

Creve Coeur Olive Street Pharmacy and Owner Agree To Pay \$1,507,808.50 To Resolve Lawsuit

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ST. LOUIS – The United States has reached a civil settlement with Olive Street Pharmacy, LLC (Olive Street) and pharmacy technician Irina Shlafshiteyn (Shlafshiteyn) resolving a civil complaint bringing claims under the False Claims Act (FCA) and

Controlled Substances Act (CSA) for damages, statutory penalties, and injunctive relief related to the unlawful dispensing of controlled substances, including controlled substances that were submitted to Medicaid or Medicare for reimbursement. As part of the settlement, Olive Street and Shlafshiteyn agreed to pay \$1,507,808.50, an amount that was based in part on their ability to pay.

According to the civil complaint filed by the United States, Olive Street, a retail pharmacy located in Creve Coeur, Missouri, and Shlafshiteyn, its 25 percent owner and managing employee, repeatedly dispensed prescriptions for controlled substances while disregarding warning signs of diversion, or “red flags,” indicating the prescriptions were not legitimate. The United States alleged that the types of red flags that Olive Street and Shlafshiteyn ignored included clear instances of tampering with written prescriptions; dangerous combinations of drugs commonly sought after for recreational purposes; and amounts of opioids that exceeded CDC guidance by as much as 17.5 times the recommended maximum daily dosage.

In the complaint, the United States further accused Olive Street of routinely dispensing prescriptions for Subsys, an oral fentanyl spray, which is subject to heightened FDA restrictions and indicated only for opioid-tolerant patients experiencing breakthrough pain due to cancer. The United States contended that Olive Street and Shlafshiteyn knowingly dispensed high dosages of Subsys to patients who did not qualify for the drug, and that the vast majority of the Subsys Olive Street dispensed was prescribed by Philip Dean, M.D. Dean, a Warrenton, Missouri neurologist, pleaded guilty to illegally distributing prescription opioids in 2018, including to women with whom he had lived and with whom he had had personal relationships.

The United States alleged that even though Shlafshiteyn knew Dean was having intimate relationships with at least one of the women for whom he was prescribing controlled substances, Shlafshiteyn and others at her direction continued to dispense Dean’s controlled substance prescriptions to that patient and to other patients of Dean. Further, according to the civil complaint, as the managing employee of Olive Street, Shlafshiteyn had the control and authority to effect compliance with the FCA and CSA.

According to the settlement agreement, effective September 30, 2021, Shlafshiteyn surrendered her Missouri pharmacy technician license and Olive Street terminated its enrollment in the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy (TIRF REMS) Program, the FDA-mandated program that had allowed Olive Street to dispense immediate-release fentanyl drugs like Subsys. The parties further agreed to enter into a consent decree of permanent injunction prohibiting Shlafshiteyn from participating in the dispensing of controlled substances or being employed by any establishment that does so, prohibiting Olive Street from seeking enrollment in the TIRF REMS Program, and detailing many additional specific

parameters limiting the circumstances under which Olive Street is permitted to continue dispensing controlled substances.

“Medical professionals have the legal obligation to ensure the dispensing of prescriptions are for legitimate medical purposes,” said Inez Davis, the Drug Enforcement Administration’s Diversion Program Manager for the states of Missouri and Kansas, and southern Illinois. “In this case, the pharmacy abandoned its corresponding responsibility and ignored the clear signs that powerful medications, like oral fentanyl spray, were being prescribed far beyond the recommended guidance. This settlement sends a message that DEA will not accept actions that put people’s lives at risk.”

Under the settlement agreement, Shlafshiteyn is excluded from participating in the federal healthcare programs for a period of 10 years, and Olive Street is bound by the terms of a corporate integrity agreement governing its ability to continue participating in the federal programs.

“Health care providers who unlawfully dispense controlled drugs risk the health of their patients and pose a threat to society,” said Curt L. Muller, Special Agent in Charge of the Department of Health and Human Services, Office of Inspector General. “We will continue to work with our law enforcement partners to protect the integrity of federal health programs and hold accountable individuals who endanger beneficiaries.”

“The Missouri Attorney General’s Medicaid Fraud Control Unit aids in conducting complex investigations and prosecutions to ensure that those who game the Medicaid system for personal gain are held accountable,” added Missouri Attorney General Eric Schmitt. “We’re proud of our work in this case, and our work across the state to hold bad actors accountable and save taxpayer money.”

The Office of Inspector General of the Department of Health and Human Services, Drug Enforcement Administration, Federal Bureau of Investigation and the Missouri Attorney General’s Medicaid Fraud Control Unit investigated the case. Assistant United States Attorney Amy Sestric handled the case.