UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

UNITED STATES OF AMERICA,	)	
	:	
Plaintiff,	)	
	:	
v.	)	**Case No. 2:13-CR-56**
	:	Judge Greer
ANINDYA KUMAR SEN,	)	
PATRICIA POSEY SEN, and	:	
EAST TENNESSEE CANCER AND	)	
BLOOD CENTER, P.C.,	:	
Defendants.	)	

INDICTMENT

The Grand Jury charges:

At all times material herein:

General Allegations

A. Introduction and Background

1. East Tennessee Cancer & Blood Center, P.C., (hereinafter "ETCBC"), was a professional corporation with locations in Greeneville and Johnson City, Tennessee providing care and treatment for patients with cancer and blood diseases.

2. Anindya Kumar Sen, M.D., a medical doctor licensed to practice medicine in the State of Tennessee, was president, owner, and managing physician of ETCBC.

3. Patricia Posey Sen, wife of Dr. Sen, was employed as practice manager for ETCBC.

4. As part of the treatment of patients for cancer and other diseases, ETCBC purchased large amounts of assorted prescription drugs, to include chemotherapy drugs, which were prescribed by Dr. Sen and were administered and dispensed through ETCBC. Reimbursement for

the drugs and their administration was sought from the Medicare and Medicaid (TennCare) programs, as well as other health benefits programs.

5. Clinical Care was a business in Calgary, Alberta, 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.

The U.S. Food and Drug Administration

6. The United States Food and Drug Administration ("FDA") is 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 enforces statutes which require that drugs bear labels and labeling that enable health care providers and consumers to use them in a safe manner and that the drugs are 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).

7. 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

8. Under the FDCA, drugs include: 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).

9. Under the FDCA, a drug is deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it is not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug is also deemed to be a prescription drug if a new drug application approved by the FDA limits 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.

10. 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 are "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)

ALOXI ® (Palonosetron Injection)

AVASTIN® (Bevacizumab Injection)

BONIVA ® (Ibandronate)

ELOXATIN® (Oxaliplatin Injection)

EPREX ® (Erythropoietin/Epoetin Alfa)

ERBITUX ® (Cetuximab Injection)

FASLODEX ® (Fulvestrant Injection)

GEMZAR® (Gemcitabine Hydrochloride)

HERCEPTIN® (Trastuzumab Injection)

HYCAMTIN ® (Topotecan Injection)

NEULASTA ® (Pegfilgrastim Injection)

NEUPOGEN ® (Filgrastim Injection)

RECLAST ® (Zoledronic Acid Injection)

RITUXAN® (Rituximab Injection)

TAXOTERE® (Docetaxel Injection)

VELCADE ® (Bortezomib)

VENOFER ® (Iron Sucrose)

ZOMETA® (Zoledronic Acid Injection)

Misbranding

11. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug is "misbranded" under the FDCA unless the labeling bears 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 "misbranded" if the label fails to bear the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A); 21 C.F.R. § 201.100(b)(1). 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

12. The Medicare program is a federal health care program providing benefits to persons who are over the age of 65 or disabled. Medicare is administered by the Centers for Medicare and Medicaid Services (CMS), a federal agency under the United State Department of Health and Human Services. Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries." The Medicare program includes coverage for health care services and treatment under two primary components, hospital insurance (Part A) and medical insurance (Part B). Enrollment of providers, processing of claims for reimbursement, and payment of claims to health care providers are handled by Medicare Administration Contractors (MACs), private insurance companies contracted by CMS to operate the Medicare program. Claims are paid from Federal funds.

13. TennCare is the State of Tennessee's Medicaid health care benefit program for the indigent. Services to TennCare recipients are provided through managed care organizations ("MCOs"), private insurance companies that receive payment from the State of Tennessee from state and Federal funds to provide health care services. Blue Cross-Blue Shield of Tennessee and United Healthcare operate the MCOs providing health care benefits to TennCare recipients in eastern Tennessee. While MCOs enter into their own contracts with providers and set their own fee schedules, the MCOs do so under the terms of the contracts with TennCare and other Federal and state laws, regulations, and policies.

14. Medicare and TennCare are "health care benefit program(s)," as defined by Title 18, United States Code, Section 24(b).

15. 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. For chemotherapy drugs, physicians are also reimbursed for the cost of "infusing," that is, administering the drugs. Coverage for such drugs and the infusion of the drugs is also provided by TennCare through the MCOs.

16. 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.

17. The Medicare program, along with TennCare and other government and private health benefits programs, 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.

Misbranded Drugs At East Tennessee Cancer and Blood Center

18. In April 2009, the defendants began ordering drugs from Clinical Care, and Clinical Care began shipping misbranded unapproved drugs to ETCBC, to include the drugs listed above, where the drugs were administered to patients and claims for reimbursement for the drugs were submitted to Medicare, TennCare, and other health benefits programs.

19. The drugs provided by Clinical Care to ETCBC 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. Many of the drugs were shipped directly to Dr. Sen at ETCBC from locations outside the United States, to include the United Kingdom. Packaging and documents shipped with the drugs showed that the drugs were foreign drugs being shipped from foreign countries.

20. When nurses and other staff raised concerns that packaging for chemotherapy drugs which were being obtained by ETCBC from Clinical Care bore labeling in foreign languages, establishing that the drugs were not approved for use in the United States, defendant Patricia Posey Sen told the staff that there were no problems with the drugs, or words to that effect.

21. ETCBC obtained misbranded unapproved drugs, to include the drugs listed above, from Clinical Care from approximately April 2009 to March 2012, purchasing over $3 million in

misbranded unapproved drugs, providing those drugs to their patients, and billing Medicare, TennCare, and other government and private health benefits programs approximately $3.2 million for the unapproved drugs.

22. The labeling for the prescription drugs purchased by ETCBC from Clinical Care 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 Clinical Care 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, 610.61(n), (r). The drugs' labeling did not bear the symbol "Rx only" required for drugs being distributed in the United States. 21 U.S.C. § 353(b)(4)(A); 21 C.F.R. § 201.100(b)(1). None of the drugs purchased by ETCBC came from registered drug establishments, were annually listed as drugs being produced at registered drug establishments, or contained National Drug Codes.

23. All of the prescription drug Rituximab (marketed in the United States as Rituxan®) ordered by ETCBC and provided by Clinical Care was labeled "MabThera®." The labeling for the Rituximab obtained by ETCBC said 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 manufactured at that facility. The FDA can also routinely inspect that California-based drug establishment.

24. ETCBC received the prescription drug Bevacizumab from Clinical Care labeled as "Altuzan®." Altuzan® is a drug manufactured by 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 Turkey. By contrast, the FDA-approved version of Bevacizumab that is made for legal use in the United States is labeled "Avastin®." Avastin® is manufactured in a registered drug establishment in California. This drug establishment annually lists the drug Avastin® with the FDA as a drug that it is manufactured at that facility. The FDA can also routinely inspect that California-based drug establishment.

25. Further, some of the drugs which ETCBC ordered from Clinical Care, to include Rituximab (both Rituxan® and MabThera®), were drugs which must be "cold chained," that is, prescription drugs that require a uniform cold temperature during shipment. The U.S. labeling for Rituxan® 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

1. Paragraphs 1 through 25 of the General Allegations section of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

The Conspiracy and Its Objects

2. From in or around April 2009, and continuing to in or around March 2012, in the Eastern District of Tennessee and elsewhere, the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C.,

knowingly and willfully conspired and agreed with other persons known and unknown to the grand jury, to commit offenses against the United States, to wit:

(a) with the intent to defraud and mislead, causing the introduction into interstate commerce of drugs that were misbranded within the meaning of the Food, Drug, and Cosmetic Act in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) and the misbranding provisions described in counts 2 through 30.

(b) fraudulently and knowingly importing and bringing into the United States merchandise contrary to law in violation of 18 U.S.C. § 545.

Manner and Means of the Conspiracy

3. The defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., received and caused to be received drugs which had been unlawfully imported and distributed in the United States, the drugs not having been approved for importation and distribution in the United States and misbranded within the meaning of the Food, Drug, and Cosmetic Act.

4. The defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., delivered and caused the unapproved and misbranded drugs to be delivered to patients at ETCBC.

5. The defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., and others did mislead and conceal from other staff and employees at ETCBC that unapproved drugs were being purchased by the clinic and administered to patients.

6. The defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., caused to be submitted to Medicare,

TennCare, and other health care benefit programs claims for unapproved drugs which were not properly reimbursable.

Overt Acts

In furtherance of the conspiracy and to effect the objects of the conspiracy, the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., and others known and unknown committed or caused to be committed the following overt acts, among others, in the Eastern District of Tennessee and elsewhere:

1. On or about the dates listed below in Counts 2 through 30 below, the defendants caused the introduction into interstate commerce of the prescription drugs described below that were misbranded within the meaning of the Food, Drug, and Cosmetic Act.

2. On or about the dates listed below in Counts 31 through 37, the defendants imported and brought into the United States and cause to be imported and brought into the United States the prescription drugs as described below contrary to law.

All in violation of Title 18, United States Code, Section 371.

COUNTS TWO THROUGH THIRTY

(Causing the Introduction into Interstate Commerce of Misbranded Drugs)

1. Paragraphs 1 through 25 of the General Allegations section of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

2. On or about the dates listed below, in the Eastern District of Tennessee and elsewhere, the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., aided and abetted by and aiding and abetting each other, with the intent to defraud and mislead, caused the introduction into interstate commerce of a

quantity of the prescription drugs described below that were 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 201.100;

(b) the drug's labeling failed to bear the symbol "Rx only," 21 U.S.C. § 353(b)(4)(A); 21 C.F.R. § 201.100(b)(1), and;

(b) the drug came from a foreign drug establishment 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. 21 U.S.C. §§ 352(o), 360(j).

Count	Drug	Date of Invoice	Date Received
Count 2	Aloxi® 0.25mg/5ml	January 6, 2011	January 11, 2011
Count 3	Aloxi® 0.25mg/5ml	April 14, 2011	April 25, 2011
Count 4	Aloxi® 0.25mg/5ml	June 2, 2011	June 7, 2011
Count 5	Aloxi® 0.25mg/5ml	September 8, 2011	September 9, 2011
Count 6	Altuzan® 100mg/4ml	March 10, 2011	March 14, 2011
Count 7	Altuzan® 100mg/4ml	April 7, 2011	April 8, 2011
Count 8	Altuzan® 400mg/16ml	April 7, 2011	April 8, 2011
Count 9	Altuzan® 400mg/16ml	June 9, 2011	June 14, 2011
Count 10	Altuzan® 100mg/4ml	August 11, 2011	August 16, 2011
Count 11	Altuzan® 400mg/16ml	August 11, 2011	August 16, 2011
Count 12	Avastin® 400mg/16ml	January 27, 2011	February 1, 2011
Count 13	Bonviva® 3mg/3ml	December 13, 2010	December 27, 2010

Count 14	Bonviva® 3mg/3ml	January 27, 2011	February 1, 2011
Count 15	Bonviva® 3mg/3ml	June 30, 2011	July 6, 2011
Count 16	Bonviva® 3mg/3ml	September 29, 2011	October 4, 2011
Count 17	Bonviva® 3mg/3ml	December 2, 2011	December 8, 2011
Count 18	Mabthera® 500mg/50ml	March 10, 2011	March 14, 2011
Count 19	Mabthera® 100mg/10ml	March 10, 2011	March 14, 2011
Count 20	Mabthera® 100mg/10ml	May 3, 2011	May 4, 2011
Count 21	Mabthera® 500mg/50ml	June 9, 2011	June 14, 2011
Count 22	Mabthera® 100mg/10ml	June 9, 2011	June 14, 2011
Count 23	Mabthera® 500mg/50ml	August 18, 2011	August 23, 2011
Count 24	Mabthera® 100mg/10ml	August 18, 2011	August 23, 2011
Count 25	Mabthera® 500mg/50ml	December 8, 2011	December 13, 2011
Count 26	Mabthera® 100mg/10ml	December 8, 2011	December 13, 2011
Count 27	Neupogen® 470mcg/0.5ml	January 17, 2011	January 18, 2011
Count 28	Neupogen® 470mcg/0.5ml	March 3, 2011	March 4, 2011
Count 29	Venofer® 100mg/5ml	April 28, 2011	May 12, 2011
Count 30	Venofer® 100mg/5ml	May 5, 2011	May 10, 2011

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 352(f)(l), 352(o), 360(j), 353(b)(4)(A), and 18 U.S.C. § 2.

COUNTS THIRTY-ONE THROUGH THIRTY-SEVEN

(Receiving Merchandise Imported Contrary To Law)

1. Paragraphs 1 through 25 of the General Allegations section of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

2. On or about the dates listed below, in the Eastern District of Tennessee, the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., aided and abetted by and aiding and abetting each other, did fraudulently and knowingly import and bring into the United States and cause to be imported and brought into the United States, merchandise, that is, prescription drugs, as described below, contrary to law, in that:

(a) the drugs were unapproved for introduction into interstate commerce in the United States, in violation of Title 21, United States Code, Sections 331(d) and 355; and

(b) the drugs were misbranded, in violation of Title 21, United States Code, Sections 331(a), 352(f), 352(o), 360(j), and 353(b)(4)(A);

and knowing the same to have been imported contrary to law:

Count	Date	Drugs
Count 31	October 12, 2011	Altuzan®, Erbitux®, and Herceptin®
Count 32	October 27, 2011	Aloxi®, Alimta®, Hycamtin®, Velcade®, and Zometa®
Count 33	November 1, 2011	Altuzan®, Erbitux®, Mabthera®, and Neupogen®
Count 34	January 10, 2012	Altuzan®, Erbitux®, Eprex®, and Neupogen®
Count 35	January 24, 2012	Altuzan®, Erbitux®, and Neulastim®
Count 36	February 7, 2012	Altuzan® and Erbitux®
Count 37	February 14, 2012	Altuzan®, Erbitux®, and Neupogen®

All in violation of Title 18, United States Code, Sections 545 and 2.

COUNT THIRTY-EIGHT

(Conspiracy To Commit Health Care Fraud)

1. Paragraphs 1 through 25 of the General Allegations of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

2. From in or around April 2009 and continuing through in or around March 2012, in the Eastern District of Tennessee and elsewhere, the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., and other co-conspirators known and unknown, did willfully and knowingly combine, conspire, confederate and agree with each other and others, known and unknown to the Grand Jury, to violate Title 18, United States Code, Section 1347, that is, to execute a scheme and artifice to defraud health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare, TennCare and other health care benefit programs, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, said health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services.

Purpose of the Conspiracy

3. It was a purpose of the conspiracy for the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., and others to unlawfully enrich themselves by, among other things, submitting false and fraudulent claims to Medicare, TennCare and other health care benefit programs.

Manner and Means

4. The manner and means by which the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., sought to accomplish the purpose of the conspiracy included, among others, the following:

(a) the defendants and others obtained drugs which had not been approved for importation and distribution in the United States;

(b) the defendants administered the drugs and caused the drugs to be administered to patients at ETCBC;

(c) the defendants caused to be submitted to Medicare, TennCare, and other health care benefit programs claims for reimbursement for the drugs, knowing the claims were not properly reimbursable, causing to be made false representations that the drugs provided were approved for distribution in the United States.

All in violation of Title 18, United States Code, Section 1349.

FORFEITURES

As a result of the commission of the felony offense charged in Count 38 of this Indictment, any property, real or personal, of the defendants, ANINDYA KUMAR SEN, PATRICIA POSEY SEN, and EAST TENNESSEE CANCER & BLOOD CENTER, P.C., which constitutes, or was derived from, proceeds the defendants obtained, directly or indirectly, as the result of such violations shall be forfeited to the United States.

In the event that any property, real or personal, involved in the offense described in Count 38 of this Indictment or any property traceable to such property, as a result of any act or omission of the defendant (1) cannot be located upon the exercise of due diligence; 2) has been transferred or sold to, or deposited with a third party; (3) has been placed beyond the jurisdiction of

the Court; (4) has been substantially diminished in value; or (5) has been commingled with other property which cannot be divided without difficulty, the defendants shall forfeit any other property of the defendant.

[18 U.S.C. § 982(a)(2)(B) and 21 U.S.C. § 853]

A TRUE BILL:

[redacted]

FOREPERSON

Approved:

WILLIAM C. KILLIAN
United States Attorney

By: _____
M. Neil Smith
Assistant United States Attorney

By: _____
Ben D. Cunningham
Special Assistant United States Attorney