

20 November, 2000

Docket Management Branch  
Food and Drug Administration  
Dept. of HHS, Room 123  
12420 Parklawn Drive  
Rockville MD 20857

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Re: Docket # OOP-1499, (Remove Alosetron from the market)

Dear Madam/Sir,

I am writing to you to try to let you know how strongly I am against the removal of alosetron hydrochloride (Lotronex) from the market. I feel that my life without Lotronex will return to a hell that I am afraid I cannot adequately explain to you. But I must attempt that explanation.

I am 50 years old. I have been a registered dietitian for 27 years. I have worked for the [redacted] Health Department, as a public health nutritionist, for the last 14 years. I did not have a moment of gastro-intestinal problems in my life until I was 46 years old. Absolutely none. Then, at 46 years of age, I had a very major surgery on my right foot. Up until that point, I had had GI reactions to the anesthesia I had been exposed to during a childhood tonsillectomy, and to the one other surgery I had, on my left ankle. But after a few hours post op from those earlier surgeries, I had no problems. However, after the major surgery on my right foot, I was sent home with very strong pain medications, as my foot had been broken in 5 places, fused in 2 places, my arch rebuilt, and a very large bunion removed. For 30 days, I vomited and had severe reactions to the pain medications. Finally, I was removed from all meds and just screamed from pain when I needed to, until the foot healed, several months later.

After that I developed Irritable Bowel Syndrome. Since IBS is diagnosed through a diagnosis by exclusion, it took almost a year of tests, and 5 doctors, before it was a confident diagnosis. Many people think IBS is just diarrhea, so what's the big deal. Let me try to explain what happened to my life, my family, my marriage.

I would get sick 3-5 times a week. Getting sick with IBS for me, consists of GI cramping, diarrhea, and total body exhaustion. The cramping ranges from bad to childbirth levels. I am not exaggerating. I usually had to put a washcloth into my mouth when I was having the attack (as I call them), so as not to frighten my son or make my husband feel even more helpless listening to my screams. The diarrhea is the least of the problems, but it does mean I need to be near a toilet all the time. This is not so hard in some cities in the U.S. But it makes travel near to impossible. The third symptom, total body exhaustion and aching, often meant lying in bed for hours, to even a day. This affected my job, of course.

IBS is NOT just having to go to the toilet a few extra times a day. How I wish that were true. For me, it ruined much of my life for the last 5 years. Imagine how this affects your family. They live daily with the fear that their mother or wife will be violently ill at any time. Plans have to be changed all the time. This is especially hard for children to understand. It was so difficult for my husband to deal with this, for 4 years. It affected our communication, our sexual life, our free time together. Twice, we came close to separating. But I have a most wonderful spouse; we have gone to marital counseling several times around the affect this disease was having on the whole family. And we are struggling to keep our strong marriage, strong.

The financial cost has been enormous. In just the first year alone, there was one year of blood and stool tests, ultra sounds, upper and lower GI dye tests, and endoscopies, and more than 15 physician office visits. There have been anywhere from 6 to 10 physician visits a year since that first year. There have been the huge costs of lost work, counseling, and medications.

I received my medical care for IBS from [redacted] of the [redacted] Gastroenterology Clinic in [redacted]. His clinic was one of the trial sites for Lotronex. When I first met [redacted] he wanted to put me on Lotronex, which was into its second year of

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trials then. But in order to do that he would have had to randomize me, and take me off all medications for 6-8 weeks prior to beginning Lotronex. He felt that I was too ill to take such risks. It took him 1 1/2 years to find a combination of other medications that slowly helped me reduce the number of attacks from 15 a month to 3-5 a month. I had side affects from these medications, and finding the right dose for me was very difficult. The combination of medications raised my blood pressure and for the first time in my life I became hypertensive. I then had to go on a medication to reduce my blood pressure, after all my physicians (gastroenterologist, internist, and gynecologist) agreed I was too ill from the IBS to take me off the IBS medications, despite the moderate hypertension.

During these years [redacted] told me that I seemed to be the ideal candidate for Lotronex, given my pattern of symptoms and my health other than the IBS. He told me that he saw very positive responses in many patients to it. He promised me that if it was approved by the FDA, he would immediately notify me so I could begin taking it, while slowly tapering off my other medications.

As you know, Lotronex was approved for females with IBS that was predominantly diarrhea. On May 4, 2000 I began taking Lotronex. I was started with 1/4 the normal dose, and slowly titrated the dose up as the dose of my other IBS medications slowly was decreased. I went off the other medications and went on a full Lotronex dose in July, 2000. Since May 4, I have had an IBS attack 4 times. That is 4 times in 6 1/2 months! I cannot tell you what this has meant to me. I want to live now, every day. I feel I can cope with my problems now. It has returned normalcy to my marriage and family. Yes, we can now occasionally eat out at a restaurant (impossible for 4 years). And I can conceive of traveling for pleasure, once again.

Then I heard that the FDA is considering removing Lotronex from the market due to several deaths of people who were taking Lotronex. I know that deaths of people taking a drug is not synonymous with the drug causing the deaths. I also know that all medications (even aspirin) have side affects and that physicians must learn how to prescribe a particular medication carefully, and that patients must learn to recognize side affects and what to do about them.

Being in the public health nutrition field, I am extremely aware of the great role that the FDA plays in securing the safety of the public's food and medications. I understand and appreciate that responsibility. I never imagined I would be writing to you about a personal matter that seems to me at this moment to hold my very life in balance. There are no other good medications for IBS for me. I don't know what I will do without Lotronex. Life hardly seemed worth it to me, before Lotronex. Please, please, don't take it off the market. Do emphasize the importance of proper prescribing and dosing to physicians. Do make the public aware of potential dangers. But please, don't make me return to a very private hell.

Please feel free to contact me if you have any questions. I would fly from Seattle to Maryland with one hour notice if it would help my chances to continue to be able to take Lotronex. Thank you for your attention to this very personal matter.

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