

Lotronex Action Group  
Corey Miller

Mr. Thomas H. Perez  
Office of Executive Programs  
5600 Fishers Lane  
HFD-21  
Building 5630, Room 1093  
Rockville, MD 20857

RE: Lotronex Public Advisory Committee Meeting - 4/23/02

April 3, 2002

Dear Mr. Perez:

I am a Co-founder and Coordinator of the Lotronex Action Group. Enclosed are the following items to be submitted as part of the public record for the Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Subcommittee of the Advisory Committee for Pharmaceutical Science (docket #12538 and #12539):

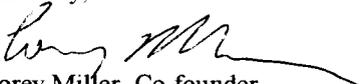
- 1. An open letter to the FDA from the Lotronex Action Group defining the characteristics of the typical person suffering from diarrhea predominant Irritable Bowel Syndrome.
- 2. A petition to the FDA from the LAG requesting permanent access to Lotronex.
- 3. A letter from Jackie Wood, Ph.D. to former Commissioner Jane Henney regarding denial of Lotronex to the populous.
- 4. A letter from U.S. Representative Lincoln Diaz-Balart to former Commissioner Jane Henney seeking restricted distribution of Lotronex.
- 5. Multiple letters of personal stories regarding positive results of the use of Lotronex from members of the Lotronex Action Group.

I have enclosed dozens of personal stories and letters from members of the LAG in support of the return of Lotronex. I have enclosed a large quantity of letters in contrast to your advice to submit only a few. Please understand that for many that suffer from this debilitating illness, this is their only voice. They cannot attend the meeting due to their physical condition, and it would be unthinkable for me, as their representative, to let them feel they have no way to take part in this process. While I am sure the advisory committee members will not read them all, I hope that some are reviewed.

As you know, I will be speaking during the public comment portion of the advisory committee meeting on behalf of the hundreds of members of the Lotronex Action Group. I look forward to the opportunity to let the patients voice be heard.

Thank you for help in this matter.

Sincerely,

  
Corey Miller, Co-founder  
Lotronex Action Group

Enclosures

3840 OPHI - 44 - MILLER

Lotronex Action Group  
ATTN: Mr. Corey Miller

**An Open Letter to the  
Food and Drug Administration**

May 21, 2001

To Whom It May Concern:

The Lotronex Action Group (LAG), a group of former users of the medicine Lotronex (alosetron hydrochloride), is deeply concerned about how perceptions of diarrhea-predominant Irritable Bowel Syndrome (IBS-D) may be affecting the Food and Drug Administration's consideration of risks and benefits related to use of Lotronex or other IBS-D treatments.

Although IBS-D is viewed as a non-fatal disease, its effects are often debilitating. The typical sufferer of IBS-D is a 40 year-old female with primary symptoms including daily explosive diarrhea attacks and severe daily abdominal discomfort. The most common secondary side effects include panic attacks, depression, withdrawal from social and family activities, severe disruption of daily activities, and malnutrition.

The typical IBS-D patient has suffered from the illness since early teenage years. The adverse impact of IBS-D on patient quality of life is dramatic, causing the typical sufferer to forgo many aspects of life that others take for granted. For example, some of our members have been forced to relinquish their social lives. Others have given up careers, and live as captives in their own homes. People fortunate enough to have met an understanding partner and to have children are often unable to attend family functions or participate in other common daily family activities. In many cases, this inability to lead a 'normal' life causes severe depression and suicidal thoughts. When IBS-D patients try to take part in daily activities, they are often subject to panic attacks when confronted by situations in which a restroom is not nearby, or suffer embarrassing 'accidents' of defecation.

IBS in general has been estimated to occur in 15-30% of the female population, and this illness is not uncommon in males. IBS generally occurs in two types: diarrhea predominant or constipation predominant. It also can occur at a variety of severity levels, ranging from general discomfort to debilitation. The Lotronex Action Group is comprised of women and men suffering from the most severe and debilitating symptoms of IBS. Many of us have found Lotronex to be the only effectively treatment for IBS-D, enabling many patients to assume normal adult lives for the first time.

The widely held view from those not suffering from the illness is that IBS-D is not life threatening, and is only an inconvenience. The Lotronex Action Group firmly believes this view is misconceived and erroneous. The illness is debilitating, as described above, for a large proportion of sufferers. 'Zero' risk tolerance is not an appropriate regulatory perspective for Lotronex or any other effective treatment for IBS-D.

All medicines have some level of risk. Current unavailability of Lotronex leaves many patients with no satisfactory treatment option. Some turn to other prescription medicines not suited for the illness, while others abuse over-the-counter medicines like Pepto-Bismol and Immodium with serious potential adverse consequences.

The members of the Lotronex Action Group are prepared to accept risks related to use of Lotronex or other effective treatments for IBS-D. We are also prepared to participate in programs to better characterize risks related to use of Lotronex or other treatments, and to work with the FDA to reduce those risks to the extent possible. We request that you reexamine and redefine the severity of IBS-D and the level of risk that is tolerable for an effective treatment for this debilitating condition. IBS-D, while not directly deadly, can be life threatening and causes severe damage to the quality of the lives of the sick and their families.

Sincerely,

The Lotronex Action Group

Maria Zargo, Coordinator  
Corey Miller, Coordinator  
Tom Bell, Coordinator

In Partnership with the IBSGroup

Jeffrey Roberts, President

**(About the LAG: The Lotronex Action Group is comprised of former users of Lotronex and has no affiliation with nor receives any funding from any pharmaceutical company or other organization.)**

# LOTRONEX ACTION GROUP

www.lotronexactiongroup.org • lotronexactiongroup@yahoo.com

March 21, 2001

Dr. Bernard Schwetz D.V.M, Ph.D.  
Acting Principal Deputy Commissioner,  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Schwetz:

The Lotronex Action Group, an international organization representing former users of the drug alosetron (Lotronex, GlaxoSmithKline), hereby petitions the Food and Drug Administration (FDA), pursuant to the Federal Food, Drug and Cosmetic Act 21, U.S.C. Section 355(e)(3), and 21 C.F.R. 10.30, to immediately work with the manufacturer GlaxoSmithKline to permanently provide access and safe distribution of the drug to those diagnosed with diarrhea-predominant Irritable Bowel Syndrome.

The Lotronex Action Group believes the drug to be safe, if dispensed properly, and that the benefits of Lotronex far outweigh the potential risk for adverse side effects. [1]

## Safety

We have utilized the data from a survey conducted by the Irritable Bowel Syndrome Self Help Group by former and current Lotronex users. [2]

The results re: side effects from taking Lotronex:

Constipation (123)	25%
Diarrhea (10)	2%
Ischemic Colitis (4)	1%
Nausea (13)	3%
Abdominal Discomfort - Pain (29)	6%
Sleep Disorder (3)	1%
Other (15)	3%
None (288)	59%
Total Selections = 485	

**DrugVoice conducted research with over 2,000 IBS patients, many of who were former Lotronex users [3]. Research revealed a large number of users who experienced life-changing benefits from Lotronex. Others, however either did not benefit or experienced side effects that forced them to discontinue the medication or reduce their dosage. These results indicate that an important need for Lotronex exists, but that it is critical to monitor and target its use to the appropriate patient population.**

### **Conclusions**

**Symptoms of diarrhea-predominant IBS include urgent and explosive bowel movements, abdominal cramping, gas and nausea. Research suggests that IBS is one of the most common functional GI disorders. But although IBS is not a life-threatening disease, it can severely diminish a person's quality of life.**

**Members of the Lotronex Action Group, along with many other IBS sufferers, have reported a complete cessation of their IBS symptoms while taking Lotronex. The Lotronex Action Group acknowledges that Lotronex has not helped everyone and that some who took the medication experienced side effects. However, it is the strong belief of the Lotronex Action Group that Lotronex is safe if dispensed properly, with benefits far outweighing the potential risk for adverse side affects.**

**The FDA will have best served patients with diarrhea-predominant Irritable Sydrome by working with the manufacturer GlaxoSmithKline to permanently provide access and safe distribution of this drug.**

### **ENVIRONMENTAL IMPACT STATEMENT**

**Nothing requested in this petition will have an impact on the environment.**

### **CERTIFICATION**

**We certify that, to the best of our knowledge and belief, this petition includes all information and views on which this petition relies, and that it includes representative data and information known to the petitioners, which are unfavorable to the petition.**

Yours sincerely,



Corey Miller  
Coordinator  
cmiller@carlsonsolutions.com

Tom R. Bell, Psy.D.  
Coordinator  
trbell@home.com

Jeffrey Roberts  
Coordinator  
jeffrey-roberts@ibsgroup.org

Lotronex Action Group

Email: [lotronexactiongroup@yahoo.com](mailto:lotronexactiongroup@yahoo.com)  
URL: <http://www.lotronexactiongroup.org>

[1] Supported electronic petition with 1,105 signatures at [www.lotronexactiongroup.org](http://www.lotronexactiongroup.org) (03/21/01)

[2] An non-profit Internet self help health site about Irritable Bowel Syndrome [www.ibsgroup.org](http://www.ibsgroup.org) and [www.IBSwatch.com](http://www.IBSwatch.com) (12/00-03/01)

[3] A consumer research and strategic advisory firm [www.DrugVoice.com](http://www.DrugVoice.com) (06/00-12/00)

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November 6, 2000

Jane Henney, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Henney:

My name is Jackie D. Wood. My title is Professor of Physiology & Cell Biology and Internal Medicine in the College of Medicine and Public Health of The Ohio State University. I served as Chair of the Department of Physiology in the University of Nevada School of Medicine from '79 to '85 and Chair of the Department of Physiology at Ohio State from '85 to '97. My Ph.D. is from the Department of Physiology and Biophysics, University of Illinois, Urbana in 1969. I was the first to record nerve impulses from single neurons in the enteric nervous system and this became the topic for my dissertation. My entire career has been oriented to investigation of the neurophysiology of the enteric nervous system. I coined the tongue-in-cheek expression, brain-in-the-gut in one of my 143 peer-reviewed publications on the enteric nervous system. My research on the enteric nervous system has been funded continuously by no less than two grants from the NIH each year since 1971.

I was enlisted as a consultant by the GlaxoWellcome Company for the development of their drug alosetron (Lotronex) because alosetron is a highly selective antagonist for the 5-hydroxytryptamine 5-HT<sub>3</sub> receptor subtype and my laboratory group was the first to report in 1979 the excitatory actions of 5-HT on impulse firing in enteric neurons.

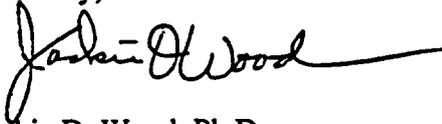
My purpose in writing is to comment on the adverse publicity the drug has received in the popular press as a result of an unproven connection of the drug with ischemic colitis as a side effect. We know precisely how the drug works as an enteric neuromodulator. Both secretomotor neurons in the intestinal submucous plexus and spinal sensory afferents from both small and large bowel express excitatory 5-HT<sub>3</sub> receptors. The receptors at these sites are exposed to relatively high levels of 5-HT following its release from enterochromaffin cells in the mucosa and certain inflammatory/immune cells. Alosetron, like other selective 5-HT<sub>3</sub> blocking drugs presently on the market, acts to suppress the action of 5-HT at these sites. This action at secretomotor neurons accounts for efficacy in the treatment of diarrhea. Action at the 5-HT<sub>3</sub> receptors on spinal afferents accounts for efficacy in treatment of abdominal pain

and discomfort. Alosetron is more effective than other 5-HT<sub>3</sub> antagonists because it binds more tightly to the receptor and is therefore effective in lower doses with a longer pharmacokinetic half-life.

Alosetron is the only drug presently available with proven efficacy in the treatment of the diarrhea predominant form of the irritable bowel syndrome in women. My concern is that the drug is in danger of being removed from the market based on unfounded contention that ischemic colitis can result from its actions in the gut. Ischemic colitis is a large vessel disease associated with a number of systemic vascular conditions (eg., clotting disorders and atherosclerosis). We know very well the mechanism of action of alosetron in the gut. The actions are neural at the level of the enteric nervous system – there is no evidence for any actions on the intestinal vasculature. The primary side effect of alosetron is constipation, that can result from blocking the excitatory action of 5-HT on the secretomotor innervation of the intestinal crypts. My colleagues in gastroenterology and primary care generally agree that the constipation is a readily manageable event if it should occur in their patients.

Given that we know of no scientific basis for the drug to produce intestinal ischemia and based on the positive outcomes of the clinical trials, as well as a growing body of anecdotal accounts of efficacy, my opinion is that consideration for denial of access to the drug for a significant patient population is unjustified.

Sincerely,

A handwritten signature in cursive script that reads "Jackie D. Wood". The signature is written in black ink and is positioned above the typed name.

Jackie D. Wood, Ph.D.  
Professor of Physiology & Cell Biology  
And Professor of Internal Medicine  
Chairman Emeritus, Department of Physiology

LINCOLN DIAZ-BALART  
21ST DISTRICT, FLORIDA  
COMMITTEE ON  
RULES  
VICE CHAIRMAN,  
SUBCOMMITTEE ON  
RULES AND ORGANIZATION  
OF THE HOUSE  
COMMITTEE ON  
INTERNATIONAL RELATIONS  
(SENIORITY RETAINED)



PLEASE REPLY TO:  
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WASHINGTON, DC 20515-0921  
(202) 225-4211  
DISTRICT OFFICE:  
 8825 N.W. 53RD TERRACE  
SUITE 102  
MIAMI, FL 33166  
(305) 470-8665

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515-0921  
December 18, 2000

The Honorable Jane E. Henney, MD  
Commissioner  
Food and Drug Administration  
The Parklawn Building, RM: 14-71  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Commissioner:

A very urgent matter has been brought to my attention, which requires FDA review as soon as possible. Specifically, I write to request your assistance in permitting restricted drug distribution of the medication "Lotronex." This action is critically necessary for patients currently on the medication who have reaped the health benefits of this treatment.

It is my understanding that the Glaxo Wellcome Corporation recently chose to withdraw Lotronex from the market. I have also been informed that this action was taken following a determination by the FDA that the drug's adverse effects merited one of two options: marketing withdrawal or a restricted drug distribution program.

Constituents of mine whom I represent from the 21<sup>st</sup> Congressional District have written to me and have informed me that their family has experienced the miraculous benefits of this medication in connection with their son's treatment. Their son has suffered from Irritable Bowel Syndrome for most of his 30 years, but never as severely as in the last five years. His parents inform me that before being placed on the medication, he suffered chronic diarrhea attacks, severe and unhealthy weight loss, and almost complete social withdrawal. After taking Lotronex for six months, he was able to resume a normal diet and a normal schedule of activities.

**The Honorable Jane E. Henney**  
**December 18, 2000**  
**Page Two**

Consistent with all applicable laws and regulations, I respectfully request your assistance in urgently recommending restricted distribution of Lotronex to ensure that patients experiencing the drug's positive effects can lead normal lives. Please do not hesitate to contact my Washington office at (202) 225-4211 should you have any questions or concerns regarding this request. Thank you in advance for your expeditious consideration of this request.

Cordially,



Lincoln Diaz-Balart

I am a 68yr old male attorney in Columbus Ohio. Started having IBS problems in the early '60's. The gastroenterologist who did my physicals then, said "get out from under the stress and it will go away". Attitude was it was all caused by stress. Several years later with a bout of hemerroids, the family M.D. prescribed Lomotil to reduced the D. One pill a day was OK, then in 10 years it was up to two pills twice a day. I began noticing trouble with certain foods in the 70's such as stilton or blue cheese (mold) lettuce, wine (metabisulfates) etc. After increasing the lomotil to 8 pills a day I could see that I needed some other help, so went on line and found Dr. Michael Camilleri at Mayo Clinic, Rochester, Minn. who agreed to take me on as a patient. In October '99 he did a complete physical, including colonoscopy, and concluded that I had IBS-D as previously indicated by other MD's. He was doing a third level FDA program on aleosetron (lotronex). What they were looking for was colon motility, or how fast does food go through the colon. These studies were done over a six week period, and the conclusion was that lotronex slows down the passage of food through the colon. I was given a precription for Zofran which I took from Nov.99 to March 2000 when the lotronex became available. I had absolutely no adverse reactions to lotronex at 2 pills per day. Now I, like others, am cutting them in half and taking 1/2 pill per day.

Prior to this, when in jury trials as an attorney, I frequently packed clean underwear in my briefcase. Often I had to excuse myself from office clients, and still occasionally have to cancel clientrts.

Socially, I have been embarrassed many times in restaurants (imagine taking your fiancee to a 5 star restaurant in Cincinnati, and having explosive D), on the golf course ( explosive D on the 4th or 5th hole with no bathroom and only tree leaves to clean yourself) or out sailing (at least I could jump in the water to get clean).

In addition, the attacks of explosive D cannot be attributed to what was most recently eaten unless I was dumb enough to eat onions. These attacks are always folllowed by exhaustion, tiredness or an inability to continue what I was doing until the next day. The attacks also led to prolapsed bowl, more hemerroids, and more visits to the doctor. In my case, with tests and MRI's I was able to rule out H-pylori, lactose intolerance, gall bladder, or other internal organ involvement.

As I get older. I find that there are more and more foods that I am sensitive to which create IBS-D reactions, which can occur in the middle of the night as well as during the day with no onset indications.

June 24, 2001

Corey Miller

My name is \_\_\_\_\_ and I am a 49 year old male and had IBS for over 40 yrs until Lotronex came along. I have a 15 year old daughter that I could finally take to the movies and she talked me into going to Times Square. (We live in Brooklyn, NY) I had not been there in over 20 years. It was one of the best days of my life I do not drive so I take the subway all the time to work. There used to be bathrooms on the subways but they had to close them many years ago because of the crime. Every morning when my alarm clock would go off a feeling of terror and dread used to come over me because of having to deal with my IBS.

Lotronex changed not just my life but also my wife's and my daughters. When my daughter was young I would not take her anywhere with me because I was afraid if I had to run to the bathroom what would I do with her? I was afraid to leave her by herself if I took her to the park. However, Lotronex changed all that. I gained about 20 pounds, which was great. Now I am afraid that I am going to go back to the way I was before. I have about 2 weeks supply left, which I am taking sparingly. I have work for the NYC Department of Environmental Protection (I'm a civil servant) for 16 years and I'm on probation and was penalized 4 days pay because I was out over 100 days last year because of IBS. If I'm out more than 3 days without pay they will fire me. They tried to fire me or force me on disability. The week before the hearing I started taking Lotronex and I started to make it to work every day, my job is a 1 hour ride on the subway without any bathrooms around.

At times I had to resort to wearing Depends, that is an extremely humbling experience. Thank God that I never had to make use of one that I was wearing, its just like having a security blanket. I feel better leaving in the morning if I am having problems getting out of the house, sometimes the fear of not finding a bathroom is like a snow ball effect and that makes the attack worse.

I do not understand why they said Lotronex only works for women.

I actually sent e-mail on the web with my name and address saying that if anyone has any Lotronex that they are not going to use to send it to me anonymously. I think that it is illegal to do that but I do not care.

We all should have hope now knowing that someone found the right ingredients that work for IBS. I pray a lot and I know that He will pull us through.

Have faith we will all get through this.

*This one I wrote in March 2001:*

I lost almost 20 lb. since I wrote that letter. I had finally gained and weighed 155 lb. which was perfect for me I felt great.

Someone read my letter that was printed in the NY TIMES newspaper found out my phone number called me and sent me 32 Lotronex pills that they had and did not need. I'm rationing them my dose was 2 pills a day I take a half now and then, I need to take the full dose of 2 pills a day for it to make a real difference. My doctor has me on Prozac which works similar but on the brain Lotronex worked directly on the intestines. I'm saving them, my wife has to go into the hospital to have Retina surgery to try and restore her eye sight. She did all the driving I don't drive I never could go for the road test because of my IBS. There is a lot I missed out on in the past and when I started taking Lotronex I could not believe how good I felt to feel like a normal human being. I never new what that was like.

***Today is June 24, 2001:***

I am on medical leave from my job because of my IBS-D return. I was hoping to be back at work for the ~~NY City Dept Environ~~ on by the end of this month. I was hoping that Lotronex would be available to us by then but it does not look like it. It looks like I will have to request another months medical leave.

—

I have suffered from severe, chronic IBS-D for approximately 15 years. My story is very much like that of others in our group. The pain, explosive, unpredictable diarrhea destroyed the quality of my life and that of my family. I cannot count the times I was unable to go to my children's activities, had to make excuses at work for not being able to attend meetings, trips, etc. Going out socially is never fun - it is filled with anxiety and panic. Simple things like going to a movie, out to eat are impossible. The depression at times is crushing. I have tried every available therapy - medical and psychological. I have taken numerous drugs, many not prescribed for IBS in attempts to find relief. I have had just about every GI test known to mankind. Nothing helped!

Then came Lotronex. At first, I became very constipated on the recommended dose of 2 pills per day. But, for someone with uncontrollable diarrhea to be constipated - well I knew I was on the right track. With my GI doctor's knowledge, I cut my dose down to ½ pill per day. The results were remarkable. I felt like a normal person. I began to have a life. The quality of my life improved dramatically. I was able to be in a car for more than 15 minutes without panicking. I went out to eat. I took a 2 hour drive with my family. I was more confident at work. I was able to be more social with friends and family. The cloud of depression was lifting.

I want and need my life back! I want to be able to sit through my son's college graduation in 2 years. I want to take a trip with my husband. It is not fair that we finally had something and then it is taken away. No drug is risk free. Let informed patients and physicians decide what is appropriate for individual patients.

Please bring Lotronex back. I can't face a lifetime of this agony.

No, it's not cancer, heart disease or Alzheimer's. It's not "life-threatening" they say. It's "all in your head" or "you're suffering from depression." What am I referring to? You probably already know because I'm aware of the numerous letters you've been receiving regarding IBS and, more specifically, the Lotronex issue. I know this is just "one more letter" for you, but **please** hear my plight. It may sound identical to the last letter you've just read, all the more reason why this is so important for you to try and understand my/our view.

I'm a 41 year-old female. I have a wonderful husband and a bright, beautiful seven-year old son. Life has been good to us for the most part, nothing major to complain about. I have, however, suffered from IBS for many years (started in my 20's). Although I had consulted with a gastroenterologist early on, I managed to live with my IBS (alternating diarrhea/constipation) without medication. I completed college, had a career and a life that was better than most. One year ago in April, I had to have my gallbladder removed. Unfortunately, an inherited family disease – just about everyone including aunts and uncles has had theirs removed. I was not spared. I thought that my digestive problems were over when this happened only to realize that my IBS symptoms had worsened tremendously. I would wake up in the morning only to have to "run" to the restroom. This would go on throughout the day no matter what I ate. I'm sure you've had some bouts of abdominal incontinence in your past. Can you just imagine what it's like to experience this misery eight or ten times per day? Let me tell you what it feels like. You have now gone from being a productive, full-time working mother (I held a human resources position in the corporate office of a world-renowned organization) a loving wife, likable friend and positive contributor to society - to a highly anxious, depressed and housebound individual. I can no longer make short trips to the grocery store without first making sure that I've spotted the location of the restroom and take extra precautions not to eat anything beforehand. This, of course, is only possible if I'm not too exhausted to leave the house that day at all, let alone take care of my family.

The bottom line is, Lotronex has been the only drug out there, prescription or non, that has given me my life back and my peace of mind. I've been on tranquilizers for months – sedating but does nothing for the IBS. As soon as I eat something, the problem returns with a vengeance. I've tried antidepressants which make me feel even worse, both physically and mentally (just irritates the bowels even more and causes more anxiety – a vicious cycle). I've tried other medications as well with no improvement. Lotronex calms the bowels down and regulates the digestive system better. My anxiety subsided immediately once this medication became effective. I couldn't believe the difference. I was now able to eat foods I haven't been able to eat for years – healthy fibrous foods, vegetables, etc. I was now getting the proper nutrients. It actually felt good to become constipated for one day, and the fiber took care of that problem. I was able to "function" again. What a relief! I wasn't crazy after all!

It is my firm belief that those individuals who ran into problems with this drug either were not diagnosed properly (I had a colonoscopy to verify IBS), already had ischemic colitis or constipation problems, were taking other medications that may have interfered with it or, **most importantly, were taking too much.** From the very beginning I explained that the two tablets per day might just be too strong for some people. I took only one half tablet per day, which was plenty to keep me diarrhea free. The dosage should be adjusted accordingly to how each patient reacts to it. I don't believe that a 5'3", 140lb. individual should take the same dosage as a 6'0, 200lb. individual. The key here is to work with your doctor in explaining these things early on and adjusting the dosage. If one is having severe constipation problems even with the smallest dosage, then the patient and doctor should have the common sense to stop the drug. This should not be a "one size fits all" scenario. Those of us who are benefiting from this medication (and I've been on it since July, 2000 with absolutely no problems) should not be penalized for those who should not be taking it to begin with. I'm still taking it because I have a small amount left and will continue to take it until it runs out. I cried the day I heard it was taken off the market, and I will probably be hysterical when my supply runs out.

M.

## My Story

I am a 59 year old woman who has been having recurrent bouts of severe diarrhea for over nine years. At first, it was rather like having the 24-hour stomach flu for a week, but it gradually got worse and worse. The episodes of frequent (20-30 times a day) and painful explosive diarrhea were truly frightening and, of course, completely life limiting. My primary care physician sent me to a gastroenterologist who seemed to have no idea whatsoever about what was going on with me. His method of "diagnosis" was to guess that I had one condition, treat me for that, and when I got no better or got worse, he would try another "diagnosis" and "treatment." I had blood tests until my arms looked like I had been mainlining heroin, I took innumerable specimens to the lab (when I could leave the house), and tried dozens of medications, diets, stress reducing regimens, etc. etc. While all of this was going on I was, of course, on an emotional roller-coaster between hope and despair. About the only bright spot in all of this was that I had a colonoscopy and was reassured that I did not have colon cancer.

After about two years of this, I had what I can only call a spontaneous remission. I suddenly stopped being symptomatic, stopped taking all medication and was fine for about three years. Then suddenly the symptoms reappeared. This time I went to a different GI specialist. She scheduled me for another colonoscopy. This one showed no signs of ulcerative colitis (or cancer), but the biopsy did reveal that I had collagenous colitis.

I was prescribed a very high dose of prednisone which stopped the diarrhea. However, I did suffer many other side-effects since this is by no means a benign drug. My blood pressure shot up, I had bouts of tachycardia, I developed acute insomnia, my osteoporosis quickly got worse, and I developed glaucoma. These are some of the short-term effects. Long term, I can expect liver and kidney damage. With my doctor's supervision, after the initial high (30 mgs/day) dosage, I started to decrease the dosage to keep all these side-effects to a minimum. Once I got to a certain level (about 15 mgs/day of prednisone) the diarrhea returned.

This was when my GI doctor prescribed Lotronex even though I was not an IBS patient. Within a week I was having normal bowel movements. For the first time in three YEARS!! I was able to get my life back and function as a relatively normal human being. For the seven months that I was on Lotronex I experienced no side-effects whatsoever although I was carefully educated and monitored by both my doctor and my pharmacist as to what to be aware of. We gradually reduced my dosage to 1 mg/day.

Then came the recall. I was devastated. I got the news at the pharmacy and burst into tears. I had some Lotronex stockpiled and my doctor gave me samples that she had left. I reduced my dosage to 1 mg/3 days thinking that that way I could make it to maybe August. Apparently, the dosage was too low because at the end of February I started with the diarrhea again and have been virtually housebound ever since. I was so sick on the 20<sup>th</sup> of March that I had to stay home from my grandson's 5<sup>th</sup> birthday party. I called my GI doctor and reluctantly we have started me back on high dosages of prednisone which has slowed the frequency of diarrhea, but has not eliminated it entirely. I am still taking prednisone and trying to slowly wean myself off it. I am afraid that when I get to a certain point, the frequency of the diarrhea will come back. I do not know where to turn.

I am furious that something that was helping me so much has been pulled from the market because of side-effects. It is okay for me to poison myself on a daily basis with prednisone, though? It does not make any sense and I am continually trying to explain this to myself. It is MY body and I am willing to take whatever risks that are entailed with Lotronex. I have had to take an early retirement because of my condition and, like I have said, there are days when I do not dare leave the house. There are days when I do not make it to the toilet from my bed. Indeed, it is a descent into hell.

June 26, 2001

Corey Miller

Apparently my bouts with 'gastritis' while attending college were the beginnings of IBS. Of course, that was not known to me at the time. And this was the one case where ignorance was bliss! Do you think I wanted to know at the age of 20 that I would be hit by this debillitating condition that would have NO REMEDIES ? I mean at age 20 I figured family health history of breast cancer and heart attacks would be what ailed me....here I am in my 50's living with IBS.

In the early days of these symptoms, the doctors were saying it was stress and/or poor diet. They were wrong - DEAD WRONG. When I was on lotronex I was under the same amount of stress I have always had AND ate all the foods I had previously cut out of my life and I HAD NO IBS SYMPTOMS! How is that for a research study!

If you expect my story to include the daily abdominal pain and cramping, diarrhea, fecal incontinence, embarrassment and pure hell that all the others have written about - you are DEAD RIGHT! The symptoms are not the issue - the people who suffer from them are. IBS is and has been a known, legitimate condition. Until Lotronex came along what we did not know is how to manage it. From March thru November of 2000 I left my house with out a care in the world. I no longer had to plan my trips via every rest room between point A and point B. I did not have to take along extra clothing in case I did not find a rest room in time. I could go out with my husband - anywhere - anytime and leave the fear and pain behind. Pre-lotronex I could not eat one morsel of food if I had to leave the house for the simplest of tasks like going to the grocery store or picking up the dry cleaning...One morsel of food - ANY food and I was a prisoner in my own bath room...some days I could not eat until late evening, when I knew I could stay home and close to the bathroom. I could not even make a dental appointment 3 or 4 weeks in advance like they wanted me to do...how would I know what kind of a day I would be having in 3 or 4 weeks? I found a part time job where I could work a certain amount of hours each week and I could pick the hours and was able to work it in - around the IBS flare-ups.

I had always envisioned that after my children were grown, I would have time for myself and my projects and a little travel as well. That was when the IBS got the worst and still is. Now I have no plans. The cruel removal of Lotronex cancelled all plans for a future. And why? That is the burning question. What REALLY prompted its removal? The benefits of Lotronex far outweigh the risks. Any educated human being can find the data that supports this finding. I can only sit in my home and wonder what might have been - and how I might have been able to make a difference in this society by working fulltime somewhere. Now my God-given talents are wasted...and by whose authority?

I watch the TV commercials for Imodium and the taxi driver who "gotta go" and see some of the stigma of bathroom talk eroding and that is a good thing. Perhaps now we can continue the 'bathroom talk' and get the sufferers out of there and into mainstream America. This is a real condition and it has a REAL solution-Lotronex.

I hope and pray I can walk down the aisle on my daughter's wedding day..but without Lotronex  
who can predict what kind of an IBS day I will have?!!!!-

June 24, 2001

Corey Miller

I am a 51 year old woman and have been diagnosed with IBS since I was 13 years old. Lately the episodes have gotten longer and the pain has gotten worse. I was getting the runs and severe pain and going to the bathroom at least 10 times a day. Going anywhere in a car was impossible. The motion of the car had a laxative effect on me. I know every bathroom in my area. The use of public bathrooms has not always been pleasant. They are usually dirty and I don't like going to the bathroom when the possibility of someone walking in and listening to me moan and groan is embarrassing to say the least.

Since my IBS effects me mostly in the morning, I don't eat breakfast out which is my favorite meal to eat out and I can't plan long car trips. I must give myself a minimum of 2 hours to prepare before I go anywhere.

My Gastroenterologist has tried many types of medications to help. LOTRONEX was my only salvation! It stopped the urgency, the pain and the diarrhea. I had no reaction to this medication and went into a state of panic when I was told I could not get this medication anymore.

My doctor agrees with this statement that Lotronex worked for me and also wants it back on the market.

Please give us back the medication that has worked for so many.

Thank you,

I am a 35 year old female -- a mother of 2 young children. I was diagnosed with IBS 2 1/2 years ago -- I have no idea how this disease found me, although my grandmother has had it for over 50 years. She was told countless times that it was in her head, housewife stress; all the physicians had a very cavalier attitude toward her symptoms. My grandmother is now almost 94 and still has IBS, but also has alzheimer's - the only benefit is that has taken away the shame of incontinence and frequent urgency because she cannot remember what happened 5 minutes ago.

I was confused, embarrassed, ashamed and frightened when IBS slowly descended into my life and gradually over 6 months got worse and worse. I was told more than once by primary care physicians that there was nothing wrong with me. They did test for parasites, occult blood, nothing showed up out of the ordinary. Only when we changed health insurances and consequently changed doctors did I get some human response from a Dr. who, after thoroughly checking me over and confirming that I have never had a constipatory reaction with IBS, he then talked to me about Lotronex. I tried it immediately, making sure on a daily basis that I was not constipated. Finally, for the first time in almost 3 years I felt better, normal, and had my energy back. I could do things with my family again. I was not in pain. My quiet anxiety was gone. And, very importantly: this disease was not in my head. Sometimes you don't realize how awful you feel, until those symptoms have been removed. And that is just what Lotronex did. Lotronex allowed me to successfully live my life for 5 months with absolutely no adverse effects. Upon hearing of the withdrawal of Lotronex, I felt so incredibly depressed. Currently, I have been dealing with the diarrhea using Imodium and Caltrate daily, but nothing takes away the stomach ache pain and the nausea. I have a standard rule: never EVER eat anything in the morning, until at least 11:00 or 12:00. And I am very careful about what I eat. Yet I often am in a lot of pain and discomfort and have to decline invitations to go out to anywhere and am often late. It is such an embarrassing and shameful invisible disease, it would be very easy to become severely depressed, but I am scraping by -- waiting for Lotronex or another medication similar to Lotronex to again be available. I am very aware of all the risks of Lotronex -- and I would go back on it again in a New York Minute. In this age of up and coming medications, there are so many out there for every affliction - you cannot turn on the television without seeing a multitude of advertisements for all kinds of medication. They all have adverse effects - some more serious than others. If some man wants more energy in his sex life, he can have his viagra - adverse reactions be damned. I just want to live. I want to be able to leave my house. I want my life back.

I am a 40-year-old female that has struggled with IBS for many years. I have always been a "bathroom person", having to run to the bathroom at the drop of a hat. My IBS has gotten worse over the past few years as I've gotten older. I tried various medications and a controlled diet, but nothing worked. I became so sick last spring that I could hardly function in my daily life. The constant bowl movements, gas and daily nauseous feeling really took a toll on me. I was missing many days of work, couldn't go to the grocery store, exercise or even socialize. I was calling my gastrologist almost everyday crying on the phone asking him to please help me. He gave me some samples of Lotronex and within a week I felt NORMAL! I was so happy and very excited to feel so good. I was having regular bowl movements, I no longer felt nauseous and I could eat anything I wanted. I finally had my life back thanks to Lotronex!

When Lotronex was pulled from the market, I was very devastated! I thought how can this happen, I finally found something that works for my IBS. I am one of the lucky ones who have some Lotronex left. I use it very sparely and I'm experiencing IBS symptoms due to the low dose I'm currently taking. I'm becoming increasingly nervous as each day passes, as the FDA and GSK have not resolved the Lotronex issue. I fear for my future and quality of life if Lotronex is not brought back. I'm afraid I will lose my job if I don't have access to Lotronex and I won't know how I will pay my bills and save for retirement.

Please listen to my plea and help put Lotronex back on the market; it truly is a miracle drug!

Regards,

I am a 37 year old female with IBS. I didn't know that term when I was

6, I just knew that I was sick alot. I can still remember my mother massaging my belly while I was on the toilet, crying with terrible abdominal pain. She was a nurse, very caring, telling me that it would all be over soon. Now, I find myself helping my 6 year old the same way. This "syndrome" is not just debilitating to the victim, but it is hereditary. The first time I went to a Gastroenterologist about my problem I remember him saying, " I can't help who your parents are". He sees many patients with this problem and believes it is highly hereditary. I can vouch for that, because I can see the same symptoms in my daughter, and my father suffers from IBS.

I could go on forever about how IBS has affected my life with my husband, my children, my social life. All have suffered tremendously, and I wonder now how different my life would be if I never had to worry about going to the bathroom. I have had the embarrassing episodes of going in my car on the way to work, "sorry boss, but I got in an accident". You can't say I had a bathroom accident in my car! I am now retired at age 37. I couldn't take it anymore. My children try to understand when I can't go on their field trips. My husband tries to understand when we have to decline an invitation to go out. My freinds try to understand when I decline an invitation to have a girls night out. But the reality is I wish I could do all of these things.

When Lotronex was released I truly led a normal life. I went on the field trips, I went out with my husband and friends - I didn't even care if we had to ride in a car with another couple. I had no fear of an attack. That is the POINT. With Lotronex the fear went away. I knew nothing would happen!! I can still take Immodium and Lomotil, but only after an attack starts - this does not help my problem. I find myself always waiting for the next attack to occur. The other night I was woken up by pains that can only be compared to labor (and I know- I have 3 children). I had terrible diarrhea for hours - laying on the bathroom floor praying to God to stop the pain. This is not a life!!

How can anyone justify removing a drug that takes away this agony from so many people? My life is not at risk. I do not have cancer. But I am alive. I am suffering. I deserve the chance at having a normal productive life where I can work, be a mother to my children and a good wife. Please let me have that chance. Bring Lotronex back!

Lotronex was a Godsend for me. I had suffered from symptoms of IBS for five years when it went on the market. My IBS didn't cause pain too often. Mine often produced violent, explosive episodes of diarrhea, which altered my life drastically. I would usually have to stop at a bathroom during my 20-minute drive to work. Often I would have to leave work or not even show up due to my bouts of diarrhea. Many days I was captive in my house because I dared not leave the security of having a bathroom close and available.

No drug or combination of drugs ever affected my symptoms. The only way I could be certain I would have no bouts of diarrhea was to not eat. Frequently I would not eat for four days if I knew an event was upcoming that I needed to attend. If there was no food in my system, I couldn't have diarrhea.

Lotronex changed all that. My body reacted quickly to the drug. Within a couple months, I was so "normal" that I had renewed confidence and began really living my life again, becoming involved in many activities that were unthinkable prior to Lotronex. My quality of life is dependent upon Lotronex. Without it, I am not really living; I am merely working my way from bathroom to bathroom.

June 29, 2001

Corey Miller

My name is \_\_\_\_\_ and I have been suffering from IBS all my life. It started out as "nervous diarrhea", meaning that whenever I was nervous, even as a small child, about performance of any kind (a test in school, piano recitals, church talks) I had diarrhea. This situation continued throughout my childhood and became worse as I reached adolescence and started menstruating. I always knew when my period was to start because I had horrible abdominal cramping and severe diarrhea the day before and during my entire cycle. Over the years I learned that certain foods made the situation even worse, but I also learned that even if I ate NOTHING, I still had horrible cramping and diarrhea.

Despite this nasty condition I was able to have a wonderful, productive life: I attended college on a vocal performance scholarship (in spite of terrible diarrhea before each vocal performance) and graduated with a degree in History. I sang in a prestigious university choir that competed nationally and internationally. I served a Mormon mission to Rome, Italy for 18 months in the late 1970s. I went to graduate school at UCLA and received a Master's degree in history. I eventually married a wonderful man and moved with him to Washington, D.C., where we each had jobs—he with an accounting firm and I with the federal government as a political analyst. I did all these exciting things while suffering with undiagnosed IBS-D.

Soon after I started working in Washington, my condition took a definite turn for the worse: I had almost continual cramping, diarrhea and nausea and began experiencing horrendous migraine headaches right after the diarrhea. I saw an internist who referred me to a gastroenterologist who gave me a battery of tests (ruling out parasites) and then gave me a colonoscopy, which thankfully came up "normal." This led to my official diagnosis of Irritable Bowel Syndrome in 1984. I had many deeply embarrassing experiences with IBS while at work; one in particular stands out in my mind. I was scheduled to give a briefing to several top U.S. policymakers on an intelligence-gathering trip I had taken to the Mediterranean area. Of course I was nervous and I tried to prepare by taking recommended medications such as Lomotil and Bentyl. I was about 10 minutes into the briefing when I got that old familiar, unmistakable feeling that I needed to leave and leave NOW! I arose, looked at my watch, asked the policymakers who were there to hear ME to please excuse me a moment, and RAN to the ladies' room where I remained for 45 minutes.

When you have a bad "IBS moment," you experience horrible abdominal cramping, profuse sweating, chills, violent shaking, and headache to the point that sometimes you're unable to even stay on the toilet seat—you must lie on the bathroom floor until you have the strength to get up, clean yourself up, and try to return to your desk. Fortunately my boss was a fellow-IBS sufferer and she was able to cover for me for the duration of the briefing. However, these episodes continued at work and at home in spite of any preemptive measures I tried to take. Work became a living hell, as I had to plot out a course between home and the office which provided a restroom at about 10-minute interval. I kept this up for four years until I decided I just couldn't take it anymore. I also had my first child during this time. I looked into several career options and determined that a career in academe would be more flexible than a regular 8-5 job, and I decided to look into a Ph.D. program in history. I applied to Georgetown University in 1989 and was offered a fellowship for that fall, which meant that I was to take a full load of coursework and was also responsible for teaching an undergraduate course as part of my fellowship requirements. Once again, I did all this with the burden of IBS-D; often I had to speedily exit from classes where I was a student as well as the classes that I was teaching. Gratefully my students (and professors) were very understanding and my work didn't suffer greatly. I was able to finish my coursework successfully and had great reviews from my students, but once again it was all clouded over by IBS.

My husband's work transferred the family to the Chicago area in 1991, and I saw this as a great opportunity to be a stay-at-home mom and forget about trying to work fulltime. I was also starting research for my dissertation and was attempting to have a second child. My daughter was born in 1992,

and my IBS-D worsened noticeably shortly thereafter. When my daughter was 2 years old, I became an adjunct faculty member at a college 90 minutes away and tried to teach one lower-level history class. While I love being in the classroom--and frankly I have a gift for teaching--I found that the 90-minute commute in busy Chicago traffic with the spectre of DIARRHEA constantly hanging over my head proved nearly unbearable. Once again, I had to plot my commute according to where all the public restrooms were, not necessarily the quickest or most direct route to the college. Once again, my students were very understanding when I got that old, familiar feeling and had to unexpectedly leave my own lecture for an unspecified time so I could run to the restroom. I have always tried to live as normal a life as possible, to show that IBS wouldn't be the controlling factor of my life, but this disease takes its toll over time and I finally gave up trying to hold down any kind of job in 1994. Fortunately my husband's salary is enough for us to live on, but my training as an analyst, historian and educator, as well as my experience as a semi-professional singer in several choral groups (in Washington, Chicago and Minneapolis) makes it devastating to have IBS come in and ruin my entire life as it has.

And I haven't even begun to talk about the effects of IBS on my family: how many times have my children had to walk themselves to the busstop because I've been too ill to accompany them? How many school programs and performances have I had to miss because of IBS? The look of disappointment and heartbreak on their faces because of this damnable disease is almost more than I can bear. It may not be technically life-threatening, but it is life-altering for the WORST. It is completely out of anyone's control: no matter what you eat, when you eat, where you eat, no matter how meticulous or careful you might be, IBS has a mind and life and will of its own and will act up when it damn well pleases. It is a disgusting, filthy, depleting, embarrassing, draining, depressing illness, and I resent it with all my soul. I resent that it has robbed me of my former life, that it has robbed my husband of the wife he married, that it has robbed my children of a functional mother.

I very much appreciate your consideration of my letter. I enjoyed a semblance of a normal life last year when I began taking Lotronex. I appreciate the concerns of those who regulate prescription medications and for the care they have for the public's safety and well-being. I suffered some ill side-effects when I first began taking Lotronex (such as severe constipation) but after working closely with my gastroenterologist I was able to find a "good" dosage and benefitted greatly. I was even able to volunteer at my children's schools and to teach two history classes at Marymount University. However, since the withdrawal of Lotronex I find that not only has IBS in all its monstrous implications returned, but all my feelings of depression, futility, fear and panic about IBS have returned as well. I agree that any and all medications need to be carefully monitored by patients and their doctors, especially in the initial phases of treatment. I respectfully request that you carefully consider returning Lotronex to those of us who benefitted so greatly from it, and do it sooner than later. The quality of life--not only for us IBS sufferers, but for all those whom we love and with whom we live and work--is at stake here.

Thank you again.

Sincerely yours,

June 29, 2001

Corey Miller

I have contacted Dr. Woodcock, Dr. Raczowski, GlaxoSmithKline and others to express my support for placing Lotronex back on the market. Based on news accounts which suggest the FDA and Glaxo may not allow this drug back on the market, I thought I should share with you my family's personal experience with IBS to illustrate the great need for this drug and its beneficial effects for sufferers.

My son is a 22 year old college student at a top university. For reasons we may never understand, he developed IBS at college and has suffered from it for the last several years. He is a good student. He is socially involved and has held multiple offices in his fraternity, including president. Nonetheless, his IBS has gotten to the point where he is reluctant to go places and pursue opportunities because he may have an immediate need for a restroom. My son is frequently invited to out of town events and conferences based on his position in the fraternity. He feels he cannot go because of IBS. He was selected as one of the top students in his program and invited to go to France to study. He similarly felt he could not go. He is one semester from graduation and is now hesitant about finding a job because of the same restroom proximity requirements. IBS is limiting my talented, friendly, and popular son's life. Without Lotronex, I fear it may ultimately transform this wonderful, social person into a virtual recluse.

My son has been back and forth to doctors. No cause for his IBS was found and none of the multiple medications prescribed was effective. That is, until our doctor prescribed Lotronex for him. My son described Lotronex as a near miracle cure. He said he took one tablet a day or every other day and he virtually never had diarrhea again. He stopped worrying so much about needing a bathroom and even went to Spain. Then Lotronex was taken off the market. He is now suffering from the same restricted lifestyle I described above.

As I hope our story illustrates, some people have a great need for this drug. It allows them to do the things we take for granted like having a job, going across town to a store or restaurant, and traveling. I am an attorney and understand product liability concerns. With respect to these concerns, I believe the disabling nature of IBS provides the sufficient balance to warrant availability of Lotronex despite the potential risks. Just as we as a society accept the risks associated with drugs for many life threatening or impairing conditions, so should we as a society accept the risks associated with Lotronex to treat IBS. Due to its severely disabling nature, IBS should not be treated any differently than any other drug prescribed for serious conditions, particularly if there is nothing comparable available. Furthermore, as a mother, I am certainly concerned about the side effects a drug may have on my child. In the case of Lotronex, however, I believe the drug is safe if prescribed to the right patients with adequate patient education (e.g. that the doctor should be immediately contacted if constipation or other symptoms develop)

In conclusion, I respectfully request the FDA take all steps necessary to support and encourage Glaxo to put Lotronex back on the market. Thank you for your consideration.

Sincerely,

June 30, 2001

Corey Miller

To Whom It May Concern:

I am 29 Years old & have been suffering with IBS - D since age 15. I have one of the worst cases of it seen in my area. I am 5'5 and have weighed about 100 lbs. all my life. I cannot keep food in me for more than 30 min. without passing it out. Before Lotronex I was on Levbid...I even passed the PILLS out whole! My doctors gave me Lotronex when it came out. I had it the day they got the samples. I started taking it in April & stopped taking it in mid-May (Yes, I stocked up on them in fear of the market withdrawal)

Lotronex turned my life around. I actually had a life. I wasn't running bathroom to bathroom. I wasn't scared to go places in fear of having an accident. And the pain...let's not even go there! Since the day I started Lotronex it has worked wonders for me. I went from being sick 15 + times a day to never. I never had ONE problem on Lotronex. Not a pain, not a cramp, no urgency..nothing! I gained 15 lbs. in the first (2) months! I felt great! It had no side effects like all the other drug concoctions I've been on.

I was first prescribed 2 Lotronex's a day. That constipated me. I then consulted my doctor AS INSTRUCTED who told me to stop taking them & once I gained 'normalcy' to take 1 pill a day instead (cut the pill in half) AS SHE WAS INSTRUCTED. I believe that if Lotronex was introduced in .05 mgs. per pill instead of 1mg. & patients started at a minimum dosage of (.05 mgs) daily...there would have never been a problem. I think we would all be a bunch of happy Lotronex takers. I believe that they over estimated the power of this drug. I went from taking 4 Levbids daily (1000 mgs) to taking .05 mg of Lotronex daily (sometimes 1 mg daily when highly stressed). What a mg. difference.

I BEG OF YOU to PLEASE give me my life back...PLEASE re-release Lotronex! I have been on: Librax, Levbid, Buspar, Bentyl, & now Remeron. I do not suffer from depression or anxiety but Remeron blocks the same receptors. It works about 60 - 70 % of the time. All these drugs have terrible side effects...believe me I know. They range from sleepiness, dryness, sexual dysfunction, chemical dependency, memory loss, create kidney stones & form crystals in your urinary tracts, nervousness, & the list goes on.

PLEASE do not give up on Lotronex. It is such a wonderful drug for millions of people. I don't know if you can imagine yourself taking a bottle of X-Lax per day & functioning. But if you could imagine taking X-Lax...while working, playing with your kids, going on vacation, driving from here to there, etc. You would understand the struggles we must go through daily. There are people out there that couldn't even attend their college graduations this year in fear that they may have to get up & go. That is how dysfunctional our lives are. Our lives do not revolve around our families or our loved ones ...they revolve around a toilet. I'm not kidding either.

I hope that you do everything in your power to re-release Lotronex (& quickly). I hope that I shed some light on what a typical day is like for us. I hope that you find it in your heart to help us continue to fight for this drug. I cannot stress how important this is for millions of people like myself. Without it our "lives are down the toilet", literally.

If you have any questions please feel free to contact me.

Thank You For Your Time,

June 26, 2001

Corey Miller

My "personal story" and position regarding Lotronex is best summarized in the following letter to Dr. John Senior:

Dear Dr. Senior:

I understand that you are involved with the decision whether to return Lotronex to the market. I ask you to give proper consideration to the profound, life-altering, suffering of those, such as myself, with severe IBS-D, and the lack of any effective alternative treatment. How often, in the course of our lives, do we have the opportunity to bring relief to hundreds-of-thousands of individuals who suffer from a debilitating, chronic, disease? We presently have that opportunity - we have to allow those suffering from IBS-D to have access to Lotronex. I urge you to do everything in your power to make this happen.

The initial decision to remove Lotronex from the market failed to recognize the severity with which IBS patients' lives can be impacted. Being house-bound, or struggling during every outing may not be fatal, but has a strong impact on quality-of-life. Drugs for other non-fatal conditions, such as sexual dysfunction, are allowed to remain on the market in spite of known risks, due to quality-of-life benefits. The same should hold true for Lotronex.

I am a 43 year old male who has suffered from severe IBS-D since age 9. Although the severity of my illness has varied, it has had a profound impact on my life. There have been spans of many years where I've had to refrain from ALL activity other than that which was essential to survival. Simple activities, such as grocery shopping, or getting a hair-cut are traumatic. Even though I've lived close to work, commuting with IBS has been torture. I've tried all forms of treatment, including extensive psychotherapy, relaxation therapy and medication and have found, at best, modest improvement.

Lotronex has been the ONLY effective therapy for my IBS. Since my Lotronex supply has been depleted, I've encountered difficulties that threaten both my home life and my career. My frustration is compounded knowing the medication I need exists, and is only unavailable due to considerable mis-information regarding IBS.

You have, quite properly, made known the potential dangers of Lotronex, however, I beg you to leave the risk/benefit assesment of Lotronex to well informed patients and their physicians. Personally, given the choice of living 20 years as a free man or 40 years in prison, I would choose freedom. Please allow me to make that choice.

Thank you for your consideration,

June 28, 2001

Corey Miller

I was officially diagnosed with Irritable Bowel Syndrome in February of 1993. Since that time, I have undergone multiple tests (Sigmoidoscopy, Lower GI, Upper GI and Lactose Intolerance Test) to confirm this diagnosis. Bowel disorders are common in my family as a brother and cousin have Crohn's disease and 2 cousins have IBS. Needless to say, I was happy not to have Crohn's, but I still find it difficult living with IBS.

"Living" with IBS is a bit of an oxymoron. When you have IBS you are never able to truly "live". You are always concerned about where bathrooms are located, whether you will be doubled over with excruciating pain and whether or not you will have to explain your situation to others around you. The thought of going on vacation and traveling away from home causes me such anxiety that I hardly ever do it. Going away for a week to the New England School of Banking as I did 5 years ago was a monumental decision. Not because of the impact it had on my career, but because I took a chance that my stomach would not cause me trauma. As it was, my stomach got more attention from me than the curriculum did. Going to the graduation ceremony at the end of the week I was popping Immodium and praying that the pain would subside.

This is but a brief example of how IBS has affected my life. I deal on a daily basis with the "status" of my stomach. This, in turn, determines what I can do during the day. Will I be able to make it to work on time? Or, once I get there, will I be in the bathroom 5-6 times (on average)? Can I go to the gym and exercise, or should I just stay home? Shopping at the mall? Well...how close are the bathrooms? Maybe it's better not to go.

The average person cannot imagine what it is like to always be thinking ahead in terms of what you eat. If I eat some popcorn I better not be going anywhere the next day. Salad for lunch? No way. Can't eat fresh vegetables unless I plan to be at home later on and want to deal with the cramps and diarrhea. It becomes easiest to just eat bland foods. This, however, does not result in a balanced diet. Consequently, I have other health related issues.

June 5, 2000, was one of the most memorable days of my life. That was the day I began taking Lotronex. For me, taking 2 pills a day was too much. After discussing it with my gastroenterologist, I began taking 1/2 to 1 pill a day, only after having a bowel movement. This prevented any problems with constipation. The pain was gone along with the anxiety I used to experience. I went on vacation to Prince Edward Island and Charleston, SC. I made 4 trips home to Virginia via airplane without any problems. Movies, shopping, early morning meetings, etc, were finally not a problem.

November 29, 2000, was also a memorable day. I received a phone call from a dear friend who told me that Lotronex had been pulled from the market. I instantly called in a refill prescription to my pharmacist. He filled it this one last time. I began hoarding my pills and taking only 1/2 a pill every other day.

May 29, 2001, was the last day I took Lotronex. I have gone back to being an

anxious person who is constantly thinking about the condition of my stomach. I've had a few "attacks" and have had to pull out the Immodium (which has been untouched since before the Lotronex).

For myself and the millions of other IBS sufferers who have had their lives restored due to Lotronex, I BEG the FDA and GlaxoSmithKline to quickly reach an agreement regarding the return of Lotronex. You have an obligation to those of us who are suffering to return a medication that allows us to live full lives as you do. To do otherwise would be discriminating against 15-20% of the American population. Allow us to have the freedom that you all so easily enjoy.

Sincerely,

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June 28, 2001

Corey Miller

To Whom it May Concern:

It has been over 30 years since I was diagnosed with IBS as a teenager in 1970. Since that time, I have tried a variety of medications to help, including Elavil, Lomotil, Xanax, Immodium, Bentyl, Librax, Belladonna, to name a few. My symptoms have been controlled, but with constant diarrhea which had never abated. These symptoms affected my work, family, and social life.

ENTER LOTRONEX. When I was tried on Lotronex last year, it was nothing short of a miracle. The constant growling, urgency, pain, and diarrhea were magically stopped. I noticed that I enjoyed eating, socializing, even working again.

You can imagine my chagrin when I heard that Lotronex was taken off the market by Glaxo. Since that time, I immediately switched to a low dose (one-half pill daily), and have continued to have good results. This has been the best year of my IBS life, for sure.

My Lotronex is almost gone. I am dreading the thought of returning to life before Lotronex. Naturally, I have begun working to help restore this amazing product to those of us who have had their lives changed by it. Through contact on the Internet with the Lotronex Action Group, I have written numerous letters and E-mails toward restoring this product.

I would be glad to give whatever information would be helpful to you.

Sincerely,

June 28, 2001

Corey Miller

To Whom It May Concern:

I am 34 years old and have been suffering from IBS-D since I was 12 years old, although I did not know what it was at the time. When I was in school, I can remember having frequent bouts of IBS in the morning and dreading getting on the school bus. Fortunately, my family lived on a dead end street where the bus would turn around before stopping at my house so I had access to a bathroom until just before the bus arrived. While riding on the bus, I would often be distracted by the pain IBS would cause and unable to interact with my friends on the bus. During my school years I would fight my urge to have a bowel movement to avoid using the school restrooms. Because of the pain and the urgency, I frequently had to be excused to go the restroom. My teachers did not understand what I was going through and frequent visits to the restroom were unwelcome. The frequent visits to the restroom were embarrassing, but even worse, the boys restroom stalls did not have doors. The pain was difficult and came in cycles, but if I made it to lunch I was usually okay for the rest of the day.

As I got older, my IBS symptoms worsened, and I became increasingly aware of the whereabouts of restrooms and did not want to go anywhere unless I knew where they would be. I used to regularly attend church, but by the time I was attending college, I stopped going because of the embarrassment of frequently leaving Sunday school class or church service to go to the restroom. As my symptoms worsened, I sought help from several gastroenterologists and went through a battery of tests including an upper GI, lower GI, and a flexible sigmoidoscopy. I was diagnosed as having IBS and now had a name for my condition, however, I had no effective treatment. My doctors had me try increasing my fiber intake and taking medications that included Bentyl, Librax, Levsin, Zolof, Paxil, and others. Nothing seemed to work. One doctor simply stated that IBS was a condition that I would eventually grow out of.

Meanwhile, IBS significantly affected my life socially, academically, and professionally. At college I tried to schedule classes in the afternoon, because my worst attacks occurred in the morning. For one class I had to ask to be excused for making a presentation because of the close relationship of stress to my condition and my fear of embarrassment. While an intern I had to travel from Atlanta to the Florida panhandle. I don't know how many times I stopped to find a restroom. At least I was traveling by myself. It was worse traveling with friends, asking to stop frequently to use the restroom and explaining myself, "My stomach is not feeling very well today."

As time went on, my condition worsened, and I began finding ways to avoid my problem. I avoided going with my friends anywhere I was not confident a restroom would be nearby. I began to become amazed at occupations of those who were ordinarily without access to a restroom, such as policemen, bus drivers, couriers, etc. I could not imagine having any

occupation that was inflexible about taken a restroom break. A friend of the family's suggested an occupation as an air traffic controller. With my IBS, I would have been putting lives in danger by not being able to focus all of my attention to the required tasks. This occupation was out of the question.

Fortunately my education was engineering and I have been able to keep to a flexible schedule. My IBS, however, has still affected me professionally. I avoid early morning meetings and lunches with colleagues because of my problem. Travel is absolutely a nightmare, whether it is by automobile or plane. I have missed a flight because of IBS attacks, and many times I have been late arriving to my destination by automobile because of frequent stops along the way. Once, I had to be excused from jury duty because I could not make the trip on the transit system from the suburbs to downtown.

At its worse, my drive to work is excruciating. While living in Atlanta, getting caught in traffic during an IBS attack is excruciatingly painful and dangerous. The pain and urgency is unbearable and draining. Redirection of my attention from the road to control of my bowels was dangerous. Maintaining the proper priorities under an attack is difficult when the only thing you think about is how to make the pain go away. Relief is either a bathroom or an extremely undesirable alternative.

Last year, my wife and I welcomed a baby boy to our family. At the time of his birth, I was taking Lotronex. This miracle drug made it possible for me to be with my wife during his birth. Through September to February I had a normal life as an adult for the first time and was not afraid to travel, go to lunch, or even breakfast. I did not have the pain anymore, and I was thoroughly enjoying my life with my family. All of this ended in February when my supply of Lotronex was depleted.

Since that time, I have had to make frequent stops on my way to work, on one occasion pulling off of the interstate to use a wooded area as a restroom. I also came very close to missing a flight when traveling for work. I came close to missing a visit to a children's park with my son, nephew, and niece. Although we made it to the park, when there I had an IBS attack.

I do not want to miss out on life's experiences with my son and my wife. I need to have control of my life so that I can take care of and enjoy my family. Only Lotronex has given me this, but it was taken away. Please give Lotronex back to me so that my son can have a Dad, my wife can have a husband, and I can have a life.

Sincerely,

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June 28, 2001

Corey Miller

In 1997 I woke up one morning with severe diarrhea, cramping, etc. It continued for over 3 weeks. It seemed to clear up briefly and then unexpectedly reoccurred approximately 1 month later. It seemed that I had contracted some type of parasite or bacteria but none was found. Previous to this, I had virtually no bowel/stomach problems. Weeks turned into 3 months and I was becoming progressively weaker, thinner and sicker. I had a colonoscopy and endoscopy with nothing found. Again they tested for parasites, bacteria, etc., none was found. I had food allergy tests run with only a few found. My doctors became increasingly alarmed in that I had lost over 30 lbs in appx 3 months. The endless trials of anticholinergics and then antidepressants were pretty much useless. One pill Remeron helped slightly with the anxiety and depression that began once this beast of a sickness took hold. Months turned into a year and I requested a laproscopy. Once my doctors agreed, they found adhesions wrapped around my intestines (they were not endometrial) and were completely dumbfounded regarding where they came from. The surgery helped slightly but not much.

The illness had severely limited my life due to the mind numbing pain and cramping that I lived with on a daily basis. Nothing really worked, as in cured me, until the Lotronex. I got my life back. I can pretty much eat what I want, when I want it. I've have slowly tapered from 2 a day to ½ a day, Half the month (when I'm ovulating and menstruating) I don't need the drug at all. I have tried to completely stop the drug with poor results. For the first 15 days of my cycle I'm sick daily. It's only in the last half that I'm okay. So, you see I still really need the drug.

I have been very careful with the drug and have had virtually no side effects. It is a hell of a lot easier to take than antidepressants, anticholinergics and pain killers, with far less of a grind to my body. My life truly was a living hell when I was sick. Many days I could barely work. I slept through entire weekends zoned out on pain killers. I wasn't good for anyone or anything. I'm far more healthy and productive now. I fully understand the risks (however small I feel they are) to Lotronex and still choose to take it. I will be running out soon and need the drug to be re-released.

I realize that many feel that IBS is not life threatening, however, I feel it is. Many folks become so depressed that they take their own lives. In addition, the multitude of drugs that I was taking couldn't be good in the long run for my liver, kidneys, etc. I strongly urge the FDA, Glaxo and Janet Woodcock to work out some type of limited use provision if they will not blanketly release the drug. There are many of us who have used the drug in excess of a year and are fine. There seems to be a very low risk for us who have been using the drug. Please honor my request and the request of the support group to put lotronex back on the market. Thank you.

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June 28, 2001

Corey Miller

My story starts back in 1999. I was helping a friend get through a tough time in her life. It was so frustrating to watch someone's life get so disrupted by their own body. Soon after she began to get back on her feet again, I started to develop stomach problems. At first I thought it was a stomach virus, but as the months wore on I realized it was something more. I had a constant pain in my side, I was bloated, crampy, and always belching. At first I thought, I'll figure this out and move on with my life, but I soon realized my body would become my own worst enemy.

My personal life looked perfect, a loving husband, 2 wonderful children, a beautiful house and a good job, but for some reason I was feeling like I was losing control. My body began to react by having constant diarrhea. Soon the diarrhea was taking over my life. My primary care physician ordered various tests and referred me to a gastroenterologist at Beth Israel in Boston. From blood work to the most abrasive, a colonoscopy, every test came back negative. While undergoing all these tests I was still trying to lead a normal life which proved to be almost impossible. My son was having trouble at school, I would be constantly crying saying, why me? Why is this happening to me? The worst guilt was feeling like I wasn't there for my family, but I knew I had to find out what was wrong with my body.

As the months dragged on and every test came back negative, I started to lose weight and patience. I started to have panic attacks, endless nights of sleeplessness and absenteeism from work. Every meal I ate would be gone within 15 minutes of digestion. I started to have "accidents" at work, always carrying around a spare pair of clothes. I kept a food log, I changed my diet, I tried homeopathic medicines, I saw a nutritionist, I joined a gym because I heard that exercise was good for "nervous" people. Nothing worked. My total weight loss was 20 lbs. (I was only 127 to begin with). It was at this time, I was put on an anti-depressant medication. While this soon relieved the panic attacks, it did nothing for the diarrhea. Oh how I actually wanted a test to come back positive for something, anything that would explain this, but no such luck.

I was probably 5 months into this nightmare, when I had a discussion with my gastroenterologist. She had just come back from a medical conference and was introduced to this new drug called Lotronex. She decided I was the perfect candidate for this drug. All I had to do was wait 2 more weeks until the drug came on the market. I was so excited to finally see some light at the end of the tunnel!

I started taking Lotronex and within 4 weeks I started to see improvement. I was no longer crampy, I started to eat more than just bread and rice. I kept saying to my husband, can it be true, am I finally getting better?? I couldn't believe the dramatic difference. Within a month I was gaining weight, eating and starting to feel like I could go out in public again. I could actually workout at the gym and not have to rush to the bathroom, I started to eat at restaurants again, (this was something that was out of the question for 6+ months). For the first time in months, my body was "regular" again. My social life started to come back because I finally felt "safe" to go out into public.

For 9 months, life was good, but then that all changed in December. While recovering from gall bladder surgery, I got a call from my gastroenterologist. The news couldn't have come at a worse time. She informed me that Lotronex was being pulled from the market. I immediately burst into tears on the phone with her, saying how can that be? Who would do such a cruel thing? But the news was true. My hope was that although I would have to stop taking the medication, maybe my body would have cured itself somehow. Maybe by just being on the anti-depressant medication, that would be enough for my body to continue to be normal. No such luck.

Within 5 weeks, I was back to square one.

As I'm writing this letter to you, I am brought back to a time in my life that actually hurts to think about. My husband and children are what carried me through this dark time in my life. I have learned to live with IBS but not without frustration and anger. I live off of Imodium, and find myself taking it more frequently than before. I am back to having "accidents", and at 32 years old, is this something I should have to worry about? I try and put things in perspective now. I try and think, well there are people worse off than me, if this is my biggest problem then I guess I shouldn't complain! Some days its hard to be an optimist. I can't help but feel sorry for myself and the other people who suffer like I do.

Lotronex was THE ONLY thing that helped me. I was able to function as a normal person and forget that I had a debilitating disease. Now I am reminded daily that I no longer have Lotronex in my life. I still have my last empty blue pill bottle. For some reason I can't throw it away. I hope someday I can replace it with a full bottle. I, along with every Lotronex user, knows what a difference this drug can make in our lives. With guidelines, and special doctor/patient care, I believe this drug can be put back on the market safely to those in need. I hope we can make a difference. With any kind of luck, the FDA will understand our desperation and reconsider their decision.

Yours truly,

June 26, 2001

Corey Miller

I'll be happy to explain the benefits I had while on Lotronex. I was diagnosed with IBS about 12 years ago. I have been through a variety of unpleasant tests, which triggered a variety of medications. I have tried virtually everything on the market for IBS with "D". I had horrible side effects and no help with the symptoms. Going out to dinner with my husband, enjoying a park with my kids were impossible for me. Things that many people take for granted, I was unable to do. Then...came Lotronex. I was skeptic as I thought it was another trial that wouldn't help. I saw immediate results! I had no pain, I was able to enjoy my life again. I understand that IBS is not a life threatening disorder, however it is majorly life altering. I had no trouble with the medication, it was a dream come true for me and my family. Since I've been off of it, my symptoms have progressively gotten worse and I'm taking boxes of immodium to get through my daily routines. I wish that the FDA would consider the wonderful benefits that so many of us have experienced. My Gastrointestinal Specialist was as upset as myself when she contacted me about the pulling of it from the shelves. Please listen to our stories and reconsider.

Thank you,

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**This is my story my name is [redacted] I live in [redacted] and I have 3 boys. I have suffered with IBS and Ulcerative colitis since I was about 17 it has just gotten worse over the years. I am never able to go on any school trips with my kids or attend any school functions. I am always in the bathroom with severe pain and for hours going in and out of the bathroom. It is so difficult to say no to my boys when they ask if I can please go with them on a school trip or attend a class function. I can't even take my kids to school and pick them up. But when I was on Lotronex all that guilt and depression, pain, urgency to go had stopped. I was able to do things I was never able to do before. My children were so happy to see me pick them up at school the look on there faces is something you never forget. We were out as a Family more having fun and no fear of having to run to the bathroom where ever I was. But now that Lotronex is gone Im back to the suffering all over again. I was able to gain weight on Lotronex now Im back down to 100 pounds. Doctors fear I may loose even more My children fear I may loose more. I try to hide all this pain from my children but its not that easy when your taking over the bathroom. They keep coming to the door to make sure I am ok if I need anything. My children think I am dying. This is so unfair for children to see, when there is something out there that can help me that sits on the shelf waiting for approval while I sit here in agony. Please help us bring back Lotronex so that I may live to see my children grow and not miss out on special occasions. I am 38 years old I think I have a long time yet to live an exciting life and only Lotronex can make that happen. Thank you**

June 30, 2001

Corey Miller

I am a 41 year old male who benefited greatly from taking Lotronex. For the last 12 years, I have been receiving treatment for IBS-D. I have been to the gastroenterologists, the internal medicine specialists, and the counselors. I have had all the unpleasant tests, the various medications, the biofeedback, and nothing gave me much relief. I felt like I was on a medical merry-go-round.

I changed from being a fairly gregarious, outgoing person, into a virtual recluse. I became a control freak, trying to pattern all my daily activities around assured proximity to a bathroom. My career suffered, as my job at the time required a lot of travel, and "confinement" on an airplane was a worst-case scenario for me. The dread of it caused me to have severe anxiety attacks. I endured episodes of such distress and embarrassment that it is painful even to recall them.

A couple of episodes that I can describe are typical and illustrative: While travelling in Japan I was seized with a severe attack of IBS. I begged the gentlemen with whom I traveled to get me to a bathroom ASAP. They stopped our car at the nearest place of business and I rushed into the office and found the bathroom. When I emerged, there was a lot of yelling, and it turned out that I had failed to remove my shoes, and had scuffed up their beautiful wooden inlaid floor. I was mortified. I believe that my associates had to pay for the damages.

On another occasion, while travelling with business associates on an airplane that was about to land, I was faced with the choice to either disregard the "fasten seat belt" sign and go to the bathroom, or soil my clothing. I went to the bathroom, despite the objections of the stewardess. When the plane landed, I was told by the stewardess to stay on board because "the captain wants to speak to you and find out just what is your problem". Everyone on the plane heard these exchanges, including my traveling companions. I was treated like a criminal. I have endured numerous similar episodes. It would be an understatement to say that my outlook on life had become very negative, and that my quality of life was much reduced. I violently object to anyone who would describe such ordeals with IBS as a "vexing inconvenience".

Lotronex changed everything. I had read Dr. Michael Gershon's book "The Second Brain" on research regarding the enteric nervous system, and I had a basic understanding about the unique mechanism of Lotronex, and I anxiously anticipated its' introduction. I started taking it when it became available. It worked wonders for me. I had "normal" bowel function for the first time in years. I began to socialize again. I rebuilt relationships with friends and family. I began to be able to do my job properly, and was able to purchase the company that I had managed for five years. I do not claim that Lotronex completely "cured" me of the IBS, but it certainly enabled me to take control and to effectively manage the problem. I never experienced any noticeable adverse side effects from the Lotronex. I was never constipated.

And then they pulled the plug by removing Lotronex from the market. I am doing the best I can to manage the IBS. I am now taking other medications that have more side effects, and are far less effective. I manage to persevere and get things done, but my quality of life has deteriorated markedly. I cannot overstate my personal conviction that the beneficial effects of Lotronex far, far outweigh the possible negative consequences. I think most folks with severe IBS are taking medications of one type or another. All of these medications have some potential for adverse consequences. Logically, it is not valid to measure the risk of taking Lotronex against taking no medications. One must measure the risk of taking Lotronex versus these other medications. Viewed this way, I think it is clear that Lotronex should be made available once again.

I feel like I have seen the promised land, but have been prevented from crossing the river to go on over. The phrase "cruel and unusual punishment" comes to mind. Americans are meant to have basic individual freedoms, and the responsibilities that go with them. I am perfectly capable of making my own

risk vs. benefit analysis regarding Lotronex, and of deciding whether to take it. I do not need some self-styled consumer watchdog group to make decisions for me. I resent the litigious nature now prevailing in our society that has stifled progress in this so many other areas. Government bureaucracy has a similar effect. If this mindset prevails, no drug company will be willing to do the research to develop new and better medications. Everyone will suffer. It is time for common sense to prevail and to make Lotronex available once again.

June 30, 2001

Corey Miller

I was very surprised to watch the news recently and see that there is a possibility that Lotronex may be put back on the market. I ran into work to tell my co-workers, all nurses, my news. My family and friends have known for some time about my IBS and have been very sympathetic to my special diet needs, having to leave work, church, and other outings unexpectedly because of my illness. Life revolves around what I can eat, activities to participate in that are near a bathroom, and knowing that at any time things may have to be put on hold for others because I'm sick. I have been using the last of my Lotronex sparingly and alternate it with Pepto-Bismol and Immodium in order to function daily. Lotronex has been a blessing by restoring my life back to normal. Without it, the daily fears have returned and I am unsure how I can continue my employment as a social worker, as I travel frequently, visiting patients in their homes.

Sincerely,

June 29, 2001

Corey Miller

My name is \_\_\_\_\_ . I am a 34 yr. old female with one child and IBS which I have lived with for well over 8 years now. After the birth of my daughter I was told I had IBS. Months after various trips to this doctor and that doctor, test after test and medication after medication finally I had a diagnosis; Irritable Bowel Syndrome. When my Doctor informed me of what it was I was relieved but later when he told me there was no cure and minimal medications to manage the symptoms I began to become concerned. Years after being diagnosed my IBS had steadily become worse and it was out of control by the time I went to see my doctor with complaints of the constant pain and uncontrollable diarrhea. He informed me that there has been a break through in the studies with IBS and a new medication was currently available. The medication was called Lotronex. The day he had given me my first sample was the day my whole life had changed.

Prior to taking my first Lotronex tablet I had spent years driving to work with a diaper on for the "just in case" accident. It took me a while to get a clue as to how quickly an attack of IBS would hit me and if I was not near a restroom in seconds it was all over. Several times I had to stop on my way to work and change clothes then I discovered that wearing a diaper of my then toddler was ok to get me by. This has gone on for years and of course my child is out of diapers now but I am not. I wear adult diapers weekly to avoid having to scrub the leather seats in my car. I cannot tell anyone who has not suffered with IBS how uncomfortable it can be to freak out about going out to dinner with your husband or family, how much anxiety that comes with going to a movie, the grocery store or to run errands in general because you are always thinking about the what if's... This disease will in fact rule your life and it does to many of us with IBS. For me IBS dictates my daily routine in fact there is no set routine for me because there cannot be. I cannot plan and expect to be able to do or go anywhere without allowing for some sort of flare up and waiting for the "just in case". No one should have to live this way when there is help out there and the help really works.

I remember the February I was given Lotronex. After years of taking all of the different medications the Doctors use for IBS there was hope. I had had an appointment with my physician Dr. David Peura at the University of Virginia. Dr. Peura is a pioneer in his field of medicine (GI and Hepatology) and holds a high seat at the University in addition. I came to Dr. Peura that day telling him of terrible diarrhea and the pain that was so bad I could not stand it anymore. We had tried everything at this point and they worked for a while but then it would get to the point to where I needed something else. My Dr. told me of the new drug Lotronex. He said there were some excellent results in patients with Diarrhea predominant IBS. That day I want to note I was sick before arriving at the office and had to wear a diaper on the 3 hour drive to the University. Dr. Peura wrote me a perscription for Lotronex and gave me some samples he had to get me through until I could reach the pharmacy back home. We covered dosage info, risks and how important it was to keep in touch. I agreed to all of his requirments and I left to go home with a heart full of hope and the fantasy of having a normal life again. That day we stopped at a

Wendy's (which is not my usual thing but it was the only thing available at the time) to eat and I also figured it was a good place to take my first dose of Lotronex. After eating I began to cramp as I normally do and I took my first blue pill. I swear to you in a matter of minutes my pain was gone, no bloating, no gas and no urgency whatsoever. I was amazed. I kept taking Lotronex and my dosage was regulated to approximately 1 tablet every 3 days or so and it was usually every 4 days. I would take an additional tablet if needed or I had a flare up. This medication worked like a miracle. I no longer needed diapers, I did not have the horrible cramps or bloating and the gas that would double me over in pain. I had normal bowel movements approximately 3 times per week and this was completely unusual for me because I never knew what being regular really was. There was no more diarrhea and no more urgency all of that was gone. I could go out to dinner with my husband, enjoy a movie with my husband and daughter, and most of all I could attend things with my daughter. I was able to focus on my job and I would arrive on time to work and missed days were minimal...

One day in May or June of 2000 I was told by my pharmacist that Lotronex was being withdrawn from the market. In my refill he had given me some information on some serious side effects and the risks involved with the drug then informed me that this would be my last refill. I was horrified. Months had passed and I was able to function like a normal human being, wife and mother. No more diapers, no more diarrhea or cramping or days missed from work. No more of having to explain why mommy is sick and cannot attend this play or a field trip. My miracle was gone. After taking my last pill of Lotronex I then began taking an anti-depressant to help with the pain and slowing down the gut once again, and behold... back where I was before Lotronex entered my life. Now I wear diapers again, I have uncontrollable diarrhea, I cannot attend those school outings with my daughter and I have cancelled more get togethers with relatives and friends than I care to mention. Most importantly I have had to listen to numerous attacks from my upper level management at work about missed days from work, forcing me to inform them of this "disability" and outline specific accommodations in an effort to permit me to remain productive at work. I cannot tell you how belittling this is and how it will strike down a persons self esteem. I have almost lost my job, had to ask my doctor for endless letters explaining what illness I have and how it effects me and how it can be debilitating and many times renders me unable to drive or leave the home.

It is essential that Lotronex is returned to the market as soon as possible so those like me who suffer day in and day out can begin to regain their confidence again and begin to function as normal adults.

**BRING BACK LOTRONEX...PLEASE LISTEN TO MY OUTCRY..I WANT TO BE A PART OF MY DAUGHTERS FUTURE AND BE AMONG THE SOCIAL HUMAN BEINGS..... PLEASE RELEASE LOTRONEX AGAIN.**

Regards,

June 29, 2001

Corey Miller

I felt like I was given my life back while on Lotronex. I do not know how else to say it. I was given a bit of confidence. I could travel some to see friends. I could cheat on my diet. I gained weight. I was still very careful about my diet. I could not eat a normal diet like normal people. I have two part time jobs, none of which I can accomplish under any circumstances. Knowing how your colon will work with Lotronex gives one the incentive to live life as full as you can.

I am in a bad cycle now. I was never on Lotronex when I was in a bad period. I would like to know how I would be if I was on Lotronex full time. Now I have so much sensitivity to food and medicine, that the Dr. does not know what to do with me. Some medicines do work, however I have such bad reactions to the medicines, they have to pull me off. When they made the photo of my GI system, The technician said she had never seen the pleasant drink go through any ones system as quick as mine. I understand others plight. Bring Lotronex back!

I developed IBS-D when I became pregnant with my now 13 yr. old son. At first I thought it was just a part of being pregnant but it continued. I was finally diagnosed with it after 5 embarrassing years, given some sort of prescription that didn't help and was sent on my way. Life with IBS became worse as the years rolled along. Every aspect of my life was effected. I was limited to career choices (no travel, no am meetings) though I was a Human Resource Manager. Even driving to work was specifically on a route with restrooms. Limited social events, dating and dining out only after I had taken exceeded amounts of anti-diarrhea medications. My son's soccer games threw me into sheer panic because of no RR on the fields. No exercise such as walks, raking leaves, or classes because it only seemed to aggravate my colon. I finally went into clinical trials 2 years ago which was for Lotronex and Cilestron. I drove the clinical people nuts because I would personally increase my dosages until I came up with the correct dosage for me- which was a big no no and finally completed the trials. Lotronex was prescribed for me last September, in time for my wedding. I was finally on my way to becoming my pre IBS person again. What joy it was to discover each day things I could do again. The terror I felt when Lotronex was withdrawn was devastating. I do have 12 Tablets left for special events, however my everyday living is again guided by restroom location. I found out about LAG last winter. Though I am somewhat of a spectator of the group, I have done plenty of emailing, phone calling, etc to fight for a return of joyful living. Thank you.

I'm 48 years old and was diagnosed with IBS 22 years ago. I own a small business which is severely hurting due to my inability to travel and meet customers. I tried most of the previous IBS meds over the years and had side effects with all. (and not one of them was 100%) I started taking Lotronex in April of 2000 and after a week...had NO side effects and no IBS symptoms. I was able to travel and even fly overseas and life was great. Even my husband of almost 30 years noticed the change. We were able to go out for dinner after 22 years of eating in! (not a big deal unless you have had IBS) We went on car trips and didn't worry about making a mad dash to the nearest McD's for the restroom. I've been off Lotronex for almost 6 months and life sucks again.

I am a 43 year old male who has suffered from severe IBS-D since age 9. Although the severity of my illness has varied, it has had a profound impact on my life. There have been spans of many years where I've had to refrain from ALL activity other than that which was essential to survival. Simple activities, such as grocery shopping, or getting a hair-cut are traumatic. Even though I've lived close to work, commuting with IBS has been torture. I've tried all forms of treatment, including extensive psychotherapy, relaxation therapy and medication and have found, at best, modest improvement.

Lotronex has been the ONLY effective therapy for my IBS. Since my Lotronex supply has been depleted, I've encountered difficulties that threaten both my home life and my career. My frustration is compounded knowing the medication I need exists, and is only unavailable due to the actions of mis-informed zealots.

You have, quite properly, made known the potential dangers of Lotronex, however, **I beg you to leave the risk/benefit assesment of Lotronex to well informed patients and their physicians.** Personally, given the choice of living 20 years as a free man or 40 years in prison, I would choose freedom. Please allow me to make that choice.

Thank you for your consideration,

My story is a long one since I have suffered from IBS for 24 years. I won't bother you with all of the details but I need to tell you that for 23 years I spent my life worried and stressed over IBS, in pain sometimes so intense it felt like labor contractions (and I know what they feel like- I have two children), embarrassed at times I may not have made it to a restroom, guilty because of missed work, spending work time in the restroom for hours, missing out on "quality" time with my kids and husband, missed vacations and events with family and the list goes on and on. I am sure you have heard that IBS rules one's life and no truer words have been uttered. IBS forces you to make decisions like should I interview for that job-I may have an attack or Should I go on that class trip with my son-they may not have bathrooms, or should I walk the dog- I may not make it back in time, Should I go to the beach with my family-are their bathrooms at the beach? and that list goes on and on. The simplest pleasures are often denied to an IBS sufferer and I for one have had enough. Not only have I had it, but then to be given a brief tease, if you will, Lotronex of course- is the cruelest thing in the world-only to be snatched away without our voices meaning anything.

I am begging you to do whatever you have to, to get this drug available to the people who need it and want it and who will use it responsibly fully aware of the risks that have been noted. I and so many others would like to return to those few brief months when you could walk out of your door and the first thing on your mind is not-God, I hope I make it to work today!

No one ever said life is fair but there is a lot of needless suffering going on out there and that is unfair when the treatment exists and will not be granted upon those that need it just to be able to live a somewhat normal life.

I know you are listening as I have seen evidence of it. Please continue to listen and please help us.

Sincerely,

My name is Sharyn, and I have suffered from IBS-D for approximately half of my 32 years. It's hard to believe that my life is controlled by thoughts of "Where is the nearest bathroom?" anywhere I go.

I have a three year old daughter who loves to go to the zoo (Can't go there- too long of a drive!) And to the park (Can't go there-no bathrooms!). How can I continue to sit at home while my husband enjoys these things with her, and I can't? How can I continue to answer her embarrassing question, "Mommy, why do you go to the bathroom so much?"

I have managed to keep working, although I often find it extremely difficult to get to work, as I have to map out and decide every morning whether I can go the direct route with no place to stop, or the long way, just in case I have an emergency. I never accept invitations from my colleagues to go to nearby restaurants, I know that is just asking for trouble!

One year ago, everything was different!!! That's when I was taking Lotronex. I couldn't believe that I had lived without this product for so long, and I never wanted to live without it again!!! I got to drive all the way from Virginia to Florida without worries! I got to go to amusement parks without worries! Ate in restaurants without worries! Went for walks with my family! I finally thought I was free from the pain, embarrassment and seclusion that IBS-D has caused me! It was a miracle!!!

I was devastated when Lotronex was pulled from the market, and have been trying to find a suitable replacement ever since, without luck. I saw a Gastroenterologist shortly after stopping Lotronex to see if there was anything else I could try. After the recommendation of fiber therapy (which I consider a joke!) failed, they called for a colonoscopy, just to rule out disease. They found absolutely no damage from taking Lotronex. Why can I not experience the benefits that this medicine has to offer me once again???

Sincerely

I am a psychologist and it was as a psychologist that I began my involvement with the lotronex action group after hearing from my patients what this medication had meant to them and how its loss affected their lives. While both personally and professionally I do not believe that medication is the answer to all of lifes problems it does appear that in their action on specific debilitating aspects of irritable bowel syndrome, lotronex and other new medications being developed for this as-yet-poorly understood syndrome have the potential to help transform and revitalize lives that have been devastated by this 'vexing inconvenience.'

I was initially diagnosed approximately ten years ago and have been evaluated numerous times with the same essential result and have tried countless medications and regimens with little substantial change in my ability to function normally as a contributing member of society. I have been forced to limit my practice and investigate alternative directions for earning a livelihood. While I was able maintain a home and successfully raise two daughters, this 'inconvenience' severely affected my ability to function as a father and husband and regretfully has had a major impact on all family members in many ways

**June 24, 2001**

**Corey Miller**

**I am a 70-year-old female who has suffered for YEARS with IBS. My IBS is characterized by deep swings between diarrhea and constipation. As time went on, my symptoms kept getting worse and worse; i.e., the swings were getting closer and closer together, so that I was having severe attacks of diarrhea almost every 3rd day. Additionally, the severity had gotten so bad that when I had diarrhea, I would have sessions of vomiting and blackouts.**

**Then my doctor prescribed Lotronex. I was blessed with great improvement and only needed to take anywhere from one-half tablet to one whole tablet each day. I still had my swings, but the spread went from every 3rd to about to about every 10th day, and the severity of the diarrhea was no more than soft or loose stool for a few hours.**

**The use of Lotronex not only guaranteed that I could plan my life for any day of the week, but it also reduced the severity to no more than a minor annoyance. Needless to say, Lotronex went off the market, and my comfort and freedom disappeared! I have begun taking a probiotic; it helps, but certainly not to the degree of safety I had with Lotronex. *Nothing* compares to the benefits of Lotronex!!!**

**I certainly hope (and pray) that one day Lotronex will again be made available to those of us who benefited so greatly.**

June 24, 2001

Corey Miller

My story is simply that I have suffered for over 20 years with IBS- TERRIBLE pain and diarrhea. I was put on Lotronex last year and my symptoms were gone! Though I experienced occasional constipation, I was able to work with my gastroenterologist to adjust the dosing appropriately. Unfortunately, since Lotronex was taken off the market, I am back to a pattern of missing work and curtailing social activities because of my IBS symptoms. I can only hope that the FDA will approved the use of lotronex again.....

June 24, 2001

Corey Miller

The minute Lotronex was recalled, I called the Pharmaceutical company in dispair. I even checked the internet for International Pharmacies that might carry Lotronex. But I'm getting ahead of myself,,,

At the age of 30 (I'm now 50) I developed IBS. It was really no surprise since my mother had 9 siblings and all 6 girls have IBS, including all of their daughters. I would giggle as I would see my Aunts "running" through the mall to make it through the bathroom. I was a teenager and had no such problem.

I would have bouts of diarrhea now and then after the age of 30 but could usually find a bathroom "in time". After the birth of my daughter at age 36, I began to have more severe problems to the point where I was afraid that I would be embarrassed because I couldn't hold it in.

For my 40th birthday, my family took me out for a lavish luncheon and I had to leave to pick up my daughter at preschool. On the way to her school (about 1/2 hour drive) I felt the urge. I could not make it. Frantically I reached in the back seat and found a McDonald's Halloween bucket which held many Happy Meal Toys. I tossed the toys on the floor and "tried" to use the bucket as a toilet. Not much success and I don't need to remind any of you IBS sufferers what a mess that was. That was my turning point.

I could no longer eat out without the fear of having to have loose bowels. I would turn down dinner invitations with friends, stay away from any situation where I wasn't close to a bathroom, wouldn't ride in a car with friends after eating, my life was a mess. After years of keeping this a secret, I finally told my friends that I couldn't ride with them due to IBS. This somewhat helped me convince them that I wasn't a flake. The anxiety associated with IBS is paralyzing, it is a life ruining situation. I lived on Lomotil for extreme emergencies but didn't like its effects.

After several years of this suffering, I begged my husband to buy a van conversion that had a toilet. Yes, a toilet. The van is big, bulky, hard to park and a gas guzzler. But better to drive that than to have to pull over on the freeway and poop out the door. I've even considered adding a seatbelt to the "bathroom" so that when we are on the road, I can use it. And believe me, I use it. Not even the comfort of having your own toilet can keep me from going.

Last year a dear friend said that her doctor had prescribed a medication for her that she thought might help me. My physician knows that I have IBS so prescribed Lotronex for me. What a God-send! Within

3 days I was having normal bowel movements. An actual log! I immediately knew that 2 pills were too much for me and being someone that was all too familiar with my bodily functions decided to take 1/2 a pill in the morning and 1/2 a pill in the afternoon. The perfect scenario.

I was a new person. My husband, daughter and I flew to Hawaii and I had the best time. No worries about driving home from the Luau. No worries about being in a strange airport. I could finally take a vacation without my van toilet. I had absolutely NOOOOOOO side effects from this medication, just normal bowel movements. I told my husband that I would be so depressed if they ever took it off the market. He's had random bouts with IBS so he knows my pain and terror.

Well, my worst fears came true. Lotronex was taken off the market. I immediately stopped taking the medication, NOT BECAUSE I WAS AFRAID, but because I wanted to keep some in case I needed it. Well guess what. We are going back to Hawaii in July and I have enough to get me through the trip. I will not let my IBS EVER take control of me again. I want to live life to the fullest, I know how to read my body's signals, I would NEVER let myself get constipated to the point that I let it go for a week. I am a responsible adult and can think for myself. Should you take me off of unopposed Estrogen just because I still have a uterus and breasts?? No, let me be the one to have checkups more often than needed.

I applaud you all, please do all that you can to convince the FDA to bring our hope back to the marketplace. Or let them live one day in our shoes.

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Lotronex had been my "little blue miracle." I had first been diagnosed with IBS over 20 years ago. I had tried everything up until then: bulk fibers, cutting out caffeine, MSG, Lomotil, Levsinex and Paxil (which only tended to make me feel like a monotone zombie with no sex drive). I had been on Lotronex for 8 months before it was pulled from the market and had absolutely no incidence of diarrhea during that time. I was even able to travel to Europe with my family! For the first time in my life I had begun to feel like a so called "normal person." Gone were the dreaded fears of having an attack and needing to find the nearest scummy public restroom.

When I first heard the news that Glaxo was pulling Lotronex off of the market, I was inconsolable. I couldn't believe how unfair it was to have been given a chance at a full life and then to have it taken away. I developed a "junkie mentality" rationing and counting down to the end of my pills. I swore that if there were a black market for Lotronex that I would be out there on the streets tracking it down.

I cried in my doctor's office as she wrote me a prescription for Belladonna (just to appease me I suppose.) As far as she was concerned, We had exhausted all other treatments.

I am now back to suffering with the cramping, gas, bloating and urgency associated with this disease. It takes such a toll on ones body as well as the psyche. It just seems so cruel and unfair having to live this way again knowing that there is a treatment out there that finally worked for me and helped me to live my life to it's fullest.

I am 45 years old and have suffered from IBS for over 25 years. I have been fired, lost a husband and lived a life being tied to the bathroom for most of those years. The only time I could go out in public was when I self medicated myself with drugs from outside of the USA. I am afraid of the damage I have done and am now once again doing to my body but I have little choice. I have to work to support myself. I have suffered countless "accident" by attacks of diarrhea so bad, I have to keep a change of clothes in my car and at work. I have few friends since I cannot go to restaurants, movies all enjoyable things people take for granted. I suffer such pain after eating that I am afraid to eat until night time when I am home and can take the pain killers I surround myself with. My Doctor tells me Lotronex is the perfect pill for me as I not only had no complications on it, but it actually made my body function normally for the first time in years. I went out to eat, went on vacation and never even looked for the public restrooms for the first time. It was heaven but all to soon I was sent back to my hellish existance when my miracle pills were recalled. I had 10 months of quality of life. Now I know what I am missing and my life is intolerable. My neighbors call me the crazy cat lady because only animals can tolerate the lifestyle I am forced to endure. Crazy, because I am always so mean. But when your in pain, you can't stand around being nice to people. I have been ashamed of my condition and hid from the world never even knowing there were so many others like me. I want my Lotronex back. Knowing I don't have to exist like this is so depressing.

June 26, 2001

Corey Miller

I have been a sufferer of IBS for over eleven years now. My doctor introduced me to Lotronex in July of 2000 after a colonoscopy and several blood tests revealed nothing but an irritable bowel. I took the recommended dose of 1 mg twice daily for four days. The medication worked immediately! I was so surprised because I had been very skeptical over the years and many doctors pushing other medications and not even knowing what the problem was. By the fourth day, I was a bit constipated. So, common sense told me to cut back on the dose. Luckily, I still have some Lotronex left since I could get a three month supply through my prescription plan. If I would have known of the withdrawal in November, I would have sent out for another three month supply! I take one half to one tablet a day. This drug is absolutely wonderful! I could not imagine what life will go back to when it is gone. My life actually seemed "normal" for once. I can remember such embarrassing times as barely being able to make it home from a restaurant and literally "going" in my pants! I am only 31, I do not need that in my life! I would never wish this disorder on anyone and if I know anyone that has IBS, I can certainly relate. This is not something that is in my mind or made up! If anyone thinks that, I would like them to take a laxative everyday for two weeks, or better yet, one week, because I know they could not last for two days! That is how miserable this disorder is! It strikes anytime and anywhere--it has no mercy! Please bring Lotronex back, even if it is in a lower strength. As I mentioned above, one half to one tablet worked well for me. From July of 2000 to June of 2001, I have only had two separate bouts with diarrhea. Previous to Lotronex, I had diarrhea five days a week, three or four times a day and believe me, that is no way to have to live each day! I hope this letter and many others bring back this wonderful drug.

Sincerely,

June 26, 2001

Corey Miller

I was diagnosed 11 years ago with IBS. I think i have suffered since i was a child. My father also was a undiagnosed IBS sufferer. I have taken Levson, LevBid, Liberix, immprimine, trazazone, elavil, lomotil, tincture of opium, darvocet etc..... My GI had all but given up on me until Lotronex. After about 3 days i noticed a big difference in the way i was feeling. Two pills were to much for me so i cut the dose to one pill a day with great success. I had normal movements and the pain and spasms were calming down. I work with special needs children so i am lucky there is always more than one person in the room when i was having an attack. Field trips were frightening for me. I would load up on lomotil and take a dose of tincture of opium. Now i am back to doing that again. i hope we can get lotronex back. I am having a very bad day today. If you need more information please contact me.

Thank You,

June 25, 2001

Corey Miller

I have had IBS-D for about 5 years. It has impacted my life and has had many embarrassing moments, such as not being able to reach a bathroom in time and soiling clothes. I never know when I might not feel well. This is exasperated by going to the bathroom 8-10 times plus per day. Good days are 3-4 bowel movements., but this is still not normal for a person to have bowel movements that many times in a day. I am using diet and calcium to add in prevention. Of course, it's not perfect. I have acquired an intolerance to Imodium since I took it too much, obviously. So, this is now not available to me. The only medicine that helped was Lotronex and it's suppression of too much Serotonin in the gut. This really helped. Lotronex should be looked at more carefully with pill doses smaller to meet individual needs. This was a great medicine and a miracle one for me. It was devastating when it was taken away. Lotronex can help a lot a people and needs to be brought back. You have my vote to bring it back.

June 24, 2001

Corey Miller

Now, briefly, I have been Lactose Intolerant since birth, can eat some hard cheese and an ice cream now and then if I use Lactaid tabs. I use Lactose free milk when I need to use milk for cooking. Cannot even stand the sight of milk itself. the problem has gotten worse as I have gotten older. I have had an "accident" in a department store dressing room which I think probably is the worst thing that happened to me. Have had to stop every couple of miles when going somewhere, until I finally get emptied out. Last year I was going to play golf with some gals and got two miles from home and they had to take me back home, where I stayed. They weren't happy with me. Man, many times I have gotten myself 1/2 mile from my home and turned around to come back to the bathroom.

The doctor is giving me some meds now that help but nothing is as good as Lotronex was for me. I felt as if I finally was a normal person after all these years.  
Many more experiences but that should suffice.

June 24, 2001

Corey Miller

I have suffered from IBS for four years. I participated in a study for Lotronex in 1998 at the University of North Carolina, Chapel Hill hospital before it came on the market. I was not told whether or not I was given Lotronex or a placebo; however, I knew that I did not have a placebo because I experienced a dramatic change. It was absolutely wonderful! When the drug came on the market in 2000, I was contacted by the hospital and was informed that I indeed had been given Lotronex when I participated in the study. I immediately called my doctor and she prescribed it for me. My life completely changed from that point on. I was not a prisoner in my home. I felt free to travel, go out to eat, and get on with my life. When the drug was pulled from the market in November, I was devastated. My symptoms have surfaced again, and I have once again become a prisoner in my own home. If doctor's were better informed regarding this drug, the problems that initially occurred with it could have been avoided. Doctors need to understand that there are two types of IBS, and if the patient suffers at all from constipation that they do not need to be given Lotronex. It is my understanding that it is specifically for people with the type of IBS that causes chronic diahrrea. Please don't take this drug from the people that have been given their lives back because of it, and make us have to wait four or five more years for another solution. Just educate the doctor's and patients regarding it. Any drug can be fatal if not properly prescribed. Lotronex is not immodium. If you have diahrrea once in a blue moon, you do not need Lotronex; doctors need to realize that. Please don't punish thousands for the mistakes of a few doctors. I beg of you to please give me back my life!!

June 24, 2001

Corey Miller

I am a 22-year-old male, and I've been suffering from IBS since I was 12 years old. Going on ten years now, I've had 3-4 bouts of diarrhea a day. As if that weren't enough, I've now developed hemorrhoids, which means each visit to the porcelain gods has now become a bloody mess. It's no way for a young, active male to live. It's no way for anyone to live.

For almost a year of my life, I was cured, all because of Lotronex. At first when Lotronex came along, I was skeptical--I had been on almost every bowel-related medication that existed, and none had worked. By the end of my first week on Lotronex, however, it was like I had found my miracle drug. I took two pills a day and my bowels were completely normal. No constipation, no side effects -- just beautiful, formed stools. My life improved dramatically. No longer did I have to plan my class schedule around buildings that I knew had private toilets. No longer did I have to explain to my roommates why I had to run (literally) to the bathroom in the middle of dinner. No longer did I have to feel ashamed -- this was a medical condition, not a condition brought on by a stressful Ivy league lifestyle, as some of my doctors had suggested. It wasn't my fault, and it could be cured.

When Lotronex was pulled from the market, I could not comprehend it at all. How could someone make me go back to my previous life when I knew it didn't have to be that way? It was one thing to live with IBS knowing that there was no cure -- but to live with it knowing that there is a cure and that I'm not allowed to have it? It made me angry and depressed. I started seeing a therapist. While my outlook on life has improved, the rage is still there -- and I still cannot believe that Lotronex is still banned.

Lotronex needs to come back, and I am so happy to know that there are people fighting for it to come back no matter what. We will not give up. This is not a fight for something to make our lives better; it is a fight for something to make our lives worth living again.

Thank you.

**June 24, 2001**

**Corey Miller**

**I am a 28 year old mother of two with IBS-D. I found out that what is was about a year ago. I had my gallbladder out 3 years ago and I just thought that it was my system getting adjusted. After every meal it was a mad dash for the bathroom. I use to drive separately from everyone else so that I could get home before an attack. I finally got the courage up to ask my OBGYN at a check up about a year ago. He told me that I had IBS and that they had a new drug to treat it. I was so excited. He told me that I should take one twice a day, and then we may be able to cut the dose in half. He also told me that it might take up to two weeks to work. It only took about 3 days, and I did cut my dose in half. I was so happy! I finally got to enjoy meals out without the mad dash to the bathroom. Our family started having a "family night" at McDonalds. The children got to play on the play ground for as long as they like. Now we are unable to do that because mommy has to run to the bathroom (I hate public restrooms!). I have tried other options, but nothing has helped me.**

**Lotronex was the best thing that happened to me. I can no longer enjoy eating out with my family and traveling. Please let all of us with IBS-D lead a normal life.**

June 24, 2001

Corey Miller

I have had IBS since I was 21. I am now 43. At first it wasn't so bad but in the last 10 years it has gotten really bad. I have IBS with explosive bouts of diarrhea that can happen anytime anywhere. I have had accidents in the grocery store and in the car when I couldn't get to the restroom fast enough. I have about 10 seconds to reach a restroom. I have had to stop my car on the side of the road to use the restroom on the way to work in the mornings. I have had to leave work because of the stomach pains and diarrhea. I have never been able to take a vacation or go places with my children because I have to have access to a restroom at all times. Then last year everything changed. Lotronex was put on the market. My doctor called me at home to let me know about this new drug. It started working very soon after I started taking it. No more diarrhea. I could go anywhere I wanted to, eat anything I wanted to and I didn't miss any work. I even took my daughter to the ocean for a vacation. 10 hours in the car and I never had to stop to have diarrhea. Not one time going or coming. It was great, my life was great I was so happy and relieved. Then as fast as my happiness came it left. When they recalled Lontronex I only had a few pills left. I didn't even know it had been recalled until I went to fill my prescription. I went straight to my doctor and he didn't have any. He said if he did he would give them to me. He said the FDA acted rashly on removing the drug from the market. I never had any side effects at all unless you call extreme happiness a side effect. How is my life now? Back to the same hell it was before Lontronex. I don't go anywhere I cancelled our vacation this year to the disappointment of my daughter because I know I cannot travel and I'm back to trying to get to work without having an accident. The people of Public Citizen have no idea of what were dealing with everyday and I would not wish IBS on anyone not even them.

June 24, 2001

Corey Miller

my story i am sure is similar to everyone else's. i am 43 yrs old and have had ibs since i was around 17. i have been to several drs and had tests and am sure i have ibs. i have tried levsin, bentyl, librax, zolof, donnatal, fiber, just about everything to help. nothing has worked as well as lotronex. all other drugs make you sleepy, dry mouth and etc. i had no side effects with lotronex at all. it was wonderful. i have never felt the freedom to go anywhere anytime. as soon as anyone mentions going somewhere I start getting nervous and my stomach starts hurting. so many times i have gotten ready to go somewhere but the only place i can go is to the bathroom.

if i do travel all i can think about is where the bathrooms are. i used to think it was all in my head but after being on the ibs/group bulletin board i have found that it is real. i have 3 children 15, 21,24. i never once was able to go on a school trip with them just because i might have to make a dash to restroom. to get on a bus would be unthinkable. i always like to be the driver just in case i have to stop. also the stops might not be short. sometimes i have to stay in bathroom 30 or 40 minutes. or worse keep going back for several times. sometimes it is even hard to wait in line at mcdonalds or grocery store. luckily i live within 5 minutes to my work and don't have to worry about commuting everyday and i can go to bathroom anytime i need at work. there would be no way i could drive a distance to work everyday or have a job that i could not go on break anytime. it's hard to even go walking in the evenings for fear a pain might hit. i don't always have pain but sometimes it is very bad and other times i just have to go immediately. there is no thinking about it. when i go shopping the first thing i look for is the restroom just in case. i have taken lotronex since last june. i started out taking 2 pills/daily. when it was taken off market i had some left but i cut back to 1 pill daily. it worked great. later i cut back to 1/2 daily and it did not work as well. i have about 1 wk supply left and am saving for my sons wedding in august. i am already worrying about wedding. i am worried i might have to go during wedding. Can you imagine if the mother of groom had to get up and leave during wedding? Please bring lotronex back!!

I am a 30 year old female from [redacted] I have had IBS for 11 years. When I was 19, I was in the car with a boyfriend and had to use the bathroom...IMMEDIATELY. I didn't think I could make it. After that episode, I have been scared to leave the house. Of course I have to leave, but I am always looking for the bathroom. I have canceled many engagements with friends and family, because I was scared of needing a bathroom. My family did not look at this as a real problem and didn't understand. Actually they still don't 100% yet. My family tells me if I have to go just go, they do not understand that it is painful and embarrassing. I will not go in a car with anyone except my husband, just in case I need to use the rest room. It doesn't just come out... I have cramping and I am in pain for hours before and after an episode. How can I ask a couple on our way to dinner if they can wait 2 hours while I have a diarrhea attack? Well, I don't and do not even leave the house.

I had many tests done about 10 years ago and was told it is IBS and that it was all in my head. They gave me many prescriptions, but nothing. So, I began to think it was in my head too. To add to this I am also lactose intolerant and don't like red meat, so as you can see eating is a chore too! I about 20 lb. over weight, because all I eat is bagels and bread (high carbs). They bind me and that's what I need. I have bought cases of Immodium over the years, but after 3 days of Lotronex I have not bought any since. OK OK to make a long story short, I have been asked to be in about 10 weddings and worried until they were finally over, including my own, in case I got sick and ruined someone's wedding. I have many more horror stories.

I went on vacation and my husband was annoyed cause I would not do anything without a bathroom. I promised him that when we got home I would go to the doctor. I did. Lotronex was just released and the doctor said "Michele this is your answer." I could not drive the car fast enough. After 3 days!!! I was sooooo much better. Now I used the bathroom once or twice a month instead of 3 or 4 times a day. I was going daily and it was normal.

I needed to get better for my new born son. He is 7 months now. I didn't want him to miss out cause mommy doesn't like to go out of the house. I could not do that to him too!!! I live close to NYC and took day trips with my son and husband, I was a person again. I felt great. I went for dinner, movies, central park etc....and yes I still looked for a bathroom, but I didn't need it. YEAH!!!!

Then D day came and my husband called and said "that Lotronex was recalled and the insurance would not cover it, but I could buy it" of course...I did. It was very expensive, but worth every dime. You can't put a price on a new life.....Now, I have been without for about 1 month and it got bad. My doctor prescribed a medication that I took years ago called LIBRAX CAPS along with PAXIL it is ok. I mean nothing like before with LOTRONEX.

Hey not to get all feministic here, but if this drug was for men too do you think it would of been recalled? Men have always made decisions and they effect women.

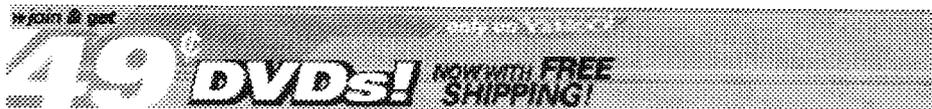
The first time I took LOTRONEX i needed one a day for about a week, after that i took 2, but why didn't the doctors of these poor women know to reduce the amount of the meds if they were so constipated? I mean we can't forget the victims here either. Why were they not educated about their meds?

I am a teacher, but now a stay at home mom and want to give my child his mother back.

I am sorry this is so long, but how can I put 11 years in one letter. Please lets get Lotronex back!!!!

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**To:** lotronex@yahoogroups.com

**Date:** Mon, 25 Feb 2002 09:10:48 EST

**Subject:** [LAG] Personal Story

**Reply-to:** lotronex@yahoogroups.com

Corey Miller:

I am leaving on a driving trip this morning to see family down south, a trip I am only able to make because I am currently on the study drug Cilansetron. I wanted to write you my personal story to put with the others for the meeting in April. I would love to be able to attend the meeting but am not sure I can do a plane trip, even on this new drug, because I still periodically have some bad days although my situation is much improved. I strongly support the return of Lotronex and will be with you all in spirit if I can't be there in person.

"I am a 67 year old female who has had colon problems for most of my life - the last 20 years it has just gotten increasingly worse. In 1995, I had a severe attack of uncontrollable diarrhea while on vacation in the Grand Tetons which required hospitalization for acute dehydration. Three months later I had gallbladder surgery. These two events seemed to jumpstart my IBS symptoms to a new level. It got much harder to hold down my job and I was finally forced to retire 2-1/2 years ago from my position as Administrative Assistant to the Library Director for our local library, a job I dearly loved. The urgency issue and periodic incontinent episodes made working an impossibility.

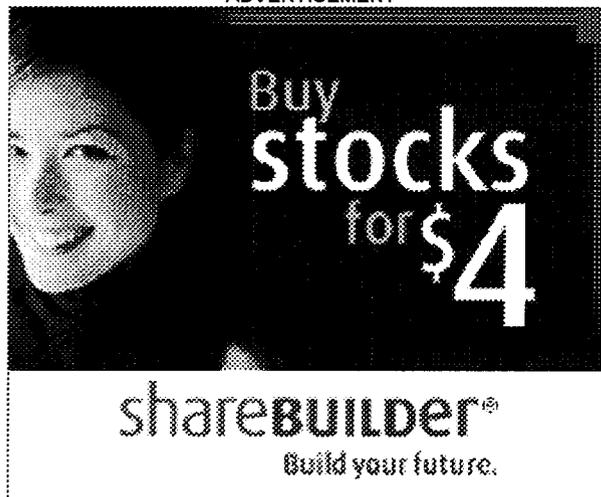
During the last 10 years especially, I tried a variety of things to help this condition. Gastroenterologists were big on prescribing Metamucil, Citrucel, Fibercon, etc. and kept telling me that I wasn't giving it a fair try. Many times it just made it worse. They also consistently said that I had to realize my condition wasn't life threatening. Of course we all know that but I don't think the doctors realize how life-altering IBS is. Bentyl, Lomotil and Immodium were other drugs tried over the years. When Lotronex was made available, I was the first patient to have it prescribed in my doctor's practice. It was like a miracle. After an initial problem with some constipation, we lowered the dosage and it worked beautifully. From April to December of 2000, I felt like I was given a new lease on life. When the drug was withdrawn, I was devastated. I didn't have a big supply so it wasn't long before I was back into the groove of multiple loose to diarrhea bowel movements, severe urgency problems, incontinent episodes, and horrific bloating, gas and abdominal distension.

This past summer out of desperation, my internist prescribed Amitriptyline for two months for me in an effort to see if this would improve my IBS. It didn't and there were some troubling side effects. I then tried Remeron for two months with the same results. I also tried cholestyramine but that seemed to make the condition worse. The sad part is that we are all trying all kinds of medication, many of them with their own troubling side effects, when Lotronex worked so beautifully with no side effects if properly prescribed and taken.

Our youngest daughter lives in France and we have been unable to visit her because there is no way I could make a long airplane trip like that. Countless other social engagements are impossible to plan or attend because of this condition and you begin to feel totally housebound.

I urge the FDA and Glaxo to please reconsider their decision on Lotronex and bring it back for the thousands of IBS sufferers who were so greatly helped by this marvelous drug."

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To unsubscribe from this group, send an email to:  
[lotronex-unsubscribe@yahoogroups.com](mailto:lotronex-unsubscribe@yahoogroups.com)

The Lotronex email watch list was organized by members of the IBS Self Help Group. Visit the discussion forum about Lotronex at <http://www.ibsgroup.org/cgi-local/ubbcgi/Ultimate.cgi>

The Lotronex website is <http://www.lotronexactiongroup.org>

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From: [redacted]

Date: Sun, 17 Feb 2002 21:39:50 -0500 (EST)

To: cmiller

Subject: Lotronex - my personal success story

Corey Miller, Coordinator  
Lotronex Action Group

Corey -

I have IBS-D and have been using Lotronex, since it was FDA approved on 2/9/00, with absolutely NO adverse side effects whatsoever.

Before Lotronex was available, I spent my life worrying about my IBS-Diarrhea and I was not able to live a normal life. I would have a problem standing in a grocery store line, driving my car plus doing many other normal daily activities.

Since I started taking Lotronex, I have had immediate and complete relief from this horrible and painful disease. I am now able to live a normal life, free from the debilitating IBS abdominal pain, cramping, urgency and diarrhea. Without Lotronex, I am extremely limited as to the quantity and kinds of food I can eat, and my body will not properly digest food and I lose considerable weight. Since I am not a large woman, this large weight loss is extremely harmful, unhealthy and dangerous for me.

Presently, there is no comparable drug to Lotronex on the market and my gastroenterologist offered me no relief before Lotronex was made available and he has very recently told me that if Lotronex is not returned to the market, he can do nothing effective at all to relieve my debilitating IBS-Diarrhea.

I have used Lotronex, with GREAT SUCCESS and with NO PROBLEMS, and it has enabled me to live and maintain a normal life.

I pray that Lotronex will immediately be brought back to the market and made available to me.

Hopefully yours,

Inbox for cmiller30080@yahoo.com

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[Printable View - Full Headers](#)**Date:** Thu, 24 Jan 2002 02:27:11 -0700**To:** cmiller**From:****Subject:** Lotronex story

Hello, Corey.

I don't think I've ever written my story. I hope you find the following helpful. I still can't read very well, so am not proof reading as carefully as I would like. Feel free to make any corrections needed. I would probably rewrite it significantly if I could see better.

-----

It was not quite 2 years ago that I was in my doctor's office, and asked about a new drug I had heard about, for irritable bowel syndrome with diarrhea. The news was it had been tested with women, but not with men, and I wanted to know if it was effective with men. I had tried all kinds of medications since I was 12, and while some controlled the diarrhea, they did not relieve the cramping and pain. The drug rep happened to be in his office, so he went to ask about it, and came back with some samples. His said his understanding was it had not been tested extensively with men, as IBS-D was more predominant in women, but there had been some success with men.

Two days later the pain, the cramping, and the diarrhea were all gone. For the first time in years I slept all night without being awakened by stomach cramps. I felt great. By the end of the week I was showing signs of constipation. Since I had another appointment with my doctor in a couple of weeks, I stopped the medicine on my own, until the constipation cleared, then went back on a half dose. This was still too much, and I settled on half a tablet once a day. Three quarters a tablet would have worked better, but it was too hard to cut the tablets that way. I had a few pains and some mild cramping, and occasional loose stools on that dosage, but that was very acceptable compared to what I had lived with for most of my life. I can trace my irritable bowel struggles back to age 12, when the cramps were so bad I would end up falling out of my desk onto the floor in the school classroom.

I reported the change in dose to my doctor, and he said he was having good results with other patients, though some also had to reduce the dose.

No one had ever found a solution that worked. As a teenager I was told I was responding emotionally to growing up, or trying to get out of going to school. In college, I had all kinds of procedures done, which caused lots of pain and embarrassment, but did not lead to any resolution. In my 20's and 30's, I saw specialists at the University of San Francisco, who finally decided I must have colitic arthritis. But again, not treatments, not prescriptions worked, and that diagnosis was abandoned. I was sent to counseling, and tried antidepressants. But nothing helped the irritable bowel.

I learned to make it a point to avoid eating for some time before any major trip. I also had to avoid a lot of foods for a couple of days before I did anything that prohibited jumping up to run for the bathroom. I had to give up a lot of things that friends and family did. I tried to not let it bother me, and just take it as part of life.

Then I got the Lotronex, and discovered what it was like to live a normal life. It was great to be able to sit through a shift at work and not get in trouble for having to take unscheduled and long breaks in the restroom. My employer appreciated it, too. I discovered that certain kinds of hot peppers taste wonderful. I could eat the pizza my daughter brought home from work. I started loosing weight, as I could eat more salads and raw foods; fiber didn't irritate my bowel any more. My hemorrhoids cleared up, too. My doctor was also pleased with the results.

I had to go off the medicine for a while, from June, 2000, to September of that year. I had major brain surgery, and one of the experts was concerned there could be unexpected side affects. I was glad to get back on those little blue pills. However, I started having other stomach problems, probably related to nerve damage during the brain surgery. In December of 2000, while checking in for an esophagogastroduodenoscopy, I was informed that Lotronex had been taken off the market. The GI specialist wrote me out a prescription for a couple of medications I had used before, and that had never worked. I was devastated, and that's the best way to put it.

To survive "an extended procedure in a delicate part of the brain", as the surgeon put it, just ot have my life limited by loosing access to this medicine, was a bitter pill to swallow, if you'll pardon the pun. I wrote to the FDA and Glaxo, and their responses were simply to blame each other. Several communications over a period of time left me with a strong impression that the issues were politics and money, rather patient welfare and safety.

I have read everything that is publicly available regarding the safety of Lotronex, and possible side affects such as ischemic colitis. I know first hand that the dosage needs to be monitored or some patients can experience severe constipation. I am concerned about the potential risks. But the very worst statistics put forth by some groups are no worse or better than those for some other medications I'm having to take. And none of those improve my quality of life as much as Lotronex did.

From my perspective, it was unjustified and intolerable for Glaxo and FDA to give me a taste of a normal, pain free life, then snatch it away with no recourse. The medication should have been made available on a compassionate use program, at the very least. I agree that there do need to be more controls or warnings put in the hands of doctors and/or patients. But drawing out the discussion so long, and failing to make the medication available to those who were already using is with success, is unethical and unconscionable, to my thinking. I encourage the Food and Drug Administration, and GlaxoSmithKline, to resolve the issue quickly in a compassionate, safe, and economical manner.

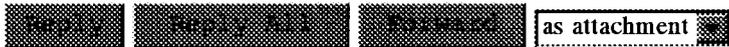
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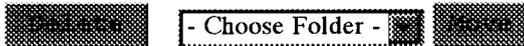


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**From**

**Date:** Thu, 24 Jan 2002 08:21:53 EST

**Subject:** My IBS Story

**To:** cmiller30080@yahoo.com

To Whom It May Concern:

I have suffered from and been diagnosed with IBS for 15+ years. My symptoms were and is again constant diarrhea, nausea and at times dizziness. By constant diarrhea I mean almost daily episodes with sever cramping and watery, mucousy stools. Periodic explosive diarrhea. At times I have no warning, one-second I would be fine the next is this urgent need to use the restroom. In these cases I would at times soil myself before getting to a restroom even if it was only a few steps away. Those are the worst. You can't imagine how humiliating and degrading one feels when this happens unless you've experienced it yourself. The physical and mental anguish is beyond description for me. This condition has affected my whole family. I missed a great deal of my children's activities as they were growing up because of this and was unable to contribute anything to anything. My husband had to take on many additional responsibilities, as I was afraid of leaving the house in case I should have an attack while out. I felt like deadweight. Just taking up space. Through the years I have tried several different medications, which have had little or no effect on my IBS.

When I heard about the new medication for IBS diarrhea prone individuals I made an appointment with my GI doctor. Before he would prescribe Lotronex I once again had to go through testing to eliminate other possible causes. When all tests came back negative he wrote a prescription for Lotronex. Of course after having tried all sorts of other medications with no relief I was somewhat skeptical. It was about 2 or 3 weeks after beginning the Lotronex that I started to notice a reduction in my symptoms. But low and behold it worked, IT REALLY WORKED. I personally experienced no adverse side effects while on Lotronex. The daily cramping and diarrhea stopped. My stools were solid and formed. I would have only one movement a day (which was a blessing all on its own). My quality of life was definitely on the rise. I felt like I finally had a life. I was able to accept invitations for social events without worrying about defaulting. Previously I had pretty much of a non-existent social life. I was finally able to commit to things and didn't have to worry about not being able to see it to the end. I was slowly regaining confidence in myself. I was just beginning to get over my fears associated with the IBS. I knew it would take awhile to overcome my fears that I associated with IBS, as I had lived with them for these 15+ years. I was just beginning to feel confident and secure getting out and enjoying life and traveling with my family. Before Lotronex my quality of life pretty much sucked. When I heard about the withdraw of Lotronex from the market I was dismayed. The only thing that

enjoying life and traveling with my family. Before Lotronex my quality of life pretty much sucked. When I heard about the withdraw of Lotronex from the market I was dismayed. The only thing that has worked was being taken away from me. My supply of Lotronex ran out in September 2001. Shortly there after all symptoms returned. Please for the love of God give us back our life line. I realize that IBS is not a life threatening condition but it might as well be. How and what can a person contribute to society that is homebound and unable to actually experience and take part in life beyond the bathroom?

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From

Date: Wed, 23 Jan 2002 11:26:59 EST

Subject: My story

To: cmiller30080@yahoo.com

Corey,

Below is a letter I wrote to Dr. Woodcock recently. I hope you can use it.

Dear Dr. Woodcock, et. al.,

I am one of the many individuals who has written to you previously regarding the withdrawal of the drug Lotronex, which has been the only effective drug I have found in 25+ years of suffering from IBS-D. While using Lotronex, my IBS-D became a non-issue. I understand that there has been some progress toward re-releasing this drug. I have not written to you repeatedly, like some of the other Lotronex Action Group members, but I strongly urge you and all of the addressees to consider the needs of the patients who were significantly helped to live a NORMAL life thru the use of this drug.

Not only was our IBS-D under control, but the chronic dry mouth and other side effects of many of the other drugs used to treat IBS-D was not there. This may seem like a small price to pay for using some of these drugs, but once you have begun having receding gums and require periodontal cleanings and are urged by your dental team to take this issue seriously or eventually suffer tooth loss, you have to start making choices. I could also discuss the rectal distress caused by this condition, but you probably understand that having from 6-12 BM's per day, often of the loose and acidic type, causes long-term problems.

My choice has been to stop taking drugs that do not help me, regardless of the recommendations of my primary physician, proctologist, or gastroenterologist and to be cautious with trigger foods (lettuce, onions, corn). However, when I have several BM's in the morning before I have even had a chance to eat, I know that foods are not the only triggers. The only thing that gives me any relief at this point is Imodium-AD, and it is not as effective as it use to be. I will still have another BM within 4-8 hrs.

I am currently unemployed (the result of being on a medical leave for another condition and being replaced), so my stress level is lessened (being unemployed is also stressful), but once I find new employment (as a computer programmer) and have to return to being oncall 24/7, as soon as the pager goes off, I will have to run to the bathroom. I have tried to avoid these types of stresses, and haven't been oncall for 2 1/2 yrs., but in the current economy and with 20+ years invested in this industry, it is not possible to be as restrictive in job responsibilities or to make career changes.

I realize that this note is long, but I wanted to let you know how important this is to many people who are now at the mercy of the FDA and GlaxoSmithKline. PLEASE, find a way to return this drug to us.

May I also wish you a happy holiday season and good health.

Sincerely,

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From: ... To: cmiller30080@yahoo.com

Subject: My Lotronex Story

Date: Mon, 10 Dec 2001 00:25:23 -0700

Corey, I have been a silent participant in the LAG for many months. I am so happy to see that there is some action (4/23) but afraid to get my hopes up. Here is my story, which is probably quite similar to many others. Thanks to all of you who are so active for the cause.

I have suffered with IBS-D for about 17 years. The disorder was somewhat under control with Prozac and Librax for several years. However, in the past 4 years, my condition has worsened. I experienced a wonderful 7 months on Lotronex before it was removed from the market. I began taking 2 tablets a day and soon was able to take 1 and have normally functioning bowels. Now I am back to medications that do not directly deal with the diarrhea, but may have the side effect of lessening the diarrhea: amitriptyline and librax. I must resort to using Immodium quite frequently in order to function at my job. This puts me on the constipation/diarrhea rollercoaster, with almost constant abdominal pain. While taking Lotronex, I experienced no negative side effects. People without IBS don't realize that every decision an IBS sufferer makes is centered around his/her bowel functions. Where are the bathrooms? And the anxiety associated with the disorder is enormous. I am willing to accept some possible negative side effects, although I didn't experience any while I was on Lotronex, in order to live a complete life. I feel trapped and stifled by IBS. Cheryl

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June 26, 2001

Corey Miller

Lotronex changed my life. I have had IBS (diarrhea only) for 20+ of my 41 years. Each year it has gotten worse. I don't believe stress is the only factor that causes IBS although it certainly does affect it. Therefore, each year, I have more negative experiences caused by my IBS that consequently have added to my stress and thereby increased my IBS. A negative experience is an episode of profound embarrassment caused by an unexpected, uncontrollable bout of painful, urgent diarrhea.

One example is the time I was returning from a pleasant evening out with my husband and daughter when, in the middle of a residential neighborhood, one mile from my house, I had an IBS attack. I had my husband pull over the car so I could run to a grove of trees in a persons yard and have explosive diarrhea. My options were have incontinent diarrhea in my vehicle in front of my family or diarrhea in a strangers yard (at dusk) where I was mostly out of my families view. That is a terrible, embarrassing predicament for any once proud adult to be in. I have been in my vehicle, alone, stuck in rush hour traffic, and had incontinent episodes.

These experiences, and hundreds like them (close calls, fear of incontinence, disgust from my family and friends) have shaped the way I plan and lead my life. I have had a job within five miles of my home for the last 15 years. I have picked an occupation that keeps me in an office and therefore near bathroom facilities. I avoid plane trips (one or two bathrooms for a hundred or so people and restrictions on times I can be out of my seat to use them), eating out (food may or may not stimulate an attack, what are the odds and am I willing to play them on any given day), avoid stop and go traffic (no dear, I cannot go to the grocery store until 7pm when rush hour is over) and trips to my beloved beach ( a minimum one hour drive through mostly undeveloped area - although I don't mind as much at night because I can jump out of my car like a common stray and use a tree) to name a few limitations this disorder has placed on my life.

Magically one day, a doctor I work with, mentioned a new drug out for IBS. When she explained it was a prophylactic drug not a "stop it once it happens" drug, I was ecstatic. How do I get such a wonderful drug. She offered me a few samples. The 2 weeks I took the drug, one tab twice a day, were amazing. Not a single attack and reduced pain with digestion. I immediately asked my Doctor for a prescription. He was unfamiliar with the drug and would not order it. (A MD that tended to pat me on the head and tell me to relax and it would all go away). Obviously, I changed to the female MD (that also suffers from IBS) that was familiar with the drug.

I took it from May to when it was pulled from the shelves and felt so much better. The habits that controlled my life were fading. I knew that even if I had a meal, I probably would not be sick 95% of the time. I went out with friends and family more. I made a trip on the airplane from Florida to Wisconsin and back with out the help of antihistamines to put me in a sedated state. I went to public places and did not obsess on where the closest bathroom was. I felt like a normal,

proud person. I was starting to make plans for a cruise with my husband of 24 years, something I would never do before. We went to the beach almost every weekend we could - including beaches three and four hours away. I would even venture out for short walks down the beach (something I had previously avoided because there are not public restrooms on the beach. I had to stay within the property lines of my hotel room to be secure.)

Then the terrible day when I was at WalMart picking up my prescription. I had called in the refill the day before. I ran in to pick it up, as the technician handed me the bag, the pharmacist realized it was Lotronex, and with the notice she had just received from her superiors in her hand, refused to dispense the drug to me. She read the withdrawal statement to me as I stood in the center of the WalMart pharmacy, sobbing uncontrollably. I had heard the discussions of the possibility of the removal of Lotronex from the market but I never really believed them. They could not remove this miracle drug. I compared this feeling to the feeling that a cancer patient would have that is getting better on her chemotherapy only to have it withdrawn from the market because others were prescribing or using it incorrectly. True, IBS will not kill me, but it is killing my spirit, and what am I without a spirit? Lotronex must be returned to the market. I will submit to any tests, trials, follow ups that you deem necessary. I am only here to support your decision. Please give me back my spirit!

Sincerely,

**To Whom It May Concern:**

I would like to express my dismay regarding the recent withdrawal of Lotronex, which was a medication used to treat Irritable Bowel Syndrome. There are currently hundreds of thousands of patients unnecessarily suffering.

IBS is a debilitating and chronic gastrointestinal disorder that affects up to 20 percent of adults, 70 percent of whom are women. IBS is second to the common cold as the leading cause of absenteeism from work. IBS symptoms vary; however, the most common ailments are diarrhea, constipation (or both), fecal urgency, abdominal pain, abdominal cramping, excessive gas, fatigue, headaches and muscle weakness.

I am only 27 years old, and I have suffered from IBS for eight years now. They have been the most miserable years of my life. When my Gastroenterologist told me about this new "wonder drug" called Lotronex, I was so excited! I thought to myself, "Great! Maybe I can have my life back now!" Then, nine months later, my hopes were shattered.

With a background in the medical field, I am quite aware that IBS is not a life threatening disorder. However, it is a life prohibiting condition. When one is afflicted with IBS, it is nearly impossible to enjoy life. When I go out to a dinner and movie, I could care less where the fire exits are. All I care about is where the bathrooms are. All through dinner, I wonder if what I just ate is going to make my bowels cramp. Then, at the movie, I have to sit in the aisle seat in case I have to run off to the rest room. Or, maybe I will end up with severe gas pain and bloating instead. If I am in a crowded place, such as a concert, my anxiety level is so high at times that I begin having panic attacks. This is because I am afraid I will have an immediate need for a rest room, and I may not find one in time.

Traveling is nearly impossible. What if I am in the car, nowhere near a rest area, and have that dreaded urgency? Once again, I generally have panic attacks by the time I get out of town. How would you like to live your life like that? Not your first choice? Well, GlaxoSmithKline, the

FDA, and Public Citizen have made that choice for IBS sufferers! If you do not have IBS, you do not understand how afflicting this condition can be. I am not only concerned with traveling and public places. This condition affects my job as well. Statistically, IBS is the second most common reason for absenteeism, next to the common cold. I cannot perform my job duties if I am in the rest room all day! By the end of the day, I am exhausted. After dealing with conditions that coincide with my IBS such as; headaches, fatigue, muscle weakness, and sharp stabbing pains in my lower abdomen, I am left feeling drained physically and emotionally.

I fully understand the side effects and risks of Lotronex. I feel I should make the decision to take the medication, not some corporate bureaucrat. I know that Lotronex may have caused life-threatening side effects (which has not been proven). Did you know 66 people have died from taking Accutane (also a medication for a non-life threatening condition)? How many deaths do you think have been caused by Viagra, Celebrex, or Tylenol?! Why are these drugs still available? At least acne and arthritis patients have alternative medications they can take. Lotronex was the only viable medication to treat IBS, and it has been taken away?

After two weeks of taking Lotronex, I felt like a new person. I had my life back! I was able to go to public places and travel. I could eat and drink anything I wanted and I had no cramps, no urgency, and no gas pain. Those were the happiest months of my life! Why did it have to be taken away?

To Whom It May Concern,

It was suggested by our LAG group that you might be interested in hearing some stories about former Lotronex users. I am a special needs teacher of 26 years. Lotronex changed my life as well as those around me. I was able to go to my son's new house, eat supper, and see my granddaughter's room and her kitty. Every week she asks me to come again, but traveling, socializing, and eating out is something I've had to restrict now that I'm out of Lotronex.

I've had IBS symptoms for years, but I lived with it until I was diagnosed with Multiple Sclerosis in 1990. As my mobility decreased my ability to get to the bathroom in time and take care of any accidents myself decreased. Now if I have an "episode" at work, I have to drive home sitting in fecal matter, and wait until someone can come and help me in the bathroom. Of course, by then, I'm not pleasant at all and require a shower and change of clothes. I have a Foley catheter in and this is not too healthy an activity so I'm having monthly urinary tract infections right now.

Have you ever seen the look on a child's face when he watches you enjoy his birthday "treat"? It's one of the things that keeps teachers at their jobs. Before, I would take his treat, put it on my desk, and tell him I was saving it for later. To be able to enjoy it with the whole class was thrilling for me, and now that I've tasted that joy I miss it.

When thinking about this Lotronex issue, please remember we have the medical knowledge and technology to provide humanity with this wonderful drug. The production and distribution of this drug is necessary to improve the quality of life for the many former users. We'd like to have the free will to make the choice about how we want to live our lives.

To Whom It May Concern:

I am writing in support of the drug, Lotronex, which is a treatment for IBS. I am a 25 year old woman who has suffered from IBS for six years. I have taken numerous other medications, altered my diet, and tried anything else suggested by my doctor with very little improvement. When my doctor suggested trying Lotronex in June 2000, I was very excited to try it. I took Lotronex from early June 2000 until March 2001 when my supply ran out. I had no bad effects from the medication and it eliminated almost all of my symptoms of IBS.

Lotronex was a miracle to me. It gave me my life back again since I was able to attend work everyday, attend social events, and leave my house whenever I chose to. Without Lotronex, this is not the case. I will get sick on a moment's notice so it is impossible to make plans ahead of time because I almost always have to cancel them. I am afraid to go out in public because I never know when I will have an attack. Foods that I can eat safely one day make me very sick a week later. I am 5'9" tall and weigh 120 pounds. I have lost 10 to 15 pounds since being off Lotronex because I am unable to eat many foods and at sometimes everything makes me sick no matter what I eat. I sometimes eat nothing but plain white toast and applesauce and that can make me sick. While on Lotronex, I was able to eat almost anything. I was able to eat out at a restaurant which I hadn't done in a very long time.

IBS is not a life-threatening disease, but it is a life-altering disease. It changes every aspect of your life and takes control of your life. I want to take control of this disorder again by taking Lotronex. Lotronex is the miracle that IBS sufferers waited a long time for. It is unfair to show us how we can live a normal life and then take it away from us.

Please return Lotronex to the market so that other IBS sufferers like myself do not have to suffer one day more. Thank you for your time!

June 24, 2001

Corey Miller

I am one the millions who suffer from Irritable Bowel Syndrome. I can not begin to convey to you the embarrassment and humiliation of being in a meeting, grocery store or out with other people and realizing that you bowels are moving and you have absolutely no control of them. Needless to say, I avoid leaving my house. What a life. And then, there is the pain.....IBS is extremely common. One out of five suffer from it and it is the second leading cause of worker absenteeism. Many people don't know they have an illness. They just think it's the way they are. I've had this for over 25 years and I went eight to ten years without being diagnosed. I thought it was my "nervous stomach" or "hectic lifestyle" and I was too embarrassed to ask my doctor. Finally, I did. He gave me the name of my problem, but unfortunately, there was not much he could do to help me. Over the years, I have taken all the medications that slow down the intestinal track. Some didn't work at all, some worked a little. Nothing helped me enough to be able to have a normal lifestyle.

And then magically, Lotronex was introduced. For all too short of time I could work, have a social life and be free of excruciating pain. I could go on those school fieldtrips with my kids, shop, enjoy life. Then it was taken away from me. I can not tell you the depression this news put me in. I took Lotronex all the months it was available. I had no adverse side effects.

Part of what makes this such a difficult illness is that we don't know when the IBS is going to hit. Most of us have the same triggers, i.e., going out to eat, vacations. But many more times, it comes totally out of the blue. Lotronex kept those attacks away. Most of the time, there it great pain and you know you need to get to the bathroom fast. But other times, all of a sudden, you realize your bowels are moving and you're not going to make it in time. I have been six feet away from the toilet setting the VCR and not made it in time. Six feet..... Many times I wake at two or three in the morning, after going to sleep fine, with indescribable pain.

Unless you have had IBS, you have no idea how devastating and debilitating it is. We can't go out with our families and friends and that causes great strain in our relationships. Lotronex allowed me to have a life again. I pray that it will not continue to be taken away from me. There are so very many who desperately need it.

June 24, 2001

Corey Miller

To those who understand and the others which can only try... here is my story on ibs.

My name is Kathy Bleidorn, I'm not ashamed anymore to tell people that when talking about ibs, after being apart of LAG and finding that so many people have it in the world, I know that I am not alone. I, too, know the fear of venturing outside my front door, even my bathroom door least an attack would prey upon me... but let me start at the beginning...

I remember, although I'm sure I had it before then, having my first ibs attack in first grade. Laying on the floor listening to my teacher tell us a story, everybody gathered around her. My stomach started to make funny noises, the cramping, hot flashes across my body and not knowing what was going on, tears forming in the corners of my eyes. I was a shy kid, not wanting to even raise my hand to answer a known question, let alone asking to be excused to see the nurse.

I'm twenty-five now and just a few years ago found at least a name to my "problem". My parents weren't cruel, they just never accepted diarrhea as being sick, so they never took me to a doctor. Doctors won't call it a disease, because they cannot find anything physically wrong with you... instead they call it a "condition". Whatever that means. Even now doctors don't know how to cure this mystery "condition" that effects so many people. I've heard it all - "lactose intolerance, no caffeine, no chocolate" and my favorite of "you need to stress less". Yeah, right... I'm single, college educated, have a good job, nice place to live - what do I have to stress about? I knew in my heart something wasn't right and what hurt more than the pain was the lack of understanding. I've had all the tests, ultrasounds, blood samples and even the dreaded barium lower GI. Never will I willingly go through THAT again. All to no conclusion.

I could tell you countless stories of how ibs has interrupted my life, but that would be at least a novel's worth and those are memories even I try to forget. Let's just say it ranges from being in the middle of a field in marching band in full uniform having an attack, to riding in the car in the middle of nowhere begging to keep pulling over at every exit, to going into work early everyday to get into the bathroom before everybody else. People that have ibs know the tricks of the trade - finding bathrooms that nobody uses, excuses not to go out, taking immodium in large doses if they do and always, always knowing where the closest bathroom is. It was an everyday occurrence. No wonder people like us want to live alone.

So what is one of my "episodes" as doctors like to put them. It starts with sudden sick feeling deep in the gut. With God willing, I will be at home and not somewhere I can't escape. I can tell when I'm going to have an attack before the pain even starts by feeling on the right side of my large intestine the liquid mass contained there. It starts to move up and over to the left side where the cramping begins, the gas, my temperature starts to rise, I break out in a cold sweat and the pain being so bad you want to throw up. Feverently praying that it just moves out of your system so you can breath again. Trying to relax is out of the situation, that's like telling a person with Asthma to just start breathing okay. After about 2-3 bouts of this, with any luck, you've got a few hours to recover. And recovery is needed. You're drained, out of breath, and more than anything mad at the world for having to go through this.

Telling yourself... THIS IS NOT NORMAL, WHY CAN'T I BE NORMAL LIKE EVERYBODY ELSE?

I should note that the only other time I didn't have ibs was when I was on Accutane, it pretty much dried up everything inside me so for six months I was in heaven. But you can't be on Accutane forever, so the ibs came back, and that prompted me to try and find a doctor to see if he/she could link the effects of Accutane with anyother drug out there. I got little attention...

Then came Lotronex. It was my first official visit to an internist and he gave it to me to try. Like most people, I got constipated right away since I took two pills a day. But after four days of no movement whatsoever, I knew something was wrong. Not too wrong since I was thrilled to be constipated, just not for four days since I was still eating and nothing was coming out. I'd like to think I'm pretty bright, so I cut my pills down to half in the morning and half at night. It worked perfect. I could eat what I wanted and never have a problem... even when I was on my period, which usually made things a lot worse. At long last, I was normal and right away, no time to be wasted here, I was out and about enjoying life to the fullest.

Then they took Lotronex away. My coworker in passing told me they were taking it off the market. It was like somebody slapped me across the face. WHAT? I tried to fill my last order only to find that they stopped filling Lotronex the day before. I called the drug company but to no avail. With only one thing left to do... I cried.

My supply of Lotronex would of lasted me probably a year since I kept getting the full perscription and taking half. Heck, it was for insurance purposes to be cheaper. I decided I had to find another way to survive. To finally have a full life and then have it taken away is cruel and I couldn't live that way again. Didn't want to... even considered suicide. I got on the net and found a book and website call "Eat Without Fear". They listed things that triggered ibs and what to do to prevent other attacks. I was on my last straw, so I stopped taking the Lotronex and started my strict diet of no dairy products, no red meat, no caffeine, no eggs, no fried food, no alcohol/pop, no wheat bran or nuts or popcorn. The list goes on and on. Luckily I like eating bland foods or it really would of been tough. To be honest, I think it was the dairy or a combination of many things, but my symptoms are far and few between now. I take Calcium and drink green tea and exercise a lot. The good thing is the ibs is dormant currently, the bad thing is that I'm almost five foot five and I weigh 109 pounds. I've lost in six months 17 pounds. My coworkers comment about it and so does my family. I tell them, "well, I can either eat what I want and be sick everyday, or watch what I eat and lose weight." Where is the happy medium? Also, I take half an immodium in the morning and half at night. To be honest again, I don't think I need it, but I'm too afraid not to take it.

Am I any less of support of Lotronex coming back? No way, if my symptoms flare up again I need to know that there is something out there that can help... not just another doctor saying "sorry, try some more immodium". I have been following LAG from almost the beginning. Although I'm not very vocal, I pay close attention to all the emails in every listing. Even the thought of this group coming through and bringing Lotronex back to the market puts a smile on my face and tears to my eyes. What a wonderful group of people... to pull together in "our" crises and prevail in victory. And yes, this is a war and we're fighting the battle everyday against people like Public Citizen and even the random folks at the FDA which are also against it.

I don't know what else to say... but please bring Lotronex back to the market... then maybe we'll all "relax".

Sincerely,

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I

June 24, 2001

Corey Miller

I am a female, age 35, suffering with IBS since the age of 21.

I have tried everything over the past years with no relief until Lotronex.

For people who do not suffer from IBS, one cannot know the feeling from day to day living in fear, in isolation and even in humiliation.

You cannot eat out, you cannot attend any social event, you are afraid of food. Your entire life revolves around the bathroom. My IBS controls my life because it limits my time with my family, my children. Unless a bathroom was around I cannot or will not attend many activities my children are involved in. That is not fair to them when there is medication that can help me. In April of this year, I was forced to leave a job I had just recently started due to IBS. I had several days of D and being in pain day after day and not being able to eat. I called my Gastro and he prescribed Lotronex. He informed me of the side effect of constipation. He started me on 2 tabs due to my serious symptoms at the time. In 2 days the D stopped. I continued on the Lotronex but after a week I had trouble going to the bathroom so I immediately stopped and called my doctor back. He advised to stop until I had a BM and then continue with the Lotronex but at a lower dose. He said I would have to find the dose that was right for me. I stopped for a couple of days and restarting it to  $\frac{1}{2}$  tab a day, which I then upped to 1 tab a day. I also was advised by him to drink plenty of fluids while on it, which I did. That helped me so much, it was amazing. I DID NOT HAVE 1 BOUT OF D for the entire time I was on Lotronex. I felt like a different person. After a couple of months I felt so secure and confident that I could eat out and actually have a social life, it just didn't seem possible. It was hard to believe after dealing with D all your life and then it suddenly stops and you're able to do things and eat things that you never before would even think of. It takes time for your mind to feel secure in saying it is okay to do that or it is okay to eat that. I could live a normal life and it was a miracle. I had normal BM's and went every other day with NO constipation. I was well informed about

Lotronex and my doctor said to find the right dose, which I did and I was never happier in my entire life!!! My husband could not believe how it worked so well. It definitely takes an understanding spouse to deal with IBS. It really was a miracle drug. My husband and I actually went out to dinner and then to a movie, forget about going out to eat but doing both was such a great feeling to do after many years of just hoping I would make it through a movie without problems. We had been very active in taking our kids places, TOGETHER. My husband doing things without me made our family living very stressful and it affected my kids as well. My children were used to me not going places but didn't understand why. They just knew me as always being sick or not feeling good and that's why I never could go and feeling very guilty and crying at times because I could not go. Lotronex dramatically changed my life until the recall. When I stopped the Lotronex, within 3 days the D came back. I have been so depressed and so terribly mad. I never thought I would have to deal with IBS again. I sit at my new job panicking every minute of the day. I have gone back to my old eating habits of starving myself all day until I get home, and even then hardly eating thinking about having D the next day on my way to work. It's a nightmare all over again. In all the years nothing has worked that has been prescribed for me as well as over the counter medication .....until LOTRONEX. I don't want to deal with starving and the constant headaches due to a bad diet and coming home feeling sick and not being there for my children because I don't feel well. I lived that life long enough. The LAG, which I am a part of, is working so hard to make everyone understand how Lotronex brought us back to life, back to living normal lives. It is now summer with so many activities that I planned on doing are now just wiped away. I'm just too frightened to attend anything away from a toilet or even go on a vacation this year or any year from now on unless I have Lotronex. I desperately need Lotronex back. Taking Lotronex off the market has taken my life away as well as my family's. I want my life back!!!!!!

June 24, 2001

Corey Miller

I was involved in the clinical study in San Diego to get Lotronex approved by the FDA. Almost immediately after first taking the drug I noticed my IBS was no longer a problem. I was able to have a normal life again. When Lotronex was taken off the market I couldn't believe it. I can understand that it had caused the death of some women and of course I do not want to die. However, bring Lotronex back for those of us that need it and we can be watched by our personal physicians to be sure there are no health problems.

I look forward to hearing from you.

Sincerely yours,

June 24, 2001

Corey Miller

It seemed like just about the time I was going through menopause I developed IBS-D at about the age of 53. I had never heard of IBS before this. All of a sudden one day at work I had incontinence diarrhea. I didn't know what was happening and thought there was something terribly wrong with me. It happened more and more frequently as time went on. I then started reading about IBS-D and was grateful that this happened to other people. I was even too embarrassed to go to the doctor. I didn't even tell my husband for a long time. I tried to hide it but it didn't work. I would have accidents all over the place.

I started to try natural products, avoided trigger foods, taking loads of Imodium, etc. and this helped a tiny bit. I had to avoid any social situations, dinner with friends, no more traveling and couldn't even have my grandkids visit because I couldn't take them anywhere. Sometimes I didn't make it to work and had to turn around and call in sick or go in late. Sometimes I had to leave work hoping nobody noticed what happened.

Finally, July 2000, I went to a gastro specialist even though I knew there was no cure because I had read in several books that there was no cure. I knew this group did a study on IBS-D because I read about it in the paper. I didn't participate in the study because I thought they might ask me to go off the natural product I was taking. If I had known they were testing Lotronex, I would have jumped at the chance. The doctor gave me a supply of Lotronex (I had never heard of it and had no idea it was a new drug).

I could NOT believe how wonderfully Lotronex worked for me in just one day. He did prescribe two pills a day and I got constipated. So, I called and the nurse told me to regulate the dose to fit my needs. I eventually was taking 1/2 pill a day and I had a NEW LIFE! I was traveling, eating dinner out, socializing again, having the grandkids visit, etc., etc., etc. No more 24 hour thinking about my bowels. I was FREE!

In November, 2000, I was driving to work and heard on the radio that Lotronex was being withdrawn from the market. I almost had an auto accident and started crying hysterically. I immediately called my husband at home and told him to try to renew my prescription immediately. We thought he was successful but he was NOT. I could have renewed that prescription five times because I used so little of the Lotronex. I would have had enough for four years - how stupid of me not to have known but I did not know it was a new drug. I had absolutely no side effects, I felt normal again. I can't believe we cannot get Lotronex back. I cry over it.

I stopped taking Lotronex and was back to the same old s\*\*t. S\*\*ting everywhere - you know what I'm talking about. I saved the last bit for special occasions and only have enough left now

for a three-day bachelorette party for my daughter in NYC where I will need to travel at Christmas time. And, for her wedding in May, 2002, when I will walk her down the aisle - I hope! I'm just praying that my Lotronex is still potent by then.

It took me a while to tell you my story, although I've shared it on the IBS self help group bulletin board and have called and written to GSK and the FDA. But I cry everytime I think about the terrible situation we are all in without Lotronex. And, to think it is up to some people to bring it back who have never experienced our pain, humiliation, suffering needlessly and lack of any quality of life. I am thinking about taking a sick leave because it is such a worry just getting to work and then when I'm here I'm a wreck thinking I might not make it to the bathroom. I do not want to go on the anti-depressants and other medication others are using. I now take Ibsacol, Metamucil and still lots of Imodium. But, it is a viscous circle to say the least. Tomorrow I need to go with my daughter to try on wedding gowns. I dread the thought of getting into the car.

Thanks for listening - I just beg and plead for Lotronex to come back!

June 25, 2001

Corey Miller

To Whom It May Concern:

I would like to express my dismay regarding the recent withdrawal of Lotronex, which was a medication used to treat Irritable Bowel Syndrome. There are currently hundreds of thousands of patients unnecessarily suffering.

IBS is a debilitating and chronic gastrointestinal disorder that affects up to 20 percent of adults, 70 percent of whom are women. IBS is second to the common cold as the leading cause of absenteeism from work. IBS symptoms vary; however, the most common ailments are diarrhea, constipation (or both), fecal urgency, abdominal pain, abdominal cramping, excessive gas, fatigue, headaches and muscle weakness.

I am only 27 years old, and I have suffered from IBS for eight years now. They have been the most miserable years of my life. When my Gastroenterologist told me about this new "wonder drug" called Lotronex, I was so excited! I thought to myself, "Great! Maybe I can have my life back now!" Then, nine months later, my hopes were shattered.

With a background in the medical field, I am quite aware that IBS is not a life threatening disorder. However, it is a life prohibiting condition. When one is afflicted with IBS, it is nearly impossible to enjoy life. When I go out to a dinner and movie, I could care less where the fire exits are. All I care about is where the bathrooms are. All through dinner, I wonder if what I just ate is going to make my bowels cramp. Then, at the movie, I have to sit in the aisle seat in case I have to run off to the rest room. Or, maybe I will end up with severe gas pain and bloating instead. If I am in a crowded place, such as a concert, my anxiety level is so high at times that I begin having panic attacks. This is because I am afraid I will have an immediate need for a rest room, and I may not find one in time.

Traveling is nearly impossible. What if I am in the car, nowhere near a rest area, and have that dreaded urgency? Once again, I generally have panic attacks by the time I get out of town. How would you like to live your life like that? Not your first choice? Well, GlaxoSmithKline, the FDA, and Public Citizen have made that choice for IBS sufferers! If you do not have IBS, you do not understand how afflicting this condition can be.

I am not only concerned with traveling and public places. This condition affects my job as well. I cannot perform my job duties if I am in the rest room all day! By the end of the day, I am exhausted. After dealing with conditions that coincide with my IBS such as; headaches, fatigue, muscle weakness, and sharp stabbing pains in my lower abdomen, I am left feeling drained physically and emotionally.

I fully understand the side effects and risks of Lotronex. I feel I should make the decision to take the medication, not some corporate bureaucrat. I know that Lotronex may have caused life-threatening side effects (which has not been proven). Did you know 66 people have died from taking Accutane (also a medication for a non-life threatening condition)? How many deaths do you think have been caused by Viagra, Celebrex, or Tylenol?! Why are these drugs still available? At least acne and arthritis patients have alternative medications they can take. Lotronex was the only viable medication to treat IBS, and it has been taken away?

After two weeks of taking Lotronex, I felt like a new person. I had my life back! I was able to go to public places and travel. I could eat and drink anything I wanted and I had no cramps, no urgency, and no gas pain. Those were the happiest months of my life! Why did it have to be taken away? If anyone would like to assist the thousands of Americans who suffer unnecessarily from this condition, please contact the

following organizations' Web sites: FDA.gov, GSK.com, IBSGroup.org, and the Lotronex Action Group at IBSWatch.com.

Sincerely,

This is a plea to you. If you have one ounce of compassion in your sole, please just take a few minutes from your life to read this. It's about Lotronex and will give you a true perspective on what it means to so many.

My wife has Irritable Bowel Syndrome (IBS). She is in that 5% for which it is the severest and she has had it for one and an half years. Because of this, in our 38 years together, we've never been challenged like this before. Her primary symptoms are diarrhea (D) and abdominal pain. While her "D" is your typical worse case scenario for an IBS'er, it is far easier to cope with than her abdominal pain.

My wife, Sharyn, was a 54 year old, classy woman with a bounce in her walk and a love for life that was overpowering. Her social life was overwhelming for me at times, yet so rewarding. A positive, upbeat person ... The kind you'd like to meet. That was all before IBS. In September of 99 that all changed. IBS hit full force. The abdominal pain became debilitating/crippling three to four days of each week, so bad at times that it literally put her on the floor. And, when the pain was at low rumble (that's what she calls it), she lived in fear of when it would attack again. Her words to describe it, "It's like someone very strong reaches into your gut and squeezes your intestines as hard as they can over and over again." It was not uncommon to see her spend most of a weekend in a fetal position, holding her gut and stuffing down Hydrocod, which was almost useless, and praying that the pain would go away. Just a half glass of water would cause her to cramp. Her social life became non-existent and her weight dropped 25 pounds in three months and she was slender before the weight drop. And when it was the "low rumbles" (a good day), if she'd go out, it was always a concern that the "D" would hit before she arrived at wherever she was going and once there, it was locate the bathroom first before doing whatever it was she was there for. But you know that story ... I think.

One last thing: I'm a 57-year-old man. I have cried more in the last year and a half than in our entire 38 years together. No, I'm not a wimp .... Quite the opposite. I'm from the construction industry and tough as nails. But, her suffering from this illness has torn my heart out.

## Perez, Thomas

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**From:**  
**Sent:** Thursday, April 04, 2002 5:02 PM  
**To:** perez@cderr.fda.gov  
**Subject:** Lotronex

Mr. Perez: I am writing in support of Lotronex. My symptoms began at age 25 when I began suffering cramping and diarrhea. During this seige, I was referred to internists who poked and probed, who performed all the invasive tests, who put me on special diets, who prescribed Librax and OTC drugs. The symptoms continued for a 5 month period. I lost more than 20 lbs. during that time, due to the diarrhea and the special diets. I am now 60 years old, and still plagued with IBS, sometimes more seriously than others. Throughout years of intestinal discomfort, anxiety and curtailment of normal activities (i.e. commuting by bus, morning group hikes or bike rides) I have tried biofeedback, yoga, therapy, and yet more invasive testing and failed treatments that various MDs had to offer me. (I could write a helpful book: "Public Bathroom Locations in the Bay Area", or "How IBS Has Limited My Life".) All this changed one day when I learned about Lotronex at the office of a gastroenterologist who had performed the FDA trials locally. Immediately, I had a new lease on life! I was FREE...Free to act like a normal person, without the restrictions that imprison IBS sufferers. My gastroenterologist stayed in contact with me, answering my questions and making recommendations about the dosage (although I know my body better than anyone). I needed less than the recommended dose and I dealt with the side effects (constipation) with vegetable fiber. Fortunately, I am married to an MD who knows and understands my symptoms well, and could make suggestions. He was also delighted with the change: no more rushing to find a bathroom on a car trip, no more cancelling of activities due to discomfort, no more anxiety about "can I or can't I" do this or that. I was able to eat healthier, tolerate more foods, and maintain my weight. I was a NEW PERSON for 7 months! And then the bomb fell: Lotronex was pulled. Through my personal contacts with the medical community, I was able to gather samples that would have been discarded. They are like gold to me and I dole them out only when I am at my worst. I no longer feel FREE or NORMAL. My greatest fear is when they are all gone, and I again become a prisoner to IBS. I have known both lives: before-Lotronex and after-Lotronex. I choose after. Wouldn't you? Thank you for listening.

**Perez, Thomas**

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**From:****Sent:** Thursday, April 04, 2002 12:01 PM**To:** perez@cder.fda.gov; lotronex@yahoogroups.com**Subject:** (no subject)

Tom Perez, (Please read this and let anyone see it at the April 23rd meeting)

I am going to send you my story about how IBS and Lotronex had changed my life, but first I need to let you know how strongly I feel about getting back this medicine. Imagine you are all ready to go out, but can't leave the house. Imagine you are gonna get married, but need to take so much medicine to drug you up so you do not have a diarrhea attack. Imagine your nephew wants to leave for his championship baseball game, but you are late. Imagine your father in law dies and you drive alone in the car to his funeral, because you are scared to have a diarrhea attack in the car, on the street, at the game or at the funeral. Imagine your grandma asks you to drive her to the doctor, but you just had three attacks and are scared to leave the house. These have all happened to me and many more embarrassing things.

I have been through a lot and the only thing that has ever helped was Lotronex. It should be my decision to take Lotronex. My life is meaningless this way. I let everyone down including my child, husband, family and friends. I am so depressed. Everywhere I go I am looking for a bathroom. It is not right. When I was on Lotronex I was able to go to the park, games, movies, dinner and I did not even care where the bathroom was, little did I know it would all be taken away. Please please please for, if not for us then our families give us back Lotronex. Here is my sad story.....

Hello to All...

I am a 31 year old female from NJ. I have had IBS for 12 years. When I was 19, I was in the car with a boyfriend and had to use the bathroom...IMMEDIATELY. I didn't think I could make it. After that episode and many more, I have been scared to leave the house. Of course I have to leave, but I am always looking for the bathroom. I have canceled many engagements with friends and family, because I was scared of needing a bathroom. My family did not look at this as a real problem and didn't understand. Actually they still don't 100% yet. My family tells me if I have to go just go, they do not understand that it is painful and embarrassing. I will not go in a car with anyone except my husband, just in case I need to use the rest room. My bathroom episode does not come and go quickly... I have cramping and I am in pain for hours before and after each episode. How can I ask a couple on our way to dinner if they can wait 2 hours while I have a diarrhea attack? Well, I don't ask anyone for anything. Most of the time I don't even leave the house. Many vacations, dinners, concerts, day trips and movies have been cut very short or I just don't go.

I had many many many tests done about 3, 5 and 10 years ago and was told it is IBS and that it was all in my head. They gave me many prescriptions (depression and anti spasmatic meds), but nothing. So, I began to think it was in my head too. I am also lactose intolerant and don't like red meat, so as you can see eating is a chore too! I about 20 lb. over weight, because all I eat is bagels and bread (high carbs). They bind me and that's what I need. I have bought cases of Immodium over the years, but after 3 days of Lotronex I have not bought any since. I have been asked to be in about 10 weddings and would worry until they were finally over (what if I needed a bathroom during the ceremony), including my own, in case I got sick and ruined someone's wedding, I have many more horror stories. I do not remember most of my wedding because I took something to relax me, so I did not think of my stomach problems.

We have gone on many vacations most with my husband annoyed because I would not do anything without a bathroom in site. Most people take for granted a bathroom, but to me it is my savior and at many times my only hope. I promised my husband that when we got home from vacation I would go to the doctor for my problem and so I did. Lotronex was just released and the doctor said "Michele this is your answer." I could not drive the car fast enough. After 3 days!!! I was sooooo much better. Now, I used the bathroom once or twice a month instead of 5 or 6 times a day. I was going daily and I was normal.

I needed to get better for my son. He is 17 months now and my unborn child (4 months pregnant). I didn't want him to miss out cause mommy doesn't like to go out of the house. I could not do that to him too!!! I live close to NYC and took day trips with my son and husband, I was a person again. I felt great. I went for dinner, movies, central park etc....and yes I still looked for a bathroom, but I didn't need it. YEAH!!!!

Then D day came and my husband called and said "that Lotronex was recalled and the insurance would not cover it, but I could buy it" of course...I did. It was very expensive, but worth every dime. You can't put a price on a new life.....Now, I have been without for one full year and its gotten bad. Before I got pregnant my doctor prescribed a medication that I took many years ago called LIBRAX CAPS along with PAXil, it was OK, but I

mean nothing like before with LOTRONEX.

Hey not to get all feministic here, but if this drug was for men too do you think it would have been recalled? Men have always made decisions and they effect women.

The first time I took LOTRONEX I needed one a day for about a week, after that I took 2.

So, anyway I am ready to make a difference. I called and E-mailed everyone I could. I am sending this letter out to about 100 people to get our stories out. I actually can almost cry when I know there are other people like me out there. I feel better reading letters, knowing we can make a difference. I am usually the quiet type, but when it comes to getting back my life I have a big mouth. I have lost way to many years already for this.

I was hospitalized a few times too and had many unpleasant procedures. Another nice person wrote to me and said that they work for GLAXO and want the drug back, but they feel it is never gonna happen. What can I do???? What can we do??? How do people change things that are wrong?? I am a teacher, but now a stay at home Mom and want to give my child his mother back.

I am sorry this is so long, but how can I put 12 years in one letter. I tried, but if you do not want to read this then just delete it. I see so many other stories that really touch my heart. Let's make a difference. Good luck and I hope we can do this.

Please lets get Lotronex back!!!!

Purinthal (6MP) 1 per day

Imodium AD as needed 2-6 pills per day

Do you think that all these drugs are a healthy alternative to Lotronex? I doubt it. Please help us.

Thank you for your time,

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