

## **FDA Advisory Committee Meeting for Lotronex – April 23, 2002**

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Members of the Committee, thank you for the opportunity to appear before you. I am the President and Founder of the Irritable Bowel Syndrome Self Help Group.

The 11,000 member Irritable Bowel Syndrome Self Help Group has endeavored, since 1987, to educate and provide support for people who have IBS and to encourage both medical and pharmaceutical research to make our lives easier via our successful internet website for sufferers.

While taking Lotronex, IBS sufferers reported a complete cessation of their symptoms and it changed their lives for the better.

Following the withdrawal of Lotronex from the market in November 2000 the IBS Self Help Group was flooded by messages from former Lotronex users who were desperate for access to the medication. Within a month the Lotronex Action Group was established to bring about access to the medication.

In the spring of 2001 the Lotronex Action Group submitted a 1,000 named petition, to the FDA asking it to immediately work with the manufacturer GlaxoSmithKline to permanently provide the drug to those diagnosed with diarrhea-predominant Irritable Bowel Syndrome. The petition used data from an electronic survey conducted by the Irritable Bowel Syndrome Self Help Group that identified the side effects from taking Lotronex.

**59% of those surveyed indicated that they had no side effects at all.**

Through the months of March-April 2002 the IBS Self Help Group surveyed Irritable Bowel Syndrome sufferers about what type of restrictions, if any, they would be willing to accept for access to IBS medications.

**59% of those surveyed responded that medicines specific to IBS should be accessible to a sufferer diagnosed by a family physician (or gastroenterologist) and not only a gastroenterologist.**

It is important to distinguish between having only a gastroenterologist vs. a family physician provide a prescription since many sufferers do not have access to a specialist either because they do not live in a community supported by one or because their medical coverage does not provide access to one. If a decision

was made to allow only gastroenterologists to prescribe Lotronex, then many IBS sufferers would have difficulty getting access to it.

The survey also said that **63% are willing to agree to participate in a survey about use and side-effects, while taking Lotronex, sponsored by the pharmaceutical and/or FDA agency.**

Finally, **96% of respondents say they would sign an *Informed Consent form* in order to gain access to a medication.**

Our surveys show that IBS sufferers are prepared to accept risks related to the use of Lotronex and other effective treatments for IBS. They are also prepared to participate in programs to better characterize risks related to the use of Lotronex, and other treatments, and to work with the FDA to reduce those risks as much as possible.

The IBS Self Help Group and IBS Association are prepared to place specific risk management information about Lotronex on their websites in order to reach out to the IBS community. With close to 4,000,000 monthly visitor hits, the highly active websites can be utilized as a vehicle to educate and provide signs and symptoms about Lotronex.

In conclusion, IBS sufferers' quality of life was dramatically improved with access to Lotronex. IBS sufferers are prepared to accept the risks associated with its use and to work with the FDA to reduce those risks.

Thank you.