

Department of Justice

Carlton S. Shier, IV Acting United States Attorney Eastern District of Kentucky

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CONTACT: Gabrielle Dudgeon PHONE: (859) 685-4887

E-MAIL: gabrielle.dudgeon@usdoj.gov

Nicholasville Compounding Pharmacy and Its Owner Sentenced for Unlawful Distribution of Prescription Drugs

FRANKFORT, Ky. – A compounding pharmacy based in Nicholasville, and its owner, were sentenced in federal court on Wednesday, by U.S. District Judge Gregory F. Van Tatenhove, for unlawful distribution of compounded prescription drugs. Tailor Made Compounding (TMC) was sentenced to three years probation and forfeited \$1,788,906.82. The owner, Jeremy Delk, was sentenced to three years probation, including four months home incarceration, 100 hours of community service, a \$20,000 fine, and a prohibition from participating in a business involving the distribution of prescription drugs.

Delk was sentenced on his guilty plea to one count of unlawfully engaging in wholesale distribution of a prescription drug, without licensing TMC as a wholesale distributor with the Kentucky Board of Pharmacy. According to his plea agreement, from October 23, 2018 through May 14, 2020, TMC sent 112 vials of Methylcobalamin, a prescription form of vitamin B12, to a licensed physician who operated an anti-aging/wellness clinic in the Greater Los Angeles area. Rather than sending individualized, patient-specific prescriptions to TMC, as is required by law, this physician made bulk orders of Methylcobalamin without issuing prescriptions or providing accurate patient names. Delk, as owner and chief executive officer of TMC, knowingly caused TMC to fill and ship bulk, wholesale distributions of Methylcobalamin to the physician, knowing that TMC had never applied for permission from the Kentucky Board of Pharmacy to act as a wholesale distributor of prescription drugs. When authorities from the FDA and the Kentucky Board of Pharmacy inspected TMC, between August 20 and October 24, 2018, Delk took steps to hide records of TMC's wholesale distributions of Methylcobalamin, as well as other records.

TMC was sentenced on its guilty plea to one count of distributing unapproved new drugs throughout the United States, from October 25, 2018 through April 1, 2020. Specifically, TMC pleaded guilty to unlawful distribution of selective androgen receptor modulators ("SARMS") and other substances that the FDA had not approved for distribution in the United States. SARMS are synthetic chemicals designed to mimic the effects of testosterone and other anabolic steroids. Products containing SARMS were often marketed and sold for body-building purposes. According to the plea agreement, TMC also unlawfully distributed other unapproved new drugs, including BPC 157, Cerebrolysin, CJC 1295, DSIP, Epitalon, GW 501516, Ipamorelin, LGD-4033, LL-37, Melanotan II, MK 677, PEG-MGF, Selank, and Semax. In connection with the plea, TMC agreed to forfeit \$1,788,906.82, representing its 2019 sales for these products

Tailor Made and Delk pleaded guilty in October 2020.

Carlton S. Shier, IV., Acting United States Attorney for the Eastern District of Kentucky; Mark S. McCormack, Special Agent in Charge, FDA Office of Criminal Investigations, Metro Washington Field Office; and James Robert Brown, Jr., Special Agent in Charge, Federal Bureau of Investigation jointly announced the sentences.

The investigation was conducted by the FDA and the FBI. The United States was represented by Assistant U.S. Attorney Kate K. Smith.