

Teach prescribers about dangers of longacting pain meds: FDA

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Abuse, misuse, deaths from narcotic pain meds on the rise.

(HealthDay) -- As part of its efforts to curb the abuse of narcotic painkillers, the U.S. Food and Drug Administration is requiring drug makers to educate doctors about the risks of long-acting and extended-release forms of the drugs.

"Prescription-<u>drug</u> abuse is our nation's fastest-growing drug problem," FDA commissioner Dr. Margaret Hamburg said during a Monday afternoon press conference.

Commonly prescribed drugs that come in longer-acting forms include <u>oxycodone</u>, <u>morphine</u> and fentanyl.

The continuing-education programs will be based on FDA-created



blueprints. The agency expects the more than 20 companies that make these drugs to provide grants to firms that specialize in medical continuing education. These firms will, in turn, develop and administer the programs under FDA supervision and provide them to doctors for free.

Although all <u>opioid</u> painkillers carry risk of abuse, overdose and death, the extended-release and time-release forms of the drugs are particularly risky. Because they act in the body over longer periods, they are more likely to cause problems, Hamburg said.

"The number of people harmed by these long-acting or extended-release opioids due to misprescribing, misuse and abuse ... continues to increase dramatically," Hamburg said.

In 2008, nearly 15,000 Americans died from <u>overdoses</u> of these drugs. In 2009, there were more than 15,500 deaths from opioid painkillers -almost four times as many as in 1999, according to the U.S. <u>Centers for</u> <u>Disease Control and Prevention</u>.

In addition, more than 2 million emergency-room visits in 2010 involved abuse or misuse of prescription drugs -- almost half of all drug-related visits. Of these visits, more than 15 percent involved opioid medications, Hamburg said.

The drugs are widely prescribed. It is estimated that nearly 23 million <u>prescriptions</u> for extended-release and long-acting opioids were issued in 2011, Hamburg said. It is estimated that more than 320,000 prescribers listed with the U.S. Drug Enforcement Administration wrote at least one prescription for opioid painkillers in 2011, according to the FDA.

Despite these problems, Hamburg said, patients who need these drugs must have access to them.



"Educating health care professionals on how to safely prescribe extendedrelease and long-acting opioids is essential to address this critical public health issue," she said.

The FDA hopes that over the next three years, 60 percent of the 320,000 prescribing doctors will have been trained, Hamburg said.

Along with the programs for doctors, the FDA also is mandating that manufacturers provide FDA-approved patient-education materials on the safe use of these drugs. The material appears on a single page in consumer-friendly language, and will be given to patients every time they fill a prescription.

Both the drug companies and the FDA will review the progress and success of these programs. Based on the reviews, the agency may require the companies to provide additional elements to ensure success.

The first programs under the FDA's new requirement are expected to be launched by March 1. Although no doctor currently is required to take the two- to three-hour continuing-education program, the Obama administration is urging Congress to make such programs mandatory.

More information: For more about narcotic painkillers, visit the <u>U.S.</u> <u>National Library of Medicine</u>.

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