UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. (1) BARRY J. CADDEN, (2) GLENN A. CHIN, (3) GENE SVIRSKIY, (4) CHRISTOPHER M. LEARY, (5) JOSEPH M. EVANOSKY, (6) SCOTT M. CONNOLLY, (7) SHARON P. CARTER, (8) ALLA V. STEPANETS, (9) GREGORY A. CONIGLIARO, (10) ROBERT A. RONZIO, (11) KATHY S. CHIN, (12) MICHELLE L. THOMAS, (13) CARLA R. CONIGLIARO, (14) DOUGLAS A. CONIGLIARO, Defendants.	14CR10363-RGS JCB CRIMINAL NO. VIOLATIONS: 18 U.S.C. § 1962(c) (Racketeering); 18 U.S.C. § 1962(d) (Racketeering Conspiracy); 18 U.S.C. § 371 (Conspiracy); 18 U.S.C. § 1341 (Mail Fraud); 21 U.S.C. § 331(a) (Introduction of Adulterated Drugs into Interstate Commerce); 21 U.S.C. § 331(a) (Introduction of Misbranded Drugs into Interstate Commerce); 18 U.S.C. § 401(3) (Contempt); 31 U.S.C. § 5324 (Structuring); 18 U.S.C. § 2 (Aiding and Abetting); 18 U.S.C. §§ 1963; 981(a)(1)(C); 21 U.S.C. § 853; 31 U.S.C. § 5317; & 28 U.S.C. § 2461(c) (Forfeiture)

THE GRAND JURY CHARGES THAT:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

1. New England Compounding Pharmacy, Inc., doing business as New England Compounding Center ("NECC"), was a Massachusetts corporation licensed as a pharmacy in the Commonwealth of Massachusetts by the Massachusetts Board of Registration in Pharmacy ("MABOP"). NECC's principal place of business was located in Framingham, Massachusetts. From in or about 1998 until October 2012, NECC held itself out as a compounding-only pharmacy. Compounding was the preparation, mixing, assembling, packaging, and labeling of a drug pursuant to a valid, patient-specific prescription from a medical practitioner. NECC made purportedly sterile drugs within two clean rooms – Clean Room 1 and Clean Room 2 – which were purported to be controlled environments with low levels of environmental contamination. NECC sold drugs identified as sterile to medical facilities located throughout the country. From January through October 2012, NECC generated revenue of approximately $32.4 million.

2. Medical Sales Management, Inc. ("MSM") was a Massachusetts corporation that shared ownership with NECC. MSM provided sales and administrative services to NECC, including a sales force, finance department, purchasing department, human resources department, and information technology. MSM was paid a service fee by NECC. MSM's sales representatives sold drugs on behalf of NECC to customers throughout the country.

The Defendants

3. The defendant **BARRY J. CADDEN** ("**CADDEN**") was an individual residing in Wrentham, Massachusetts. Defendant **CADDEN** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid prescription from a medical practitioner. Defendant **CADDEN** was an owner and director of NECC, and served as NECC's President, head pharmacist, and Manager of Record. Defendant **CADDEN** oversaw all of the operations of NECC. Defendant **CADDEN** was an owner and

director of MSM, and served as MSM's Treasurer. Defendant **CADDEN** trained and instructed the MSM sales representatives, and routinely communicated with them about specific customer orders and accounts.

4. The defendant **GLENN A. CHIN** ("**CHIN**") was an individual residing in Canton, Massachusetts. **CHIN** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about April 2004 until October 2012, **CHIN** was employed as a pharmacist at NECC. In or about January 2010, **CHIN** was promoted to a supervisory pharmacist role at NECC, overseeing all aspects of NECC's production and personnel in the two clean rooms.

5. The defendant **GENE SVIRSKIY** ("**SVIRSKIY**") was an individual residing in Ashland, Massachusetts. **SVIRSKIY** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about August 2007 until October 2012, **SVIRSKIY** was employed as a pharmacist at NECC. **SVIRSKIY** worked in Clean Room 1, and was a supervising pharmacist in Clean Room 2.

6. The defendant **CHRISTOPHER M. LEARY** ("**LEARY**") was an individual residing in Marlborough, Massachusetts. **LEARY** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about March 2011 until October 2012, **LEARY** was employed as a pharmacist at NECC. **LEARY** worked in Clean Rooms 1 and 2.

7. The defendant **JOSEPH M. EVANOSKY** ("**EVANOSKY**") was an individual residing in Haverhill, Massachusetts. **EVANOSKY** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid

prescription from a medical practitioner. From in or about April 2011 until October 2012, **EVANOSKY** was employed as a pharmacist at NECC. **EVANOSKY** worked in Clean Room 1.

8. The defendant **SCOTT M. CONNOLLY** ("**CONNOLLY**") was an individual residing in Brockton, Massachusetts. From in or about September 2007 until January 2009, **CONNOLLY** was a pharmacy technician licensed in the Commonwealth of Massachusetts by the MABOP. Pharmacy technicians assisted licensed pharmacists in dispensing prescription drugs. In or around January 2009, **CONNOLLY** voluntarily surrendered his pharmacy technician license in connection with a disciplinary action. From in or about January 2010 until August 2012, **CONNOLLY** was employed as a pharmacist technician at NECC. **CONNOLLY** worked as a pharmacy technician in Clean Room 2.

9. The defendant **SHARON P. CARTER** ("**CARTER**") was an individual residing in Hopkinton, Massachusetts. **CARTER** was a pharmacy technician licensed in the Commonwealth of Massachusetts by the MABOP. Beginning in or about September 2000, **CARTER** was employed at NECC in various capacities. In or about February 2012, **CARTER** was promoted to the position of NECC's Director of Operations, overseeing NECC's order processing, packaging, and shipping personnel.

10. The defendant **ALLA V. STEPANETS** ("**STEPANETS**") was an individual residing in Framingham, Massachusetts. **STEPANETS** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about January 2008 until October 2012, **STEPANETS** was employed as a pharmacist at NECC. **STEPANETS** worked in, among other areas at NECC, the packing area checking orders prior to shipment to NECC's customers.

11. The defendant **GREGORY A. CONIGLIARO** ("**GREG CONIGLIARO**") was an individual residing in Southborough, Massachusetts. **GREG CONIGLIARO** was an owner and director of NECC, and served as NECC's Vice President, Secretary, Treasurer, and General Manager. **GREG CONIGLIARO** was responsible for regulatory compliance for NECC. **GREG CONIGLIARO** was an owner and director of MSM, and served as MSM's Secretary.

12. The defendant **ROBERT A. RONZIO** ("**RONZIO**") was an individual residing in North Providence, Rhode Island. Beginning in or about February 2010, **RONZIO** was employed at MSM. Beginning in or about September 2011, **RONZIO** served as the national sales director for NECC, and supervised the MSM sales representatives assigned to sell NECC drugs.

13. The defendant **KATHY S. CHIN** ("**KATHY CHIN**") was an individual residing in Canton, Massachusetts. **KATHY CHIN** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about November 2010 until October 2012, **KATHY CHIN** was employed as a pharmacist at NECC. **KATHY CHIN** worked in the packing area checking orders prior to shipment to NECC's customers.

14. The defendant **MICHELLE L. THOMAS** ("**THOMAS**") was an individual residing in Framingham, Massachusetts. **THOMAS** was a pharmacist licensed in the Commonwealth of Massachusetts by the MABOP to dispense drugs pursuant to a valid prescription from a medical practitioner. From in or about March 2012 until August 2012, **THOMAS** was employed as a pharmacist at NECC. **THOMAS** worked in the packing area checking orders prior to shipment to NECC's customers.

15. The defendant **CARLA R. CONIGLIARO** ("**CARLA CONIGLIARO**") was an individual residing in Winter Park, Florida and Dedham, Massachusetts. **CARLA CONIGLIARO** was the majority shareholder of NECC, and served as a director of NECC.

16. The defendant **DOUGLAS A. CONIGLIARO** ("**DOUG CONIGLIARO**") was an individual residing in Winter Park, Florida and Dedham, Massachusetts. **DOUG CONIGLIARO** was the husband of **CARLA CONIGLIARO**. **DOUG CONIGLIARO** was an owner and director of MSM, and served as MSM's President.

United States Pharmacopeia

17. The United States Pharmacopeial Convention was a scientific non-profit organization that published the United States Pharmacopeia ("USP"), the official pharmacopeia of the United States. The USP set standards for the identity, strength, quality, and purity of medicines.

18. Section 9.01(3) of Title 247 of the Code of Massachusetts Regulations required all pharmacists licensed in the Commonwealth of Massachusetts to follow the standards set forth in the USP.

19. Chapter 797 of the USP ("USP-797") set forth the standards for compounding drugs identified as sterile. All compounding personnel were responsible for understanding the fundamental practices and procedures outlined in USP-797 for developing and implementing appropriate procedures, and for continually evaluating the procedures and quality of sterile drugs.

20. USP-797's standards were meant to prevent harm, including death, to patients that could result from non-sterility of drugs. Non-sterility of purportedly sterile drugs was especially dangerous to patients when the drugs would be administered into the patients' body cavities, central nervous systems, vascular systems, eyes, and joints.

21. USP-797 defined high-risk compounding as, among other things, using non-sterile ingredients to create sterile drugs. High-risk compounding posed the greatest threat to patients because, among other things, it required compounding personnel to sterilize non-sterile ingredients.

Use of Ingredients

22. USP-797 prohibited the use of an ingredient in drugs when the beyond use date ("BUD"), or expiration date, of the ingredient had been exceeded. USP-797 noted that careful consideration and evaluation of non-sterile ingredients was especially warranted when the drug would be administered into the vascular system, central nervous system, or eyes of patients.

Sterilization

23. One way to sterilize drugs was through the use of an autoclave, which exposed the drugs to high pressure saturated steam. To achieve sterilization through autoclaving, USP-797 required that the drugs be exposed to steam at 121° under pressure of one atmosphere for a duration verified by testing; USP-797 defined this duration as usually 20 to 60 minutes. Autoclaving drugs at a lower temperature, a lower pressure, or for less time could result in the drugs not being sterile. USP-797 required verification of the effectiveness of the sterilization process for the quantity and type of containers of drugs through the use of a biological indicator. A biological indicator was a packaged resistant, spore-forming bacterium that provided a defined and stable resistance to a sterilization process. The sterilization process was validated when the packaged resistant, spore-forming bacterium within the biological indicator was destroyed. Given the critical importance of sterilization, the USP required that the description of steam sterilization conditions and durations for specific drugs be included in written documentation in the compounding facility.

Sterility Testing

24. USP-797 mandated that all high-risk drugs prepared in groups of more than 25 individual single-dose packages or multiple-dose vials be tested for sterility consistent with the standards set forth in Chapter 71 of the USP ("USP-71"). In addition, USP-797 mandated that all high-risk drugs, regardless of the quantity, with assigned BUDs beyond 24 hours at room temperature be sterility tested. USP-71 defined sterility as the absence of the growth of microorganisms over a 14-day period. USP-71 set forth the minimum number of articles (*i.e.*, vials, syringes, bags) from varying batch sizes that had to be sterility tested to meet USP requirements.

25. USP-797 allowed for the dispensing of high-risk drugs to patients prior to the receipt of sterility test results if the patient and the physician were notified of the potential risk, and an immediate recall was instituted if microbial growth was observed during the test. Any positive sterility test result should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls to identify the sources of contamination and to correct problems in the methods or processes.

Labeling

26. Chapter 1 of the USP ("USP-1") defined an injectable drug as a preparation intended for "parenteral administration," meaning that the preparation was injected through the skin or other external boundary tissue, so that the active substances it contained were administered, using gravity or force, directly into a blood vessel, organ, tissue, or lesion. Drugs labeled as injectable were required to be prepared scrupulously by methods designed to ensure that they met standards for sterility stated in USP-797 and USP-71.

27. Labels on injectable drugs were required to state the name of the preparation, the percentage content of drug or amount of drug in a specified volume, the route of administration, a statement of storage conditions, an expiration date, the name and place of business of the manufacturer, and an identifying lot number. The identifying lot number had to be capable of yielding the complete manufacturing history of the specific drug, including all manufacturing, filling, sterilizing, and labeling operations.

Cleaning and Disinfecting

28. USP-797 required scrupulous attention to cleaning and disinfecting the sterile compounding areas to minimize environmental contact as a source of microbial contamination of sterile drugs. USP-797 required all cleaning and disinfecting practices and policies to be included in written standard operating procedures ("SOPs") and to be followed by all compounding personnel.

Environmental Monitoring

29. To evaluate the cleaning and disinfecting practices at a compounding facility, USP-797 required surface and air sampling of the sterile compounding areas. USP-797 identified microbial contamination from improperly cleaned and disinfected work surfaces as a major source of contamination of sterile drugs.

30. USP-797 required a compounding facility to establish "action" levels for microbial contamination. If surface or air sampling revealed contamination above an "action" level, USP-797 required a re-evaluation of the compounding facility's practices and procedures. In addition, USP-797 required an investigation into the source of the contamination, the elimination of the source, re-cleaning and re-disinfecting of the area, and re-sampling. If the surface or air sampling consistently revealed elevated levels of microbial growth, USP-797 required the

compounding facility to consult with competent microbiology personnel. If the surface or air sampling revealed highly pathogenic microorganisms that could be potentially fatal to patients receiving the purportedly sterile drugs, such as mold, USP-797 required the compounding facility to immediately remedy the issue, regardless of whether an "action" level was reached, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

Personnel Training and Testing

31. USP-797 required compounding personnel to be adequately skilled, educated, instructed, and trained to properly compound sterile drugs. To ensure proper aseptic technique, compounding personnel were required to perform media-fill testing, which was a process simulation using a microbiological growth medium instead of a drug. Media-fill testing was used to validate the aseptic techniques of compounding personnel and ensure that the processes employed would produce sterile drugs without microbial contamination. Compounding personnel were required to perform media-fill testing prior to performing any sterile compounding, and semiannually thereafter.

32. USP-797 required gloved-fingertip sampling of all compounding personnel to monitor any microbial contamination on the gloved-hands of compounding personnel. USP-797 identified direct touch contamination as the most likely means of introducing microorganisms into sterile drugs. If personnel gloved-fingertip sampling revealed contamination above an "action" level, USP-797 required a review of hand hygiene and garbing procedures, glove and surface disinfection procedures, and work practices. If the personnel gloved-fingertip sampling consistently revealed elevated levels of microbial growth, USP-797 required the compounding facility to consult with competent microbiology personnel. If the personnel gloved-fingertip sampling revealed highly pathogenic microorganisms that could be potentially fatal to patients

receiving the sterile drugs, such as mold, USP-797 required the compounding facility to immediately remedy the issue, regardless of whether an "action" level was reached, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

COUNT 1
(18 U.S.C. § 1962(c) – Racketeering)

[DEFENDANTS (1) CADDEN, (2) CHIN, (3) SVIRSKIY, (4) LEARY, (5) EVANOSKY, (6) CONNOLLY]

33. The allegations contained in paragraphs 1 through 8, and 17 through 32 are re-alleged and incorporated herein by reference.

The Enterprise

34. NECC and MSM constituted an "enterprise" as defined by Title 18, United States Code, Section 1961(4) (hereinafter, "the enterprise"), that is, a group of legal entities associated in fact. The enterprise constituted an ongoing organization whose members functioned as a continuing unit for a common purpose of achieving the objectives of the enterprise, which was to obtain money and property including through the means of materially false and fraudulent pretenses, representations, and promises. The enterprise was engaged in, and its activities affected, interstate and foreign commerce.

Manner and Means of the Enterprise

MSM's Representations to Customers

35. NECC's primary business was high-risk compounding, that is, using non-sterile ingredients to create sterile drugs. Defendant (1) **CADDEN** instructed the MSM sales force to falsely represent to customers that NECC was providing the highest quality compounded medications. MSM's sales force and its marketing materials distributed to hospitals and medical facilities throughout the country falsely claimed NECC was USP-797 compliant, meaning that it

met the USP standards for compounding sterile drugs. MSM's marketing materials also falsely claimed that NECC had a strictly enforced environmental monitoring program and a comprehensive end-product testing program for its drugs. Each quarter, MSM issued a Quality Assurance Report Card ("QA Report Card") to NECC customers signed by defendant (1) **CADDEN**. The QA Report Cards for the first and second quarters of 2012 falsely reported environmental monitoring results at NECC during the respective quarters. The QA Report Card for the second quarter of 2012 also falsely listed no sterility, endotoxin, or other out-of-specification test results from the testing of NECC's drugs during the time period.

NECC's Production Practices

36. NECC's production of purportedly sterile drugs by the pharmacists and pharmacy technicians in Clean Rooms 1 and 2 failed to comply with the standards of the USP and the regulations promulgated by the MABOP in several ways, including:

a. Beginning in at least 2008 and continuing until in or around October 2012, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** used, caused others to use, and approved the use of expired and expiring ingredients in the compounding of purportedly sterile drugs in violation of USP-797. To conceal the use of the expired ingredients from regulators, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** completed, caused others to complete, and approved the completion of written documentation with fictitious expiration dates.

b. Beginning in at least 2009 and continuing until in or around October 2012, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** used, caused others to use, and approved the use of expired or expiring stock solutions in the compounding of purportedly sterile drugs and to fill customer orders in violation of USP-797. To

conceal the use of the expired or expiring stock solutions from regulators, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** labeled, caused others to label, and approved the labeling of the final drugs with a new NECC lot number and BUD.

c. Beginning in at least 2009 and continuing until in or around October 2012, defendants (1) **CADDEN**, (2) **CHIN**, (4) **LEARY**, and (5) **EVANOSKY** failed and caused others to fail to properly sterilize drugs in violation of USP-797. Drugs were routinely autoclaved for a period of 15 to 17 minutes in duration, less than the 20-minute duration identified in NECC's formulation worksheets for specific drugs and USP-797. Defendants (1) **CADDEN**, (2) **CHIN**, (4) **LEARY**, and (5) **EVANOSKY** never verified and caused others to verify the effectiveness of the sterilization process through the use of a biological indicator as required by USP-797.

d. Beginning in at least 2009 and continuing until in or around October 2012, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** mixed, caused others to mix, and approved the mixing of stock solutions of different drug lots to fill customer orders in violation of USP-797. The mixing of the lots was done to fill orders and conceal the use of an expiring older lot or the use of a newer lot that had not been tested. For stock drug products, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, and (4) **LEARY** falsely labeled, caused others to falsely label, and approved the false labeling of drugs sent to customers with either the newer lot number in the case of an expiring older lot, or the older lot number in the case of an untested newer lot. For custom drug products, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** labeled, caused others to label, and approved the labeling of drugs sent to customers with a new, third NECC lot number for the specific customer order.

e. Beginning in at least 2006 and continuing until in or around October 2012, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** failed and caused others to fail to properly test drugs for sterility in violation of USP-797. Only two samples of each batch of drugs were taken for testing regardless of the size of the batch; only one of the two samples was sent for sterility testing. Defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** also sampled, caused others to sample, and approved the sampling from batches of stock solutions, and not the filled vials, of drugs that NECC shipped to customers for patient use.

f. Beginning in at least 2008 and continuing until in or around October 2012, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** caused shipments to NECC customers of purportedly sterile drugs that were never tested and for which test results had not yet been received. The physicians and patients were not notified of the potential risk of using the untested drugs. In circumstances in which microbial growth was later detected in sterility tests, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** never instituted a recall, and never notified the physicians or patients to whom the drugs were sent of the adverse results.

g. Beginning in or around March 2010 and continuing until in or around August 2012, defendant (6) **CONNOLLY**, who had voluntarily surrendered his pharmacy technician license in or around January 2009, worked as a pharmacy technician in Clean Room 2 filling cardioplegia drugs for hospital customers. Cardioplegia drugs were used for the intentional and temporary cessation of cardiac activity during cardiac surgery. Defendant (6) **CONNOLLY**'s unlicensed status was known to defendants (1) **CADDEN**, (2) **CHIN**, and (3) **SVIRSKIY**. Defendant (6) **CONNOLLY** was supervised by defendants (2) **CHIN** and (3) **SVIRSKIY**.

Defendant (6) **CONNOLLY** supervised the other pharmacy technicians in Clean Room 2. To conceal his presence from regulators, defendant (6) **CONNOLLY** operated the equipment in Clean Room 2 using defendant (1) **CADDEN**'s username and password. During his time working as a pharmacy technician at NECC, defendant (6) **CONNOLLY** was not administered a media-fill test to verify his aseptic technique.

NECC's Cleaning and Disinfecting Practices

37. NECC's cleaning and disinfecting practices in Clean Rooms 1 and 2 failed to comply with the standards of USP-797 and the regulations promulgated by the MABOP in several ways, including:

a. Beginning in at least 2009 and continuing until in or around October 2012, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** failed and caused others to fail to properly clean and disinfect Clean Rooms 1 and 2 as required by USP-797.

b. Defendant (2) **CHIN** instructed pharmacy technicians working in Clean Room 1 under his supervision to prioritize production over cleaning and disinfecting. Accordingly, cleaning and disinfecting tasks in Clean Room 1 were often either poorly completed or not completed at all.

c. Beginning in at least 2010 and continuing until in or around October 2012, defendant (2) **CHIN** instructed pharmacists and pharmacy technicians working in Clean Room 1 under his supervision to fraudulently complete cleaning logs at the end of the month purporting to show that NECC Clean Room 1 was properly cleaned and disinfected.

d. Beginning in at least January 2012, NECC's surface and air sampling produced alert-level and action-level results from throughout the Clean Room 1 suite of rooms – the main

clean room, the gown room, the crimp room, and the prep room. Moreover, beginning in at least January 2012, NECC's personnel gloved-fingertip sampling revealed the presence of microorganisms on the hands of NECC compounding personnel, including defendants (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY**, while compounding and filling drugs, including within the glove boxes in Clean Room 1. From January 2012 through September 2012, NECC's surface and air sampling and personnel gloved-fingertip sampling from the Clean Room 1 suite of rooms produced the following results:

Week	Surface Sampling Action/Alert	Microorganisms Listed	Air Sampling Action/Alert	Gloved-Fingertip Sampling Results
1/06/2012	Action	Mold	Not tested	1 technician
1/12/2012	Action	Bacteria	Action	—
1/19/2012	Alert	—	Not tested	—
1/26/2012	Action	Bacteria/Mold	Action	—
2/02/2012	Action	Bacteria/Mold	Not tested	**(5) EVANOSKY**
2/08/2012	Action	—	Alert	—
2/16/2012	Action	Bacteria/Mold	Not tested	—
2/23/2012	Action	Bacteria/Mold	Action	**(2) CHIN** and 3 technicians
3/01/2012	Action	Bacteria/Mold	Not tested	—
3/08/2012	Action	Bacteria/Mold	Alert	1 technician
3/15/2012	Action	Bacteria/Mold	Not tested	1 technician
3/22/2012	Action	—	Alert	**(3) SVIRSKIY**
3/29/2012	Action	Bacteria/Mold	Not tested	**(3) SVIRSKIY**
4/5/2012	Action	Mold	Action	**(5) EVANOSKY**
4/12/2012	Action	Bacteria/Mold	Not tested	**(4) LEARY** and 1 technician
4/20/2012	Action	—	—	1 technician
4/26/2012	Action	—	Not tested	—
5/3/2012	Action	—	Action	—

Week	Surface Sampling Action/Alert	Microorganisms Listed	Air Sampling Action/Alert	Gloved-Fingertip Sampling Results
5/10/2012	Action	Bacteria/Mold	Not tested	—
5/17/2012	Action	—	Action	—
5/24/2012	Action	Bacteria/Mold	Not tested	—
5/31/2012	Action	Bacteria/Mold	Action	—
6/7/2012	Action	Bacteria	Not tested	1 technician
6/13/2012	Action	Bacteria/Mold	Alert	1 technician
6/21/2012	Action	Mold	Not tested	—
6/28/2012	Action	Bacteria/Mold	Action	2 technicians
7/5/2012	Action	Mold	Not tested	—
7/12/2012	Action	Mold	Action	**(3) SVIRSKIY** and 2 technicians
7/18/2012	Action	—	Not tested	2 technicians
7/26/2012	Action	Mold	Action	**(2) CHIN, (5) EVANOSKY**, and 1 technician
8/2/2012	Action	Bacteria/Mold	Not tested	1 technicians
8/9/2012	Action	Bacteria	Action	2 technicians
8/16/2012	Action	—	Not tested	**(4) LEARY**
8/23/2012	Action	Mold	Action	1 technician
8/30/2012	Action	—	Not tested	**(5) EVANOSKY**
9/6/2012	Action	—	Action	—
9/13/2012	Action	Bacteria/Mold	Not tested	1 technician
9/20/2012	Action	Bacteria/Mold	Action	2 technicians

e. Defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** were notified of action-level sampling hits from the Clean Room 1 rooms.

f. Despite the action-level sampling hits recorded in thirty-seven out of thirty-eight weeks in 2012, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** did not conduct a re-evaluation of their practices and procedures as required

by USP-797. Defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** did not conduct an investigation into the source of the contamination as required by USP-797. Defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** did not consult with a competent microbiologist, infection control professional, or industrial hygienist regarding the mold consistently found in the Clean Room 1 rooms during 2012 as required by USP-797.

The Racketeering Violation

38. From in at least 2006 and continuing until in or around October 2012, within the District of Massachusetts and elsewhere, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, and (6) **CONNOLLY**, along with others known and unknown to the Grand Jury, being persons employed by and associated with the enterprise described above, which enterprise was engaged in and the activities of which affected interstate commerce, did knowingly and unlawfully conduct and participate, directly and indirectly, in the conduct of the affairs of that enterprise, through the pattern of racketeering activity set forth below in paragraphs 39 through 71.

The Pattern of Racketeering Activity

39. The pattern of racketeering activity as defined in Title 18, United States Code, Section 1961(1) and 1961(5), consisted of the following acts:

Racketeering Acts 1 through 52: Methylprednisolone Acetate

40. The defendants named below committed the below-described Racketeering Acts:

Racketeering Acts 1 through 27: Mail Fraud

The Scheme

41. From in or around May 2012 to in or around October 2012, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN** devised and intended to devise a scheme and artifice to defraud NECC's customers and the patients of those customers and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises.

42. The purpose of the scheme and artifice to defraud was to enrich defendants (1) **CADDEN** and (2) **CHIN** and NECC, by selling for a profit to NECC's customers and the patients of those customers, preservative-free methylprednisolone acetate 80 mg/ml, a steroid labeled as injectable, which was made in a manner that did not meet the standards set forth in the USP and, therefore, could not be labeled and sold as a sterile drug.

The 05212012@68 Lot

43. It was part of the scheme and artifice to defraud that on or about May 21, 2012, defendant (2) **CHIN**, acting under the direction of defendant (1) **CADDEN**, compounded a 12.5 liter stock lot of preservative-free methylprednisolone acetate 80 mg/ml with lot number 05212012@68 (the "05212012@68 lot") in Clean Room 1. Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, attempted to sterilize the 05212012@68 lot in the autoclave for 15 minutes and 4 seconds, rather than 20 minutes as stated in the written formula instructions and USP-797. Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, did not verify the sterilization process used for the 05212012@68 lot through the use of a biological indicator as required by USP-797.

44. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN** filled two 5 milliliter vials from the batch of the 05212012@68 lot to be sent to an independent laboratory for testing. On or about June 5, 2012, based on a single 5 milliliter vial, the independent laboratory issued a report indicating the 05212012@68 lot was sterile. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN** directed pharmacy technicians to fill and supervised pharmacy technicians in filling vials with the 05212012@68 lot on repeated occasions to fulfill NECC's customer orders. Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, did not conduct any sterility testing of the filled vials of the 05212012@68 lot, which NECC shipped to customers for patient use.

45. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, directed pharmacy technicians and other NECC personnel to label the vials filled with the 05212012@68 lot as injectable. During the time that the 05212012@68 lot was compounded and filled, NECC recorded action-level environmental sampling results every week in the Clean Room 1 rooms but did not take any action to remediate the issues as required by USP-797.

46. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, directed that filled vials of the 05212012@68 lot be sent out of Clean Room 1 for shipment by private and commercial interstate carrier to NECC's customers for use on the patients of those customers. From on or about June 8, 2012, through on or about July 27, 2012, approximately 6,500 vials labeled as the 05212012@68 lot were sent to NECC's customers throughout the country.

The 06292012@26 Lot

47. It was part of the scheme and artifice to defraud that on or about June 29, 2012, defendant (2) **CHIN**, acting under the direction of defendant (1) **CADDEN**, compounded a 12.5 liter stock lot of preservative-free methylprednisolone acetate 80 mg/ml with lot number 06292012@26 (the "06292012@26 lot"). Defendant (2) **CHIN,** with the knowledge of defendant (1) **CADDEN**, attempted to sterilize the 06292012@26 lot in the autoclave for 15 minutes and 5 seconds, rather than 20 minutes as stated in the written formula instructions and USP-797. Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, did not verify the sterilization process used for the 06292012@26 lot through the use of a biological indicator as required by USP-797.

48. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN** filled two 5 milliliter vials from the stock of the 06292012@26 lot to be sent to an independent laboratory for sterility testing. On or about July 17, 2012, based on a single 5 milliliter vial, the independent laboratory issued a report indicating the 06292012@26 lot was sterile. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN** directed pharmacy technicians to fill and supervised pharmacy technicians in filling vials with the 06292012@26 lot on repeated occasions to fulfill NECC's customer orders. Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, did not conduct sterility testing of the filled vials of the 06292012@26 lot, which NECC shipped to customers for patient use.

49. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, directed pharmacy technicians and other NECC personnel to label the vials filled with the 06292012@26 lot as injectable. During the time that the 06292012@26 lot was compounded and filled, NECC recorded action-level environmental

sampling results every week in the Clean Room 1 rooms but did not take any action to remediate the issues as required by USP-797.

50. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN,** with the knowledge of defendant (1) **CADDEN**, directed that filled vials of the 06292012@26 lot be sent out of Clean Room 1 for shipment by private and commercial interstate carrier to NECC's customers for use on the patients of those customers. From on or about July 16, 2012, through on or about August 27, 2012, approximately 6,200 vials labeled as the 06292012@26 lot were sent to NECC's customers throughout the country.

The 08102012@51 Lot

51. It was part of the scheme and artifice to defraud that on or about August 10, 2012, defendant (2) **CHIN**, acting under the direction of defendant (1) **CADDEN**, compounded a 12.5 liter stock lot of preservative-free methylprednisolone acetate 80 mg/ml with lot number 08102012@51 (the "08102012@51 lot"). Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, attempted to sterilize the 08102012@51 lot in the autoclave for 15 minutes and 4 seconds, rather than 20 minutes as stated in the written formula instructions and USP-797. Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, did not verify the sterilization process used for the 08102012@51 lot through the use of a biological indicator as required by USP-797.

52. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN** filled two 5 milliliter vials from the stock of the 08102012@51 lot to be sent to an independent laboratory for sterility testing. On or about August 28, 2012, based on a single 5 milliliter vial, the independent laboratory issued a report indicating the 08102012@51 lot was sterile. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN** directed pharmacy

technicians to fill and supervised pharmacy technicians in filling vials with the 08102012@51 lot on repeated occasions to fulfill NECC's customer orders. Defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, did not conduct sterility testing of the filled vials of the 08102012@51 lot, which NECC shipped to customers for patient use.

53. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, directed pharmacy technicians and other NECC personnel to label the vials filled with the 08102012@51 lot as injectable. During the time that the 08102012@51 lot was compounded and filled, NECC recorded action-level environmental sampling hits every week in the Clean Room 1 rooms but did not take any action to remediate the issues as required by USP-797.

54. It was further part of the scheme and artifice to defraud that defendant (2) **CHIN**, with the knowledge of defendant (1) **CADDEN**, directed that filled vials of the 08102012@51 lot be sent out of Clean Room 1 for shipment by private and commercial interstate carrier to NECC's customers for use on the patients of those customers. From on or about August 17, 2012, through on or about September 25, 2012, approximately 4,600 vials labeled as the 08102012@51 lot were sent to NECC's customers throughout the country.

The Mailings

55. On or about the dates listed below, defendants (1) **CADDEN** and (2) **CHIN**, having devised and intending to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, for the purpose of executing such scheme and artifice and attempting to do so, deposited and caused to be deposited matters and things – to wit, vials of the 05212012@68, 06292012@26, and

08102012@51 lots, each labeled as injectable – to be sent and delivered by private and commercial interstate carrier to NECC's customers and the patients of those customers as specified below:

Racketeering Act	Date	Description	Destination
1	8/8/2012	400 5 ml vials of 06292012@26	Michigan Pain Specialists, Brighton, Michigan
2 3	7/17/2012 8/14/2012	100 1 ml vials of 06292012@26 120 1 ml vials of 06292012@26	Specialty Surgery Center, Crossville, Tennessee
4 5 6 7	6/27/2012 7/25/2012 8/13/2012 9/4/2012	500 1 ml vials of 05212012@68 500 1 ml vials of 06292012@26 500 1 ml vials of 06292012@26 500 1 ml vials of 08102012@51	St. Thomas Outpatient Neurological Center, Nashville, Tennessee
8 9 10 11 12	6/25/2012 7/16/2012 8/2/2012 8/28/2012 9/17/2012	125 1 ml vials of 05212012@68 125 1 ml vials of 05212012@68 150 1 ml vials of 06292012@26 130 1 ml vials of 08102012@51 100 1 ml vials of 08102012@51	OSMC Outpatient Surgery Center, Elkhart, Indiana
13 14	8/15/2012 9/25/2012	100 1 ml vials of 06292012@26 100 1 ml vials of 08102012@51	South Bend Clinic, South Bend, Indiana
15 16	7/5/2012 8/15/2012	150 1 ml vials of 05212012@68 150 1 ml vials of 06292012@26	Marion Pain Management, Ocala, Florida
17 18	8/13/2012 9/25/2012	85 5 ml vials of 06292012@26 300 1 ml vials of 08102012@51	Box Hill Surgery Center, Abingdon, Maryland
19 20 21 22	7/9/2012 7/26/2012 8/17/2012 9/7/2012	200 1 ml vials of 05212012@68 200 1 ml vials of 06292012@26 200 1 ml vials of 06292012@26 200 1 ml vials of 08102012@51	Insight Imaging, Roanoke, Virginia
23 24 25 26 27	6/25/2012 7/13/2012 8/7/2012 8/14/2012 9/20/2012	20 1 ml vials of 05212012@68 20 1 ml vials of 05212012@68 40 1 ml vials of 06292012@26 80 1 ml vials of 06292012@26 60 1 ml vials of 08102012@51	High Point Surgery Center, High Point, North Carolina

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

Racketeering Acts 28 through 35: Second Degree Murder – Michigan

56. On or about the dates listed below, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN**, acting in wanton and willful disregard of the likelihood that the natural tendency of their actions would cause death or great bodily harm, caused the deaths of the individuals listed below, that is, the individuals died as a result of receiving injections of the 06292012@26 lot of methylprednisolone acetate made and sold by NECC:

Racketeering Act	Date of Injection	Individual	Location of Injection	Date of Death
28	8/16/2012	Karina Baxter	Brighton, Michigan	9/23/2012
29	8/20/2012	Paula Brent	Brighton, Michigan	11/17/2012
30	8/29/2012	Gayle Gipson	Brighton, Michigan	10/26/2012
31	8/21/2012	Donna Kruzich	Brighton, Michigan	10/8/2012
32	9/6/2012	Lyn Laperriere	Brighton, Michigan	10/17/2012
33	8/16/2012	Mary Plettl	Brighton, Michigan	11/3/2012
34	9/18/2012	Sally Roe	Brighton, Michigan	10/18/2012
35	9/10/2012	Emma Todd	Brighton, Michigan	3/22/2013

All in violation of Chapter 750, Michigan Compiled Laws, Section 317 and Chapter 767, Michigan Compiled Laws, Section 39.

Racketeering Acts 36 through 42: Second Degree Murder – Tennessee

57. On or about the dates listed below, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN** knowingly, that is, acting with an awareness that their conduct was reasonably certain to cause death, and unlawfully killed the individuals listed below, that is, the individuals died as a result of receiving injections of the 05212012@68, 06292012@26, and 08102012@51 lots of methylprednisolone acetate made and sold by NECC:

Racketeering Act	Date of Injection(s)	Individual	Location of Injection	Date of Death
36	8/31/2012	Marie Hester	Nashville, Tennessee	11/1/2012
37	7/27/2012 8/17/2012 8/31/2012	Eddie Lovelace	Nashville, Tennessee	9/17/2012
38	8/29/2012 9/26/2012	Donald McDavid	Crossville, Tennessee	11/4/2012
39	8/21/2012 9/4/2012 9/18/2012	Diana Reed	Nashville, Tennessee	10/3/2012
40	7/30/2012	Thomas Rybinski	Nashville, Tennessee	9/29/2012
41	9/17/2012	Carol Wetton	Nashville, Tennessee	4/16/2013
42	8/23/2012	Earline Williams	Nashville, Tennessee	10/15/2012

All in violation of Title 39, Tennessee Code, Sections 13-210, 11-302, and 11-402.

Racketeering Acts 43 through 45: Second Degree Murder – Indiana

58. On or about the dates listed below, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN**, knowingly, that is, acting with an awareness of a high probability that their conduct would result in death, killed the individuals listed below, that is, the individuals died as a result of receiving injections of the 05212012@68, 06292012@26, and 08102012@51 lots of methylprednisolone acetate made and sold by NECC, and defendants (1) **CADDEN** and (2) **CHIN** have committed other murders:

Racketeering Act	Date of Injection(s)	Individual	Location of Injection	Date of Death
43	8/22/2012 9/7/2012	Pauline Burema	Elkhart, Indiana	10/10/2012
44	9/14/2012	Kathy Dillon	Elkhart, Indiana	11/5/2012

Racketeering Act	Date of Injection(s)	Individual	Location of Injection	Date of Death
45	9/6/2012 10/1/2012	Alice Machowiak	South Bend, Indiana	12/10/2012

All in violation of Title 35, Indiana Code, Sections 42-1-1, 41-2-2, 50-2-9, and 41-2-4.

Racketeering Acts 46 through 48: Second Degree Murder – Maryland

59. On or about the dates listed below, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN** created a very high degree of risk to the lives of the individuals listed below, and, conscious of such risk, acted with extreme disregard of the life-endangering consequences, thereby causing the deaths of the individuals listed below, that is, the individuals died as a result of receiving injections of the 06292012@26 and 08102012@51 lots of methylprednisolone acetate made and sold by NECC:

Racketeering Act	Date of Injection(s)	Individual	Location of Injection	Date of Death
46	9/5/2012	Bahman Kashi	Abingdon, Maryland	1/28/2013
47	8/31/2012	Brenda Rozek	Abingdon, Maryland	9/16/2012
48	7/20/2012 8/24/2012	Edna Young	Abingdon, Maryland	12/31/2012

All in violation of Title 2, Maryland Code, Section 204 and Title 4, Maryland Code, Section 204.

Racketeering Acts 49 through 50: Second Degree Murder – Virginia

60. On or about the dates listed below, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN** willfully and purposefully embarked upon a course of wrongful conduct likely to cause death and great bodily harm, and unlawfully killed the individuals listed below, that is, the individuals died as a result of receiving injections of the

05212012@68, 06292012@26, and 08102012@51 lots of methylprednisolone acetate made and sold by NECC:

Racketeering Act	Date of Injection(s)	Individual	Location of Injection	Date of Death
49	8/13/2012 9/19/2012	Kathy Sinclair	Roanoke, Virginia	1/19/2013
50	9/6/2012	Douglas Wingate	Roanoke, Virginia	9/18/2012

All in violation of Title 18.2, Virginia Code, Sections 32 and 18.

Racketeering Act 51: Second Degree Murder – Florida

61. On or about the dates listed below, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN**, acting imminently dangerous to another and demonstrating a depraved mind without regard for human life, unlawfully killed the individual listed below, that is, the individual died as a result of receiving an injection of the 06292012@26 lot of methylprednisolone acetate made and sold by NECC:

Racketeering Act	Date of Injection	Individual	Location of Injection	Date of Death
51	9/6/2012	Godwin Mitchell	Ocala, Florida	3/18/2013

All in violation of Florida Code, Sections 782.04(2) and 777.011.

Racketeering Act 52: Second Degree Murder – North Carolina

62. On or about the dates listed below, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN** and (2) **CHIN**, acting in a manner inherently dangerous to human life so recklessly and wantonly as to manifest a mind utterly without regard for human life and social duty and deliberately bent on mischief, unlawfully killed the individual listed below, that is, the

individual died as a result of receiving an injection of the 06292012@26 lot of methylprednisolone acetate made and sold by NECC:

Racketeering Act	Date of Injection	Individual	Location of Injection	Date of Death
52	8/28/2012	Elwina Shaw	High Point, North Carolina	10/19/2012

All in violation of North Carolina General Statutes Sections 14-17(b) and 14-5.2.

Racketeering Acts 53-63: Shipments of Untested Lots

63. The defendants named below committed the below-described Racketeering Acts:

Racketeering Acts 53-63: Mail Fraud

The Scheme

64. From in or around July 2012 through October 2012, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, and (5) **EVANOSKY** devised and intended to devise a scheme and artifice to defraud NECC's customers and the patients of those customers, and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, in that NECC shipped to its customers throughout the country drugs identified as sterile and containing certain ingredients prior to receiving the results of testing confirming the sterility and quality of the drugs. NECC failed to inform its customers that independent sterility testing had not yet been completed at the time of the shipments. In instances in which the independent laboratory issued non-sterile or otherwise out-of-specification results, NECC failed to notify the customers of the results, institute a recall, and conduct an investigation into the source of the results as required by USP-797.

The Mailings

65. On or about the dates listed below, the defendants listed below, having devised and intending to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, for the purpose of executing such scheme and artifice and attempting to do so, deposited and caused to be deposited matters and things – to wit, untested drugs identified as sterile and containing certain ingredients – to be sent and delivered by private and commercial interstate carrier to NECC's customers to be used on the patients of those customers as set forth below:

Racketeering Act	Defendants	Date of Shipment	Description	Destination	Testing Result
53	(1) **CADDEN**, (2) **CHIN**	7/24/2012	150 bacitracin 20 ml syringes	Good Shepherd Hospital, Barrington, Illinois	Not sterile
54	(1) **CADDEN**, (3) **SVIRSKIY**	8/7/2012	18 polymyxin-bacitracin irrigation bags	Glens Falls Hospital, Glens Falls, New York	Not sterile
55	(1) **CADDEN**, (4) **LEARY**	8/27/2012	18 polymyxin-bacitracin irrigation bags	Glens Falls Hospital, Glens Falls, New York	Not sterile
56	(1) **CADDEN**, (5) **EVANOSKY**	8/28/2012	20 polymyxin-bacitracin irrigation bags	Winchester Hospital, Winchester, Virginia	Not sterile
57	(1) **CADDEN**, (5) **EVANOSKY**	8/30/2012	20 polymyxin-bacitracin irrigation bags	Winchester Hospital, Winchester, Virginia	Not sterile
58	(1) **CADDEN**, (2) **CHIN**	9/11/2012	100 potassium chloride injectables	Port Huron Hospital, Port Huron, Michigan	Not sterile

Racketeering Act	Defendants	Date of Shipment	Description	Destination	Testing Result
59	(1) **CADDEN**, (5) **EVANOSKY**	9/24/2012	50 cardioplegia solution (low-K)	Brigham and Women's Hospital, Boston, Massachusetts	Not sterile
60	(1) **CADDEN**, (2) **CHIN**	9/27/2012	60 potassium chloride bags	Sentara Norfolk General Hospital, Norfolk, Virginia	Not sterile
61	(1) **CADDEN**, (4) **LEARY**	2/23/2012	300 lidocaine-bupivacaine-hyaluronidase injections	Massachusetts Eye and Ear Institute, Boston, Massachusetts	Sub-potent
62	(1) **CADDEN**, (4) **LEARY**	8/21/2012	50 55 ml pericapsular injections	Oakleaf Surgical Hospital, Eau Claire, Wisconsin	Missing epinephrine
63	(1) **CADDEN**, (4) **LEARY**, (5) **EVANOSKY**	9/17/2012	15 clindamycin-gentamicin-polymyxin bags	Florida Hospital Waterman, Tavares, Florida	Missing polymyxin

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

Racketeering Acts 64-68: Shipments of Expired Drugs

66. The defendants named below committed the below-described Racketeering Acts:

Racketeering Acts 64-68: Mail Fraud

The Scheme

67. From in or around January 2008 through July 2012, in the District of Massachusetts and elsewhere, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, and (4) **LEARY** devised and intended to devise a scheme and artifice to defraud NECC's customers and the patients of those customers and to obtain money and property by means of materially false and fraudulent

pretenses, representations, and promises, in that they made drugs using an ingredient that had expired on or about January 23, 2007, in violation of USP-797. To mask the use of the expired ingredient, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, and (4) **LEARY** completed, caused others to complete, and approved the completion of written documentation with fictitious expiration dates. Defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, and (4) **LEARY** caused the drugs to be shipped to NECC's customers throughout the country without notifying them of the use of the expired ingredient. The drugs were labeled with fictitious BUDs indicating expiration dates three to six months after the date the drugs were made.

The Mailings

68. On or about the dates listed below, the defendants listed below, having devised and intending to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, for the purpose of executing such scheme and artifice and attempting to do so, deposited and caused to be deposited matters and things – to wit, drugs made with an expired ingredient in violation of USP-797 – to be sent and delivered by private and commercial interstate carrier to NECC's customers to be used on the patients of those customers as set forth below:

Racketeering Act	Defendants	Date of Shipment	Description	Destination
64	(1) **CADDEN**, (3) **SVIRSKIY**	7/7/2011	6 25 mg/ml methotrexate injectables	USC University Hospital, Los Angeles, California
65	(1) **CADDEN**, (4) **LEARY**	7/8/2011	8 4 mg/ml methotrexate injectables	Augusta Eye Associates, Fisherville, Virginia

Racketeering Act	Defendants	Date of Shipment	Description	Destination
66	(1) **CADDEN**, (2) **CHIN**	10/31/2011	6 25 mg/ml methotrexate injectables	Southboro Medical Group, Southboro, Massachusetts
67	(1) **CADDEN**, (2) **CHIN**	2/15/2012	25 25 mg/ml methotrexate injectables	Decatur Memorial Hospital, Decatur, Illinois
68	(1) **CADDEN**, (2) **CHIN**, (4) **LEARY**	6/8/2012	10 4 mg/ml methotrexate injectables	Retina Group of Washington, Chevy Chase, Maryland

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

Racketeering Acts 69-78: Unlicensed Pharmacy Technician

69. The defendants named below committed the below-described Racketeering Acts:

Racketeering Acts 69-78: Mail Fraud

The Scheme

70. From in or around March 2010 to in or around August 2012, in the District of Massachusetts and elsewhere, the defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, and (6) **CONNOLLY** devised and intended to devise a scheme and artifice to defraud NECC's customers and the patients of those customers and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, in that NECC represented to its customers that it complied with Massachusetts pharmacy regulations even though defendant (6) **CONNOLLY**, who had voluntarily surrendered his pharmacy technician license in or about January 2009, worked as a pharmacy technician in Clean Room 2 filling cardioplegia orders for hospital customers in violation of Massachusetts law. To conceal his presence from regulators,

defendant (6) **CONNOLLY** operated the equipment in Clean Room 2 using defendant (1) **CADDEN**'s username and password.

The Mailings

71. On or about the dates listed below, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, and (6) **CONNOLLY**, having devised and intending to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, for the purpose of executing such scheme and artifice and attempting to do so, deposited and caused to be deposited matters and things – to wit, drugs made by an unlicensed pharmacy technician – to be sent and delivered by private and commercial interstate carrier to NECC's customers to be used on the patients of those customers as set forth below:

Racketeering Act	Defendants	Date of Shipment	Description	Destination
69	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	3/25/2010	7 cardioplegia solution bags	Lewis-Gale Medical Center, Salem, Virginia
70	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	10/21/2010	10 cardioplegia (cold induction high K) bags	Osceola Regional Medical Center, Kissimmee, Florida
71	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	12/21/2010	10 cardioplegia solution bags	Baptist Medical Center, Jacksonville, Florida

Racketeering Act	Defendants	Date of Shipment	Description	Destination
72	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	3/30/2011	8 cardioplegia solution bags	North Shore Medical Center, Salem, Massachusetts
73	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	6/29/2011	20 cardioplegia (high K) solution bags	Sunrise Medical Center, Las Vegas, Nevada
74	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	11/15/2011	10 cardioplegia (induction formula) bags	St. Vincent's Hospital, Birmingham, Alabama
75	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	2/22/2012	20 cardioplegia (high K) solution bags	Sunrise Medical Center, Las Vegas, Nevada
76	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	6/4/2012	30 cardioplegia (cold induction) bags	St. Peter's Hospital, Albany, New York
77	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	7/12/2012	25 cardioplegia solution bags	West Virginia University, Morgantown, West Virginia
78	(1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (6) **CONNOLLY**	8/8/2012	20 cardioplegia (high K) solution bags	Sunrise Medical Center, Las Vegas, Nevada

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

All of the above done in violation of Title 18, United States Code, Section 1962(c).

COUNT 2
(18 U.S.C. § 1962(d) – Racketeering Conspiracy)

[DEFENDANTS (1) CADDEN, (2) CHIN, (3) SVIRSKIY, (4) LEARY, (5) EVANOSKY, (6) CONNOLLY, (7) CARTER, (8) STEPANETS]

72. The allegations contained in paragraphs 1 through 10, 17 through 32, and 34 through 37 are re-alleged and incorporated herein by reference.

73. Beginning in at least 2006 and continuing until in or around October 2012, within the District of Massachusetts and elsewhere, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, (6) **CONNOLLY**, (7) **CARTER**, and (8) **STEPANETS**, along with others known and unknown to the Grand Jury, being persons employed by and associated with the enterprise described above, which enterprise was engaged in and the activities of which affected interstate commerce, unlawfully and knowingly conspired to violate Title 18, United States Code, Section 1962(c), that is, to conduct and participate, directly and indirectly, in the conduct of the affairs of that enterprise through a pattern of racketeering activity, as that term is defined by Title 18, United States Code, Sections 1961(1) and (5), consisting of multiple acts indictable under Title 18, United States Code, Section 1341 (mail fraud).

Manner and Means of the Conspiracy

74. It was part of the conspiracy that defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, and (6) **CONNOLLY** defrauded NECC's customers and the patients of those customers, by selling for a profit: purportedly sterile drugs that were made and tested in a manner that did not meet the standards set forth in USP-797 and USP-71; untested drugs identified as sterile and containing certain ingredients that were made in violation of USP-797 and tested in violation of USP-71; drugs made with an expired ingredient in violation of USP-797; and drugs made by an unlicensed pharmacy technician in violation of Massachusetts

law. It was further part of the conspiracy that defendants (7) **CARTER** and (8) **STEPANETS** knowingly confirmed and authorized shipments of orders to be sent to NECC customers of drugs that were improperly tested, drugs for which test results had not yet been received, drugs that were not tested at all, and drugs that were made with an expired ingredient.

75. It was further part of the conspiracy that defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, (6) **CONNOLLY**, (7) **CARTER**, and (8) **STEPANETS** each agreed that a conspirator would commit at least two acts of racketeering in the conduct of the affairs of the enterprise.

All done in violation of Title 18, United States Code, Section 1962(d).

COUNT 3
(18 U.S.C. § 371 – Conspiracy to Defraud the United States)

[DEFENDANTS (1) CADDEN, (7) CARTER, (8) STEPANETS, (9) GREG CONIGLIARO, (10) RONZIO]

76. The allegations contained in paragraphs 1 through 3, and 9 through 12 are re-alleged and incorporated herein by reference.

77. From in or around 1998, the exact date being unknown to the Grand Jury, through in or around October 2012, within the District of Massachusetts and elsewhere, defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, (9) **GREG CONIGLIARO**, and (10) **RONZIO**, knowingly and willfully conspired and agreed together and with each other, and with other persons known and unknown to the Grand Jury, to defraud the United States of and concerning its governmental functions and rights, hereinafter described, that is, of and concerning its right to have its business and its affairs, and particularly the transaction of the official business of the Food and Drug Administration ("FDA"), conducted honestly and impartially, free from corruption, fraud, improper and undue influence, dishonesty, unlawful impairment, and obstruction.

Manner and Means of the Conspiracy

78. It was part of the conspiracy that defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, (9) **GREG CONIGLIARO**, and (10) **RONZIO** would, by deceit, craft, trickery, and dishonest means, defraud the United States by interfering with and obstructing the lawful governmental functions of the FDA, in that defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, (9) **GREG CONIGLIARO**, and (10) **RONZIO** purported to be operating NECC as a state-regulated pharmacy, dispensing drugs pursuant to valid, patient-specific prescriptions as required by Massachusetts law, rather than as a drug manufacturer distributing drugs in bulk to customers without prescriptions and thereby subject to heightened regulatory oversight by the FDA.

79. It was further part of the conspiracy that defendants (1) **CADDEN** and (9) **GREG CONIGLIARO** falsely represented to the FDA and the MABOP that NECC, as a pharmacy, dispensed drugs only upon receipt of valid, patient-specific prescriptions as required by Massachusetts law. Furthermore, defendants (1) **CADDEN** and (9) **GREG CONIGLIARO** falsely represented that NECC was a compounding pharmacy and not a manufacturer, and therefore defendants (1) **CADDEN** and (9) **GREG CONIGLIARO** claimed NECC was not subject to FDA oversight.

80. It was further part of the conspiracy that defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, and (10) **RONZIO** instructed the MSM sales force to inform customers they needed to provide names of patients for orders of drugs.

81. It was further part of the conspiracy that defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, and (10) **RONZIO** instructed the MSM sales force to inform customers that

NECC would not include the patients' names on the labels affixed to the drugs, thereby allowing the facilities to use the drugs for any patient.

82. It was further part of the conspiracy that defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, and (10) **RONZIO** used and caused others to use the names of patients supplied by NECC's customers to create fraudulent prescriptions for drugs.

83. It was further part of the conspiracy that defendants (1) **CADDEN**, (7) **CARTER**, and (8) **STEPANETS** reused and caused others to reuse the names of patients from the same order or previous orders supplied by NECC's customers to create fraudulent prescriptions for drugs.

84. It was further part of the conspiracy that defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, and (10) **RONZIO** shipped and caused others to ship drugs to NECC's customers without any patient names, and then used and caused others to use the names of patients received after the drug shipments to create fraudulent prescriptions for those or subsequent orders.

85. It was further part of the conspiracy that defendants (1) **CADDEN**, (7) **CARTER**, and (8) **STEPANETS** used and caused others to use the names of celebrities, fictional characters, doctors, and medical staff to create fraudulent prescriptions for drugs.

86. It was further part of the conspiracy that defendant (1) **CADDEN** waived the need for patient names for customers' first orders, that defendants (1) **CADDEN**, (7) **CARTER**, and (10) **RONZIO** waived the need for patient names for subsequent orders for certain other customers, and that defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, and (10) **RONZIO** used and caused others to use the name of the hospital or medical facility as the patient name to create fraudulent prescriptions.

87. It was further part of the conspiracy that defendants (1) **CADDEN** and (7) **CARTER** created ratios of fraudulent prescriptions to number of drug units sold for NECC's various drugs,

and defendants (1) **CADDEN**, (7) **CARTER**, and (10) **RONZIO** instructed NECC staff and the MSM sales force on the ratios of how many patient names would be needed for each order size.

Overt Acts

88. In furtherance of the conspiracy and to effect the objects of the conspiracy, defendants (1) **CADDEN**, (7) **CARTER**, (8) **STEPANETS**, (9) **GREG CONIGLIARO**, and (10) **RONZIO** committed the following overt acts, among others, in the District of Massachusetts and elsewhere:

Representations to Regulators

89. On or about May 20, 2003, in response to an FDA inspection of NECC, defendant (1) **CADDEN** wrote to the FDA, "we are not subject to (nor are we voluntarily subjecting ourselves to) current good manufacturing practices (cGMPs) as promulgated by the FDA, since we are a compounding pharmacy, not a manufacturer."

90. On or about October 1, 2004, in response to an FDA inspection of NECC, defendant (9) **GREG CONGILIARO** falsely wrote to the FDA, NECC "compounds numerous different sterile and non-sterile preparations to fill patient-specific, physician prescriptions." Defendant (9) **GREG CONGILIARO** further falsely noted, "[w]e always compound only the amount we anticipate will be required based on our prescribing physician's historical prescribing patterns." Defendant (9) **GREG CONGILIARO** concluded by stating, "we are a small-scale, family-run, compounding-only pharmacy, not a manufacturer. As such we are not subject to GMP."

91. On or about January 5, 2007, in response to an FDA Warning Letter issued to NECC, defendant (1) **CADDEN** falsely wrote to the FDA, "NECC dispenses compounded medications upon the receipt of valid prescriptions. We are engaged in the practice of pharmacy and comply with the Massachusetts Board of Registration in Pharmacy's laws and rules." With respect to an

allegation that NECC had informed its customers to provide names of staff members instead of patients, defendant (1) **CADDEN** falsely wrote, "[t]his allegation contradicts all of our standard operating procedures."

NECC's Fraudulent Practices

92. On or about September 15, 2010, defendant (1) **CADDEN** sent an e-mail to defendant (10) **RONZIO** in response to a complaint from a potential customer about supplying patient names with a drug order. In the e-mail, defendant (1) **CADDEN** wrote:

> Unfortunately we are a 'pharmacy'...how can you get medication from a pharmacy without a prescription which must contain a patient name. We must connect the patients to the dosage forms at some point in the process to prove that we are not a MFG. They can follow up each month with a roster of actual patients and we can back-fill. If we just sell drugs we are a MFG. We can label with office name but process patients in our data base [sic].

93. On or about October 13, 2010, in response to an NECC customer's request to use the word "generic" on a drug label, defendant (8) **STEPANETS** wrote to the MSM sales representative:

> [Defendant (1) **CADDEN**] and I looked over the label...the reason is the word GENERIC is on there...this is a big red flag for manufacturing. Since we are not a manufacturer, I cannot put that on the label. We are getting into "misbranding" and all sorts of things. So, to avoid any potential issues, we can say something like "compounded for..."

94. On or about May 2, 2011, defendant (7) **CARTER** sent defendant (1) **CADDEN** an e-mail stating that an NECC customer was providing the names of staff members for its orders. In response, defendant (1) **CADDEN** wrote, "I will speak to rep. There are better ways to do this. Same names all the time makes no sense."

95. On or about August 9, 2011, an MSM sales representative sent an e-mail to defendant (1) **CADDEN** stating, "[c]urrent customer since 05' [sic] ordering $7,200 a month in

methylprednisolone. They refuse to provide names and have not since they began ordering with us...Is it ok to process without names?" Defendant (1) **CADDEN** replied, "Yes...OK."

96. On or about September 23, 2011, defendant (7) **CARTER** sent an e-mail to an MSM sales representative to inform him that a customer did not provide patient names for the order, but that "[w]e processed it using old pt names."

97. On or about February 23, 2012, defendant (1) **CADDEN** sent an e-mail to defendants (7) **CARTER** and (10) **RONZIO** regarding the processing of orders for hospitals. In the e-mail, defendant (1) **CADDEN** wrote that a hospital "[g]ives patient names with orders but may be patients from 'last month.' We now process and label the bags [of drugs] with these names...We now want to pack as 'Bulk' + label with facility name label while still processing patient names into data base [sic]."

98. On or about March 13, 2012, defendant (8) **STEPANETS** sent an e-mail to defendant (1) **CADDEN** in which she wrote, "I know that [specific NECC customers] are exempted from patient names for now. Can you please send a list of [specific NECC customers] to all confirming staff, please."

99. On or about March 20, 2012, defendant (8) **STEPANETS** sent an e-mail to an MSM sales representative in which she wrote about a specific NECC customer, "facility uses bogus patient names that are just ridiculous!" The sales representative replied, "[t]hese are RIDICULOUS." Defendant (8) **STEPANETS** responded that the order was sent out anyway.

100. On or about May 21, 2012, defendant (1) **CADDEN** sent an e-mail to defendant (7) **CARTER** with the subject line "RX processing." Defendant (7) **CARTER** amended the e-mail and forwarded it to all NECC order-processing staff. The e-mail was printed out and hung in the

cubicles of NECC order-processing staff. In the e-mail, defendants (1) **CADDEN** and (7) **CARTER** wrote:

> The MAX total number of units (vials, syringes, etc..) per patient must make sense. I must be able to logically explain to a regulator why we processed x# of units per patient.
> We must process only complete names.....not (K. Smith)
> A facility can't continuously provide the same roster of names.....unless they are truly treating the exact same patients over and over again!
> All names must resemble "real" names.....no obviously false names! (Mickey Mouse.
> 10ml multi-dose vials, must be (1:1).....one vial per patient
> 5ml, 2ml, 1ml (pf) single dose vials (MP40-pf, TA40-pf....etc).....can be processed as (5:1 or 3:1). Many patients come back over and over again for a series of injections over many weeks/few months.
> Can process multiple meds for same patient on a single order.(example: facility orders omnipaque + betamethasone SP (pf).....can process 3-5 of each for single patient = series of injections
> Can process 3-5 Avastin syringes per patient name = this is a chronic treatment, patients are injected every month or so.....
> If you have any questions then ask.
> The 3 per prescription must be logical.....#20 LET gel per patient does NOT make sense!
> LET gel.....3:1
> Combo drops, 1ml...2:1
> Combo drops 3ml+1:1
> Avastin 5:1
> (pf) steroids 1ml, 2ml, 5ml....5:1
> Omni/isov....5:1.....
> Hydroxyp[rogesterone [sic] 1ml...can 20:1. long time series of injections
> Ondansetron/Metoclopramide/Ketorolac/Prochlorperazine/
> Nalbuhine – 10 units/pt

101. On or about August 24, 2012, defendant (10) **RONZIO** forwarded part of the above e-mail from defendants (1) **CADDEN** and (7) **CARTER** to the MSM sales force with the subject line "HUUUUUUUUUUUUUGE IMPORTANCE!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!." At the bottom of the e-mail, defendant (10) **RONZIO** wrote:

> DO NOT GIVE RATIOS!!!!!!!!!!!!!! IT'S THE WRONG THING TO SAY PERIOD!!!!!!!! I CANNOT STRESS THIS ENOUGH TO ALL OF YOU!!!!!! ITS [sic] WILL BE A FATAL ERROR FOR YOU!!!!!!! I KNOW I DON'T HAVE TO SAY THIS BUT ALSO NEVER PUT ANYTHING IN WRITING.....OTHER KEY WORDS NEVER TO SAY ARE BACKFILL.....OR ANYTHING ALONG THOSE LINES.....!!!!

NECC's Fraudulent Prescriptions

102. In furtherance of the conspiracy and to effect the objects of the conspiracy, defendants (1) **CADDEN**, (7) **CARTER**, and (8) **STEPANETS** committed and caused to be committed the following additional acts, among others, in the District of Massachusetts and elsewhere:

Overt Act	Date of Shipment	Location	Description	Fake Patient Names Listed on NECC Prescriptions
A	10/28/2009	San Marcos, Texas	10 vials of betamethasone repository (pf) 6 mg/ml, 5 vials of 10 ml methylprednisolone acetate 40 mg/ml	Big Baby Jesus, Weslie Willis, Method Man
B	11/23/2009	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	John Meier, Lisa Kudro, David Spade, Ryan Reynolds, Matthew Perry, Tyler Perry, Roy Rogers
C	12/21/2009	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	Michael Baldwin, Alex Baldwin, Steven Baldwin, Billy Baldwin, Diana Ross, Michael Jackson, Daily Niner, Chris Rock
D	2/18/2010	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	Fast Man, Wonder Woman, Fat Albert, Wayne Newton, Cyndi Lopler, John Candie, Pewe Herman, Josh Grovan, Nelly Fertado

Overt Act	Date of Shipment	Location	Description	Fake Patient Names Listed on NECC Prescriptions
E	4/22/2010	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	Robert Redford, William Dafoo, Lucy Lue, Freddy Mercury, Martha Stewart
F	6/11/2010	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	John Pfizer, Gerry Schlitz, Pat Blue, Bud Weiser, Richard Coors, Michael Keystone, Adam Foster, Samuel Adams, John Killian, Raymond Rollingrock
G	8/26/2010	San Marcos, Texas	8 vials of 10 ml triamcinolone 40 mg/ml	Hugh Jass
H	9/14/2010	San Marcos, Texas	10 vials of dexamethasone, 5 vials of 10 ml methylprednisolone acetate 40 mg/ml	Freddie Mae, Fannie Mac
I	11/16/2010	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	Fast Phil, Parma Reigns, Hindsight Man, Peggy Octavius, John No, Silver Surfer, Ned Flanders, Ted Nuget, Bob Barker, Burt Reynolds
J	12/30/2010	San Marcos, Texas	10 vials of betamethasone repository (pf) 6 mg/ml, 10 vials of methylprednisolone acetate 40 mg/ml, 10 vials of triamcinolone 40 mg/ml	Betty Ford, Jimmy Carter, Bill Clinton
K	5/3/2011	San Marcos, Texas	20 vials of betamethasone repository (pf) 6 mg/ml, 5 vials of methylprednisolone acetate 40 mg/ml, 5 vials of triamcinolone 40 mg/ml	Donald Trump, Calvin Klein, Jennifer Lopez

Overt Act	Date of Shipment	Location	Description	Fake Patient Names Listed on NECC Prescriptions
L	8/2/2011	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	John Stewart, Craig Killborne, David Letterman, Jay Leno, Jimmy Kimmel, Al Bundie, Johnny Knoxville, Dick Van Dike
M	8/29/2011	Jonesboro, Georgia	20 vials of triamcinolone 40 mg/ml, 60 combo #4 eye drops	Mike Myers, Bella Swan, William Tweedy, Stefan Salvatore, Sookie Stackhouse, Ruby Falls
N	2/7/2012	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	Dale Earnhardt, Johnny Johnson, Jerry Jone, Jimmy Stewart, Mark McGrath, Bobby Lebonny, Tom Brokohy, Chris Rock
O	3/8/2012	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	Flash Gordon, Long John, Tony Tiger, Chester Cheeto, Stuart Little, John Strong, Bill Ransic, Tom Landry
P	3/20/2012	Elkhart, Indiana	12 vials of betamethasone repository (pf) 2 mg/ml	L.L. Bean, Filet O'fish, Rug Doctor, Squeaky Wheel, Dingo Boney, Coco Puff, Harry Potter
Q	4/9/2012	Lincoln, Nebraska	60 vials of betamethasone repository (pf) 6 mg/ml	Mary Lamb, Ginger Rogers, Mike Marker, Carrol Sharpie

The Eye Block Incident

103. In furtherance of the conspiracy and to effect the objects of the conspiracy, defendants (1) **CADDEN** and (9) **GREG CONIGLIARO** committed and caused to be committed the following additional acts, among others, in the District of Massachusetts and elsewhere:

104. On or about May 14, 2012, the MABOP began an investigation of NECC after learning that a sub-potent eye block was compounded by NECC and dispensed to a Massachusetts hospital for use on patients. The eye block, which was an anesthetic used in eye surgeries, failed

to properly anesthetize the patients' eyes, causing them to experience pain during surgery. As part of the investigation, the MABOP requested from NECC, among other things, copies of the prescriptions for the dispensed eye block.

105. On or about May 31, 2012, defendant (1) **CADDEN** wrote an e-mail to defendant (9) **GREG CONIGLIARO** informing him that the eye block was dispensed in February 2012 without any prescriptions. Defendant (9) **GREG CONIGLIARO** responded, "call [the Massachusetts hospital] and ask nonchalantly for a patient roster for the 170 syringes and ask where all the rest of the syringes are." Defendant (1) **CADDEN** replied, "I will try but unless she is dumb she will smell a skunk...."

106. On or about June 4, 2012, defendant (1) **CADDEN** e-mailed defendant (9) **GREG CONIGLIARO** a prescription template and a list of identified surgical patients of the Massachusetts hospital who underwent surgical procedures during a one-week period in February 2012.

107. On or about June 4, 2012, defendant (9) **GREG CONIGLIARO** instructed his staff to create 300 fraudulent prescriptions for the surgical patients of the Massachusetts hospital identified by defendant (1) **CADDEN**.

108. On or about June 14, 2012, defendant (1) **CADDEN** submitted NECC's response to the MABOP, in which defendant (1) **CADDEN** wrote that he was including in an attachment "[t]hree hundred (300) patient-specific transcribed prescriptions #1320237 - #1320536 which are retained per [NECC's standard operating procedure]." The attachment contained the 300 fraudulent prescriptions made upon instructions by defendants (9) **GREG CONIGLIARO** and (1) **CADDEN**.

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

COUNTS 4 – 56
(18 U.S.C. § 1341 – Mail Fraud)

[DEFENDANTS (1) CADDEN, (2) CHIN, (3) SVIRSKIY, (4) LEARY, (5) EVANOSKY, (6) CONNOLLY]

109. The allegations contained in paragraphs 1 through 8, and 17 through 32 are re-alleged and incorporated herein by reference.

The Scheme to Defraud

110. Beginning in at least 2006 and continuing until in or around October 2012, within the District of Massachusetts and elsewhere, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, and (6) **CONNOLLY**, along with others known and unknown to the Grand Jury, devised and intended to devise a scheme and artifice to defraud NECC's customers and the patients of those customers and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises.

The Purpose of the Scheme

111. The purpose of the scheme and artifice to defraud was to enrich NECC and defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, and (6) **CONNOLLY**, by selling to NECC's customers and the patients of those customers for a profit: purportedly sterile drugs that were made and tested in a manner that did not meet the standards set forth in USP-797 and USP-71; untested drugs identified as sterile and containing certain ingredients that were made in violation of USP-797 and tested in violation of USP-71; drugs made with an expired ingredient in violation of USP-797; and drugs made by an unlicensed pharmacy technician in violation of Massachusetts law.

Manner and Means

112. The manner and means whereby the scheme and artifice to defraud was to be accomplished are set forth in paragraphs 35 through 37, which are re-alleged and incorporated herein by reference.

The Mailings

113. On or about the dates listed below, the defendants listed below, having devised and intending to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, for the purpose of executing such scheme and artifice and attempting to do so, deposited and caused to be deposited matters and things – to wit, drugs – to be sent and delivered by private and commercial interstate carrier to NECC's customers to be used on the patients of those customers as set forth below:

Count	Defendants	Date of Shipment	Description	Destination
4	**(1) CADDEN, (2) CHIN**	8/8/2012	400 5 ml vials of 06292012@26	Michigan Pain Specialists, Brighton, Michigan
5 **6**	**(1) CADDEN, (2) CHIN**	7/17/2012 8/14/2012	100 1 ml vials of 06292012@26 120 1 ml vials of 06292012@26	Specialty Surgery Center, Crossville, Tennessee
7 **8** **9** **10**	**(1) CADDEN, (2) CHIN**	6/27/2012 7/25/2012 8/13/2012 9/4/2012	500 1 ml vials of 05212012@68 500 1 ml vials of 06292012@26 500 1 ml vials of 06292012@26 500 1 ml vials of 08102012@51	St. Thomas Outpatient Neurological Center, Nashville, Tennessee
11 **12** **13** **14** **15**	**(1) CADDEN, (2) CHIN**	6/25/2012 7/16/2012 8/2/2012 8/28/2012 9/17/2012	125 1 ml vials of 05212012@68 125 1 ml vials of 05212012@68 150 1 ml vials of 06292012@26 130 1 ml vials of 08102012@51 100 1 ml vials of 08102012@51	OSMC Outpatient Surgery Center, Elkhart, Indiana

Count	Defendants	Date of Shipment	Description	Destination
16 17	(1) CADDEN, (2) CHIN	8/15/2012 9/25/2012	100 1 ml vials of 06292012@26 100 1 ml vials of 08102012@51	South Bend Clinic, South Bend, Indiana
18 19	(1) CADDEN, (2) CHIN	7/5/2012 8/15/2012	150 1 ml vials of 05212012@68 150 1 ml vials of 06292012@26	Marion Pain Management, Ocala, Florida
20 21	(1) CADDEN, (2) CHIN	8/13/2012 9/25/2012	85 5 ml vials of 06292012@26 300 1 ml vials of 08102012@51	Box Hill Surgery Center, Abingdon, Maryland
22 23 24 25	(1) CADDEN, (2) CHIN	7/9/2012 7/26/2012 8/17/2012 9/7/2012	200 1 ml vials of 05212012@68 200 1 ml vials of 06292012@26 200 1 ml vials of 06292012@26 200 1 ml vials of 08102012@51	Insight Imaging, Roanoke, Virginia
26 27 28 29 30	(1) CADDEN, (2) CHIN	6/25/2012 7/13/2012 8/7/2012 8/14/2012 9/20/2012	20 1 ml vials of 05212012@68 20 1 ml vials of 05212012@68 40 1 ml vials of 06292012@26 80 1 ml vials of 06292012@26 60 1 ml vials of 08102012@51	High Point Surgery Center, High Point, North Carolina
31	(1) CADDEN, (2) CHIN	7/24/2012	150 bacitracin 20 ml syringes	Good Shepherd Hospital, Barrington, Illinois
32	(1) CADDEN, (3) SVIRSKIY	8/7/2012	18 polymyxin-bacitracin irrigation bags	Glens Falls Hospital, Glens Falls, New York
33	(1) CADDEN, (4) LEARY	8/27/2012	18 polymyxin-bacitracin irrigation bags	Glens Falls Hospital, Glens Falls, New York
34	(1) CADDEN, (5) EVANOSKY	8/28/2012	20 polymyxin-bacitracin irrigation bags	Winchester Hospital, Winchester, Virginia
35	(1) CADDEN, (5) EVANOSKY	8/30/2012	20 polymyxin-bacitracin irrigation bags	Winchester Hospital, Winchester, Virginia
36	(1) CADDEN, (2) CHIN	9/11/2012	100 potassium chloride injectables	Port Huron Hospital, Port Huron, Michigan

Count	Defendants	Date of Shipment	Description	Destination
37	**(1) CADDEN, (5) EVANOSKY**	9/24/2012	50 cardioplegia solution (low-K)	Brigham and Women's Hospital, Boston, Massachusetts
38	**(1) CADDEN, (2) CHIN**	9/27/2012	60 potassium chloride bags	Sentara Norfolk General Hospital, Norfolk, Virginia
39	**(1) CADDEN, (4) LEARY**	2/23/2012	300 lidocaine-bupivacaine-hyaluronidase injections	Massachusetts Eye and Ear Institute Boston, Massachusetts
40	**(1) CADDEN, (4) LEARY**	8/21/2012	50 55 ml pericapsular injections	Oakleaf Surgical Hospital, Eau Claire, Wisconsin
41	**(1) CADDEN, (4) LEARY, (5) EVANOSKY**	9/17/2012	15 clindamycin-gentamicin-polymyxin bags	Florida Hospital Waterman, Tavares, Florida
42	**(1) CADDEN, (3) SVIRSKIY**	7/7/2011	6 25 mg/ml methotrexate injectables	USC University Hospital, Los Angeles, California
43	**(1) CADDEN, (4) LEARY**	7/8/2011	8 4 mg/ml methotrexate injectables	Augusta Eye Associates, Fisherville, Virginia
44	**(1) CADDEN, (2) CHIN**	10/31/2011	6 25 mg/ml methotrexate injectables	Southboro Medical Group, Southboro, Massachusetts
45	**(1) CADDEN, (2) CHIN**	2/15/2012	25 25 mg/ml methotrexate injectables	Decatur Memorial Hospital, Decatur, Illinois
46	**(1) CADDEN, (2) CHIN, (4) LEARY**	6/8/2012	10 4 mg/ml methotrexate injectables	Retina Group of Washington, Chevy Chase, Maryland

Count	Defendants	Date of Shipment	Description	Destination
47	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	3/25/2010	7 cardioplegia solution bags	Lewis-Gale Medical Center, Salem, Virginia
48	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	10/21/2010	10 cardioplegia (cold induction high K) bags	Osceola Regional Medical Center, Kissimmee, Florida
49	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	12/21/2010	10 cardioplegia solution bags	Baptist Medical Center, Jacksonville, Florida
50	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	3/30/2011	8 cardioplegia solution bags	North Shore Medical Center, Salem, Massachusetts
51	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	6/29/2011	20 cardioplegia (high K) solution bags	Sunrise Medical Center, Las Vegas, Nevada
52	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	11/15/2011	10 cardioplegia (induction formula) bags	St. Vincent's Hospital, Birmingham, Alabama
53	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	2/22/2012	20 cardioplegia (high K) solution bags	Sunrise Medical Center, Las Vegas, Nevada
54	**(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY**	6/4/2012	30 cardioplegia (cold induction) bags	St. Peter's Hospital, Albany, New York

Count	Defendants	Date of Shipment	Description	Destination
55	(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY	7/12/2012	25 cardioplegia solution bags	West Virginia University, Morgantown, West Virginia
56	(1) CADDEN, (2) CHIN, (3) SVIRSKIY, (6) CONNOLLY	8/8/2012	20 cardioplegia (high K) solution bags	Sunrise Medical Center, Las Vegas, Nevada

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

COUNTS 57 – 90
(21 U.S.C. §§ 351(a)(2)(A), 331(a), and 333(a)(2) – Introduction of Adulterated Drugs into Interstate Commerce with Intent to Defraud and Mislead – Insanitary Conditions)

[DEFENDANTS (1) CADDEN, (2) CHIN, (3) SVIRSKIY, (4) LEARY, (5) EVANOSKY]

114. The allegations contained in paragraphs 1 through 7, 17 through 32, and 37 are re-alleged and incorporated herein by reference.

115. From in or around May 2012 through in or around October 2012, within the District of Massachusetts and elsewhere, the defendants listed below, with the intent to defraud and mislead, caused to be introduced and delivered for introduction into interstate commerce the drugs set forth below contrary to the provisions of Title 21, United States Code, Section 351(a)(2)(A), in that the defendants listed below prepared, packed, and held the drugs under insanitary conditions whereby they may have been contaminated with filth and whereby they may have been rendered injurious to health, and the act resulted in the drugs being adulterated, each such instance being a separate count in the Indictment:

Count	Defendants	Date of Shipment	Description	Destination
57	(1) CADDEN, (2) CHIN	8/8/2012	400 5 ml vials of 06292012@26	Michigan Pain Specialists, Brighton, Michigan
58 59	(1) CADDEN, (2) CHIN	7/17/2012 8/14/2012	100 1 ml vials of 06292012@26 120 1 ml vials of 06292012@26	Specialty Surgery Center, Crossville, Tennessee
60 61 62 63	(1) CADDEN, (2) CHIN	6/27/2012 7/25/2012 8/13/2012 9/4/2012	500 1 ml vials of 05212012@68 500 1 ml vials of 06292012@26 500 1 ml vials of 06292012@26 500 1 ml vials of 08102012@51	St. Thomas Outpatient Neurological Center, Nashville, Tennessee
64 65 66 67 68	(1) CADDEN, (2) CHIN	6/25/2012 7/16/2012 8/2/2012 8/28/2012 9/17/2012	125 1 ml vials of 05212012@68 125 1 ml vials of 05212012@68 150 1 ml vials of 06292012@26 130 1 ml vials of 08102012@51 100 1 ml vials of 08102012@51	OSMC Outpatient Surgery Center, Elkhart, Indiana
69 70	(1) CADDEN, (2) CHIN	8/15/2012 9/25/2012	100 1 ml vials of 06292012@26 100 1 ml vials of 08102012@51	South Bend Clinic, South Bend, Indiana
71 72	(1) CADDEN, (2) CHIN	7/5/2012 8/15/2012	150 1 ml vials of 05212012@68 150 1 ml vials of 06292012@26	Marion Pain Management, Ocala, Florida
73 74	(1) CADDEN, (2) CHIN	8/13/2012 9/25/2012	85 5 ml vials of 06292012@26 300 1 ml vials of 08102012@51	Box Hill Surgery Center, Abingdon, Maryland
75 76 77 78	(1) CADDEN, (2) CHIN	7/9/2012 7/26/2012 8/17/2012 9/7/2012	200 1 ml vials of 05212012@68 200 1 ml vials of 06292012@26 200 1 ml vials of 06292012@26 200 1 ml vials of 08102012@51	Insight Imaging, Roanoke, Virginia
79 80 81 82 83	(1) CADDEN, (2) CHIN	6/25/2012 7/13/2012 8/7/2012 8/14/2012 9/20/2012	20 1 ml vials of 05212012@68 20 1 ml vials of 05212012@68 40 1 ml vials of 06292012@26 80 1 ml vials of 06292012@26 60 1 ml vials of 08102012@51	High Point Surgery Center, High Point, North Carolina
84	(1) CADDEN, (2) CHIN	7/24/2012	150 bacitracin 20 ml syringes	Good Shepherd Hospital, Barrington, Illinois
85	(1) CADDEN, (3) SVIRSKIY	8/7/2012	18 polymyxin-bacitracin irrigation bags	Glens Falls Hospital, Glens Falls, New York

Count	Defendants	Date of Shipment	Description	Destination
86	**(1) CADDEN, (4) LEARY**	8/27/2012	18 polymyxin-bacitracin irrigation bags	Glens Falls Hospital, Glens Falls, New York
87	**(1) CADDEN, (5) EVANOSKY**	8/28/2012	20 polymyxin-bacitracin irrigation bags	Winchester Hospital, Winchester, Virginia
88	**(1) CADDEN, (5) EVANOSKY**	8/30/2012	20 polymyxin-bacitracin irrigation bags	Winchester Hospital, Winchester, Virginia
89	**(1) CADDEN, (2) CHIN**	9/11/2012	100 potassium chloride injectables	Port Huron Hospital, Port Huron, Michigan
90	**(1) CADDEN, (2) CHIN**	9/27/2012	60 potassium chloride bags	Sentara Norfolk General Hospital, Norfolk, Virginia

All in violation of Title 21, United States Code, Sections 351(a)(2)(A), 331(a), and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS 91 – 94
(21 U.S.C. §§ 352(a), 331(a), and 333(a)(2) – Introduction of Misbranded Drugs into Interstate Commerce with the Intent to Defraud and Mislead – False and Misleading Labeling)

[DEFENDANTS (1) CADDEN, (2) CHIN, (3) SVIRSKIY, (4) LEARY]

116. The allegations contained in paragraphs 1 through 6, 17 through 32, and 36 are re-alleged and incorporated herein by reference.

117. From in or around July 2011 through in or around June 2012, within the District of Massachusetts and elsewhere, the defendants listed below, with the intent to defraud and mislead, caused to be introduced and delivered for introduction into interstate commerce the drugs set forth below whose labeling was false and misleading in any particular, contrary to the provisions of Title 21, United States Code, Section 352(a), each such instance being a separate count in the Indictment:

Count	Defendants	Date of Shipment	Description	Destination
91	(1) CADDEN, (3) SVIRSKIY	7/7/2011	6 25 mg/ml methotrexate injectables	USC University Hospital, Los Angeles, California
92	(1) CADDEN, (4) LEARY	7/8/2011	8 4 mg/ml methotrexate injectables	Augusta Eye Associates, Fisherville, Virginia
93	(1) CADDEN, (2) CHIN	2/15/2012	25 25 mg/ml methotrexate injectables	Decatur Memorial Hospital, Decatur, Illinois
94	(1) CADDEN, (2) CHIN, (4) LEARY	6/8/2012	10 4 mg/ml methotrexate injectables	Retina Group of Washington, Chevy Chase, Maryland

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

COUNTS 95 – 109
(21 U.S.C. §§ 353(b)(1), 331(a), and 333(a)(2) –
Introduction of Misbranded Drugs into Interstate Commerce
with the Intent to Defraud and Mislead – No Prescriptions)

[DEFENDANTS (1) CADDEN, (8) STEPANETS, (11) KATHY CHIN, (12) THOMAS]

118. The allegations contained in paragraphs 1 through 3, 10, and 13 through 14 are re-alleged and incorporated herein by reference.

119. From in or around December 2009 through in or around March 2012, within the District of Massachusetts and elsewhere, the defendants listed below, along with others known and unknown to the Grand Jury, with the intent to defraud and mislead, caused to be dispensed the drugs set forth below contrary to the provisions of Title 21, United States Code, Section 353(b)(1), in that the defendants listed below caused the drugs to be introduced and delivered into interstate commerce without the valid prescription of a practitioner licensed by law to administer the drugs,

and the act resulted in the drugs being misbranded, each such instance being a separate count in the Indictment:

Count	Defendant(s)	Date of Shipment	Location	Description	Fake Patient Names Listed on NECC Prescriptions
95	**(1) CADDEN**	12/21/2009	Lincoln, Nebraska	60 vials of betamethasone repository	Michael Baldwin, Alex Baldwin, Steven Baldwin, Billy Baldwin, Diana Ross, Michael Jackson, Daily Niner, Chris Rock
96	**(8) STEPANETS**	2/18/2010	Lincoln, Nebraska	60 vials of betamethasone repository	Fast Man, Wonder Woman, Fat Albert, Wayne Newton, Cyndi Lopler, John Candie, Pewe Herman, Josh Grovan, Nelly Fertado
97	**(8) STEPANETS**	4/22/2010	Lincoln, Nebraska	60 vials of betamethasone repository	Robert Redford, William Dafoo, Lucy Lue, Freddy Mercury, Martha Stewart
98	**(8) STEPANETS**	6/11/2010	Lincoln, Nebraska	60 vials of betamethasone repository	John Pfizer, Gerry Schlitz, Pat Blue, Bud Weiser, Richard Coors, Michael Keystone, Adam Foster, Samuel Adams, John Killian, Raymond Rollingrock
99	**(1) CADDEN**	8/26/2010	San Marcos, Texas	8 vials of 10 ml triamcinolone	Hugh Jass
100	**(1) CADDEN**	9/14/2010	San Marcos, Texas	10 vials of dexamethasone, 5 vials of 10 ml methylprednisolone acetate	Freddie Mae, Fannie Mac

Count	Defendant(s)	Date of Shipment	Location	Description	Fake Patient Names Listed on NECC Prescriptions
101	**(8) STEPANETS**	11/16/2010	Lincoln, Nebraska	60 vials of betamethasone repository	Fast Phil, Parma Reigns, Hindsight Man, Peggy Octavius, John No, Silver Surfer, Ned Flanders, Ted Nuget, Bob Barker, Burt Reynolds
102	**(8) STEPANETS**	12/30/2010	San Marcos, Texas	10 vials of betamethasone repository, 10 vials of methylprednisolone acetate, 10 vials of triamcinolone	Betty Ford, Jimmy Carter, Bill Clinton
103	**(8) STEPANETS**	5/3/2011	San Marcos, Texas	20 vials of betamethasone repository, 5 vials of methylprednisolone acetate, 5 vials of triamcinolone	Donald Trump, Calvin Klein, Jennifer Lopez
104	**(11) KATHY CHIN**	8/2/2011	Lincoln, Nebraska	60 vials of betamethasone repository	John Stewart, Craig Killborne, David Letterman, Jay Leno, Jimmy Kimmel, Al Bundie, Johnny Knoxville, Dick Van Dike
105	**(11) KATHY CHIN**	8/29/2011	Jonesboro, Georgia	20 vials of triamcinolone, 60 combo #4 eye drops	Mike Myers, Bella Swan, William Tweedy, Stefan Salvatore, Sookie Stackhouse, Ruby Falls
106	**(11) KATHY CHIN**	2/7/2012	Lincoln, Nebraska	60 vials of betamethasone repository	Dale Earnhardt, Johnny Johnson, Jerry Jone, Jimmy Stewart, Mark McGrath, Bobby Lebonny, Tom Brokohy, Chris Rock

Count	Defendant(s)	Date of Shipment	Location	Description	Fake Patient Names Listed on NECC Prescriptions
107	**(11) KATHY CHIN**	3/8/2012	Lincoln, Nebraska	60 vials of betamethasone repository	Flash Gordon, Long John, Tony Tiger, Chester Cheeto, Stuart Little, John Strong, Bill Ransic, Tom Landry
108	**(8) STEPANETS, (12) THOMAS**	3/20/2012	Elkhart, Indiana	12 vials of betamethasone repository	L.L. Bean, Filet O'fish, Rug Doctor, Squeaky Wheel, Dingo Boney, Coco Puff, Harry Potter
109	**(12) THOMAS**	4/9/2012	Lincoln, Nebraska	60 vials of betamethasone repository	Mary Lamb, Ginger Rogers, Mike Marker, Carrol Sharpie

All in violation of Title 21, United States Code, Sections 353(b)(1), 331(a), and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS 110 – 127
(18 U.S.C. § 401(3) – Criminal Contempt)

[DEFENDANTS (13) CARLA CONIGLIARO, (14) DOUG CONIGLIARO]

120. The allegations contained in paragraphs 15 through 16 are re-alleged and incorporated herein by reference.

121. From in or around February 2013 through in or around March 2013, within the District of Massachusetts and elsewhere, defendants (13) **CARLA CONIGLIARO**, the majority shareholder of NECC, and (14) **DOUG CONIGLIARO**, did willfully and knowingly disobey and resist lawful orders of a Court of the United States, that is, the temporary restraining order (Document 22) and preliminary injunctive relief order (Document 51) issued by the Honorable Henry J. Boroff on January 28, 2013, and February 12, 2013, respectively, in the United States Bankruptcy Court for the District of Massachusetts in the case, In re: New England Compounding Pharmacy, Inc., Case Nos. 12-19882-HJB, 13-01040-HJB (adversary action), by transferring

approximately $33.3 million of assets of defendant (13) **CARLA CONIGLIARO** as listed below, each such transfer being a separate count in the Indictment:

Count	Date/Type of Transaction	Amount	Originating Account/ Account Number	Receiving Account/ Account Number	Receiving Account Opening Date
110	2/1/2013 Wire Transfer	$3,300,000	Merrill Lynch New York, New York No. ***-*0872	USAA Financial Advisors San Antonio, Texas No. ****5428	1/31/2013
111	2/4/2013 Wire Transfer	$7,000,000	Merrill Lynch New York, New York No. ***-*0872	USAA Financial Advisors San Antonio, Texas No. ****5428	1/31/2013
112	2/4/2013 Wire Transfer	$6,500,000	Merrill Lynch New York, New York No. ***-*0872	SunTrust Bank Atlanta, Georgia No. *********2822	12/31/2012
113	2/5/2013 Check	$500,000	SunTrust Bank Atlanta, Georgia No. *********2822	Florida Bank of Commerce Orlando, Florida No. ***6704	2/5/2013
114	2/5/2013 Check	$500,000	SunTrust Bank Atlanta, Georgia No. *********2822	BankFirst Winter Park, Florida No. *****0369	2/5/2013
115	2/5/2013 Check	$500,000	SunTrust Bank Atlanta, Georgia No. *********2822	PNC Bank Pittsburgh, Pennsylvania No. **-****-6896	2/5/2013
116	2/5/2013 Check	$500,000	SunTrust Bank Atlanta, Georgia No. *********2822	CNL Bank Orlando, Florida No. ***0113	2/5/2013
117	2/5/2013 Check	$500,000	SunTrust Bank Atlanta, Georgia No. *********2822	Regions Bank Birmingham, Alabama No. *****6303	2/5/2013
118	2/21/2013 Check	$250,000	SunTrust Bank Atlanta, Georgia No. *********2822	Susquehanna Bank Lititz, Pennsylvania No. *******9388	2/21/2013
119	2/21/2013 Check	$250,000	SunTrust Bank Atlanta, Georgia No. *********2822	Susquehanna Bank Lititz, Pennsylvania No. *******9388	2/21/2013

Count	Date/Type of Transaction	Amount	Originating Account/ Account Number	Receiving Account/ Account Number	Receiving Account Opening Date
120	3/18/2013 Check	$3,000,000	Merrill Lynch New York, New York No. ***-*0872	Seacoast National Bank Vero Beach, Florida No. ******8506	3/18/2013
121	3/18/2013 Wire	$1,000,000	SunTrust Bank Atlanta, Georgia No. *********2822	Florida Bank of Commerce Orlando, Florida No. ***6704	2/5/2013
122	3/18/2013 Wire	$1,000,000	SunTrust Bank Atlanta, Georgia No. *********2822	BankFirst Winter Park, Florida No. *****0369	2/5/2013
123	3/18/2013 Wire	$1,000,000	SunTrust Bank Atlanta, Georgia No. *********2822	PNC Bank Pittsburgh, Pennsylvania No. **-****-6896	2/5/2013
124	3/18/2013 Wire	$1,000,000	SunTrust Bank Atlanta, Georgia No. *********2822	CNL Bank Orlando, Florida No. ***0113	2/5/2013
125	3/18/2013 Wire	$1,000,000	SunTrust Bank Atlanta, Georgia No. *********2822	Regions Bank Birmingham, Alabama No. *****6303	2/5/2013
126	3/18/2013 Wire	$500,000	SunTrust Bank Atlanta, Georgia No. *********2822	Susquehanna Bank Lititz, Pennsylvania No. *******9370	2/21/2013
127	3/19/2013 Wire	$5,000,000	USAA Financial Advisors San Antonio, Texas No. ****5428	SunTrust Bank Atlanta, Georgia No. *********2822	12/31/2012

All in violation of Title 18, United States Code, Sections 401(3) and 2.

COUNT 128
(18 U.S.C. § 371 – Conspiracy to Commit Structuring)

[DEFENDANTS (13) CARLA CONIGLIARO, (14) DOUG CONIGLIARO]

122. The allegations contained in paragraphs 15 through 16 are re-alleged and incorporated herein by reference.

123. From in or around September 2010 through in or around March 2014, within the District of Massachusetts and elsewhere, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO**, knowingly, willfully, and for the purposes of evading the reporting requirements of Section 5313(a) of Title 31, United States Code, and the regulations promulgated thereunder, conspired and agreed together and with each other, and with other persons unknown to the Grand Jury, to structure and assist in structuring transactions with domestic financial institutions, that is, Middlesex Savings Bank, SunTrust Bank, and TD Bank respectively, and to cause and attempt to cause such institutions to fail to file Currency Transaction Reports required by Section 5313 for currency transactions in excess of $10,000.

Manner and Means of the Conspiracy

124. It was part of the conspiracy that defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** obtained sums of cash in excess of $10,000 from bank accounts held at Middlesex Savings Bank, SunTrust Bank, and TD Bank, through ATM and counter withdrawals structured in a manner to prevent the domestic financial institutions from filing Currency Transaction Reports.

Overt Acts

125. In furtherance of the conspiracy and to effect the objects of the conspiracy, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** committed the following overt acts, among others, in the District of Massachusetts and elsewhere:

126. Between on or about September 27, 2010, and January 25, 2013, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** did, as a pattern of illegal activity, make approximately 504 structured cash withdrawals, totaling approximately $389,680.26, from a

joint checking account at Middlesex Savings Bank with an account number ending in "6521," for the purpose of causing Middlesex Savings Bank to fail to file Currency Transaction Reports.

127. Between on or about February 4, 2013, and December 4, 2013, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** did, as a pattern of illegal activity, make approximately 148 structured cash withdrawals, totaling approximately $111,103.50, from a joint checking account at SunTrust Bank with an account number ending in "7568," for the purpose of causing SunTrust Bank to fail to file Currency Transaction Reports.

128. Between on or about February 13, 2013, and March 13, 2014, a period of 393 days, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** did, as a pattern of illegal activity, make approximately 124 structured cash withdrawals, totaling approximately $71,558.25, from a joint checking account at TD Bank with an account number ending in "0263," for the purpose of causing TD Bank to fail to file Currency Transaction Reports.

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

COUNT 129
(31 U.S.C. § 5324(a) – Structuring)

[DEFENDANTS (13) CARLA CONIGLIARO, (14) DOUG CONIGLIARO]

129. The allegations contained in paragraphs 15 through 16 are re-alleged and incorporated herein by reference.

130. From in or around September 2010 through in or around January 2013, within the District of Massachusetts and elsewhere, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** did, as part of a pattern of illegal activity involving more than $100,000 in a 12-month period, knowingly and for the purpose of evading the reporting requirements of Section 5313(a) of Title 31, United States Code, and the regulations promulgated thereunder,

structure and assist in structuring transactions with a domestic financial institution, that is, Middlesex Savings Bank, and cause and attempt to cause such institution to fail to file Currency Transaction Reports required by Section 5313 for currency transactions in excess of $10,000.

131. Specifically, between on or about September 27, 2010, and January 25, 2013, a period of 851 days, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** did, as a pattern of illegal activity, make approximately 504 structured cash withdrawals, totaling approximately $389,680.26, from a joint checking account at Middlesex Savings Bank with an account number ending in "6521," for the purpose of causing Middlesex Savings Bank to fail to file Currency Transaction Reports.

All in violation of Title 31, United States Code, Sections 5324(a) and the regulations promulgated thereunder, and Title 18, United States Code, Section 2.

COUNT 130
(31 U.S.C. § 5324(a) – Structuring)

[DEFENDANTS (13) CARLA CONIGLIARO, (14) DOUG CONIGLIARO]

132. The allegations contained in paragraphs 15 through 16 are re-alleged and incorporated herein by reference.

133. From in or around February 2013 through in or around December 2013, within the District of Massachusetts and elsewhere, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO**, did, as part of a pattern of illegal activity involving more than $100,000 in a 12-month period, knowingly and for the purpose of evading the reporting requirements of Section 5313(a) of Title 31, United States Code, and the regulations promulgated thereunder, structure and assist in structuring transactions with a domestic financial institution, that is,

SunTrust Bank, and cause and attempt to cause such institution to fail to file Currency Transaction Reports required by Section 5313 for currency transactions in excess of $10,000.

134. Specifically, between on or about February 4, 2013, and December 4, 2013, a period of 303 days, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** did, as a pattern of illegal activity, make approximately 148 structured cash withdrawals, totaling approximately $111,103.50, from a joint checking account at SunTrust Bank with an account number ending in "7568," for the purpose of causing SunTrust Bank to fail to file Currency Transaction Reports.

All in violation of Title 31, United States Code, Sections 5324(a) and the regulations promulgated thereunder, and Title 18, United States Code, Section 2.

COUNT 131
(31 U.S.C. § 5324(a) – Structuring)

[DEFENDANTS (13) CARLA CONIGLIARO, (14) DOUG CONIGLIARO]

135. The allegations contained in paragraphs 15 through 16 are re-alleged and incorporated herein by reference.

136. From in or around February 2013 through in or around March 2014, within the District of Massachusetts and elsewhere, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO**, did knowingly and for the purpose of evading the reporting requirements of Section 5313(a) of Title 31, United States Code, and the regulations promulgated thereunder, structure and assist in structuring transactions with a domestic financial institution, that is, TD Bank, and cause and attempt to cause such institution to fail to file Currency Transaction Reports required by Section 5313 for currency transactions in excess of $10,000.

137. Specifically, between on or about February 13, 2013, and March 13, 2014, a period of 393 days, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** did, as a pattern of illegal activity, make approximately 124 structured cash withdrawals, totaling approximately $71,558.25, from a joint checking account at TD Bank with an account number ending in "0263," for the purpose of causing TD Bank to fail to file Currency Transaction Reports.

All in violation of Title 31, United States Code, Sections 5324(a) and the regulations promulgated thereunder, and Title 18, United States Code, Section 2.

RACKETEERING FORFEITURE ALLEGATIONS

The Grand Jury further charges that:

138. Upon conviction of any violation of Title 18, United States Code, Section 1962 as alleged in Counts 1 and 2 of this Indictment, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, (6) **CONNOLLY**, (7) **CARTER**, and (8) **STEPANETS** shall forfeit to the United States, jointly and severally, pursuant to Title 18, United States Code, Section 1963:

a. any interest acquired or maintained in violation of Title 18, United States Code, Section 1962;

b. any interest in, security of, claim against, or property or contractual right of any kind affording a source of influence over, any enterprise established, operated, controlled, conducted, or participated in the conduct of, in violation of Title 18, United States Code, Section 1962; and

c. any property constituting, or derived from, any proceeds obtained, directly or indirectly, from racketeering activity or unlawful debt collection in violation of Title 18, United States Code, Section 1962.

The property to be forfeited includes, but is not limited to:

a. any and all salaries, bonuses, stock distributions, retirement contributions and accounts, health and life insurance benefits including premium payments, and any and all other benefits obtained through employment by and association with the entities named in the racketeering enterprise alleged in Counts 1 and 2 from 2006 through October 2012;

b. one BMW M3 purchased on or about April 26, 2011, from BMW of Sudbury;

c. one Sailfish Boat purchased on or about March 2, 2010, from Port Harbor Marine, Inc.;

d. any jewelry purchased on or about December 23, 2010, and on or about December 21, 2011, from DeScenza Diamonds;

e. any clock, timepiece, or other luxury good purchased on or about January 11, 2012, from Delaney Antique Clocks;

f. the real property located at 13 Manchester Drive, Wrentham, Massachusetts, including all buildings, appurtenances and improvements thereon, more particularly described in a Quitclaim Deed recorded at Book 20971, Page 264 at the Norfolk County Registry of Deeds;

g. the real property located at 15 Manchester Drive, Wrentham, Massachusetts, including all buildings, appurtenances and improvements thereon, more particularly described in a Quitclaim Deed recorded at Book 28437, Page 144 at the Norfolk County Registry of Deeds;

h. the real property located at 17 Manchester Drive, Wrentham, Massachusetts, including all buildings, appurtenances and improvements thereon, more particularly described in a Quitclaim Deed recorded at Book 28437, Page 148 at the Norfolk County Registry of Deeds; and

i. the real property located at 25 Newport Avenue, North Kingstown, Rhode Island, including all buildings, appurtenances and improvements thereon, more particularly described in a Warranty Deed recorded at Book 2437, Page 174 at the North Kingstown Office of the Town Clerk.

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

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 that cannot be divided without difficulty,

it is the intention of the United States, pursuant to Title 18, United States Code, Section 1963(m), to seek forfeiture of any other property of the defendants up to the value of the property described in paragraph 138.

All pursuant to Title 18, United States Code, Section 1963 and Rule 32.2(a) of the Federal Rules of Criminal Procedure.

MAIL FRAUD FORFEITURE ALLEGATIONS

The Grand Jury further charges that:

140. Upon conviction of any violation of Title 18, United States Code, Section 1341 as alleged in Counts 4 through 56 of this Indictment, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, and (6) **CONNOLLY** shall forfeit to the United States, jointly and severally, pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), any property, real or personal, that constitutes, or is derived from, proceeds traceable to the commission of the offenses. The property to be forfeited includes, but is not limited to:

a. one BMW M3 purchased on or about April 26, 2011, from BMW of Sudbury;

b. one Sailfish Boat purchased on or about March 2, 2010, from Port Harbor Marine, Inc.;

c. any jewelry purchased on or about December 23, 2010, and on or about December 21, 2011, from DeScenza Diamonds;

d. any clock, timepiece, or other luxury good purchased on or about January 11, 2012, from Delaney Antique Clocks;

e. the real property located at 13 Manchester Drive, Wrentham, Massachusetts, including all buildings, appurtenances and improvements thereon, more particularly described in a Quitclaim Deed recorded at Book 20971, Page 264 at the Norfolk County Registry of Deeds;

f. the real property located at 15 Manchester Drive, Wrentham, Massachusetts, including all buildings, appurtenances and improvements thereon, more particularly described in a Quitclaim Deed recorded at Book 28437, Page 144 at the Norfolk County Registry of Deeds;

g. the real property located at 17 Manchester Drive, Wrentham, Massachusetts, including all buildings, appurtenances and improvements thereon, more particularly described in a Quitclaim Deed recorded at Book 28437, Page 148 at the Norfolk County Registry of Deeds; and

h. the real property located at 25 Newport Avenue, North Kingstown, Rhode Island, including all buildings, appurtenances and improvements thereon, more particularly described in a Warranty Deed recorded at Book 2437, Page 174 at the North Kingstown Office of the Town Clerk.

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

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 that cannot be divided without difficulty,

it is the intention 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 defendants up to the value of the property described in paragraph 140.

All pursuant to Title 18, United States Code, Section 981(a)(1)(C), Title 28, United States Code, Section 2461(c), and Rule 32.2(a) of the Federal Rules of Criminal Procedure.

FDCA FORFEITURE ALLEGATIONS

The Grand Jury further charges that:

142. Upon conviction of any violation of Title 21, United States Code, Sections 351(a)(2)(A), 352(a), 353(b)(1), 331(a), and/or 333(a)(2) as alleged in Counts 57 through 109 of this Indictment, defendants (1) **CADDEN**, (2) **CHIN**, (3) **SVIRSKIY**, (4) **LEARY**, (5) **EVANOSKY**, (8) **STEPANETS**, (11) **KATHY CHIN**, and (12) **THOMAS** shall forfeit to the United States, jointly and severally, pursuant to Title 21, United States Code, Section 334 and Title

28, United States Code, Section 2461(c), any quantities of drugs described in Counts 57 through 109 that were introduced into interstate commerce in violation of Title 21, United States Code, Sections 351(a)(2)(A), 352(a), 353(b)(1), 331(a), and/or 333(a)(2).

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

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 that cannot be divided without difficulty,

it is the intention 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 defendants up to the value of the property described in paragraph 142.

All pursuant to Title 21, United States Code, Sections 334 and 853, Title 28, United States Code, Section 2461(c), and Rule 32.2(a) of the Federal Rules of Criminal Procedure.

STRUCTURING FORFEITURE ALLEGATIONS

The Grand Jury further charges that:

144. Upon conviction of any violation of Title 31, United States Code, Section 5324(a) as alleged in Counts 129 through 131 of this Indictment, defendants (13) **CARLA CONIGLIARO** and (14) **DOUG CONIGLIARO** shall forfeit to the United States, jointly and severally, pursuant to Title 31, United States Code, Section 5317, all property, real or personal, involved in the

offenses and any property traceable to such property, including but not limited to at least $578,324.61 in United States currency.

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

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 that cannot be divided without difficulty,

it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 31, United States Code, Section 5317(c)(1)(C) and Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendants up to the value of the property described in paragraph 144.

All pursuant to Title 31, United States Code, Section 5317 and Title 28, United States Code, Section 2461 and Rule 32.2(a) of the Federal Rules of Criminal Procedure.

A TRUE BILL

[redacted]

Foreperson of the Grand Jury

[redacted]

AMANDA R.M. STRACHAN
GEORGE P. VARGHESE
Assistant United States Attorneys

JOHN W.M. CLAUD
Trial Attorney
United States Department of Justice
Consumer Protection Branch

DISTRICT OF MASSACHUSETTS: December 16, 2014

Returned into the District Court by the Grand Jurors and filed.

[redacted]

Deputy Clerk 11:55 12/16/14