UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	**Case No. 2:12-CR-116**
v.	)	
WILLIAM RALPH KINCAID,	)	
Defendant.	)	

INFORMATION

The United States Attorney charges:

At all times relevant to this Information:

1. East Tennessee Hematology-Oncology Associates, P.C., doing business as McLeod Cancer and Blood Center, Johnson City, Tennessee (hereinafter "McLeod Cancer"), was a professional corporation providing care and treatment for patients with cancer and blood diseases.

2. William R. Kincaid, M.D., a medical doctor licensed to practice medicine in the State of Tennessee, was president, majority owner, and managing partner of McLeod Cancer.

3. Millard Ray Lamb, M.D., a medical doctor licensed to practice medicine in the State of Tennessee, was a part owner of and practiced medicine in McLeod Cancer.

4. Charles Olugbenga Famoyin, M.D., a medical doctor licensed to practice medicine in the State of Tennessee, was a part owner and practiced medicine in McLeod Cancer.

5. Michael Dean Combs was employed as business manager for McLeod Cancer.

6. As part of the treatment of patients for cancer and other diseases, McLeod Cancer

purchased large amounts of assorted prescription drugs, to include chemotherapy drugs, which were prescribed by Drs. Kincaid, Lamb, and Famoyin and were administered and dispensed through McLeod Cancer. Reimbursement for the drugs and their administration was sought from the Medicare and Medicaid (TennCare) programs, as well as other health benefits programs.

7. Quality Specialty Products (QSP) was a business in Winnipeg, Canada, offering for sale to physicians and other health care providers in the United States drugs which had been obtained from foreign sources and which had not been approved by the U.S. Food and Drug Administration for distribution or use in the United States. QSP later did business jointly with a business called Montana Healthcare Solutions, Inc.(MHS), Belgrade, Montana.

The U.S. Food and Drug Administration

8. The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq.* ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce and foreign commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforced statutes which required that drugs bore labels and labeling that enabled health care providers and consumers to use them in a safe manner and that drugs were listed by and manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. 21 U.S.C. §§ 352(f), 352(o) and 360(c).

9. Under the FDCA, anyone manufacturing, preparing, compounding, or processing prescription drugs for sale and use in the United States must annually register with the FDA as a

drug establishment and provide a list to FDA of the drugs which are being manufactured for commercial distribution. 21 U.S.C. §§ 360(a)(1), 360(b), 360(i) and 360(j). The FDCA's registration requirement applies to both businesses located within the United States and drug establishments outside of the United States that import their drugs into the United States. 21 U.S.C. §§ 360(b), 360(i). Any drug establishment, located within or outside of the United States, may be inspected by FDA or officials of foreign governments that act cooperatively with FDA. 21 U.S.C. §§ 360(h), 360(i)(3).

Prescription Drugs

10. Under the FDCA, drugs included: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, articles intended to affect the structure or any function of the body of man, and "biological products" applicable to the prevention, treatment, or cure of a disease or condition of human beings. 21 U.S.C. § 321(g)(1)(B) and (c); 42 U.S.C.§ 262(i).

11. Under the FDCA, a drug was deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug was also deemed to be a prescription drug if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355.

12. The drugs listed below, using the names under which the drugs are marketed in the United States, are used primarily to treat individuals with cancer, and are often "infused" into cancer patients intravenously, meaning the purity and efficacy of these prescription drugs is very

important for patients. All of these drugs were "prescription drugs" pursuant to 21 U.S.C. § 353(b)(l) because of their toxicity or other potentiality for harmful effect, and could lawfully be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs:

ABRAXANE® (Paclitaxel Injection)

ALIMTA® (Pemetrexed Injection)

AVASTIN® (Bevacizumab Injection)

ELOXATIN® (Oxaliplatin Injection)

GEMZAR® (Gemcitabine Hydrochloride)

HERCEPTIN® (Trastuzumab Injection)

RITUXAN® (Rituximab Injection)

TAXOTERE® (Docetaxel Injection)

ZOMETA® (Zoledronic Acid Injection)

Misbranding

13. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug is misbranded under the FDCA unless the labeling bore adequate directions for use. 21 U.S.C. § 352(f). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R.§ 201.5. All words, statements, and other information required to appear on drug labeling by the FDCA must be in the English language, unless the drug is solely distributed in Puerto Rico or a United States territory. 21 C.F.R. § 201.15(c)(l). A drug is also "misbranded" if it was manufactured, prepared, propagated, compounded, and processed in any establishment in any state not duly registered with FDA. 21 U.S.C. § 352(o). Finally, any drug is misbranded if it came from a domestic or foreign drug establishment and that drug was not

annually listed with the FDA by the establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment. 21 U.S.C. §§ 352(o), 360(j).

Reimbursement for Cancer Drugs

14. Medicare Part B currently covers a limited number of outpatient prescription drugs and biologicals (collectively referred to as drugs). Those that are covered include injectable drugs administered by a physician; certain self-administered drugs, such as oral anti-cancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

15. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 established a new methodology for Medicare Part B reimbursement of most covered drugs. Effective January 1, 2005, reimbursement to physician practices for drugs is generally set at 106 percent of the average sales price (ASP). The ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that quarter. The ASP is net of any price concessions and excludes certain sales, including those at a nominal charge.

16. The Medicare program, along with other government health benefits programs (to include TennCare, Tennessee's Medicaid program, and the Federal Employees Health Benefits Plan) provide reimbursement only for FDA-approved drugs, and a physician or health care provider submitting a claim for reimbursement for a covered drug represents that the drug administered or dispensed was an FDA-approved drug.

17. The U.S. Department of Health and Human Services Office of Inspector General

reported to Congress in 2005 that physician practices in the specialties of hematology, hematology/oncology, and medical oncology could generally purchase drugs from FDA-approved sources for the treatment of cancer patients at less than the established reimbursement rates. Further, FDA reported that there were no shortages within the United States of the above-listed drugs during the period 2007-2012.

Misbranded Drugs At McLeod Cancer and Blood Center

18. In September 2007, Dr. Lamb received a fax mailer from QSP which offered for sale certain prescription drugs, including chemotherapy drugs, along with price information for the drugs, the prices being less than what McLeod Cancer had been paying to purchase the drugs from FDA-approved sources in the United States. A decision was made by Drs. Kincaid, Lamb, and Famoyin to have Combs begin ordering drugs from QSP, and QSP began shipping misbranded unapproved drugs to McLeod Cancer, to include the drugs listed above, where the drugs were administered to patients and claims for reimbursement were submitted to Medicare, TennCare, and other health benefits programs.

19. The drugs provided by QSP to McLeod Cancer were drugs from foreign sources that were not inspected and approved by the FDA, to include drugs which had been distributed in Turkey, India, the European Union, and elsewhere.

20. In late 2007 and early 2008, nurses at McLeod Cancer observed that packaging for chemotherapy drugs which were being obtained by McLeod Cancer from QSP bore labeling in foreign languages, establishing that the drugs were not approved for use in the United States. After the nurses raised their concerns with Drs. Kincaid, Lamb and Famoyin and with Combs, the decision was made to stop ordering drugs from QSP.

21. In approximately August 2009, Dr. Kincaid and Combs were re-contacted by QSP. A meeting was held with a QSP representative, Dr. Kincaid, Combs and a fourth person at a Johnson City, Tennessee restaurant where Dr. Kincaid decided McLeod Cancer would resume purchasing misbranded unapproved drugs from QSP.

22. To prevent the nurses from learning that McLeod Cancer was again purchasing unapproved foreign 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 by Combs and others to Combs' office at McLeod Cancer and then placed by a pharmacy technician into the clinic's drug storage and control system. FDA-approved drugs obtained from legitimate U.S. drug manufacturers and distributors were still shipped directly to McLeod Cancer.

23. McLeod Cancer obtained misbranded unapproved drugs, to include the drugs listed above, from QSP and MHS from approximately September 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 $2.5 million for the unapproved drugs.

24. The labeling for the prescription drugs purchased by McLeod Cancer from QSP and MHS was different than the versions of these drugs that had been approved for sale in the United States by the FDA. For example, some of the labeling for some of the drugs from QSP/MHS was in foreign languages. Other drugs' labeling did not provide dosage information or express the potency of the drugs in a standard format. 21 C.F.R. §§ 201.56, 610.6l(n), (r). None of the drugs purchased by McLeod Cancer came from registered drug establishments, were annually listed as

drugs being produced at registered drug establishments, or contained National Drug Codes.

25. All of the prescription drug Rituximab (marketed in the United States as Rituxan®) ordered by McLeod Cancer and provided by QSP/MHS was labeled "MabThera®." The labeling for the Rituximab obtained by McLeod Cancer says that the drug came from an unregistered drug establishment located in Switzerland that did not provide FDA with an annual list of any drugs manufactured there and was distributed after manufacturing by another company located in New Delhi, India. By contrast, the FDA-approved version of Rituximab that is made for legal use in the United States is labeled "Rituxan®." Rituxan® is manufactured in a registered drug establishment in Vacaville, California. This drug establishment annually lists the drug Rituxan® with the FDA as a drug that it is manufacturing at that facility. The FDA can also routinely inspect that California-based drug establishment.

26. Further, Rituximab (to include both Rituxan® and MabThera®) is a drug which must be "cold chained," that is, a prescription drug that requires a uniform cold temperature during shipment. The U.S. labeling for this drug requires storage of the drug in a refrigerator at 2° to 8°C (36° to 46°F), and cautions that the drug should not be frozen or shaken. Failure to properly ship and store the drug can render it ineffective.

COUNT ONE

27. Paragraphs 1 through 26 of the General Allegations section of this Information are re-alleged and incorporated by reference as though fully set forth herein.

28. On or about November 7, 2011, in the Eastern District of Tennessee and elsewhere, the defendant, WILLIAM RALPH KINCAID, aided and abetted by and aiding and abetting others, with the intent to defraud and mislead, received in interstate commerce and

delivered for pay and otherwise a quantity of the prescription drug marketed in the United States as Rituxan®, 100 milligram/10 milliliter strength, imported from the United Kingdom to Johnson City, Tennessee, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act in that:

(a) the drug's labeling failed to bear adequate directions for use, 21 U.S.C. § 352(f)(l); 21 C.F.R. § 201.5, and;

(b) the drug came from a foreign drug establishment located in Switzerland and that drug was not annually listed with the FDA by that establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment.

All in violation of 21 U.S.C. §§ 33l(c), 333(a)(2), 352(f)(l), 352(o), 360(j) and 18 U.S.C. § 2.

APPROVED:

WILLIAM C. KILLIAN
UNITED STATES ATTORNEY

By: _____
M. NEIL SMITH
ASSISTANT UNITED STATES ATTORNEY