

THE
NATIONAL LAW REVIEW

DOJ Enters into \$225 Million Settlement with Opioid Manufacturer to Resolve Criminal and Civil Investigations

Wednesday, June 26, 2019

On June 5, 2019, the Department of Justice (DOJ) announced a global settlement with Insys Therapeutics (Insys) that preliminarily resolves criminal and civil cases against the opioid manufacturer in a number of jurisdictions. Under the terms of the settlement, Insys [agreed](#) to pay a total of \$225 million – \$195 million in civil remedies and \$30 million in criminal restitution (comprising a \$2 million fine and \$28 million in forfeiture). In addition to the monetary penalties, Insys entered into a 5-year deferred prosecution agreement with DOJ, as well as a 5-year Corporate Integrity Agreement (CIA) and Conditional Exclusion Release with the Office of Inspector General (OIG), and an operating subsidiary of Insys pleaded guilty to mail fraud.

In recent years, Insys has been the subject of myriad investigations tied to the marketing of its drug Subsys, a “powerful... but addictive” sublingual spray. This settlement comes in the aftermath of the criminal conviction of Insys executives in Massachusetts federal court earlier this year, and a series of convictions obtained against health care providers by DOJ across the country (see [here](#) and [here](#) for discussions of previous criminal cases dating to 2015). To resolve this case “Insys agreed to a detailed statement of facts outlining its criminal conduct with respect to the illegal marketing of Subsys,” and Insys’s operating subsidiary will plead guilty to five counts of mail fraud. Insys will pay a \$2 million criminal fine and has agreed to \$28 million in forfeiture as part of the criminal resolution.

Insys also faced civil False Claims Act (FCA) liability arising from a number of *qui tam* whistleblower suits filed against the company, alleging the submission of false or fraudulent claims for services under unlawful kickback arrangements (see our analysis of one such action [here](#)). According to the government and multiple whistleblowers, Insys allegedly paid kickbacks to physicians and nurse practitioners to induce prescriptions of Subsys, including through payments for “sham speaker program speeches,” employment of “prescribers’ relatives and friends” and “lavish meals and entertainment.” This settlement now resolves five *qui tam* FCA actions brought against Insys in which DOJ had intervened – and which had been on hold pending resolution of the criminal charges against the company – in exchange for a payment of \$195 million and agreement to additional remedies.

In addition to the foregoing, Insys agreed to enter into a 5 year CIA and Conditional Exclusion Release, which DOJ described as “unprecedented.” OIG opted against pursuing exclusion of Insys from federal health care programs due to Insys’s “extensive cooperation... in the prosecution of culpable individuals and its agreement to enhanced CIA requirements.” OIG instead required Insys to agree to a statement of facts and acknowledge that such facts provide a basis for permissive exclusion, and OIG will only provide a release of its permissive exclusion authority for Insys upon fulfillment of Insys’s obligations under the CIA. In its announcement of the settlement, DOJ noted that OIG’s reservation of its release of permissive exclusion authority for Insys is counter to its normal practice in FCA settlements of providing such a release for parties to a CIA.

The government’s approach to this settlement, including the requirement that a corporation plead guilty to mail fraud and the significant criminal and civil monetary penalties imposed on Insys, illustrates that heightened sanctions for corporate misconduct are continuing amidst the opioid crisis. OIG’s crediting of corporate

Robinson+Cole

Article By [Robinson & Cole LLP](#)
[Conor O. Duffy](#) [Health Law Diagnosis](#)

[Biotech, Food, Drug](#)
[Health Law & Managed Care](#)
[Litigation / Trial Practice](#)
[Consumer Protection](#)
[All Federal](#)

cooperation in the prosecution of individuals as a basis for not pursuing exclusion reiterates the government's emphasis on individual accountability for corporate misconduct, and could signal to other corporate defendants the potential benefit of cooperation that leads to convictions of individuals. Following publication of this settlement, Insys [announced](#) that it would file voluntary cases under Chapter 11 of the U.S. Bankruptcy Code.

This post was co-authored by Michael Lisitano, legal intern at Robinson+Cole. Michael is not yet admitted to practice law.

Copyright © 2019 Robinson & Cole LLP. All rights reserved.

Source URL: <https://www.natlawreview.com/article/doj-enters-225-million-settlement-opioid-manufacturer-to-resolve-criminal-and-civil>