

October 4, 1994

Food and Drug Administration
5600 Fishers Lane Rockville,
MD. 20857

Dear Sir or Madam:

Recently I heard a statement that was attributed to Dr. Kessler: "Any doctor who gives a drug for a non-approved use is committing a crime". Could you please let me know if this is an accurate premise, and if so - how this statement relates to the use of the drug Lupron (leuprolide acetate) for many non-approved indications.

I would also like to ask whether the FDA could please provide me with any adverse event reports compiled in relation to this drug, and any information that you have on it's indication for use in fertility treatment.

The 1994 PDR states Lupron causes fetal abnormalities in lab animals at 1/600th the-human dose, the drug is considered teratogenic, it is labeled as a Category X drug, and is not approved by the FDA for use in ovulation induction. Is there an explanation as to how such a chemical can be used to assist in conception?

Would it be possible to obtain a history of the drug, it's development, chemical formula, and it's application and approval process? This and any other information that you might have on Lupron would be appreciated. If necessary, consider that this request is made under the Freedom of Information Act.

Thank you for your time and assistance.

Sincerely,

Lynne Millican