IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	**CRIMINAL NO. 11-181**
v.	**:**	**DATE FILED: March 22, 2011**
BRIAN PARKER **MICHELLE PFEIFFER**	**:**	**VIOLATIONS: 18 U.S.C. § 371 (conspiracy - 1 count)**
	:	**21 U.S.C. §§ 331(a), 331(k), 333(a)(2), 353(b)(1), 352(a) (introduction of misbranded drugs in interstate commerce - 13 counts)** **21 U.S.C. §§ 331(p), 333(a)(2), 360 (failure to register an establishment in which drugs are manufactured or prepared - 1 count)** **Notice of forfeiture**

I N D I C T M E N T

COUNT ONE

THE GRAND JURY CHARGES THAT:

At all times material to this Indictment:

Introduction

1. The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug and Cosmetic Act ("FDCA"). Among the purposes of the FDCA was to assure that drugs sold for consumption or administration to humans, or for other use by humans, are safe, effective, and bear labeling containing only true and accurate information. The

FDA's responsibilities under the FDCA included regulating the manufacture, labeling and distribution of all drugs shipped or received in interstate commerce.

2. Under the FDCA, every person upon first engaging in the manufacture, preparation, propagation, compounding or processing of drugs in any establishment owned or operated by such person was required to immediately register his name, place of business, and all such establishments. (21 U.S.C. § 360(c)). The terms "manufacture, preparation, propagation, compounding or processing" include repackaging or otherwise changing the container, wrapper, or labeling of any drug from the original place of manufacture to the person who makes the final sale to the ultimate consumer or user. (21 U.S.C. § 360(a)(1)).

3. The term "label" was defined as a display of written, printed, or graphic matter upon the immediate container of any article (21 U.S.C. § 321(k). The term "labeling" was broader, and included all labels and other written, printed or graphic matter upon any article, including drugs, or any of its containers or wrappers, or accompanying such article. (21 U.S.C. § 321(m)).

4. Under the FDCA, drugs were defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man (21 U.S.C. § 321(g)(1)(B)); articles intended to affect the structure or any function of the body of man (21 U.S.C. § 321(g)(1)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)).

5. Certain drugs were prescription drugs under the FDCA, including: (a) those drugs which, because of their toxicity or other potentiality for harmful affect, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the

supervision of a practitioner licensed by law to administer such drug; and (b) those drugs limited by an FDA-approved application to use under the professional supervision of a licensed medical practitioner (21 U.S.C. § 353(b)(1)(A),(B)).

6. Under the FDCA, it was a prohibited act to introduce or deliver for introduction, or to cause the introduction or delivery for introduction, into interstate commerce a drug that was misbranded (21 U.S.C. § 331(a)).

7. A drug was misbranded if, among other things:

a. its labeling was false or misleading in any particular (21 U.S.C. 352(a));

b. its label did not bear the name and place of business of the manufacturer, packer, or distributor, including the street address, city and zip code (21 U.S.C. § 352(b); 21 C.F.R. § 201.1(i));

c. its label did not contain the established name and quantity of each active and inactive ingredient; (21 U.S.C. § 352(e)(1)(A)(ii),(ii));

d. its labeling failed to bear adequate directions for its use (21 U.S.C. § 352(f)(1));

e. it is an imitation of another drug (21 U.S.C.§ 352(i)(2)), or it is offered for sale under the name of another drug (21 U.S.C. § 352(i)(3));

f. it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered with

the Secretary of Health and Human Services pursuant to 21 U.S.C. § 360 (21 U.S.C. § 352(o)); or

g. the drug was a prescription drug dispensed without a valid prescription (21 U.S.C. § 353(b)(1)).

8. The FDCA provided that before a new drug can be shipped in interstate commerce, its manufacturer must obtain FDA approval of a New Drug Application, an Abbreviated New Drug Application (for generic drugs), or an Investigational New Drug Application (for drugs being researched in humans) (21 U.S.C. §§ 355(b), (j),(i)). To receive approval to market a drug, the manufacturer must submit information showing that the new drug is safe and effective for its intended use. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50.

The Drugs

9. "Viagra" was a drug within the meaning of 21 U.S.C. § 321(g)(2),(3) and a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(l)(B). Viagra was the trade name for Pfizer, Inc.'s FDA-approved erectile dysfunction drug containing the active ingredient sildenafil citrate. FDA had not approved any generic drugs containing sildenafil citrate.

10. "Cialis" was a drug within the meaning of 21 U.S.C. § 321(g)(2),(3) and a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(l)(B). Cialis was the trade name for an FDA-approved erectile dysfunction drug manufactured by Eli Lilly & Company that contained the active ingredient tadalafil. FDA had not approved any generic drugs containing tadalafil.

11. "Superman" was a drug that combined the active ingredients sildenafil citrate, and tadalafil. There was no FDA- approved drug that combines Viagra's active ingredient sildenafil citrate and Cialis's active ingredient tadalafil.

12. "GHRP-6" or "Growth Hormone Releasing Agent Protein" was a peptide or protein-based drug popular with body builders for increasing strength and muscle mass but was not FDA-approved for any indication.

13. "IGF' or "Insulin Growth Factor" was a peptide or protein-based drug popular with body builders for increasing strength and muscle mass but was not FDA -approved for any indication.

14. From on or about August 15, 2009 to at least on or about October, 2010, in Philadelphia, in the Eastern District of Pennsylvania and elsewhere, defendants

BRIAN PARKER and
MICHELLE PFEIFFER

conspired and agreed, together and with others known and unknown to the grand jury, to:

(a) commit an offense against the United States by introducing into interstate commerce, delivering for introduction into interstate commerce, and causing the introduction and delivery for introduction into interstate commerce, with intent to defraud and mislead, certain misbranded drugs, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2); and

(b) knowingly defraud the United States and its agencies by impeding, impairing, and defeating the lawful government functions of the United States Food and Drug Administration to protect the health and safety of the public by ensuring that drugs marketed and distributed in the United States were safe and effective for their intended uses, were

manufactured in an establishment which was registered with the Secretary of Health and Human Services, were not dispensed without a valid prescription, and that the labeling of such drugs bore true and accurate information, contained the name and place of business of the manufacturer, and bore adequate directions for use.

MANNER AND MEANS

It was a part of the conspiracy that:

15. Defendant BRIAN PARKER advertised on internet websites whose audience is primarily body builders and athletes. Visitors to these websites and message boards would discuss the benefits and dosing of different performance enhancing drugs.

16. Defendant BRIAN PARKER offered prescription drugs for sale without asking for a prescription from a licensed medical practitioner, an act that caused the drugs to become misbranded. These prescription drugs included Cialis, Viagra and "Superman." Superman was a drug that defendant PARKER identified as a combination of 20 mg. Cialis and 40 mg. of Viagra.

17. Defendant BRIAN PARKER advertised brand name prescription drugs — Cialis, Viagra, and a combination of Cialis and Viagra – but did not provide the drugs manufactured by Eli Lilly and Pfizer, instead providing imitations of those drugs that he manufactured.

18. Defendant BRIAN PARKER did not seek approval from FDA to distribute the drugs he manufactured into interstate commerce, nor did he register his manufacturing facility with FDA.

19. Defendant BRIAN PARKER accepted orders for prescription drugs via email using the pseudonym "Dedicated1" and the email address 1@cyber-rights.net. When accepting orders, defendant PARKER instructed customers to write messages in their drug orders in an attempt to conceal the true nature of the transaction.

20. Defendants BRIAN PARKER and MICHELLE PFEIFFER manufactured misbranded drugs in their residence, converting bulk active and inactive ingredients into capsules or tablets.

21. Defendants BRIAN PARKER and MICHELLE PFEIFFER created labels bearing false or misleading information for the misbranded drugs.

22. Defendants BRIAN PARKER and MICHELLE PFEIFFER created and used the brand name "Volume X Pharms" to market and sell their misbranded drugs.

23. Defendants BRIAN PARKER and MICHELLE PFEIFFER shipped in interstate commerce misbranded drugs with labeling that is false or misleading and lacking required information, including adequate directions for use and warnings.

24. Defendants BRIAN PARKER and MICHELLE PFEIFFER sold the misbranded prescription drugs to customers and received thousands of dollars of cash in return.

25. Defendants BRIAN PARKER and MICHELLE PFEIFFER attempted to conceal their criminal activity and their profits by using fictitious names when accepting Western Union wire transfers, by enlisting co-conspirators who would accept online payments for drugs using PayPal, and by placing fictitious names and addresses on outgoing U.S. Mail parcels.

OVERT ACTS

In furtherance of the conspiracy, defendants BRIAN PARKER and MICHELLE PFEIFFER, committed the following overt acts, among others, in the Eastern District of Pennsylvania, and elsewhere:

1. On or about August 15, 2009, defendants BRIAN PARKER and MICHELLE PFEIFFER opened an online U.S. Postal Service "Click-N-Ship" account.

2. On or about March 18, 2010, defendant BRIAN PARKER sent an electronic mail message containing a price list to a customer known to the grand jury as "Frank." The defendant offered for sale, among other items, "DEALS OF THE WEEK," which included "2 CIALIS OR VIAGRA 60$" and "2 SUPERMAN 80$." Superman pills were described as "20mg cialis 40mg Viagra."

3. On or about March 22, 2010, defendant BRIAN PARKER sent an electronic mail message to a customer known to the grand jury as "Frank," containing instructions to send Western Union payment to Michelle Pfeiffer.

4. On or about March 22, 2010, defendants BRIAN PARKER and MICHELLE PFEIFFER retrieved a Western Union wire payment of $360.00 in Brick, New Jersey. Defendant PFEIFFER completed the Western Union payment paperwork and defendant PARKER accepted the currency from the sales clerk.

5. On or about March 22, 2010, defendants BRIAN PARKER and MICHELLE PFEIFFER caused to be sent a package containing misbranded drugs, including Superman and a drug falsely labeled as Cialis, from New Jersey to Philadelphia, PA.

6. On or about April 27, 2010, defendant BRIAN PARKER sent an electronic mail message containing a price list to a customer known to the grand jury as "Frank." The

defendant offered for sale, among other items, "DEALS OF THE WEEK" which included "2 CIALIS OR VIAGRA 60$."

7. On or about May 8, 2010, defendants BRIAN PARKER and MICHELLE PFEIFFER caused to be sent a package containing misbranded drugs, including drugs falsely labeled as Cialis and Viagra, from New Jersey to Philadelphia, PA.

8. On or about May 24, 2010, defendant BRIAN PARKER sent an electronic mail message containing a price list to a customer known to the grand jury as "F.S." The defendant offered for sale, among other items, GHRP-6.

9. On or about May 24, 2010, defendant BRIAN PARKER sent an electronic mail message to a customer known to the grand jury as "F.S." containing instructions to make a PayPal transaction for misbranded drugs. The email instructed the customer to send $75.00 via PayPal and include only the phrase "** Web U-G Service Windows 7 Install Help **" in the subject line.

10. On or about May 28, 2010, defendants BRIAN PARKER and MICHELLE PFEIFFER caused to be sent a package containing misbranded drugs, including GHRP-6, from New Jersey to Philadelphia, PA.

11. On or about August 24, 2010, defendant BRIAN PARKER sent an electronic mail message containing a price list to a customer known to the grand jury as "M.W." The defendants offered for sale, among other items, "Cialis 20 mg 50 pills in a sealed bottle" and IGR LR3 1000mcg.

12. On or about September 17, 2010, defendant BRIAN PARKER sent an electronic mail message to a customer known to the grand jury as "M.W." containing Western

Union wire payment instructions for misbranded drugs. The email instructed the customer to use the test question and answer feature so defendant PARKER would not need to show identification to retrieve the money.

13. On or about September 23, 2010, defendant BRIAN PARKER retrieved a Western Union wire payment of $175.00 in Toms River, New Jersey.

14. On or about September 25, 2010, defendants BRIAN PARKER and MICHELLE PFEIFFER caused to be sent a package containing misbranded drugs, including Insulin Growth Factor and a drug falsely labeled as Cialis, from New Jersey to Philadelphia, PA.

All in violation of Title 18, United States Code, Section 371.

COUNTS TWO THROUGH SIX

THE GRAND JURY FURTHER CHARGES THAT:

1. The allegations of paragraphs 1 through 13 and 15 through 25 of Count One of this indictment are realleged here.

2. On or about the dates identified below, in Philadelphia, in the Eastern District of Pennsylvania and elsewhere, defendants

BRIAN PARKER and
MICHELLE PFEIFFER,

with the intent to defraud and mislead, introduced into interstate commerce, delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce from the State of New Jersey to the State of Pennsylvania, of the following prescription drugs that were misbranded because: (1) the label of the identified drug did not bear the name and place of business of the manufacturer as required by Title 21, United States Code, Section 352(b); (2) the labeling for the identified drug failed to bear adequate directions for use as required by Title 21 United States Code Section 352(f)(1); (3) the identified drug in Counts 2, 4, 5 and 6 was sold under the name of another drug in violation of Title 21, United States Code, Section 352(i)(3); and (4) the drugs were manufactured in an establishment which was not registered with the Secretary of Health and Human Services, as required under Title 21, Section 360, United States Code:

Count	Ship Date	Brand Name of Drug/Active Ingredient(s)
2	March 22, 2010	Cialis/Tadalafil
3	March 22, 2010	Superman/Tadalafil and Sildenafil Citrate
4	May 7, 2010	Cialis/Tadalafil

5	May 7, 2010	Viagra/Sildenafil Citrate
6	September 22, 2010	Cialis/Tadalafil

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

COUNTS SEVEN THROUGH ELEVEN

THE GRAND JURY FURTHER CHARGES THAT:

1. The allegations of paragraphs 1 through 13 and 15 through 25 of Count One of this indictment are realleged here.

2. On or about the dates identified below, in Philadelphia, in the Eastern District of Pennsylvania and elsewhere, defendants

BRIAN PARKER and
MICHELLE PFEIFFER,

with the intent to defraud and mislead, caused drugs to become misbranded while held for sale (whether or not the first sale) after shipment in interstate commerce in that they dispensed the following prescription drugs without the prescription of a medical practitioner licensed by law to administer such drug as required by Title 21, United States Code, Section 353(b):

Count	Ship Date	Brand Name of Drug/Active Ingredient(s)
7	March 22, 2010	Cialis/Tadalafil
8	March 22, 2010	Superman/Tadalafil and Sildenafil Citrate
9	May 7, 2010	Cialis/Tadalafil
10	May 7, 2010	Viagra/Sildenafil Citrate
11	September 22, 2010	Cialis/Tadalafil

All in violation of Title 21, United States Code, Sections 331(k) and 333(a)(2).

COUNTS TWELVE THROUGH FOURTEEN

THE GRAND JURY FURTHER CHARGES THAT:

1. The allegations of paragraphs 1 through 13 and 15 through 25 of Count One of this indictment are realleged here.

2. On or about the dates identified below, in Philadelphia, in the Eastern District of Pennsylvania and elsewhere, defendants

BRIAN PARKER and
MICHELLE PFEIFFER,

with the intent to defraud and mislead, introduced into interstate commerce, delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce from the State of New Jersey to the State of Pennsylvania, the following prescription drugs that were misbranded because: (1) the label of the identified drug did not bear the name and place of business of the manufacturer as required by Title 21, United States Code, Section 352(b); (2) the labeling for the identified drug failed to bear adequate directions for use as required by Title 21, United States Code Section 352(f)(1); (3) the label was false and misleading by claiming the identified drug was for research use only, in violation of Title 21, United States Code, Section 352(a); and (4) the drugs were manufactured in an establishment which was not registered with the Secretary of Health and Human Services, as required under Title 21, Section 360, United States Code:

Count	Ship Date	Name of Drug/Active Ingredient
12	March 22, 2010	IGF/Insulin Growth Factor
13	May 27, 2010	GHRP-6/Growth Hormone Releasing Agent Protein 6
14	September 22, 2010	IGF/Insulin Growth Factor

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

COUNT FIFTEEN

THE GRAND JURY FURTHER CHARGES THAT:

1. The allegations of paragraphs 1 through 13 and 15 through 25 of Count One of this indictment are realleged here.

2. Beginning no later than August 15, 2009, and continuing to at least October 2010, in the District of New Jersey, defendants

BRIAN PARKER and
MICHELLE PFEIFFER,

with the intent to defraud and mislead, engaged in the manufacture, preparation, propagation, compounding, or processing of a drug and failed to register their establishment with the Secretary of Health and Human Services, as required under Title 21, Section 360, United States Code.

All in violation of Title 21, United States Code, Sections 331(p) and 333(a)(2).

NOTICE OF FORFEITURE

THE GRAND JURY FURTHER CHARGES THAT:

1. As a result of the violations of Title 21, United States Code, Sections 331(a), 331(k), 333(a)(2), 352(a) and 353(b)(1) set forth in this indictment, defendants

BRIAN PARKER and
MICHELLE PFEIFFER

shall forfeit to the United States of America any quantities of Viagra, Cialis, Superman, Growth Hormone Releasing Agent Protein and Insulin Growth Factor which, between August 15, 2009 and October, 2010 were misbranded when introduced into or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of Title 21, United States Code, Section 331, be introduced into interstate commerce.

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, that is $225,000.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c).

A TRUE BILL:

_____
FOREPERSON

_____
ZANE DAVID MEMEGER
United States Attorney