

# FDA warns of fatal risks from mixing opioids and sedatives (Update)

August 31 2016, by Matthew Perrone

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Health officials are strengthening warnings about the potentially fatal consequences of mixing prescription painkillers and sedatives like Xanax, saying the combination can lead to breathing problems, coma and death.

The Food and Drug Administration said it will add a boxed warning—the strongest type—to nearly 400 medications about the interaction, including opioid painkillers, opioid-containing cough medicines and benzodiazepines, which are used to treat anxiety, insomnia and seizure disorders.

Painkillers and sedatives are among the most commonly prescribed medications in the U.S., but both drug types slow users' heart rate and breathing.

FDA officials said the number of opioid patients receiving sedatives increased by 41 percent, or roughly 2.5 million patients, between 2002 and 2014. Overdose deaths linked to non-medical use of the drug combination tripled between 2004 and 2011, according to figures from the agency.

The federal announcement followed a petition from health directors in 16 states and 12 cities filed in February.

"We said, we cannot wait and called upon the FDA to save lives now," said Baltimore City Health Commissioner Dr. Leana Wen, who spoke to

reporters on an FDA call about the announcement.

Wen, an emergency medicine specialist, cited figures estimating that 1 in 3 accidental opioid overdose deaths in the U.S. also involve sedatives.

While current drug labels and medical guidelines already caution against mixing the drugs, Wen said doctors still routinely prescribe them in combination. For instance, a patient injured in a car accident might receive an opioid for pain and a benzodiazepine to control muscle spasms.

FDA officials said they hoped the elevated warning would get the attention of doctors who have not heeded earlier notices.

Along with the new drug labels the FDA will require drug manufacturers to distribute pharmacy pamphlets to patients highlighting the risks of the combination.

The FDA has come under fire for not doing more to stem the tide of fatal overdoses tied to prescription opioids, potentially addictive medications that include OxyContin, Vicodin, Percocet and numerous generic equivalents. The number of deaths linked to the medications has increased more than fourfold over the last 15 years.

FDA Commissioner Dr. Robert Califf has pledged to take a series of steps designed to reduce opioid abuse. His confirmation by Senate lawmakers was held up earlier this year by lawmakers concerned about the FDA's approach to tackling opioid abuse, which has been termed an epidemic by public health authorities.

In 2014, more than 17,000 people died from overdoses linked to opioid pain medications, including drugs like oxycodone, hydrocodone and fentanyl, according to the Centers for Disease Control and Prevention.

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