

Department of Justice

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ST. VINCENT HOSPITAL AGREES TO PAY \$2,000,000 TO RESOLVE DEA CIVIL PENALTY DISPUTE

Settlement with U.S. involves record-keeping and diversion violations relating to Schedule III –V controlled substances

Susan W. Brooks, U. S. Attorney for the Southern District of Indiana, and Dennis A. Wichern, Assistant Special Agent in Charge (ASAC) of the United States Drug Enforcement Administration, today announced that St. Vincent Hospital and Health Care Center, Inc. of Indianapolis, Indiana has agreed to pay the United States \$2,000,000.00 to settle alleged record keeping deficiencies regarding its receipt and storage of Schedule III-V controlled substances at its Clinic Pharmacy located in Indianapolis. The violations were uncovered by an audit conducted by Drug Enforcement Administration (DEA) Diversion Investigators The United States and St. Vincent Hospital have filed a Consent Decree with the United Stated District Court, Southern District of Indiana, and the court entered that Consent Decree on July 23, 2007. The Consent Decree requires St. Vincent Hospital to pay \$1.2 million to the United States within 30 days of the entry of the Consent Decree. The remaining penalty is deferred, conditioned on St. Vincent Hospital's continued compliance with the terms of the Consent Decree.

The Complaint filed by the United States alleged that a DEA investigation revealed that St. Vincent Hospital failed to keep accurate records and make accurate reports under the laws designed to safeguard the public against diversion of the most abused classes of legally manufactured and prescribed drugs. The Complaint alleges that DEA discovered that St. Vincent Hospital was unable to accurately account for approximately 623,843 tablets of hydrocodone. Hydrocodone, a Schedule III narcotic drug is an often abused prescription drug and commonly diverted to street trade if not properly accounted. As a direct result of the investigation, St. Vincent Hospital has taken significant steps to bring each of its pharmacies into full compliance with the law and has stated that the facilities have substantially remediated the alleged violations. Deferral of additional stipulated civil penalties is contingent upon successful compliant conduct by St. Vincent Hospital pharmacy operations. The Consent Decree states that the United States

had alleged a broad array of violations, including failure to provide effective controls and procedures to guard against theft and diversion of controlled substances.

Code, Section 801 et seq., created "a closed system" of distribution for controlled substances in which every facet of the handling of the substances – from their manufacture to their consumption by the ultimate user – is subject to pervasive government controls. The law prevents the diversion and abuse of legitimate controlled substances, while at the same time ensuring an adequate supply of those substances needed to meet the medical and scientific needs of the United States. ASAC Wichern said that "The St. Vincent settlement sends an unequivocal message: When DEA registrants fail to maintain the records required by law to ensure that drugs like hydrocodone are not diverted, they endanger the American public. Such violators will be discovered, investigated, and penalized to safeguard America."

United States Attorney Brooks said that "Compliance with the Controlled Substances Act is vital to the United States' efforts to protect the public from illegal trafficking of narcotics. Those licensed to handle controlled drugs must know that the United States expects strict compliance with the Act; that the United States is aggressively monitoring those systems; and, that the United States will demand accountability for the drugs that registrants are licensed to handle." Brooks added that "The United States appreciates St. Vincent Hospital's efforts to obtain compliance with the record-keeping regulations, and its voluntary accountability for the deficiencies discovered by the audit."

According to Assistant U. S. Attorney Thomas E. Kieper, lead counsel for the government, the investigation was conducted by Diversion Investigators from the Drug Enforcement Administration, the United Drug Task Force and the Hamilton/Boone County Drug Task Force.

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