

Goal of Labeling Changes: Better Prescribing, Safer Use of Opioids

Consumers and health care professionals will soon find updated labeling for extended-release and long-acting opioid pain relievers to help ensure their safe and appropriate use.

In addition to requiring new labeling on these prescription medications, the Food and Drug Administration (FDA) is also requiring manufacturers to study certain known serious risks when these drugs are used long-term.

"The new labeling requirements and other actions are intended to help prescribers and patients make better decisions about who benefits from the use of these medications. They also are meant to reduce problems associated with their use," says Douglas Throckmorton, M.D., deputy director of regulatory programs in FDA's Center for Drug Evaluation and Research. "Altogether, the actions we're now announcing are part of FDA's efforts to make opioids as safe as possible for those who need them," Throckmorton adds.

He noted that the actions come after careful analysis of new safety information, including reviews of medical literature, and consideration of input from patients, experts and many other interested parties.



How Labeling Will Change

Opioids work by changing the way the brain perceives pain. They are available by prescription as pills, liquids, and skin patches. Extended-release and long-acting (ER/LA) forms pose a greater safety concern because—as their names suggest—they produce

their effects for a longer period, and many contain higher doses compared with immediate release or opioid/non-opioid combination products. They include, to name a few, long acting versions of opioids such as morphine, oxycodone, and fentanyl.

Currently, labeling on these ER/

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LA opioids indicate they are for "the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

However, the updated indication for when to prescribe and take these medicines will, when finalized, emphasize that other, less potentially addictive, treatment options should be considered first.

FDA is requiring labeling that says the drugs are "indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

The "limitations of use" portion of the new labeling retains language indicating that the drugs are not intended for use as an "as-needed" pain reliever. Furthermore, the new labeling adds: "Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve [Tradename] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain."

This new labeling language emphasizes that patients in pain should be assessed not only by their rating on a pain intensity scale, but also based on a more thoughtful determination that their pain — however it may be defined — is severe enough to require daily, around-the-clock, long-term opioid treatment, and for

which alternative treatment options are inadequate.

This framework better enables prescribers to make decisions based on a patient's individual needs, given the serious risks associated with ER/LA opioids, against a backdrop of alternatives such as immediate release (IR) opioids and non-opioid pain relievers. It allows prescribers to make an assessment of pain relative to a patient's ability to perform daily activities or enjoy a reasonable quality of life.

FDA-approved labeling of these pain relievers already describes the effects on newborns of exposure to these drugs while in the mother's womb and warns against use by women during pregnancy and labor and while nursing. The new labeling, however, will provide more detail and will elevate the risk of neonatal opioid withdrawal syndrome (NOWS) to the most prominent position in labeling—a boxed warning. Symptoms of NOWS may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.

Postmarket Studies

Recognizing the need for more scientific data about the benefits and risks of ER/LA opioids when used over long periods, FDA also decided to require drug companies to conduct longer term studies and trials of ER/LA opioid pain relievers on the market.

The companies must evaluate long-term use, with the goal of assessing a variety of known serious risks, including misuse, abuse, addiction, overdose, and death, as well as the risks of developing increasing sensitivity to pain.

Education to Reduce Risk

Following implementation of the safety labeling changes, certain educational materials for patients and health care professionals will be modified to reflect the new labeling for the ER/LA opioid pain relievers. As part of the new labeling changes, opioid manufacturers also must revise a paper handout patients receive with their prescription.

The ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) will also be updated after the labeling changes are finalized. The ER/LA Opioid Analgesics REMS requires manufacturers to make available continuing education courses for health care professionals who prescribe these drugs. The courses, from accredited sources, teach about risks and safe prescribing and safe use practices of these medications.

"By improving information about the risks of ER/LA opioid pain relievers and by clarifying the populations for whom the benefits outweigh the risks, we aim to improve the safe and appropriate use of these products," says Throckmorton.

He adds: "This is not the first or last initiative, and we will continue supporting broader efforts to solve the serious public health problems associated with the misuse and abuse of opioids."

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