

in his last few years to go through the trial or have access to the medicines that had the promise to improve his eyesight. Patients today must be clinically perfect candidates for FDA trial medicines to boost the overall results. My suggestion is to make these medicines available to people who might be high risk but have nothing to lose (Ebola patients and others).

Also, during my research for the book, many compounders are actually pharmacists that happen to own companies. Over time, many of these compounders have obtained multiple compounding sites, and face issues that are a mix of business, pharmaceutical compounding, and compliance issues. It is my recommendation that the National Association of Boards of Pharmacy (NABP) work with the FDA and state boards of pharmacy members to develop programs for the owners of compounding facilities that center on governance, leadership, and compliance with FDA regulations. This would help the owners feel less threatened by the new regulations, and enhance their effectiveness in balancing the production of safe compounded drugs for patients and operating a business that produces a return on the owner's investment.

SUMMARY—TITLE II: DRUG SUPPLY CHAIN SECURITY ACT

Title II of the Drug Quality and Security Act is called the Drug Supply Chain Security Act. Many insiders call it the Track and Trace Act. The objective of Title II is to facilitate the exchange of information at the individual package level about where a pharmaceutical drug has been in the supply chain. The law requires the FDA, within 10 years of November 27, 2013, to accomplish the following: enable verification of the legitimacy of the drug product identifier down to the package level, enhance detection and notification of illegitimate products in the drug supply chain, and facilitate more efficient recalls of drug products.

The FDA is already working with pharmaceutical drug manufacturers, wholesale distributors, repackagers, and pharmacies to develop a new system. This new system will include product identifiers, product tracing, product verification, detection and response procedures to quarantine and investigate suspect pharmaceutical drugs, and notification procedures (FDA and other stakeholders) when illegitimate drugs are found. Title II also includes provisions for wholesale distributors to report their licensing statuses and contact information to the FDA (good move), and for