



METROPOLITAN
GASTROENTEROLOGY
GROUP, P.C.

November 20, 2000

Jane Henney, M.D. 9590 '00 DEC -6 AM 1:01
Food and Drug Administration
Dept. of Health and Human
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Dear Doctor Henney:

As a practicing Gastroenterologist in the D.C. Metropolitan Area, I am writing to give you a Gastroenterologist's viewpoint on some of the controversy surrounding Lotronex (Alosetron Hydrochloride). Those of us who have been dealing with some of the more complicated cases of IBS for a number of years, have welcomed better understanding of the pathophysiology of this condition and new agents more specifically targeted to what may be "the root cause". Obviously, some of the concerns regarding the reports of cases of ischemic damage to the colon are of some concern. I, after reviewing some of the details of the reported cases, have less concerns. I understand that any serious drug consequences which can be directly attributable to a medication for a benign disease has to be carefully monitored. However, the serious consequences of this "benign disease" cannot be under-estimated. I have a number of individuals who cannot socialize, whose marriages have been threatened, whose quality of life has diminished dramatically. All of us who treat this condition, understand well that many individuals are totally disabled by it and welcome any new therapeutic modalities. I have placed a number of individuals on this product and have found it to be very beneficial with no side affect other than the predicted constipation. This side affect has been easily handled by reducing the dose of the medication.

I know I join a number of practicing physicians who hope the FDA will monitor this drug, but certainly continue to allow it to be used in those indicated clinical situations.

I hope this information has been useful in your deliberations.

Sincerely yours,

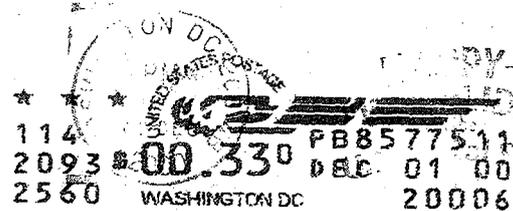
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