine.

I was serving as Chairman of the full Energy and Commerce Committee at the time this all happened and immediately launched an investigation to find out what went wrong. I won't go through the full history of what happened then, but I will say that those at NECC who were responsible were brought to justice and this committee crafted legislation to empower the FDA to ensure that heinous acts of negligence like this one never happen again.

That legislation, the Drug Quality and Security Act (DQSA), is currently being implemented by the FDA. It takes a number of measures to ensure safety, not the least of which are much-needed restrictions on the use of bulk-compounded material as opposed to FDA-approved products when there is not a clinical need to do so.

I am pleased to see Commissioner Gottlieb here to update us on how DQSA implementation is going and what we in Congress can do to help move the process along.