



Opioid manufacturer agrees to \$2 billion resolution of criminal, civil investigations

March 14, 2024

WASHINGTON — Endo Health Solutions Inc., now in bankruptcy, agreed to resolve criminal and civil investigations on February 29 related to its sales and marketing of the opioid drug Opana ER with INTAC, according to a U.S. Department of Justice press release.

The criminal resolution includes the second-largest set of criminal financial penalties ever levied against a pharmaceutical company, including a fine of \$1.086 billion and a \$450 million criminal forfeiture, the release said.

The United States also reached an agreement in Endo's bankruptcy case to settle its monetary claims arising from the criminal and civil settlements, as well as additional tax and healthcare related claims. Under the bankruptcy agreement, the government will be paid up to \$464.9 million over 10 years. Endo's entry into all of these agreements is subject to the approval of the U.S. Bankruptcy Court, Southern District of New York, the release said.

As part of the criminal resolution and in addition to the financial penalties, Endo agreed to plead guilty in federal court, Eastern District of Michigan, to charges that it violated the Federal Food, Drug and Cosmetic Act by introducing misbranded drugs into interstate commerce. Endo will admit that from April 2012 through May 2013, some of its sales representatives marketed Opana ER to prescribers by touting the drug's purported abuse deterrence, tamper resistance, and/or crush resistance despite a lack of clinical data supporting those claims. In addition, approved labeling for Opana ER did not provide adequate information for healthcare providers to safely prescribe Opana ER for use as an opioid that is abuse deterrent. The investigation, supported by the Amtrak Office of Inspector General, found that some Amtrak employees and dependents were prescribed the misbranded drug.

Endo also agreed to a civil settlement of \$475.6 million to resolve its civil liability under the False Claims Act. According to the DOJ press release, Endo allegedly knew health care providers were prescribing Opana ER for non-medically accepted indications; allegedly ignored or minimized employee concerns that certain prescribers were believed to be engaged in abuse, diversion, or pill mill prescribing; and allegedly had its sales representatives target prescribers who prescribed a high volume of Opana ER or opioids in general to further increase prescriptions.

The proposed resolution includes a corporate criminal release regarding conduct related to the sale, marketing, and distribution of Opana ER, but does not release any individual criminal liability. Another condition in the resolution requires that Endo cease to operate in its current form and not emerge from bankruptcy. In addition, as part of the resolution with the opioid claimants, Endo's affiliates have agreed to a Voluntary Operating Injunction that restrains opioid marketing and sales and requires Endo to turn over millions of documents related to its role in the opioid crisis for publication in a public online archive.

In addition to Amtrak OIG, the case was investigated by the FBI, Drug Enforcement Administration, Health and Human Services OIG, Food and Drug Administration Office of Criminal Investigations, Veterans Affairs OIG, Office of Personnel Management OIG, and the Defense Criminal Investigative Service. More information is available in the Department of Justice press release: <https://direc.to/kZ1H>.

Reports of fraud, waste, or abuse, including suspected pandemic relief fraud; criminal or unethical acts affecting Amtrak's property or operations; or mismanagement in Amtrak programs or operations can be made 24 hours a day via the Amtrak OIG Hotline at 1-800-468-5469 or online at <https://direc.to/hPAu>.

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