

EnforceMintz — Novel Criminal Charges and Emerging Civil Trends from Opioid Enforcement in 2024

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In past years we have discussed how opioid-related enforcement efforts have remained a top federal and state priority ([here](#), [here](#), and [here](#)). In 2024, opioid-related enforcement efforts continued across the entire opioid supply chain, and two themes dominated the most significant opioid cases and resolutions of 2024. First, two major settlements from the past year highlight examples of allegations that crossed a line, prompting the government to pursue criminal charges. Second, a number of recent cases against pharmacies involve a common theory of liability based on the Controlled Substances Act (CSA), which served as the basis for civil liability under the False Claims Act (FCA).

Opioid-Related Criminal Resolutions

In February 2024, Endo, a pharmaceutical manufacturer that previously filed for bankruptcy, reached a [global resolution of various criminal and civil investigations](#) into the company's sales and marketing of opioid drugs. The company agreed to pay the government \$464.9 million over 10 years (though the actual total payment amount will likely be much lower due to bankruptcy).

To resolve the criminal investigation, Endo agreed to plead guilty to a one-count misdemeanor charge for violations of the federal Food, Drug, and Cosmetic Act (FDCA). That charge related to the company's marketing of the drug's purported abuse deterrence, tamper-resistant, or crush-resistant properties to prescribers, despite a lack of supporting clinical data. In the plea agreement, the company admitted responsibility for misbranding its opioid drug by marketing the drug with a label that failed to include adequate directions for its claimed abuse deterrence use, in violation of the FDCA.

More recently, in December 2024, McKinsey & Company, a worldwide management consulting firm, [agreed to pay \\$650 million to resolve criminal and civil investigations](#) related to the firm's consulting work for Purdue Pharma, the maker of OxyContin. As noted in the government's press release, the McKinsey resolution was the first time a management consulting firm has been held criminally responsible for its advice resulting in a client's criminal conduct.

The two-count criminal charging document accused McKinsey of conspiring to misbrand a controlled

substance and obstruction of justice. The conspiracy charge related to McKinsey's work to "turbocharge" OxyContin sales by targeting high-volume opioid prescribers. The obstruction charge arose from the alleged deletion by a senior partner of certain documents related to the company's work for Purdue. To resolve those charges, McKinsey entered into a five-year deferred prosecution agreement (DPA). Under the DPA, McKinsey agreed not to do any consulting work related to the marketing, sale, or distribution of controlled substances and agreed to implement significant changes to its compliance program. Separately, the former McKinsey senior partner who allegedly destroyed records relating to the company's work for Purdue was charged with obstruction of justice and agreed to plead guilty to that charge.

These two resolutions are relevant to all entities in the opioid supply chain, from manufacturers to consultants and all stakeholders in between. Sales and marketing practices, or abuse deterrence claims or practices targeting prescribers based on volume, can lead to both civil liability and potential criminal exposure.

Pharmacies Face Potential FCA Liability Based on CSA Violations

On the civil side, three opioid enforcement actions were particularly noteworthy. Three years ago, we [highlighted](#) some of the first pharmacy-related resolutions, which showed that pharmacies were "next in line" for opioid related enforcement. In 2024, two substantial settlements involved alleged CSA violations giving rise to FCA liability. A third FCA lawsuit filed in December 2024 against the nation's largest pharmacy shows that this trend will likely continue in 2025 and beyond.

In July 2024, Rite Aid and its affiliates [agreed to settle](#) allegations brought by the government related to its opioid dispensing practices. Rite Aid had previously filed for bankruptcy, so the settlement agreement involved a payment of \$7.5 million, plus a general unsecured claim of \$401.8 million in the bankruptcy case.

The government alleged that Rite Aid pharmacists dispensed unlawful prescriptions and failed to investigate "red flags" before dispensing opioid prescriptions, then improperly submitted claims to the government for reimbursement of those prescriptions. The government alleged that the company dispensed unlawful prescriptions by (1) filling so-called "trinity" prescriptions, which are a combination of opioid, benzodiazepine, and muscle relaxants; (2) filling excessive quantities of opioid prescriptions; and (3) filling prescriptions written by prescribers previously identified as suspicious by pharmacists.

Similarly, in December 2024, Food City, a regional grocery store and pharmacy based in Virginia [agreed to pay \\$8.48 million](#) to resolve allegations that it dispensed opioids and other controlled substances in violation of the CSA and the FCA. Like the Rite Aid case, the government alleged that these prescriptions were medically unnecessary, lacked a legitimate medical purpose, or were not dispensed pursuant to valid prescriptions. The government alleged that Food City ignored "red flags" including, among other things, (1) prescribers who wrote unusually large opioid prescriptions; (2) early refills of opioids; (3) prescriptions for unusual quantities or combinations of opioids; and (4) patients who were filling prescriptions for someone else, driving long distances to fill prescriptions, or paying cash for prescriptions.

Also in December 2024, the Department of Justice [announced that it had intervened](#) in a nationwide lawsuit alleging that CVS Pharmacy filled unlawful prescriptions in violation of the CSA and sought reimbursement for those prescriptions in violation of the FCA. The lawsuit is currently pending. The theory of liability asserted against CVS is similar to the Rite Aid and Food City cases: CVS allegedly

filled unlawful prescriptions, ignored “red flags” of abuse and diversion, and sought reimbursement from federal health care programs for unlawful prescriptions in violation of the FCA.

Under the CSA and applicable regulations, pharmacists dispensing controlled substances, like opioids, have a “corresponding responsibility” to ensure that the prescription was issued for a legitimate medical purpose. 21 C.F.R. § 1306.04(a). Exercising that corresponding responsibility requires identifying and resolving “red flags” **before** filling a prescription. There is no defined list of what the government deems to constitute “red flags” and determining the existence of red flags is often context dependent. Because FCA lawsuits based on alleged CSA violations appear to be a growing trend, these three cases provide helpful guidance for companies seeking to mitigate risk by implementing corporate compliance programs designed to identify and resolve “red flags” related to opioid prescriptions.

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