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Brenda F. Compton  
Lotronex Hearing  
April 23, 2002

I want you to go on a field trip with me, if you will. It is my son's sixth grade class trip to the Georgia State Capital in Atlanta. We board a bus in Flowery Branch, Georgia and begin the one-hour ride. Fifteen minutes into the trip with three other moms, two teachers and 43 excited eleven-year-olds the cramp hits my gut like a piercing knife. And the panic begins. I am soiling my pants.

Because this is a common occurrence, I have on my own version of a diaper and lined panties. I pray no one notices the odor. Our school bus arrives and pulls to the Capital steps. I have already made my way to the front so that I can get to the ladies room as inconspicuously as possible. I change. I hide ruined under pants among paper towels in the wastebasket. I try to regain my composure. I go back out to join my son and his group. And it all begins again.

This is a scene I have lived out virtually all of my adult life. Limiting my shopping and social life to places based on the convenience of the location of rest rooms. All the while knowing there will still be times when I can't get there in time. And I will sit and cry on a strange toilet seat.

After chewing anti-diareecheal tablets I emerge humiliated, hoping none of the people I ran past on the way in are still there. Then, when I'm convinced it can't get any worse, it does.

On June 25, 1998, I have emergency surgery to remove my ovaries due to the discovery of a grapefruit-size tumor believed to be malignant. And in a matter of two hours I go from no menopausal symptoms to post-menopausal trauma and depression.

The bouts with diarrhea come more often and more violent and I mean that in a literal sense of the word. I begin to lose weight at an alarming pace and drop from just over 100 pounds to 88 pounds. My physician, Dr. Brenda Kawalski performs every conceivable and invasive test to try to find a cause. But there is none. Her only conclusion is I have a disease called Irritable Bowl Syndrome. Meanwhile over the coming weeks and months, I continue to lose weight. The doctor orders a bone density scan because I have now reached 77 pounds with no body fat. She discovers my body is absorbing bone to simply stay alive. She thinks psychotherapy might help—just to cope, if for nothing else.

Then, on May 9, 2000, I go to my doctor for another visit. But this time there's hope. She tells me a new drug called Lotronex has just been released and she wants me to try it. I take my first tablet that afternoon. The diarrhea continues. The next day I take two more. And the diarrhea continues. But on the third day, it slows noticeably. And on May 12, it is gone.

Over the coming days, I deal with the fear that it will return. But it doesn't. My weight loss stops and in the months to come my husband begins to tease me about becoming fat. And my life is a new experience.

Then I remember seeing the morning news on November 28<sup>th</sup> but nothing else for the rest of the day. Lotronex had been pulled from the market and my world crumbled.

Is that overly dramatic? I don't think so. The availability of the only medication that had allowed me to live a normal life for seven wonderful months was gone. Today I take another drug prescribed by my doctor. Admittedly though not as frequently, the diarrhea still comes. And once again the humiliation and fear are back. Once again I prepare myself with liners and protective panties when I must go out. Once again I locate the ladies room in every shop, store or building I enter. And once again my self-esteem is in doubt.

So today I am before you as a wife, a mother, a grandmother and one of countless women who are robbed of life when the solution is as simple as giving us back Lotronex.

Thank you.

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Mark C. Klein

March 27, 2001

**TO WHOM IT MAY CONCERN:**

Re: Brenda Compton

Ms. Compton is a 54 year old patient of mine whom I have been caring for since June of 1998. She has a long history of irritable bowel syndrome. This causes chronic diarrhea. There is a strong element of anxiety associated with this and she has had a lot of issues to deal with over the past two years. Her weight has been very difficult to control and she has been down as low as 79 pounds at a height of 4'11". Her chief problem has been with persistent diarrhea. We have worked this up for any other causes and have not found anything over than her irritable bowel. She had been tried on various medications, but these were ineffective until the Lotronex came out. When she was started on the Lotronex, her symptoms improved dramatically. She has been well controlled on the Lotronex since she was started on this in ~~August~~ <sup>May</sup> of 2000. She has never had any adverse side symptoms or side effects related to the Lotronex. From a medical standpoint, I believe that this has been very beneficial to the patient as her weight has remained stable and her symptoms have been well controlled. The patient understands that this medication has been taken off the market at the recommendation of the FDA, however, given the fact that she has responded well to it with no adverse side effects she understands and accepts the risks that may be involved. We are requesting that the manufacturer and/or the FDA reconsider the reasons for pulling this drug off the market. Although we are aware that some people had adverse side effects to it there are also thousands of women who benefitted from this. We would, therefore, request that reconsideration be given to this medication.



Brenda C. Kowalske, M.D.

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