

Lotronex Action Group
Corey Miller
4640 Vinings Central Run
Smyrna, GA 30080
678-641-3106

A

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):

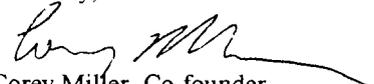
- 1. An open letter to the FDA from the Lotronex Action Group defining the characteristics of the typical person suffering from diarrhea predominant Irritable Bowel Syndrome.
- 2. A petition to the FDA from the LAG requesting permanent access to Lotronex.
- 3. A letter from Jackie Wood, Ph.D. to former 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

Lotronex Action Group
ATTN: Mr. Corey Miller
4640 Vinings Central Run
Smyrna, GA 30080

**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.)