

# UPDATE



Partnership for a Drug-Free New Jersey

DRUGS  
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IN NJ!

Update No. 84

Fall 2017

## Enforcement Activities and the Opioid Crisis

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The battle to stem the tide of the opioid epidemic has many fronts. As the epidemic is top-of-mind in the nation's collective consciousness, extending to the President and state governors, the fight has also turned to the courts. Recently the New York Attorney General announced that a coalition of 41 Attorneys General from around the country have issued subpoenas on a number of pharmaceutical manufacturers and distributors. The subpoenas seek information on the methods the manufacturers and distributors employ in marketing opioids to prescribers.

A number of states and municipalities have already filed lawsuits against some manufacturers, based in part, on a theory that opioids are aggressively marketed to prescribers and patients while concomitantly downplaying the risk of addiction. Some of the lawsuits attempt to employ elements of the Federal Controlled Substances Act 21 USC §811, that require participants in the controlled substance supply chain to monitor, investigate, and report suspicious orders for prescription opiates.

The Federal government is also flexing its criminal prosecutorial muscle against manufacturers of opiates. Several pharmaceutical executives and managers, formerly employed by Insys Therapeutics, Inc., including its founder, have been indicted on charges that they led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe the fentanyl-based pain medication Subsys.

The focus is not limited to manufacturers and distributors, physicians and other prescribers are also targets of government enforcement actions. Several prescribers have been swept up in the Insys indictments. Both the FBI and the New Jersey Attorney General have campaigns to reach out to patients that have been prescribed Subsys, seeking the names of the prescribers. A number of New Jersey physicians have been investigated by the Board of Medical Examiners for their opioid prescribing habits.

The attention to the opioid crisis is certain to continue, and prescribers will remain a focus, and may be further swept into the prosecutions of drug manufacturers. Prescribers are well advised to evaluate any relationships with drug company marketers. Moreover, prescribers should create, and adhere to, a well drafted opioid compliance plan, which will both improve patient care and avoid potential regulatory pitfalls.

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From [NJ.com](http://NJ.com)



## N.J. sues major opioids maker over 'evil' practices

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By S.P. Sullivan [ssullivan@njadvancemedia.com](mailto:ssullivan@njadvancemedia.com), NJ Advance Media for NJ.com

TRENTON -- New Jersey's attorney general on Thursday formally filed a lawsuit accusing a major U.S. drug manufacturer of fueling the state's opioid addiction crisis by aggressively pushing its painkillers.

The suit accuses Arizona-based Insys Therapeutics, Inc. of breaking state laws and potentially killing patients by marketing a highly addictive opioid aimed at cancer patients for wider use.

The complaint was filed against the backdrop of a spiraling overdose death rate in New Jersey, where an NJ Advance Media investigation earlier this year found doctors were profiting off a spike in prescriptions for fentanyl, a highly potent synthetic opioid

It also comes as attorneys general in more than 40 states are investigating the marketing and sales practices of drug makers.

"The conduct alleged in our lawsuit is nothing short of evil," Attorney General Christopher Porrino said on Thursday.

A spokesman for Insys Therapeutics, which produces the fentanyl variant known as Subsys, did not respond to a message seeking comment Thursday.

Porrino said the company allegedly pushed for "broad-based consumption" of the drug, which is meant for patients who are gravely ill.

"We contend that the company used every trick in the book, including sham speaking and consulting fees and other illegal kickbacks, in a callous campaign to boost profits from the sale of its marquee drug Subsys," the attorney general said.

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The four-count complaint came a day after sources told NJ Advance Media that Porrino's office was investigating the practices of several drug companies, including Insys and the Connecticut-based Purdue Pharma, which is not named in the new lawsuit.

According to a copy of the suit, Insys is accused of violating New Jersey's Consumer Fraud Act and False Claims Act.

The lawsuit attributes the company's behavior to the death of "at least one" New Jersey resident, 31-year-old Sarah Fuller, who overdosed on fentanyl she had been prescribed to treat fibromyalgia last year.

It also alleges that New Jersey's state employee health benefits plans had paid more than \$10 million to reimburse Subsyst prescriptions over a four-year period.

The company, which authorities claim hiked the price of Subsyst annually, sold more than \$74 million worth of the drug in New Jersey alone, according to the attorney general.

Authorities say Subsyst was approved by the federal Food and Drug Administration for the "narrow" purpose of treating cancer pain in patients who had developed a tolerance to opioids.

NJ Advance Media's July investigation found oncologists only accounted for a small fraction of fentanyl prescriptions, which were being handed out by family doctors, nurse practitioners and physician's assistants at a much higher rate.

The Attorney General's Office claims Insys representatives aggressively pushed doctors to consider "off label" uses of the drug -- "even to podiatrists and other specialty practitioners who typically would have little call to prescribe" potent painkillers.

Sources previously told NJ Advance Media that Porrino's office had also subpoenaed multiple drug companies as it weighed additional lawsuits, but Thursday's complaint was targeted only at Insys.

Lee Moore, a spokesman for the attorney general, said the office does not comment on its pending investigations.

"However, Attorney General Porrino has said publicly that he is deeply concerned about whether and to what extent the marketing and sales practices of certain pharmaceutical companies contributed to the opioid crisis we are suffering in New Jersey, and he has said publicly that our office is committed to taking a close look at that conduct," Moore said.

*NJ Advance Media staff writer Claude Brodesser-Akner contributed to this story.*