IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	**CRIMINAL NO. 19-**
v.	**:**	**DATE FILED:**
THOMAS J. WHALEN	**:**	**VIOLATIONS:**
	:	**18 U.S.C. § 1347 (health care fraud – 1**
	:	**count)**
	:	**18 U.S.C. § 545 (importation contrary to law**
	:	**– 1 count)**
	:	**21 U.S.C. § 841(a)(1) (distribution of a**
	:	**controlled substance – 2 counts)**
	:	**Notices of forfeiture**

I N F O R M A T I O N

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this Information:

1. Defendant THOMAS J. WHALEN was a doctor of osteopathy whose practice area focused on the treatment of chronic conditions, such as rheumatoid arthritis, inflammations, and chronic pain. Defendant WHALEN was licensed to practice medicine in the State of Delaware and the Commonwealth of Pennsylvania.

2. Defendant THOMAS J. WHALEN owned Rheumatology Consultants, P.C., doing business as Whalen Rheumatology Group ("WRG"), a Pennsylvania corporation with offices located at 117 North Eagle Road, Havertown, Pennsylvania; 310 Exton Commons, Exton, Pennsylvania; and 5223 West Woodmill Drive, # 41, Wilmington, Delaware.

3. Defendant THOMAS J. WHALEN and WRG participated in numerous federal and private insurance health care plans, including the Medicare Program, federal health

care plans paid for by the Office of Personnel Management, and private plans administered by Independence Blue Cross.

The Medicare Program

4. The Medicare Program ("Medicare") was a federally-funded health care program that provided benefits to persons who were at least 65 years old or disabled. Medicare was administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services ("HHS"). Individuals who received benefits under Medicare were referred to as Medicare "beneficiaries."

5. Medicare was a "health care benefit program" as defined in Title 18, United States Code, Section 24(b).

6. Medicare was divided into multiple parts: Part A covered hospital inpatient care, Part B covered physicians' services and outpatient care, Part C was Medicare Advantage Plans, and Part D covered prescription drugs. Medicare coverage for prescription drugs was primarily provided under the voluntary Medicare Part D benefit. However, under certain circumstances, Medicare covered a limited number of outpatient drugs under its Part B benefit. This included drugs furnished incident to a physician's service (that is, drugs that were infused or injected in physicians' offices or hospital outpatient settings).

7. In order for a drug to meet Medicare's Part B coverage requirements, the drug had to be in a form that was not usually self-administered, furnished by a physician, and administered by the physician or auxiliary personnel employed by the physician and under the physician's personal supervision. Any charge for the drug was included in the physician's claim to Medicare as an expense to the physician. Additionally, the use of the drug must have been

safe and effective and otherwise reasonable and necessary. Medicare considered FDA-approved drugs safe and effective for purposes of this requirement when used as specified on the labeling.

8. A medical provider was required to enroll with the Medicare program in order to submit claims for payment to CMS. To enroll in the Medicare program, a medical provider was required to enter into an agreement with CMS in which the provider agreed to comply with all applicable statutory, regulatory, and program requirements for reimbursement from Medicare. By signing the Medicare enrollment application, the provider certified that the provider understood that payment of a claim was conditioned on the claim and the underlying transaction complying with Medicare regulations, Medicare program instructions, the law, and on the provider's compliance with all applicable conditions of participation in Medicare.

Other Insurance Programs

9. The Office of Personnel Management ("OPM") served as the chief human resources agency and personnel policy manager for the federal government. Among its many duties, OPM managed the Federal Employees Health Benefits Program ("FEHBP"). FEHBP benefits were afforded to all federal employees and their family members who chose from over 300 FEHBP contracted health insurance carriers. Benefits were administered by private insurance companies and paid for, in large part, by OPM. A medical provider must have been enrolled with OPM as a participating provider in order to submit claims to OPM for medical services to federal employees and their family members.

10. Independence Blue Cross ("IBC") was a private insurance company that offered health insurance plans for individuals and families throughout Southeastern Pennsylvania. IBC was the largest health insurer in the Philadelphia area and offered a wide variety of health plans, including managed care and traditional indemnity insurance. A medical

provider must have been enrolled with IBC as a participating provider in order to submit claims to IBC for medical services.

11. Like Medicare, OPM and IBC required that any drug prescribed by a participating provider must be safe and effective and otherwise reasonable and necessary. According to OPM and IBC, drugs that were approved for marketing by the FDA were considered safe and effective for purposes of this requirement when used as specified on the labeling.

The Federal Food, Drug, and Cosmetic Act

12. The Federal Food, Drug, and Cosmetic Act ("FDCA"), protected the public from, among other things, drugs that were misbranded, adulterated, or otherwise unsafe. A drug or device was misbranded if it failed to bear the FDA-approved label or if the label was not in the English language. The FDA enforced the FDCA and its responsibilities included regulating the manufacture and distribution of drugs shipped or received in interstate commerce.

13. A "drug," among other things, included articles intended for use to diagnose, cure, mitigate, treat, or prevent a disease, or to affect the structure or any function of the body. A "prescription drug," among other things, was a drug which, because of its toxicity or other potential harmful effect, or because of its method of use, was unsafe except under the supervision of a licensed practitioner.

Relevant Drugs

14. Remicade was an antibody biologic prescription drug that was used to treat numerous conditions, including rheumatoid arthritis, psoriatic arthritis, ulcerative colitis,

Crohn's disease, and ankylosing spondylitis.[1] It was administered by a health care professional through intravenous infusion.

15. Orencia was a biologic prescription drug that was used to treat rheumatoid arthritis. It was administered by a health care professional through intravenous infusion.

16. Prolia/Xgeva, were biologic injections that were used to treat osteoporosis. Both injections were administrated by a health care professional.

17. Synvisc and Synvisc-One were biologic injections that were used to treat knee osteoarthritis. Both injections were administered by a health care professional: Synvisc was comprised of a series of three injections, while the newer Synvisc-One® was comprised of only one injection.

18. Boniva was an injectable prescription drug that was used to treat osteoporosis. It was administered by a health care professional through intravenous infusion.

The Fraudulent Scheme

19. From in or about January 2014 to in or about March 2018, defendant THOMAS J. WHALEN agreed with others known and unknown to the United States to execute, and executed, a scheme to enrich himself and others, as follows:

a. by purchasing, importing, and distributing non-FDA approved misbranded injectable medications;

b. by providing beneficiaries with non-FDA approved injectable medications; and

[1] A biologic is a drug made from complex molecules manufactured using living cells. While most drugs are chemicals synthesized from other chemicals, biologics are much more expensive due to their complex manufacturing process.

c. by submitting and causing to be submitted claims to Medicare, OPM, IBC and other health care benefit programs, for the provision of injectable medications, specifically, Remicade, Orencia, Prolia/Xgeva, Synvisc and SynviscOne, and Boniva, when, in fact, non-FDA approved misbranded injectable medications were provided to the beneficiaries.

20. From in or about January 2014 to in or about March 2018, defendant THOMAS J. WHALEN together with others, submitted and caused to be submitted approximately $2.3 million in claims to Medicare, OPM, IBC and other health care benefit programs for the provision of misbranded non-FDA approved prescription drugs, including Remicade, Orencia, Prolia/Xgeva, Synvisc and SynviscOne, and Boniva, and was paid approximately $1.1 million.

21. From at least in or about January 2014 to in or about March 2018, in the Eastern District of Pennsylvania, and elsewhere, defendant

THOMAS J. WHALEN,

knowingly and willfully executed, attempted to execute, and aided and abetted the execution of, a scheme and artifice to defraud one or more health care benefit programs, as defined in Title 18, United States Code, Section 24(b), that is, Medicare, OPM, and IBC, and to obtain, by means of materially false and fraudulent pretenses, representations and promises, money and property owned by, and under the custody and control of, Medicare, OPM, and IBC, in connection with the delivery of and payment for health care benefits, items and services.

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

COUNT TWO

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

At all times material to the Information:

1. Paragraphs One through Twenty-One of Count One are incorporated here.

2. On or about March 20, 2018, in the Eastern District of Pennsylvania, and elsewhere, defendant

THOMAS J. WHALEN

fraudulently and knowingly imported and brought into the United States, and aided and abetted the importation into the United States of, merchandise contrary to law, that is, vials of misbranded Remicade that were not FDA approved.

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

COUNTS THREE AND FOUR

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

At all times material to the Information:

1. Paragraphs One and Two of Count One are incorporated here.

The Controlled Substances Act

2. The Controlled Substances Act ("CSA") governed the manufacture, distribution, and dispensation of controlled substances in the United States. With limited exceptions for medical professionals, the CSA made it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense a controlled substance or conspire to do so.

3. Medical practitioners, such as physicians, who were authorized to prescribe controlled substances by the jurisdiction in which they were licensed to practice medicine, were authorized under the CSA to prescribe or otherwise distribute controlled substances, if they were registered with the Attorney General of the United States. 21 U.S.C. § 822(b); 21 C.F.R. § 1306.03. A medical practitioner must have been registered with the DEA in order to prescribe controlled substances. Upon application by the practitioner, the DEA assigned a unique registration number to each qualifying medical practitioner.

4. Chapter 21 of the Code of Federal Regulations, Section 1306.04, which governed the issuance of prescriptions, provided that a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

5. The CSA and its implementing regulations set forth which drugs and other substances were defined by law as "controlled substances," and assigned those controlled substances to one of five schedules (Schedule I, II, III, IV, or V) depending on their potential for

abuse, likelihood of physical or psychological dependency, accepted medical use, and accepted safety for use under medical supervision.

6. A controlled substance assigned to Schedule II had a high potential for abuse, was highly addictive, and had a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Abuse of a Schedule II controlled substance could have led to severe psychological and/or physical dependence. Pursuant to the CSA and its implementing regulations, oxycodone was classified as a Schedule II controlled substance.

7. Defendant THOMAS J. WHALEN prescribed Schedule II controlled substances outside the usual course of professional practice and not for a legitimate medical purpose to patients. Specifically, defendant WHALEN prescribed oxycodone to patients despite having received and reviewed urine drug screening test results for these patients that contained negative results for the controlled substances that defendant WHALEN prescribed for the patients and/or positive results for illicit drugs, such as heroin and cocaine.

8. On or about each of the dates listed below, in the Eastern District of Pennsylvania, and elsewhere, defendant

THOMAS J. WHALEN,

knowingly and intentionally distributed and dispensed, outside the course of professional practice and not for a legitimate medical purpose, a mixture and substance containing a detectable amount of a Schedule II controlled substance (each distribution constituting a separate count of this Information):

COUNT	APPROXIMATE DATES OF DISTRIBUTION	PATIENT'S INITIALS	SUBSTANCE	APPROXIMATE WEIGHT
3	February 2016 to April 2018	J.J.	Oxycodone	24.98 g
4	November 2016 to September 2017	D.M.	Oxycodone	28.28 g

All in violation of Title 21, United States Code, 841(a)(1), (b)(1)(C).

NOTICE OF FORFEITURE #1

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. As a result of the violation of Title 18, United States Code, Section 1347, set forth in this Information, the defendant

THOMAS J. WHALEN

shall forfeit to the United States of America any property that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of such offense, including, but not limited to, the sum of $1,116,845.02.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

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

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 18, United States Code, Section 982(a)(7).

NOTICE OF FORFEITURE #2

THE GRAND JURY FURTHER CHARGES THAT:

1. As a result of the violation of Title 21, United States Code, Section 841(a)(1), (b)(1)(C), set forth in this Information, the defendant

THOMAS J. WHALEN

shall forfeit to the United States of America:

(a) any property used or intended to be used, in any manner or part, to commit, or to facilitate the commission of, such violations; and

(b) any property constituting, or derived from, proceeds obtained, directly or indirectly, from the commission of such violations.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

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

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty;

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

seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Section 853.

WILLIAM M. MCSWAIN
United States Attorney
Eastern District of Pennsylvania