

FDA News Release

Kentucky oncology practice and its manager plead guilty to purchasing and selling unapproved chemotherapy drugs

For Immediate Release

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Release

Hematology and Oncology Center (HOC) PLLC of Somerset, Kentucky has pleaded guilty to federal charges that the firm purchased and sold unapproved and improperly labeled chemotherapy drugs. HOC's former office manager, Natarajan Murugesan, also pleaded guilty to assisting with these activities, which are violations of the Federal Food, Drug, and Cosmetic Act. The charges were brought by the U.S. Attorney's Office for the Eastern District of Kentucky.

Agents from the FDA's Office of Criminal Investigations led this investigation with assistance from the U.S. Department of Health and Human Services' Office of Inspector General.

"The FDA commends the U.S. Attorney's Office, Eastern District of Kentucky, for pursuing these allegations and for helping protect U.S. consumers from potentially receiving counterfeit, ineffective, or contaminated medicines," said Philip Walsky, acting director of the FDA's Office of Criminal Investigations. "The FDA is committed to ensuring that consumers have access to high-quality drugs that are safe and effective."

The criminal charges relate to a civil settlement agreed to in January 2014 by HOC, Murugesan, and N Mullai, M.D. Dr. Mullai was not charged criminally. Under the earlier civil settlement, HOC, Murugesan, and Mullai agreed to pay \$2,000,000, plus interest, to resolve charges that they violated the False Claims Act. These charges included submitting false claims to the Medicare program for misbranded, unapproved chemotherapy drugs administered through HOC's Somerset, Kentucky, clinic.

HOC obtained substantial amounts of chemotherapy drugs and other cancer treatment drugs from a foreign drug distributor in Canada operating under the name Quality Specialty Products (QSP). These drugs were obtained from Turkey, India, the European Union, and other international locations. Often, the drugs arrived at HOC with labels and dosage instructions in foreign languages. In 2012, the FDA sent letters to medical practices, including HOC alerting them that the cancer medicines they purchased from QSP were unapproved and potentially counterfeit.

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- Local doctor pleads guilty in misbranding drugs case
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm402803.htm>
- July 12, 2013: **Paul Daniel Bottomley sentenced in U.S. District Court**
<http://www.fda.gov/iceci/criminalinvestigations/ucm360948.htm>
- June 11, 2013: **Johnson City physician sentenced for unapproved foreign drugs**
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Related Information

- January 13, 2012: FDA notifies health care providers about the risk of purchasing unapproved injectable cancer medications from unlicensed sources**
<http://www.fda.gov/downloads/drugs/drugsafety/drugintegrityandsupplychainsecurity/ucm287717.pdf>
- Letters to doctors about risks of purchasing medications from foreign or unlicensed suppliers**
<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm>
- July 12, 2012: Counterfeit version of Avastin in U.S. distribution**
<http://www.fda.gov/drugs/drugsafety/ucm291960.htm>

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