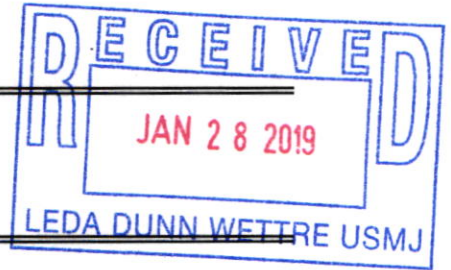


**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**



UNITED STATES OF AMERICA : Hon. Leda Dunn Wettre
:
v. : Mag. No. 19-8001
:
KEITH KOVALESKI and :
INES MALTEZ :

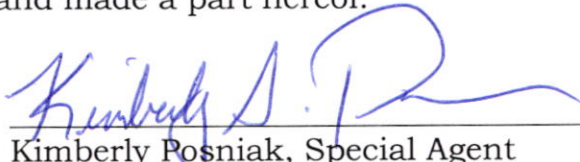
I, Kimberly Posniak, being duly sworn, state the following is true and correct to the best of my knowledge and belief.

SEE ATTACHMENT A

I further state that I am a Special Agent with the United States Food and Drug Administration, Office of Criminal Investigations, and that this complaint is based on the following facts:

SEE ATTACHMENT B

continued on the attached page and made a part hereof.



Kimberly Posniak, Special Agent
United States Food and Drug Administration
Office of Criminal Investigations

Sworn to before me and
subscribed in my presence,
January 28, 2019
at Newark, New Jersey



HONORABLE LEDA DUNN WETTRE
UNITED STATES MAGISTRATE JUDGE

ATTACHMENT A

From in or about 2014 to in or about January 2019, in the District of New Jersey and elsewhere, defendants

KEITH KOVALESKI and
INES MALTEZ,

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

- (a) defraud the United States Food and Drug Administration by impeding, impairing, and disturbing the FDA's lawful and legitimate function of protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act, one purpose of which is to ensure that drugs sold for human use are safe, effective, and bear labeling that contains true and accurate information; and
- (b) commit offenses against the United States, specifically and with the intent to defraud and mislead, that is:
 - (1) cause the introduction of misbranded drugs into interstate commerce, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2);
 - (2) cause the receipt of misbranded drugs in interstate commerce and the delivery and proffered delivery thereof for pay and otherwise, in violation of Title 21, United States Code, Sections 331(c) and 333(a)(2); and
 - (3) cause the introduction of an unapproved new drug into interstate commerce, in violation of Title 21, United States Code, Sections 331(d), 355(a), and 333(a)(2);

and did acts as set forth in the complaint to effect the object of the conspiracy.

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

ATTACHMENT B

I, Kimberly Posniak, a Special Agent with the United States Food and Drug Administration, Office of Criminal Investigations, have been personally involved in the investigation of this matter. The information contained in the complaint is based upon my personal knowledge, as well as information obtained from other sources, including: (a) statements made or reported by various witnesses with knowledge of relevant facts; (b) my review of publicly available information; and (c) my review of evidence, including video surveillance, business records, bank records and other documents. Because this complaint is being submitted for the limited purpose of establishing probable cause, it does not include every fact that I have learned during the investigation. Where the contents of documents and the actions and statements of others are reported herein, they are reported in substance and in part, except where otherwise indicated.

BACKGROUND

1. At all times relevant to this Complaint:

a. Defendant Keith Kovaleski ("KOVALESKI") was an Amtrak employee and a resident of South Amboy, New Jersey. KOVALESKI was the principal of AA Peptide LLC, a/k/a All American Peptide ("AAP").

b. Defendant Ines Maltez ("MALTEZ") was a resident of Sayreville, New Jersey.

c. Co-Conspirator-1 ("CC-1") was a resident of South Amboy, New Jersey.

d. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs and medical devices 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. ("FDCA") and other pertinent laws and regulations.

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

structure or any function of the body of people or other animals. 21 U.S.C. § 321(g)(1). The “intended use” of an article meant the objective intent of the persons legally responsible for the labeling of that article. The intent was determined by such persons’ expressions or the circumstances surrounding the distribution of the article, for example, labeling claims, advertising matter, and oral or written statements by such persons or their representatives. Intended use could also be determined by evidence that the article was, with the knowledge of such persons or their representatives, offered and used for a purpose for which it was neither labeled nor advertised. 21 C.F.R § 201.128.

3. Under the FDCA, a “prescription drug” was: (a) 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 (b) 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 a drugs. 21 U.S.C. § 353(b)(1).

4. A “new drug” was, among other things, any drug not generally recognized among qualified experts as both safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 321(p). A “new drug” could not be lawfully introduced or delivered for introduction into interstate commerce unless an approval of that drug was granted by FDA through the New Drug Application process. 21 U.S.C. § 355(a).

5. A drug was misbranded if: (a) its labeling was false or misleading in any particular, 21 U.S.C. § 352(a); (b) it did not contain adequate directions for use, 21 U.S.C. § 352(f) and 21 C.F.R. § 201.5; (c) it was a prescription drug and was dispensed without a valid prescription, 21 U.S.C. § 353(b)(1); or (d) it was a prescription drug, and its label failed to bear the statement “Rx only” at any time prior to dispensing, 21 U.S.C. § 353(b)(4)(A). The FDCA also prohibited introducing or delivering for introduction into interstate commerce new drugs not approved by the FDA under 21 U.S.C. § 355. 21 U.S.C. §§ 331(d).

6. As set forth below, there is probable cause to believe that defendants KOVALESKI and MALTEZ, along with others, engaged in a scheme to enrich themselves by marketing and distributing misbranded drugs and unapproved new drugs using the United States Postal Service (the “USPS”).

EVIDENCE OF THE CONSPIRACY

7. AAP was an entity that used its website, www.allamericanpeptide.com, (the “AAP Website”) to market and distribute substances used by bodybuilders and others engaged in weight training to enhance performance and mitigate the side effects of performance-enhancing

substances. KOVALESKI registered AAP with the State of New Jersey on or about March 26, 2014, and listed his South Amboy, New Jersey residence ("KOVALESKI's Residence") as AAP's location.

8. The AAP Website directed customers to email AllAmericanPeptide@gmail.com (the "AAP Email Account") to complete their purchases. The evidence reveals that KOVALESKI was likely the user of the AAP Email Account. In this regard, the AAP Email Account was subscribed to by KOVALESKI. The recovery email address for the AAP Email Account was amtrakkeith@gmail.com, another email address subscribed to by KOVALESKI and used by KOVALESKI on the application for AAP's PO Box. The phone number associated with the AAP Email Account was subscribed to by KOVALESKI, and in certain outgoing emails from the AAP Email Account, the sender referred to himself as "Keith."

9. Between in or about April 2018 and December 2018, an undercover law enforcement agent ("UC"), using an undercover email address (the "UC Email Account") made five separate undercover purchases of misbranded drugs and unapproved new drugs from the AAP Website. Each undercover purchase was made through the AAP website without a prescription, and none of the substances purchased contained an "Rx-only" designation on their labels. None of the substances purchased from AAP contained adequate directions for use or warnings regarding known side effects.

Undercover Purchase 1

10. On or about April 19, 2018, the UC ordered one bottle of "Cabaser" from the AAP Website. Shortly after placing the order, the UC received an email from the AAP Email Account with an order summary and order number. In response to an inquiry from the UC, the AAP Email Account sent an email to the UC directing the UC to mail a USPS Money Order to KOVALESKI's Residence. On or about April 20, 2018, the UC sent a \$100 money order to KOVALESKI's Residence. On or about April 27, 2018, the UC received a parcel containing the "Cabaser" at an undercover PO Box in Newark, New Jersey (the "UC PO Box"). The package had a return label marked "AAP LLC PO Box 3069 South Amboy, NJ 08879" (the "AAP PO Box"). The AAP PO Box was registered to KOVALESKI, with CC-1 listed as an authorized user.

11. Laboratory testing showed that the "Cabaser" contained cabergoline. Cabergoline was the active ingredient in an FDA-approved prescription drug that was used to treat high levels of prolactin, which could cause unwanted breast milk. Websites marketed towards bodybuilders promote products containing cabergoline to counter the side effects of taking illegal steroids.

12. The \$100 money order used to purchase the "Cabaser" was deposited on or about May 8, 2018 into a TD Bank account for AAP ending in 602 (the "AAP TD Bank Account"), for which KOVALESKI was the sole signatory. The back of the money order was endorsed with KOVALESKI's name.

Undercover Purchase 2

13. On or about May 9, 2018, the UC ordered one bottle of "MK-2886 (Ostarine)" and 40 30 mg capsules of "TAD/C." Following this order, the UC was instructed via email from the AAP Email Account to send a money order to the AAP PO Box. The UC sent a \$148 money order to the AAP PO Box on or about May 10, 2018, and on or about May 24, 2018, the UC received a parcel at the UC PO Box containing the "MK-2866 (Ostarine)" and the "TAD/C" capsules.

14. Laboratory testing showed that the "TAD/C" capsules contained approximately 130 milligrams of tadalafil, the active ingredient in Cialis, a prescription drug approved by the FDA to treat erectile dysfunction. This quantity of tadalafil is significantly more than the highest recommended dosage in the FDA-approved prescription drug Cialis.

15. Laboratory testing also showed that the bottle marked "Ostarine" contained ostarine. Ostarine was a new drug that has not been approved by the FDA, but was marketed to bodybuilders to treat muscle wasting.

16. The \$148 money order was deposited into the AAP TD Bank Account on or about May 15, 2018. The back of the money order was endorsed with CC-1's name.

Undercover Purchase 3

17. On or about October 20, 2018, the UC ordered a "stack," i.e. a group of supplements designed to interact to enhance performance. The "stack" included one bottle of "YK-11," two bottles of "MK-677," two bottles of "LGD-4033," and two bottles of "MK-2866 (Ostarine)." According to publicly available information, "YK-11," "MK-677," and "LGD-4033" are marketed to body builders as performance-enhancing substances. None of them have been approved by the FDA.

18. On or about October 20, 2018, the UC emailed the order confirmation to the AAP Email Account and requested to pay by Bitcoin, one of the payment options listed in promotional emails from the AAP Email Account. On or about October 20, 2018, the AAP Email Account sent a Bitcoin address in response. On or about October 20, 2018, the UC paid that Bitcoin address .0515736 BTC (\$330.07).

19. The “stack” arrived at the UC PO Box on or about October 23, 2018.

Undercover Purchase 4

20. On or about December 4, 2018, the UC made another purchase of “TAD/C” through the AAP website. After receiving the order confirmation, the UC emailed the AAP Email Account and requested to pay for the order using Bitcoin. On or about December 4, 2018, the AAP Email Account emailed the UC a different Bitcoin address, and on or about December 5, 2018, the UC sent .02349 BTC (\$89.79 USD) to that Bitcoin address.

21. On or about December 10, 2018, the UC received a parcel containing approximately 40 blue capsules. The packaging stated that the contents were “TAD/C – 30 mg.” Laboratory testing revealed that the TAD/C actually contained approximately 108 milligrams of tadalafil, significantly more than the highest recommended dosage in the FDA-approved prescription drug Cialis. Five latent fingerprints lifted from the adhesive side of the tape removed from bubble wrap used inside of the package matched MALTEZ’s fingerprints.

Undercover Purchase 5

22. On or about December 21, 2018, the UC placed an order for “Clomiphene” and “Tamoxifen” on the AAP website. Tamoxifen Citrate was an FDA-approved prescription drug used to treat breast cancer, and Clomiphene Citrate was an FDA-approved prescription drug used to treat infertility in women. Both drugs were promoted for use among bodybuilders to counter the negative side effects of performance-enhancing substances. On or about December 21, 2018, the AAP Email Account sent the UC a third Bitcoin address, and on or about December 21, 2018, the UC sent .0195 BTC (\$77.71 USD) to that address.

23. On or about December 27, 2018, the UC received a parcel at the UC PO Box containing two glass bottles, one labeled “Tamoxifen” and the other labeled “Clomiphene Citrate.” MALTEZ’s fingerprints matched latent fingerprints lifted from the adhesive side of the label affixed to the bottle of “Clomiphene” and the adhesive side of the tape removed from bubble wrap used inside of the package.

OTHER EVIDENCE OF MISBRANDING, MISUSE, ILLEGAL MANUFACTURING, AND RECEIPT OF ILL-GOTTEN GAINS

24. The AAP website included a bogus legal disclaimer that its products were intended for laboratory research use only, and not as drugs or food. KOVALESKI employed the bogus “research chemicals” disclaimer to conceal that he and others were distributing misbranded drugs and

unapproved new drugs for human consumption. Evidence that these drugs were intended for human consumption is as follows:

- a. The AAP Website included consumer reviews which commented on, among other things, the performance-enhancing effects of many of AAP's products. Based on these reviews, it was clear that AAP's customers intended to use its products for human consumption. For example, in a review for the "TAD/C" dated April 18, 2018, a customer's review on the AAP Website described his personal use of the pills with his wife, and how they improved his sexual performance.
- b. In a June 27, 2018 email exchange with a customer in Arizona who wrote that he was using AAP products for hamstring tears and shoulder and elbow tendinitis, the AAP Email Account sent an email that stated:

I had tendinitis a few months back . . .What I did was recon[stitute] TB & BPC – shooting directly into the elbow tendon twice a day with an insulin syringe. In 3 days all pain was gone !!!! And I was back to benching 1000lbs (lol) . . . Id like you to try my protocol in recon[stitut]ing both – loading syringe with both and shooting it twice a day into your elbow.¹

TB likely was a reference to TB500 and BPC likely was a reference to BPC 157, both substances marketed to bodybuilders as performance enhancing and sold on AAP's website.

- c. In a July 11, 2018 email to the AAP Email Account, a customer wrote, "Hello Kieth, I know I've asked you this periodically over the last couple of years, however, have you considered changing your position on carrying the DHT derivatives again?? I'm telling you..the [DHT derivatives] you sent me a couple times was absolutely amazing." The greeting to "Kieth" likely was to KOVALESKI. "DHT derivatives" likely was a reference to dihydrotestosterone, a type of anabolic steroid that is not an FDA-approved drug. On or about July 12, 2018, the AAP Email Account responded explaining that the problem was that the supplier for DHT required a \$16,000 minimum for each item. On or about July 12, 2018, the customer responded, "Good grief...that absolutely DOES suck!!! Because for me..and I'm an old man, Kieth...but I've taken alot'a juice over the years and those samples

¹ Emails are reproduced here in their original form, including any typographical errors.

you sent me..def some of the best chems I have ever put in the machine.”

25. The investigation has revealed evidence that KOVALESKI operated AAP from KOVALESKI's Residence, with the assistance of MALTEZ and CC-1. First, trash obtained from KOVALESKI's Residence contained a Priority Mail envelope that was marked “return to sender.” The return address of the envelope was the AAP PO Box. In addition to AAP's business registration, which listed KOVALESKI's Residence as AAP's location, AAP's business accounts at JPMorgan Chase and TD Bank both listed KOVALESKI's Residence as AAP's address.

26. Second, on or about January 7, 2019, law enforcement agents conducting surveillance observed MALTEZ arrive at KOVALESKI's Residence at approximately 9:10 a.m., driving a white Toyota Rav-4 with a New Jersey license plate registered to another individual with the same last name. At approximately 1:45 p.m., agents observed MALTEZ leave in a car driven by CC-1. Agents observed multiple USPS parcels in CC-1's vehicle through the rear window. CC-1 drove to a Post Office in South Amboy, where AAP maintained its PO Box. MALTEZ and CC-1 unloaded approximately 149 packages, all bearing the return address of “AAP LLC,” at AAP's PO Box. These included packages addressed to South Dakota, Louisiana, and California.

27. Third, video surveillance showed a white Toyota Rav 4, consistent with the one MALTEZ was observed driving, at KOVALESKI's Residence on other occasions. For example, video surveillance showed a white Rav 4 arriving at KOVALESKI's Residence on or about August 6, 2018 at approximately 9:07 a.m. and departing at approximately 12:27 p.m. On or about October 22, 2018, the video again showed a white Rav 4 arriving at approximately 9:03 a.m. and departing at approximately 12:14 p.m. On both of those days, AAP parcels were mailed out from a post office in South Amboy.

28. There is evidence that, in addition to distributing misbranded drugs and unapproved new drugs, KOVALESKI manufactured certain misbranded drugs and unapproved new drugs:

- a. In an email exchange with a customer in New Hampshire who ordered AAP's sexual performance enhancement pills, the AAP Email Account wrote on or about January 21, 2017, “I make these FAST & use whatever caps I have lying around.” KOVALESKI likely wrote this email. In addition to the evidence described above that KOVALESKI was the user of the AAP Email Account, when arranging payment for this order, the user of the AAP Email Account referenced that the payment was going to “my wife” and referenced KOVALESKI's wife by name.

- b. On or about April 10, 2018, the AAP Email Account responded to a customer in Indiana who wrote to complain that the sexual performance enhancement pills that he purchased contained baking soda with the following: "This is the owner. I've been making: Cialis, Viagra, and [other performance enhancement pills] 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"

29. AAP received payment for its products through various means, such as money orders and through third-party electronic payment services that enabled customers to transfer money electronically, including Payment Vendor 1, Payment Vendor 2, and Payment Vendor 3. AAP electronic payments were directed to multiple receiver accounts belonging to KOVALESKI, MALTEZ, CC-1, and others. For example, on or about September 12, 2018, the AAP Email Account instructed a customer who had placed an order on the AAP Website:

Please reply back to this email after payment is made. I need your order number and full name. Download the [Payment Vendor 1] app on your phone and verify your credit card When sending [Payment Vendor 1] please be """"""""""COMPLETELY DISCREET"""""""""" IN THE COMMENT SECTION . . . JUST PUT 🍷 or ✨ or 🍷emoji DO NOT DO NOT PUT ANYTHING THAT HAS TO DO WITH ORDER NUMBERS...Receiver name below @Inesmtz

Once sent just reply to this email chain that payment is sent and you will receive tracking will follow within 2 business days
PLEASE ALWAYS ASK FOR NEW RECEIVER INFORMATION
BECAUSE RECEIVER MAY CHANGE AT ANY TIME

MALTEZ opened the receiver account @Inesmtz with Payment Vendor 1 on or about September 9, 2018. From on or about September 12, 2018 to on or about December 17, 2018, the @Inesmtz account received a total of approximately \$9,504 in deposits, most of which contained an emoji consistent with the AAP payment instructions above.

30. Substantially similar payment instructions directing customers to different receiver accounts, including accounts associated with KOVALESKI, CC-1, and others, were routinely sent from the AAP Email Account. For example, customers were directed to pay a Payment Vendor 1 account in the name "K Kovo" (the "K Kovo Account"). The K Kovo Account was opened on or about May 19, 2015 using KOVALESKI's social security number and date of

birth, and was set up to transfer money into a joint TD Bank account for KOVALESKI and CC-1 (the "KOVALESKI and CC-1 Account").

31. A review of bank records showed that from in or about January 2016 to in or about April 2018, there were approximately \$102,795 in deposits from Payment Vendor 1 into the KOVALESKI and CC-1 Account. During that same time there were approximately \$3,939 in deposits from Payment Vendor 2 in the same account. The KOVALESKI and CC-1 Account also received approximately \$27,267 in deposits from Payment Vendor 3 from in or about March 2018 to in or about April 2018. Records from a joint Chase bank account for CC-1 and CC-1's adult daughter showed that from in or about January 2017 to in or about May 2018, there were approximately \$27,846 in deposits from Payment Vendor 1. An account at Fifth Third Bank for which CC-1 was the only signatory received approximately \$22,981 in deposits from Payment Vendor 1 from in or about January 2018 to in or about September 2018.

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