

FILED
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CLERK U.S. DISTRICT COURT
NORTHERN DISTRICT OF OHIO
CLEVELAND

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

MAHMOUD MUSTAFA, and
ZACRESHA JACKSON,

Defendants.

CASE NO.:

1 : 15 CR 111

JUDGE POLSTER

INFORMATION

The United States Attorney charges:

GENERAL ALLEGATIONS

1. The United States Food and Drug Administration (FDA) was the agency of the United States responsible for, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Section 301 et seq.

2. Viagra was a drug within the meaning of Title 21, United States Code, Section 321(g)(1)(C), and further was a prescription drug within the meaning of Title 21, Section 353(b)(1)(A), in that, due to its toxicity and other potentiality for harmful effect, Viagra was not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Viagra was also a prescription drug within the meaning of Title 21, United States Code,

Section 353(b)(1)(B), because its application approved by the FDA under Title 21, United States Code, Section 355, limited Viagra to use under the professional supervision of a physician.

3. The FDA-approved Package Insert (labeling) for Viagra stated that Viagra was indicated for the treatment of erectile dysfunction. The labeling also stated:

The evaluation of erectile dysfunction should include a determination of potential underlying causes and the identification of appropriate treatment following a complete medical assessment.

The FDA-approved labeling for Viagra warned of “a potential for cardiac risk” in certain patients; warned that “prior to prescribing VIAGRA, physicians should carefully consider whether their patients with underlying cardiovascular disease could be affected adversely . . .”; warned that there “is no controlled clinical data on the safety or efficacy of VIAGRA” in certain patient populations; and warned of possible interactions with other drugs.

4. Viagra was manufactured by Pfizer, Inc., at facilities located outside of the State of Ohio, and sent to Ohio for distribution to consumers in Ohio, and elsewhere.

5. Cialis was a drug within the meaning of Title 21, United States Code, Section 321(g)(1)(C), and further was a prescription drug within the meaning of Title 21, Section 353(b)(1)(A), in that, due to its toxicity and other potentiality for harmful effect, Cialis was not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Cialis was also a prescription drug within the meaning of Title 21, United States Code, Section 353(b)(1)(B), because its application approved by the FDA under Title 21, United States Code, Section 355, limited Cialis to use under the professional supervision of a physician.

6. The FDA-approved Package Insert (labeling) for Cialis stated that Cialis was indicated for the treatment of erectile dysfunction. The labeling also stated:

Evaluation of erectile dysfunction and BPH¹ should include an appropriate medical assessment to identify potential underlying causes, as well as treatment options.

The FDA-approved labeling for Cialis warned of “a degree of cardiac risk” in certain patients; warned that Cialis “should not be used in men for whom sexual activity is inadvisable as a result of their underlying cardiovascular status[;]” and warned of possible interactions with other drugs.

7. Cialis was manufactured by Eli Lilly and Company, Inc., at facilities located outside of the State of Ohio, and sent to Ohio for distribution to consumers in Ohio and elsewhere.

8. The Federal Food, Drug, and Cosmetic Act made it unlawful to commit any act with respect to a drug if the act was done while the drug was held for sale after shipment in interstate commerce and resulted in the drug being misbranded. Title 21, United States Code, Section 331(k). A prescription drug, such as Viagra, was misbranded while held for sale when it was dispensed without the prescription of a physician and without the FDA-approved Package Insert. Title 21, United States Code, Section 353(b)(1).

9. Because Viagra and Cialis were commonly known to be drugs that were related to sexual function, a market for them sprang up outside of the normal contours of doctor-patient relationships. In this market, consumers acquired Viagra and Cialis without receiving the protections from misuse that were attendant to acquiring the drug through a physician as contemplated in the FDA approved labeling. In so doing, consumers were falsely led to believe that taking Viagra and Cialis was safe and free from serious potential side effects.

¹ Benign Prostatic Hyperplasia

COUNT 1

(Conspiracy to Distribute Misbranded Pharmaceuticals)

The United States Attorney further charges:

10. Paragraphs 1 through 9 of the General Allegations are incorporated as though realleged in their entirety herein.

11. From on or about June 6, 2008, and continuing through on or about August 5, 2010, the exact dates being unknown to the United States Attorney, in the Northern District of Ohio, Eastern Division, and elsewhere, MAHMOUD MUSTAFA and ZACRESHA JACKSON, defendants herein, did knowingly and voluntarily, combine, conspire, confederate, and agree with each other and others known and unknown to the United States Attorney, with the intent to defraud and mislead, to dispense a quantity of the prescription drugs Viagra and Cialis contrary to the provisions of Title 21, United States Code, Section 353(b)(1), in that the Viagra and Cialis was dispensed without the prescription of a practitioner licensed by law to administer Viagra and Cialis, and while the Viagra and Cialis was held for sale after shipment in interstate commerce, and the act resulted in the Viagra and Cialis being misbranded, in violation of Title 21, United States Code, Sections 331(k) and 333(a)(2).

OBJECTIVE OF THE CONSPIRACY

12. The objective of the conspiracy was for the Defendants to unjustly enrich themselves by unlawfully stealing prescription Viagra and Cialis from the Cleveland Clinic and reselling it to others through Defendant MUSTAFA's retail convenience store.

MANNER AND MEANS

13. The manner and means by which the objectives of the conspiracy were accomplished included, but were not limited to, the following:

a. Defendant ZACRESHA JACKSON was employed as a pharmacy technician in the retail pharmacy of the Taussig Cancer Center, at the Cleveland Clinic, located at 2010 East 90th Street, Cleveland, Ohio, in the Northern District of Ohio, Eastern Division.

b. Defendant MAHMOUD MUSTAFA operated a business called Euclid Convenient Express, at 15848 Euclid Avenue, East Cleveland, Ohio, in the Northern District of Ohio, Eastern Division.

c. JACKSON agreed to steal bottles of Viagra and Cialis pills from the retail pharmacy and sell them to MUSTAFA. JACKSON understood that MUSTAFA would re-sell the pills to consumers.

d. MUSTAFA sold individual Viagra and Cialis pills to customers, without requiring consumers to provide any form of prescription. Consumers were not informed that Viagra and Cialis were prescription drugs and that they should seek medical advice before consuming them. Consumers were not required to consult with a physician before obtaining the prescription drugs. Consumers were not informed concerning the potential dangers associated with taking these prescription drugs. This lack of information and warnings misled consumers about the safety of using Viagra and Cialis without medical supervision. The Euclid Convenient Express did not submit to regulation by FDA or regulatory bodies of the State of Ohio responsible for regulating the business of pharmacies.

OVERT ACTS

14. In furtherance of the aforesaid conspiracy, and to effect the object of the conspiracy, the defendants or one of their co-conspirators committed and caused to be committed in the Northern District of Ohio and elsewhere, at least one of the following overt acts:

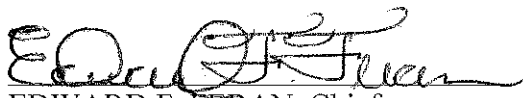
a. On or about the dates listed below, JACKSON stole the approximate quantity listed below of 100 mg Viagra, and re-sold them to MUSTAFA:

Overt Act	Date	Quantity of pills
1	3/2/2010	160
2	3/29/2010	200
3	4/6/2010	200
4	4/14/2010	200
5	4/23/2010	200
6	4/29/2010	200
7	6/8/2010	200
8	6/14/2010	130
9	6/18/2010	100
10	6/28/2010	200

b. **Overt Act Eleven:** On or about May 11, 2009, MUSTAFA dispensed a quantity of the prescription drug Viagra without the prescription of a practitioner licensed by law to administer Viagra, and defendant did so while the Viagra was held for sale after shipment in interstate commerce, and the act resulted in the Viagra being misbranded, all in violation of Title 18, United States Code, Section 371.

STEVEN M. DETTELBACH
United States Attorney

By:


EDWARD F. FERAN, Chief
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