

**Gastroparesis and Dysmotilities
Association
GPDA**

www.gpda.net

Press Release

**Jeanne Keith-Ferris, RN, BScN
President/Founder**

FOR IMMEDIATE RELEASE: November 19, 2004

Washington, DC

FDA fallout with medications; will this women's digestive disease continue to be left in the lurch?

For anyone who is suffering from a life-threatening or debilitating chronic illness, good medications bring hope, relief from suffering, and a return to quality of life. In this setting, the risks of a medication's side effects may pale in comparison to one's severe, non-medically managed illness.

In the current environment of "blockbuster" drugs being pulled from the market, all eyes once again are on the FDA. The latest fallout will possibly mean a grinding down and slowing of new drug approvals for very needy diseases and may usher in an era of "hyper-caution" within the FDA.

Again, young women who are primarily afflicted with a poorly understood digestive disease will be caught in the ensuing mess at the FDA.

This digestive disease, called "gastroparesis", encompasses a family of poorly defined digestive diseases of impaired or weakened motor function within various regions of the digestive tract. Gastroparesis, or delayed gastric emptying, is the most common of these diseases, which represent mild to severe dysfunction of the upper digestive system and affect the "motility" or peristaltic action of the gut.

While gastroparesis is readily recognized in association with diabetics as another type of neuropathy affecting the stomach, what is not well known is that the largest group to be affected with gastroparesis is found in those who develop this digestive disease for unknown, or in medical terms, "idiopathic" reasons. Of these idiopathic cases, 70% to 80% are young women.

While a poorly recognized digestive disease that primarily affects women struggles to

find a place on our health-care radar screen for new drug developments, and patients anxious to get their hands on proven, safe, and effective drugs, the fear is that this digestive disease will be lost again in the current cacophony between congress, the FDA, the drug industry, and litigation.

When one mentions irritable bowel syndrome, it is quickly equated with women's health issues. And everyone is familiar with the digestive problems of heartburn with motility-like symptoms of bloating, nausea, abdominal discomfort and fullness after a few bites of food.

These commonly occurring motor problems of the digestive tract, irritable bowel syndrome, and dyspepsia are all in the same family of neurological dysfunctions of the digestive system.

While these neurological dysfunctions of the gut don't just end there, they can also progress to digestive failure. The patient group — mainly young women — who suffer from disorders of the upper digestive system, has been “invisible” and left out of the loop for serious research and development for new drugs. Three million Americans suffer from gastroparesis.

But the story gets worse. One hand is all it takes to count the medical treatments available for treating gastroparesis. Called prokinetic or pro-motility drugs, these medications enhance the emptying power of the stomach and help to relieve symptoms. All of the current medications used to treat this debilitating digestive disease have been borrowed from other medical uses.

One drug that was being developed by Janssen Pharmaceutical, and which this patient population could call its “own”, was domperidone or Motilium. This medication had received full approval by the FDA, only to have that approval overturned. No doubt the blow-up of another blockbuster drug, cisapride or Propulsid, may have had something to do with the eleventh-hour FDA denial of domperidone.

Domperidone, for those who respond to this medication, allows patients with gastroparesis to be able once again to eat and sleep because symptoms are effectively subdued. Without domperidone, patient's symptoms of nausea, vomiting and abdominal pain may escalate to the point of needing “enteral” nutrition to halt spiraling weight loss. This form of nutrition relies upon a tube placed from the outside of the abdomen, entering into the small intestine for liquid feedings.

Domperidone is approved worldwide and has been in use for patients with gastroparesis for over 20 years. It is safe and effective, but did not make the cut with the FDA. What does that leave? American patients have to rely upon three older drugs for the treatment of their gastroparesis, and the safety record of these drugs does not stack up to that of domperidone.

In June of this year, the FDA put out an “Import Alert” on domperidone warning of the cardiac hazards of this drug. Though top gastroenterologists around the world have used this drug for decades, leaders in gastroenterology report that they have never observed a cardiac problem with this medication. Many gastroenterologist experts are baffled by the FDA’s statement of cardiac risk regarding domperidone. Guilt by association to cisapride seems to be the issue.

Will Americans still be able to import for personal use their prescription domperidone? It all depends upon the FDA’s compliance division’s willingness to listen to rational arguments and to realize the seriousness of this women’s health problem that has largely been ignored.