FDA Asks Drugmaker to Pull Its Dangerous Opioid From the Market

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In an unprecedented move, the U.S. Food and Drug Administration (FDA) has ordered a drug manufacturer to pull one of its prescription painkillers from the market, citing its contribution to the continuing escalation of the country's opioid addiction crisis, The Independent reports.

The FDA has requested that Pennsylvania-based drugmaker Endo Pharmaceuticals pull its extended-release opioid Opana ER from all U.S. pharmacies immediately, after several reports have revealed serious risks among people who have been smashing up the drug and injecting it. If Endo does not voluntarily pull Opana ER from the market, the FDA has threatened to officially revoke its approval of the medication.

The FDA's decision comes in the midst of an accelerating opioid epidemic across the United States. Since 2010, reports show that mortality rates in nearly every state have risen and that overdose-related deaths appear to be a major culprit. Hepatitis C virus (HCV) rates are also on the rise across the country, with new cases of the liver virus recently hitting a 15-year high, according to the U.S. Centers for Disease Control and Prevention (CDC).

According to FDA officials interviewed about the request to pull the drug from U.S. pharmacies, Opana use has also been associated with recent outbreaks of HIV, hepatitis C and a serious blood disorder spread through needles shared among users after injecting the drug. Additionally, officials have said the risks associated with the drug outweigh the benefits.

Health officials also say the uptick in drug-related deaths and illness seem to be shadowing mortality trends from the 1980s and 1990s, when HIV ravaged injection drug user communities alongside the crack cocaine epidemic.