FDA Works to Reduce Risk of Opioid Pain Relievers

People who suffer chronic pain face a good news/bad news situation in choosing a treatment. There are powerful medicines called opioids that can help manage pain when prescribed for the right condition and when used properly. But when prescribed by physicians to patients who should not receive them, or when used improperly or for recreational purposes, they can cause serious harm, including overdose and death.

To reduce these risks as much as possible, the Food and Drug Administration (FDA) has approved a risk management plan for a class of opioid medications, known as extended-release (ER) and long-acting (LA) opioid analgesics, used to treat moderate to severe chronic pain. This plan is designed to ensure that health care professionals are trained on how to properly prescribe these medicines and how to instruct their patients about using them safely.

"There are a limited number of options available for the treatment of pain. Opioids are one option, but they carry a significant risk of misuse, abuse, overdose and death," says Sharon Hertz, M.D., deputy director of FDA's Division of Anesthesia, Analgesia and Addiction Products. "We're trying to help physicians manage the risks and improve the safety of using these medicines."

FDA's risk management plan affects more than 20 ER/LA opioid companies. They will be required to make educational training available for health care professionals on the safe prescribing of ER/LA opioid medications, as well as carry out other new activities to reduce the risks of these drugs. FDA told drug makers in April 2011—in concert with a White House campaign against prescription drug abuse—that they must develop this program, called the Risk Evaluation and Mitigation Strategy (REMS).

For patients, the benefit is two-fold. First, Hertz notes that health care professionals who participate in the REMS program will have more knowledge and awareness and can have frank conversations with their patients about the risks and appropriate use

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of opioids. A new patient counseling document will be available for prescribers to use when talking to their patients about these medications.

The REMS also includes an updated Medication Guide—a paper handout for patients that the pharmacist will provide when a patient receives an ER/LA opioid medication. This document, Hertz says, is written in plain language to simply explain how to safely use ER/LA opioid medicines.

Powerful Drugs

Opioids—so named because they are synthetic versions of opium—are narcotics that work by changing the way the brain perceives pain. They are available— in forms that include pills, liquids and skin patches—to treat moderate to severe chronic pain. Hertz explains that the ER/LA opioids are more of a safety concern than immediate-release formulas because they are stronger and either stay in the body longer or are released into the body over longer periods of time. The drugs that will be required to have a REMS include:

- Avinza
- Butrans (transdermal buprenorphine)
- Dolophine (methadone)
- Duragesic (transdermal fentanyl)
- Embeda
- Exalgo (hydromorphone)
- Kadian
- MS Contin
- Opana ER (oxymorphone).
- Oramorph (all morphines)
- OxyContin (oxycodone)

"When too much is taken, the risk of overdose is serious and it can cause death," says Hertz. "We've seen that happen to people who overdose accidentally when they are taking an opioid for pain and to others who are taking it to get high."

Hertz says that's why it's important that patients securely store their medications, both to prevent the accidental exposure of family members and to keep them away from others looking to get high.

And patients should not be sharing their pain relievers, Hertz says. "Just because it's safe for the patient, doesn't mean it's safe for someone else," she says, noting that there have been cases of people overdosing and dying after taking an opioid medication prescribed for a friend or family member.

Opioid education

The centerpiece of the new REMS for the ER/LA opioid medicines is education for prescribers. Companies that make ER/LA opioid analgesics are required to make available for free or at nominal cost continuing education courses from accredited providers. These courses for health care professionals (including physicians, nurse practitioners, and physician assistants) would contain key concepts and messages developed by FDA about risks and safe prescribing and safe use practices.

FDA expects companies to train at least 60% percent of the 320,000 prescribers of ER/LA opioids within three years from when training is available. Hertz says the goal is that prescribers will ultimately have patients who are better informed and feel more confident about their ability to use the drugs safely.

Medication and Counseling Guides

Hertz says the new Medication Guide is a one-page document that is concise and consistent among products, with the same general safety information for each product. This includes:

- Instructions not to change your dose without consulting your doctor.
- The signs that indicate you may have taken too much medication.
- Instructions to seek emergency help in an overdose situation.

The advice would be tailored further for individual medications, such as any instructions regarding interactions with food and beverages.

The patient counseling document includes:

- A list of do's and don'ts
- Information on when to call your health care provider or emergency services
- A place for patient specific information from your health care provider

Periodic assessments will be conducted by the companies and by FDA to determine the effectiveness of the REMS program.

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