Analysis of FDA Adverse Events Data Reveals at Least 106 Serious Conditions Reported Among Reglan Users

An analysis of the Food and Drug Administration's Adverse Event Reporting System has identified at least 106 cases of tardive dyskinesia or other movement disorders reported among users of Reglan or its generic version, metoclopramide. Tardive dyskinesia is a neurological disorder characterized by involuntary, repetitive movements of the extremities, including lip smacking, grimacing, tongue protrusion, rapid eye movements or blinking, puckering and pursing of the lips, or impaired movement of the fingers. These symptoms are rarely reversible and there is no known treatment.

(Vocus) May 8, 2009 -- An analysis of the Food and Drug Administration's Adverse Event Reporting System has identified at least 106 cases of tardive dyskinesia or other movement disorders reported among users of Reglan or its generic version, metoclopramide.

Reglan and metoclopramide were approved by the FDA only for short-term treatment of certain gastrointestinal conditions, such as gastroesophageal reflux disease or diabetic gastroparesis. However, the manufacturers of these drugs derive substantial profit from their long-term use. The drugs work by speeding up the movement of the stomach muscles, which helps to increase the rate at which food moves from the stomach to the intestines.

In February 2009, the FDA forced the manufacturers of Reglan and metoclopramide to add a "black-box" warning to their labels about the strong connection between tardive dyskinesia and the long-term use of Reglan. Tardive dyskinesia is a neurological disorder characterized by involuntary, repetitive movements of the extremities, including lip smacking, grimacing, tongue protrusion, rapid eye movements or blinking, puckering and pursing of the lips, or impaired movement of the fingers. These symptoms are rarely reversible and there is no known treatment.

Because the risk of tardive dyskinesia may be greatest in patients who have taken Reglan or metoclopramide for an extended period, the FDA required a warning stating that chronic use of the drugs should be avoided, except in rare cases. According to the drug's label, Reglan should only be prescribed for short-term use of four to 12 weeks. The safety of Reglan and metoclopramide use for longer than 12 weeks has not been studied.

"Tardive dyskinesia is a debilitating disease which substantially alters the quality of one's life. It may affect thousands who used Reglan or metoclopramide," says Shamus B. Mulderig, Managing Attorney of the Pharmaceutical and Medical Device Litigation Department at Hissey Kientz, LLP. "Tardive dyskinesia is a horrible affliction, is not reversible and has no cure. And because the FDA's Adverse Event Reporting System is a voluntary reporting system, the number of reports received so far may seriously understate how widespread this affliction may be."

Reglan is also linked to a serious and potentially fatal syndrome known as Neuroleptic Malignant Syndrome (NMS). Symptoms of NMS include hyperthermia, muscle rigidity, altered consciousness, irregular pulse, blood pressure or heartbeat or other symptoms.

An analysis conducted by the FDA found that, at a minimum, 20% of patients taking the drugs did so for longer than the three month maximum set by the agency. Other studies have identified Reglan and metoclopramide as the single most common cause of drug-induced movement disorders, including tardive dyskinesia.

"In addition to forcing the manufacturers to place a black box warning on the labels of Reglan and metoclopramide, the FDA required these companies to conduct a risk evaluation and mitigation strategy to ensure that patients are provided with a medication guide that discusses the risks associated with these drugs," says Mulderig. "Unfortunately, these measures taken by the understaffed and underfunded FDA come much too late for the individuals who have already developed tardive dyskinesia or NMS from the long-term use of Reglan."

About Hissey Kientz, LLP

Hissey Kientz, LLP is currently accepting cases involving individuals who may have developed tardive dyskinesia after using Reglan, as well as those affected by mesothelioma, asbestosis or lung cancer as a result of asbestos exposure; the Ortho Evra patch; digoxin toxicity from Digitek; pulmonary hypertension caused by Fen-Phen; the Composix Kugel mesh hernia patch; renal failure caused by Trasylol; the Duragesic or fentanyl pain patch; Raptiva; FELA railroad injuries; 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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