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**MADIGAN REACHES \$4.5 MILLION SETTLEMENT WITH DRUGMAKER INSYS FOR DECEPTIVELY SELLING & MARKETING
HIGHLY ADDICTIVE OPIOID PAINKILLER**

***Attorney General's Settlement with Drug Company That Peddled Prescription Opioid for Unapproved Uses Will Fund
Drug Treatment in Illinois Communities***

Chicago — Attorney General Lisa Madigan today announced a \$4.45 million settlement with the pharmaceutical company Insys Therapeutics Inc. (Insys) for deceptively marketing and selling a highly addictive opioid drug for an array of treatments that were not approved by the Food And Drug Administration (FDA).

The settlement resolves Madigan's 2016 lawsuit against Insys for its sale of Subsys, which is significantly more powerful than morphine and intended exclusively for the treatment of breakthrough cancer pain. Madigan alleged Insys deceptively promoted and sold Subsys to treat a wide variety of pain, such as back and neck pain, even though the drug was not approved for those uses.

"Insys pushed a highly addictive opioid in complete disregard for patients' health to increase company profits," Madigan said. "It's unethical, greedy behavior by companies like Insys that is responsible for creating the opioid epidemic and resulting overdose deaths in our state."

Madigan will use the \$4.45 million from the settlement to address the significant increase in opioid abuse in communities throughout Illinois.

Madigan's settlement requires Insys to comply with the Illinois Consumer Fraud Act, the Illinois and federal Food, Drug, and Cosmetic Acts, and the Federal Anti-Kickback Statute. It also requires Insys to:

- Create an Opioid Abuse Detection Program to identify prescribers who are abusing or aiding in the abuse of opioids;
- Restrict promoting Subsys only to oncologists and prescribers who have affirmatively stated they currently treat or are likely to treat patients with cancer pain;
- Prevent Insys employees from communicating with an Illinois patient's insurance company regarding prior authorization of an opioid;
- Limit the number of times a prescriber can host an Insys speaker program and the number of times a prescriber can attend an Insys speaker program; and
- Prohibit sales representatives from communicating about a particular patient with a prescriber, initiating direct communication with a patient, or having access to a patient's medical records.

Madigan alleged that Insys illegally marketed its painkiller to doctors who prescribed high volumes of opioid drugs instead of focusing its marketing on oncologists treating cancer patients, who are the intended recipients of the drug. Insys' irresponsible promotion of a prescription opioid was particularly concerning as studies indicate that people who abuse prescription opioids frequently move on to using heroin as a cheaper and more readily available alternative. According to the American Society of Addiction Medicine, four out of five new heroin users started their addiction by misusing prescription painkillers.

Madigan's investigation of Insys revealed the company was marketing Subsys broadly as a treatment for breakthrough pain associated with chronic conditions, including back and neck pain, despite the lack of FDA approval for those uses. Insys also pushed doctors to prescribe the higher and more expensive doses of Subsys, contrary to FDA mandates aimed at keeping patients on the lowest effective dose.

Madigan's investigation also revealed that doctors across the country were rewarded for prescribing Subsys to non-cancer patients for off-label uses, including payments for sham speaking events and dinners at expensive restaurants.

In Illinois, the top Subsys prescriber was Dr. Paul Madison, who wrote approximately 58 percent of the Subsys prescriptions in the state. Madison was an anesthesiologist who treated few, if any, cancer patients. More than 95 percent of the Subsys prescriptions written by Dr. Madison did not relate to breakthrough cancer pain. Madison was indicted by the U.S. Attorney's Office in Chicago for billing insurers for procedures he did not perform. The Illinois Department of Financial and Professional Regulation suspended Madison's medical license in November 2016.

The Illinois Department of Public Health (IDPH) reported 2,278 drug-related overdose deaths during 2016, which represents a more than 44 percent increase from drug-related deaths reported by IDPH in 2013. Of the total drug-related deaths in 2016, over 80 percent, or 1,826 deaths, were opioid-related fatalities.

Division Chief Deborah Hagan, Chicago Bureau Chief Susan Ellis, Medical Director Dr. Monique Anawis, MD, JD and Assistant Attorney General Paige Boggs handled the lawsuit and settlement for Madigan's Consumer Protection Division.

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