

FDA Announces Stronger Safety Warnings for Some Opioid Painkillers



The U.S. Food and Drug Administration (FDA) has announced safety labeling changes for extended-release and long-acting opioid painkillers.

The new labels will call attention to the dangers of abuse and possible death, Reuters reports. They will also highlight the risks to babies whose mothers take the medicines, in a prominent boxed warning. The labels will appear on drugs including OxyContin, a long-acting form of oxycodone. Other opioids include fentanyl and morphine.

The drug labels currently state they are indicated for patients with moderate to severe pain. The new labels will indicate the drugs should be used only by patients in pain that is severe enough to require daily, constant, long-term opioid treatment, who have not had adequate pain relief from other medicines.

The FDA will also require additional studies of the drugs to assess risks of abuse, overdose and death.

"The FDA is invoking its authority to require safety labeling changes and postmarket studies to combat the misuse, abuse, addiction, overdose and death from these potent drugs that have harmed too many patients and devastated too many families and communities," FDA Commissioner Margaret Hamburg said in a news release.