

# FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

*FDA Drug Safety Podcast*

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Welcome to the FDA Drug Safety Podcast for health care professionals from the Division of Drug Information. This is Lesley Navin, Advanced Practice Nurse.

**On April 9, 2019** FDA announced we have received reports of **serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased.** These include **serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.**

While we continue to track this safety concern as part of our ongoing monitoring of risks associated with opioid pain medicines, **we are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.** Examples of common opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone.

**Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms.** These symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.

**Health care professionals should not abruptly discontinue opioids in a patient who is physically dependent.** When you and your patient have agreed to taper the dose of opioid analgesic, consider a variety of factors, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. **No standard opioid tapering schedule exists that is suitable for all patients.**

**Create a patient-specific plan to gradually taper the dose of the opioid and ensure ongoing monitoring and support, to avoid serious withdrawal symptoms, worsening of the patient's pain, or psychological distress.** this is practically possible by prescribing tapering medication (tapering strips) using *shared decision making*

We are continuing to monitor this safety concern and **will update the public if we have new information.** We are also including new prescribing information on other side effects including central sleep apnea and drug interactions and have updated the information on proper storage and disposal of these medicines that is available on our Disposal of Unused Medicines (</drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know>) webpage.

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving opioids or other medicines to the FDA MedWatch program at MedWatch (</about-fda/medwatch-fda-safety-information-and-adverse-event-reporting-program-html>).

A link to the full communication detailing specific information, including tapering information for health care professionals, can be found at Drug Safety Communications (</drugs/drug-safety-and-availability/drug-safety-communications>).

If you have drug questions, you can reach us at [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) (<mailto:druginfo@fda.hhs.gov>). Thank you for listening.

## Related Information

- **FDA Drug Safety Communication: FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering** (</drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes>)
- **FDA Drug Safety Podcast: FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering (MP3 - 4.1MB)** (</media/123270/download>)

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