

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
	:	
v.	:	Crim. No. 22-
	:	
JON PAUL DADAIAN	:	21 U.S.C. §§ 353(c)(3)(A), 331(t) &
	:	333(a)(2)

INFORMATION

The defendant having waived in open court prosecution by Indictment, the United States Attorney for the District of New Jersey charges:

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

1. The United States Food and Drug Administration (“FDA”) is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399i (the “FDCA”).

2. The FDCA defines a “drug” to include “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man,” “articles . . . intended to affect the structure or any function of the body of man,” and articles intended for use as components of other drugs. 21 U.S.C. § 321(g)(1)(B), (C) and (D).

3. Under the FDCA, “prescription drugs” are drugs that, because of their toxicity and other potential for harmful effects, and/or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A). A drug is also a prescription drug if the FDA requires it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA’s approval of the drug. 21 U.S.C. § 353(b)(1)(B).

4. The FDCA prohibits “the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title,” which includes prescription drugs which were purchased by “a public or private hospital or other health care entity.” 21 U.S.C. §§ 331(t) & 353(c)(3)(A).

5. 21 U.S.C. § 353(c)(3)(A) provides, in relevant part, that “[n]o person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug (i) which is subject to subsection (b), and (ii)(I) which was purchased by a public or private hospital or other health care entity.”

6. A “health care entity” is defined as: “[A]ny person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in § 203.22(h) and (i), a person cannot simultaneously be a ‘health care entity’ and a retail pharmacy or wholesale distributor.” 21 C.F.R. 203.3(q).

7. At all times relevant to this Information:

a. Herceptin® was an FDA-approved drug manufactured by Drug Manufacturer

1. It contained the active ingredient trastuzumab. Herceptin® was indicated for treatment of patients with metastatic breast cancer, adjuvant breast cancer, and metastatic gastric cancer.

b. Rituxan® was an FDA-approved drug manufactured by Drug Manufacturer 1.

It contained the active ingredient rituximab. Rituxan® was indicated for several treatments, including, among others, treatment of adult patients with non-Hodgkins lymphoma and chronic lymphocytic leukemia, and pediatric patients aged 6 months or older with mature B-cell non-Hodgkins lymphoma and mature B-cell acute leukemia.

c. Herceptin® and Rituxan® were each a “drug” under the FDCA because each was intended for use in the treatment of disease in man. 21 U.S.C. § 321(g)(1)(B). In addition, Herceptin® and Rituxan® were each a “prescription drug” drug within the meaning of 21 U.S.C. § 353(b)(1)(A) and (B). Herceptin® and Rituxan® were also each a “biological product.” The term “biological product” includes a wide range of products, such as viruses, toxins, vaccines, blood, proteins and other specific similar substances “applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i)(1). Biological products are produced from a variety of natural sources—human, animal, or microorganism.

8. Many products met the definition of both “drug” and “biological product.” Pursuant to 42 U.S.C. § 262(j), the FDCA applies to biological products subject to regulation under Title 42.

9. Most biological products require specific storage conditions including protection from exposure to light and heat, as indicated in the product labeling, to maintain their safety, purity, and potency. Typically, such products are referred to as “cold chain” products, meaning that they must be refrigerated within a narrow cold-temperature range at all times—from the time the products are manufactured until the time that the products are administered to a patient. If the biological products are not kept under the proper conditions, they quickly will degrade, though the degradation may not be visibly discernable. Accordingly, manufacturers of biological products, as well as their licensed authorized distributors, tightly control the sale and distribution of such products.

10. Also at all times relevant to this Information, to ensure and maintain the safety and efficacy of Herceptin® and Rituxan®, Manufacturer 1 provided that Herceptin® and Rituxan®

should be stored and handled so as to avoid exposure to light and heat, proscribing a narrow temperature range within which these cold chain drugs must be maintained. In general, Manufacturer 1 also limited distribution of Herceptin® and Rituxan® to authorized pharmaceutical distributors who, in turn, were permitted only to sell to authorized purchasers.

THE DEFENDANT AND OTHER INDIVIDUALS AND ENTITIES

11. At all times relevant to this Information:

a. Defendant JON PAUL DADAIAN was a physician licensed by the state of New Jersey to practice medicine, and he was also registered with the Drug Enforcement Administration (“DEA”) to dispense controlled substances.

b. Defendant JON PAUL DADAIAN was a board-certified anesthesiologist and pain management specialist who practiced medicine through his professional corporation and medical practice, Jon Paul Dadaian PC. Jon Paul Dadaian PC had offices at several locations in New Jersey, including an Office in Elmwood Park, New Jersey.

c. Through his medical practice, Jon Paul Dadaian PC, defendant JON PAUL DADAIAN provided diagnostic and medical treatment to patients. Both defendant JON PAUL DADAIAN and Jon Paul Dadaian PC were “health care entities” as that term is defined in 21 C.F.R. 203.3(q).

d. Defendant JON PAUL DADAIAN maintained and used a bank account in the name of his medical practice, Jon Paul Dadaian PC, at Bank 1, with the last four digits 3603 (“Dadaian Bank Account 1”).

e. In or about February 2016, defendant JON PAUL DADAIAN opened or allowed to be opened a bank account in the name of Jon Paul Dadaian PC at Bank 2, with the last four digits 4551 (“Dadaian Bank Account 2”). Dadaian Bank

Account 2 was opened for the purpose of allowing other individuals not named as defendants herein, including Individual 1 and Individual 2 (collectively, “Individuals 1 and 2”), to purchase and pay for prescription drugs that were ordered in defendant JON PAUL DADAIAN’s name and using his medical license and DEA registration.

f. Businesses 1 and 2 are New Jersey corporations that were “wholesale distributors” engaged in the “wholesale distribution” of prescription drugs, as defined as 21 C.F.R. § 203.3(cc), (dd). Businesses 1 and 2 operated out of offices located in Sewaren, New Jersey. Businesses 1 and 2 are owned, operated, and/or controlled by individuals not named as defendants herein, including Individual 1, Individual 2, Individual 3, and Individual 4 (collectively, “Individuals 1-4”).

g. Individuals 1-4 also owned, operated and/or controlled additional New Jersey corporations, hereinafter referred to collectively as Businesses 3-6, which were related to Businesses 1 and 2 and which also engaged in transactions involving expensive prescription drugs, including the biologic products described herein.

THE SCHEME

12. Individuals 1 and 2 recruited and used defendant JON PAUL DADAIAN and Jon Paul Dadaian PC to purchase expensive prescription drugs—primarily, cold-chain biologic infusion medications that typically are used to treat cancers, macular degeneration, and autoimmune diseases, including but not limited to Herceptin® and Rituxan®—under false pretenses so that Individuals 1 and 2 could resell these prescription drugs at a profit through Businesses 1 and 2.

13. In making such purchases, defendant JON PAUL DADAIAN, Individuals 1-3, and Businesses 1 and 2 made, and caused to be made, numerous false and misleading statements to the

pharmaceutical manufacturers and their authorized distributors. These false and misleading statements included, but were not limited to, the following:

- a. Defendant JON PAUL DADAIAN and Jon Paul Dadaian PC was the actual purchaser of the prescription drugs;
- b. Defendant JON PAUL DADAIAN and Jon Paul Dadaian PC used such prescription drugs to treat patients through defendant JON PAUL DADAIAN's medical practice;
- c. Defendant JON PAUL DADAIAN and Jon Paul Dadaian PC were entitled to discounted pricing on such prescription drugs, which the pharmaceutical manufacturers limited to community physicians who used such prescription drugs to treat their patients and others similarly situated; and
- d. The prescription drugs were not being resold or redistributed.

14. By recruiting and using physicians and their medical practices, such as defendant JON PAUL DADAIAN and Jon Paul Dadaian PC, Individuals 1 and 2 were able to obtain prescription drugs from the pharmaceutical manufacturers' authorized distributors that they would not otherwise have been permitted to purchase, which they were then able to sell at a profit through Businesses 1 and 2.

15. In some instances, by using defendant JON PAUL DADAIAN and Jon Paul Dadaian PC to purchase their prescription drugs, Individuals 1 and 2 also obtained discounted community physician pricing for these prescription drugs. The discounted community physician pricing was based upon specialized discounts that the pharmaceutical manufacturers only offered to treating physicians and others similarly situated. Individuals 1 and 2, and their Businesses 1 and 2, would not have been qualified to receive this favorable community physician pricing if they had attempted to purchase the prescription drugs directly from the pharmaceutical manufacturers.

16. From in or about June 2012 through in or about April 2018, defendant JON PAUL DADAIAN used his medical license, and allowed others, including Individuals 1-3, to use his medical license, in order to purchase various prescription drugs. These prescription drugs were primarily expensive cold-chain biologic infusion medications typically used to treat cancer, macular degeneration, and autoimmune diseases, including but not limited to Herceptin® and Rituxan®. These prescription drugs were then diverted from the normal pharmaceutical distribution supply chain and subsequently distributed in unauthorized transactions, including further transfers and resale to other customers, as described herein.

17. None of the prescription drugs that defendant JON PAUL DADAIAN and Jon Paul Dadaian PC purchased on behalf of Individuals 1 and 2, or that Individuals 1-3 and others caused to be purchased in defendant JON PAUL DADAIAN's name and using his medical license, were actually administered (or intended to be administered) to treat defendant JON PAUL DADAIAN's own patients, as required by the applicable contract terms. Accordingly, defendant JON PAUL DADAIAN did not qualify to purchase the prescription drugs, nor did he qualify for the special discounted prices on these prescription drugs that were given by pharmaceutical manufacturers to treating physicians who ordered these medications for use in their own medical practices.

18. Instead of using the prescription drugs to treat his own patients, defendant JON PAUL DADAIN sold and transferred the prescription drugs to Businesses 1 and 2, at the direction of Individuals 1 and 2. Defendant JON PAUL DADAIAN also allowed others, including Individuals 1-3, to sell and transfer the prescription drugs to Businesses 1 and 2.

19. In exchange for allowing Individuals 1-3 and Businesses 1 and 2 to use defendant JON PAUL DADAIAN and Jon Paul Dadaian PC to purchase prescription drugs, defendant JON PAUL DADAIAN was paid approximately \$130,500. Individuals 1 and 2 made and directed the making of such payments into Dadaian Bank Account 1 from bank accounts in the names of

Businesses 1 and 2, as well as from bank accounts of other business entities which Individuals 1 and 2 owned, operated and/or controlled.

20. The vast majority of the prescription drugs that were purchased using defendant JON PAUL DADAIAN's medical license were delivered to defendant JON PAUL DADAIAN's medical office in Elmwood, New Jersey, and were later transported to the offices of Businesses 1 and 2 in Sewaren, New Jersey at the direction of Individuals 1-3. This transportation arrangement was put in place in order to mislead the pharmaceutical manufacturers and their authorized distributors as to the identity of the actual purchaser—*i.e.*, Businesses 1 and 2—and the fact that the prescription drugs were being resold for profit.

21. After the prescription drugs arrived at the offices of Businesses 1 and 2, Individuals 1-3 directed and controlled the repackaging and redistribution of the prescription drugs to Businesses 1 and 2's customers, some of which were also entities engaged in the business of distributing prescription drugs, including retail pharmacies and other wholesale distributors.

22. Initially, defendant JON PAUL DADAIAN used Dadaian Bank Account 1 to make payments for the prescription drugs that had been ordered in his name and using his medical license. Defendant JON PAUL DADAIAN was then reimbursed for the cost of those prescription drugs by and at the direction of Individuals 1 and 2, on behalf of Businesses 1 and 2, from monies paid from bank accounts in the names of Businesses 1 and 2, as well as other bank accounts under the control of Individuals 1 and 2.

23. After Dadaian Bank Account 2 was opened in or about February 2016, Individuals 1-3 operated and controlled Dadaian Bank Account 2 and used it to pay for the purchases of prescription drugs. Individuals 1-3 replenished Dadaian Bank Account 2 with monies from bank accounts held in the names of Businesses 1 and 2, as well as other bank accounts under the control of Individuals 1 and 2, as needed.

24. During the period from in or about June 2012 through in or about April 2018, defendant JON PAUL DADAIAN and Jon Paul Dadaian PC sold and transferred, and allowed others, including Individuals 1-3, to sell and transfer, the prescription drugs which previously had been purchased in defendant JON PAUL DADAIAN's name and using his medical license, to Businesses 1 and 2.

25. By way of example, on or about the dates listed below, defendant JON PAUL DADAIAN and Jon Paul Dadaian PC purchased and allowed Individuals 1-3 to purchase the below-listed prescription drugs in the following approximate amounts, and at the below indicated approximate discounted community physician prices, to which defendant JON PAUL DADAIAN was not entitled. Those prescription drugs were not administered or dispensed by defendant JON PAUL DADAIAN to treat his patients, but rather were sold and transferred from defendant JON PAUL DADAIAN and Jon Paul Dadaian PC to Businesses 1 and 2. In order to deceive the authorized pharmaceutical distributors as to the use of the prescription drugs, each of those prescription drugs was received by defendant JON PAUL DADAIAN and/or his office staff at his medical office in Elmwood Park, New Jersey and then transported, at the direction of Individuals 1-3, to Businesses 1 and 2 in Sewaren, New Jersey. After arriving at Businesses 1 and 2, the prescription drugs were repackaged and sold to customers of Businesses 1 and 2, at the direction of Individuals 1-3, and at a significant profit, as indicated by the approximate amounts listed below.

INITIAL PURCHASE OF MEDICATIONS BY/THROUGH DEFENDANT & JON PAUL DADAIAN PC				RESALE AT A PROFIT BY BUSINESSES 1 AND 2	
DATE PURCHASED BY/THROUGH DADAIAN	PRODUCT & INVOICE NUMBER(S)	PURCHASE PRICE FROM AUTHORIZED DISTRIBUTOR	DISCOUNT	INVOICE DATE, NUMBER, & SALES PRICE	PROFIT
03/15/2016	444 HERCEPTIN 440 MG 20 ML (Inv. Nos. 312662103741, 312662103742)	\$1,671,500.16	\$ [REDACTED]	03/11/2016 \$1,833,720.00 (Customer 1/Inv. No. 60311515)	\$162,219.84

INITIAL PURCHASE OF MEDICATIONS BY/THROUGH DEFENDANT & JON PAUL DADAIAN PC				RESALE AT A PROFIT BY BUSINESSES 1 AND 2	
DATE PURCHASED BY/THROUGH DADAIAN	PRODUCT & INVOICE NUMBER(S)	PURCHASE PRICE FROM AUTHORIZED DISTRIBUTOR	DISCOUNT	INVOICE DATE, NUMBER, & SALES PRICE	PROFIT
3/16/2016	605 RITUXAN 10 MG/ML 50 ML SDV 1/EA (Inv. Nos. 0310499167175, 0310499167178 through 0310499167188)	\$2,216,756.30	\$ [REDACTED]	3/9/2016 \$2,462,350.00 (Customer 1/Inv. No. 6030950)	\$245,595.70
6/14/2017	150 HERCEPTIN 440MG MDV W/DIL 1/EA (Inv. Nos. 31280081860 through 31280081863)	\$596,137.50	\$ [REDACTED]	\$658,891.50 6/9/2017 (Customer 1/ Invoice No. 70609506)	\$62,754
11/15/2017	220 RITUXAN 10 MG/ML 50 ML SDV 1/EA (Inv. Nos. 31371139341032 through 31371139341035)	\$889,277.40	\$ [REDACTED]	\$1,003,695 11/10/2017 (Customer 2/ Invoice No. 4012)	\$114,417.60
11/29/2017	680 HERCEPTIN 150 MG SDV LYO PWD 1/EA (Inv. No. 313784626943 through 313784626945)	\$953,543.60	\$ [REDACTED]	\$1,088,000 11/28/2017 (Customer 1/ Invoice No. 71125501)	\$134,456.40

(Continued on the next page.)

26. On or about November 29, 2017, in the District of New Jersey and elsewhere, the defendant,

JON PAUL DADAIAN,

did, with the intent to defraud and mislead, sell, and transfer to Businesses 1 and 2, a prescription drug, that is, approximately 680 units of Herceptin®, which had been previously purchased by a health care entity, that is, Dr. Jon Paul Dadaian and Jon Paul Dadaian PC, contrary to 21 U.S.C. § 353(c)(3)(A).

In violation of 21 U.S.C. §§ 331(t) and 333(a)(2).

A handwritten signature in dark ink, appearing to read "Philip R. Sellinger b7c".

PHILIP R. SELLINGER
United States Attorney

CASE NUMBER: 22-

**United States District Court
District of New Jersey**

UNITED STATES OF AMERICA

v.

JON PAUL DADAIAN

INFORMATION FOR

21 U.S.C. §§ 353(c)(3)(A), 331(t) & 333(b)

PHILIP R. SELLINGER

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