Jonathan Rosenfeld's Nursing Homes Abuse Blog

Even After Warnings, Reglan Continues To Be Prescibed And Cause Devastating Problems For Many Patients

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In a previous post, I talked about Reglan (Metoclopramide), a drug commonly used to relieve heartburn in patients with GERD (gastroesophageal reflux disease) or to relieve symptoms of slow stomach emptying for people with diabetes. Well, it turns out that this drug can also cause tardive dyskinesia (TD). Tardive dyskinesia is abnormal muscle movements, mostly in the face muscles, that you have no control over. TD has no treatment, and the symptoms might not go away even you stop taking raglan.

Clearly, TD is not a minor side effect. The FDA took action requiring manufacturers of the drug to add a "black box" warning about the drug's risks. The U.S. National Library of Medicine – National Institute of Health Website now includes an IMPORTANT WARNING in its information for metoclopramide (better known as Reglan) –

"Taking metoclopramide may cause you to develop a muscle problem called tardive dyskinesia. If you develop tardive dyskinesia, you will move your muscles, especially the muscles in your face in unusual ways. You will not be able to control or stop these movements. Tardive dyskinesia may not go away even after you stop taking metoclopramide. The longer you take metoclopramide, the greater the risk that you will develop tardive dyskinesia. Therefore, your doctor will probably tell you not to take metoclopramide for longer than 12 weeks. The risk that you will develop tardive dyskinesia is also greater if you are taking medications for mental illness, if you have diabetes, or if you are elderly, especially if you are a woman. Call your doctor immediately if you develop any uncontrollable body movements, especially lip smacking, mouth puckering, chewing, frowning, scowling, sticking out your tongue, blinking, eye movements, or shaking arms or legs.

Jonathan Rosenfeld represents victims of nursing home abuse and neglect throughout the country. For more information please visit Nursing Homes Abuse Blog (www.nursinghomesabuseblog.com), Bed Sore FAQ (www.bedsorefaq.com) or call Jonathan directly at (888) 424-5757.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with metoclopramide and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm) or the manufacturer's website to obtain the Medication Guide. Talk to your doctor about the risks of taking metoclopramide."

The FDA's medication guide also includes warnings about how Reglan can cause tardive dyskinesia. TD (as a result of Reglan) is most common in the elderly, especially elderly women.

Reglan Drug Timeline

- June 1985 – FDA approved metoclopramide – FDA approved metoclopramide for short-term use (less than 12 weeks).

- February 26, 2009 – FDA Press Release – "FDA Requires Boxed Warning and Risk Mitigation Strategy for Metoclopramide-Containing Drugs – Agency warns against chronic use of these products to treat gastrointestinal disorders"

- March 2009 – FDA's MedWatch Safety Alerts, March 2009 – FDA alert discussing boxed warning. Also, manufacturers must ensure that patients receive a medication guide with the drug risks each time they receive the medication from a pharmacy.

Prescribing Reglan

At the time of the FDA's decision to require a black box warning, more than 2 million Americans were taking metoclopramide drugs. Reglan was commonly prescribed for patients suffering from acid reflux, GERD (gastroesophageal disorders), and nausea. According to the FDA, metoclopramide is only recommended for short-term treatment (≤ 3 months) of gastrointestinal disorders.

However, many patients have taken Reglan for longer periods of time, increasing their risk of TD. In many cases, Reglan was a treatment option that

offered positive results in treating gastroesophageal problems, but it came with a serious risk. Reglan now carries a warning against frequent and long-term use, but this warning came too late for many people who now suffer from lasting side effects such as tardive dyskinesia. Older people, especially older women, and people who have been taking Reglan for a long time are most at risk for tardive dyskinesia.

Metoclopramide was even prescribed to women suffering from morning sickness. In a June 2009 article, MSNBC reported about a study in the New England Journal of Medicine that showed that metoclopramide could be prescribed to pregnant women suffering from morning sickness in the first trimester without causing harm to their babies. The drug was prescribed to pregnant women for short-term use and most women in the study only took the drug for 7 days.

Morning sickness is most common in the first trimester, but it can last throughout pregnancy for some women. Because morning sickness can last longer than the 12-week maximum that the FDA recommends in order to reduce the risk of TD, it seems misleading and inappropriate that the reports would not at least mention the FDA black box warning. The risks associated with long-term use of a drug should be discussed, or at least mentioned, when discussing a new use of a drug, especially to inform potential users of all possible risks.

Status of Reglan Litigation

Reglan has been prescribed to numerous patients since it was approved in 1985. And, according to the FDA, over 2 million Americans use metoclopramide. According to the drug makers, there have been over 20 years of Reglan litigation.

On June 3, 2009, the U.S. Judicial Panel on Multidistrict Litigation denied the plaintiffs request to consolidate the Reglan litigation during pretrial proceedings in a Multidistrict Litigation (MDL). This motion was filed by plaintiffs in 15 different Reglan lawsuits in 11 different district courts. The drug makers opposed the consolidation, citing that since the first Reglan case was filed in 1988, there have been more than 20 years of Reglan litigation, and 80% of those cases were resolved.

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The Panel determined that there was no single common defendant and most questions that remained were too complex or numerous to support consolidation, despite the cases involving the common factual issue about whether Reglan causes tardive dyskinesia.

In one of the Reglan cases, a woman from Arkansas alleges that she developed TD after taking Reglan for over a year. Her case alleges that she did not have access to the FDA's warnings. The lawsuit states that almost one-third of all patients taking Reglan took the drug for at least a year, increasing their risk for TD. These patients trusted their doctors to make informed and safe decisions about their medical treatment, and they also trusted the drug companies to test the drugs and provide information to patients so they could make informed decisions. Some of the lawsuits claim that the drug makers knew about the risk of tardive dyskinesia for decades. Unfortunately in the case of Reglan, the system seems to have let people down.

If you believe that you or a loved one suffered an injury after taking Reglan, we would honor the opportunity to speak with you. In certain situations, a lawsuit may be pursued against the drug manufacturer and the physician who was prescribing it at the time. As will all of our cases, we prosecute drug-related claims on a contingency basis-- clients never pay any expenses out of their pocket. (888) 424-5757.

Thank you to Heather Keil, J.D. for her assistance with this Nursing Homes Abuse Blog entry.

Sources:

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eMedicine: Tardive Dyskinesia

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National Institute of Neurological Disorders and Stroke: NINDS Tardive Dyskinesia Information Page

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