

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT E.D.N.Y.

★ JUL 22, 2015 ★

LONG ISLAND OFFICE

JMM:CPK
F. #2012R00759

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----- X

UNITED STATES OF AMERICA

SUPERSEDING
INDICTMENT

- against -

WILLIAM SCULLY,
also known as "Liam Scully,"

Defendant.

Cr. No. 14-208 (S-1) (ADS)
(T. 18, U.S.C., §§ 371, 545, 981(a)(1)(C),
982(a)(2)(B), 1341, 1343, 1349, 2320(a)(4),
2323(b), 2 and 3551 et seq.; T. 21, U.S.C.,
§§ 331(a), 331(c), 331(d), 331(t), 333(a)(2),
333(b)(1)(D), 334, 355 and 853(p); T. 28,
U.S.C., § 2461(c))

----- X

THE GRAND JURY CHARGES:

INTRODUCTION

At all times relevant to this Superseding Indictment, unless otherwise indicated:

The Food and Drug Administration's Regulation of Drugs

1. Congress enacted the Federal Food, Drug and Cosmetic Act ("FDCA"), which is set forth in Sections 301 to 397 of Title 21 of the United States Code, to protect the public from, among other things, drugs that were misbranded and unapproved new drugs, or drugs not proven to be safe and effective for their intended uses.

2. The United States Food and Drug Administration ("FDA") was the agency of the United States responsible for enforcing the provisions of the FDCA. The FDA's responsibilities included regulating the manufacturing, labeling, and distribution of prescription drugs shipped or received in interstate commerce.

3. The responsibilities of the FDA included (1) inspecting facilities where drug products were labeled and packaged, (2) examining the records at such facilities to determine whether the drugs were packaged and labeled under conditions in which their quality could be assured, (3) examining the facilities and controls used, and, where appropriate, (4) preventing products that were improperly packaged and labeled from reaching the marketplace.

4. Title 21, United States Code, Section 321(g)(1)(B) defined "drugs" as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man." Title 21, United States Code, Section 321(g)(1)(C) also defined "drugs" to include "articles . . . intended to affect the structure or any function of the body of man."

5. A drug was a "new drug" if it was "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof" 21 U.S.C. § 321(p)(1). To be lawfully introduced into interstate commerce, new drugs required an approved marketing or investigational application. 21 U.S.C. §§ 331(d) and 355. "Approved marketing or investigational applications" included new drug applications ("NDAs"), abbreviated new drug applications ("ANDAs"), and investigational new drug applications ("INDs"). 21 U.S.C. § 355.

6. The FDA's approval for a new drug covered only the drug described in the NDA, ANDA, or IND. A new drug which, or the labeling of which, was slightly different, in any manner whatsoever, from what was described in the NDA, ANDA, or IND was not

considered the same drug and could not be lawfully marketed without its own separately approved NDA, ANDA, or IND.

7. "Prescription drugs" were those drugs, which because of their toxicity and other potential harmful effects, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. A drug was also a "prescription drug" if the FDA required it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug.

8. Under the FDCA, "label" meant a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of the FDCA that any word, statement, or other information appear on the label was not considered to be complied with unless such a word, statement, or other information also appeared on the outside container or wrapper, if any there be, of the retail package of such article, or was easily legible through the outside container or wrapper.

9. The FDCA defined "labeling" to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

10. Pursuant to Title 21, United States Code, Section 321(g)(2), "[t]he term "counterfeit drug" meant a drug which, or the container or labeling of which, without authorization, bore the trademark, trade name, or other identifying mark, imprint, or device ... of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely

purported or was represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.”

Relevant Prescription Drugs

11. Avastin was the trademark name for a drug that was used to treat certain cancers and was a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B).

The FDA initially approved Avastin for use in the United States in 2004.

Altuzan was the foreign version of Avastin and was not approved by the FDA for use in the United States.

12. Aloxi was the trademark name for a drug that was used to prevent chemotherapy-induced nausea and vomiting and was a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA initially approved Aloxi for use in the United States in 2003.

13. Aredia was the trademark name for a drug that was used to inhibit accelerated bone resorption induced by tumors and was a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA initially approved Aredia for use in the United States in 1998.

14. Botox was the trademark name for a drug that was used, among other purposes, to treat migraine headaches, overactive bladders, urinary incontinence, and upper limb spasticity, and was a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA initially approved Botox for use in the United States in 1991.

15. Rituxan was the trademark name for a drug that was used, among other purposes, to treat certain cancers and rheumatoid arthritis, and was a prescription drug within

the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA initially approved Rituxan for use in the United States in 1997. Mabthera, the foreign version of Rituxan, was a drug that was not approved by the FDA for use in the United States.

16. Remicade was the trademark name for a drug that was used, among other purposes, to treat Crohn's disease and ulcerative colitis, and was a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA initially approved Remicade for use in the United States in 1998.

17. Mirena was the trademark name for a drug that was used, among other purposes, as a contraceptive and was a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA approved Mirena for use in the United States in 2000.

Misbranding

18. The FDCA set forth various ways in which a drug was deemed to be misbranded. Among other ways, a drug was deemed to be misbranded if its labeling was false or misleading in any particular manner. 21 U.S.C. Section 352(a).

19. A drug was also deemed to be misbranded if any word, statement, or other information required to appear on the label or labeling was not prominently placed thereon. 21 U.S.C. Section 352(c). Under FDA regulations, a drug was deemed to be misbranded under section 352(c) unless "all words, statements, and other information required by or under authority of the act to appear on the label or labeling [] appear thereon in the English language" 21 C.F.R. Section 201.15(c)(1).

20. A drug was also deemed to be misbranded if its labeling lacked adequate directions for use. 21 U.S.C. Section 352(f)(1). FDA regulations defined "adequate

directions for use” as directions under which a layman could use a drug safely and for the purposes for which it was intended without a doctor’s supervision. 21 C.F.R. Section 201.5.

21. Unlike over-the-counter drugs, which were intended for self-administration, prescription drugs by their very nature were safe for use only under the supervision of a licensed practitioner. 21 U.S.C. Section 353(b)(1)(A). To allow for the lawful movement of prescription drugs in interstate commerce, FDA regulations exempted prescription drugs from the adequate-directions-for-use requirement if they met certain conditions. 21 C.F.R. Section 201.100. Prescription drugs intended for foreign distribution were not FDA approved for sale in the United States and did not meet the conditions that would allow their lawful distribution in interstate commerce. 21 C.F.R. Section 201.100(c)(2).

22. One such condition required that labeling “on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented.” 21 C.F.R. Section 201.100(c)(1).

23. Under FDA regulations, the words, statements, and other information required by or under authority of the FDCA to appear on the labeling were required to be 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. 21 C.F.R. Section 201.15. Such information was required, with certain exceptions, to appear on the label in the English language. 21 C.F.R. Section 201.15(c)(1).

24. Under the FDCA, a drug was deemed to be misbranded if it was a prescription drug and its label did not bear the phrase “Rx only.” 21 U.S.C. Section 353(b)(4)(A).

Unlicensed Wholesale Distribution of Prescription Drugs

25. Oxaliplatin, Velcade, Zometa, Venofer, Avastin, Mabthera, Remicade and Mirena IUDs (the “Prescription Drugs”) were drugs within the meaning of Title 21, United States Code, Section 321(g)(1)(c) intended to be used for, among other things, the treatment of cancer and lymphoma, and due to their toxicity and other potential for harmful effects, the Prescription Drugs were not safe for use except under the supervision of a practitioner licensed by law and administered as such. As such, the Prescription Drugs were “prescription drugs” within the meaning of Title 21, United States Code, Section 353(b)(1)(A) and (B).

26. These Prescription Drugs were manufactured at facilities outside the State of New York and sent to New York in interstate commerce for distribution to consumers in New York State and elsewhere in interstate commerce.

27. The FD&C Act required that persons engaged in the wholesale distribution of prescription drugs in interstate commerce in a state be licensed by the state in accordance with guidelines established by the FDA. Title 21, United States Code, Section 353(e)(2)(A). The wholesale distribution of prescription drugs means distribution to someone other than a consumer or patient. Title 21, United States Code, Section 353(e)(3)(B).

28. In order for an individual or corporation to engage in wholesale distribution in interstate commerce of prescription drugs and be in compliance with the FD&C Act, that individual or corporation must hold a valid "Prescription Drug Wholesaler" license in a state where that individual or corporation operates a facility from which that individual or corporation makes shipments of prescription drugs.

29. The defendant WILLIAM SCULLY, also known as "Liam Scully," without a "Prescription Drug Wholesaler" license for Taranis Medical Corp. issued by the State of New York obtained wholesale quantities of the Prescription Drugs and other prescription drugs and distributed them unlawfully in interstate commerce through Taranis Medical Corp. from the Eastern District of New York.

The Defendant and the Companies

30. The defendant WILLIAM SCULLY, also known as "Liam Scully," was the owner and operator of Pharmalogical, Inc., d/b/a Medical Device King ("Pharmalogical"), and Medical Device King ("MDK"), companies in Great Neck, New York, which imported and sold prescription drugs to customers who were health care providers. SCULLY was the owner and operator of Taranis Medical Corp., which purchased misbranded drugs ordered by Pharmalogical and resold them to customers.

31. The defendant WILLIAM SCULLY, also known as "Liam Scully," resided in Commack, New York and used the websites and e-mail addresses www.pharmalogicalinc.com, www.medicaldeviceking.com, www.taranismedical.com, taranismed@yahoo.com and medev1@yahoo.com in connection with the sale of prescription drugs.

32. The websites www.pharmalogicalinc.com and www.medicaldeviceking.com (“MDKwebsites”) and www.taranismedical.com were used to make sales to customers.

The Fraud Scheme

33. In or about and between February 2009 and July 2013, the defendant WILLIAM SCULLY, also known as “Liam Scully,” together with others, engaged in a scheme designed to fraudulently induce customers to purchase prescription drugs that were misbranded in that they were not approved by the FDA for use in the United States. In furtherance of this scheme, SCULLY placed photographs of certain prescription medications, which were approved by the FDA for introduction and delivery for introduction into interstate commerce in the United States, on MDK websites in order to mislead customers to believe that the drugs were approved when, in truth and in fact, as SCULLY then and there well knew and believed, the drugs that they sold were not approved by the FDA for use and introduction and delivery into interstate commerce in the United States.

34. The defendant WILLIAM SCULLY, also known as “Liam Scully,” together with others, obtained misbranded drugs from foreign suppliers using the email address of medev1@yahoo.com and, on behalf of MDK, received payment from customers by credit card, wire transfer and business check from purchasers of misbranded drugs. SCULLY received, and caused to be received, on behalf of Pharmalogical, shipments of misbranded drugs through United States Mail Priority and Express Mail. SCULLY also sent, and caused to be sent, on behalf of Pharmalogical, Medical Device King and MDK, shipments of

misbranded drugs using commercial interstate carriers, to wit: United Parcel Service of America, Inc. ("UPS") and FedEx Corporation ("FedEx").

35. It was part of the conspiracy that the defendant WILLIAM SCULLY, also known as "Liam Scully," and others electronically ordered prescription drugs from, among other places, the countries of Scotland, Turkey, United Kingdom, Cayman Islands, Canada, United Arab Emirates, Switzerland and India for sale in the United States, knowing that such prescription drugs were not FDA approved and therefore were not permitted to be distributed and used in the United States.

36. It was a further part of the conspiracy that the defendant WILLIAM SCULLY, also known as "Liam Scully," and others, knowing that the prescription drugs obtained from the countries set forth in paragraph 35 above, among others, were not approved for sale in the United States, shipped such drugs using commercial interstate carriers to customers who had ordered them either by telephone or from the MDK websites that falsely advertised such drugs as genuine, safe and approved for sale in the United States.

37. Similarly, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, falsely represented to prospective customers during telephone calls that the prescription drugs the customers purchased were approved for sale and use in the United States when SCULLY knew that this was not true.

38. For example, when prospective customers ordered Avastin, the defendant WILLIAM SCULLY, also known as "Liam Scully," and others sent, and caused to be sent to the customers, via UPS, Altuzan, a prescription medication not approved for introduction and delivery for introduction into interstate commerce in the United States.

Likewise, when customers ordered Rituxan, defendant SCULLY and others sent, and caused to be sent to customers, via UPS, Mabthera, a prescription medication not approved for introduction and delivery for introduction into interstate commerce in the United States.

39. On or about May 24, 2012, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, possessed numerous misbranded drugs, having imported them with the intention of selling them, as set forth below:

Drug Quantity and Type	Method of Misbranding
62 Mirena IUDs	Lacked phrase "Rx only" on label; lacked English language label and labeling; lacked adequate directions for use
53 vials of Aloxi	Lacked phrase "Rx only" on label; lacked English language label and labeling; lacked adequate directions for use
24 bottles of Aclasta	Lacked phrase "Rx only" on label; lacked adequate directions for use
12 bottles of Velcade	Lacked phrase "Rx only" on label; lacked adequate directions for use
12 bottles of Vidaza	Lacked phrase "Rx only" on label; lacked English language label and labeling; lacked adequate directions for use
18 Implanon subdermal contraceptive implants	Lacked phrase "Rx only" on label; lacked English language label and labeling; lacked adequate directions for use
6 vials of Botox	Lacked phrase "Rx only" on label
5 bottles of Venofer	Lacked phrase "Rx only" on label; lacked adequate directions for use
4 vials of Zometa	Lacked phrase "Rx only" on label; lacked adequate directions for use
3 vials of Mabthera	Lacked phrase "Rx only" on label; lacked adequate directions for use
1 syringe of Avonex	Lacked phrase "Rx only" on label; lacked English language label and labeling; lacked adequate directions for use

Drug Quantity and Type	Method of Misbranding
1 box Plavix	Lacked phrase "Rx only" on label; lacked adequate directions for use
1 box Lipitor	Lacked "Rx only" on label; lacked English language label and labeling; lacked adequate directions for use

COUNT ONE
(Conspiracy to Commit Wire Fraud)

40. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

41. In or about and between February 2009 and July 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally conspire to devise a scheme and artifice to defraud customers of Pharmalogical and MDK, and to obtain money from them by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing such scheme and artifice, to transmit and cause to be transmitted, by means of wire and radio communication in interstate and foreign commerce, writings, signs, signals, pictures and sounds, contrary to Title 18, United States Code, Section 1343.

(Title 18, United States Code, Sections 1349 and 3551 et seq.)

COUNTS TWO THROUGH EIGHTEEN
(Wire Fraud)

42. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

43. On or about the dates set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally devise a scheme and artifice to defraud customers of MDK, and to obtain money and property from them, by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing and attempting to execute such scheme and artifice, cause writings, signals, pictures and sounds to be transmitted by means of wire communication in interstate and foreign commerce, as set forth below:

Count	Approximate Date of Wire	Description of Wire	Recipient
Two	1/18/2011	Fax	Advanced Women's Health Care 206 Cornelia St. Plattsburgh, New York 12901
Three	9/26/2011	telephone call	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Four	10/13/2011	telephone call	Sierra Nevada Cancer Center 1460S. Curry Street, Suite 100, Carson City, Nevada 89703
Five	11/28/2011	telephone call	Sierra Nevada Cancer Center 1460S. Curry Street, Suite 100, Carson City, Nevada 89703
Six	11/28/2011	credit card transaction	Dr. R. Daniel Jacob, 4228 Houma Blvd., Suite 340, Metarie, Louisiana 70006
Seven	11/28/2011	email order confirmation	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey 07940

Count	Approximate Date of Wire	Description of Wire	Recipient
Eight	2/23/2012	telephone call	Sierra Nevada Cancer Center 1460S. Curry Street, Suite 100, Carson City, Nevada 89703
Nine	3/15/2012	Fax	Lone Star Surgical Specialist, P.A., 2250 FM 51 South, Decatur, Texas 76234
Ten	4/23/2012	credit card transaction	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Eleven	4/24/2012	credit card transaction	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Twelve	5/01/2012	credit card transaction	Kingston Oncology Hematology, 368 Broadway, Suite 403, Kingston, New York 12401
Thirteen	5/02/2012	email order confirmation	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey 07940
Fourteen	5/10/2012	credit card transaction	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Fifteen	5/22/2012	business check	South Shore Neurologic Associates, 77 Medford Avenue, Suite E, Patchogue, New York 11772
Sixteen	6/11/2012	wire transfer	Jersey Hematology Oncology Infusion Center, 9238 Kennedy Boulevard, North Bergen, New Jersey 07047

Seventeen	7/20/2012	telephone call	Mehta and Mehta 36 Osprey Avenue, Riverhead, New York 11901
Eighteen	8/20/2012	telephone call	South Shore Neurologic Associates, 77 Medford Avenue, Suite E, Patchogue, New York 11772

(Title 18, United States Code, Sections 1343, 2 and 3551 et seq.)

COUNT NINETEEN
(Conspiracy to Commit Mail Fraud)

44. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

45. In or about and between February 2009 and July 2013, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally conspire to devise a scheme and artifice to defraud customers of Pharmalogical and MDK, and to obtain money and property from them by means of materially false and fraudulent pretenses, representations and promises and, for the purpose of executing such scheme and artifice, did cause to be delivered by private commercial interstate carriers one or more mail matters and things, to wit: packages containing misbranded drugs, according to the directions thereon, contrary to Title 18, United States Code, Section 1341.

(Title 18, United States Code, Sections 1349 and 3551 et seq.)

COUNTS TWENTY THROUGH THIRTY-SIX
(Mail Fraud)

46. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

47. On or about the dates set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally devise a scheme and artifice to defraud customers of Pharmalogical, MDK and Taranis Medical Corp., and to obtain money and property from them, by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing and attempting to execute such scheme and artifice, did place and cause to be placed in mail matters and things, to wit: packages of misbranded drugs to be delivered by private commercial interstate carriers for delivery, according to the instructions thereon, as set forth below:

Count	Approximate Date of Mailing	Drug Mailed	Address of Recipient
Twenty	9/26/2011	Altuzan and Mabthera	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Twenty-One	10/13/2011	Altuzan and Mabthera	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Twenty-Two	11/28/2011	Botox	Dr. R. Daniel Jacob 4228 Houma Blvd., Suite 340 Metairie, Louisiana 70006

Count	Approximate Date of Mailing	Drug Mailed	Address of Recipient
Twenty-Three	11/28/2011	Altuzan	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Twenty-Four	11/29/2011	Aloxi	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey 07940
Twenty-Five	12/19/2011	Mirena IUDs	Advanced Women's Health Care 206 Cornelia St. Plattsburgh, New York 12901
Twenty- Six	2/23/2012	Mabthera and Aloxi	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Twenty-Seven	4/23/2012	Altuzan (Avastin)	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Twenty-Eight	4/24/2012	Altuzan (Avastin)	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Twenty-Nine	5/01/2012	Mabthera	Kingston Oncology Hematology, 368 Broadway, Suite 302, Kingston, New York 12401
Thirty	5/02/2012	Aredia and Aloxi	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey 07940
Thirty- One	5/10/2012	Mabthera	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Thirty- Two	5/22/2012	Mabthera	South Shore Neurologic Associates 77 Medford Avenue, Suite E, Patchogue, New York 11772

Count	Approximate Date of Mailing	Drug Mailed	Address of Recipient
Thirty-Three	6/11/2012	Mabthera	Jersey Hematology Oncology Infusion Center 9238 Kennedy Boulevard, North Bergen, New Jersey 07047
Thirty- Four	7/20/2012	Remicade	Mehta and Mehta 36 Osprey Avenue Riverhead, New York 11901
Thirty- Five	8/20/2012	Botox	South Shore Neurologic Associates 77 Medford Avenue, Suite E, Patchogue, New York 11772
Thirty- Six	10/17/2012	Botox	Lone Star Surgical Specialists, P.A., 2250 FM 51 South, Decatur, Texas 76234

(Title 18, United States Code, Sections 1341, 2 and 3551 et seq.)

COUNT THIRTY-SEVEN

(Conspiracy to Distribute Misbranded Drugs)

48. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

49. In or about and between February 2009 and July 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and willfully conspire to introduce and deliver for introduction into interstate commerce, with the intent to defraud and mislead, drugs that were misbranded, contrary to Title 21, United States Code, Sections 331(a) and 333(a)(2).

50. In furtherance of the conspiracy and to effect the objects thereof, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, committed and caused to be committed, among others, the following:

Overt Acts

(a) On or about September 26, 2011, SCULLY and others caused a package containing Altuzan and Mabthera to be shipped from Great Neck, New York by MDK to Sierra Nevada Cancer Center in Carson City, Nevada.

(b) On or about May 1, 2012, SCULLY and others caused a package containing Mabthera, to be shipped from Great Neck, New York by MDK to Kingston Oncology Hematology in Kingston, New York.

(Title 18, United States Code, Sections 371 and 3551 et seq.)

COUNTS THIRTY-EIGHT THROUGH FIFTY-FOUR
(Introduction of Misbranded Drugs Into Interstate Commerce)

51. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated by reference as if fully set forth herein.

52. On or about the dates as set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally introduce and cause to be introduced into interstate commerce, with the intent to defraud and mislead, one or more misbranded drugs:

Count	Approximate Date of Introduction	Drug Mailed	Address of Recipient
Thirty-Eight	9/26/2011	Altuzan and Mabthera	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Thirty-Nine	10/13/2011	Mabthera and Aloxi	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Forty	11/28/2011	Botox	Dr. R. Daniel Jacob 4228 Houma Blvd., Suite 340, Metairie, Louisiana 70006
Forty-One	11/28/2011	Altuzan	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Forty-Two	11/29/2011	Aloxi	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey 07940
Forty-Three	12/19/2011	Mirena IUDs	Advanced Women's Health Care 206 Cornelia St. Plattsburgh, New York 12901
Forty-Four	2/23/2012	Mabthera and Aloxi	Sierra Nevada Cancer Center 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Forty-Five	4/23/2012	Altuzan (Avastin)	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314

Count	Approximate Date of Introduction	Drug Mailed	Address of Recipient
Forty- Six	4/24/2012	Altuzan (Avastin)	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Forty- Seven	5/01/2012	Mabthera	Kingston Oncology Hematology, 368 Broadway, Suite 403, Kingston, New York 12401
Forty- Eight	5/02/2012	Aredia and Aloxi	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey 07940
Forty- Nine	5/10/2012	Mabthera	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Fifty	5/22/2012	Mabthera	South Shore Neurologic Associates 77 Medford Ave., Suite E, Patchogue, New York 11772
Fifty- One	6/11/2012	Mabthera	Jersey Hematology Oncology Infusion Center 9238 Kennedy Boulevard, North Bergen, New Jersey 07047
Fifty- Two	7/20/2012	Remicade	Mehta and Mehta 36 Osprey Avenue, Riverhead, New York, 11901

Count	Approximate Date of Introduction	Drug Mailed	Address of Recipient
Fifty-Three	8/20/2012	Botox	South Shore Neurologic Associates 77 Medford Ave., Suite E, Patchogue, New York 11772
Fifty-Four	10/17/2012	Botox	Lone Star Surgical Specialists, P.A., 2250 FM 51 South, Decatur, Texas 76234

(Title 21, United States Code, Sections 331(a) and 333(a)(2); Title 18, United States Code, Sections 2 and 3551 et seq.)

COUNTS FIFTY-FIVE THROUGH SEVENTY-ONE

(Receipt of Misbranded Drugs in Interstate Commerce and Delivery Thereof for Pay)

53. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated by reference as if fully set forth herein.

54. On or about the dates set forth below, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did knowingly and intentionally, and with the intent to defraud and mislead, receive in interstate commerce from locations outside the United States and cause the receipt in interstate commerce from locations outside the United States and cause the delivery and proffered delivery thereof for pay, to the locations listed below one or more drugs that were misbranded:

Count	Approximate Date of Delivery	Drug Delivered	Recipient
Fifty- Five	9/26/2011	Altuzan and Mabthera	Sierra Nevada Cancer Center, 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Fifty- Six	10/13/2011	Mabthera and Aloxi	Sierra Nevada Cancer Center, 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Fifty- Seven	11/28/2011	Botox	Dr. R. Daniel Jacob, 4228 Houma Blvd., suite 340, Metairie, Louisiana 70006
Fifty- Eight	11/28/2011	Altuzan	Sierra Nevada Cancer Center, 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Fifty- Nine	11/29/2011	Aloxi	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey, 07940
Sixty	12/19/2011	Mirena IUDs	Advanced Women's Health Care 206 Cornelia St. Plattsburgh, New York 12901
Sixty- One	2/23/2012	Mabthera and Aloxi	Sierra Nevada Cancer Center, 1460 S. Curry Street, Suite 100, Carson City, Nevada 89703
Sixty- Two	4/23/2012	Altuzan (Avastin)	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Sixty- Three	4/24/2012	Altuzan (Avastin)	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314

Count	Approximate Date of Delivery	Drug Delivered	Recipient
Sixty- Four	5/01/2012	Mabthera	Kingston Oncology Hematology, 368 Broadway, Suite 403, Kingston, New York 12401
Sixty- Five	5/02/2012	Aredia and Aloxi	Metropolitan Pharmacy Services, Inc. 235 Main St., Box #299 Madison, New Jersey, 07940
Sixty- Six	5/10/2012	Mabthera	Hematology & Oncology Center of Iowa 95 University Ave. Des Moines, Iowa 50314
Sixty- Seven	5/22/2012	Mabthera	South Shore Neurologic Associates 77 Medford Ave., Suite E, Patchogue, New York 11772
Sixty- Eight	6/11/2012	Mabthera	Jersey Hematology Oncology Infusion Center 9238 Kennedy Boulevard, North Bergen, New Jersey 07047
Sixty- Nine	7/20/2012	Remicade	Mehta and Mehta 36 Osprey Avenue, Riverhead, New York 11901
Seventy	8/20/2012	Botox	South Shore Neurologic Associates 77 Medford Ave., Suite E, Patchogue, New York 11772
Seventy- One	10/17/2012	Botox	Lone Star Surgical Specialists, P.A., 2250 FM 51 South, Decatur, Texas 76234

(Title 21, United States Code, Sections 331(c) and 333(a)(2); Title 18, United

States Code, Sections 2 and 3551 et seq.)

COUNT SEVENTY-TWO
(Fraudulent Importation and Transportation of Goods)

55. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

56. In or about and between February 2009 and July 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, did (a) knowingly and wilfully, with intent to defraud the United States, smuggle, or clandestinely introduce or attempt to smuggle or clandestinely introduce into the United States any merchandise which should have been invoiced, or made out or passed, or attempted to pass, through the customhouse any false, forged, or fraudulent invoice, or other document or paper and (b) knowingly, intentionally and fraudulently import and bring into the United States merchandise contrary to law, and did receive, conceal, buy, sell and facilitate the transportation, concealment and sale of such merchandise after importation, to wit: misbranded drugs, knowing such merchandise to have been imported and brought into the United States contrary to law.

(Title 18, United States Code, Sections 545, 2 and 3551 et seq.)

COUNT SEVENTY-THREE
(Trafficking in Counterfeit Drugs)

57. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

58. On or about and between April 6, 2012 and April 24, 2012, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as Liam Scully, together with others, did knowingly and intentionally traffic in one or more counterfeit drugs, to wit: prescription cancer drugs.

(Title 18, United States Code, Sections 2320(a)(4), 2 and 3551 et seq.)

COUNT SEVENTY-FOUR

(Introduction of Unapproved New Drugs Into Interstate Commerce)

59. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

60. In or about and between February 2009 and July 2013, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as "Liam Scully," together with others, with the intent to defraud and mislead, introduced and delivered into interstate commerce, and caused to be introduced and delivered into interstate commerce new drugs that were in violation of Title 21, United States Code, Section 355, in that they were not the subject of an approved NDA, approved ANDA or effective IND on file with FDA, to wit: Mirena IUD, Remicade, Aclasta, Velcade, Vidaza, Implanon, Venofer, Zometa, Mabthera, Avonex, Aredia, Aloxi and Altuzan.

(Title 21, United States Code, Sections 331(d), 333(a)(2) and 355; Title 18, United States Code, Sections 2 and 3551 et seq.)

COUNT SEVENTY-FIVE
(Unlicensed Wholesale Distribution of Prescription Drugs)

61. The allegations contained in paragraphs one through thirty-nine are realleged and incorporated as if fully set forth in this paragraph.

62. In on or about and between June 2012 and July 2013, within the Eastern District of New York and elsewhere, the defendant WILLIAM SCULLY, also known as “Liam Scully,” together with others, through Taranis Medical Corp., knowingly engaged in the wholesale distribution of prescription drugs, to wit: Oxaliplatin, Velcade, Zometa, Venofer, Avastin, Mabthera, Remicade and Mirena IUDs and other prescription drugs in interstate commerce, contrary to Title 21, United States Code, Section 353(e)(2)(A), to wit: the defendant caused the wholesale distribution through Taranis Medical Corp. of the prescription drugs and other prescription drugs at a time when Taranis Medical Corp. was not licensed as a “Prescription Drug Wholesaler” in New York or any other state, contrary to Title 21, United States Code, Section 331(t) and 333(b)(1)(D).

(Title 21, United States Code, Sections 331(t), 333(b)(1)(D) and 355; Title 18, United States Code, Sections 2 and 3551 et seq.).

CRIMINAL FORFEITURE ALLEGATION AS TO
COUNTS ONE THROUGH THIRTY-SIX

63. The United States hereby gives notice to the defendant that upon his conviction of any of the offenses charged in Counts One through Thirty-Six, the government will seek forfeiture in accordance with Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), which require any person convicted of such offenses to forfeit any property, real or personal, constituting or derived from proceeds

traceable to such offenses or a conspiracy to commit such offenses including but not limited to, a sum of money equal to at least approximately \$17 million dollars.

64. If any of the above-described forfeitable property, 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;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described in this forfeiture allegation.

(Title 18, United States Code, Section 981(a)(1)(C); Title 21, United States Code, Section 853(p); Title 28, United States Code, Section 2461(c))

CRIMINAL FORFEITURE ALLEGATION
AS TO COUNTS THIRTY-SEVEN THROUGH SEVENTY-ONE AND SEVENTY-FOUR

65. The United States hereby gives notice to the defendant that, upon his conviction of any of the offenses charged in Counts Thirty-Seven through Seventy-One and Seventy-Four, the government will seek forfeiture in accordance with Title 21, United States

Code, Section 334 and Title 28, United States Code, Section 2461(c), which provides for the forfeiture of any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce.

66. If any of the above-described forfeitable property, 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;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described in this forfeiture allegation.

(Title 21, United States Code, Sections 334 and 853(p); Title 28, United States Code, Section 2461(c))

**CRIMINAL FORFEITURE ALLEGATION
AS TO COUNT SEVENTY-TWO**

67. The United States hereby gives notice to the defendant that, upon his conviction of the offense charged in Count Seventy-Two, the government will seek forfeiture

in accordance with (a) Title 18, United States Code, Section 982(a)(2)(B), which requires any person convicted of such offense to forfeit any property, constituting, or derived from, proceeds obtained directly or indirectly, as a result of such offense, and (b) Title 18, United States Code, Section 545 and Title 28, United States Code, Section 2461(c), which require the forfeiture of any merchandise introduced into the United States in violation of Title 18, United States Code, Section 545, including but not limited to counterfeit drugs, or the value thereof.

68. If any of the above-described forfeitable property, 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;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described in this forfeiture allegation.

(Title 18, United States Code, Sections 545 and 982(a)(2)(B); Title 21, United States Code, Section 853(p))

**CRIMINAL FORFEITURE ALLEGATION
AS TO COUNT SEVENTY-THREE**

69. The United States hereby gives notice to the defendant that, upon his conviction of the offense charged in Count Seventy-Three, the government will seek forfeiture in accordance with Title 18, United States Code, Section 2323(b), which requires any person convicted of such offense to forfeit any property, the making or trafficking of which is prohibited under Title 18, United States Code, Section 2320, any property used, or intended to be used, in any manner or part, to commit or facilitate the commission of such offense, and any property constituting or derived from proceeds obtained directly or indirectly as a result of such offense, including but not limited to a sum of money equal to at least approximately \$17 million.

70. If any of the above-described forfeitable property, 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

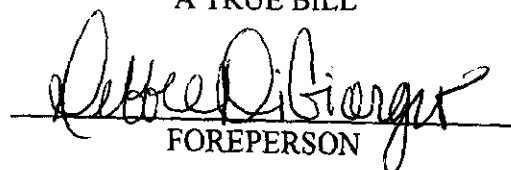
divided without difficulty;

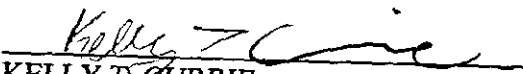
it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as

incorporated by Title 18, United States Code, Section 2323(b)(2), to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described in this forfeiture allegation.

(Title 18, United States Code, Section 2323(b); Title 21, United States Code, Section 853(p))

A TRUE BILL


FOREPERSON


KELLY T. CURRIE
ACTING UNITED STATES ATTORNEY
EASTERN DISTRICT OF NEW YORK

E. #2012R00759
FORM DBD-34
JUN. 85

No. 14-CR-208 (S-1)(ADS)

UNITED STATES DISTRICT COURT
EASTERN District of NEW YORK
CRIMINAL DIVISION

THE UNITED STATES OF AMERICA


vs.

WILLIAM SCULLY,

Defendant.

SUPERSEDING INDICTMENT

(T. 18, U.S.C., §§ 371, 545, 981(a)(1)(C), 982(a)(2)(B), 1341, 1343, 1349, 2320(a)(4), 2323(b), 2 and 3551 et seq.; T. 21, U.S.C., §§ 331(a), 331(c), 331(d), 331(t), 333(a)(2), 333(b)(1)(D), 334, 355 and 853(p); T. 28, U.S.C., § 2461(c))

A true bill.


Foreperson

Filed in open court this _____ day,
of _____ A.D. 20 _____

Clerk

Bail, \$ _____

Charles P. Kelly, Assistant U.S. Attorney (631) 715-7866