



SIGNIFICANT CASES INVOLVING BLACK MARKET CANCER DRUGS

AUGUST 2013

Ohio (ZOMETA, KYTRIL, TAXOTERE, GEMZAR, ELOXATIN AND OTHERS): 7 oncologists indicted for allegedly importing non-FDA approved cancer medications.

Virginia (ALIMTA, ANZEMET, ELOXATIN, FASLODEX, GEMZAR, HERCEPTIN, MABTHERA, VELCADE, XEOMIN, ZOMETA): 11 people indicted on 17 charges related to their association with Gallant Pharma International, which is alleged to have conducted an \$8.6 million prescription drug importation scheme.

JUNE 2013

Tennessee (ALIMTA, ALOXI, ALTUZAN, BONVIVA, ERBITUX, HERCEPTIN, HYCAMTIN, MABTHERA, NEUPOGEN, VELCADE, VENOFEER, ZOMETA): Dr. Anindya Kumar Sen and Patricia Posey Sen indicted on 37 charges related to the introduction of misbranded and unapproved drugs into interstate commerce and Medicaid fraud.

APRIL 2013

Montana (AVASTIN): Paul Daniel Bottomley pleaded guilty to concealing the importation of non-FDA approved drugs. Sentenced in July 2013 to 5 years of probation, 200 hours of community service and \$4.4 million in restitution. His company, Montana Healthcare Solutions, was a source of counterfeit Avastin in February 2012.

JANUARY 2013

California (RITUXAN): Oncologist Joel I. Bernstein charged with introducing a foreign drug containing Rituxan into interstate commerce and a related count of fraudulent billing. Pleaded guilty in June 2013. Sentenced to 1 year of probation and over \$2 million in fines and penalties.

NOVEMBER 2012:

Missouri (AVASTIN, NEUPOGEN): Richard J. Taylor charged with distributing imported, adulterated cancer medicines, including drugs damaged by poor temperature control. After pleading guilty, he was sentenced to serve 18 months and forfeit almost \$4 million in July 2013.

Tennessee (ABRAXANE, ALIMTA, AVASTIN, GEMZAR, HERCEPTIN, RITUXAN, TAXOTERE, ZOMETA): Dr. William Kincaid, the owner of McCleod Blood and Cancer Center, charged with receiving imported Rituxan with intent to defraud. His plea agreement revealed a much larger scope of illegal importation. Sentenced in June 2013 to serve 2 years and pay \$2.6 million in settlement of civil claims.

SEPTEMBER 2012

Tennessee (ABRAXANE, ALIMTA, AVASTIN, GEMZAR, HERCEPTIN, RITUXAN, TAXOTERE, ZOMETA): Michael Dean Combs, the business manager of McCleod Blood and Cancer Center, indicted for receiving a misbranded drug. Sentenced to 3 years probation and a \$4,000 fine after pleading guilty in April 2013.

Florida (GEMZA, TAXOTERE, ELOXATIN, ZOMETA AND KYTRIL): Martin Paul Bean, III, the proprietor of GlobalRxStore, indicted for 35 counts related to the sale of over \$7 million in unapproved foreign oncology drugs to American medical practices between 2005 and 2011. Pleaded guilty in February 2013. Sentenced to serve 2 years, forfeited personal property and \$19,270 in restitution.

APRIL 2012

California (GEMZAR): Maher Idriss, the owner of a licensed pharmacy wholesaler, Oberlin Medical Supply, charged with and pleaded guilty to storing and shipping foreign prescription cancer drugs in conspiracy with Martin Paul Bean, III. Sentenced to 3 years supervised release with 8 months home detention and a \$2,000 fine.



BLACK MARKET CANCER DRUGS (cont.)

JANUARY 2012

California (ALTUZAN, HERCEPTIN, MABTHERA, NEUPOGEN): James Newcomb, the owner of Ban Dune Marketing, charged with conspiring to distribute imported cancer medications that were adulterated as a result of poor storage and shipping. Pleaded guilty in February 2012. Sentenced to serve 2 years and forfeit \$1.4 million in August 2012.

Missouri (HERCEPTIN, MABTHERA, NEUPOGEN): Dr. Abid Nisar indicted for receiving and distributing a foreign version of Rituxan imported from the United Kingdom through Ban Dune Marketing. The plea agreement states that Nisar purchased a large quantity of discount foreign drugs in 2010 and submitted false insurance claims for his purchases. Sentenced to 2 years probation, 200 hours of community service and more than \$1 million in restitution.

JULY 2011:

Utah (ZOMETA, GEMZAR, ARANESP): Michael Lawrence O'Donnell indicted on 24 counts related to distributing diverted, non-FDA approved drugs, including Botox, Zometa, Gemzar and Aranesp, without a license. Pleaded guilty to 1 count of shipping Botox to a New York practice. Sentenced in August 2013 to serve a year in federal prison.

Maryland: Dr. Isabella Martire charged with introducing a misbranded drug into interstate commerce. Martire's plea agreement, filed in August 2011, states that she purchased nearly \$200,000 of misbranded drugs and treated patients with them.

JUNE 2011

Florida (ARIMIDEX): Canadian pharmacist Andrew Strempler indicted on 3 counts of mail and wire fraud to misrepresent the source of medicines to customers ordering medicine from RXNorth. Sentenced in January 2013 to serve 4 years, forfeit \$300,000 and pay a fine of \$25,000 for 1 charge of conspiracy to commit mail fraud.

DECEMBER 2010

California (SUPPLEMENTS THAT CONTAINED NIMESULIDE): Kurt Donsbach, who practiced medicine without a license, pleaded guilty to 13 felony charges, including selling misbranded drugs to cancer patients while misrepresenting them as "natural" remedies. Sentenced to a year in jail and 10 years probation in April 2011.

JUNE 2009

Arizona (SODIUM DICHOROACETATE): Canadian Hazim Gaber indicted on 5 counts of wire fraud for selling a counterfeit version of an unapproved cancer drug to at least 65 victims in the United States. Sentenced in August 2010 to 33 months and \$150,000 in fines and restitution.

FEBRUARY 2009

California (INDIAN AND HONDURAN DRUGS LISTED IN THE INDICTMENT: DAXOTEL, DOCEMIL, DOCETAX, EMOTRON, ESPOGEN, FARMORUBICINA, GRAFEEL, GRASTIM, IRNOZEN, OXIDACH): Vinod Chandrashekm Patwardhan, MD charged with 19 counts related to importing unapproved or misbranded oncology drugs and fraudulently billing government healthcare programs. Convicted in May 2009 of conspiracy, 2 counts of introducing misbranded drugs into interstate commerce with intent to defraud or mislead and 3 counts of smuggling. Sentenced to 5 years probation with 9 months of house detention, 1000 hours of community service and more than \$1.3 million in fines and restitution.

AUGUST 2007

Texas (CASODEX): Kevin Xu indicted on 9 counts of trafficking in misbranded and counterfeit pharmaceuticals, including medicines that treat prostate cancer, from which Xu realized \$1.5 million in profits in 2007 alone. Xu was sentenced to serve 78 months in federal prison after being convicted in July 2008.





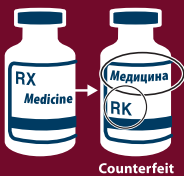
How can patients and medical practices protect their patients?



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.ug/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.ug/healthcare_pros.



Counterfeit

PATIENTS receiving treatments in medical offices should ask their doctors to see the medication's packaging. **Examine the product packaging for accurate labeling, good condition of the package, and the language of the labeling.** All prescriptions approved for sale in the US should have product descriptions in English.

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