

Black Market Drugs in Virginia, 2011-2016

Since 2012, when the FDA discovered counterfeit Avastin in the United States' drug supply, it has warned 45 clinics in Virginia to stop buying black market drugs from unlicensed foreign distributors.

20 FDA warnings were for the purchase of non FDA-approved oncology drugs from Medical Device King, illegal Canadian distributor Gallant Pharmaceutical, or subsidiaries of online pharmacy giant Canada Drugs.com. Counterfeit Avastin that contained water and mold, but no active ingredient, was among the products that these companies sold to American medical practices. Betty Hunter, an American cancer patient who was treated with this counterfeit, had a reaction so severe that her nurse stopped her infusion. Hunter died in August 2011.¹

23 of those warnings involved customers of TC Medical, a company that pleaded guilty in May 2015 to smuggling orthopedic injections, rheumatology infusions, cosmetic devices (including counterfeit Botox), ophthalmology products, and oncology drugs sourced from India, Turkey, France, Italy, and other countries.²

Other Counterfeit Drug Incidents in Virginia

May 2015: SB Medical, Inc. and TC Medical Group mailed products to Virginia doctors while falsely claiming their products were FDA-approved, and often shipped medicines without the temperature controls to maintain their effectiveness and safety. At least one doctor notified the company that patients required emergency room treatment after she treated them with the questionable Botox SB Medical had sold her.

They smuggled non FDA-approved orthopedic injections, rheumatology infusions, cosmetic devices, ophthalmology products, and oncology drugs from India, Turkey, France, Italy, and other countries, and sold them to clinics in the

¹ Jeanne Whalen, "Turkish Drug Exporter Ozay Draws U.S. Scrutiny," *The Wall Street Journal*, April 7, 2014, <http://www.wsj.com/news/articles/SB10001424052702303546204579435692215579758>.

² "FDA Issues Letters to Doctors Who May Have Purchased Counterfeit or Unapproved Prescription Drugs" US Food and Drug Administration, <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm439169.htm>; "Canadian Companies Fined \$45 Million and Ordered to Forfeit an Additional \$30 Million for Smuggling Misbranded Pharmaceuticals into the United States," US Department of Justice, August 21, 2015, <https://www.justice.gov/usao-edva/pr/canadian-companies-fined-45-million-and-ordered-forfeit-additional-30-million-smuggling>.

United States. SB Medical, Inc., TC Medical Group and 5 individual conspirators pleaded guilty in May 2015.³

May 2014: 39 non FDA-approved medications for cancer, Crohn's disease, eczema, migraine, osteoarthritis, psoriasis, and other life-threatening conditions with questionable therapeutic value were sold by northern Virginia-based Gallant Pharmaceuticals to over 300 medical practices in 34 US states and DC. The medication came from unreliable sources, packaging missed vital 'black box' warnings, and temperature sensitive medications were not shipped safely. One cold chain drug took two weeks to get to the US during a heat-wave. At best, these drugs can be ineffective. At worst, patients develop reactions that compromise future treatment.

Trans-shippers in the UK and Canada broke large shipments of counterfeit medication from Turkey and India and other countries into small packages that would be overlooked by customs inspectors.

The medications were mailed to a drop shipper, Anoushirvan R. Sarraf, an MD who received hundreds of boxes of Gallant's products at his cosmetic clinic in McLean, Virginia. He passed along most of the medicines to Gallant, but kept deeply discounted black market cosmetic drugs, which he used on his patients without their knowledge.⁴

By May 2014, twelve individuals—executives, sales representatives, administrative staff and others—had been convicted and sentenced in connection with the case.

December 2011: Fairfax County, Virginia police seized thousands of doses of counterfeit prescription medication from stores when residents were hospitalized

³ "Canadian Company and Drop Shipper Plead Guilty to Conspiracy to Smuggle and Sell Misbranded Prescription Pharmaceuticals," US Food and Drug Administration, May 7, 2015, <http://www.fda.gov/ICECI/CriminalInvestigations/ucm446226.htm> and Indictment, USA vs TC Medical Group et, al., Case 1:14-cr-00397-AJT, US District Court for the Eastern District of Virginia, filed December 3, 2014, http://www.safemedicines.org/wp-content/uploads/TC_Medical.pdf.

⁴ Indictment, USA vs Gallant Pharmaceutical, Inc, et, al., Case 1:13-cr-00130-CMH, US District Court for the Eastern District of Virginia, filed March 27, 2013, <http://www.safemedicines.org/wp-content/uploads/Gallant-Pharma-Indictment.pdf>; "Illegal Drug Company Gallant Pharma And Co-Founder Sentenced," US Department of Justice, May 9, 2014, <https://www.justice.gov/usao-edva/pr/illegal-drug-company-gallant-pharma-and-co-founder-sentenced>; "Owner Of McLean MedSpa Sentenced For Illegally Importing Non-FDA-Approved Drugs And Using On Patients," US Department of Justice, July 18, 2014, <https://www.justice.gov/usao-edva/pr/owner-mclean-medspa-sentenced-illegally-importing-non-fda-approved-drugs-and-using>.

after taking them. The drugs, which included painkillers, birth control pills, antibiotics and other drugs allegedly smuggled into the country from Central America.⁵

⁵ Natalie Lopez and Julie Carey, "Several Virginia Stores Raided in Counterfeit Prescriptions Investigation," 4 Washington, December 2, 2011, <http://www.nbcwashington.com/news/local/Several-Virginia-Stores-Raided-in-Counterfeit-Prescriptions-Investigation-134939968.html>.