

authority and background checks for personnel with strict regulations on the hiring of known felons in specific, related categories.<sup>13</sup>

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## FROM PLANNING TO EXECUTION

The FDA is working hard to comply with the Drug Quality and Security Act's requirements. There are a lot of questions to be answered, followed by policies and procedures to be implemented for all participants in the pharmaceutical drug supply chain. The development of standards and pilot programs with the industry supply chain participants places the FDA in an unenviable position of getting a consensus among disparate interests. Protecting consumers from counterfeit, adulterated, and contaminated drugs that can be harmful is a very good objective.

Protecting industry participants from stolen drugs is also a very good objective. As I identified in the introduction, prescription painkillers are very popular with the drug cartels. According to a survey, the cost to buy prescription painkillers at a pharmacy versus the street corner is about the same.<sup>14</sup> How do the bad guys get the prescription painkillers to sell through the illegal market at the same price as the local pharmacy? The simple answer is that they must be stealing the drugs. The FDA is trying to put together a program to address the weaknesses in the pharmaceutical drug supply chain.

Some observers have been asking the question, "Didn't we try this before with ePedigree?" The answer is in part yes and in part no. Let's take a look at the ePedigree initiative, why it did not take hold as a program, and what can be done differently with the Drug Quality and Security Act.

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## BACK TO THE FUTURE

The FDA defines a drug pedigree as a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them.<sup>15</sup> An electronic pedigree, or ePedigree, is an electronic pedigree document.

In early 2007, EPCglobal ratified the pedigree standard as an international standard that specified an Extensive Markup Language (XML)