



Amtrak employee and wife plead guilty to selling \$3 million worth of misbranded and unapproved new drugs

For Immediate Release

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NEWARK, N.J. — An Amtrak employee and his wife pleaded guilty this week for marketing and distributing over \$3 million worth of misbranded drugs and unapproved new drugs, according to the U.S. Attorney's Office, District of New Jersey.

Sylvia Kovaleski, 43, of South Amboy, pleaded guilty on Tuesday by videoconference in U.S. District Court to one count of conspiring to distribute misbranded drugs and unapproved new drugs. Keith Kovaleski, 57, pleaded guilty to the same charge on Monday. As part of their plea agreements, the Kovaleskis must forfeit over \$3 million in criminal proceeds.

According to court documents, the Kovaleskis owned and operated All American Peptide. From 2014 to January 2019, All American Peptide 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.

Through their company, the Kovaleskis sold prescription drugs such as tadalafil, the active ingredient in Cialis; SARMS, a drug used by bodybuilders as an alternative to steroids; peptides, also used as performance enhancing substances; and other drugs that had not been approved for human use by the U.S. Food and Drug Administration.

The Kovaleskis used their South Amboy basement as a manufacturing facility to make and label AAP products, some capsules containing dosages of tadalafil higher than the highest recommended dosage. They failed to provide adequate directions for use for their products, such as frequency of administration, dosage information, or warnings about side effects.

The conspiracy charge carries a maximum potential penalty of up to five years in prison and a maximum potential fine of up to \$250,000 or twice the gross gain or loss, whichever is greatest. Sentencing for both defendants is scheduled for July 26, 2022.

In addition to the Amtrak Office of Inspector General, the case was investigated by the FDA Office of Criminal Investigations and the U.S. Postal Inspection Service. The government is represented by Assistant U.S. Attorneys Cari Fais and Barbara Ward. More information is available in the press release from the U.S. Attorney's Office: <https://direc.to/hN5W>.

Reports of fraud, waste, or abuse; criminal or unethical acts affecting Amtrak's property or operations; or mismanagement in Amtrak programs or operations can be made 24 hours a day via the Amtrak OIG Hotline at 1-800-468-5469 or online at <https://direc.to/hPAu>.

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