



Department of Justice

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JOHNSON CITY PHYSICIAN SENTENCED TO SERVE TWO YEARS IN PRISON FOR UNAPPROVED FOREIGN DRUGS

GREENEVILLE, Tenn. – William Ralph Kincaid, 68, of Johnson City, Tenn., was sentenced on June 10, 2013, by the Honorable J. Ronnie Greer, U.S. District Court Judge, to serve 24 months in federal prison.

Kincaid pleaded guilty in December 2012, to receiving misbranded drugs with intent to defraud or mislead in violation of the Food, Drug and Cosmetics Act. Kincaid faced a term of up to three years in prison and fines of up to \$250,000.

As set out in his plea agreement, Kincaid was a physician and managing partner for East Tennessee Hematology-Oncology Associates, P.C., doing business as McLeod Cancer and Blood Center, Johnson City, Tennessee (McLeod Cancer), a professional corporation providing care and treatment for patients with cancer and blood diseases. McLeod Cancer purchased large amounts of prescription drugs, to include chemotherapy drugs, which were administered through the clinic; McLeod Cancer then sought reimbursement through the Medicare and Medicaid/TennCare programs as well as other health benefits programs.

Beginning in 2007, McLeod Cancer began obtaining drugs from a Canadian business, Quality Specialty Products (QSP). The drugs had been obtained from foreign sources and had not been approved by the U.S. Food and Drug Administration (FDA) for distribution or use in the United States. The FDA has responsibility for enforcing the Food, Drug and Cosmetics Act to ensure the health and safety of the American public. The safety and efficacy of drugs is protected by requiring that any manufacturer or distributor of drugs in the United States be registered with and approved by the FDA. Drugs with labeling in a language other than English or from foreign sources not registered with the FDA are considered “misbranded.” Further, the FDA regulates the distribution of drugs to ensure they are handled properly so as not to lose their efficacy (such as becoming too hot or cold).

After nurses at McLeod Cancer raised concerns in late 2007 and early 2008 about chemotherapy drugs with foreign labeling, the clinic stopped ordering drugs from QSP. However, in August 2009, Kincaid and Michael Combs, McLeod Cancer’s business manager, met with a QSP representative and began ordering misbranded unapproved drugs. Dr. Kincaid directed Combs to have the drugs shipped to a storage business in Johnson City which Dr. Kincaid owned in part. The drugs, after having been received at the storage business, were transported to Combs' office at McLeod Cancer and then placed by a pharmacy technician into the clinic's drug storage and control system where the misbranded drugs were mingled with FDA-approved drugs from legitimate sources. FDA-approved drugs obtained from legitimate

U.S. drug manufacturers and distributors were still shipped directly to McLeod Cancer and not to the storage business.

McLeod Cancer obtained misbranded unapproved drugs, to include the drugs ABRAXANE®, ALIMTA®, AVASTIN®, ELOXATIN®, GEMZAR®, HERCEPTIN®, RITUXAN®/MABTHERA®, TAXOTERE®, and ZOMETA®, from approximately September 2007 to early 2008 and from August 2009 to February 2012, purchasing over \$2 million in misbranded unapproved drugs, providing those drugs to their patients, and billing Medicare, TennCare, and other government health benefits programs approximately \$2.3 million for the unapproved drugs.

In imposing sentence, Judge Greer stated “it was about greed” and the “motivation was to make more money.” Judge Greer acknowledged that while it was impossible to know which patients had received the unapproved drugs, the “emotional harm” to patients from not knowing whether they had received unapproved drugs contributed to the seriousness of the offense.

Kincaid, through his attorney, advised Judge Greer that he had entered into an agreement with the United States and the State of Tennessee to pay \$2.55 million in settlement of civil claims under the False Claims Act for false and fraudulent claims for reimbursement submitted to the Medicare and TennCare programs for unapproved drugs. Kincaid also made an initial payment of \$500,000 pursuant to the settlement agreement.

Judge Greer allowed Kincaid to remain on bond pending designation of an institution for service of sentence by the U.S. Bureau of Prisons.

“This conviction sends a message to all medical providers and practitioners that federal criminal penalties await those who distribute misbranded and potentially unsafe drugs, especially those used in cancer treatment. The FDA's regulatory system is designed to protect patients from substances such as these.” said U.S. Attorney William C. Killian.

“The FDA's Office of Criminal Investigations is committed to protecting the public health by aggressively pursuing unscrupulous medical practitioners who jeopardize their patients' safety with unapproved medications,” said John Roth, Director of FDA's Office of Criminal Investigations. “The FDA applauds the hard work of the U.S. Attorney's Office, the Federal Bureau of Investigation, and the Tennessee Bureau of Investigation in bringing about this successful result.”

Agencies involved in this investigation included Food & Drug Administration Office of Criminal Investigation, Federal Bureau of Investigation, and Tennessee Bureau of Investigation. Assistant U.S. Attorney Neil Smith represented the United States.

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