UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

CASE NO. 8:15-cr-183-30AEP

D. ANDA NORBERGS

21 U.S.C. § 331(c)
21 U.S.C. § 333(a)(2)
18 U.S.C. § 545
18 U.S.C. § 1341
18 U.S.C. § 1347
18 U.S.C. § 492 (forfeiture)
18 U.S.C. § 982 (forfeiture)
28 U.S.C. § 2461(c) (forfeiture)

SUPERSEDING INDICTMENT

The Grand Jury charges:

Introduction

At all times relevant to this Superseding Indictment:

A. Relevant Law under the Food, Drug, and Cosmetic Act

1. The Food and Drug Administration ("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"). Among the responsibilities of the FDA under the FDCA was the regulation of the manufacturing, labeling, and distribution of all drugs and drug components marketed in the United States in interstate commerce, including the importation of drugs from outside the United States, as well as determining whether new drugs were safe and effective for their intended uses before they were introduced into the U.S. marketplace.

2. Under the FDCA, "drugs" were defined, in pertinent part, as articles intended for use in the cure, mitigation, treatment or prevention of disease in a person; articles (other than food) intended to affect the structure or function of the body of a person; or articles intended for use as components of other drugs.

3. Under the FDCA, the term "label" meant a display of written, printed, or graphic matter upon the immediate container of any article. The term "labeling" was broader, and included all labels, as well as other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

4. Under the FDCA, a "prescription drug" was

a. any drug which, because of its toxicity and other potential for harmful effects, or the method of its use, or the collateral measures necessary to its use, was not considered safe for use except under the supervision of a practitioner licensed by State law to administer such drugs; or

b. any FDA-approved drug which was limited by its approval to use under the professional supervision of a practitioner licensed by law to administer prescription drugs.

5. The FDA was also responsible for reviewing New Drug Applications ("NDAs") to determine whether a new drug was safe and effective for its intended uses; a new drug could not be lawfully marketed in the United States unless and until the FDA approved an NDA for that drug.

6. Among other disclosures, every NDA was required to contain information regarding the intended uses of the drug; specifications, components, processes and controls used during manufacture of the drug itself; specifications related to containers and closure systems, packaging materials and methods; and the product labeling, including exterior labeling and package inserts. FDA's

determination about the safety and efficacy of a drug, which was the basis for approval, was based on the product being manufactured at a specified facility, in a specific strength and dosage form, and packaged, held, and labeled in a specific manner. Thus, an "approved" new drug was not merely the pill, tablet, or liquid that was produced at an FDA-registered and approved manufacturing facility. Rather, all aspects of a drug were required to match the description of the drug in the FDA-approved NDA. So, if a drug differed in any manner from the description in the FDA-approved NDA, it was not the approved drug, and the safety and efficacy of that drug was unknown.

7. Under the FDCA, a drug was misbranded if, among other things:

   a. all the words, statements, and other information required by or under authority of the FDCA to appear on the labeling was not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; among other things, this meant the required information on the labeling had to appear in the English language; or

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

8. A drug was also misbranded if its labeling failed to bear adequate directions for use. "Adequate directions for use" meant that the directions were sufficient for a layperson to safely use the drug and for the purposes for which it was intended. Directions under which a layperson can use a drug safely cannot be written for a prescription drug because such drugs can, by definition, only be used safely at the direction, and under the supervision, of a licensed practitioner. FDA-approved prescription drugs with their approved labeling were exempt from

having adequate directions for use by a layperson under specific circumstances. But unapproved prescription drugs that did not meet all the conditions for an exemption from the requirement of having adequate directions for use were necessarily misbranded.

9. The FDA had approved NDAs for prescription drugs with the names in the chart below. Included in the chart is also the active ingredient for those prescription drugs. These prescription drugs were used primarily to treat individuals with cancer.

FDA-Approved Drug	Active Ingredient
Neulasta	Pegfilgrastim
Procrit	Epoetin Alfa
Rituxan	Rituximab
Treanda	Bendamustine
Zometa	Zoledronic Acid

B. The Medicare Program (Reimbursement for Cancer Drugs)

10. 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).

11. 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.

12. The Medicare program only paid, or provided reimbursement for, drugs that were safe and effective, and otherwise reasonable and necessary for the individual patient. Moreover, per Medicare, drugs approved for marketing by the FDA were considered safe and effective when used for indications specified on the labeling. Conversely, Medicare, or its fee-for-service contractor, would deny payment for drugs which had not received final marketing approval by the FDA, unless CMS had made a specific exception and instructed otherwise.

13. Thus, in order for Medicare to pay for the use of an FDA-approved drug, it was required that: (a) the drug was used on or after the date of the FDA's approval; (b) administration of the drug was reasonable and necessary for the individual patient; and (c) all other applicable Medicare coverage requirements were met.

14. Accordingly, a physician, or provider, submitting a claim for reimbursement for a covered drug represented that, among other things, the drug

was FDA-approved or that CMS made a specific exception for coverage of the drug.

15. 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, including the Health Care Common Procedure Coding System ("HCPCS"), National Drug Codes ("NDC"), 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, including the FDA-approved chemotherapy and supportive drugs listed above. A provider's claims for reimbursement were submitted to Medicare using the CMS Form 1500, Health Insurance Claim Form, or electronic submissions containing the same information.

C. **Foreign Distributors / Suppliers of Prescription Drugs**

16. Various foreign entities manufactured drugs for foreign markets that purportedly contained the same active ingredients as certain FDA-approved drugs; in some circumstances, the FDA-approved drug and foreign drug may have even shared the same trade name, while in other circumstances the names differed in one or more respects. Regardless, these foreign-made drugs had not been approved by the FDA and, as a result, the drugs' safety and efficacy were unknown. The foreign trade names for some of these non-FDA-approved drugs were as listed in column C below:

A	B	C
U.S. Trade Name (FDA-Approved Drug)	**Active Ingredient**	**Foreign Trade Name (Not FDA-Approved) (No CMS Exception)**
Neulasta	Pegfilgrastim	Neulastim
Procrit	Epoetin Alfa	Eprex
Rituxan	Rituximab	MabThera
Treanda	Bendamustine	Ribomustin
Zometa	Zoledronic Acid	Zometa

17. Quality Specialty Products ("QSP"), operating out of Winnipeg, Canada, and Cancer Drugs Online (d/b/a QS Supplies) were businesses that sold one or more of the drugs listed above in column C to physicians and other health care providers in the United States that had been obtained from foreign sources, which drugs (a) had not been approved for marketing by the FDA and (b) had not otherwise been designated by CMS as covered drugs for Medicare program purposes.

18. The unapproved foreign-sourced drugs listed above in Column C were routinely sold at much lower prices by QSP and Cancer Drugs Online to health care providers in the United States as purported substitutes for the FDA-approved prescription drugs listed in Column A.

D. <u>The Defendant and East Lake Oncology</u>

19. D. Anda Norbergs was an oncologist licensed to practice medicine in the State of Florida. Norbergs was the head doctor and president of East Lake

Oncology, PA ("ELO"), a Health Care Clinic Establishment ("HCCE") located within the Middle District of Florida that provided care and treatment for patients with cancer and other medical conditions.

20. As part of the treatment of patients for cancer and other diseases, Norbergs ordered and purchased large amounts of assorted prescription drugs, to include chemotherapy drugs, which were prescribed by Norbergs or one of her physician employees and administered and dispensed to patients at ELO. Reimbursement for these drugs and their administration was sought from Medicare programs, as well as other health care benefit programs.

21. Florida law required entities, such as ELO, to secure an HCCE permit from the Florida Department of Health in order to purchase drugs. Norbergs, as ELO's owner and designated qualifying practitioner, signed and submitted ELO's HCCE application in or about September 2009, which application was approved in or about October 2009.

22. Per that HCCE application, Norbergs affirmed, in part, that she understood that ELO and Norbergs, as the qualifying practitioner, were required to comply with Chapter 499, Florida Statutes, which, in part, prohibited as unlawful "[t]he receipt of any drug . . . that is . . . misbranded, and the delivery or proffered delivery of such drug . . . for pay or otherwise."

23. In or about May 2007, Norbergs signed and submitted to Medicare a completed form CMS-855I, or a "Medicare Enrollment Application" for physicians and non-physician practitioners, to provide services to Medicare program beneficiaries and to bill the Medicare program for those services.

24. In Norbergs's Medicare Enrollment Application to Medicare, Norbergs certified, in pertinent part:

* * *

> 4. I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> 8. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard for their truth or falsity.
>
> * * *

25. Norbergs also signed and submitted an EDI Enrollment Form to First Coast Services Options, Inc., a CMS contracted intermediary and carrier, so that Norbergs could electronically submit Medicare claims for payment.

26. In the submitted EDI Enrollment Form, Norbergs acknowledged, among other things, her understanding that:

> . . . all claims [submitted would] be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law.

27. Norbergs received multiple warnings or notices during 2011 and 2012 that it was prohibited for her and ELO to purchase and administer

prescription drugs that were misbranded and unapproved by the FDA. For example, on or about April 5, 2012, Norbergs received a letter from the FDA that clearly warned, in part:

> Purchasing prescription drug products, such as injectable cancer medications, from foreign or unlicensed suppliers puts patients at risk of exposure to drugs that may be fake, contaminated, improperly stored and transported, ineffective, and dangerous. In virtually all cases, purchasing unapproved prescription drugs from foreign sources violates the Federal Food, Drug, and Cosmetic Act and is illegal.
>
> FDA requests that you cease using, and retain and secure *all* remaining products purchased from . . . foreign or unlicensed U.S. sources . . . .

28. Contrary to the FDCA prohibitions and Medicare rules, and notwithstanding Norbergs's acknowledgements made in ELO's HCCE application, Norbergs, after September 2009, ordered and directed others at ELO to order misbranded and unapproved prescription drugs from foreign sources, including QSP and Cancer Drugs Online, for administration to ELO patients. Moreover, said ELO patients were not informed about nor did they consent to the use of the misbranded and unapproved drugs as part of their treatment for cancer and other diseases. Norbergs also correspondingly submitted or caused to be submitted claims for reimbursement to Medicare and other private health care benefit programs for the purchase and administration of the misbranded and unapproved drugs.

29. The misbranded and unapproved prescription drugs purchased by ELO from QSP and other foreign distributors were typically shipped to ELO from a location outside the United States, such as the United Kingdom. Further, the

packaging and documents shipped with the drugs indicated that the drugs were associated with foreign countries.

30. For example, from in or about January 2011, to in or about March 2012, Norbergs caused ELO to purchase from QSP over $700,000 in misbranded prescription drugs that lacked FDA-approval, including some of the unapproved drugs listed above in paragraph 16, column C; administered or caused to be administered the misbranded and unapproved drugs to ELO patients; and caused ELO to submit claims to Medicare and other public and private health care benefits programs.

31. In certain instances, the unapproved and misbranded foreign drugs purchased by ELO shared a trade name with an FDA-approved drug product. However, when that occurred, the labeling for the misbranded and unapproved prescription drugs purchased by ELO from QSP and other foreign distributors differed from the FDA-approved drug labeling. For example, the labeling for some of the misbranded unapproved drugs from foreign distributors was printed in a foreign language and failed to include, in English, certain required information. Other misbranded and unapproved drugs' labeling did not even bear the symbol "Rx only."

COUNTS ONE THROUGH SIX
(Receipt and Delivery of Misbranded Drugs in Interstate Commerce)

32. The Introduction section of this Superseding Indictment is re-alleged and incorporated by reference as though fully set forth herein.

33. On or about the dates listed below, in the Middle District of Florida

and elsewhere,

D. ANDA NORBERGS,

the defendant herein, with the intent to defraud and mislead, received in interstate commerce the drugs described in the chart below, which drugs were misbranded within the meaning of the Food, Drug, and Cosmetic Act in the following ways:

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

b. words, statements, and other information required on the labeling to be in English language did not appear in the English language; and

c. the labeling failed to bear the symbol "Rx only";

and did deliver and proffer delivery of these drugs for pay and otherwise.

COUNT	MISBRANDED DRUG	FOREIGN DISTRIBUTOR	COUNTRY SHIPPED FROM	DATE OF RECEIPT
ONE	Ribomustin	QSP	United Kingdom	09/22/2011
TWO	Ribomustin	QSP	United Kingdom	12/07/2011
THREE	Zometa	Cancer Drugs Online	Great Britain	12/31/2011
FOUR	Zometa	Cancer Drugs Online	United Kingdom	04/16/2012
FIVE	Zometa	Cancer Drugs Online	United Kingdom	05/28/2012
SIX	Zometa	Cancer Drugs Online	United Kingdom	06/28/2012

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

COUNTS SEVEN THROUGH SEVENTEEN
(Receipt and Delivery of Misbranded Drugs in Interstate Commerce)

34. The Introduction section of this Superseding Indictment is re-alleged

and incorporated by reference as though fully set forth herein.

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

D. ANDA NORBERGS,

the defendant herein, with the intent to defraud and mislead, received in interstate commerce the drugs described in the chart below, which drugs were misbranded within the meaning of the Food, Drug, and Cosmetic Act in that the labeling failed to bear adequate directions for use, and did deliver and proffer delivery of these drugs for pay and otherwise.

COUNT	MISBRANDED DRUG	FOREIGN DISTRIBUTOR	COUNTRY SHIPPED FROM	DATE OF RECEIPT
SEVEN	MabThera	QSP	United Kingdom	09/22/2011
EIGHT	MabThera	QSP	United Kingdom	12/07/2011
NINE	Neulastim	QSP	United Kingdom	12/07/2011
TEN	Eprex	QSP	United Kingdom	12/29/2011
ELEVEN	Neulastim	QSP	United Kingdom	01/05/2012
TWELVE	Neulastim	QSP	United Kingdom	01/27/2012
THIRTEEN	Neulastim	QSP	United Kingdom	02/24/2012
FOURTEEN	MabThera	QSP	United Kingdom	02/24/2012
FIFTEEN	Neulastim	QSP	United Kingdom	02/28/2012
SIXTEEN	MabThera	QSP	United Kingdom	03/06/2012
SEVENTEEN	Neulastim	QSP	United Kingdom	03/06/2012

All in violation of Title 21, United States Code, Sections 331(c) and

333(a)(2), and Title 18, United States Code, Section 2.

COUNTS EIGHTEEN THROUGH TWENTY-NINE
(Smuggling Goods Into the United States)

36. The Introduction section of this Superseding Indictment is re-alleged and incorporated by reference as though fully set forth herein.

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

D. ANDA NORBERGS,

the defendant herein, did knowingly receive, buy, and facilitate the transportation and sale of merchandise imported contrary to law, that is, the misbranded drugs described in the chart below, knowing that the misbranded drugs had been imported and brought into the United States contrary to Title 21, United States Code, Section 331(a).

COUNT	MISBRANDED DRUG	FOREIGN DISTRIBUTOR	COUNTRY SHIPPED FROM	DATE OF RECEIPT
EIGHTEEN	Ribomustin and MabThera	QSP	United Kingdom	09/22/2011
NINETEEN	Ribomustin, MabThera, and Neulastim	QSP	United Kingdom	12/07/2011
TWENTY	Eprex	QSP	United Kingdom	12/29/2011
TWENTY-ONE	Neulastim	QSP	United Kingdom	01/05/2012
TWENTY-TWO	Neulastim	QSP	United Kingdom	01/27/2012
TWENTY-THREE	Zometa	Cancer Drugs Online	Great Britain	12/31/2011
TWENTY-	Neulastim and	QSP	United	02/24/2012

COUNT	MISBRANDED DRUG	FOREIGN DISTRIBUTOR	COUNTRY SHIPPED FROM	DATE OF RECEIPT
FOUR	MabThera		Kingdom	
TWENTY-FIVE	Neulastim	QSP	United Kingdom	02/28/2012
TWENTY-SIX	Neulastim and MabThera	QSP	United Kingdom	03/06/2012
TWENTY-SEVEN	Zometa	Cancer Drugs Online	United Kingdom	04/16/2012
TWENTY-EIGHT	Zometa	Cancer Drugs Online	United Kingdom	05/28/2012
TWENTY-NINE	Zometa	Cancer Drugs Online	United Kingdom	06/28/2012

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

COUNTS THIRTY THROUGH FORTY
(Health Care Fraud)

Introduction

38. The Introduction section of this Superseding Indictment is re-alleged and incorporated by reference as though fully set forth herein.

Scheme and Artifice

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

D. ANDA NORBERGS,

the defendant herein, did knowingly and willfully devise and intend to devise a scheme and artifice to defraud Medicare, a health care benefit program, and for obtaining money and property owned by and under the custody and control of

Medicare by materially false and fraudulent pretenses, representations, and promises.

Manner and Means

40. The substance of the manner and means by which the defendant sought to execute the scheme and artifice included, among others, the following:

a. It was part of the scheme and artifice that, to wrongfully increase her profits, Norbergs would and did purchase or cause to be purchased from QSP and other foreign distributors the following, among other, misbranded drugs: Ribomustin, Neulastim, Eprex, MabThera, and Zometa, none of which had received marketing approval by the FDA nor otherwise been designated by CMS as a covered drug for Medicare program purposes (hereinafter "unapproved drugs").

b. It was a further part of the scheme and artifice that the misbranded and unapproved drugs purchased or caused to be purchased by Norbergs were sent to ELO via the United States Postal Service or other private or commercial interstate carrier.

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

d. It was a further part of the scheme and artifice that Norbergs would not and did not disclose to these ELO patients that they were receiving misbranded and unapproved drugs purchased from foreign distributors.

e. It was a further part of the scheme and artifice that Norbergs would and did submit or cause to be submitted to the Medicare program false and fraudulent claims for reimbursement, which falsely and fraudulently represented that covered Medicare program drugs had been administered to those ELO patients when, in truth and in fact, misbranded and unapproved drugs had been administered.

f. It was a further part of the scheme and artifice that Norbergs would and did submit or cause to be submitted to supplemental health insurance providers claims for reimbursement for drugs administered to ELO patients.

g. It was a further part of the scheme and artifice that, on occasion, Norbergs would and did collect or cause to be collected copayments and coinsurance payments from ELO patients based on the portion of claims unpaid for by Medicare and the supplemental health insurance providers.

h. It was a further part of the scheme and artifice that Norbergs and others would and did perform acts and make statements to hide and conceal the scheme and artifice and the acts committed and executed in furtherance thereof.

Execution of the Scheme and Artifice

41. On or about the dates listed below in each count, within the Middle District of Florida, and elsewhere, the defendant, aided and abetted by others, knowingly and willfully executed and attempted to execute the above-described scheme and artifice to defraud the Medicare program, a federal health care benefit program, as defined by Title 18, United States Code, Section 24(b), and to obtain,

by means of false and fraudulent pretenses and representations, money and property under the custody and control of the Medicare program, in connection with the delivery of and payment for health care benefits, items, and services, by submitting claims to the Medicare program for treatment of the patients listed below, that falsely and fraudulently represented the listed covered drugs had been administered on the associated dates of service when, in truth and in fact, unapproved and misbranded versions of said drugs had been administered.

COUNT	CLAIM DATE	PATIENT	DRUG & SERVICE PROVIDED
THIRTY	09/26/2011	M.S.	J9310 Rituximab Injection (MabThera)
THIRTY-ONE	09/29/2011	S.M.	J9310 Rituximab Injection (MabThera)
THIRTY-TWO	09/30/2011	C.K.	J9310 Rituximab Injection (MabThera)
THIRTY-THREE	12/13/2011	A.B	J9310 Rituximab Injection (MabThera)
THIRTY-FOUR	12/13/2011	A.B.	J9033 Bendamustine Injection (Ribomustin)
THIRTY-FIVE	12/14/2011	A.B.	J9033 Bendamustine Injection (Ribomustin)
THIRTY-SIX	12/29/2011	J.M.	J0885 Epoetin Alfa Injection (Eprex)
THIRTY-SEVEN	01/05/2012	A.L.	J2005 Pegfilgrastim Injection (Neulastim)
THIRTY-EIGHT	01/27/2012	A.L.	J2005 Pegfilgrastim Injection (Neulastim)

COUNT	CLAIM DATE	PATIENT	DRUG & SERVICE PROVIDED
THIRTY-NINE	03/06/2012	K.P.	J9310 Rituximab Injection (MabThera)
FORTY	06/15/2012	S.B.	J3487 Zoledronic Acid Injection (Zometa)

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

COUNTS FORTY-ONE THROUGH FORTY-FIVE
(Mail Fraud)

Introduction

42. The Introduction section of this Superseding Indictment is re-alleged and incorporated by reference as though fully set forth herein.

Scheme and Artifice

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

D. ANDA NORBERGS,

the defendant herein, did knowingly and willfully devise and intend to devise a scheme and artifice to defraud, and for obtaining money and property from Medicare and ELO patients by means of materially false and fraudulent pretenses, representations, and promises.

Manner and Means

44. The Manner and Means section from the Health Care Fraud allegations relating to Counts Thirty through Forty of this Superseding Indictment

are re-alleged and incorporated by reference as though fully set forth herein for purposes of alleging the manner and means.

Execution of the Scheme and Artifice

45. On or about the date set forth below, within the Middle District of Florida and elsewhere, for the purpose of executing and attempting to execute the scheme and artifice to defraud and attempting to do so, and for obtaining money and property from Medicare and ELO patients by means of materially false and fraudulent pretenses, representations, and promises,

D. ANDA NORBERGS,

defendant herein, aided and abetted by others, did knowingly and willfully cause to be delivered by mail and any private and commercial interstate carrier, according to the direction thereon, and at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter and thing, that is, a parcel containing the misbranded and unapproved drugs described in the chart below:

COUNT	DATE	MISBRANDED DRUG	SENT FROM / TO	PATIENT
FORTY-ONE	09/21/2011	MabThera	United Kingdom to Florida	S.M. and C.K.
FORTY-TWO	12/06/2011	MabThera and Ribomustin	United Kingdom to Florida	A.B
FORTY-THREE	01/04/2012	Neulastim	United Kingdom to Florida	A.L.
FORTY-FOUR	03/02/2012	MabThera	United Kingdom to Florida	K.P.
FORTY-FIVE	05/28/2012	Zometa	United Kingdom to Florida	S.B.

All in violation of Title 18, United States Code, Sections 1341 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, Section 982.

2. Upon conviction of any of the violations alleged in Counts One through Seventeen and Thirty through Forty-Four of this Superseding 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.

3. Upon conviction of any of the violations alleged in Counts Eighteen through Twenty-Nine of this Superseding Indictment, the defendant shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(2)(B), any property constituting, or derived from, proceeds the person obtained directly or indirectly, as the result of such violation.

4. The property to be forfeited includes, but is not limited to, a forfeiture money judgment of at least $700,000.

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: _____
Adam M. Saltzman
Assistant United States Attorney

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

FORM OBD-34
APR 1991

No.

UNITED STATES DISTRICT COURT
Middle District of Florida
Tampa Division

THE UNITED STATES OF AMERICA

vs.

D. ANDA NORBERGS

SUPERSEDING INDICTMENT

Violations:

Title 21, United States Code, Section(s) 331(c) and 333(a)(2)
Title 18, United States Code, Section(s) 545, 1341 and 1347

FILED
2016 APR -7 PM 4:03
CLERK US DISTRICT COURT
MIDDLE DISTRICT FLORIDA
TAMPA FLORIDA

A true bill,

Foreperson

Filed in open court this 7th Day

of April, 2016.

Clerk

Bail $_____

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