

FDA Acts to Reduce Harm from Opioid Drugs

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The White House on Tuesday unveiled a multi-agency plan aimed at reducing the “epidemic” of prescription drug abuse in the U.S.—including an FDA-backed education program that zeros-in on reducing the misuse and misprescribing of opioids.



Gil Kerlikowske, director of the White House Office of National Drug Control Policy, says the plan—a collaborative effort involving agencies of the departments of Justice, Health and Human Services, Veterans Affairs, Defense, and others—provides a national framework for reducing prescription drug abuse and the diversion of prescription drugs for recreational use.

“The toll our nation’s prescription drug abuse epidemic has taken in communities nationwide is devastating,” says Kerlikowske. “We share a responsibility to protect our communities from the damage done by prescription drug abuse.”

Key elements of the plan—called *Epidemic: Responding to America’s Prescription Drug Abuse Crisis*—include:

- expansion of state-based prescription drug monitoring programs
- recommending convenient and environmentally responsible ways to remove unused medications from homes
- supporting education for patients and health care providers
- reducing the number of “pill mills” and doctor-shopping through law enforcement

FDA Opioid Strategy

In concert with the White House plan, the Food and Drug Administration (FDA) is announcing a new risk reduction program—called a Risk Evaluation and Mitigation Strategy—for all extended-release and long-acting opioid medications.

Opioids are synthetic versions of opium that are used to treat moderate and severe pain.

FDA experts say extended-release and long-acting opioids—including OxyContin, Avinza, Dolophine, Duragesic, and eight other brand names—are extensively misprescribed, misused, and abused, leading to overdoses, addiction, and even deaths across the United States. FDA says

a 2007 survey revealed that more than half of opioid abusers got the drug from a friend or relative.

Opioids—such as morphine and oxycodone—are used to treat moderate and severe pain. Over the past few decades, drug makers have developed extended-release opioid formulas to treat people in pain over a long period.

The new REMS plan focuses primarily on: educating doctors about proper pain management, patient selection, and other requirements and improving patient awareness about how to use these drugs safely. As part of the plan, FDA wants companies to give patients education materials, including a medication guide that uses consumer friendly language to explain safe use and disposal.

FDA wants drug makers to work together to develop a single system for implementing the REMS strategies. Toward that goal, FDA is now notifying opioid makers that they must propose a REMS plan within 120 days.

Janet Woodcock, director of FDA’s Center for Drug Evaluation and Research, says this risk management strategy is designed to improve pain management, while preserving patient access to these needed medications.

“This will be an important step toward addressing what has become a critical public health problem,” she says.

Doctor training, patient counseling, and other risk reduction measures developed by opioid makers as part of the REMS are expected to become effective by early 2012. They will be required for various brand name products known under the generic names:

- hydromorphone
- oxycodone
- morphine
- oxymorphone
- methadone
- transdermal fentanyl
- transdermal buprenorphine

Widespread Problem

FDA estimates that more than 33 million Americans age 12 and older misused extended-release and long-acting opioids during 2007—up from 29 million just five years earlier. And in 2006, nearly 50,000 emergency room visits were related to opioids.

"Opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients, but we know that they pose serious risks when used

improperly—with serious negative consequences for individuals, families, and communities," says FDA Commissioner Margaret A. Hamburg, M.D. "The prescriber education component of this Opioid REMS balances the need for continued access to these medications with stronger measures to reduce their risks."

Although doctor training is not mandatory under the REMS plan, other federal agencies are working to get Congress to link mandatory physician training to the already required Drug Enforcement Administration registration number that doctors must have to prescribe controlled substances.

FDA will also require the risk management plan to include a way to determine if the education programs are helping to reduce problems associated with long-acting and extended-release opioids, as well as allowing patients who need opioids to get them.

FDA has had the power to request companies to develop REMS since 2007. The plans may also include medication guides and patient package inserts.

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