

Insys Therapeutics executives, makers of oral fentanyl spray, convicted of racketeering

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Last week, Dr. John Kapoor, founder of Arizona-based Insys Therapeutics Inc., and four colleagues were found guilty of conspiring to bribe and force physicians to prescribe a highly addictive painkiller called SUBSYS, which is an oral spray of the synthetic opioid fentanyl, a drug that is 50 to 100 times more potent than morphine.

They were also convicted of misleading insurers into paying for the drug. According to Reuters, Dr. Kapoor, a billionaire, is the highest-ranking pharmaceutical executive to be convicted in the United States in connection with the opioid crisis. He faces up to 20 years in federal prison.

As of 2016, Dr. Kapoor was worth \$2.1 billion, with his shares in Insys representing \$650 million of his net worth. At that time, the company's stock was up 296 percent since its 2013 initial public offering. However, it was noted by critics that its \$331 million in sales in 2015 was due in large part to use of SUBSYS by patients without cancer. SUBSYS was approved in 2012 by the Food and Drug Administration (FDA) to be used only for cancer patients with intractable pain.

Since 2015, Insys and the sales representatives and prescribing physicians on its payroll have been embroiled in legal battles over alleged violations of federal anti-kickback statutes, based on charges that Insys has been paying physicians to prescribe the drug. CBS News correspondent Jim Axelrod reported that in 2016 Insys made 18,000 payments to doctors that totaled over \$2 million.

By 2016, Insys found itself under investigation by several states for unapproved uses of the drug. It had already settled with the state of Oregon for \$1.1 million. Last year, the company paid more than \$150 million to resolve a US Justice Department investigation into its schemes to pay kickbacks to

doctors to prescribe the powerful opioid medication. Dr. Kapoor was arrested in October of 2017.

According to US Attorney Andrew E. Lelling, "Today's conviction marks the first successful prosecution of top pharmaceutical executives for crimes related to the illicit marketing and prescribing of opioids. Just as we would street-level drug dealers, we will hold pharmaceutical executives responsible for fueling the opioid epidemic by recklessly and illegally distributing these drugs, especially whole conspiring to commit racketeering along the way."

Amidst mounting legal troubles and an uncertain future, Insys shares have fallen more than 90 percent.

The opioid crisis began in the early 1990s, specifically with Purdue Pharma and its drug Oxycontin. State and federal regulators noted a sudden dramatic rise of deaths attributed to opioids as well as a sharp increase in the practice of prescribing narcotics for the treatment of pain.

Purdue gave false assurances to physicians and patients that its product had a very low risk of causing addiction. The FDA essentially rubber-stamped its findings and set the stage for what is considered as the first wave of the opioid crisis. To increase sales, the company promoted the use of opioids for non-cancer-related pain, even though efficacy and risk data was lacking. By 1999, more than 86 percent of patients using opioids were non-cancer patients.

Over the following decade, the pharmaceutical industry was effective in preventing restrictions on opioid over-prescribing through lobbying and use of advocacy groups. Court proceedings protected the pharmaceutical companies and their executives, while sealing the courts' findings from the public.

The second wave of the opioid crisis took hold around 2010 when measures to decrease opioid

prescribing led to deaths associated with the abuse of heroin. With restrictions placed on the prescription of narcotics, heroin was cheap and widely available. Death associated with heroin abuse rose 286 percent from 2002 to 2013, according to the National Capital Poison Center. Because heroin is usually injected, the crisis also contributed to a rise in communicable diseases such as HIV/AIDS and hepatitis B and C.

The third and current wave began in 2013 with the rapid increase in illicitly manufactured synthetic opioids such as fentanyl. A study by Kiang, Basu, Chen and Alexander published in *JAMA Network Open* earlier this year noted that opioid-related mortality rates from synthetic opioids had rapidly increased in the Eastern United States, while mortality associated with natural and semi-synthetic drugs such as oxycodone had remained stable.

The study found that in 28 states, the mortality rate from synthetic opioids had more than doubled every two years. In the District of Columbia, the rate had tripled every year since 2013.

The authors wrote: “Most opioid-related deaths are occurring among young and middle-aged adults. This equates to a significant loss of life. Nationally, overall opioid-related mortality resulted in 0.36 years of life expectancy lost in 2016, which was 14 percent higher than deaths due to firearms and 18 percent higher than deaths due to motor vehicle crashes; 0.17 years of life expectancy lost was due specifically to synthetic opioids.”

Among the 64,000 drug overdoses in 2016, the sharpest rise was seen among those using synthetic opioids. As of 2017, 29,000 deaths in the US were attributable to fentanyl analogs.



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