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March 11, 2002

Tom Perez M.P.H.
Center for Drug Evaluation and Research
Food and Drug Administration HFD-21
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Perez,

This letter is intended to add to your background knowledge about the drug, Lotronex, which will be discussed at a meeting on April 23, 2002. I have suffered from IBS-D for 50 years. It has affected my life so profoundly that the condition has to be called a disability. I have had medical care throughout my life; and I have had the tests, and tried the suggestions. It's no secret by now, that absolutely nothing worked until Lotronex became available.

Over the years, I have been to Internists, Gastroenterologists, Psychiatrists, and Allergists. Doctor's have prescribed medications for illnesses that I don't even have, just because one side effect of the medication is constipation! I have taken Phenobarbital in the 1960's, Librium and Meprobamates in the 1970's, and Tricyclics in the 1980's. I have taken Prozac, Busbar, and Valium for the anxiety caused by uncontrollable diarrhea and periodic incontinence; and the depression over the hopelessness and sadness caused by missing out on most of the things that other people can do. Of course, I have used starvation, Pepto Bismol, Kaopectate, Imodium, and Lomotil in huge quantities to try to "get through" certain occasions.

When I took my first Lotronex, I had absolutely immediate relief. All my life, my abdominal area has been in a constant state of turmoil. With one Lotronex, my digestive system quieted down, so that area of my body was no more noticeable to me than my arm or leg. It was so extraordinary that I felt as if someone else's body had been attached to my head. I never had one episode of diarrhea again! I just had NO idea that other people felt like that, because I had never felt normal in my life.

I had read the insert that came with Lotronex, and had talked to my doctor about the medication. After two or three days, it occurred to me that now that I was processing my food like normal people, I should eat like a normal person. I had no need to eliminate foods from my diet or fast when I had to go somewhere. I could now eat whole grains, a greater variety of vegetables, and raw fruits. Knowing that constipation could be a side effect of Lotronex use, I started eating a bran cereal for breakfast, an apple with my lunch and taking one teaspoon of Metamucil at night. In short, I started behaving like a normal 59 year old woman. The balance between a normal diet and Lotronex worked perfectly for me. The suggested dosage of one pill in the morning and one pill at night was just right.

When, in November of 2000, the drug was pulled, I cried. Frankly, I didn't know how I could go on. I was devastated. I was fortunate to be able to go out that day and pick up enough refills to last me for one year. The fact that it cost me all the money I had saved to have the house painted was never given a second thought. After about six months, I got worried about the day I would run out, and I tried taking a smaller amount in an effort to make my pills last longer. Within 36 hours, I was feeling as bad as I ever felt. There has been talk among some, that a lower dose is the answer. NO, that will not work for everyone.

A combination of good medical practice, and common sense is all that is needed. Not all people are alike. Lotronex is no different from any other medication. It has to be used by people who have the illness it was made to treat. The people using it have to be aware of how they feel and consult their doctor if they are not responding as expected. This medication is for people who cannot eat out anywhere/anytime, cannot have company or visit others, cannot belong to clubs, go to work, take vacations, do volunteer work, or even grocery shop without elaborate planning and intense anxiety. This medication is for people who have a big dark secret and have to let others think they are anti-social, unpredictable, and weird rather than to have anyone know the truth. Normalcy is available for us, please return Lotronex to the market.

Sincerely,
Lynn Owens