

Perez, Thomas

From: Laura Bell
Sent: Tuesday, April 02, 2002 10:15 AM
To: pereztc@cdcr.fda.gov
Subject: Lotronex

I am writing to you because I will not be able to attend the FDA Advisory meeting scheduled for 4/23.

I have suffered from severe IBS -D for over 16 years. I have been to numerous physicians, had every GI test known to mankind, tried every treatment and medication, including therapy, all to no avail. My quality of life was so badly hurt by my IBS that I considered suicide on many occasions. The only thing that stopped me was the thought of my 2 sons growing up without a mother. Then, in March of 2000, my GI doctor, who happens to be the Chairman of GI at a very large and well known university, gave me a prescription for Lotronex. The effect was nothing short of miraculous. Gone was the constant lower abdomen pain, the cramps, spasms and uncontrollable diarrhea. I was able to live a normal life. I was able to go to my son's soccer games. I was able to go to work without major anxiety everyday. My husband and I were able to take a trip for the first time in many years. I began to enjoy life again and not view everyday as a major struggle just to get through. My family was so happy.

My doctor prescribed 2 pills per day. After about 3 days I became constipated. However, after suffering from diarrhea for so many years, I knew I was on the right track. I stopped the medication for 2 days and then started on a lower dose. I took 1/2 pill per day the rest of the time I had Lotronex and felt great.

The day Lotronex was taken off the market was one of the worst days of my life. I became severely depressed. After having lived like a normal human being, I was back to the torture of my pre-Lotronex life.

I am unable to attend the FDA meeting because of my IBS. However, I want the people there to understand how very debilitating IBS can be. Things you take for granted, like going to a park, going out to eat, taking a trip, or even just going to the market are very difficult for people like me. Lotronex changed all that. I was able to live like a normal human being.

My 25th wedding anniversary is coming up this Fall. My husband wants to take a trip tp celebrate. I want to be able to go. My son graduates from high school this Spring. I want to be able to go. Please, please understand what this drug means to people like me. It gave me back a life! No drug is entirely risk free. I took Lotronex for over a year with no ill effects other than constipation at a higher dose. One size does not fit all. The dosage needs to be regulated to fit the individual patient. Doctor's need to be educated as to the correct patients to get medications. Patients need to be given information as to possible side effects and what to look for. (I was given all the info from my doctor.)

I am sorry this email went on this long. This means so very much to me and others like me. Please keep this in mind.

Thank you

Laura G. Bell
Risk Manager