

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Hon. Susan D. Wigenton, U.S.D.J.
 :
 v. : Crim. No. 23-
 :
 ANISE KACHADOURIAN : 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.
 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.
 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” 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 ANISE KACHADOURIAN was a physician licensed by the state of New Jersey to practice medicine, and she was also registered with the Drug Enforcement Administration (“DEA”) to dispense controlled substances.
 - b. Defendant ANISE KACHADOURIAN was a board-certified oncologist who practiced medicine through her professional corporation and medical practice, Anise Kachadourian MD LLC. Anise Kachadourian MD LLC had offices at several locations in New Jersey, including an office in Union, New Jersey.
 - c. Through her medical practice, Anise Kachadourian MD LLC, defendant ANISE KACHADOURIAN provided diagnostic and medical treatment to patients. Both defendant ANISE KACHADOURIAN and Anise Kachadourian MD LLC were “health care entities” as that term is defined in 21 C.F.R. 203.3(q).
 - d. Defendant ANISE KACHADOURIAN maintained and used a bank account in the name of her medical practice, Anise Kachadourian MD LLC, at Bank 3, with the last four digits 4173 (“Kachadourian Bank Account 1”).
 - e. Jon Paul Dadaian, who is named as a co-conspirator but not as a defendant herein, 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.

f. 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.

g. Through his medical practice, Jon Paul Dadaian PC, Jon Paul Dadaian provided diagnostic and medical treatment to patients. Both 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).

h. Businesses 1 and 2 are New Jersey corporations that were “wholesale distributors” engaged in the “wholesale distribution” of prescription drugs, as defined in 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”).

i. 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 ANISE KACHADOURIAN and Anise Kachadourian MD LLC 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 furtherance of this purchasing arrangement, on or about October 10, 2016, defendant ANISE KACHADOURIAN entered into a written employment contract with Business 2, which was signed by Individual 1 on behalf of Business 2, and by which defendant ANISE KACHADOURIAN agreed to provide “duties as needed” to Business 2 in return for \$5,000 per month. The only “duties” performed by defendant ANISE KACHADOURIAN under the contract were to purchase and facilitate the unlawful purchase of prescription drugs for resale.

14. In making such purchases, defendant ANISE KACHADOURIAN, 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 ANISE KACHADOURIAN and Anise Kachadourian MD LLC was the actual purchaser of the prescription drugs;
- b. Defendant ANISE KACHADOURIAN and Anise Kachadourian MD LLC used such prescription drugs to treat patients through defendant ANISE KACHADOURIAN’s medical practice and/or a non-existent infusion clinic, which was discussed by Individuals 1-3 and defendant ANISE KACHADOURIAN, but which was never actually formed or operated; and
- c. The prescription drugs were not being resold or redistributed.

15. By recruiting and using physicians and their medical practices, such as defendant ANISE KACHADOURIAN and Anise Kachadourian MD LLC, 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.

16. From in or about October 2016 through in or about January 2019, defendant ANISE KACHADOURIAN used her medical license, and allowed others, including Individuals 1-3, to use her medical license 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 ANISE KACHADOURIAN and Anise Kachadourian MD LLC purchased on behalf of Individuals 1 and 2, or that Individuals 1-3 and others caused to be purchased in defendant ANISE KACHADOURIAN's name and using her medical license, were actually administered or intended to be administered to treat defendant ANISE KACHADOURIAN's own patients as required by the applicable contract terms with the pharmaceutical manufacturers and distributors.

18. Instead of using the prescription drugs to treat her own patients, defendant ANISE KACHADOURIAN sold and transferred the prescription drugs to Businesses 1 and 2, at the direction of Individuals 1 and 2. Defendant ANISE KACHADOURIAN 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 ANISE KACHADOURIAN and Anise Kachadourian MD LLC to purchase prescription drugs, defendant ANISE KACHADOURIAN was paid approximately \$170,000. Individuals 1 and 2 made and directed the making of such payments into Kachadourian Bank Account 1 from a bank

account that they controlled at Bank 4, held in the name of Business 2 and having the last four digits 3846.

20. The vast majority of the prescription drugs that were purchased using defendant ANISE KACHADOURIAN's medical license were shipped to either: (a) defendant ANISE KACHADOURIAN's office in Union, New Jersey;¹ or (b) co-conspirator Jon Paul Dadaian's medical office in Elmwood, New Jersey. At the direction of Individuals 1-3, the drugs were then transported to the offices of Businesses 1 and 2 in Sewaren, New Jersey. 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. During the period from in or about October 2016 through in or about January 2019, defendant ANISE KACHADOURIAN and Anise Kachadourian MD LLC sold and transferred, and allowed others, including Individuals 1-3, to sell and transfer, the prescription drugs which previously had been purchased in defendant ANISE KACHADOURIAN's name and using her medical license, to Businesses 1 and 2.

23. By way of example, on or about the dates listed below, defendant ANISE KACHADOURIAN and Anise Kachadourian MD LLC purchased and allowed Individuals 1-3 to

¹ Some of these drugs were then redirected by defendant ANISE KACHADOURIAN, her office's staff, and/or a sign posted on defendant ANISE KACHADOURIAN'S office door to Business 6, a business that was located in the same building as defendant ANISE KACHADOURIAN's office and that was owned, operated and/or controlled by Individual 1.

purchase, via false and fraudulent statements, the below-listed prescription drugs in the following approximate amounts. After arriving at Businesses 1 and 2 in the manner described in paragraph 20, above, 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 DRUGS FROM AUTHORIZED DISTRIBUTOR BY/THROUGH DEFENDANT ANISE KACHADOURIAN & ANISE KACHADOURIAN MD LLC			RESALE AT A PROFIT BY BUSINESSES 1 AND 2	
DATE PURCHASED	PRODUCT & INVOICE NUMBER(S)	PURCHASE PRICE	CUSTOMER PURCHASE ORDER DATE, NUMBER, & SALES PRICE	PROFIT
4/30/2018 & 5/2/2018	550 HERCEPTIN 150 MG (2 orders of 275 units) (Inv. Nos. 11017587908 & 11017600014)	\$832,166.50	3/5/2018 550 HERCEPTIN 150 MG for \$1,017,500 (Customer 1/Purchase Order No. 80305512)	\$185,333.50
4/26/2018	168 HERCEPTIN 150 MG (Inv. No. 11017581039)	\$254,189.04	4/16/2018 168 HERCEPTIN 150 MG for \$336,000 (Customer 1/Purchase Order No. 80416505)	\$81,810.95
5/2/2018	14 RITUXAN 500 MG 50ML (Inv. No. 11017599330)	\$63,273.92	4/25/2018 14 RITUXAN 500 MG 50 ML for \$70,000 (Customer 3/Purchase Order No. 18-1030)	\$6,726.08
5/22/2018	18 HERCEPTIN 150 MG (2 orders of 9 units) (Inv. Nos. 11017658797 & 11017662320)	\$27,234.54	5/17/2018 18 HERCEPTIN 150 MG for \$37,800 (Customer 2/Purchase Order No. 4383)	\$10,565.46

24. On or about April 26, 2018, in the District of New Jersey and elsewhere, the defendant,

ANISE KACHADOURIAN,

did, with the intent to defraud and mislead, sell, and transfer to Businesses 1 and 2, a prescription drug, that is, approximately 168 units of Herceptin®, which had been previously purchased by a health care entity, that is, Dr. Anise Kachadourian and Anise Kachadourian MD LLC, contrary to 21 U.S.C. § 353(c)(3)(A).

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



PHILIP R. SELLINGER
United States Attorney

CASE NUMBER: 23-_____

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

UNITED STATES OF AMERICA
v.
ANISE KACHADOURIAN

INFORMATION FOR

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

PHILIP R. SELLINGER
UNITED STATES ATTORNEY
FOR THE DISTRICT OF NEW JERSEY

DIANA VONDRA CARRIG
SARA ALIYA ALIABADI
ASSISTANT U.S. ATTORNEYS
CAMDEN, NEW JERSEY
856-757-5026
