

due to a bee sting. The doctor immediately recognizes the symptoms and attempts to administer a shot of epinephrine. What if the epinephrine were not available? The same social incentive applies to medical facilities as well.

As humans, we cannot adequately forecast these scenarios, and our best social response is to produce enough of the products necessary for demand to always be met. In this imperfect world this always leads to an excess supply. With the passage of time, excess supply transforms into excess risk as the drugs move past their expiration date.

Most manufacturers accept it as a cost of doing business and have built in a certain allowance into the procurement agreements between them and retailers and wholesale distributors. When the excess supply is reconciled against the return goods policy, the debit/credit memos are issued, and then the intended path for the product is to be destroyed. We go into this in depth later in the chapter.

THE DRUG QUALITY AND SECURITY ACT: BACK TO THIRD-PARTY LOGISTICS PROVIDERS

As we discussed in Chapter 6, under Title II of the Drug Quality and Security Act, all third-party logistics providers (3PLs) must have a valid state or federal license or licenses and be in full compliance with all reporting requirements. They are considered authorized before federal licensing regulations are effective, unless the FDA makes certain findings and gives notice. By November 27, 2015 (or the second anniversary of the signing of H.R. 3204 into law), the FDA is required to develop new federal standards for licensing of 3PLs and a federal system for 3PL licensing for use when a state system does not meet federal standards. Beginning November 27, 2014, 3PLs must report their licensing status and contact information to the FDA. As of January 1, 2015, all trading partners in the pharmaceutical drug supply chain must be authorized.⁴

The FDA defines 3PLs as “an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.”⁵

Casually we telephoned three 3PLs that handle pharmaceutical drugs to find out if they were licensed by their respective states. The answer was yes,