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5 April 2002

Mr. Thomas H. Perez
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Testimony for meeting on April 23, 2002 RE LOTRONEX

Dear Mr. Perez:

Please do what you can to keep LOTRONEX off the market. My sister Anne DuPre Royall in Mt. Pleasant, South Carolina, was in a LOTRONEX study from October 1999 through December 1, 1999. She had severe pain as a result of taking this drug and had to spend two days in the hospital.

As you know, FDA approved LOTRONEX on February 9, 2000 for use in the treatment of IBS in women whose predominant bowel symptom is diarrhea. FDA subsequently received numerous reports of serious and fatal gastrointestinal adverse events in patients who were administered LOTRONEX.

I understand that the FDA pulled LOTRONEX off the market in November 2000. However, it has also come to my attention that GlaxoWellcome (now GlaxoSmithKline or GSK) is trying to put this dangerous drug back on the market. As you are aware, FDA has received numerous adverse event reports associated with the use of Lotronex, including reports of death and surgery due to complications of constipation as well as reports of eschemic colitis.

I implore you and the FDA to please stand your ground on your decision of November 2000 and not give in to the commercial pressure of GlaxoSmithKline.

Sincerely yours,

Julia Royall