2019R000572/KS & CF

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
	:	
	:	Crim. No. 19-
v.	:	
	:	18 U.S.C. §§ 371, 982(a)(7), and 2;
	:	21 U.S.C. §§ 331(a), (d), and (p),
KEITH KOVALESKI and	:	333(a)(2), 334, and 853(p); and
SYLVIA KOVALESKI	:	28 U.S.C. § 2461(c)

INDICTMENT

The Grand Jury in and for the District of New Jersey, sitting in Newark, charges:

COUNT 1
(Conspiracy to Defraud and Mislead the FDA and HHS and to Introduce and Deliver Into Interstate Commerce Misbranded Drugs and Unapproved New Drugs)

INTRODUCTION

1. At all times relevant to Count 1 of this Indictment:

a. Defendant KEITH KOVALESKI ("KOVALESKI") resided in South Amboy, New Jersey and Naples, Florida. KOVALESKI was employed as an Assistant Foreman by Amtrak.

b. Defendant SYLVIA KOVALESKI ("SYLVIA KOVALESKI") resided in South Amboy, New Jersey and Naples, Florida, and was married to KOVALESKI. KOVALESKI and SYLVIA KOVALESKI shall be referred to collectively as "the KOVALESKIS."

c. Ines Maltez ("Maltez") worked for the KOVALESKIS at their residence in South Amboy (the "South Amboy Residence").

The FDA and The Food, Drug, and Cosmetic Act

d. The United States Food and Drug Administration (the "FDA") was the federal agency within the United States Department of Health and Human Services ("HHS") responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs were safe and effective for their intended uses and bore labeling that contained true and accurate information. The FDA's responsibilities included regulating the manufacture and distribution of drugs, including prescription drugs, shipped or received in interstate commerce, as well as the labeling of such drugs. The FDA carried out its responsibilities by enforcing the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "FDCA") and other pertinent laws and regulations.

e. Under the FDCA, the term "drug" included any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or an article (other than food) intended to affect the structure or any function of the body of man or other animals.

f. Under the FDCA, a "prescription drug" was: (i) any drug intended for use in humans that, because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures necessary for its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, or (ii) a drug which was limited by a legally approved application for use under the professional supervision of a practitioner licensed by law to administer such drugs.

g. The FDCA required that any new drug be the subject of a new drug application ("NDA"), reviewed and approved by the FDA, before it could be distributed in interstate commerce. A new drug was any drug for which there were not sufficient published,

adequate and well-controlled studies to permit qualified experts to reach a consensus that the drug was safe and effective for each of its labeled uses. If there was no new drug application ("NDA"), an investigational new drug application ("IND") for the drug had to be in effect to permit the drug to be distributed for research purposes. To obtain FDA approval of an NDA, the sponsor had to demonstrate, to the FDA's satisfaction, that the drug was both safe and effective for each of its claimed uses. Under certain circumstances, manufacturers could market a generic version of a previously approved drug; however, generic products also required FDA review and the approval of an abbreviated new drug application ("ANDA") before distribution could commence. The FDA approval process included a review of the product labeling and directions for use. The FDCA prohibited introducing or delivering for introduction into interstate commerce new drugs not approved by the FDA under 21 U.S.C. § 355.

h. The FDCA prohibited introducing or delivering for introduction into interstate commerce misbranded drugs. Under the FDCA, a drug was misbranded if: (i) its labeling was false or misleading in any particular; (ii) it did not contain adequate directions for use; or (iii) it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered with the Secretary of HHS. The term "manufacture, preparation, propagation, compounding, or processing" included repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who made final delivery or sale to the ultimate consumer or user. The FDCA required that any person who owned or operated an establishment in the United States that manufactured, prepared, propagated, compounded, or processed drugs be duly registered with the Secretary of HHS through the FDA. This including registering the name of the

person who owned or operated the establishment, the place of business for the establishment, and a point of contact email address.

The KOVALESKIS' Home Drug Business

i. The KOVALESKIS co-owned and operated AA Peptide LLC, a/k/a All American Peptide ("AAP"), primarily from their South Amboy Residence. The KOVALESKIS used a website, www.allamericanpeptide.com (the "AAP Website"), to market and distribute AAP's products.

j. "Allamericanpeptide@gmail.com" was an email address (the "AAP Email Account") identified as the contact email on the AAP Website used by the KOVALESKIS.

k. The KOVALESKIS, through AAP, offered products that were labeled with the same names as those of FDA-approved generic prescription drugs. The generic names for these prescription drugs were the same as the active pharmaceutical ingredient ("API") in each respective drug, *e.g.,* Anastrozole - with a capital "A" - was the name of a generic FDA-approved drug that contained anastrozole as an API. These products were labeled with the following:

i. Anastrozole, exemestane, raloxifene, letrozole, and tamoxifen, all of which were names of FDA-approved generic prescription drugs manufactured by various manufacturers, used to treat breast cancer, and which were known decrease estrogen in the body and/or to block the effects of estrogen;

ii. TAD/C, which contained tadalafil and was AAP's name for Tadalafil, which was the same name as an FDA-approved generic prescription drug manufactured by various manufacturers, used to treat erectile dysfunction;

iii. Caber, a/k/a Cabaser, which contained cabergoline and was AAP's name for Cabergoline, which was the same name as an FDA-approved generic prescription drug manufactured by Ingenus Pharmaceuticals, among others, used to treat hyperprolactinemic disorders, *i.e.*, high levels of the prolactin hormone, which could cause unwanted breast milk;

iv. Clomiphene Citrate, which was the same name as an FDA-approved generic prescription drug manufactured by Par Pharmaceutical that was used to treat infertility in women;

v. Albuterol, which was the same name as an FDA-approved generic prescription drug used for the treatment of lung diseases, such as asthma and chronic obstructive pulmonary disease;

vi. Dutasteride, which was the same name as an FDA-approved generic prescription drug used to treat enlarged prostates in men; and

vii. T3, another name for Liothyronine Sodium, which was the same name as an FDA-approved generic prescription drug used to treat hypothyroidism.

None of the foregoing AAP products had been approved by the FDA for human use.

l. The KOVALESKIS, through AAP, also offered products on the AAP Website that were categorized as "SARMs," which was an abbreviation for "selective androgen receptor modulators." SARMs were used by body-builders as an alternative to steroids. AAP offered SARMs capsules and liquids on the AAP Website, to include the following: GW 501516, LGD-4033, MK 2866 (Ostarine), MK 677, S4, SR-9009, YK-11, and RAD 140 (capsules and liquid). None of the foregoing products had been approved by the FDA for human use.

m. The KOVALESKIS, through AAP, also offered products on the AAP Website that were categorized as "peptides." Peptides were polymers composed of 40 or fewer amino acids, and were used as performance-enhancing substances. The peptides offered by AAP included the following: BPC 157, CJC (NO Dac), CJC (With Dac), DSIP, Fragment 176 191, GHRP2, GHRP6, Ipamorelin, MT2, a/k/a/ "melanotan," PT141, and TB500, a/k/a "Thymosin Beta." None of the foregoing had been approved by the FDA for human use.

n. The KOVALESKIS, through AAP, also offered several products, which were neither peptides nor SARMs, that had not been approved by the FDA for human use. These included the following:

i. Clenbuterol, which was the API in several prescription drugs, including Dilaterol, Spiropent, and Ventipulumin, all of which were available for sale in foreign markets for the treatment of lung disorders, such as asthma; and

ii. Dapoxetine, which was the API in Priligy and Westoxetin, both of which were available for sale in foreign markets for the treatment of premature ejaculation in men.

o. The products identified in subparagraphs (k)-(n) above shall be referred to collectively as "the AAP Products."

p. The KOVALESKIS well knew that they were operating an illegal drug business and that the FDCA prohibited certain activities, including selling misbranded drugs. This was exemplified by, among other things, this provision on the AAP Website that the KOVALESKIS controlled and used: "The purchaser further warrants that any material produced with any product shall not be adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and shall not be materials which may not, under Sections 404, 505, or 512 of the Act, be introduced into interstate commerce...."

THE CONSPIRACY

2. From at least as early as in or about May 2014 through in or about January 2019, in the District of New Jersey, and elsewhere, defendants

KEITH KOVALESKI and
SYLVIA KOVALESKI,

and others, did knowingly and intentionally combine, conspire, confederate and agree to:

(a) defraud the FDA and HHS by impeding, impairing, and obstructing the FDA's and HHS's lawful and legitimate function of protecting the health and safety of the American public by enforcing the FDCA, one purpose of which was to ensure that drugs sold for human use were safe, effective, and bore labeling that contained true and accurate information; and

(b) commit offenses against the United States, namely:

(i) with the intent to defraud and mislead, introducing and delivering for introduction misbranded drugs into interstate commerce, and causing same, contrary to Title 21, United States Code, Sections 331(a) and 333(a)(2); and

(ii) with the intent to defraud and mislead, introducing and delivering for introduction unapproved new drugs into interstate commerce, and causing same, contrary to Title 21, United States Code, Sections 331(d) and 333(a)(2).

Object of the Conspiracy

3. The object of the conspiracy was for the KOVALESKIS and others to obtain substantial revenues and profits by illegally offering for sale and selling misbranded drugs and unapproved new drugs, and causing such drugs to be shipped in interstate commerce, including to customers in the United States, and by affirmatively concealing material information from the FDA and HHS.

Manner and Means

4. It was part of the conspiracy that:

a. The KOVALESKIS, primarily through the internet, offered for sale and sold more than thirty products, including those identified in paragraph 1 (k)-(n). The KOVALESKIS marketed these products to, and intended these products to be used by, body-builders and others who wanted to build muscle, lose fat, and/or improve sexual function. The KOVALESKIS did this by, among other things, maintaining customer reviews on the AAP Website that commented favorably on the performance-enhancing qualities of the AAP Products. For example, in a review for TAD/C, a/k/a "Tadalafil", dated April 18, 2018, a customer described his personal use of the pills with his wife, and how they improved his sexual performance. A review of MK-2866 (Ostarine) on the AAP Website dated December 25, 2016 stated, "Very good at building muscle and losing fat." A review of Clenbuterol on the AAP Website dated May 14, 2018 stated, "Such good stuff! Properly dosed and always prime. 3rd

time ordering the clen and will keep on. Sheds those extras in a good stack. Just does wonders. Great product and clean!"

b. The KOVALESKIS also wrote and sent email messages from the AAP Email Account providing advice and recommendations to customers about how to use their products for optimal performance-enhancing results. For example, an email from the AAP Email Account on or about January 20, 2017, to an AAP customer in New Hampshire who ordered AAP's sexual performance enhancement pills instructed: "Take 3 hours PRIOR & get ready for Fireworks."

c. The KOVALESKIS, through the AAP Website, also referred customers to an eroids.com blog, which contained user reviews of performance-enhancing products including those sold by AAP. These reviews included comments about consumers' personal experiences with AAP Products and their performance-enhancing qualities.

d. The KOVALESKIS primarily used the basement of the South Amboy Residence as a manufacturing facility to make and label AAP Products in liquid, pill, capsule and other forms. This included making, or causing to be made, homemade capsules containing baking soda and tadalafil. It also included affixing homemade labels for the AAP Products. The KOVALESKIS had not registered with the Secretary of HHS to manufacture, prepare, propagate, compound, or process, drugs. As such, the AAP Products were misbranded because they were drugs that were manufactured, prepared, propagated, compounded, and processed by the KOVALESKIS at the South Amboy Residence, an unregistered establishment.

e. The KOVALESKIS also misbranded the AAP Products by not including adequate directions for use for the AAP Products. Typically, the label on the AAP Products included no instructions for use or only an instruction to "shake well" and/or to "keep out of

reach of children." On the pre-made liquids, the KOVALESKIS failed to include the concentration of the solution, which was necessary dosing information. For all AAP Products, the KOVALESKIS failed to include on the AAP Products' labels: (a) the frequency of administration or application; (b) the route or method of administration or application; (c) the time of administration or application; (d) the duration of administration or application; and (e) the quantity of dose, including usual quantities for each of the uses for which the drug was intended and usual quantities for persons of different ages and different physical conditions. Likewise, the AAP Website and other AAP Products' labeling did not include adequate directions for use, as defined by the FDCA, and, at a minimum, did not include the information contained in (a)-(e) above. The KOVALESKIS also misbranded their drugs by falsely representing on the AAP Products' labeling (which included the AAP Website) that their products were for research purposes.

f. The KOVALESKIS, through AAP, also introduced into interstate commerce at least two new drugs for which AAP had not received approval: (a) clenbuterol, which was not approved by the FDA for human use, and (b) TAD/C, which was AAP's name for Tadalafil (the "New Drugs"). The New Drugs were not generally recognized as safe and effective when used as prescribed, recommended, and suggested by AAP. The KOVALESKIS never submitted an NDA, INDA, or ANDA, for the New Drugs. The FDA, therefore, did not have an opportunity to review, let alone approve, the API, labeling, manufacturing process or the directions for use for the New Drugs, as required by the FDCA.

g. The KOVALESKIS accepted orders for their internet business through the AAP Email Account, and would send order confirmations and payment instructions to customers once those orders were received. The KOVALESKIS accepted payments and received payments

for the AAP Products through money orders, which were typically sent to the South Amboy Residence or a P.O. Box in South Amboy, New Jersey registered in the name of AAP (the "South Amboy P.O. Box"); bitcoin; and through third-party electronic payment services ("Payment Processors") that enabled customers to transfer money electronically.

h. To avoid detection that they were operating an unlawful business, and that the payments were business proceeds, the KOVALESKIS instructed AAP customers sending payments through the Payment Processors to click the "friends and family" option on the Payment Processors' internet sites for sending money (and not the "goods and services" option). The KOVALESKIS also instructed customers to use emojis, which are pictures that appear in electronic messages, in the subject lines instead of order numbers to further make the transactions appear to be personal in nature and not business-related. The KOVALESKIS warned customers that if they were not discreet, their funds would be returned and they would be banned from the AAP Website.

i. The KOVALESKIS created and maintained multiple accounts with the Payment Processors and recruited certain individuals (the "Receivers"), including Maltez, to open accounts with the Payment Processors for the purpose of accepting customer payments for the AAP Products. SYLVIA KOVALESKI managed AAP's use of the receiver accounts by directing customers to a specific receiver account for each transaction. The KOVALESKIS accepted AAP's proceeds from the Receivers, and in some instances, instructed the Receivers to deposit funds directly into certain bank accounts. The KOVALESKIS paid certain of the Receivers for their services.

j. The KOVALESKIS deposited payments for their misbranded and unapproved new drugs in at least two bank accounts: a TD Bank account opened on or about

May 30, 2014 by KOVALESKI, to which SYLVIA KOVALESKI became a signatory in or about July 2015 (the "TD Bank Account"), and a Chase Bank account opened by the KOVALESKIS on or about October 16, 2017 (the "Chase Bank Account") (collectively, the "AAP Bank Accounts").

k. In order to avoid the FDA's scrutiny, the KOVALESKIS included disclaimers in the "Terms and Conditions" section of the AAP Website falsely stating that AAP's products were intended for research and/or laboratory use only, when, in reality, AAP's Products were meant for personal use.

l. To further conceal their unlawful business, the KOVALESKIS also caused the Terms and Conditions section of the AAP Website to indicate that AAP would not sell its products to anyone who was not using said products for their intended use, *i.e.*, laboratory or research purposes, and further indicated that anyone who was not using the AAP Products for those purposes would be "committing a fraudulent act for which they could be held liable." Specifically, the AAP Website stated, "All users of AllAmericanPeptide.com are required to fully understand that any communication which leads us to believe that you will use these products in a manner other than that which they are intended will result in a refusal to sell alert being emailed to you[.] [A]ll collected information will be added to our internal 'banned' database which every order is checked against. We will absolutely under no circumstances tolerate the misuse of AllAmericanPeptide.com or the products contained/sold herein." Contrary to these warnings, as described above, the KOVALESKIS knowingly sold their products for human use, and not to institutions or clinical laboratories for the purpose of conducting research.

m. As a result of their unlawful activities, the KOVALESKIS, through AAP, earned in excess of $2.5 million in revenue.

Overt Acts

5. In furtherance of the conspiracy and to effect its objects, the KOVALESKIS and others committed and caused to be committed the following overt acts in the District of New Jersey and elsewhere:

a. On or about July 18, 2015, in Old Bridge, New Jersey, SYLVIA KOVALESKI signed a Business Account Maintenance Form to become an authorized signatory on the TD Bank Account.

b. SYLVIA KOVALESKI discussed the labeling of AAP products with Maltez, including on the following dates:

i. On or about December 27, 2016, SYLVIA KOVALESKI sent a text message to Maltez telling Maltez that she and her mom could clean, count, and label AAP Products at the South Amboy Residence, if they were available.

ii. On or about January 3, 2017, SYLVIA KOVALESKI sent a text message to Maltez stating, "Fill orders and then put them in the porch as soon as you are done because I have a pick up scheduled. Just use the big bins. Then label all the clen liquid. Then cut some bubble wrap and clean. Thank you[.]"[1]

iii. On or about March 1, 2017, SYLVIA KOVALESKI sent a text message to Maltez directing her to "count and label T3." SYLVIA KOVALESKI further advised, "If you need labels on Friday please wake up my daughter to print them. Thank you[.]"

c. On or about October 16, 2017, in Old Bridge, New Jersey, the KOVALESKIS opened the Chase Bank Account, signing signature cards to be authorized users of the account.

[1] Where quoted, text messages and emails are set forth verbatim.

d. On or about October 27, 2017, KOVALESKI sent a text message to an individual ("Receiver 1") stating that if Receiver 1 was willing to get a Payment Processor account and accept a few payments for KOVALESKI, that KOVALESKI would "pay 15% each transaction."

e. On or about October 29, 2017, in response to a text message from Receiver 1 asking who all of the payments were from, KOVALESKI wrote, "Aap customers."

f. On or about March 12, 2018, SYLVIA KOVALESI directed Maltez in the following manner:

i. SYLVIA KOVALESKI sent a text message in which she directed Maltez to count "Clen" *i.e.*, clenbuterol, and then to "label."

ii. SYLVIA KOVALESKI sent a text message to Maltez stating, "Ok so there is a box coming today that's very large with all the peptides and liquids that you need to label. So check front porch[.]"

g. The KOVALESKIS coordinated their responses to customer inquiries about the AAP Products through the AAP Email Account, including on or about April 10, 2018, when:

i. SYLVIA KOVALESKI forwarded to KOVALESKI an email from an AAP Customer in Indiana, in which the customer complained that the tadalafil capsules that he had purchased were full of baking soda;

ii. KOVALESKI sent SYLVIA KOVALESKI a text message with the following response for the customer: "This is the owner , Ive been making : Cialis, Viagra and cock -bombs for 4 years now , have sold probably 10,000 packs with THEE BEST reviews on the internet , and GUESS WHAT ? I've always cut it with baking soda !!! In closing , ENJOY";

iii. In a follow-up text message, KOVALESKI further instructed SYLVIA KOVALESKI to copy and paste the response; and

iv. SYLVIA KOVALESKI used the AAP Email Account to send KOVALESKI's response to the customer in Indiana.

h. On or about April 21, 2018, SYLVIA KOVALESKI applied for the South Amboy P.O. Box, identifying the KOVALESKIS as the users of the South Amboy P.O. Box.

i. On or about October 18, 2018, SYLVIA KOVALESKI sent Maltez a text message instructing Maltez to deposit money into the Chase Bank Account because "the balance in there is low. And that's where all my postage comes out of."

j. The KOVALESKIS and their Receivers accepted payments from AAP customers, including on the following dates:

i. On or about October 20, 2018, Maltez accepted a payment in the amount of approximately $234 from a customer who ordered four packages of "TAD/C" to be sent to Illinois, and was instructed, via the AAP Email Account, to pay one of Maltez's receiver accounts.

ii. On or about November 9, 2018, KOVALESKI accepted a payment in the amount of approximately $248 from a customer who ordered, among other things, two bottles of "Ostarine" to be sent to New Mexico, and was instructed by the AAP Email Account to pay one of KOVELESKI's receiver accounts.

iii. On or about November 9, 2018, KOVALESKI transferred the $241 from the "Ostarine" order to the TD Bank Account.

k. The KOVALESKIS continued to coordinate their responses to customer inquiries about AAP Products, including on or about November 14, 2018, when:

i. SYLVIA KOVALESKI forwarded to KOVALESKI an email that a customer in South Carolina sent to the AAP Email Account requesting dosage information on T3;

ii. KOVALESKI sent SYLVIA KOVALESKI a text message with the following response for the customer: "I'm gonna ship you out a bottle tomorrow & I'll throw 2 shreadabull in with it – ONLY TAKE ONE on an empty stomach , no clen , Just the red cap – As far as t3 , never mess with my thyroid , that stuff is dangerous if you don 't pyramid up & then Back down properly...";

iii. KOVALESKI further instructed SYLVIA KOVALESKI by text message, "Send that"; and

iv. SYLVIA KOVALESKI emailed KOVALESKI's response to the customer in South Carolina.

l. In or about January 2019, SYLVIA KOVALESKI and Maltez shipped three separate packages from the South Amboy Post Office, all bearing the return address of AAP at the South Amboy P.O. Box, to States outside of the State of New Jersey, and containing unapproved new drugs and misbranded drugs. The packages included the following:

i. A package with a delivery address in Cameron Park, California containing 40 pills in a package labeled, "TAD / C – 30MG x 40."

ii. A package with a delivery address of Canton, South Dakota containing products labeled: (1) "Frag 176-191 5 MG"; (2) "LGD 10MG – 30ML is an investigational selective androgen receptor modulator for treatment of conditions such as muscle wasting and osteoporosis. KEEP OUT OF REACH OF CHILDREN. Shake well before each use"; (3) "S4 (ANDARINE) – 25MG X 30ml SHAKE WELL BEFORE EACH USE. Keep out of the reach of children"; and (4) MK-2866 Ostarine Ostarine, also known as MK-2866 is a SARM (selective androgen receptor module) created by GTx avoid and treat muscle wasting. Keep out of the reach of children. Shake well before each use."

iii. A package with a delivery address of Metairie, Louisiana containing products labeled: (1) "T3 (Liothyronine Sodium) 200 mcg x 30 ML. Keep out of the reach of children. SHAKE WELL BEFORE EACH USE"; and (2) "Clenbuterol 200 mcg x 30 ML. Keep out of the reach of children. SHAKE WELL BEFORE EACH USE."

m. On or about January 28, 2019, the KOVALESKIS shipped and caused to be shipped from the South Amboy Post Office approximately 93 packages with a return address of AAP at the South Amboy P.O. Box. The packages contained:

i. misbranded drugs, including:

A. A package with a delivery address of Wilmington, Illinois and containing one bottle labeled, "Tamoxifen 20mg x 30 ML. Keep out of the reach of children. Shake well before each use" and one bottle

labeled, "Exemestane 25mg X 30 ML Keep out of the reach of children. Shake well before each use";

B. A package with a delivery address of Salem, Ohio containing one bottle labeled, "ANASTROZOLE 1mg X 30ml Keep out of the reach of children. Shake well before each use" and one bottle labeled, "Tamoxifen 20mg x 30 ML. Keep out of the reach of children. Shake well before each use";

C. A package with a delivery address of Madison, Alabama containing one bottle labeled, "RALOXIFENE 50MG X 30ml KEEP OUT OF REACH OF CHILDREN";

D. A package with a delivery address of Las Vegas, Nevada containing one bottle labeled, "Tamoxifen 20mg x 30 ML. Keep out of the reach of children. Shake well before each use" and one bottle labeled, "Letrozole 2.5mg X 30ml Keep out of reach of children. Shake well before each use";

E. A package with a delivery address of Toledo, Ohio containing two bottles labeled, "Pfizer CABASER 1 mg Tablets Cabergoline 20 Tablets For oral administration Each tablet contains cabergoline 1 mg Keep out of reach of children Do not store above 25 C";

F. A package with a delivery address of Leesburg, Virginia containing one bottle labeled, "T3 (Liothyronine Sodium) 200 mcg x 30 ML. Keep out of the reach of children. SHAKE WELL BEFORE EACH USE";

G. A package with a delivery address of Colorado Springs, Colorado containing four vials labeled, "BPC 157 5mg";

H. A package with a delivery address of Denton, Texas containing two vials labeled, "CJC – 1295 With DAC 2mg", two vials labeled, "IPAMORELIN 5MG", and one vial labeled, "Delta Sleep Inducing Peptide (DSIP) 5mg";

I. A package with a delivery address of Panama City Beach, Florida containing two vials labeled, "(AP) CJC–1295 NO DAC 2mg" and one vial of labeled, "(AP) Melanotan II";

J. A package with a delivery address of Jacksonville, Alabama containing two vials labeled, "Frag 176-191 5 MG";

K. A package with a delivery address of Cedar Park, Texas containing three vials labeled, "GHRP-6 X 5mg";

L. A package with a delivery address of Indianapolis, Indiana containing one bottle labeled, "GW-501516 10mg x 30ml";

M. A package with a delivery address of Houston, Texas containing one bottle labeled, "MK-2866 Ostarine Ostarine, also known as MK-2866 is a SARM (selective androgen receptor module) created by GTx avoid and treat muscle wasting. Keep out of the reach of children. Shake well before each use";

N. A package with a delivery address of Boerne, Texas, containing two bottles labeled, "LGD 10MG – 30ML is an investigational selective androgen receptor modulator for treatment of conditions such as muscle wasting and osteoporosis. KEEP OUT OF REACH OF CHILDREN. Shake well before each use";

O. A package with a delivery address of Green Mountain Falls, Colorado containing one bottle labeled "SR9009 20MG – 30ML KEEP OUT OF REACH OF CHILDREN", one bottle labeled "S4 (ANDARINE) – 25MG X 30ml SHAKE WELL BEFORE EACH USE. Keep out of the reach of children", and one bottle labeled, "RAD140 15MG – 30ML KEEP OUT OF REACH OF CHILDREN"; and

P. A package with a delivery address of Martinez, California containing two bottles labeled, "MK-677 25mg X 30m ml Ibutamoren is a non-peptidic, potent, long-acting, orally-active, and selective agonist of the ghrelin receptor and a growth hormone secretagogue. Keep out of reach of children. This product should not be mis-branded, misused or mis-labelled. Store in room temperature. KEEP AWAY FROM CHILDREN."

ii. Unapproved new drugs and misbranded drugs, including:

A. A package with a delivery address of Augusta, Georgia containing 40 pills inside a package labeled, "TAD / C – 30MG x 40"; and

B. A package with a delivery address of Lawrenceburg, Kentucky containing one bottle labeled, "Clenbuterol 200 mcg x 30 ML. Keep out of the reach of children. SHAKE WELL BEFORE EACH USE."

In violation of Title 18, United States Code, Section 371.

COUNTS 2 to 11
(Introduction of Misbranded Drugs Into Interstate Commerce)

1. Paragraphs 1 and 4-5 of Count 1 are hereby incorporated and realleged as if fully set forth herein.

2. On or in or about the dates set forth below, in the District of New Jersey, and elsewhere, defendants

KEITH KOVALESKI and
SYLVIA KOVALESKI,

with intent to defraud and mislead, introduced and delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, misbranded drugs as set forth below. Each of the specified drugs was misbranded in one and more of the following ways: (a) it was manufactured, prepared, propagated, compounded, and processed in an establishment not registered with the Secretary of HHS as required; (b) its labeling was false and misleading; and (c) it did not contain adequate directions for use:

Count	Date	Customer	Destination City	Drug
2	January 2019	C.S.	Cameron Park, California	Tadalafil
3	January 2019	M.P.	Metairie, Louisiana	Clenbuterol
4	January 2019	D.H.	Canton, SD	Ostarine
5	January 28, 2019	C.O.	Augusta, Georgia	Tadalafil
6	January 28, 2019	A.J.	Lawrenceburg, Kentucky	Clenbuterol
7	January 28, 2019	T.S.	Salem, Ohio	Tamoxifen
8	January 28, 2019	B.B.	Wilmington, Illinois	Tamoxifen and Exemestane
9	January 28, 2019	H.N.	Madison, Alabama	Raloxifene
10	January 28, 2019	B.F.	Leesburg, Virginia	T3

11	January 28, 2019	A.A.	Toledo, Ohio	Cabergoline

In violation of Title 21, United States Code, Section 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNTS 12 to 15
(Introduction of Unapproved New Drugs Into Interstate Commerce)

1. Paragraphs 1 and 4-5 of Count 1 are hereby incorporated and realleged as if fully set forth herein.

2. On or in or about the dates set forth below, in the District of New Jersey, and elsewhere, defendants

KEITH KOVALESKI and
SYLVIA KOVALESKI,

with intent to defraud and mislead, introduced and delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, unapproved new drugs as set forth below, that were in violation of Title 21, United States Code, Section 355(a), in that that they were not the subject of an approved NDA, approved ANDA or effective IND on file with the FDA:

Count	Date	Customer	Destination City	Drug
12	January 2019	C.S.	Cameron Park, California	Tadalafil
13	January 2019	M.P.	Metairie, Louisiana	Clenbuterol
14	January 28, 2019	C.O.	Augusta, Georgia	Tadalafil
15	January 28, 2019	A.J.	Lawrenceburg, Kentucky	Clenbuterol

In violation of Title 21, United States Code, Section 331(d) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNT 16
(Unregistered Drug Manufacturing Facility)

1. Paragraphs 1 and 4-5 of Count 1 are hereby incorporated and realleged as if fully set forth herein.

2. From at least as early as in or about August 2014 through in or about January 2019, in the District of New Jersey, and elsewhere, defendants

KEITH KOVALESKI and
SYLVIA KOVALESKI,

with intent to defraud and mislead, operated an establishment in the District of New Jersey engaged in the manufacture, preparation, propagation, compounding, and processing of drugs without registering with the Secretary of HHS as required.

In violation of Title 21, United States Code, Sections 331(p) and 333(a)(2), and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATIONS

1. Upon conviction of one or more of the offenses charged in Counts 1 through 15 of this Indictment, defendants KOVALESKI and SYLVIA KOVALESKI shall forfeit to the United States:

(a) pursuant to 18 U.S.C. § 982(a)(7), all property, real and personal, that constituted and was derived, directly and indirectly, from gross proceeds traceable to the commission of the offenses; and

(b) pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c), any and all misbranded drugs and unapproved new drugs that were introduced and delivered for introduction into interstate commerce contrary to the provisions of 21 U.S.C. § 331.

2. If any of the above-described forfeitable property, as a result of any act or omission of the KOVALESKIS:

(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 21 U.S.C. § 853(p), as incorporated by 28 U.S.C.

§ 2461(c), to seek forfeiture of any other property of the defendants up to the value of the above forfeitable property.

A TRUE BILL

[redacted]

FOREPERSON

[redacted]

Craig Carpenito

CRAIG CARPENITO
UNITED STATES ATTORNEY

CASE NUMBER: 19-_____

United States District Court
District of New Jersey

UNITED STATES OF AMERICA

v.

KEITH KOVALESKI and
SYLVIA KOVALESKI

INDICTMENT FOR
18 U.S.C. §§ 371, 982(a)(7), and § 2;
21 U.S.C. §§ 331(a),(d), and (p),
333(a)(2), 334, and 853(p); and
28 U.S.C. § 2461(c)

A True Bill.

[redacted]

_____
Foreperson

[redacted]

CRAIG CARPENITO
UNITED STATES ATTORNEY
NEWARK, NEW JERSEY

KAREN D. STRINGER
CARI FAIS
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