Hissey Kientz Concerned That Patients Have Not Been Provided With Crucial Information About Digitek Recall Despite the Dangers of Digoxin Toxicity

Hissey Kientz, LLP is concerned that despite a recent recall notice for the heart drug Digitek, the drug's manufacturer has failed to provide any additional information on how long the heart medication was being improperly manufactured. According to a press release issued by the manufacturer, some Digitek tablets may have been manufactured at double their normal strength, meaning that patients could receive a double dose of the drug, leading to an overdose. A Digitek overdose could lead to severe side effects, including heart attack, stroke or death.

Austin, TX (Vocus) August 16, 2008 -- The law firm of Hissey Kientz, LLP is concerned over recent reports that many heart patients may not have been fully informed by the drug's manufacturer about problems with the heart drug Digitek. Drugmaker Actavis Totowa issued a nationwide recall notice for the heart drug Digitek (digoxin) on April 25, 2008.

In a press release announcing the recall notice, the company stated that some Digitek tablets may have been manufactured at twice their normal thickness, meaning that patients could receive a double-dose of the drug. This increased exposure could cause patients to suffer an overdose, leading to heart attack, stroke or death.

But according to a statement by the Food and Drug Administration published on May 1, 2008, since the Digitek recall was issued doctors and patients have received no additional information on how long the drug was being produced at twice the normal strength. The public has also not been notified on how many lots of the heart medication were improperly manufactured and when this problem was first detected.

"Actavis has a responsibility to provide consumers with all the available safety information about the manufacturing problems connected with the Digitek recall," says attorney Mike Hissey with Hissey Kientz, LLP in Austin, Texas. "The public has a right to know how long this problem has been going on and how many patients could be affected. Many consumers were only made aware of the problems with Digitek when their pharmacist or doctor told them about the recall notice."

Digitek is prescribed to patients with heart problems in order to treat congestive heart failure, an irregular heartbeat or other symptoms. Digitek is a form of the heart medication digitalis, which helps to strengthen the beating of the heart muscles and relieve the symptoms of patients with these conditions. It is also known generically as digoxin.

However, when administered in too high of a dose, digoxin drugs such as Digitek may cause digoxin toxicity, resulting in an overdose. Symptoms of a Digitek overdose include unusual changes in vision, dizziness, irregular heartbeat, abnormally low blood pressure or heart rate, nausea, vomiting or other symptoms. In severe cases, digoxin toxicity can lead to a heart attack or stroke, which can result in death.

The FDA sent warning letters to Actavis in September 2006 and February 2007 after the agency uncovered manufacturing problems at the plant where Digitek is produced. The FDA stated in these letters that because of quality control problems at the plant, drugs made there were "adulterated," making it impossible to determine if they were being manufactured at the correct strength.

Actavis also issued a recall notice on August 1, 2008 for every single drug produced at the New Jersey plant where Digitek was manufactured. The recall notices were issued after an FDA inspection earlier this year revealed that the company had continued to violate “standards for good manufacturing practices,” according to a statement by the company, even after it had received two previous warning letters for similar infractions.

Digitek tablets manufactured by Actavis Totowa were distributed by UDL Laboratories and Mylan Pharmaceuticals. Tablets distributed by UDL were sold under the label “UDL,” while those distributed by Mylan were sold under the name “Bertek.” Patients who were taking Digitek before the recall notice was issued may wish to speak with their doctors to discuss alternate forms of treatment.

Dozens of patients who suffered severe injuries after using Digitek have filed lawsuits against the manufacturer and distributors of the drug. These lawsuits have alleged that Digitek was dangerously and defectively manufactured, putting patients at risk of severe and potentially fatal side effects due to an overdose.

About Hissey Kientz, LLP
Hissey Kientz, LLP is currently accepting cases involving individuals who may have been injured as a result of a Digitek overdose. Hissey Kientz, LLP also represents those who contracted mesothelioma or lung cancer as a result of asbestos exposure, and those injured by the Ortho Evra patch, Trasylol, the Composix Kugel mesh patch, the Duragesic patch (fentanyl), gadolinium MRI contrast dyes or other defective drugs and devices. To learn more about the firm and other drug cases, visit Hissey Kientz, LLP (www.hkllp.com) or call toll-free at (866) 275-4454.

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