4

Related Stories

Halloween Contact Lenses Can Be Horror Story for Eyes

Infections From Tainted Steroids Ranged in Severity: Update

'Love Hormone' Might Heighten the Placebo Effect

Study Probes Why Truckers Use Booze, Illicit Drugs

Anesthesia Technique May Affect Survival After Breast Cancer Surgery: Study

Stress Leads Some Doctors to Abuse Prescription Drugs, Study Says

FDA Urges Tighter Controls on Certain Prescription Painkillers

Large supplies of often-abused drugs such as Vicodin should be harder to obtain, agency says

By Dennis Thompson
HealthDay Reporter

THURSDAY, Oct. 24 (HealthDay News) -- The U.S. Food and Drug Administration has recommended tighter controls on prescriptions for painkillers such as Vicodin and Lortab that contain the powerful narcotic hydrocodone.

The change will cut in half the number of refills that patients can get before seeing their doctor to get a new prescription, the agency said Thursday.

Patients also will have to take a prescription to their pharmacy to have it filled, rather than have a doctor call it in.

The FDA announced that it will also ask in mid-December that all prescription medications containing hydrocodone be reclassified as "Schedule II" medications.

As Schedule II drugs, these painkillers will be subject to the same type of strict control as other narcotics with the highest potential for abuse, including OxyContin, methadone, fentanyl, Adderall and Ritalin.

The FDA has been spurred to action by epidemic levels of prescription drug abuse in the United States, said Dr. Janet Woodcock, director of the agency's Center for Drug Evaluation and Research.

The agency struggled over the impact that the change might have on patients, she said, but decided that public health concerns have become paramount.

"These are very difficult tradeoffs that our society has to make," Woodcock told *The New York Times*. "The reason we approve these drugs is for people in pain. But we can't ignore the epidemic on the other side."

One out of every five Americans has used prescription drugs for non-medical purposes at some time, according to the U.S. National Institutes of Health. Some 22 million Americans have misused prescription painkillers since 2002.

About 131 million prescriptions for medications containing hydrocodone were issued to an estimated 47 million patients in 2011. According to government estimates, that's equivalent to about 5 billion pills, the *Times* reported.

Dr. Lynn Webster, president of the American Academy of Pain Medicine, said: "This decision will mean there will be far less hydrocodone prescribed, and far less of it diverted [for abuse]. There will be an increase in health care costs due to more frequent office visits and co-pays, but it will take a bite out of the prescription drug crisis. We can't have status quo. We can't be doing what we have been doing for the last two decades."

The new regulations could take effect as early as next year, Woodcock said. The U.S. Department of Health and Human Services must approve the recommendation before it can be adopted by the U.S. Drug Enforcement Administration, which has been pushing for tougher regulation of hydrocodone medications.

Patients currently can refill a prescription for a drug containing hydrocodone five times during a six-month period before having to return to their doctor for a new prescription.

The new regulations would cut that period down to three months before a new prescription is required.

Public health experts supported the FDA's decision.

"There's no question that these are important changes in the right direction," said Dr. G. Caleb Alexander, co-director of the Center for Drug Safety and Effectiveness at Johns Hopkins School of Public Health in Baltimore. "The FDA plays a critical role in helping to reduce the toll that this epidemic has taken. The clinical community and public health community will welcome these changes."

However, Alexander said doctors and regulators need to keep an eye on problems for patients that result from the tighter control.

"The bottom line is these kind of complex policies are often hard to predict," he said. "They can have both intended or unintended consequences."

Earlier this year, an FDA advisory panel voted 19 to 10 in favor of reclassifying hydrocodone-based painkillers as Schedule II drugs.

More information

There's more on the dangers of prescription painkiller abuse at the U.S. Centers for Disease Control and Prevention.

SOURCES: Lynn Webster, M.D., president, American Academy of Pain Medicine; G. Caleb Alexander, M.D., co-director, Center for Drug Safety and Effectiveness, Johns Hopkins School of Public Health, Baltimore; *New York Times*

Last Updated: Oct. 25, 2013