

MAN, COMMITTEE ON
COMMERCE, EICE, AND
TRANSPORTATION
COMMITTEE ON ARMED SERVICES

United States Senate

1839 SOUTH ALMA SCHOOL ROAD
SUITE 375 MESA, AZ
85210 (602)491-4300

2400 EAST ARIZONA
BILTMORE CIRCLE
SUITE 1150
PHOENIX, AZ 85016
(602) 952-2410

450 WEST PASEO REDONDO
SUITE 200
TUCSON, AZ 85701
(520) 670-6334

TELEPHONE FOR HEARING IMPAIRED
(202) 224-7132
(602)952-0170

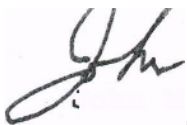
May 27, 1999

Dear Ms. Millican:

Enclosed please find, a copy of the response which you should have received from the Food and Drug Administration in answer to my inquiry on your behalf, regarding lupron.

I hope the information is of use to you. If you have any further questions or comments on this matter, please do not hesitate to get in touch with me.

Again, thank you for contacting me. I am always glad to have the opportunity to be of assistance.



Sincerely,

John McCain United States Senator
JM/ina

DEPARTMENT OF HEALTH & HUMAN SERVICES

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May 21, 1999

Dear Ms. Millican:

Thank you for your recent inquiry to Senator John McCain, regarding the drug Lupron Depot (leuprolide acetate). Senator McCain has asked us to respond directly to you.

The Food and Drug Administration (FDA or the Agency) has approved leuprolide acetate in different dosages and for different indications. Lupron Depot Injection (leuprolide acetate), manufactured by Tap Holdings, was first approved by FDA on October 22, 1990, for the treatment of endometriosis. Lupron Depot Pediatric Kit was approved on April 16, 1993, for treatment of children with central precocious puberty; Lupron Depot Injection was approved on March 30, 1995, for the treatment of leiomyoma uteri (uterine fibroids); Lupron Depot Three-Month Injection was approved on December 22, 1995, for the palliative treatment of advanced prostatic cancer; and Lupron Depot Three-Month Injection was approved on March 7, 1997, for the treatment of endometriosis.

FDA's primary purpose is to ensure that drug products are safe and effective for use as directed in the labeling. Unfortunately, all drug products contain risks as well as benefits and it is often impossible to predict which individuals may have increased sensitivity to particular drugs. After thorough review of all the required data prior to marketing, FDA's decision to market a new drug is based on the answers to two questions: (1) Do the results of well-controlled studies provide substantial evidence of effectiveness? and (2) Do the results show the product is safe under the conditions of use in the proposed labeling? Safe, in this context, means that the benefits of the drug appear to outweigh the risks.

We realize that when an approved drug becomes widely used in clinical practice, health care professionals may observe

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differences from clinical trial results in both the incidence and/or types of adverse drug experiences. After approval of a new drug, the sponsor is required to provide periodic safety reports to FDA. FDA

monitors these reports to determine if any safety problems or trends can be identified. In addition, FDA regulations require that the person whose name appears on the label of a marketed product as its manufacturer, packer/ or distributor, must report to FDA any serious and unexpected adverse reaction experience within 15 working days from its receipt, if there is a reasonable possibility that the drug caused the adverse experience. A large portion of adverse drug reports reach FDA through the drug manufacturers. Should safety problems emerge, FDA takes action accordingly.

FDA monitors the safety of drug products, including the incidence and severity of adverse reactions, through its MedWatch program. FDA relies on the submission of MedWatch reports from health professionals, as well as consumers, to help detect problems with marketed drug products. It is a voluntary system of reporting. The information received from a report of an adverse drug experience is added to the existing data in our Adverse Event Reporting System (AERS) database. The collected reports are monitored and observed for emerging patterns. In the event it appears there may be a potential for a widespread product problem, the Agency will initiate action as needed.

We understand the need for consumers to have information about any drugs that they, or their family members, are taking so that they can make informed decisions regarding their medical treatment and care. As you may know, FDA approves drug products both for prescription use and self-medication, and is responsible for ensuring that the benefits of these drug products outweigh their risks when used as directed in the labeling. State licensing boards, both medical and pharmacy, set the standards of practice for the professions in prescribing and dispensing products that we have allowed on the market. You may wish to contact your state medical and pharmacy boards to discuss your concerns regarding patient counseling and the dispensing of drug information to patients.

The premise of prescription drugs, such as leuprolide acetate, is that they require a "learned intermediary," such as a licensed physician, to give guidance to the patient on the safe and proper use of the medicines, and of any risks and


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precautions regarding the particular drug in question.
Selection of specific drug products or treatment

regimens for particular patients are decisions to be made between the patient and a physician who is familiar with the individuals' current health status and past medical history.

We trust this information responds to your concerns.

Sincerely,



Melinda K.
Plaisier

Interim
Associate
Commissioner
for Legislative
Affairs

cc: The
Honorable
John
McCain

United States
Senate

Washington,
D.C.
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