FDA Announces New Label Warnings on Opioid Medications

The U.S. Food and Drug Administration (FDA) has announced new requirements for safety labeling on immediate-release (IR) opioid pain medications such as oxycodone, hydrocodone and morphine. These changes are FDA’s latest action in its Action Plan to address the growing epidemic of opioid abuse in the United States, and is another “wake up call” to prescribers that the US Government is closely scrutinizing the prescription of opiates.

The FDA’s recommendations and requirements include the following:

- Recommendation that IR Opioids should only be prescribed when alternative treatment options (e.g., non-opioid pain medications or physical therapy) are inadequate or not tolerated.
- Updated dosing recommendations, including recommendations for lower initial dosages, and a warning not to abruptly stop treatment in a physically dependent patient.
- Black box warnings that chronic maternal use of opioids during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS).
- Updated labeling for all opioids to include safety information about drug interactions that can result in a serious central nervous system condition called serotonin syndrome.
- Updated labeling concerning information about opioid effects on the endocrine system and decreased sex hormone levels (androgen deficiency).

The intent and purpose of these new label warnings is to better inform and advise physicians about the risks to their patients of opioid medications. Physicians should carefully consider these risk factors in diagnosing and treating their patients.

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If you have any questions, please contact the GW attorney with whom you regularly consult.

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If you have any questions regarding this Legal Alert, please contact Barry B. Cepelewicz at (203) 316-0483.

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