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Joan Claybrook, President

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October 30, 2000

Jane Henney, M.D.  
Commissioner,  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Henney:

On August 31<sup>st</sup>, we filed a petition to immediately remove from the market the drug alosetron (Lotronex, Glaxo Wellcome), a drug for the treatment of Irritable Bowel Syndrome (IBS) because, as of August 28, 2000, it had been associated with a total of at least 26 cases of ischemic colitis. Ischemic colitis results from a lack of blood flow to the colon leading to death of bowel tissue. Thirty-eight percent of these cases occurred in women aged 50 or younger (including cases among women aged 20, 25, 32, and 33), even though ischemic colitis is extraordinarily rare in patients of this age group. An additional 10 cases very suspicious for ischemic colitis had also been reported to FDA. We also pointed out that "as the use of this drug spreads to less healthy and more poorly monitored populations, and prescribing extends beyond the 3-month duration of the clinical trials, we will surely see a continued increase in the number and severity of adverse events, and almost certainly, fatalities."

We have just obtained new information from the FDA about a sharp increase in the number of reported cases of ischemic colitis in people using alosetron. As of October 20<sup>th</sup>, reports received by the FDA now include an additional 28 cases of ischemic colitis, a more than doubling of the number of 26 cases we reported as of August 28<sup>th</sup>, for a total of 54 cases of ischemic colitis. Thirty seven of these people (69%) had to be hospitalized. Of those with known ages, 16 were 50 years or under with five being younger than 40.

In addition, there are now a total of 20 cases (ten more than the 10 reported as of August 28<sup>th</sup>) which are highly suspicious for ischemic colitis. These include diagnoses such as intestinal ischemia, intestinal perforation, mesenteric occlusion and gastrointestinal necrosis (death). Among these were four deaths

Ralph Nader, Founder

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including a death in a 50 year old woman who had mesenteric occlusion, a blockage of part of the blood supply to the intestine, which may be related to ischemic colitis.

It is irresponsible for Glaxo Wellcome and for the FDA to allow this doomed drug to stay on the market any longer. There is little if any question that it cannot ultimately survive. Why continue to endanger the health and lives of tens of thousands of people, mainly women (the drug is not approved for use in men) until a "sufficient" number of hospitalizations and further deaths occur for you to finally take action? The recent disaster regarding the amount of time it took to get Rezulin off the market in the face of mounting numbers of people who had severe liver damage or death caused by the drug should have been instructive. Not only is the drug being allowed to stay on the market but, according to information from Glaxo Wellcome, the company has been planning a major Direct-to-Consumer advertising promotional campaign for the drug.<sup>1</sup>

In addition to the life-threatening risks of alosetron, there is serious question as to how effective it is. On a scale of 0 to 4 for abdominal pain/discomfort, alosetron only relieved their symptoms 0.12 to 0.14 more than a placebo.

As we stated in our original petition: "There is no way to justify using a minimally effective drug that is only palliative for a non-life-threatening condition, and, in the process, putting women at risk of ischemic colitis, which can be life-threatening, and its serious complications, which have required intestinal surgery, including colectomy." We also pointed out that the proposed labeling changes would not adequately protect patients. FDA's Dr. Evelyn Rodriguez has found through her studies that labeling changes and "Dear Doctor" letters are not particularly helpful: "providers and patients are confused and do not understand after multiple re-labelings what the really important message is." The only effective way of protecting patients is to decide, as quickly as possible, that this drug should be banned. We hope for a rapid response to this serious issue.



Sidney M. Wolfe, MD  
Director



Elizabeth Barbehenn, PhD  
Research Analyst

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<sup>1</sup> *Scrip*, number 2550, June 21, 2000. *Financial Times*, August 26, 2000. "Glaxo was prevented from marketing it [Lotronex] directly to consumers until the new warning [now agreed upon] had been agreed."

A handwritten signature in black ink, appearing to read "Larry Sasich". The signature is fluid and cursive, with the first name "Larry" written in a larger, more prominent script than the last name "Sasich".

Larry Sasich, PharmD, MPH, FASHP  
Research Analyst

Public Citizen's Health Research Group