On June 8, 2017, the Food and Drug Administration, or FDA, publicly requested that Endo Pharmaceuticals remove their drug, Opana ER, from the market. The agency stated that the benefits of the medication no longer outweighs the risks. According to the FDA, there has been a shift in abuse that has seen an increase in crushing, snorting and injecting the medication. This increase in injection abuse has also seen an increase in HIV and Hepatitis C transmission via contaminated needles. An increase in cases of thrombotic microangiopathy, a type of blood disease, has also been seen with the increase in abuse of this medication.

Opana ER was reformulated in 2012 to prevent physical and chemical manipulation via injecting or snorting. When the reformulated version of the drug was approved by the FDA, Endo Pharmaceuticals attempted to include abuse-deterrent property labels for the drug. However, the FDA did not believe that the data showed the drug could be expected to significantly reduce abuse.

Opana ER is a semisynthetic of morphine, and is considered chemically related to hydromorphone. An overdose could cause severe consequences in someone abusing the drug. Unfortunately, most of those abusing the medication do not understand the chemistry behind the medication formulation. Opana ER is formulated in an extended release formulation, and if one crushes, dissolves, or injects this medication, the extended release mechanism is damaged. This causes all of the medication to be released at once instead of over an extended period, and an overdose could result.

This request from the FDA for Endo Pharmaceuticals to remove Opana ER from the market marks the first time they have acted to stop the sale of an opioid medication based on possible misuse of the drug. The FDA has so far only requested that the drug be removed from the market voluntarily by Endo Pharmaceuticals. If the company does not voluntarily remove it from the market, the FDA will take the steps necessary for its removal, including withdrawing their approval of the drug.

The Centers for Medicare and Medicaid Services released 2015 prescribing data for their prescription drug benefit, Medicare Part D. Medicare Part D is a government run program that subsidizes the cost of prescription medications for those covered by Medicare. According to this data, North Carolina had the highest Opana ER usage in 2015 with 5,002 Part D patients being dispensed this medication. The state with the lowest Opana ER usage in 2015 was Wyoming with 28 Part D patients being dispensed this medication. Overall, in 2015 there were a total of 45,590 Part D patients in the United States that were dispensed this medication.

Opana ER comes in a generic formulation, Oxymorphone ER. A review of the usage of all Oxymorphone formulations was conducted in the state of Kentucky. According to the trend reports generated by the Cabinet for Health and Family Services, a total of 574,120,560 controlled medication doses were dispensed in Kentucky in 2016. Out of these doses, 1,073,895 were Oxymorphone. Thus, this drug constituted 0.19 percent of all controlled substance doses dispensed in Kentucky in 2016. While this percentage does not seem very high, this number still equates to hundreds of patients who are taking just the generic formulation in Kentucky. In 2015, there were 711
Medicare Part D patients who were dispensed the brand name, Opana ER, in Kentucky.

Ultimately, Endo Pharmaceuticals agreed to remove Opana ER from the market a month after the FDA’s withdrawal request. The question that remains is if the FDA will target other opioids or the generic of Opana ER next due to the increasing rate of drug overdoses in the country. With Opana ER now being removed from the market, which other opioids will be facing scrutiny in the future?