

4

Track and Trace: Not Hide and Seek

OVERVIEW

In the first three chapters, we focused on Title I: Compounding Quality Act of the Drug Quality and Security Act. In this chapter, we review Title II: Drug Supply Chain Security Act (sometimes called the track and trace part of the law). Efforts are underway to plan the necessary steps to build an electronic system to identify and trace prescription drugs as they are distributed in the United States. As I was writing this book, the targeted completion for this system was November 27, 2024, or 10 years from the signing of the H.R. 3204 bill into law and the enactment of the Drug Quality and Security Act.

It is planned (hoped?) that this system will allow for the exchange of information “at the package level” about where a drug has been in the supply chain. There are three objectives for this new system:

1. Enable verification of the legitimacy of the drug product identifier down to the package level
2. Enhance detection and notification of illegitimate products in the drug supply chain
3. Facilitate more efficient recalls of drug products¹

During a conversation with the Food and Drug Administration (FDA), it was explained to me that the FDA is relying on the manufacturers, wholesale distributors, repackagers, and large pharmacy chains to work with them to develop this system over the next decade. Several Big Data