



The Partnership for SAFEMEDICINES

What happened?

On Feb. 14, 2012, the US Food and Drug Administration and pharmaceutical manufacturer Genentech warned the public that counterfeit versions of the anti-cancer drug Avastin had been distributed in the United States by an unauthorized foreign supplier named "Quality Specialty Products" that may also be known as "Montana Health Care Solutions". A US-based company named "Volunteer Distribution" in Gainesboro, TN is a domestic distributor of QSP's products¹.

A sample of the counterfeit product had been tested by the manufacturer and found to contain no active pharmaceutical ingredient, but it does contain other chemicals.

In a separate communication on the same day, the FDA warned 19 medical practices that purchased medications from the foreign supplier, Quality Specialty Products, that purchasing these medications from a foreign supplier is a violation of the Federal Food, Drug, and Cosmetic Act².

Are there official suppliers of Avastin within the United States? Is it easy for a physician's office to locate authorized suppliers?

Yes, they are listed on the Genentech website in a section specifically for Physicians offices. You can search on <http://www.genentechaccesssolutions.com> for "wholesalers" or go to <http://www.genentechaccesssolutions.com/portal/site/AS/menuitem.7ef3b8542d7c63460313edacd79c23a0/?vgnnextoid=359169cc87727210VgnVCM1000007dc9320aRCRD>

Was there any indication on the counterfeit product that would have alerted the Doctor, nurse or patient that the product may be unsafe?

Yes, as indicated on the photographs released by Roche, the label on the package is in French and on the reverse side it was in Arabic. Clearly these products were not for the US market, even if they were genuine.

Why would a physician's office go to an unauthorized wholesaler for life-saving medications?

The pharmacy industry publication Pharmalot has documented that the vendor in question was selling the fake version of Avastin at a discount of several hundred dollars per dose³. This price difference may have attracted the attention of the 19 medical practices the FDA warned that did business with the unauthorized distributor.

For good faith actors, what can they do to ensure appropriate sourcing?

On the provider end: check the manufacturer's web site to determine authorized wholesalers of the medications you source. More information for physicians about safely sourcing medications can be

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<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm291968.htm?source=govdelivery>

² <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm291478.htm>

³ <http://www.pharmalot.com/wp-content/uploads/2012/02/avastin-pricing-montana-sheet.jpg>



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found in the Partnership for Safe Medicines free document “LEADERS Guide for Doctors” at http://safedr.ug/for_physicians

On the patient end, ask to see the drug to ensure the drug label is in English, and query about the source of the drug. This is a patient safety concern, and the patient is the last barrier to harm and so should be part of the process.

Was there a shortage of the product at the time of the counterfeit incident?

No. "Based on information to date, FDA has determined that none of the unapproved cancer medicines received by these medical practices from Volunteer Distribution are in shortage in the United States. FDA-approved versions of these medicines are available in adequate supply to meet current demand." (*FDA communication, Feb 14, 2012*⁴)

Are there any anti-counterfeiting technologies that would have prevented this incident?

Probably not. Most proposals to date cannot account for a healthcare practitioner that intentionally circumvents the closed, secure drug supply chain that keeps Americans safe.

Is the creator of the counterfeit product known?

No responsible party has been identified.

The counterfeit product appears to have passed through a number of distributors outside the US who were either unauthorized distributors of the product or who had no expertise in pharmaceuticals. Is this a normal supply chain for this product to get to American cancer patients?

This product is manufactured within the continental United States⁵ and all the authorized distributors are within the continental United States as well. There's no logical reason an oncology practice in California would be getting this medication through a chain of suppliers in Egypt, Switzerland, Denmark, and the United Kingdom.

Is it known exactly who had possession of the counterfeit medication at as it passed from hand to hand?

Investigators have not released a documented chain of custody of the counterfeit product. Many entities were involved in the repeated sale and purchase of the product. In the world of counterfeit pharmaceuticals, the entity that ships the fake medication is often not the same entity that sells it.

Much like criminal illicit drug gangs, they separate the financial transaction from the delivery of the product in order to hide their operations from discovery by law enforcement.

⁴ <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>

⁵ <http://www.gene.com/gene/news/kits/corporate/manufacturing.html>



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Why are so many entities involved in this transaction not actually taking possession of the counterfeit product?

Most countries require special licenses to import and distribute pharmaceuticals. Many of the companies in this open, insecure supply chain do not possess those licenses. They complete the financial transaction but to avoid illegal importation, they have product shipped from a third party directly to the customer or the next entity.

What are your sources for the ownership supply chain map?

Turkey, Egypt, Syria, Switzerland: "Egyptian middleman bought fake Avastin from Turkey", Reuters, Feb. 28, 2012 <http://news.yahoo.com/egyptian-middleman-bought-fake-avastin-turkey-223108299.html>

Switzerland, Denmark, UK: "Denmark's CareMed says shipped fake Avastin unwittingly", Reuters, Feb. 17, 2012, <http://news.yahoo.com/denmarks-caremed-says-shipped-fake-avastin-unwittingly-201822338.html>

United Kingdom, St. Kitts, Tennessee, Montana, California, Illinois, Texas: "Drug distributor is tied to imports of fake Avastin", WSJ, March 7, 2012, <http://online.wsj.com/article/SB10001424052970203370604577261343974214110.html>