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Protecting the Rights of Injured Workers

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Darvocet and Darvon Withdrawn from U.S. Market Due to Risk of Abnormal Heart Activity

The drug propoxyphone – marketed and sold as Darvocet and Darvon – was recently withdrawn from the U.S. market by its manufacturer, Xanodyne Pharmaceuticals, at the request of the U.S. Food and Drug Administration (FDA). The drug, which is an opioid pain reliever used to treat mild to moderate pain, was originally approved by the FDA more than 50 years ago, in 1957, but new data has shown that it can cause serious toxicity to the heart, even when used at recommended doses.

The FDA requested that the drug be removed from the U.S. market by Xanodyne Pharmaceuticals and the drug's generic manufacturers after reaching the conclusion that the risks of the injury outweigh the drug's pain relief benefits at its current prescribed doses.

Since 1978, the FDA has received only two requests to remove the drug from the market and, until now, the FDA has concluded that the pain management benefits of the drug outweigh any possible risks associated with the drug.

In January 2009, however, an FDA advisory committee voted against the continued marketing of propoxyphene products noting that information about the drug's cardiac side effects was needed in order to evaluate its risks and benefits. Later that year, the FDA decided to permit continued marketing of the drug, but required a new boxed warning to be included on the drug's label informing patients and health care providers of the risk of a fatal overdose.

The FDA also required that the drug's manufacturer conduct a new safety study in order to answer questions about the effects of propoxyphene on the heart. The results of this study revealed that when propoxyphene was taken at recommended doses, there were significant changes to the electrical activity of the heart that could increase the risk for serious abnormal heart rhythms that could lead to sudden death. The study also revealed that the risk of serious side effects for a particular patient can change based on a number of small changes in the patient's health, such as dehydration, a change in medications or decreased kidney function.

The European Medicines Agency has already recommended that the drug's marketing authorizations be withdrawn throughout the European Union and a phased withdrawal of propoxyphene is currently underway.

The FDA has recommended that doctors and other healthcare professionals not only stop prescribing the drug and any products containing propoxyphene, but that they also contact patients currently prescribed Darvocet and Darvon or other propoxyphene-containing products and ask them to discontinue use to the drug.

If you are currently taking the drug should contact their doctor or healthcare provider as soon as possible to discuss alternative pain medication. You may also wish to consult with the experienced Chicago product liability attorneys at Ankin Law Offices regarding a possible product liability claim for any injuries that could have been caused by the drug.

Howard Ankin of Ankin Law Office LLC handles workers' compensation and personal injury cases. Mr. Ankin can be reached at (312) 346-8780 and howard@ankinlaw.com.

By Admin - CO
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