

- Had systems and processes in place to comply with verification requirements under the law
- Did not knowingly provide false transaction information
- Did not knowingly alter the transaction history²⁹

The first two are the anchors to the transaction statement. The wholesale distributor must be authorized as required under Title II of the DSCSA, and it must receive product from a person that is authorized as required under DSCSA. Let's take a look at a well-publicized case involving wholesale distributors substituting bad product for pharmaceutical drugs not even authorized by the FDA for sale in the United States.

PROBLEMS IN 2012

Despite the history and efforts by the wholesale distributors to provide safe and secure pharmaceutical drugs to patients, there are always people willing to do bad things to make money. The bad and ugly of wholesale distributors are exemplified by a situation in 2012 addressed by the FDA. Licensed wholesale distributors were caught by the FDA distributing counterfeit drugs and unapproved foreign-sourced oncology drugs.

On April 3, 2012, the FDA alerted health care professionals that a cancer drug, originating from a foreign source and purchased by U.S. medical practices, had been determined to be counterfeit. FDA lab tests confirmed that a counterfeit version of Roche's Altuzan 400 mg/16 ml (bevacizumab), an injectable cancer medication, was found in the United States and contained no active ingredient. Altuzan at the time was not approved by FDA for use in the United States but was an approved drug in Turkey. Medical practices obtained the counterfeit Altuzan and other unapproved products through foreign sources, in particular from Richards Pharma, also known as Richards Services, Warwick Healthcare Solutions, or Ban Dune Marketing, Inc. (BDMI). Many, if not all, of the products sold and distributed through this distributor have not been approved by the FDA. The agency cannot ensure that the manufacture and handling of these illegal products follows U.S. regulations, nor can the FDA ensure that these drugs are safe and effective for their intended uses.^{*30}

* This information is from the FDA drug integrity and supply chain security website.