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**Release**

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## **SAMHSA AND FDA JOIN TO EDUCATE THE PUBLIC ON THE SAFE USE OF METHADONE**

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Food and Drug Administration (FDA) today launched an initiative to help ensure the safe use of methadone. A prescription drug best known as a treatment for addiction and dependence on heroin and other narcotic pain medicines, methadone is also prescribed to treat moderate-to-severe chronic pain patients. The campaign responds to concerns about an escalating number of poisoning deaths linked to the improper use of this medication.

The public outreach effort, *Follow Directions: How to Use Methadone Safely*, is designed to inform consumers, health care professionals and treatment clinics about the safe use and misuse of the drug for both pain relief and drug addiction treatment.

Methadone is a synthetic opioid that has been used for decades to reduce drug withdrawal symptoms. Recently, it has been increasingly prescribed as a pain reliever for patients whose moderate-to-severe chronic pain does not respond to non-narcotic pain medications.

The percentage of all poisoning deaths linked to methadone has tripled in recent years, increasing from 4 percent in 1999 to 14 percent in 2004, according to the Centers for Disease Control and Prevention. Moreover, the number of poisoning deaths linked to methadone is rising faster than the number of poisoning deaths from any other narcotic drug.

Methadone may be best known for use as an addiction treatment medication, but the bigger problem and concern has been with the more recent use as an analgesic. The risk of methadone overdose is partly due to the way the drug metabolizes in the body. People who take methadone normally feel relief within four to eight hours. However, unlike other narcotic pain relievers a single dose of methadone can remain in the body anywhere from eight to 59 hours. As a result, the drug builds up to toxic levels if it is taken too often, in too high an amount, or with other medications.

“The methadone safety campaign materials provide simple instructions on how to use the medication correctly to either manage pain or treat drug addiction,” said H. Westley Clark, M.D., J.D., M.P.H., C.A.S., F.A.S.A.M., Director of SAMHSA’s Center for Substance Abuse Treatment. “Our goal for this training is to support the safe use of methadone by all patients and prescribing healthcare professionals.”

Methadone, when used for the treatment of narcotic addiction, must be dispensed by a program/clinic that is certified by SAMHSA and registered with the Drug Enforcement Administration (DEA). But when used as an analgesic, methadone may be prescribed by any

healthcare professional registered to prescribe Schedule II controlled substances, and can be dispensed by any licensed and DEA-registered pharmacy.

“Methadone is an important and beneficial drug when prescribed and used properly,” said Douglas Throckmorton, M.D., Deputy Director of the FDA’s Center for Drug Evaluation and Research. “Educational efforts like the one we are announcing today can help prevent the tragedies that occur when methadone is used improperly.”

Outreach materials about methadone for the public and health care professionals include a brochure, a poster and a fact sheet, in English and Spanish. In addition, a point-of-sale information sheet will be distributed in pharmacies where methadone is dispensed to pain management patients.

SAMHSA and the FDA will continue to work collaboratively with other federal agencies, states, health professional societies, patient advocacy groups, and other interested parties to develop and implement practical steps to reduce avoidable methadone-associated deaths.

To learn more information about the campaign, visit [www.dpt.samhsa.gov/methadonesafety](http://www.dpt.samhsa.gov/methadonesafety)

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