UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

CASE NO. 8:15-CR 183T30AEP

D. ANDA NORBERGS

21 U.S.C. § 331(c)
21 U.S.C. § 333(a)(2)
18 U.S.C. § 1347
18 U.S.C. § 492 (forfeiture)
18 U.S.C. § 982 (forfeiture)
28 U.S.C. § 2461(c) (forfeiture)

INDICTMENT

The Grand Jury charges:

Introduction

At all times relevant to this Indictment:

A. Entities

East Lake Oncology

1. D. Anda Norbergs was a doctor licensed to practice medicine in the State of Florida. Norbergs was the head doctor, owner, and operator of East Lake Oncology ("ELO"), located in Palm Harbor, Florida, within the Middle District of Florida. ELO was a professional corporation providing care and treatment for patients with cancer and other medical conditions.

2. As part of the treatment of patients for cancer and other diseases, ELO purchased large amounts of assorted prescription drugs, to include chemotherapy drugs, which were prescribed by Norbergs and administered and

dispensed through ELO. Reimbursement for these drugs and their administration was sought from Medicare programs, as well as other health care benefit programs.

Foreign Distributors / Suppliers of Prescription Drugs

3. Quality Specialty Products ("QSP") was a business operating out of Winnipeg, Canada, selling drugs to physicians and other health care providers in the United States that 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.

4. In addition to QSP, Cancer Drugs Online (d/b/a QS Supplies), Paygo-Medicare Solutions, Warwick Healthcare Solutions, Richards Pharma, GP Larys Limited (d/b/a Global Supply), and Global Rx, among others, were foreign distributors selling drugs to physicians and other health care providers in the United States that had been obtained from foreign sources and had not been approved by the FDA for distribution or use in the United States.

The U.S. Food and Drug Administration

5. The FDA was the federal agency charged with protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act ("FDCA"). The FDA's responsibilities under the FDCA included regulating the manufacturing, 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. Among those responsibilities, the

FDA enforced the requirements that labels for drugs bear sufficient information to enable health care providers and consumers to use the drugs in a safe manner, and that drugs be listed by and manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services.

6. Under the FDCA, anyone who manufactured, prepared, compounded, or processed prescription drugs for sale and use in the United States was required to register on an annual basis with the FDA as a drug establishment, and provide a list to the FDA of the drugs that were being manufactured for commercial distribution. The FDCA's registration requirement applied to both businesses located within the United States and drug establishments outside of the United States that imported drugs into the United States. Any drug establishment, located within or outside of the United States, could be inspected by the FDA or officials of foreign governments that acted cooperatively with the FDA.

B. Prescription Drugs

7. The drugs listed below, using the names under which the drugs were marketed in the United States, were used primarily to treat individuals with cancer, and were often "infused" into cancer patients intravenously. The purity and efficacy of these prescription drugs were of the utmost importance for patients' care. All of the following drugs were "prescription drugs" because of their toxicity or other potentiality for harmful effect, and could lawfully be dispensed only by prescription of a practitioner licensed by law to administer such drugs:

ABRAXANE (Paclitaxel)
AVASTIN (Bevacizumab)
ELOXATIN (Oxaliplatin)
FOSLODEX (Fulvestrant)
GEMZAR (Gemcitabine)
HERCEPTIN (Trastuzumab)
NEULASTA (Pegfilgrastim)
NEUPOGEN (Filgrastim)
PROCRIT (Erythropoietin/Epoetin Alfa)
TREANDA (Bendamustine)
RITUXAN (Rituximab)
TAXOTERE (Docetaxel)
VELCADE (Bortezomib)
ZOMETA (Zoledronic Acid)

8. Under the FDCA, a drug was deemed to be misbranded if, among other things:

a. its labeling was false or misleading in any particular; or

b. if any word, statement, or other information required to appear on the label was not in the English language; or

c. its labeling failed to bear adequate directions for use; or

d. if it was manufactured, prepared, propagated, compounded, and processed in any establishment in any state not duly registered with the FDA; or

e. if it was a prescription drug, its labeling failed to bear the "Rx only" symbol.

9. Under the FDCA, "adequate directions for use" meant that the directions were sufficient that a layman could safely use the drug and for the purposes for which it was intended. Foreign drugs frequently had different labeling (including different warnings, dosage recommendations, and indications for use) than FDA-approved versions, rendering them misbranded under the FDCA, even if the particular foreign drug bore the same brand name as the FDA-approved drug.

10. The drugs Ribomustin, Neulastim, Eprex, and MabThera were foreign versions of Treanda, Neulasta, Procrit, and Rituxan, respectively, and none had been approved by the FDA for use or distribution in the United States.

C. Medicare & Reimbursement for Cancer Drugs

11. The Medicare Program ("Medicare") was a federal "health care benefit program," as defined by Title 18, United States Code, Section 24(b), which provided medical benefits, items, and services to persons who are 65 and older, or who had certain disabilities. The Medicare program was administered by the Centers for Medicare and Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services. Individuals who received benefits under Medicare were referred to as Medicare "beneficiaries." The Medicare program included multiple components, including hospital insurance (Part A) and medical insurance (Part B).

12. The Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") of 2003 established a new methodology for Medicare Part B reimbursement for most covered drugs. Effective January 1, 2005, reimbursement for drugs was generally set at 106 percent of the average sales price ("ASP"). The ASP was a manufacturer's total sales in dollars 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.

13. The Medicare program only provided reimbursement for FDA-approved drugs that are considered safe and effective, and otherwise

reasonable and necessary. Accordingly, a physician submitting a claim for reimbursement for a covered drug represented that, among other things, the drug was FDA-approved.

14. For Medicare to ensure that claims for reimbursement from health care providers were processed in an orderly and consistent manner, requirements for standardized coding of such claims were established, to include the Health Care Financing Administration Common Procedure Coding System ("HCPCS") and National Drug Codes ("NDC"), as maintained and distributed by the U.S. Department of Health and Human Services, and Current Procedural Terminology ("CPT"), as maintained and distributed by the American Medical Association. Level II of the HCPCS was a standardized coding system that was used primarily to identify products, supplies, and services not included in the CPT codes, to include the chemotherapy and supportive drugs listed above. Claims for reimbursement were submitted to Medicare using the CMS Form 1500, Health Insurance Claim Form, or electronic submissions containing the same information.

D. <u>Foreign / Misbranded Drugs at ELO</u>

15. Beginning on an unknown date, but no later than in or about June 2009, defendant Norbergs began ordering and directing others at ELO to order drugs from QSP and other foreign distributors. These foreign distributors, including QSP, began shipping misbranded unapproved drugs to ELO, where the drugs were administered to patients. Thereafter, defendant Norbergs caused ELO to

submit claims for reimbursement for those drugs to Medicare and other private health care benefit programs.

16. The drugs provided to ELO by QSP and the other foreign distributors included drugs from foreign establishments that had not been registered with or approved by the FDA. Many of the drugs were shipped for payment by ELO and went directly to ELO from a location outside the United States, usually the United Kingdom. Packaging and documents shipped with the drugs showed that the drugs were manufactured and packaged for distribution in foreign countries.

17. From in or about January 2011, to in or about March 2012, defendant Norbergs caused ELO to purchase from QSP over $700,000 in misbranded unapproved drugs, to include the drugs listed above, administered those drugs to ELO's patients, and caused ELO to bill Medicare and other public and private health care benefits programs for the unapproved drugs.

18. The labels and labeling for the prescription drugs purchased by ELO from QSP and other foreign distributors were different than the versions of the drugs that had been approved for distribution and use in the United States by the FDA. For example, the labels and labeling for some of the drugs from these foreign distributors were in foreign languages. Other drugs' labeling did not provide dosage information or express the potency of the drugs in a standard format. The drugs' labeling did not bear the symbol "Rx only" required for drugs being distributed in the United States. The drugs purchased by ELO did not come from registered drug establishments and were not drugs which had been annually

listed as drugs being produced at registered drug establishments for distribution and use in the United States.

COUNTS ONE THROUGH NINE
(Receipt of Misbranded Drugs in Interstate Commerce)

19. Paragraphs 1 through 18 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

20. On or about the dates listed below, in the Middle District of Florida and elsewhere,

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the defendant herein, with the intent to defraud and mislead, received in interstate commerce for delivery for pay or otherwise a quantity of the prescription drugs described below, which drugs were misbranded within the meaning of the Food, Drug, and Cosmetic Act in that:

a. the labeling failed to bear adequate directions for use;

b. the labeling was false or misleading;

c. the labeling contained words, statements, or other required information that was not in English;

d. the labeling failed to bear the symbol "Rx only"; or,

e. the drug came from a foreign drug establishment and that drug was not annually listed with the FDA as being manufactured for commercial distribution in the United States.

COUNT	DRUG(S)	FOREIGN DISTRIBUTOR	DATE OF ORDER	AMOUNT PAID
ONE	Zometa	Cancer Drugs Online (U.K.)	12/21/2011	$3,710.00
TWO	Dacogen, Gemzar, Neupogen, Eprex	QSP (U.K. / Canada)	12/28/2011	$6,725.00

COUNT	DRUG(S)	FOREIGN DISTRIBUTOR	DATE OF ORDER	AMOUNT PAID
FOUR	Herceptin, MabThera, Neulastim, Erbitux, Eloxatin, Abraxane, Velcade	QSP (U.K. / Canada)	2/22/2012	$28,734.00
FIVE	Herceptin, MabThera, Erbitux, Neupogen, Neulastim, Faslodex, Eloxatin, Abraxane, Velcade	QSP (U.K. / Canada)	2/28/12	$32,199.00
SIX	Zometa	Cancer Drugs Online (U.K.)	3/29/12	$3,710.00
SEVEN	Zometa	Cancer Drugs Online (U.K.)	5/17/12	$3,690.00
EIGHT	Zometa	Cancer Drugs Online (U.K.)	6/14/12	$3,690.00
NINE	Zometa	Cancer Drugs Online (U.K.)	7/12/12	$3,710.00

All in violation of Title 21, United States Code, Sections 331(c), 333(a)(2), and 352, and Title 18, United States Code, Section 2.

COUNTS TEN THROUGH TWENTY-ONE
(Health Care Fraud)

Introduction

21. Paragraphs 1 through 18 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

Scheme and Artifice

22. Beginning on an unknown date, but at least as early as in or about June 2009, and continuing through at least in or about January of 2013, in the Middle District of Florida and elsewhere,

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the defendant herein, did knowingly and willfully execute and attempt to execute a scheme and artifice to defraud Medicare, a health care benefit program, and to obtain money and property owned by and under the custody and control of Medicare by means of materially false and fraudulent pretenses, representations, and promises, in connection with the payment for health care benefits, items, and services.

Manner and Means

23. It was part of the scheme and artifice to defraud that defendant Norbergs would and did purchase from QSP and other foreign distributors the following, among others, misbranded drugs: Ribomustin (known as Treanda in the U.S.), Neulastim (known as Neulasta in the U.S.), Eprex (known as Procrit in the U.S.), MabThera (known as Rituxan in the U.S.), and Herceptin, all of which were not approved by the FDA for distribution and use in the United States.

24. It was a further part of the scheme and artifice to defraud that defendant Norbergs would and did administer and cause to be administered to patients of ELO the aforementioned unapproved and misbranded drugs purchased from foreign distributors.

25. It was a further part of the scheme and artifice to defraud that defendant Norbergs would and did fail to inform ELO's patients of, or secure their consent to, the use of misbranded drugs purchased from foreign distributors.

26. It was a further part of the scheme and artifice to defraud that defendant Norbergs would and did submit and cause to be submitted to Medicare

claims for reimbursement, which falsely represented that the FDA-approved versions of drugs had been administered to those patients, when, in truth and in fact, as the defendant then well knew, the unapproved and misbranded versions of those drugs had been administered.

27. It was a further part of the scheme and artifice to defraud that defendant Norbergs would and did generate profits from the difference between the Medicare reimbursement rates for FDA-approved drugs and the discounted prices of the misbranded versions of those drugs that Norbergs had purchased from foreign distributors.

28. It was a further part of the scheme and artifice to defraud that defendant Norbergs and others would and did misrepresent, conceal, and hide, and cause to be misrepresented, concealed, and hidden, the purpose of the scheme and artifice to defraud and the acts committed in furtherance thereof.

Execution of the Scheme and Artifice

29. On or about the dates listed below, in the Middle District of Florida and elsewhere, the defendant knowingly and willfully executed and attempted to execute the above-described scheme and artifice by the submission of claims to Medicare for the patients listed below, falsely representing that the listed drugs had been administered on the dates of service listed below when, in truth and in fact, the unapproved and misbranded versions of said drugs had been administered.

COUNT	CLAIM DATE	PATIENT	DRUG & SERVICE PROVIDED
TEN	9/26/2011	M.S.	J9310 Rituximab Injection (MabThera)
ELEVEN	9/29/2011	S.M.	J9310 Rituximab Injection (MabThera)
TWELVE	9/30/2011	C.K.	J9310 Rituximab Injection (MabThera)
THIRTEEN	11/3/2011	C.P.	J0885 Epoetin Alfa Injection (Eprex)
FOURTEEN	12/13/2011	A.B	J9310 Rituximab Injection (MabThera)
FIFTEEN	12/13/2011	A.B.	J9033 Bendamustine Injection (Ribomustin)
SIXTEEN	12/14/2011	A.B.	J9033 Bendamustine Injection (Ribomustin)
SEVENTEEN	12/29/2011	J.M.	J0885 Epoetin Alfa Injection (Eprex)
EIGHTEEN	1/5/2012	A.L.	J2005 Pegfilgrastim Injection (Neulastim)
NINETEEN	1/27/2012	A.L.	J2005 Pegfilgrastim Injection (Neulastim)
TWENTY	3/6/2012	K.P.	J9310 Rituximab Injection (MabThera)
TWENTY-ONE	6/15/2012	S.B.	J3487 Zoledronic Acid Injection (Zometa)

All in violation of Title 18, United States Code, Sections 1347 and 2.

FORFEITURE

1. All of the allegations contained above are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Sections 492 and 982, and Title 28, United States Code, Section 2461(c).

2. Upon conviction of any of the violations of Title 18, United States Code, Sections 331 and 333 alleged in Counts One through Nine of this Indictment, the defendant shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 492, and Title 28, United States Code, Section 2461(c), any articles, devices, or other things made possessed, or used in the violation(s).

3. Upon conviction of any of the violations of Title 18, United States Code, Section 1347 alleged in Counts Ten through Twenty-One of this Indictment, the defendant shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

4. The property to be forfeited includes, but is not limited to, a forfeiture money judgment of at least $700,000, representing the proceeds of Counts Ten through Twenty-One of this Indictment.

5. If any of the property described above, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property under the provisions of Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1).

A TRUE BILL,

Foreperson

A. LEE BENTLEY, III
United States Attorney

By:
Matthew Jackson
Assistant United States Attorney

By:
Robert A. Mosakowski
Assistant United States Attorney
Chief, Economic Crimes Section

UNITED STATES DISTRICT COURT
Middle District of Florida
Tampa Division

THE UNITED STATES OF AMERICA

vs.

D. ANDA NORBERGS

INDICTMENT

Violations:

Title 21, United States Code, Section(s) 331(c) and 333(a)(2)
Title 18, United States Code, Section 1347

A true bill,

Foreperson

Filed in open court this 28th day

of May, 2015.

Clerk

Bail $_____

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