Opana® ER (oxymorphone) – Market withdrawal

- On July 6, 2017, Endo announced the voluntary market withdrawal of Opana ER (oxymorphone hydrochloride) extended-release tablets.

- Endo's announcement follows the FDA's earlier withdrawal request. Based on a review of all available postmarketing data, Opana ER demonstrated a significant shift in the route of abuse from nasal to injection following the product's reformulation.

    — Injection abuse of reformulated Opana ER has been associated with a serious outbreak of human immunodeficiency virus and hepatitis C, as well as cases of thrombotic microangiopathy.
    — However, Endo states that neither the FDA's withdrawal request nor Endo's decision to voluntarily remove Opana ER reflect a finding that the product is unsafe or ineffective when taken as prescribed.

- The FDA's decision to withdraw Opana ER follows a March 2017 FDA Advisory Committee meeting where a group of independent experts voted 18 – 8 that the benefits of reformulated Opana ER no longer outweighed its risks.

- Opana ER was first approved in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting.

- Endo plans to work with the FDA to coordinate the orderly removal of Opana ER in a manner that looks to minimize treatment disruption for patients and allows patients sufficient time to seek guidance from their healthcare professionals.