PHARMACEUTICAL DRUG COMPANIES AND THE DRUG QUALITY AND SECURITY ACT

It is Chapter 9, and my readers are probably wondering, "Where are the pharmaceutical drug companies?" For Title I and drug compounding, there is limited exposure and participation with the pharmaceutical drug manufacturers unless they manufacture ingredients and fine chemicals. The pharmaceutical manufacturers do have to be careful not to allow drug products approved overseas but not yet approved in the United States to be imported into the United States through either direct importation or drug compounding and compounding pharmacies.

For Title II, virtually all the pharmaceutical drug manufacturers have antidiversion and anticounterfeiting divisions and activities. Johnson & Johnson has its active Anti-Counterfeiting Division.[5] Pfizer works closely with the FDA and other regulatory authorities to ensure that pharmaceutical companies have the resources they need to implement the anticounterfeiting technologies that work most effectively for their products. Pfizer is working collaboratively with wholesale distributors, pharmacies, Customs and Border Protection offices, and law enforcement agencies to increase inspections, monitor distribution channels, and improve surveillance of distributors and repackagers.[6] GlaxoSmithKline has an active anticounterfeiting program, which ranges from covert and overt markers on its packages to contract demands that only GSK products be purchased from GSK.[7] The list goes on and on.

Pharmaceutical drug manufacturers focus their efforts on the packaging and serialization of their products. From a drug quality standpoint, they want to make sure that when a patient takes one of their medicines, it is in fact one of their medicines. From a drug security standpoint, diversion, adulteration, and counterfeiting strike at the heart of their business—brand equity and the protection of their brand's value. If you ask any investment advisor about a pharmaceutical drug stock, the first thing the advisor will look for is its brand portfolio. The pharmaceutical drug manufacturers spend a huge amount of money in research and development (R&D) to develop their brands. From both risk mitigation and the protection of their brand assets, they have a heightened interest to work with the supply chain participants to eliminate diversion, adulteration, and counterfeiting. The reality is they can only do so much. The risk essentially starts as they "hand off" the pharmaceutical drugs