

White Collar Criminal Defense

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Recent Decision Underscores a Hurdle in Opioid Prosecutions, as Criminal Investigations Continue

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What You Need To Know:

- A recent decision in a federal case highlights the difficulties of bringing a RICO case against opioid companies and executives for violations of the Controlled Substances Act.
- The intent requirement when using the CSA as a RICO predicate is a high hurdle to clear—it requires proving that a drug company intended that doctors would prescribe opioid medication to patients who did not need it—and the judge accordingly struck down this part of the verdict as lacking enough supporting evidence.
- The convictions in the case for a racketeering conspiracy that involved bribing doctors to prescribe the opioid medication still stand, as the wire fraud and mail fraud RICO predicates were successfully proven.
- Drug companies that manufacture or distribute opioids continue to face significant scrutiny in the form of criminal investigations and prosecutions.

On Nov. 26, U.S. District Judge Allison D. Burroughs of the District of Massachusetts issued an opinion overturning, in part, convictions in the first successful criminal prosecution involving an opioid drug manufacturer. The verdict, returned by a jury in May, found four former Insys Therapeutics executives guilty of a racketeering conspiracy under the Racketeer Influenced and Corrupt Organizations Act (RICO), finding in part that their conduct was akin to that of traditional narcotics traffickers. Insys is the manufacturer of the liquid fentanyl spray Subsys, a rapid-onset opioid. The government had argued, and the jury found, that to increase sales of the drug, Insys executives conspired with doctors to prescribe Subsys to patients who did not need it, by bribing the doctors and paying them kickbacks (including through a sham speaker program).

In her **decision**, Judge Burroughs found that there was not enough evidence to support a Controlled Substances Act (CSA) predicate for RICO.¹ Specifically, Section 841 of the CSA makes it unlawful for “any person knowingly or intentionally to manufacture, distribute, or dispense . . . a controlled substance,” except as authorized by the statute.² As described in the court’s opinion, federal case law holds that a prescriber violates the CSA only if a controlled drug is prescribed outside the usual course of professional practice and without any legitimate medical purpose.³ The judge found that, while evidence presented at trial showed that Insys wanted to sell as much Subsys as possible and was focused on getting health care practitioners to prescribe it and to prescribe it in higher doses, there was insufficient evidence that the defendants specifically intended that practitioners would prescribe Subsys

¹ Memorandum & Order on Defendants’ Motions for Judgment of Acquittal and for a New Trial, United States v. Gurry, No. 16-CR-10343 (ADB) (D. Mass. Nov. 26, 2019), ECF No. 1028 (hereinafter “Order”).

² 21 U.S.C. § 841(a)(1).

³ See Order at 17-18 (citing cases).

to patients who did not need it. Judge Burroughs rejected the government's theory that there was a "tacit understanding" among defendants and co-conspirator prescribers that the prescribers would illegally distribute Subsys, finding it equally likely that practitioners would prescribe Subsys only to patients who legitimately needed the medication, albeit in exchange for bribes.

For the same reason, the court vacated the jury's verdict on the honest-services mail and wire fraud RICO predicates. However, the court upheld the remainder of the verdict, which convicted all the defendants of a RICO conspiracy for the predicate acts of ordinary mail and wire fraud.

Judge Burroughs' decision underscores the difficulty in the government's proving the criminal intent requirement of the CSA in cases against otherwise legitimate manufacturers and distributors. Opioids are FDA-approved medications that can be and typically are prescribed for legitimate medical purposes. Consequently, the government must clear a high hurdle when trying to demonstrate that a medical practitioner entirely abdicated his or her role as a health care professional. Merely failing to adhere to the requisite standard of care is not enough; as Judge Burroughs noted, a practitioner is subject to criminal liability only "when he ceases to be a physician at all."⁴ The intent requirement is even more difficult to meet for drug companies and their executives when the CSA is used as a RICO predicate. It is not enough that a doctor prescribes a controlled medication to someone who does not need it; the

defendant drug company or executive must have intended that the doctor would illicitly prescribe it to someone who did not need it. Judge Burroughs' opinion shows how hard it is for the government to charge drug companies and their executives as if they were drug dealers.

While this decision illustrates the hurdle in using the CSA as a RICO predicate, criminal investigations into potential violations of other provisions of the CSA by opioid manufacturers continue. As reported by *The Wall Street Journal*, federal prosecutors have opened a criminal investigation into at least six companies that make or distribute opioids.⁵ The investigation is looking into whether the companies violated provisions of the CSA under which companies are required to monitor commonly abused drugs, including by reporting suspicious orders, maintaining compliance programs, and disclosing suspicious pharmacy customers to the government. This investigation follows criminal cases filed this year in New York and Ohio against two smaller opioid distributors and some of their executives. These criminal cases follow over 2,000 civil lawsuits that opioid companies have faced in recent years. While the decision in *Gurry* indicates that prosecutors will face at least one significant hurdle in future prosecutions, there are currently no signs that actions against opioid manufacturers and distributors will be letting up. To the contrary, as other avenues for criminal prosecution remain open, these companies continue to face significant scrutiny and remain a target for criminal investigation and prosecution.

⁴ See Order at 14 (citing *United States v. Zolot*, 968 F. Supp. 2d 411, 428 (D. Mass. 2013)).

⁵ Corinne Ramey, *Federal Prosecutors Launch Criminal Probe of Opioid Makers, Distributors*, *The Wall Street Journal* (Nov. 26, 2019), <https://www.wsj.com/articles/federal-prosecutors-launch-criminal-probe-of-opioid-makers-distributors-11574790494>.

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