

Perez, Thomas

From: Verna Eileen Radcliffe
Sent: Thursday, April 18, 2002 1:04 PM
To: pereztc@cder.fda.gov
Subject: Item for 4/23/02 Lotronex Meeting

Hello Tom Perez,
My name is Verna Eileen Radcliffe and I'm the author of the petition at www.petitiononline.com/LOTRONEX/petition.html

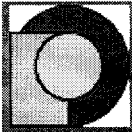
I am devastated I cannot attend the meeting but, diarrhea predominant IBS does not allow me to travel.

My own personal story has been included with the packet of documents from Jeff Roberts of the IBS Self Help Group so I won't include it here.

I know you are aware of the importance of the meeting to all of us out here in the Real World. I also know it has significant importance to the FDA as well.
The attached file represents all the signatures and comments up to midnight last nite. I plead with you to include it with the material distributed to the committee members for the April 23, 2002 meeting. The people who made comments on my petition found it as a way to be heard. Many are made by the family members of the patients. Lives have been restored only to be shattered again and they express that fact most eloquently.

Thank you for all your patience and direction.
Sincerely,

verna eileen radcliffe



A Petition to the Food and Drug Administration and GlaxoSmithKline to Return Lotronex to the Prescription Market

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To: FDA and GlaxoSmithKline

Hysteria is a powerful emotion. It leads to reactionary policy rather than cool minded, level headed, investigative procedures. The FDA is playing politics with medicine resulting in despair and life threatening depression for millions of women.

Writing to the FDA objecting to their role in the withdrawal of Lotronex from the market gained a response "acknowledging the bombardment of letters and emails they received from women who objected to this action," i.e., "...Our Center Director, Janet Woodcock MD, has written a letter responding to the overwhelming number of letters and emails we have received since withdrawal of this product. You can read this letter, dated December 15, 2000 at: <http://www.fda.gov/cder/drug/infopage/lotronex/lotronex.htm> An excerpt from this letter states; "...the FDA is ready to work with Glaxo Wellcome, as with any sponsor, to develop risk management plans to ensure appropriate patient access to medically important, effective drugs. Be assured that FDA is committed to working with pharmaceutical sponsors to facilitate the development and availability of treatment options for patients with IBS."

A call to the manufacturers of Lotronex, GlaxoWellcome, now GlaxoSmithKline, produced the information that the recall of this product had elicited thousands of calls from women "weeping" because of the withdrawal of Lotronex from the market. Women whose lives had been given back to them for a brief period of time and were now being snatched away once again. How many of them will be contemplating suicide as the only alternative?

In a letter from GlaxoSmithKline they state: "The FDA asked us to come to a meeting on November 28th prepared to discuss the withdrawal of Lotronex. The FDA may not agree that they asked us to withdraw Lotronex. At the meeting, GlaxoSmithKline suggested that Lotronex remain on the market while an independent scientific review of the clinical data was conducted. The FDA declined. In addition, we presented alternative plans to the FDA that we believed would adequately and effectively address potential risks with Lotronex, such as label modifications, restricted distribution, on-going patient education, and a new clinical and epidemiological research. FDA disagreed as to the adequacy of these programs therefore we were left with no other option other than to comply with their request for withdrawal. We are deeply disappointed with the FDA's request."

Further inquiry has it that the difficulties may have arisen from improper prescribing by the

physicians compounded by a lack of supervision by said physicians, exacerbated by the patients inability or unwillingness to exercise awareness and/or take responsibility for her own body. Constipation is not a condition that can easily be ignored yet obviously was. Constipation to a life threatening level does not occur over the course of a single day. The 450,000 prescriptions written during the 9 months Lotronex was on the market gives solid evidence to it's need but also to the possibilities of irresponsibility on the part of some physicians. Because of those abuses 5 women tragically died (3 directly attributed to Lotronex), 34 resulted in hospitalization without surgery, 10 required surgical procedures and, 21 suffered serious constipation from Lotronex, according to FDA and GlaxoSmithKline figures. Compare these figures to Viagra attributed deaths averaging 84 per month; Celebrex attributed deaths at 13.5 per month; and Lotronex attributed deaths at 0.3 per month. Meanwhile the hundreds of thousands of women in the US, not to mention the millions throughout the world (because GlaxoSmithKline has refused to release it to other markets based on their US FDA experience) have been denied their right to a "normal" life.

The FDA blithely refers us "...to our health care professionals for alternative medications." THERE ARE NO OTHER MEDICATIONS AVAILABLE that provide the benefits Lotronex does to those who suffer the excruciating pain, humiliation and isolation of uncontrollable diarrhea pre-dominant IBS.

Those three women whose tragic deaths were directly attributed to Lotronex, and the other 65 who suffered horrible side effects resulting in hospitalizations and surgery were women who failed to take responsibility for their own bodies. They and their families paid the unhappy consequences. Those side effects don't come on suddenly...forewarning was not only in the written word of the package information but they were alerted to the damaging effects by their own bodies and "chose" to ignore them.

Sympathy is hard to find in those who once again are housebound, restricted to going only to places with quick and easy access to restrooms; taking sponge baths and reduced to washing out their garments in toilets in public restrooms; leaving soiled underwear wrapped in paper towels in trash cans; and trying to walk with their backs to the wall so nobody will notice the feces stains on their clothing before they can get to their car. Then there are the experiences in the car when they cannot even get to a rest area or gas station or fast food restroom in time; suffering excruciating abdominal cramping so severe as to render their driving unsafe, then ending up sitting in a seat full of hot feces that actually creates burns on the tender tissue of the vagina. No...this is not a mentally sick, distorted message meant to disgust you but a true account of what women with the diarrhea version of IBS suffer with on a daily basis!

GlaxoSmithKline complied with every request made by the FDA until it reached the issue of requiring GlaxoSmithKline to police the physicians prescribing Lotronex. That is the job of the FDA and each individual State's medical policing organization. They are set up for that purpose, pharmaceutical companies are not. The monitoring of narcotic containing prescriptions has been done for decades by these agencies, why not do the same for Lotronex?

Please sign this petition to Return Lotronex to the Prescription Market and support those whose lives are once again in shreds.

Sincerely,

The Undersigned

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The [A Petition to the Food and Drug Administration and GlaxoSmithKline to Return Lotronex to the Prescription Market Petition](#) to FDA and GlaxoSmithKline was created by Patients who derived benefit from Lotronex, their families and friends, and all who are fed up with political medicine as practiced by the FDA. and written by [Verna Eileen Radcliffe](#). This petition is hosted here at www.PetitionOnline.com as a public service. There is no express or implied endorsement of this petition by Artifice, Inc. or our sponsors. The petition scripts are created by Mike Wheeler at [Artifice, Inc.](#) For Technical Support please use our simple [Petition Help](#) form.

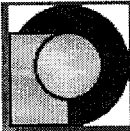
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<http://www.PetitionOnline.com/LOTRONEX/petition.html>

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A Petition to the Food and Drug Administration and GlaxoSmithKline to Return Lotronex to the Prescription Market

We endorse the A Petition to the Food and Drug Administration and GlaxoSmithKline to Return Lotronex to the Prescription Market Petition to FDA and GlaxoSmithKline.

Read the A Petition to the Food and Drug Administration and GlaxoSmithKline to Return Lotronex to the Prescription Market Petition

Sign the A Petition to the Food and Drug Administration and GlaxoSmithKline

Use the Reload button in your web browser to see new signatures

Name	Did you use Lotronex?	Comments
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