Reglan Adverse Events More Than Doubled from 2006 to 2008

Recent data from the Food and Drug Administration's Adverse Event Reporting System reveals that new cases of tardive dyskinesia or other movement disorders reported by users of Reglan (or its generic version, metoclopramide) more than doubled between 2006 and 2008. 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.

Austin, Texas (Vocus) July 7, 2009 -- Recent data from the Food and Drug Administration's Adverse Event Reporting System reveals that new cases of tardive dyskinesia or other movement disorders reported by users of Reglan (or its generic version, metoclopramide) more than doubled between 2006 and 2008, according to an analysis by Hissey Kientz, LLP. This represents a substantial increase in new adverse events related to Reglan.

"Another very striking aspect of this increase in Reglan-related side effects cases is that these were reported to the FDA before manufacturers were even requested to add a 'black-box' warning to the drugs' labels," says Shamus B. Mulderig, an attorney with Hissey Kientz, LLP. "As the agency begins to release data collected after this February's warning notice was issued, and more patients and physicians become aware of the life-altering side effects of these drugs, the number of new cases reported to the FDA will undoubtedly continue to rise."

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. 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 "black box" warning which states that no one should use the drugs for longer than three months.

"Tardive dyskinesia is a debilitating disease which substantially alters the quality of one's life. It may affect thousands who used Reglan or metoclopramide," Mulderig says. "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), according to articles published in the Archives of Internal Medicine and other medical journals. Symptoms of NMS include hyperthermia, muscle rigidity, altered consciousness, irregular pulse, blood pressure or heartbeat or other symptoms.

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"In addition to requiring the manufacturers to place a black box warning on the labels of Reglan and metoclopramide, the FDA is demanding these companies 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 (http://www.hkllp.com/) 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; primary pulmonary hypertension caused by Fen-Phen or "herbal 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 or call toll-free at (866) 275-4454.

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