

Medical journal editor uncovers questionable FDA action

The U.S. Food & Drug Administration (FDA) is under fire again -- this time from the editor of the prestigious British journal, *The Lancet*.

In a "Commentary" published in the May 19, 2001 issue, *Lancet* Editor Richard Horton explained that the drug Lotronex, used for irritable bowel syndrome, had been withdrawn from the market after being linked to five deaths.

However, according to Horton, many senior officials within the FDA are now seeking to reintroduce Lotronex, with an advisory committee meeting to do so being planned for June or July.

He comments: "This story reveals not only dangerous failings in a single drug's approval and review process but also the extent to which the FDA, and its Center for Drug Evaluation and Research (CDER) in particular, has become the servant of industry."

The willingness of the FDA to cater to the needs of the drug companies was evident in this case. Even during the pre-approval process, serious side effects such as severe constipation and ischaemic colitis (a restriction of blood flow to the colon) were noted, yet the agency approved the drug anyway.

Shortly afterwards, more problems were noticed with the drug but the FDA did nothing. "The decision was to prove fatal," said Horton.

Not all FDA scientists ignored the problem, but those who raised concerns about the drug's safety were barred from future discussions.

An independent review of research found serious flaws, yet the FDA refused to subject the drug to additional studies.

"That is where there has been a terrible failure in evaluating the safety of this drug," Horton told Reuters news service after the report was published. "The FDA is not only compromised because it receives so much funding from industry, but because it comes under incredible congressional pressure to be favorable to industry. That has led to deaths. It is an impossible conflict for safety issues to be overseen by a center that receives funding from industry to review and approve new drugs."

SOURCE: "Lotronex and the FDA: a fatal erosion of integrity," by Richard Horton, *The Lancet*, Volume 357, Issue 9268, p. 1544, May 19, 2001.