

on-the-job program at a sterile compounding pharmacy focused on compounding processes and procedures.²²

There may be additional legislation by the state of Texas when its legislature is next in session. The Drug Quality and Security Act was passed 5 months after the 2013 regular session came to a close. By law, the Texas legislature meets in regular session on the second Tuesday in January of each odd-numbered year. This means the next session starts on January 13, 2015. Under the Texas constitution, the regular session of the Texas legislature is limited to 140 days. Interestingly, the State Senate is led by the lieutenant governor, who is elected by the voters. The Speaker of the House is elected by the House members, or his or her peers. Only the governor can call a special session, a session of 30 days or less to address a governor-specific issue or piece of legislation. In most other states, the state legislatures can call themselves into a special session. Not in Texas!²³ Although the specifics are not known at press time, it is hoped that the legislation will address pharmacy compounding.

SUMMARY

The path to H.R. 3204 and the Drug Quality and Security Act began with the FDA Modernization Act of 1997. It was a well-intentioned act, yet included a clause in Section 503A that would be determined to be unconstitutional and throw the compounding industry into confusion for more than a decade.

The path to create and pass a law in the United States is convoluted and akin to making sausage. It is important to have a sponsor for a bill that has a powerful position and a vested interest in the bill itself. Representative Fred Upton became the sponsor for H.R. 3204. He is the chairman of the House Committee on Energy and Commerce, which has principal responsibility over matters relating to health care, energy, the environment, consumer safety, telecommunications, commerce, manufacturing, and trade. He is also a representative in Michigan, the hardest-hit state by the NECC tragedy.

The definitions involving compounding vary by state and person within the industry. There are definitions for traditional compounding, compound