

Perez, Thomas

From: Lisa ""
Sent: Friday, April 05, 2002 10:32 PM
To: pereztc@cder.fda.gov
Subject: PLEASE READ ---> FDA GI Advisory Meeting - Tom Perez: My Lotronex Story

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Lisa Kenney

Lotronex Action Group Member

Re: April 23, 2002 FDA/GSK GI Advisory Meeting - (Please distribute at Meeting)

April 5, 2002

Dear Tom,

I appreciate this opportunity to be heard on behalf of thousands of Irritable bowel syndrome sufferers much like myself, who at this painstaking time have no other recourse to relieve our suffering but to appeal to both the FDA and GlaxoSmithKline to PLEASE return our only hope in controlling this insidious GI disorder by restoring The single most effective and safe IBS medication called **Lotronex**. Since the withdrawal of Lotronex, our lives are now once again severely compromised in ways no other person can possibly understand except for the IBS patients, their family and friends, and their Doctors.

My name is Lisa Kenney, I'm 34 years old, and Ive been suffering with Severe IBS for over 10 yrs. Prior to May 2000, the day I first took Lotronex, living with IBS was an hourly challenge or nightmare rather. Since my senior year of College I have struggled with Unpredictable IBS. Life could never be normal. In fact, things grew worse as IBS years passed. I was amazed that I even made graduation. All the while, there was nothing available prescriptive or over the counter which successfully alleviated the horrendous symptoms of incapacitating intestinal spasms, the urgent repeated diarrhea episodes, the nausea & gutwrenching pain associated with this incredible disease. Academically, Professionally, Socially and Personally, many dreams and goals short term or long term could not be met. I had given up a great dream to become a Doctor due to this illness. While I accepted my limitations, acquired a full time job for the 10 years that followed, The emotional and physical rigors of constant pain and fear of an IBS attack remained, essentially eroding my health and self confidence at all levels, leaving me mostly in traumatic physical and emotional Isolation.

Most of those years before Lotronex came to the market, have been repressed into a Shameful blur. It is excruciating to relive that level of deprivation and humiliation. The Day lotronex was administered, was the day an IBSer's dream finally came true. I remember that joyful brief period with Lotronex profoundly. I

remember all of the youthful years I've missed, all the company I've missed, all the things I couldn't do or even simpler still, things I couldn't eat or drink, all came back, with open safe invitation. My skin and bones frame finally amassed some fat again! It was a beautiful time! No doubt I felt as "normal" and as Happy as can be!! I had Energy! There was now time for family and friends, concentration and focus at work or play, the ability to commute to work freely, a fervent desire to work and pursue greater dreams, a Lust for LIFE itself, the ability to maximize potential and appreciate Everything as if it were the first time. **Thanks to Lotronex** and the support from Loved ones and friends LIFE was made possible again! After 10 long years of suffering relentlessly, It removed the anxiety, the fear, the shame. It restored the excitement for life, the vibrance, the confidence, the love and friendships long neglected. No more hiding in the bathroom, no more hiding from the world. IT was a second chance at life!

Then the unthinkable day happened on November 28, 2000. How few months had it been? Who was counting? After a 10 year hermitage, I was reliving as normal a life as I could, until time had reversed again, everything positive, painless, powerful was taken away. In one brief moment, life would change back, to the pain we could never forget. I can't begin to describe the events and sorrow that followed... As I write my story, It's not without deep remorse and sadness. Every day since Lotronex was removed, Has been a huge step backwards. I had worked hard as a computer programmer for many years after college. But the illness without Lotronex could no longer sustain The full demanding "normal" schedule. It had been increasingly difficult for me to continue this job as it was before Lotronex, as I was barely managing until Lotronex literally SAVED my life and livelihood.

Fall of 2000, marked two deaths really, The first was losing Lotronex followed by the second which was my own- I was forced on medical leave from my job for the first time In over 10 yrs of perseverant ambition, I felt as if I had literally died. And at that time, the temptation to end it all was stronger than my will to survive. I couldn't suffer the consequences of life after lotronex, life without ability to work, life without quality of LIFE. Being disabled and home-ridden in my thirties or at any age is a cruel tormenting way to live. Seeking safe sheltering bathrooms outside of the house is no way to spend time away from home. What is having fun again? What is working? What is anything without health? What is Life without lotronex? Inconceivable needless pain. It has been a long time since my crisis, I have dreams yet to fulfill, but I am unable to do it without Lotronex. Anxious to return to a productive & professional life, I will continue to be proactive in winning Lotronex back for myself and for so many people in undeniable need of this small miracle pill.

It has been argued that Lotronex has killed or damaged lives. While those cases were unquestionably unfortunate, In comparison to the promising truth, Lotronex has SAVED so many more lives with the enhancements it renewed, the promise it has given to numerous IBS sufferers and even to the family and friends and to our Doctors as well. Collectively this drug can be viewed as the miracle breakthrough, simply the most incredible medicine of this century. As educated and intelligent consumers as well as chronic IBS sufferers, we are more than prepared to accept the low risks with the tremendous benefits of Lotronex, if it means we can "live" again and play a productive role in this society. That's the reality Lotronex brings! Please don't take away the only Hope we have for a much better life -a life that everyone should have the opportunity to seize, a life with dignity, peace and no pain. The day Lotronex returns will indeed be the happiest day of my life and to countless other sufferers as well.

Thank you very much.

Sincerely,

Lisa Kenney