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12/9/00

Commissioner Jane Henney, MD  
Dockets Management Branch  
FDA, Department of Health & Human Services  
Room 1-23  
12420 Park Lawn Drive  
Rockville, MD 20857

Dear Dr. Henney,

Please take just a few moments of your time to read my letter in its entirety.

Today I called my pharmacy to request a monthly refill of my prescription for Lotronex (developed and distributed by Glaxo Wellcome), and received with much shock and dismay the news that, under pressure from the FDA, the manufacturer of this medication had recalled the drug. I am quite literally stunned, and hope the thoughts I can gather here can convey my feelings. It is only my desperation that overrides my embarrassment to share this information with you.

One morning twelve years ago, as a healthy 33 year old woman, I got up, prepared to get ready for work, and with NO prior history of intestinal problems, began having uncontrollable, watery diarrhea. Twelve years later, at age 45, after innumerable doctors' visits, fecal tests, endoscopies, blood tests, medications, and many, many, many blank stares I was still getting up each day facing multiple bowel movements every day and always, volumunous amounts of watery diarrhea. And, no one can really tell you why. The professional medical community can give it a name--Inflammatory Bowel Syndrome--but they still can't tell you why. You face the day walking a tightrope between accepting your limitations and applying "mind over matter"; acceptance leaves you isolated--disassociated from family and friends, and overwhelmed with feelings of incompetence and anger, while the latter all too often leaves you in a situation of shame and humiliation. Over the years, I have had uncontrollable diarrhea while caught in the aisle waiting to exit an airplane, in a very crowded elevator in downtown Los Angeles, in my friend's car on a bumper-to-bumper freeway, in the supermarket checkout line, and in the middle of the shopping mall last Christmas. Many times I just do not eat any solid food the day before an "activity", but even this "plan" is inadequate. Food becomes your enemy. In the beginning when you have a "bad" experience, you cry alot. Later you just become very, very quiet.

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Three months ago I read an article about Lotronex and asked my doctor for a prescription. My life changed that day. This medication has been like a miracle for me. The last couple of months have given me a glimpse of what normal life is like--what life used to be like 12 years ago. Sometimes during the last couple of months I have even gotten greedy, and instead of just being so very grateful for this medication, I expressed thoughts of frustration that no one had developed a treatment for IBS sooner, and could have given me back the last 12 "lost" years. My punishment for being greedy is Lotronex being taken off the market and my future being snatched away almost as quickly as it was given.

I would request of you to please reconsider or review the concerns that prompted your original decision to make this medication unavailable. I do understand you are surely faced each day with decisions on treatments for far more serious diseases that hopelessly ravage the body; I ask you to understand that IBS leaves the body intact, but ravages the mind and spirit of the individual who suffers from it. Additional doctor supervision, additional warning labels, additional patient screening--make whatever restrictions are necessary, but please give those patients who may benefit from Lotronex a chance to be just normal.

Thank you for your time and attention.

Respectfully,

[Redacted signature block]