

manufacturing, and compounding for office use. What is not clear is the line between compound manufacturing and compounding for office use.

Several states have passed legislation to fill in the gaps or fix issues they know exist in regulating and providing oversight for compounding pharmacies. We looked at Massachusetts (where NECC was located), Michigan (the hardest-hit state in terms of infections and deaths from the fungal meningitis outbreak), California (always quick to attend a regulation party, but surprisingly recognized by some experts as a thought-leader in pharmaceutical drug regulation), Florida (in the past a troubled state, but recently doing great things in pharmaceutical drug regulation), and Texas (a great state that balances being business-friendly with smart regulation).

Representative Fred Upton described the intentions for the bill well when he introduced H.R. 3204 on September 27, 2013. He said, “My colleagues on both sides of the aisle on the committee and in the Senate have been relentless in their pursuit of the facts behind last year’s deadly meningitis outbreak and working to prevent any such tragedy from happening again.... Michigan has been the hardest hit by the meningitis outbreak, and the sad truth is it could have been stopped. To all the families who have lost loved ones and to those patients who continue to suffer, we say ‘never again.’”²⁴ Representative Fred Upton did a masterful job in getting a bipartisan bill passed in a very partisan Congress to address a bad situation. However, there is a lot of white space in the bill, and potentially unintended consequences of some of the language (or lack thereof) in key areas of pharmaceutical compounding. Let’s start by taking a deeper dive into pharmacy compounding and the Drug Quality and Security Act.

ENDNOTES

1. Ramsey Cox, Senate Starts Work on Compound Drug Bill, *The Hill*, 2013, <http://thehill.com/blogs/floor-action/senate/190036-senate-starts-work-on-compound-drug-bill>.
2. *FDA Background*, November 21, 1997; <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendments/totheFDCA/FDAMA/ucm089179.htm>.
3. *Thompson v. Western States Medical Center*, Legal Information Institute, Cornell University, <http://www.law.cornell.edu/supct/html/01-344.ZS.html>; <http://media.okstate.edu/faculty/jsenat/jb3163/thompsonexcerpts.html>.