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Department of Justice

U.S. Attorney's Office

District of New Jersey

FOR IMMEDIATE RELEASE

Tuesday, January 29, 2019

Middlesex County, New Jersey, Man and Woman Charged with Conspiring to Distribute Misbranded Drugs

NEWARK, N.J. – A Middlesex County, New Jersey, man and woman appeared in court today after being arrested for their roles in a scheme to market and distribute misbranded and unapproved new drugs, U.S. Attorney Craig Carpenito announced.

Keith Kovaleski, 54, of South Amboy, New Jersey, and Ines Maltez, 33, of Sayreville, New Jersey, were both charged by complaint with conspiring to distribute and cause the receipt and delivery of misbranded drugs and unapproved new drugs, and to impede the functions of the U.S. Food and Drug Administration (FDA). They were arrested today and appeared before U.S. Magistrate Judge Michael A. Hammer in Newark federal court. Both defendants were released on \$100,000 unsecured bond.

According to documents filed in this case » and statements made in court:

The FDA is responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), a law intended to assure that drugs are safe, effective, and bear accurate labeling containing all required information. The FDA regulates the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

From 2014 to January 2019, Kovaleski was the principal of AA Peptide LLC, a/k/a All American Peptide (AAP). AAP used its 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.

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 use by their customers.

Between April 2018 and December 2018, an undercover law enforcement agent made five purchases of misbranded drugs and unapproved new drugs from the AAP website. Each undercover purchase was made through the 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. Two of the purchases included pills containing tadalafil, the active ingredient in Cialis, in dosages significantly higher than the highest recommended dosage.

Maltez participated in the scheme by packaging and mailing misbranded and unapproved drugs, and by receiving payments from customers.

The conspiracy charge carries a maximum potential penalty of up to five years in prison and a fine of up to \$250,000 or twice the gross pecuniary gain or loss.

U.S. Attorney Craig Carpenito credited special agents of the FDA, under the direction of Special Agent in Charge Jeffrey J. Ebersole, FDA Office of Criminal Investigations' New York Field Office; postal inspectors with the U.S. Postal Inspection Service, under the direction of Inspector in Charge James V. Buthorn, Newark Division, and special agents of AMTRAK Office of Inspector General, under the direction of Special Agent in Charge Michael J. Waters, Eastern Field Office, with the investigation leading to the charges.

The government is represented by Assistant U.S. Attorneys Karen Stringer and Cari Fais of the Special Prosecutions Division.

The charges and allegations contained in the indictment are merely accusations, and the defendants are presumed innocent unless and until proven guilty

Attachment(s):

[Download Kovaleski.Complaint.pdf](#)

Topic(s):

Prescription Drugs

Component(s):

[USAO - New Jersey](#)

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