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Department of Justice

U.S. Attorney's Office

District of New Jersey

FOR IMMEDIATE RELEASE

Monday, July 8, 2019

Middlesex County Couple Charged with Selling Misbranded and Unapproved New Drugs and Running Drug Manufacturing Facility in Their Basement

NEWARK, N.J. – A Middlesex County, New Jersey, husband and wife were indicted today in connection with a scheme to market and distribute misbranded drugs and unapproved new drugs and manufacture drugs in an unregistered facility, U.S. Attorney Craig Carpenito announced.

Keith Kovaleski, 55, and Sylvia Kovaleski, 41, of South Amboy, New Jersey, each were charged with one count of 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) and U.S. Department of Health and Human Services (HHS), 10 counts of introducing misbranded drugs into interstate commerce, four counts of introducing unapproved new drugs into interstate commerce, and one count of manufacturing drugs without registering with the secretary of HHS. In January 2019, Keith Kovaleski was charged in a federal complaint with conspiracy and was released on bail. Both defendants will be arraigned at a date to be determined.

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

The FDA is responsible for 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 May 2014 to January 2019, the Kovaleskis owned and operated AA Peptide LLC, a/k/a All American Peptide (AAP). AAP used its website to market and distribute substances primarily 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. The Kovaleskis employed the bogus "research chemicals" disclaimer to conceal that they and others were distributing misbranded drugs and unapproved new drugs for use by their customers.

The Kovaleskis, though AAP, sold products including: (1) prescription drugs, such as tadalafil, the active ingredient in Cialis; (2) SARMS, used by body-builders as an alternative to steroids; (3) peptides, also used as performance-enhancing substances; and (4) other drugs that were not peptides or SARMS, and had not been approved for human use, for example, clenbuterol, a drug sold in foreign markets but not approved by the FDA. The Kovaleskis failed to provide adequate directions for use for these products, such as frequency of administration and other dosage information.

The Kovaleskis used their South Amboy basement as a manufacturing facility to make and label AAP products, including homemade capsules containing baking soda and tadalafil. The Kovaleskis sold tadalafil capsules that contained significantly higher dosages of the active ingredient than the highest recommended dosage.

The Kovaleskis earned more \$2.5 million through the sale of misbranded and unapproved new drugs.

The conspiracy charge carries a maximum potential penalty of up to five years in prison. Each count of introduction of misbranded drugs in interstate commerce, introduction of unapproved new drugs in interstate commerce, and operating an unregistered drug manufacturing facility carries a maximum potential penalty of three years in prison. Each charge also carries a maximum potential fine of up to \$250,000 or twice the gross pecuniary gain or loss.

U.S. Attorney Craig Carpenito credited special agents of the Food and Drug Administration, Office of Criminal Investigations, New York Field Office, under the direction of Special Agent in Charge Jeffrey J. Ebersole,; special agents of the Amtrak Office of Inspector General, under the direction of Special Agent in Charge Michael Waters; and postal inspectors with the U.S. Postal Inspection Service, under the direction of Inspector in Charge James Buthorn, Newark Division, with the investigation leading to today's indictment.

The government is represented by Assistant U.S. Attorneys Karen D. 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.Indictment.pdf](#)

Topic(s):

Drug Trafficking

Component(s):

[USAO - New Jersey](#)

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