2022R00747/DVC/SAA

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon. Susan D. Wigenton, U.S.D.J.
	:	
v.	:	Crim. No. 23-
	:	
JOEL LERNER	:	21 U.S.C. §§ 353(c)(3)(A), 331(t) &
	:	333(a)(2)

I N F O R M A T I O N

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)(l)(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: "any 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. Kadcyla® was an FDA-approved drug manufactured by Drug Manufacturer 1. It contained the active ingredient trastuzumab emtansine. Kadcyla® was indicated for the treatment of patients with HER2-positive breast cancer.

c. Lucentis® was an FDA-approved drug manufactured by Drug Manufacturer 1. It contained the active ingredient ranibizumab. Lucentis® was indicated for several treatments, including wet age-related macular degeneration, diabetic

retinopathy, diabetic macular edma, myopic choroidal neovascularization and macular edema following retinal vein occlusion.

d. Herceptin®, Kadcyla® and Lucentis® 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®, Kadcyla® and Lucentis® were each a "prescription drug" within the meaning of 21 U.S.C. § 353(b)(l)(A) and (B). Herceptin®, Kadcyla® and Lucentis® 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 biological 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. At all times relevant to this Information, to ensure and maintain the safety and efficacy of Herceptin®, Kadcyla® and Lucentis®, Manufacturer 1 provided that Herceptin®, Kadcyla® and Lucentis® 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®, Kadcyla® and Lucentis® 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 JOEL LERNER 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 JOEL LERNER was a board-certified podiatrist who practiced medicine together with several other podiatrists through their collectively-owned limited liability corporation and medical practice referred to herein as "Dr. Lerner's Medical Practice." Dr. Lerner's Medical Practice had offices at several locations in New Jersey, including offices in Union and Springfield, New Jersey.

c. Through Dr. Lerner's Medical Practice, defendant JOEL LERNER provided diagnostic and medical treatment to patients. Both defendant JOEL LERNER and Dr. Lerner's Medical Practice were "health care entities" as that term is defined in 21 C.F.R. 203.3(q).

d. In addition to his medical practice, defendant JOEL LERNER, together with another health care professional, operated and controlled a medical purchasing group referred to herein as "Medical Purchasing Group," which bought certain

medical supplies in bulk in order to pass on discounts to other physicians/practices who were members of Medical Purchasing Group. At no time, however, did Medical Purchasing Group actually buy or sell the prescription drugs at issue in this Information, *i.e.*, drugs used to treat cancers, macular degeneration, and autoimmune diseases, including but not limited to Herceptin®, Kadcyla® and Lucentis®. Rather, as explained below, Dr. Joel Lerner and others merely created the appearance that Medical Purchasing Group was the actual purchaser of the prescription drugs, in order to further their scheme.

e. Businesses 1 and 2 were 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 were 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").

f. 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. Business 6 was a pharmacy in Union, New Jersey, which was owned, operated and/or controlled by Individual 1.

THE SCHEME

12. In or about December 2014, Individual 1 recruited defendant JOEL LERNER to purchase expensive prescription drugs—primarily, cold-chain biologic infusion medications that are typically used to treat cancers, macular degeneration, and autoimmune diseases, including but

not limited to Herceptin®, Kadcyla® and Lucentis®, under false pretenses so that Individuals 1 and 2 could resell these prescription drugs at a profit through Businesses 1 and/or 2.

13. In making such purchases, defendant JOEL LERNER, 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 JOEL LERNER and Dr. Lerner's Medical Practice were the actual purchaser of the prescription drugs;

b. Defendant JOEL LERNER and Dr. Lerner's Medical Practice used such prescription drugs to treat patients through defendant JOEL LERNER's medical practice; and

c. The prescription drugs were not being resold or redistributed.

14. By recruiting and using physicians and their medical practices, such as defendant JOEL LERNER and Dr. Lerner's Medical Practice, 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. From in or about December 2014 through in or about November 2018, defendant JOEL LERNER used his medical license, and allowed others, including Individual 3, to use his 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®, Kadcyla® and Lucentis®. 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.

16. None of the prescription drugs that defendant JOEL LERNER purchased on behalf of Individuals 1-3, or that Individual 3 and others caused to be purchased in defendant JOEL LERNER's name and using his medical license, were actually administered or intended to be administered to treat defendant JOEL LERNER's own patients as required by the applicable contract terms with the pharmaceutical manufacturers and distributors.

17. Instead of using the prescription drugs to treat his own patients, defendant JOEL LERNER sold and transferred the prescription drugs to Businesses 1 and/or 2 at the direction of Individuals 1-3. In an effort to obscure the fact that he was illegally buying and selling prescription drugs purchased under his medical license, defendant JOEL LERNER sold and transferred the prescription drugs in the name of his Medical Purchasing Group, rather than in the name of his medical practice, Dr. Lerner's Medical Practice (through which he actually had purchased the drugs).

18. Individuals 1 and 2 compensated defendant JOEL LERNER for his purchase and resale of prescription drugs in two ways: (a) by paying him commissions on the prescription drugs that defendant JOEL LERNER had illegally purchased for Individuals 1 and 2 and had allowed others to purchase using his medical license; and (b) by providing discounts on various medical supplies that defendant JOEL LERNER's Medical Purchasing Group purchased from Individual 1's Business 6.

19. The vast majority of the prescription drugs that were purchased using defendant JOEL LERNER's medical license were shipped to defendant Dr. Lerner's Medical Practice's offices in Springfield or Union, New Jersey. In most instances, after being notified by defendant JOEL LERNER that the packages of drugs had arrived, Individuals 1-3 directed others to pick up

the drugs and transport them to the offices of Businesses 1 and 2. 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 of the prescription drugs—*i.e.*, Businesses 1 and/or 2—and the fact that the prescription drugs were being resold for profit.

20. 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/or 2's customers, some of which were also entities engaged in the business of distributing prescription drugs for profit, including retail pharmacies and other wholesale distributors.

21. During the period from in or about December 2014 through in or about November 2018, defendant JOEL LERNER and Dr. Lerner's Medical Practice sold and transferred in excess of $1.2 million in prescription drugs, which previously had been purchased in defendant JOEL LERNER's name and using his medical license, to Businesses 1 and/or 2.

22. By way of example, on or about the dates listed below, defendant JOEL LERNER and Dr. Lerner's Medical Practice purchased and allowed others, including Individual 3, to purchase, via false and fraudulent statements, the below-listed prescription drugs in the following approximate amounts. Using the name of his Medical Purchasing Group to conceal the true purchaser of the prescription drugs, defendant JOEL LERNER then transferred and resold the prescription drugs to Business 1, where the drugs were repackaged and sold to customers of Business 1, at the direction of Individuals 1-3, at a profit, as indicated by the approximate amounts listed below.

DR. LERNER PURCHASED DRUGS FROM AN AUTHORIZED DISTRIBUTOR VIA DR. LERNER'S MEDICAL PRACTICE	DR. LERNER TRANSFERRED AND SOLD THE DRUGS TO BUSINESS 1 VIA DR. LERNER'S MEDICAL PURCHASING GROUP	BUSINESS 1 SOLD DRUGS TO ITS CUSTOMERS FOR A PROFIT
July 12, 2018 - Dr. Lerner purchased Kadcyla® 100 mg and Kadcyla® 160 mg for $7,768.60	July 12, 2018 - Dr. Lerner invoiced Business 1 for $7,768.60	July 17, 2018 - Drugs were shipped to Customer 1 for $11,375 PROFIT: $3,606.40
August 28, 2018 - Dr. Lerner purchased 6 Lucentis® 0.3 mg/0.05ml for $7,664.82	August 28, 2018 - Dr. Lerner invoiced Business 1 for $7,664.82	August 29, 2018 - Drugs were shipped to Customer 2 for $12,900 (Inv. No. V1829CCTS-1) PROFIT: $5,235.18
September 19, 2018 - Dr. Lerner purchased Lucentis® 0.5 mg (10mg/ml) for $1,958.78	September 19, 2018 - Dr. Lerner invoiced Business 1 for $1,958.78	September 21, 2018 - Drugs were shipped to Customer 2 for $2,850 PROFIT: $891.22
November 12, 2018 - Dr. Lerner purchased 10 Herceptin® 150 mg for $15,584.30	November 12, 2018 - Dr. Lerner invoiced Business 1 for $15,584.30	November 14, 2018 - Drugs were shipped to Customer 2 for $23,175.00 PROFIT: $7,590.70

23. On or about November 12, 2018, in the District of New Jersey and elsewhere, the defendant,

JOEL LERNER,

did, with the intent to defraud and mislead, sell, and transfer to Business 1, a prescription drug, that is, approximately 10 units of Herceptin®, which had been previously purchased by a health care entity, that is, Dr. JOEL LERNER and Dr. Lerner's Medical Practice, 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.

JOEL LERNER

INFORMATION FOR

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

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