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FDA Issues NEW Warnings for Methadone Hydrochloride (DOLOPHINE HYDROCHLORIDE)

Clinicians Need to Incorporate Concepts into Informed Consent and Periodic Review Components for Compliance with Controlled Substance Prescribing Regulations

**November
2006**

Greetings!

On November 27, 2006, the U.S. Food & Drug Administration posted a series of new materials related to methadone hydrochloride (DOLOPHINE HYDROCHLORIDE). The materials include statements about: 1. Methadone's elimination half-life (8-59 hours) and how it is longer than its duration of analgesic action (4-8 hours); 2. Cross-tolerance between methadone and other opioids; 2. Methadone's ability to cause serious cardiac conduction effects, including QT interval prolongation and Torsades de Pointes. 3. The fact that there are pharmacokinetic and pharmacodynamic drug interactions between methadone and many other drugs. Thus, FDA believes that drugs administered concomitantly with methadone should be evaluated for interaction potential. 4. The fact that methadone is secreted into human milk. **Significantly, the FDA specifically stated that physicians should "avoid prescribing methadone 40 mg dispersible tablets for pain [because] this product is only FDA-approved for detoxification and maintenance treatment of narcotic addiction."** Thus,

FDA encourages health care professionals to closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments. FDA also encourages health professionals to remember [and warn patients] that "pain relief from methadone does not last as long as methadone stays in [the] body. Therefore, patients should be told "not to take more methadone than prescribed because methadone could build up in the body and cause death."

FDA released the NEW WARNINGS and materials in the following format: 1. New package label 2. New patient information 3. New physician information All health care professionals who treat pain should read these items and incorporate the recommendations and risk/benefit information into clinical practice (especially the informed consent process with the patient) and medical record documentation.

Remember, in DEA's September 6, 2006, Final Policy Statement on Dispensing Controlled Substances for the Treatment of Pain, the only controlled substance singled out by DEA is methadone. In this regard, DEA posits the question "Can methadone be used to treat pain?" DEA answers this question by referencing the Substance Abuse Mental Health Services' recent publication on Methadone Associated Mortality: A National Assessment. Again, to demonstrate compliance with legal/regulatory obligations and clinical standards of care, health care professionals should review these materials and incorporate them into clinical practice in a manner that suggests the clinician's dedication to quality pain management.



New Patient Information

The new patient information document contains information on methadone hydrochloride under the name DOLOPHINE. The document warns that it does not take the place of talking with a health care professional about medical conditions or treatments. It also recommends that the patient share the important information in this document with members of the patient's household.

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New Health Care Professional Information

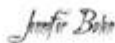
Based on the FDA's review of reports of death and life-threatening adverse events, such as respiratory depression and cardiac arrhythmias in patients receiving methadone, the FDA decided to issue new information to health care professionals on the drug. The FDA concluded that the adverse events are the possible result of unintentional methadone overdoses, drug interactions, and methadone's cardiac toxicities (QT prolongation and Torsades de Pointes). The FDA encourages those who use methadone in clinical practice to become familiar with methadone's toxicities and unique pharmacologic properties. Methadone's elimination half-life (8-59 hours) is longer than its duration of analgesic action (4-8 hours). Likewise, the FDA encourages health care professionals who use methadone for pain to carefully select and slowly titrate the drug's doses to analgesic effect, even in patients who are opioid-tolerant. In all cases, the FDA encourages health care professionals to closely monitor patients when converting

them from other opioids and changing the methadone dose, and thoroughly instruct patients how to take methadone. Healthcare professionals should tell patients to take no more methadone than has been prescribed without first discussing the matter with their provider.

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REMEMBER, the FDA IS NOT USING ITS WARNING AUTHORITY TO TELL HEALTH CARE PROFESSIONALS TO REFRAIN FROM PRESCRIBING METHADONE FOR PAIN. So please do not take this newsletter as such a message. Rather, read the FDA materials and discuss these issues in your clinical communities. Overall, I hope you find this Legal Side of Pain® update helpful. Please use the links in this update to obtain more information. If you need help, contact me. Happy Holidays!

Very truly yours,



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