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FDA Requests Painkiller Removed From the Market

June 9, 2017 – Dorsey Health Law
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The FDA has called on the drugmaker Endo Pharmaceuticals to stop selling the opioid Opana ER. The press release on June 8th reflecting this announcement marks a novel approach from the FDA, as the agency for the first time has asked a company to remove a painkiller from the market based on the public health consequences of abuse.

This opioid is an extended release version of Opana, and was first approved in 2006. As the nation increasingly faced an epidemic of opioid abuse and overdoses, the manufacturer reformulated the drug in 2012, adding a coating to the medication intended to make it harder to snort or inject the medicine. The FDA found that the product met the regulatory standards for approval, but declined to approve labeling describing the medication as having abuse deterrent properties because they found that the data did not show that the reformulation could be expected to meaningfully reduce abuse.

Despite the 2012 reformulation, an increasing number of people abused this opioid by crushing, dissolving, and injecting it. In March of 2017, a panel of advisers to the FDA voted 19-8, with one abstention, that the drug's benefits no longer outweighed the risks. Data showed that while nasal abuse fell, the rate of abuse through intravenous injection increased and the drug has been associated with outbreaks of HIV and hepatitis C, as well as a blood disorder thrombotic microangiopathy. In addition, Opana was considered at the center of an HIV outbreak in Indiana in 2015.

The opioid epidemic in the United States has prompted several novel approaches to reducing abuse, often at the state level. State level responses, including prescription drug monitoring programs, declarations of a state of emergency, and limiting prescription lengths for opioids, are being implemented across the country, at the same time that lawmakers debate the future of the Affordable Care Act which has aimed millions of dollars within the Medicaid program towards addiction treatment and prevention, and expanded the scope of the Mental Health Parity Act.

Ohio Attorney General Mike DeWine filed a lawsuit against five opioid manufacturers on

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May 31, including Endo, accusing them of misleading doctors and patients about the danger of addiction and overdose. Other states and cities have filed similar lawsuits.

Ninety-one Americans die every day from opioid overdose according to the CDC. The FDA has stated that if the company resists removal of this opioid from the market, the agency intends to take formal steps to remove it by withdrawing approval. Endo in a response stated that the company is reviewing the request and evaluating potential options as they "determine the appropriate path to move forward." This FDA action is a significant step in what will likely be a lengthy journey in which federal and state regulators (and private plaintiffs) use whatever legal authorities available to combat an increasingly damaging public health crisis.