

Perez, Thomas

From: Joe Cannon
Sent: Monday, April 08, 2002 1:12 PM
To: pereztc@cdcr.fda.gov
Subject: FDA GI Advisory Meeting - Tom Perez

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Joe Cannon

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

Mr. Perez,

I'd like to take this opportunity to voice my opinion as to the return of lotronex. I fully support it's return to the marketplace as soon as possible. I don't think it should have ever been withdrawn. I know many people were helped greatly by this drug during it's short duration of availability and how many of them have suffered greatly after it was not available to them. I myself have not used lotronex but I would like to try it as I have run out of options for treatment of my IBS diarrhea. My story is that I am 47 years of age. I've suffered with diarrhea for the last 10 years. I tried just living with it for a number of years. In late 1997 I went and had all the usual tests that IBS sufferers have and I was officially diagnosed with IBS. Since that time I have tried almost every type of over the counter and prescription medicines to help alleviate the diarrhea without much success. The one thing I never tried was Lotronex, as I had read that it was "only for women". Since that time I've found that many males had been helped by this drug. The only thing that helped to control this situation was imodium (taken daily since 1998) and Lomotil (taken as needed). During November of 2001 while having a blood test it was found that my liver enzymes were abnormally high. I had not experienced any symptoms of liver disease so I was told to quit taking the imodium and lomotil. Immediately afterwards my liver enzymes began to drop and although they are still high they are returning to more acceptable levels. However as good as it is to get my liver enzymes back to a more normal level the diarrhea has been especially bad since I stopped taking imodium and lomotil. It greatly reduces one's quality of life to be housebound or having to always know where the nearest bathroom is located. And if one has never experienced the need and urgency to go to the bathroom at any

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particular time or location then that person has no idea what it is really like to be afflicted with this "syndrome". The embarrassment and humiliation that one goes through with this disease is almost unbearable. We, as IBS sufferers, know there are risks with Lotronex as there are with any medications whether prescription or over the counter. But there are also many successes documented with Lotronex. I believe the success stories far outnumber the noted complications and I believe that every IBS sufferer would agree that the risk is well worth taking. My biggest pet peeve as an example is the situation with Viagra which has caused many more deaths and complications than Lotronex yet no one has felt compelled to pull it from the market. It's a sad statement on where the priorities are in this day and time of ours. Thank you for your time and feel free to use this letter at the advisory meeting if you think it might help.

Sincerely,
Joe Cannon