
THE NATIONAL LUPRON VICTIMS NETWORK

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LUPRON: 1999 FDA REVIEW OF LUPRON

I. FDA Completed A Review of Lupron in March, 1999

Recently, the FDA completed a review of all MedWatch Report Forms for Lupron. According to a March, 1999 FDA memo, an FDA official (epidemiologist) **reviewed over 6,000 MedWatch reports received by the FDA** and "concluded that there were **high prevalence rates for serious side effects**" and requested that the FDA merely reexamine the "product label [package insert] to ensure that these events are adequately addressed." (3)

II. FDA Has Several Options

1. The FDA reviews all MedWatch Report Forms and then decides what action(s) to take.

The available FDA actions include:

- a. **No action**
- b. **Labeling changes - including boxed warnings in the product's package insert.**

Currently there are over 260 adverse reactions reported in the package insert. If 1, or 2, or 5, or 10 more adverse reactions are reported in the package insert will it make a difference? Or, will a difference only be made when Lupron is removed from the market?

- c. **Medical alerts - "Dear Health Professional" letters or safety alerts.**

"The evidence shows that a majority of doctors either don't get or don't respond to warnings." (2)

- d. **Removing Lupron from the market**

III. The Results Of The FDA Review of Lupron

1. In its report, the FDA listed in rank order the top 35 adverse events for Lupron females, and compared it to the top 35 adverse events for Lupron males.

Top 35 Adverse Reactions Experienced By Women

Top 35 Adverse Reactions Experienced By Men

2. The FDA **stated**:

"However, it is interesting that even with these differences, the nature of reported adverse events for males and females is quite similar- indicating that the events are more likely to be due to the drug than age, gender or **underlying disorder**." (1)

3. According to this report there were 25 reports of death of females.

(1)

NOTE; "In an article in the *Journal of the American Medical Association*, then FDA Commissioner David A. Kessler revealed that 'only about 1% of serious events are reported to the FDA.'" (2)

4. According to this report there were 325 reports of hospitalizations of females. (1)

NOTE: "In an article in the *Journal of the American Medical Association*, then FDA Commissioner David A. Kessler revealed that 'only about 1% of serious events are reported to the FDA.'" (2)

IV. FDA Takes No Action After March, 1999 Review of Lupron

1. "The FDA's deputy director for the Division of Reproductive and Urologic Drug Products, said her department **did review its data** after that report [by the epidemiologist] and decided **NO additional action was needed**." (3)
2. The FDA review was completed and **NO ACTION WAS TAKEN**.
3. According to the FDA, "Our clinicians reviewed this data and reviewed the Lupron (package warnings) and we feel **the current Lupron (warnings) adequately reflects these concerns**." (3)
4. Over 6,000 MedWatch Report Forms for Lupron, containing medical information have been received by the FDA ... and the FDA did absolutely nothing.

REFERENCES

1. Food and Drug Administration. Review of Lupron; 1999
2. Moore, Thomas J. Prescription for Disaster: The Hidden Dangers in Your Medicine Cabinet. New York: Simon & Schuster, 1998.

3. The Boston Herald

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