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## Press Release

## Consumer Protection Division Charges Pharmaceutical Manufacturer Insys Therapeutics with Unfair and Deceptive Practices

Division Asserts Pattern of Distributing Opioids to "Off-Label" Patients, Money and Sexual Relationships Used as Inducements to Distribute Highly Potent Opioid

**BALTIMORE, MD** (**September 6, 2018**) – Maryland Attorney General Brian E. Frosh today announced that his Consumer Protection Division has charged Insys Therapeutics, Inc (Insys) with multiple violations of the Consumer Protection Act and is requesting relief for consumers victimized by Insys' unfair and deceptive trade practices.

Insys manufactures an extremely potent opioid, Subsys, approved only for treating "breakthrough pain in adult cancer patients." The FDA limited the use of Subsys and similar drugs to this group of patients because it believed the risks of these drugs made them inappropriate for patients with other types of pain.

According to the Consumer Protection Division's <u>statement of charges</u>, Insys and local health care providers circumvented the limited approval and targeted "off-label" patients without cancer, including patients with chronic pain syndrome, knee pain, back pain, and migraines. According to the statement of charges, more than 90-percent of Subsys prescriptions written or filled in Maryland were written for patients who never should have received the drug. The Consumer Protection Division also alleges that Insys provided tens of thousands of dollars to prescribers as inducements to prescribe Subsys to their patients.

"Opioid addiction and overdose are destroying lives in every community across Maryland," said Attorney General Frosh. "The allegations against Insys describe a calculated scheme employing doctors, pharmacists, and sales reps to increase profits and market share at the expense of the health and well-being of vulnerable patients."

According to the charges, to mask the thousands of dollars in monetary inducements to prescribers, Insys created the Insys Speaker Program, where prescribers were paid as much as \$5,000 for a single event. Insys allegedly expected that speakers deliver a "return on investment" by themselves writing an increased number Subsys prescriptions. If the speaker failed to increase prescriptions, the speaker was removed from the speaker bureau, according to the charges. The speaker program also allegedly provided a platform through which Insys could encourage inappropriate social relationships between its sales force, its Subsys prescribers, and

local pharmacists. In numerous cases across the country, including in Maryland, Insys representatives had inappropriate sexual or other intimate relationships with prescribers while encouraging them to write prescriptions for Subsys, according to the charges.

The Consumer Protection Division also charges that, to evade many insurers' strict prior authorization requirements, Insys created a sophisticated system where employees misrepresented diagnoses and illnesses to obtain payments from the insurance companies for inappropriate prescriptions. The charges indicate that Insys, knowing that Subsys prescriptions were inappropriate and unsafe, instructed its representatives to mislead patients' insurers on almost every call.

The Consumer Protection Division is requesting an order that Insys cease and desist from engaging in unfair or deceptive trade practices; return all revenue it received from the illegal prescription of Subsys; and, pay costs and pay civil penalties for each violation of the Consumer Protection Act. According to the allegations, Insys made more than \$20 million in Maryland from its conduct.