



## OPIOID MANUFACTURER SENTENCED

**Activity Date: May 2, 2024**

**Date Posted: August 21, 2024**

**Case Number: 18-0221-I**

**Web Summary: OIG-WS-2024-340**

Endo Health Solutions Inc. (EHSI) was ordered May 2, 2024, to pay \$1.086 billion in criminal fines and an additional \$450 million in criminal forfeiture—the second-largest set of criminal financial penalties ever levied against a pharmaceutical company—for violations of the federal Food, Drug and Cosmetic Act (FDCA), according to the U.S. Department of Justice.

EHSI pleaded guilty April 18, 2024, to one misdemeanor count of introducing misbranded drugs into interstate commerce. In its plea, EHSI admitted that from April 2012 through May 2013, some of its sales representatives marketed Opana ER with INTAC (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. According to the plea agreement, EHSI was responsible for the misbranding of Opana ER by marketing the drug with a label that failed to include adequate directions for its claimed abuse deterrence, in violation of the FDCA. EHSI withdrew Opana ER from the market in 2017. The investigation, supported by our office, found that some Amtrak employees and dependents were prescribed the misbranded drug.