studies would be anchored by major pharmaceutical drug companies and incorporate specific wholesale distributors, pharmaceutical retailers, and return logistics providers. The feasibility studies would embrace specific serialization, authentication, and supply chain track and trace network providers, and would be carried out under the guidance of the FDA. Due to the cost of the active RFID tags, perhaps the pilot using them would only focus on high-value, time-sensitive pharmaceutical drug products.

The technologies are available to put these two pilots or feasibility studies into practice in 6 to 9 months. Real-world feasibility studies would allow the two sets of teams to plan and implement the tracking and tracing of pharmaceutical drugs, test the results, and replan and reimplement with the appropriate modifications. The private sector can blow by the objectives of the FDA in 10 years to provide product and transaction information at each point of sale with lot information and place unique product identifiers on individual packages. With two distinct feasibility studies and with distributed and cloud computing, both approaches may be acceptable within the FDA guidelines without a massive conversion to a centralized government system.

Once again, the question will surface, who is going to pay for all of this? In the long run, two pilots or feasibility studies with existing capabilities and executed by the private sector will be vastly less expensive than a new engineered system built by the federal government to encompass any and all conditions and situations. It will also compress the time between planning and implementation, saving lives of patients as well as enormous amounts of money.

Also, having two pilots or feasibility studies will foster competition and cooperation if properly guided by the FDA. The real winners will be the FDA and, more importantly, the general public.

SUMMARY

We started the chapter by identifying that the Title II: Drug Supply Chain Security Act has three objectives: (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, and (3) facilitate more efficient recalls of drug products. We proceeded to review the seven key provisions of Title II, and to compare the past