

“What just happened with H.R. 3204, or the Drug Quality and Security Act?” The answer I received was, “We just fixed everything that was wrong legislatively with drug compounding and track and trace.” I asked, “Can you elaborate on this?” In fact, I tried three times, and finally I received an honest, non-campaign-type answer: “We set in motion the ability of the FDA and state regulatory boards to share oversight responsibilities of drug compounding and clear up the confusion of 503A. In addition, we set in motion the ability of the FDA to define the requirements for track and trace and fix what we did wrong with ePedigree six to seven years ago.”

Uh-oh. Another law was passed where the actual requirements of the law for the supply chain participants to be in compliance were “to be determined” (TBD). And track and trace? Are we “back to the future” with a modified ePedigree law? So now we are embracing all supply chain participants beyond compounding pharmacies in the new law.

QUICK LEVEL SET OF DEFINITIONS

Pharmaceutical compounding is the creation of a particular pharmaceutical drug product or medicine to fit the unique need of a patient. When a given pharmaceutical drug product is made or modified to have characteristics that are specifically prescribed for an individual patient, it is known as *traditional compounding*. When pharmaceutical compounding is done on bulk production of a given formulation rather than patient-specific production, it is known as nontraditional compounding or *compound manufacturing*. When pharmaceutical compounding is done for a specific hospital, medical facility, or a medical practice (such as a scoliosis institute) that tightly assembles patient prescriptions, it is known as *compounding for office use* or *compounding outsourcing*.¹²

One expert in this area (whose opinion I highly value) believes that the last two, compound manufacturing and compounding for office use or compounding outsourcing, are basically the same. One compounding pharmacy owner in Texas disagrees. He sells compounded medicines on a daily basis to about a dozen large physician-owned practices. These physician-owned practices place their orders with this compounding pharmacy for specific, next-day patients and their prescriptions. He said, “We have a new law, but once again, the question of what is traditional compounding versus what is compound manufacturing still persists. All that