

Reformulated OxyContin's benefit against abuse remains unclear a decade later

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A decade after Purdue Pharma LP changed OxyContin in an attempt to make it more difficult to abuse, U.S. health officials found there isn't enough evidence to show an overall benefit.

Studies show abuse by snorting or injecting the reformulated painkiller did fall, which was Purdue Pharma's aim when it changed the pill. Oral abuse, however, increased slightly, leaving the public health benefits murky, according to a summary of the studies posted by U.S. Food and Drug Administration [staff](#).

Outside advisers to the FDA will discuss the impact of the reformulated drug on Thursday and Friday to determine if the data is sufficient to show a meaningful decline in the risk of overdose. The FDA is reviewing its policies around abuse-deterrent opioids, including "alternative language that may be necessary to describe and explain these products," according to the staff report.

Because overall OxyContin abuse remained high, compared to similar prescription opioids, the reformulated version "is not necessarily safer than other marketed [opioid analgesics](#) with respect to abuse and associated risks," the staff's summary concluded.

Purdue Pharma in 2010 pulled an older version of OxyContin off the shelves and replaced it with reformulated versions meant to deter snorting and injecting. In 2013, the FDA barred generic drugmakers from selling copies of the older OxyContin.

Purdue Pharma and OxyContin have been blamed by states suing the bankrupt company for fueling the [opioid](#) overdose epidemic. Those states recently told a judge the drugmaker cost the U.S. economy more than \$2.15 trillion.

The agency has pushed companies to come up with harder-to-abuse prescription opioids, but a shift has proved difficult. Abuse-deterrent formulations make up about 2% of prescription opioid sales, according to the FDA staff. The staff report also said multiple abuse-deterrent opioids approved by the FDA have been voluntarily withdrawn or

companies aren't currently marketing them. The summary doesn't name which opioids.

The number of opioid deaths in the U.S. involving prescription painkillers fell to close to 15,000 in 2018 from more than 17,000 in 2017, according to the National Institute on Drug Abuse.

While those numbers have hovered between just under 15,000 to 17,000 since 2010, overdoses from illegal opioids like heroin skyrocketed. Heroin deaths grew five-fold between 2010 and 2018 to almost 15,000, according to NIDA.

The FDA staff point out a number of holes and missing data in the studies that were reviewed that make them difficult to interpret, with trends in opioid [abuse](#) shifting from prescription painkillers to illegal ones further complicating the issue.

Purdue Pharma said in its briefing documents for the advisory panel meeting on Thursday that overdoses did fall in patients prescribed OxyContin alone. FDA staff acknowledged this but added that OxyContin use without any other opioids was uncommon.

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