



New Law Helps Protect Patients From Counterfeit Drugs and Other Risks

A new federal law, the Drug Supply Chain Security Act, passed in 2013, will help protect patients by better securing our nation's pharmaceutical supply chain.¹

The U.S. drug supply is among the world's safest, but troubling deficiencies and risks persist. For example, several times in 2012 and 2013, the Food and Drug Administration informed doctors' offices and clinics that they may have purchased counterfeit vials of the cancer drug, Avastin.² The fake products, which contained no active ingredient, came from foreign sources and passed through a series of intermediaries, including at least one licensed U.S. wholesaler.³ It is unknown how many cancer patients received these products. In 2014 two individuals were charged with obtaining unapproved, adulterated, and counterfeit cancer prescription drugs and smuggling them into the United States.⁴

Counterfeit drugs are not the only threat: stolen, diverted, and contaminated medicines have all been found on the U.S. market as recently as 2014.⁵

To improve safety, the Drug Supply Chain Security Act will:⁶

- **Require more information about drug transactions.** Starting Jan. 1, 2015, companies in the pharmaceutical supply chain—manufacturers, repackagers, wholesalers, and pharmacies—must share specific data, including the lot number, with all trading partners for each transaction and other changes of ownership. In most cases, the data must document the full purchase and sale history of all drugs in a shipment back to the original manufacturer. This will dissuade illegal activity, such as purchasing counterfeit medicine from an unauthorized foreign supplier, by making the origin and routing of the drugs more transparent. With regular checking of transaction histories, criminals will find it more difficult to introduce unsafe or compromised medicines of unknown origin into consumer markets.
- **Require unique serial numbers on each package of drug.** By the end of 2017, nearly every individual package will carry a unique barcode. This will eventually allow companies along the entire supply chain to verify the authenticity of the drugs they acquire, making it more difficult for criminals to introduce counterfeit drugs into the pharmaceutical supply. Drug packages with fake serial numbers or with packaging that has been inappropriately altered will be easier to identify and remove from the supply chain.
- **Enhance licensure standards.** The law creates a transparent system for pharmaceutical wholesale distributors that establishes minimum standards for licensure in the United States and also requires them to report their licensing status and contact information to the U.S. Food and Drug Administration. The information will be publicly available through online databases, which will help supply chain stakeholders, including health care providers, avoid purchasing from unlicensed suppliers.
- **Build an interoperable, electronic system.** The law requires manufacturers, wholesalers, and pharmacies to use serial numbers and an electronic system by 2023, which captures and shares information in order to trace each package of medicine. The FDA and stakeholders will work together to determine how this system will

work and how data will be exchanged. The unique serial numbers will allow any pharmacy or wholesaler to verify the authenticity of a drug package.

Between now and 2023, there will be opportunities to include additional features—such as automatic checks of transaction information and routine verification of package serial numbers—that can further improve detection of illegitimate medicines before they reach patients. Automating these features might also lower costs by reducing expenses associated with labor and human error.⁷

Endnotes

- 1 Title II of the Drug Quality and Security Act of 2013, H.R. 3204, 113th Cong. (2013).
- 2 “Counterfeit Version of Avastin in U.S. Distribution,” U.S. Food and Drug Administration, accessed May 1, 2014, <http://www.fda.gov/drugs/drugsafety/ucm291960.htm>; “Altuzan (bevacizumab): Counterfeit Product—Contains no Active Ingredient,” U.S. Food and Drug Administration, accessed May 1, 2014, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm338283.htm>; “Another counterfeit cancer medicine found in U.S.—Illegal practice puts patients at risk,” U.S. Food and Drug Administration, accessed May 1, 2014, <http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/ucm298047.htm>; “Health Care Provider Alert: Another Counterfeit Cancer Medicine Found in United States: Purchasing Unapproved Drugs is Risky Business,” U.S. Food and Drug Administration, accessed May 1, 2014, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm338283.htm>.
- 3 “Counterfeit Version of Avastin in U.S. Distribution,” U.S. Food and Drug Administration.
- 4 “Two Turkish Nationals Indicted for Smuggling Counterfeit Cancer Drugs,” United States Attorney’s Office, Eastern District of Missouri, press release. Jan. 16, 2014, <http://www.fda.gov/ICECI/CriminalInvestigations/ucm383001.htm>.
- 5 “FDA Conducts Preliminary Review of Agency’s Diversion and Counterfeit Criminal Case Information,” U.S. Food and Drug Administration, accessed May 1, 2014, <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM272150.pdf>.
- 6 U.S. Food and Drug Administration website, “Drug Supply Chain Security Act (DSCSA),” accessed May 1, 2014, <http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/default.htm>.
- 7 PWC (formerly Booz & Company), “Next-Generation Supply Chains: Efficient, Fast and Tailored” (2012), http://www.pwc.com.uy/es_UY/uy/publicaciones/assets/pwc-global-supply-chain-survey-2013.pdf.

For further information, please visit:

pewhealth.org/drugsafety

Contact: Sarah Carroll, communications

Email: scarroll@pewtrusts.org

Project website: pewhealth.org/drugsafety

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