**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF OKLAHOMA**

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|---|---|---|
| **UNITED STATES OF AMERICA,** | ) | **Case No. 19-CR-58-JED** |
| | ) | |
| **Plaintiff,** | ) | **SECOND SUPERSEDING INDICTMENT** |
| | ) | |
| **v.** | ) | **[COUNTS 1 and 7 through 41: 18 U.S.C. § 1347 – Health Care Fraud; COUNT 2: 21 U.S.C. §§ 331(c) and 333(a)(2) – Fraud Relating to a Misbranded Drug; COUNTS 3 through 6: 18 U.S.C. § 1028A(a)(1) – Aggravated Identity Theft; Forfeiture Allegation: 18 U.S.C. § 982(a)(7), 21 U.S.C. § 853, 18 U.S.C. § 982(a)(2)(B), and 18 U.S.C. § 1028(b)(5) – Health Care Fraud Forfeiture]** |
| **GREGORY SINCLAIR CONNOR,** | ) | |
| | ) | |
| **Defendant.** | ) | |

**THE GRAND JURY CHARGES:**

**COUNTS ONE AND SEVEN THROUGH FORTY-ONE**
**[18 U.S.C. § 1347]**

**The Scheme**

1. From in or about August 2009 to in or about September 2017, in the Northern District of Oklahoma and elsewhere, the defendant, **GREGORY SINCLAIR CONNOR**, in connection with the delivery of and payment for health care benefits, items, and services, knowingly and willfully executed and attempted to execute a scheme and artifice to defraud a federal health care benefit program, that is, Medicare, and to obtain, by means of material false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, Medicare, as described below ("the Scheme"):

## The Purposes of the Scheme

2. The purpose of the Scheme was to enrich **GREGORY SINCLAIR CONNOR, ("CONNOR")** unlawfully by using drugs for the treatment of patients that were not federally approved and for which Medicare reimbursement could not be obtained legally, but which were cheaper to buy from unapproved sources, and for which **CONNOR** nonetheless obtained reimbursement from Medicare fraudulently as though the drugs were federally approved, thereby illegally increasing the profits gotten for **CONNOR's** clinic than would otherwise be obtained by using and obtaining reimbursement for federally approved drugs. It was further the purpose of the Scheme to conceal its existence and operations from law enforcement authorities.

## The Context of the Scheme

The Federal Food, Drug and Cosmetic Act

3. The Federal Food, Drug, and Cosmetic Act, set forth in Title 21, United States Code, Sections 301 to 399i (FDCA), and related laws and regulations governed the manufacture, packaging, distribution and use of drugs in the United States.

4. The United States Food and Drug Administration (FDA) was the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs were safe and effective for their intended uses and had labeling that contained true and accurate information. The FDA carried out its responsibilities by enforcing the FDCA and related laws and regulations.

Drugs and Prescription Drugs

5. The FDCA defined a "drug" as any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any such articles.

6. Under the FDCA, prescription drugs were drugs that, (a) because of their toxicity and other potential for harmful effects, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (b) were limited by an application approved by FDA, to use under the professional supervision of a practitioner licensed by law to administer the drugs.

Labeling and Misbranding

7. The FDCA defined "label" as "a display or written, printed, or graphic matter upon the immediate container of any article," and defined "labeling" as all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

8. Prescription drugs were misbranded if, at any time prior to dispensing, the label of the prescription drug failed to bear, at a minimum, the symbol "Rx only."

9. A drug was misbranded if, among other things, its labeling failed to bear adequate directions for it use. "Adequate directions for use" meant directions under which a layman could use a drug safely and for the purposes for which it was intended. By

definition, prescription drugs could not have directions that allowed a layman to use them safely and for the purposes for which they were intended.

10. FDA-approved prescription drugs that complied with all of the relevant federal regulations before they were dispensed were exempt from the "adequate directions for use" requirement. Those regulations required, among other things, that the drug's label bear the statement "Rx only" prior to dispensing.

FDA Approval of Drugs and Biological Products

11. Applications for FDA approval of new drugs and biological products, including Botox, were subjected to a rigorous review process. New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs) discussed in great detail how a particular drug or biological product worked, how it was manufactured, and precisely what was stated on the label and labeling. For a drug or biological product to be used in the United States, its manufacturing process, label and labeling, and packaging, as set forth in the pertinent type of application, had to be approved by the FDA. The approval process addressed the chemical composition, safety and effectiveness, and distribution of the drug or biological product; methods used in, and the facilities and quality controls used for, the manufacturing, processing and packaging of the drug or biological product; and the proposed labeling for the drug or biological product. The approval process was specific to each manufacturer and each product. Approval granted to a particular manufacturer for a particular drug or biological product to be distributed in the United States did not constitute approval of a drug or

biological product with labeling that differed from the labeling in the FDA-approved application to be imported into and distributed in the United States, even if the imported drug or biological product had the same chemical composition as the FDA-approved drug or biological product.

Medicare

12. Medicare was a federal "health care benefit program," as defined by Title 18, United States Code, Section 24(b), which provided medical benefits, items, and services to persons who were 65 and older or who had certain disabilities. Individuals who received benefits under Medicare were referred to as Medicare "beneficiaries." Medicare included several components, including hospital insurance (Part A) and medical insurance (Part B).

13. The Centers for Medicare and Medicaid Services (CMS), an agency of the United States Department of Health and Human Services (DHHS), administered Medicare, including making payments for drugs and biological products provided to Medicare beneficiaries by physicians.

14. Medicare only paid, or provided reimbursement for, drugs that were safe and effective and otherwise reasonable and necessary for the individual patient. Medicare considered drugs and biological products approved by the FDA to be safe and effective when used for indications specified on the labeling. Medicare denied payment for drugs which had not received final FDA approval, unless CMS had made a specific exception and instructed otherwise.

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

16. Accordingly, a physician or provider submitting a claim for reimbursement for a covered drug represented that, among other things, the drug was FDA-approved.

17. To ensure that claims for reimbursement from health care providers were processed in an orderly and consistent manner, Medicare established requirements for standardized coding of such claims, including the Health Care Financing Administration Common Procedure Coding System (HCPCS) and National Drug Codes (NDC), maintained and distributed by DHHS, and Current Procedural Terminology (CPT), maintained and distributed by the American Medical Association.

Botox® and Botox® Cosmetic

18. Botulinum toxin Type A was a highly potent and potentially dangerous toxin which could cause the disease botulism when present in human beings in a sufficient amount. Botulism was a muscle-paralyzing condition in which Botulinum neurotoxins secreted by the Clostridum botulinum bacteria bonded to nerve endings at the point where nerves joined muscles, preventing the nerves from signaling the muscles to contract. Botulism could result in weakness and paralysis that severely affected, among other things, the muscles that controlled breathing. Severe botulism generally resulted in death, unless the patient received proper care to ensure continued breathing. Recovery occurred only

when the affected nerves grew new endings, a process that could extend over several months, although recovery time varied greatly from case to case.

19. In or about December 1991, the FDA approved a BLA for "Botox®," the brand name of a drug containing OnabotulinumtoxinA, which was derived from Botulinum toxin type A, and manufactured by Allergan, Inc., for the treatment of cervical dystonia, a condition involving involuntary contractions of the neck muscles causing twisting or turning of the head, in adults. In or about April 2002, the FDA approved a supplement to Allergan's Botox BLA for the treatment of glabellar lines, commonly referred to as wrinkles. Under this FDA approval, Allergan's OnabotulinumtoxinA product was marketed and labeled for this supplemental usage as "Botox®® Cosmetic."

20. The FDA approvals for Botox® and Botox® Cosmetic limited them to use under the supervision of a licensed practitioner; thus, they were prescription drugs. According to their FDA-approved labeling: (a) the safe and effective use of Botox® and Botox® Cosmetic depended upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques; and (b) unopened vials of Botox® and Botox® Cosmetic were to be stored in a refrigerator at temperatures between 2° to 8° Celsius (36° to 46° Fahrenheit).

21. FDA-approved Botox® and Botox® Cosmetic included labeling specifically for the patient, called a "Medication Guide," which contained warnings for patients and instructions for when to call a doctor.

22. The FDA-approved labeling for Botox® and Botox® Cosmetic also contained a National Drug Code (also known as an "NDC number"), which was a unique, three-segment numeric identifier that was assigned to the drug.

23. On or about July 31, 2009, the FDA approved several revisions to the labeling for Botox® and Botox® Cosmetic, including: (a) the addition of a "boxed warning" (sometimes referred to as a "black box warning"), cautioning that the effects of Botox® and Botox® Cosmetic might spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism; and (b) a revision to the established name of the drug product (from "Botulinum toxin type A" to "OnabotulinumtoxinA") in order to emphasize that different Botulinum toxin type A products were not interchangeable because the units used to measure the products were different.

24. The FDA did not approve all forms of Botox available on the international market. Unapproved forms included Botox manufactured for and distributed in foreign countries under conditions that were not subject to federal law and FDA regulation and oversight. These non-FDA-approved forms of Botox, hereafter referred to as "foreign Botox," were illegally sold to the American market by distributors of foreign-market prescription drugs.

25. Foreign Botox constituted prescription drugs that had not been approved by the FDA for distribution and use in the United States, and CMS had not otherwise designated the foreign, unapproved Botox as a drug covered by Medicare for reimbursement. Dangerous aspects of foreign Botox included, among other things, the

lack of controls over how it had been stored and shipped, such that its original condition would be safely preserved until it was used for treating a patient.

The Defendant

26. **CONNOR** was a medical doctor licensed in the State of Oklahoma, who owned and operated Neurological Center of Oklahoma, located at 6585 South Yale Avenue, Suite 620, Tulsa, Oklahoma (the Clinic). In his practice at the Clinic, **CONNOR** treated various neurological disorders and diseases, of which several could be treated with FDA-approved Botox.

**The Manner and Means of the Scheme**

27. To achieve the purposes of the Scheme, **CONNOR** used the following manner and means, among others:

28. **CONNOR** caused the Clinic to order, purchase and receive illegal, foreign Botox from distributors of foreign-market prescription drugs.

29. **CONNOR** caused the Clinic to receive the illegal, foreign Botox through the United States Postal Service and private and commercial interstate carrier.

30. **CONNOR** caused the Clinic to pay less for illegal, foreign Botox than the price for legitimate, FDA-approved Botox.

31. The labels and labeling of the illegal, foreign Botox that **CONNOR** caused the Clinic to buy differed from FDA-approved Botox in the following material ways, among others:

a. They failed to bear the symbol "Rx only";

b. They failed to bear the NDC Code;

d. They failed to contain the "boxed warning";

e. They failed to contain a Medication Guide for patients;

f. They were in a language other than English; and

g. They included uses that were not part of the FDA-approved label.

32. **CONNOR** did not disclose to his patients at the Clinic that he was illegally treating them with illegal, foreign Botox purchased from foreign distributors.

33. **CONNOR** caused the Clinic to submit materially false and fraudulent claims for reimbursement to Medicare, which falsely and fraudulently represented that he had treated the Clinic's patients with FDA-approved Botox, drugs legitimately reimbursable by Medicare when, in fact and as **CONNOR** then knew, he had actually treated the patients with illegal, foreign Botox, the cost of which was not reimbursable by Medicare.

34. **CONNOR** fraudulently caused Medicare to pay the Clinic for the cost of FDA-approved Botox when, in fact, the Clinic had treated patients with cheaper, non-reimbursable, illegal foreign Botox.

35. **CONNOR** fraudulently caused Medicare to pay the Clinic pursuant to the Scheme in the total approximate amount of $223,636.99.

**The Executions of the Scheme**

36. On or about the dates stated below, **CONNOR** knowingly and willfully executed, and attempted to execute, the Scheme by injecting illegal, foreign Botox into patients, known to the Grand Jury and designated below by their initials, and then

submitting fraudulent claims to Medicare for reimbursement of the purported cost of the treatment drugs and services, in the approximate amounts stated below:

| COUNT | DATE OF SERVICE | PATIENT INITIALS | AMOUNT CLAIMED |
|---|---|---|---|
| 1 | 08/11/2014 | G.C. | $872.75 |
| 7 | 08/11/2014 | G.C. | $89.40 |
| 8 | 11/30/2016 | L.D. | $464.91 |
| 9 | 11/30/2016 | L.D. | $95.17 |
| 10 | 08/24/2016 | S.J. | $457.62 |
| 11 | 08/24/2016 | S.J. | $95.17 |
| 12 | 06/02/2014 | D.M. | $99.11 |
| 13 | 06/02/2014 | D.M. | $425.32 |
| 14 | 08/17/2016 | D.M. | $95.17 |
| 15 | 08/17/2016 | D.M. | $457.62 |
| 16 | 03/04/2014 | M.S. | $89.40 |
| 17 | 03/04/2014 | M.S. | $1,706.61 |
| 18 | 09/30/2015 | M.S. | $90.53 |
| 19 | 09/30/2015 | M.S. | $49.92 |
| 20 | 09/30/2015 | M.S. | $1,795.67 |
| 21 | 10/03/2016 | M.S. | $50.94 |
| 22 | 10/03/2016 | M.S. | $1,859.65 |
| 23 | 10/03/2016 | M.S. | $91.85 |
| 24 | 11/29/2016 | N.S. | $95.17 |
| 25 | 11/29/2016 | N.S. | $464.91 |
| 26 | 08/19/2016 | S.S. | $102.68 |
| 27 | 08/19/2016 | S.S. | $457.62 |
| 28 | 09/29/2014 | K.S. | $99.11 |
| 29 | 09/29/2014 | K.S. | $436.37 |
| 30 | 11/03/2016 | K.S. | $95.17 |
| 31 | 11/03/2016 | K.S. | $464.91 |
| 32 | 05/22/2014 | R.T. | $89.40 |
| 33 | 05/22/2014 | R.T. | $850.64 |
| 34 | 08/25/2014 | R.T. | $89.40 |
| 35 | 08/25/2014 | R.T. | $872.75 |
| 36 | 03/24/2016 | D.T. | $91.85 |
| 37 | 03/24/2016 | D.T. | $50.94 |
| 38 | 03/24/2016 | D.T. | $897.05 |
| 39 | 10/19/2016 | D.T. | $91.85 |
| 40 | 10/19/2016 | D.T. | $50.94 |
| 41 | 10/19/2016 | D.T. | $929.82 |

All in violation of Title 18, United States Code, Section 1347.

## COUNT TWO
**[21 U.S.C. §§ 331(c) and 333(a)(2)]**

Paragraphs 1 through 36 of this Second Superseding Indictment are incorporated in this Count by reference.

On or about January 25, 2017, in the Northern District of Oklahoma and elsewhere, the defendant, **GREGORY SINCLAIR CONNOR**, with the intent to defraud and mislead, received a drug in interstate commerce from Gibraltar, Great Britain, Ireland, Malta and Pakistan, namely, an illegal, foreign version of Botox that had not been approved for distribution and use in the United States by the FDA, that was misbranded in the following ways, among others:

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

b. The labeling failed to bear adequate warnings; and

c. The labeling failed to bear the symbol "Rx only" prior to dispensing warnings,

and delivered and proffered delivery of such misbranded drug for pay and otherwise.

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

## COUNT THREE
**[18 U.S.C. § 1028A(a)(1)]**

Paragraphs 1 through 36 of this Second Superseding Indictment are incorporated in this Count by reference.

On or about August 11, 2014, in the Northern District of Oklahoma and elsewhere, the defendant, **GREGORY SINCLAIR CONNOR**, did knowingly possess and use, without lawful authority, a means of identification, that is, the name and Medicare account number of another person, known to the Grand Jury and designated herein as G.C., during and in relation to a felony violation of Title 18, United States Code, Section 1347, as alleged in Counts One and Seven of this Second Superseding Indictment, knowing that the means of identification belonged to another actual person.

All in violation of Title 18, United States Code, Section 1028A(a)(1).

**COUNT FOUR**
**[18 U.S.C. § 1028A(a)(1)]**

Paragraphs 1 through 36 of this Second Superseding Indictment are incorporated in this Count by reference.

On or about August 25, 2014, in the Northern District of Oklahoma and elsewhere, the defendant, **GREGORY SINCLAIR CONNOR**, did knowingly possess and use, without lawful authority, a means of identification, that is, the name and Medicare account number, of another person known to the Grand Jury and designated herein as R.T., during and in relation to a felony violation of Title 18, United States Code, Section 1347, as alleged in Counts Thirty-Two and Thirty-Three of this Second Superseding Indictment, knowing that the means of identification belonged to another actual person.

All in violation of Title 18, United States Code, Section 1028A(a)(1).

**COUNT FIVE**
**[18 U.S.C. § 1028A(a)(1)]**

Paragraphs 1 through 36 of this Second Superseding Indictment are incorporated in this Count by reference.

On or about March 24, 2016, in the Northern District of Oklahoma and elsewhere, the defendant, **GREGORY SINCLAIR CONNOR**, did knowingly possess and use, without lawful authority, a means of identification, that is, the name and Medicare account number, of another person, known to the Grand Jury and designated herein as D.T., during and in relation to a felony violation of Title 18, United States Code, Section 1347, as alleged in Counts Thirty-Four, Thirty-Five and Thirty-Six of this Second Superseding Indictment, knowing that the means of identification belonged to another actual person.

All in violation of Title 18, United States Code, Section 1028A(a)(1).

**COUNT SIX**
**[18 U.S.C. § 1028A(a)(1)]**

Paragraphs 1 through 36 of this Second Superseding Indictment are incorporated in this Count by reference.

On or about August 17, 2016, in the Northern District of Oklahoma and elsewhere, the defendant, **GREGORY SINCLAIR CONNOR**, did knowingly possess and use, without lawful authority, a means of identification, that is, the name and Medicare account number, of another person, known to the Grand Jury and designated herein as D.M., during and in relation to a felony violation of Title 18, United States Code, Section 1347, as alleged in Counts Fourteen and Fifteen of this Second Superseding Indictment, knowing that the means of identification belonged to another actual person.

All in violation of Title 18, United States Code, Section 1028A(a)(1).

**FORFEITURE ALLEGATION**
**[18 U.S.C. § 982(a)(7), 21 U.S.C. § 853, 18 U.S.C. § 982(a)(2)(B), and 18 U.S.C. § 1028(b)(5)]**

The allegations contained in Counts One through Forty-One of this Second Superseding Indictment are hereby re-alleged and incorporated by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 982(a)(7), Title 21, United States Code, Section 853, Title 18, United States Code, Section 982(a)(2)(B), and Title 18, United States Code, Section 1028(b)(5).

Upon conviction of any of the health care fraud, fraud relating to a misbranded drug or aggravated identity theft offenses alleged in Counts One through Forty-One of this Second Superseding Indictment, as part of his sentence, the defendant, **GREGORY SINCLAIR CONNOR**, shall forfeit to the United States any property, used or intended to be used, to commit such offenses and proceeds of such offenses, including but not limited to:

**MONEY JUDGMENT**

A money judgment in an amount of at least $223,636.99, because such amount represents proceeds obtained by defendant **GREGORY SINCLAIR CONNOR** as a result of such offenses.

Pursuant to Title 21, United States Code, Section 853(p), as adopted by Title 28, United States Code, Section 2461(c), the defendant shall forfeit substitute property, up to the value of the property described above if, by any act or omission of the defendant, the property described above, or any portion thereof, cannot be located upon the exercise of due diligence; has been transferred or sold to, or deposited with, a third party; has been

placed beyond the jurisdiction of the court; has been substantially diminished in value; or has been commingled with other property which cannot be divided without difficulty. The property to be forfeited by the defendant **GREGORY SINCLAIR CONNOR** includes his interest in the following substitute properties:

**SUBSTITUTE ASSETS**

1. Real property commonly known as 6585 South Yale, Suite 620, Tulsa, Tulsa County, Oklahoma, more particularly described as Lot 1, Block 1, Section 03, Township 18, Range 13, the William K. Warren Medical Research Center Inc. Resub Subdivision;

2. Real property commonly known as 6290 East 145th Street North, Collinsville, Tulsa County, Oklahoma, more particularly described as Lot 9, Block 2, Section 27, Township 22, Range 13, Cooper Crossing II Subdivision; and

3. Real property commonly known as 8626 South Fulton Avenue East, Tulsa, Tulsa County, Oklahoma, more particularly described as Lot 11, Block 7, Section 15, Township 18, Range 13, Southern Pointe Second B6-9 Subdivision.

All pursuant to Title 18, United States Code, Section 982(a)(7), Title 21, United States Code, Section 853, Title 18, United States Code, Section 982(a)(2)(B), and Title 18, United States Code, Section 1028(b)(5).

R. TRENT SHORES
UNITED STATES ATTORNEY

A TRUE BILL

Melody N. Nelson

MELODY N. NELSON
Assistant United States Attorney

*/s/ Grand Jury Foreperson*
Grand Jury Foreperson