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

On April 9, 2019, The U.S. Food and Drug Administration (FDA) has 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 the FDA continues to track this safety concern as part of its ongoing monitoring of risks associated with opioid pain medicines, they 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.

Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, 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.

Opioids are a class of powerful prescription medicines that are used to manage pain when other treatments and medicines cannot be taken or are not able to provide enough pain relief. They have serious risks, including abuse, addiction, overdose, and death. Examples of common opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone.

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, as needed, to avoid serious withdrawal symptoms, worsening of the patient’s pain, or psychological distress (For tapering and additional recommendations, see Additional Information for Health Care Professionals).

The FDA is continuing to monitor this safety concern and will update the public if they have new information. Because they are constantly monitoring the safety of opioid pain medicines, the FDA is also including new prescribing information on other side effects including central sleep apnea and drug interactions. The FDA is also updating information on proper storage and disposal of these medicines that is currently available on our Disposal of Unused Medicines webpage.

To help FDA track safety issues with medicines, they urge patients and health care professionals to report side effects involving opioids or other medicines to the FDA MedWatch program.

For More Info
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If you have questions, contact AlohaCare Provider Relations at 973-1650 or toll-free at 1-800-434-1002.