

# Drug for Irritable Bowel Syndrome Should be Banned

The drug Lotronex (alosetron hydrochloride) should be pulled from the U.S. market because of its risk of serious side effects, the consumer group [Public Citizen](#) has said in a petition to the Food and Drug Administration (FDA). The group, founded by current Green Party Presidential candidate Ralph Nader, is asking the FDA to immediately withdraw Lotronex, a prescription drug approved last February for treating women with one type of irritable bowel syndrome (IBS).

Last week, the FDA strengthened warnings about Lotronex in response to 19 so far linking the drug to serious side effects. This makes it the be the first drug required to carry a consumer-friendly guide with every bottle to explain possible risks. The agency also toughened the cautions written for doctors.

- [Public Citizen](#) disagreed with the FDA's new warning labels, saying in its petition that Lotronex offered only "limited" relief while exposing patients to possibly life-threatening adverse effects.
- The group said its review of FDA documents showed that up to that point Lotronex had been associated with at least 26 cases of ischemic colitis, a serious condition that restricts blood flow to the colon.
- The FDA has also linked Lotronex to rare cases of severe constipation.

Public Citizen said it did not think those measures were enough to prevent further harm, or even death, from Lotronex. "You will have best protected patients when you assure that this drug is banned," the group said to the FDA.

Irritable bowel syndrome afflicts an estimated 25 million Americans, most of them women, with frequent diarrhoea, constipation or both.

An FDA official said the agency will review Public Citizen's comments. "We will carefully consider the petition," the official said.

## [Public Citizen's Health Research Group](#)

**COMMENT: This is such a sad tragedy that one would have to resort to drugs to address such a simply treated problem. The vast majority of the time [the diet](#) will resolve this problem. It is particularly helpful if large doses of beneficial bacteria are used. Common foods that seem to contribute to the problem are wheat (gluten) and milk (casein). However, other foods can contribute to the problem.**

**If [the diet](#) fails to improve the problem, there is almost always an underlying emotional issue. Typically this is related to an ongoing stress in one's life, but it can be due to previous emotional wounding that was thought to be resolved.**

Congratulations to [Public Citizen](#) for doing the valuable press release and lobbying work to help guard us against the drug companies.

## US Lets Drug Tied to Deaths Back on Market

By Denise Grady

For the first time, the Food and Drug Administration is allowing a drug to go back on the market after it was removed for safety reasons.

The drug, Lotronex, a prescription treatment for irritable bowel syndrome, will be available again in several months.

Lotronex was taken off the market in November 2000, less than 10 months after it was approved, because it was linked to severe intestinal problems and several deaths. GlaxoSmithKline, based in Britain, withdrew the drug voluntarily at the F.D.A.'s request when the two could not reach an agreement on marketing restrictions intended to reduce adverse reactions.

But thousands of patients protested the withdrawal, saying Lotronex was the only treatment to have aided them. Their pleas helped to persuade the agency and manufacturer to find a way to reinstate it.

Lotronex will return, the agency said - with restrictions. The new rules leave considerable responsibility with doctors, pharmacists and patients to use it correctly and to watch for early signs of intestinal problems, which can be fatal.

Dr. Victor Raczowski, deputy director of the F.D.A. office that evaluates gastrointestinal drugs, said that the return of Lotronex was "not part of any overall F.D.A. strategy to bring back withdrawn drugs." Rather, he said, it was a unique case in which the agency took an unusual action to help desperate patients who had no other effective treatment.

Before Lotronex was pulled from the market, **a month's supply cost \$175**. A GlaxoSmithKline spokeswoman said **the price would rise** because of the costs attached to the new marketing plan.

GlaxoSmithKline's shares rose 2.8 percent in London trading yesterday.

Lotronex was the first drug shown to be effective specifically for irritable bowel syndrome. When it was first marketed, some financial analysts predicted Lotronex would become a blockbuster treatment for GlaxoSmithKline. But it did not get the chance to become one and is unlikely to do so now, some analysts say, because of the restrictions.

At its sales peak, about 275,000 people used Lotronex. But it was withdrawn after 70 patients developed severe constipation or ischemic colitis, a lack of blood flow to the bowel. Some needed surgery. **Three deaths were linked to Lotronex use.**

More reports came in later. The F.D.A. said yesterday that as of March 8, it had been notified of 84 cases of ischemic colitis and 113 cases of serious complications from constipation. Of those with

ischemic colitis, 54 were hospitalized, 11 needed surgery and 2 died. Of the constipation cases, 83 were hospitalized, 34 had surgery and 2 died.

Even so, many other Lotronex users said that they had essentially been homebound by pain and severe diarrhea, and that Lotronex had enabled them to live normal lives for the first time in years.

Doctors who studied the drug said it greatly helped some patients, did little or nothing for many, and greatly harmed others. But it was impossible to predict into which group a patient would fall.

Under the new rules set by the F.D.A., doctors who want to prescribe Lotronex will have to enroll in a program run by GlaxoSmithKline that requires them to "self attest" that they know how to diagnose and treat irritable bowel syndrome, how to prescribe Lotronex and how to recognize and treat complications.

The doctors must also agree to explain the drug's risks and benefits to patients, give them the company's informational pamphlet and report serious adverse effects to GlaxoSmithKline or the F.D.A.

Any doctor can get into the program by self attesting. Those who do not feel qualified to prescribe the drug can take an as yet undeveloped course from GlaxoSmithKline.

Patients who want Lotronex must sign an agreement acknowledging its risks, which include a 1-in-1,000 chance of serious constipation problems and a 1-in-350 chance of ischemic colitis. Patients must also pledge to call their doctors immediately if they develop any symptoms considered to be dangerous, including constipation, new or worse bowel pain or blood in their stools.

Doctors in the program will be given special stickers to apply to prescriptions for Lotronex, and the drug's labeling will alert pharmacists not to fill prescriptions that lack stickers. Pharmacists will also be instructed not to allow refills or prescriptions that are telephoned or faxed in, to insure that patients keep in contact with their doctors.

The new plan also cuts the dose in half, to one milligram a day.

Lotronex was first approved for women with chronic diarrhea from irritable bowel syndrome, but it is now recommended only for a narrower group: women with very severe cases that have not responded to other drugs. The group amounts to less than 5 percent of all people with irritable bowel syndrome, and is estimated to be about 185,000 women.

## **New York Times June 6, 2002**

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### **DR. MERCOLA'S COMMENT:**

[E-mail to a friend](#) 

**The reason this is so insane is because the only reason this drug exists is to compensate for the incredible ignorance of physicians who should know better.**

**Folks, we are not talking about rocket science.**

**This drug is used to treat irritable bowel syndrome (IBS). IBS is one of the easiest clinical problems to treat. It has been my experience that people following the [eating plan](#) and taking care of any emotional traumas are able to resolve this 95 - 99% of the time.**

**This drug in no way, shape or form addresses the cause of the problem. Yet, people are willing to have their insurance companies pay over \$200 a month for a drug that could kill them, when the problem could be solved by changing their diet.**

**This is pure lunacy.**

**If this isn't a classic example of how desperately broken our medical system, I don't know what is.**

**The bottom line is, if you or someone you know has IBS, warn them to stay away from this drug when it is re-released.**

**Start by following the [eating plan](#). If that doesn't work, consult a knowledgeable health care professional (including [EFT](#)). You can start with the links on the bottom of my home page, but later this year I will have a definitive guide of clinicians who understand health at a foundational level.**