

DOJ's Fight Against Opioid Epidemic Includes FCA Anti-Kickback Settlement

According to the Centers for Disease Control and Prevention (CDC), 91 people lose their lives in the opioid epidemic in this country every day. That number includes overdoses from prescription opioids as well as heroin. And since 1999, fatalities stemming from prescribed opioids like hydrocodone and oxycodone have more than quadrupled.

The U.S. Department of Justice (DOJ) has asserted its commitment to fighting this national scourge. In light of that, it's much more common to find healthcare providers cautiously and carefully prescribing opioids for pain management, in limited quantities and only when deemed medically necessary.

So when a whistleblower initiated a False Claims Act (FCA) lawsuit against a pharmaceutical company, alleging that the company violated anti-kickback laws when it offered physicians remuneration to write prescriptions for an opiate that it manufactured, it's not hard to see why the government took notice. If the allegations were found to have merit, they would be sobering and disheartening indeed: the very manufacturer of an addictive drug working against the current climate of encouraging responsible opioid prescribing patterns (and potentially fueling addiction, rather than quelling it) in order to line its pockets.

Settlement reached without admission of liability

In September, the DOJ announced that Galena Biopharma, Inc. agreed to settle a *qui tam* FCA case by paying \$7.55 million (which the relator would receive \$1.2 million). The settlement agreement does not reflect an admission of liability on the pharmaceutical company's part, but merely resolves the litigation.

Pharma co. allegedly violated anti-kickback laws

Despite the fact that liability was not determined, the allegations, however, are worth noting. They include accusations of Galena paying "multiple types of kickbacks" to incentivize the prescribing of their opiate Abstral by physicians.

Some of those alleged inducements included "providing more than 85 free meals to doctors and staff from a single, high-prescribing practice; paying doctors \$5,000, and speakers \$6,000, plus expenses, to attend an 'advisory board' that was partly planned, and attended, by Galena sales team members, and paying approximately \$92,000 to a physician-owned pharmacy under a performance-based rebate agreement to induce the owners to prescribe Abstral."

(This according to the [DOJ press release](#) announcing the settlement agreement. Abstral is referred to as a "highly addictive" prescription fentanyl-based opioid.)

"Given the dangers associated with opioids such as Abstral, it is imperative that prescriptions be based on a patient's medical need rather than a doctor's financial interests," said Acting Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division. "The Department of Justice intends to vigorously pursue those who offer and receive illegal inducements that undermine the integrity of government health care programs."

Two Abstral-prescribing doctors tried, convicted, and sentenced to prison

The DOJ reports that two physicians that allegedly received illegal kickbacks from the pharmaceutical company were prosecuted and tried before a jury in the U.S. District Court for the Southern District of Alabama on charges that included (but



were not limited to) their prescribing of Abstral. Galena was said to be cooperative with the government's prosecution of the doctors. Both practitioners were convicted and sentenced to time in prison.

The DOJ noted that "the matter remains under seal" when it comes to potential allegations against companies other than Galena.

"The conduct alleged by the government and resolved by today's settlement was egregious because it incentivized doctors to over-prescribe highly addictive opioids," said Acting U.S. Attorney William E. Fitzpatrick for the District of New Jersey. "This settlement constitutes another example of the Department of Justice's ongoing efforts to battle the opioid epidemic on every front."

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