THE FDA MODERNIZATION ACT OF 1997

According to the FDA, the FDA Modernization Act of 1997 (FDAMA) is a major legislation focused on reforming the regulation of food, medical products, and cosmetics. The following are the most important provisions of the act:

- Prescription drug user fees
- FDA initiatives and programs
- Information on off-label use and drug economics
- Pharmacy compounding
- Risk-based regulation of medical devices
- Food safety and labeling
- Standards for medical products[1]

Under the pharmacy compounding provision, the FDA provides this summary:

> The act creates a special exemption to ensure continued availability of compounded drug products prepared by pharmacists to provide patients with individualized therapies not available commercially. The law, however, seeks to prevent manufacturing under the guise of compounding by establishing parameters within which the practice is appropriate and lawful.[2]

These are well-written intentions of the FDAMA in 1997, but still people throughout the pharmaceutical supply chain wanted to know what happened. This includes legislative/elected officials and patients like you and me. To pursue the answer to this question, I took a deeper dive into the FDAMA.

Section 127 of FDAMA added Section 503A to the FFDCA (remember, the FDAMA amended the FFDCA). Section 503A exempted compounded drugs from new drug laws as long as the compounded drug met several conditions/restrictions. Included in the new drug laws were the myriad and lengthy new drug requirements (FDA trials, etc.), as well as the labeling requirements. Another key condition was that the compounded drug had to be produced using current good manufacturing practices (cGMP). We will review cGMP in more depth in Chapter 2.

One big issue with FDAMA, Sections 127 and 503A, was that drug providers were prohibited from soliciting and advertising particular