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### FDA NEWS RELEASE

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TEXAS PODIATRIC  
MEDICAL EXAMINERS

#### **FDA introduces new safety measures for extended-release and long-acting opioid medications**

*Strategy emphasizes education for prescribers, patients on highly potent pain relievers*

The U.S. Food and Drug Administration today approved a risk evaluation and mitigation strategy (REMS) for extended-release (ER) and long-acting (LA) opioids, highly potent drugs approved for moderate to severe, persistent pain that requires treatment for an extended period.

The REMS is part of a federal initiative to address the prescription drug abuse, misuse, and overdose epidemic. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while ensuring access to needed medications for patients in pain.

"Misprescribing, misuse, and abuse of extended-release and long-acting opioids are a critical and growing public health challenge," said FDA Commissioner Margaret A. Hamburg, M.D. "The FDA's goal with this REMS approval is to ensure that health care professionals are educated on how to safely prescribe opioids and that patients know how to safely use these drugs."

The new ER/LA opioid REMS will affect more than 20 companies that manufacture these opioid analgesics. Under the new REMS, companies will be required to make education programs available to prescribers based on an FDA Blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education (CE) providers, who will develop and deliver the training.

The REMS also will require companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies will be required to perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

"We commend the FDA for taking action to save lives by increasing access to prescriber education," said Gil Kerlikowske, director of the Office of National Drug Control Policy. "Since day one, the Obama Administration has been laser focused on addressing the prescription drug abuse epidemic and today's action is an important contribution to this comprehensive effort."

ER/LA opioid analgesics are widely prescribed medicines with an estimated 22.9 million prescriptions dispensed in 2011, according to IMS Health, which provides services and information to the health care and pharmaceutical industries. It is estimated that more than 320,000 prescribers registered with the Drug Enforcement Administration (DEA) wrote at least one prescription for these drugs in 2011.

ER/LA opioid analgesics are associated with serious risks of overuse, abuse, misuse and death and the numbers continue to rise. According to the Centers for Disease Control and Prevention, 14,800 Americans died from overdoses involving opioids in 2008. In 2009, there were 15,597 deaths involving these medications – nearly four times as many deaths compared to 1999.

"Misuse and abuse of prescription opioids is a complex problem and demands a holistic response," said John Jenkins, M.D., director of CDER's Office of New Drugs. "The new REMS program is one component of a multi-agency, national strategy to address this important public health issue."

Key components of the ER/LA opioid analgesics REMS include:

- **Training for prescribers.** Based on an FDA Blueprint, developed with input from stakeholders, educational programs for prescribers of ER/LA opioids will include information on weighing the risks and benefits of opioid therapy, choosing patients appropriately, managing and monitoring patients, and counseling patients on the safe use of these drugs. In addition, the education will include information on how to recognize evidence of, and the potential for, opioid misuse, abuse, and addiction, and general and specific drug information for ER/LA opioid analgesics.
- **Updated Medication Guide and patient counseling document.** These materials contain consumer-friendly information on the safe use, storage and disposal of ER/ LA opioid analgesics. Included are instructions to consult one's physician or other prescribing health care professional before changing doses; signs of potential overdose and emergency contact instructions; and specific advice on safe storage to prevent accidental exposure to family members and household visitors.
- **Assessment/auditing.** Companies will be expected to achieve certain FDA-established goals for the

percentage of prescribers of ER/ LA opioids who complete the training, as well as assess prescribers' understanding of important risk information over time. The assessments also cover whether the REMS is adversely affecting patient access to necessary pain medications, which manufacturers must report to FDA as part of periodic required assessments.

It is expected that the first continuing education activities under the REMS will be offered to prescribers by March 1, 2013.

There is no mandatory requirement that prescribers take the training and no precondition to prescribing ER/LA opioids to patients. However, the Obama Administration endorsed a mandatory training program on responsible opioid prescribing practices in April 2011 as part of its comprehensive plan to address the epidemic of prescription drug abuse. The program, which would be linked to DEA registration by providers, would require legislative changes that are being pursued by the Administration.

The FDA continues to support this approach, but absent the needed legislation, intends to exercise its authority to require mandatory elements for companies and voluntary elements for prescribers – all of which are important and necessary steps to help curb the misuse and abuse of ER/ LA opioid analgesics, without being overly burdensome.

For more information:

- [Opioid Drugs and Risk Evaluation and Mitigation Strategies<sup>1</sup>](#)
- [Opioid REMS Questions and Answers<sup>2</sup>](#)
- [Consumer Update<sup>3</sup>](#)

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Page Last Updated: 07/09/2012

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#### Links on this page:

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3. </ForConsumers/ConsumerUpdates/ucm307821.htm>
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