
BACK TO THE DRUG QUALITY AND SECURITY ACT AND THE FFDCA

We will certainly let the judicial process sort out all the particulars in this case. In my opinion, the FDA should provide FDA-approved couriers with a list of known illegal Internet pharmacies so they can prescreen shipments and address them with the proper authorities.

The FDA established its Secure Supply Chain Pilot Program in 2013 to enhance the security of imported drugs. This program was launched with the participation of 13 companies prequalified by the agency and up to five selected drug products. The objective is to prevent the importation of unapproved, adulterated, or misbranded drugs. The FDA is cooperating with CBP and sharing information about the participants and the selected drug shipments.¹⁵

According to a February 21, 2014, publication by Sandler, Strauss and Rosenberg P.A., the companies accepted into the program are Above, Inc., Allergan, Inc., Estella's U.S. Technologies, Inc., Bristol-Myers Squibb Company, Colene Corporation, GE Healthcare, Inc., GlaxoSmithKline LLC, Merck Sharp & Dome Corporation, Milan Pharmaceuticals, Inc., Novartis Pharmaceuticals Corporation, Pfizer, Inc., Tea Pharmaceuticals USA, Inc., and Watson Laboratories, Inc. In this publication, Sandler, Strauss and Rosenberg said that according to the FDA, each of these companies has committed to comply with requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), has a validated secure supply chain protocol per the Customs-Trade Partnership Against Terrorism, has a plan in place to quickly correct potential problems the FDA identifies regarding importation of specific products, has effective recall and corrective action plans in place, and maintains control over its drugs from the time of manufacture abroad through entry into the United States.¹⁶

All of this is positive. However, where are the couriers? They are the Customs brokers and the transport providers. They are the ones actually handling the pharmaceutical drug shipments. They are the ones that will be responsible for the quarantine of suspected proscribed shipments, execute any recalls, and institute corrective actions necessary throughout the supply chain. I understand they provide a "service for hire" with the major pharmaceutical companies (especially the ones in the Secure Supply Chain Pilot Program). However, once the pharmaceutical drug shipments leave the manufacturer's shipping dock, it is the courier's responsibility