

## FDA Seeking Ways To Reduce Hazards Of New Medicines

By L. T. EASLEY  
Of the Associated Press

WASHINGTON — Prompted in part by recent disclosure that a new drug is being blamed for birth malformations, the government is seeking ways to reduce hazards from use of experimental medicines.

A Food and Drug Administration official said Saturday that agency for some time has been considering changes in its regulations concerning distribution of experimental drugs, and that reports on the dire effects of thalidomide when used by women during pregnancy has sharpened interest in the matter.

Thalidomide is a German drug blamed for some 3,500 severe birth deformities in West Germany and hundreds elsewhere in Britain and Western Europe.

The drug was kept off the U.S. prescription market when Dr. Frances Oldham Kelsey, an FDA physician and pharmacologist insisted for more than a year that proof of its safety was inadequate.

Although her action prevented the drug from being placed on the regular prescription market, there was some distribution of it in the United States through physicians for "investigational use" under lawful procedure. It was prescribed for morning sickness.

### SAMPLES GIVEN TO DOCTORS

The W. S. Merrell Co., of Cincinnati, an old and reputable firm, held exclusive U.S. rights to distribute thalidomide. It made samples available to about 1,200 physicians but there is no way of knowing exactly how many doctors gave it to patients.

A point in the law not widely known, is that a drug firm may make arrangements with doctors for the experimental or investigational use of a new drug without FDA approval. The law requires only that the firm keep a record of these shipments and that they are plainly labeled "caution, new drug limited by federal law to investigative use."

The doctor must sign a statement to the effect that he is qualified to investigate the safety of a drug. The doctor is not required to inform the patient that the drug is experimental, and at his discretion, may or may not charge for the prescription.

An FDA official shied away from the use of the term "human guinea pig" when it was used by a reporter. He hastened to say that no final proof of the safety and efficacy of a drug could be obtained until it had been used by human beings, and that this has been the practice in production of new drugs.

FDA Commissioner George P. Larrick said last week the firm which was distributing thalidomide in this country advised doctors to whom it had issued the drug to return all of the material it had on hand and to use no more on either males or females.

Even before that, the Merrell company had cautioned physicians to whom samples of the drug had been issued not to give it to any women of child-bearing age. That was last December—several months before the recall directive.

### SAFETY IS OVEREMPHASIS

That recall order was issued in March. Reports of births with malformations may come in a few weeks, related to use of the drug. Only last week a Phoenix, Ariz., woman who had used it petitioned the courts for authority to undergo abortion legally to avert possible birth of a deformed child. The FDA said that in this instance, the drug had been obtained from abroad.

Under existing regulations issued by the FDA, firms seeking to market new drugs must get an FDA approval to distribute drugs in interstate commerce for general sale.

The firm must set forth research that has been done on animals, and results of use on humans. The overriding emphasis of the FDA in granting this approval, or pre-clearance action, is on safety.

Questioned about the matter of physicians warning patients ahead of time that they were receiving experimental drugs, the official said that under existing law this is a matter left to the discretion of the physician.

He said there is a question, because of psychological factors, whether tests would produce true and accurate results if patients knew in advance that they were using an experimental drug.

He suggested that perhaps the answer lies in controlled tests in which volunteer individuals knew only that they were receiving medicines which might or might not incorporate an experimental drug.

## Abandoned by French

## Emaciated Dogs Roam Algeria

By MICHAEL GOLDSMITH  
Of the Associated Press

ALGIERS—On the rich Mitidja plain south of Algiers, stray dogs—left behind by their European owners—are being shot on sight for fear of a rabies epidemic.

The dogs roam the abandoned farms in search of food. Emaciated, vermin-ridden and often diseased they are a startling testimony to the decline of the once-blooming civilization of the French built in their 132 years of occupation.

All over the Mitidja and other Algerian farm areas, fields are growing to weeds and Moslem soldiers and civilians are squatting in comfortably furnished, abandoned European farmhouses.

In the cities, many European-owned homes, stores and small factories are empty and locked. Official French estimates say some 250,000 of the one million European settlers have fled Algeria rather than live under Moslem rule, and another 250,000 plan to leave. The exodus is encouraged by continuing violence and victimization, anarchy and administrative chaos in the three weeks of Algerian independence.

Most of the pieds-noirs (black-feet), as the settlers call themselves, are descended from several generations of Europeans born in Algeria. They regarded Algeria as much a part of France as Normandy, and almost unanimously sympathized with the Secret Army.

For the past three weeks, roaming bands of Moslem soldiers have picked up hundreds of Europeans apparently suspected of Secret Army activities. Many of them disappear without trace, others are released after being beaten.

Government officials deplore what they call "these excesses," but are powerless to stop them. European farmers and businessmen still here report having to pay large sums of "pro-

tection money" or "voluntary contributions" to Moslem troops and officials. Those who refuse to pay often find their homes requisitioned by dubious "authorities."

All this persuades more and more Europeans to leave.

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