Re: FDA Letter of January 23, 2002 to IBS Patients

Although I wish fervently that I could attend and participate in the Lotronex meeting on April 23, 2002, this is impossible, as I have been unable to make a trip of that length since Lotronex became unavailable. Standing in long airport lines and being required to stay in one's airplane seat for extended periods of time make travel a hopeless luxury without the benefits that Lotronex can provide.

During 2000 when I was able to obtain this medication, my life became a normal one after years of increasing pain and embarrassment with IBS. Like many other patients, I find that the condition becomes more severe as I age. A reduction in the originally-prescribed amount of Lotronex taken per day was all that was necessary to provide complete comfort without decreasing the drug's efficiency. The printed information provided in the Lotronex container was clear and certainly would have sent me running to my physician if any side effects had developed. I simply cannot understand why anyone would continue to take, or why any doctor would continue to prescribe, a medication that was causing problems severe enough to cause serious illness or death.

To address the following item in the FDA letter, "In those patients not previously treated, indiscriminant use of Lotronex can reasonably be expected to result in serious and fatal adverse events such as those previously reported", indiscriminate use of any material that one swallows may very well be expected to cause unpleasant results. Shouldn't physicians accept responsibility for properly prescribing and carefully following up on any drug they recommend to their patients? And mustn't patients assume responsibility to follow whatever instructions they are given in regard to taking or discontinuing use of a prescribed medicine?

A further statement in the letter, "A carefully designed risk management program is essential for safe use of Lotronex for patients who need it, and to effectively discourage its use for patients where the risks are likely to exceed the benefits", suggests what could be one solution to this problem. Complete removal of Lotronex from patients who obtained so much help without any difficulties was far too drastic a step when other options are possible.

Distribution of the medication by prescription from a qualified physician and purchase from a licensed pharmacy, both of which could also provide printed and oral information for its use, would seem to sufficiently limit access, but if more control is required, I am sure that those of us who suffer so greatly without Lotronex would willingly accept additional limitations. Each Lotronex user might be required to sign a statement acknowledging that he/she is aware of the possibility of side effects.

Perhaps an IBS remedy that produces no side effects for anyone will be developed in the future but, in the meantime, those of us who benefited so greatly from the use of Lotronex urge you "to find a way to make Lotronex available to people who need it". We who have had a sample of life with Lotronex know that the benefits can far outweigh any possible risks.

Ruth W. Stearns