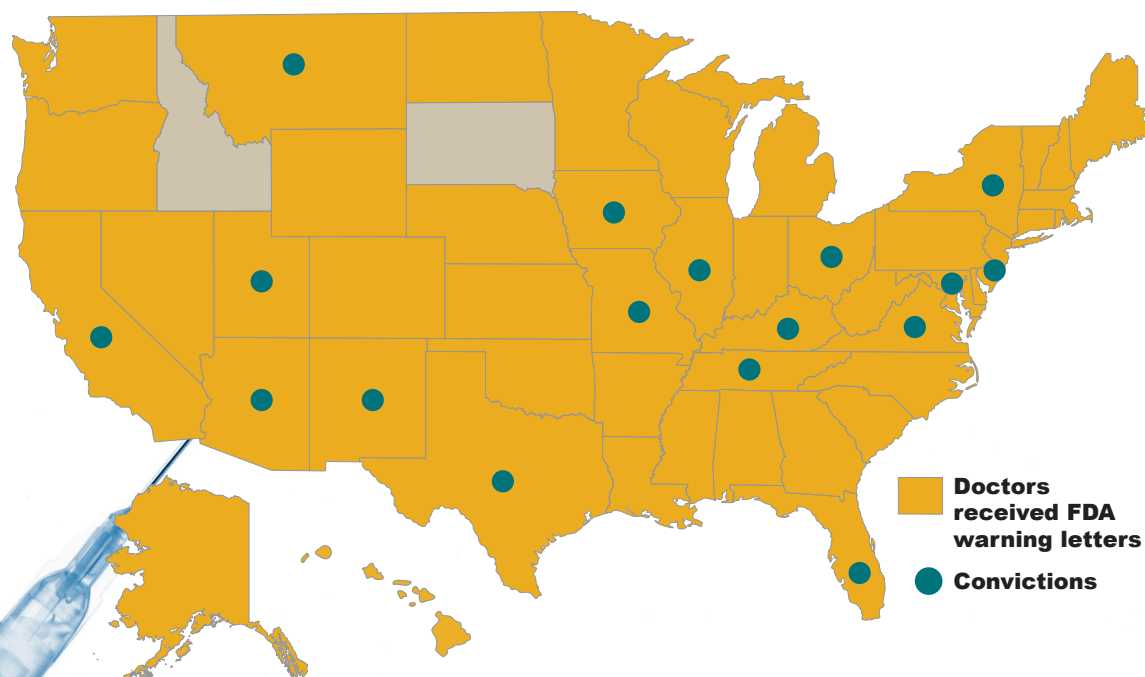


# Black Market Cancer Drugs In the U.S. 2007–2018

**Wholesale importation backfired resulting in thousands of patients endangered and physicians prosecuted**



## **Is wholesale drug importation safe? Can it be made so?**

From 2007 to 2018, American physicians and clinics have demonstrated that drug importation is not safe and is extremely difficult to make safe. Doctors thought they were saving money, but they were endangering patients and costing themselves millions in fines. They were purchasing from black market wholesalers posing as licensed distributors in Canada and other countries who sold illegally imported, expired, damaged and outright counterfeit medications—including cancer treatments. Across all therapeutic areas, the FDA has traced criminal wholesaler drug importation businesses to at least 3,000 medical practices across the United States.

**Importation is not safe, even at a wholesale level. Only licensed U.S. wholesalers selling FDA-approved medicines are safe for American patients.**

# Significant Cases Involving Black Market Cancer Drugs

**CANCER TREATMENTS LISTED IN THE PROSECUTIONS:** Abraxane, Aclasta, Alimta, Aloxi, Altuzan, Anzemet, Aranesp, Arimidex, Avastin, Camptosar, Casodex, Dacogen, Daxotel, Docemil, Docetax, Doxil, Eloxatin, Eprex, Erbitux, Espogen, Farmorubicina, Faslodex, Gemzar, Grafeel, Grastim, Herceptin, Hycamtin, Irnozen, Kytril, Leucovorin, Mabthera, Methotrexate, Neulasta, Neulastim, Neupogen, Oxidach, Reclast, Ribomustin, Rituxan, sodium dichloroacetate, Taxotere, Treanda, Velcade, Venofer, Vidaza, Zometa

## **APRIL 2018**

**MONTANA:** CanadaDrugs.com and 2 subsidiaries will pay \$34 million in fines and forfeitures for selling \$78 million in non-FDA approved medicines to U.S. doctors, including counterfeit Avastin. CEO Kris Thorkelson received 6 months house arrest, 4.5 years probation, and a \$250,000 fine for concealing a felony. In 2012, the FDA warned more than 500 medical practices to stop buying misbranded medication from subsidiaries of CanadaDrugs.com.

## **MARCH 2018:**

**NEW YORK:** Dr. Vincent Koh and his wife/office manager received a \$10,500 fine for buying and treating patients with imported oncology drugs. The couple also paid \$500,000 for submitting false claims to Medicare for the drugs.

## **AUGUST 2017:**

**FLORIDA:** Dr. Diana Anda Norbergs received a nearly 6-year sentence for importing non-FDA approved cancer drugs from multiple unlicensed suppliers.

## **MAY 2016:**

**ILLINOIS:** Dr. Ann Kinnealey relinquished her medical license to avoid prosecution for allegedly treating patients with illegal cancer drugs obtained through a CanadaDrugs.com subsidiary, Quality Specialty Products (QSP).

## **AUGUST 2015:**

**VIRGINIA:** Canadian TC Medical Group and SB Medical, Inc received a \$75 million fine for selling imported orthopedic, rheumatology, ophthalmology, and oncology drugs and cosmetic devices to over 1,000 U.S. medical practices.

## **JULY 2015:**

**MISSOURI:** Dr. Robert L. Carter received 5 years probation and more than \$2 million in fines and restitution payments for purchasing non-FDA approved medications from QSP.

## **APRIL 2015:**

**TEXAS:** South Texas Comprehensive Cancer Centers received 5 years probation and forfeited \$900,000 for buying imported cancer drugs from Montana Healthcare Solutions, which sold American medical practices counterfeit Avastin.

**UTAH:** Cache Valley Cancer Treatment and Research Clinic received 6 months probation and nearly \$1 million in fines and forfeitures for purchasing misbranded oncology drugs from QSP.

## **FEBRUARY 2015:**

**NEW YORK:** Shahradi Rodi Lamah received 6 months home detention, 3 years probation, and forfeited \$500,000 after his company, Medical Device King, distributed non-FDA approved prescription drugs, including counterfeit Avastin. In May 2013, the FDA warned 781 doctors to stop buying medicines from Medical Device King.

## **NOVEMBER 2014:**

**TEXAS:** Dr. Eduardo Miranda received 5 years probation and a \$1 million fine for importing and treating patients with non-FDA approved oncology drugs and fraudulently billing Medicare and private insurers for them.

**NEW MEXICO:** Dr. Mohamed Basel Aswad received 3 years probation and a \$2 million fine for importing

and treating his patients with non-FDA approved oncology drugs.

## **OCTOBER 2014:**

**MISSOURI:** Ozay Pharmaceutical executive Ozkan Semizoglu received a 27-month sentence for smuggling misbranded, adulterated and counterfeit cancer treatments, including fake Avastin. Owner Sabahhadin Akman received a 30-month sentence and a \$150,000 fine in January 2015.

## **JUNE 2014:**

**KENTUCKY:** Hematology and Oncology Center (HOC) and former office manager, Natarajan Murugesan received probation for charges related to buying and treating patients with imported cancer drugs from QSP. In a parallel civil case, HOC, Murugesan, and an oncologist, N. Mullai, agreed to pay \$2 million plus interest for billing Medicare fraudulently for the illegal medicines.

## **FEBRUARY 2014:**

**CALIFORNIA:** Alvarado Medical Plaza Pharmacy received a sentence to pay \$1 million in fines and restitution for billing Medicare for unapproved oncology drugs it purchased from QSP. Pharmacist William Burdine received 8 months home confinement, 5 years probation and 240 hours community service.

## **MAY 2013–MAY 2014:**

**VIRGINIA:** 12 employees of Gallant Pharma International, which sold smuggled counterfeit and misbranded chemotherapy and cosmetic injectables to U.S. doctors, cumulatively received sentences of 108 months in prison and more than \$8 million in fines and forfeitures.

**(significant cases, cont.)**

2 additional defendants, believed to be in Canada, cannot be prosecuted. In April 2015, the FDA warned more than 270 doctors nationwide to stop buying drugs from Gallant Pharmaceuticals.

**SEPTEMBER 2013–  
JANUARY 2014:**

**OHIO:** 7 oncologists who imported non-FDA approved cancer medications received probation and paid a cumulative \$2.6 million in restitution.

**SEPTEMBER 2013**

**FLORIDA:** Martin Paul Bean, III; received a 2-year sentence and a \$19,000 fine and forfeited a luxury car after selling \$7 million in unapproved foreign oncology drugs to American medical practices. Co-conspirator Maher Idriss, received 3 years supervised release, 8 months home detention, and a \$2,000 fine in October 2013.

**AUGUST 2013:**

**UTAH:** Michael Lawrence O'Donnell received a 12-month sentence after distributing diverted, non-FDA approved cancer drugs and Botox without a license. He pleaded guilty to 1 count of shipping Botox to a New York practice.

**JULY 2013**

**MONTANA:** Montana Healthcare Solutions founder Paul Bottomley received 5 years probation, 200 hours of community service and owed \$4.4 million in restitution for concealing the importation of non-FDA approved drugs, including counterfeit Avastin.

**MISSOURI:** Richards Pharma owner Richard J. Taylor received an 18-month sentence and forfeited almost \$4 million after distributing imported, adulterated cancer medicines, including drugs damaged by poor temperature control.

**JUNE 2013**

**CALIFORNIA:** Oncologist Joel I. Bernstein received a year of probation and over \$2 million in fines and penalties for fraudulent billing and introducing a foreign drug into interstate commerce.

**TENNESSEE:** Dr. William Kincaid, the owner of McCleod Blood and Cancer Center, received a 2-year sentence and paid a \$2.6 million settlement for receiving imported Rituxan with intent to defraud. His plea agreement revealed a much larger scope of illegal importation. Kincaid's business manager, Michael Dean Combs, received 3 years and a \$4,000 fine in September 2012.

**JANUARY 2013:**

**FLORIDA:** Canadian pharmacist Andrew Strempler received a 4-year sentence and a \$25,000 fine and forfeited \$300,000 after misrepresenting the source of medicines—some of them counterfeit—to customers.

**AUGUST 2012:**

**CALIFORNIA:** Ban Dune Marketing owner James Newcomb received a 2-year sentence and forfeited \$1.4 million for distributing imported cancer medications that were adulterated as a result of poor storage and shipping.

**MAY 2012**

**MISSOURI:** Dr. Abid Nisar received 2 years probation, 200 hours of community service and owed more than \$1 million in restitution for receiving and distributing a foreign version of Rituxan imported through Ban Dune Marketing.

**JULY 2011**

**MARYLAND:** Dr. Isabella Martire pleaded guilty to introducing a misbranded drug into interstate commerce after purchasing nearly \$200,000 of misbranded drugs and treating patients with them.

**AUGUST 2010**

**ARIZONA:** Canadian Hazim Gaber received a 33-month sentence and owed \$150,000 in fines and restitution after selling a counterfeit version of an unapproved cancer drug to at least 65 U.S. patients.

**SEPTEMBER 2009**

**CALIFORNIA:** Vinod Chandrashekm Patwardhan, MD received 5 years probation, 9 months of house detention, 1,000 hours of community service and owed more than \$1.3 million in fines and restitution after importing unapproved oncology drugs and fraudulently billing government healthcare programs.

**JANUARY 2009**

**TEXAS:** Kevin Xu received a 78-month sentence for trafficking in misbranded and counterfeit pharmaceuticals, including medicines that treated prostate cancer. Xu realized \$1.5 million in profits in 2007 alone.

**DOCTORS WHO HAVE PAID TO SETTLE ALLEGATIONS THAT THEY IMPROPERLY BILLED MEDICARE FOR ILLEGALLY IMPORTED CHEMOTHERAPY DRUGS:**

**TENNESSEE:** Dr. Anindya Sen, \$1.2 million (*June 2017*)

**NEW JERSEY:** Dr. Kenneth D. Nahum, pay \$1.7 million (*February 2017*)

**IOWA:** Hematology and Oncology Center of Iowa, P.C. and Dr. Magdy Elsayy, \$176,000 (*November 2016*)

**CALIFORNIA:** Dr. John F. Kiraly, \$300,000 (*May 2016*); Dr. Neelesh Bangalore, \$736,000 (*July 2015*); Dr. Prabhjit S. Purewal, \$550,000 (*February 2014*)

## HOW CAN PATIENTS AND MEDICAL PRACTICES PROTECT THEMSELVES?



**HEALTHCARE PROVIDERS** can be prosecuted for buying drugs from unlicensed sellers. Patient medications should only be purchased from wholesale drug distributors licensed in the United States.

The FDA keeps a list of verification sites by state:

<http://safedr.org/fdalicense>.

In addition to sourcing medicines safely, health care professionals can spot therapeutic failure and teach patients how to buy medications from safe sources. Learn more about protecting patients at [http://safedr.org/healthcare\\_pros](http://safedr.org/healthcare_pros).



**PATIENTS** treated in medical offices should ask to see medication packaging. Check the packaging for accurate labeling, package condition, and labeling in English. When in doubt, ask your doctor for the name of the medicine distributor. All legitimate wholesalers are licensed by your state and can be verified online.

Use <http://safedr.org/fdalicense> to find your state licensing agency.