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 April 23, 2002
 FDA Advisory Committee Meeting
 Bethesda, Maryland

As a college history major, it shocked me to read of the astronomical loss of lives from World War I, World War II and the Vietnam War. The textbook called it "man's inhumanity to man". Ironically, it was at this same time period that I began experiencing the symptoms of Irritable Bowel Syndrome. And little did I know I was about to embark on my own loss - the loss of the quality of life.

I have suffered from IBS-Diarrhea predominant since the 1960's. As members of the medical community you are well aware of the debilitating symptoms and there are other speakers here from IFFGD, LAG and IBS-SH who will reiterate them. My focus is on its treatment - such as it is!

My IBS-D journey found me tossed from doctor to doctor ...I was told I had colitis...had too much stress in my life....not enough fiber...watch my diet...not enough exercise...and the best one ...IT WAS ALL IN MY HEAD....then came the upper GI series with small bowel follow through; barium enema (my personal favorite); flex sig; colonoscopy; these were done on numerous occasions. The definitive diagnosis came from the eminent Dr. Theodore Bayless @ Johns Hopkins. But for me the treatment has remained illusive. None of the anti-spasmodics nor the anti-depressants were effective. I suffered over thirty years with IBS-D until I was prescribed Lotronex. From March of 2000 until October of 2001 I was taking Lotronex and my IBS-D symptoms were gone. On October 13, 2001, I was able to walk down the aisle at my only daughter's wedding. In fact, she has accompanied me here today to lend support. After all, when one member of a family suffers from a chronic disorder the WHOLE family suffers! I cannot emphasize this fact enough...MY IBS-D was GONE on Lotronex....I could eat or drink anything, anytime. This was a major life altering experience for me and my family...My sisters also have IBS and could not believe the turnaround. My one sister also has IBD (which goes along with the report that about one-third of IBD patients suffer from IBS also). And yet her IBD symptoms are under control! but there is NOTHING for her IBS symptoms!

The initial dosage for Lotronex had to be modified for me because of only one side effect - constipation. The moment I knew something was wrong, I contacted my doctor - as any patient would do on any drug that he or she were dispensed...He changed the dosage and all was well...until suddenly it was YANKED from the shelves. My newly found freedom to leave my house was gone. I wrote letters to all the politicians and organizations I could think of....there were email sent....phone calls made...but it was gone...then I found the Lotronex Action Group and Drug Voice and they cared about my IBS and they listened and gave power to my voice. That is how I ended up here. Oh the power of the little people when they get mobilized!

I am an educated person and it completely baffles me how this drug got pulled! Something went terribly wrong and it happened behind closed doors. I have no interest in assigning blame to GSK or the FDA or anyone else. I simply want my Lotronex returned. It was the first drug ever prescribed for IBS-D...not all IBS-D patients got to know it was out there...there was no media blitz like one sees for Nexium or Viagra (to name a few)...only several hundreds of thousands were on Lotronex at the time it was pulled...mind you there were millions of patients who gave up hope of any drug ever working for them and never even had a chance to try it! They are the Silent Sufferers that you have heard about. Now how does a disorder that affects over 40 million people get ignored for decades - then gets a drug prescription and then gets denied continued access to it...to a life-altering drug????????? Could it be that because it reportedly affects mostly women, it is another example of female health issues being ignored and now trampled on!!!

We all know there is no "one size fits all" when prescribing drugs. The dispensing and dosing are critical as well as patient awareness for ALL drugs. I deeply regret the deaths of those patients while on Lotronex and the other side effects others experienced before quitting the drug. But is that any reason to deprive the remaining hundreds of thousands of patients who benefitted from Lotronex? For us this was a safe and effective drug. We were punished because it was not right for a handful of others! And we were not allowed to express our experiences to anyone. It was just pulled...no hearings ...no second chances...last time I looked I was not living in a Third World country!...although I could be - they ignore women's health issues too!

7 drugs approved since 1993 were withdrawn due to death or serious side effects....

Redux	Approved as a diet pill in April, 1996.....	Pulled Sept. 1997
Raxar	Approved as an antibiotic in Nov. 1997.....	Pulled Oct. 1999
Posicor	Approved b.p. medication in June 1997.....	Pulled 1998
Duract	Approved as painkiller in July 1997.....	Pulled 11 months later
Rezulin	Approved for diabetes in Jan 1997.....	Pulled March 2000
Propulsid	Approved for heartburn in 1993.....	Pulled July 2000
Lotronex	Approved for IBS-D in Feb 2000.....	Pulled 11/28/2000

The patients taking 6 of these drugs there were other drugs on the market for them to switch to.- not so for Lotronex patients. Hundreds of thousands of us were left without treatment. I represent each and every one of them... We have no posterperson to take up our "cause celebre" so the task falls on each and every one of us. Now the question has been raised... was Lotronex necessary to stay on the market? Was it a life saving drug? The answer depends on who you ask... PC will state there were 5 deaths and hundreds of IC cases, so NO - Pull it! If you ask the Lotronex patient who found it to be safe AND effective - like myself, the answer is YES. Clearly it was meant for IBS-D patients ONLY... yet in all the statements I have found on the subject, they refer to it only for IBS NOT IBS-D..therein lies the problem... it was too generalized and needed to be targeted for the sole group it was meant for - IBS-Diarrhea predominant patients. I also answer that question with a question..... Since when is saving a person's quality of life of no consequence?

On 11/16/99 the GI Drug Advisory Committee met in MD and part of the statistical info to be reported there was the 13.4 days of work missed annually due to IBS. In general, the national average of days missed is only 4..9. The loss of work due to IBS is a multi billion dollar problem. I think this number is underreported. Why? Because I myself cannot even work full-time, and I am sure I am not a part of these statistics..and that there are many more like me who are part-time, on disability, took early retirement or stopped working years ago because there was no effective treatment and hence were not a part of the numbers. I have not been able to work full time since the 1980's. Now let's be honest..I am only mentioning the money issue because that is the one that grabs people's attention...the drug manufacturers will make a profit and the medical insurance industry will see a vast reduction in the cost of diagnostic testing, office visits and lab work when the patient is able to take a little blue pill daily. Currently, The highest price for this disorder is being paid by the patient. The human cost is immeasurable for IBS.

My late mother had IBS but she did not know it had a name. She hid it from everyone, but we knew something was wrong. She refused to learn to drive a car, and looking back that was her excuse for not being able to leave the house. Then it came my turn to graduate, work in civil service, marry and have children. I stayed home to raise my family - expecting to return to the labor market when they were grown. That never happened. My IBS-D has worsened with each year. The Mayo Clinic Spring 2002 report stated that 30% of IBS patients see their symptoms improve with time....I am part of the 70% that DOES NOT improve with age.

Take a good long look at the suspected Lotronex related deaths..were they e coli related, prior IC related symptoms? Was the drug properly dispensed to an IBS-D predominant patient in the first place? Now thinking of those patients who found it to be safe and effective for almost 2 years, do you think this drug was pulled prematurely? Do you think it could have been managed more successfully? I do and I am not alone.

Let me make this perfectly clear. ALL IBS patients need proper medical treatment. Whether they are constipation predominant, diarrhea predominant or alternating C and D, we need more research and drugs solely for IBS. It just so happens that as an IBS-D patient I personally know of a drug that was safe and effective and it was Lotronex and I want it back! Where are my patient rights to continued access to a drug that I did well on? Especially since there is no other IBS-D drug available!!!!

We have all suffered in silence...my mother, my sisters, my children, myself and millions of others...and for decades we have been ignored...haven't we suffered long enough? The tragic events of Sept 11th signalled the importance of doing what is morally right not just the economically feasible. Get off the bottom line and get to the top line - that is where you will find the patient name - the person who has been suffering a very long time and needs your help. Man's inhumanity to man is not only found in killing but in taking away from a person's quality of life. Thank you for your attention.

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