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November 27, 2000

Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

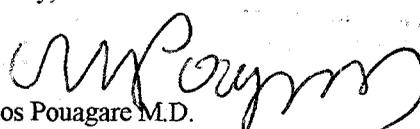
Dear Dr. Henney:

My name is Marios Pouagare. I am a Board-Certified Gastroenterologist with Digestive Specialists in Dayton, Ohio. I received my medical degree from the University of Miami in 1988. My Ph.D. is from the Department of Engineering, Pennsylvania State University, in 1984. I taught Aerospace and Mechanical Engineering at Duke University until I began medical school.

My intent in writing is to comment on my experience with the drug alosetron (Lotronex); specifically, how it has positively impacted the quality of life of my patients. Soon after alosetron became available for use, I began treatment in several female patients with diarrhea-predominant IBS. The large majority of those patients are doing extremely well with regard to reduced urgency and frequency of bowel movements and relief of their abdominal pain. More importantly, Lotronex has allowed those patients freedom to carry on their normal activities without the anxiety that often accompanies diarrhea-predominant IBS patients. Additionally, I have found Lotronex to be extremely efficacious with almost 90% of patients remaining on the drug throughout their therapy. I've had two patients that experienced constipation. In the first case, I decided to discontinue the use of the drug due to the intensity and severity of the constipation. In the second case I found value in reducing the dose of Lotronex as the constipation was of a more mild to moderate intensity. This particular patient continues to benefit from Lotronex, all be it at a reduced dose of 1mg q.d. I realize that this drug has received unfavorable publicity from the mainstream media regarding an unsubstantiated causal relationship of the drug with ischemic colitis as a side effect. In the several patients that I have treated with Lotronex I have yet to find one patient who has experienced ischemic colitis as a result of alosetron therapy.

It is my opinion that Lotronex, based upon my personal clinical experience, as well as my conversations with my peers who have used the drug and have had positive clinical outcomes, that solicitude for removal of the drug from the marketplace is unfounded in light of the significant patient population who are currently benefiting from its use.

Sincerely,


Marios Pouagare M.D.
Gastronenterologist, Digestive Specialists

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