F.D.A. Seized 25 Million Birth Control Pills in Dispute Over Advertisements

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WASHINGTON, Dec. 31 — The largest seizure of a single prescription drug in the history of the Food and Drug Administration took place recently in an action against a concern at Pearl River, N. Y.

The seizure, on F.D.A. orders involved 25 million birth control pills. The confiscation, conducted on Dec. 20 by F.D.A agents and Federal marshals had been previously disclosed but the size of the seizure had not been known.

The pills, seized from Lederle Laboratories, have a retail value of $1.3-million, according to the F.D.A. The product, called Zorane, was seized after a dispute between the drug agency and the Lederle concern that had been going on for almost a year. The F.D.A. ordered the seizure because agency officials considered some of the advertising for Zorane misleading.

Earlier this year, Lederle stopped the advertising to which the F.D.A. had objected and ran corrective advertisements stating the drug agency's objections.

Later, however, Lederle resumed use of advertisements very much like those that had raised the original objections, F.D.A. officials said.

In answer to a query concerning the seizure, Dr. Peter H. Rheinstein of the Food and Drug Administration said he believed it to be the fifth time the agency had taken such a step on the ground of misleading advertising. Three were in the nineteen-sixties and the fourth occurred last September, he said, each against a different drug company. All involved much smaller quantities of drugs than the seizure at Pearl River.

Dr. Rheinstein, who is director of the Division of Drug Advertising in F.D.A.'s Bureau of Drugs, said the Zorane seizure was believed to be the largest of a single prescription drug in F.D.A. history.

The other seizures related to advertising or promotion considered misleading by the F.D.A. involved: a drug to reduce fluid accumulation in the body; a blood vessel dilator; an antibiotic, and a drug used in treating obesity.

The seizure of Zorane does not imply any defect in the pills themselves. The Food and Drug Administration considers them to be safe and effective for contraceptive use. The objection is to advertising that, in the F.D.A. view, gave unwarranted implications that the product had special advantages in safety.

The advertisements were published this year in medical journals and other publications that circulate primarily among physicians. One such advertisement, published in February, showed the picture of a woman with a worried expression on her face reading a magazine article under the headline: " 'Pill' Takers Run the Risk of Stroke."

The advertisement carried the slogan: "Because her 'medical journals' alarm her about 'the pill' . . and because she runs to you for an answer."

Later, at F.D.A. insistence, the drug concern published an advertisement saying:

"The Food and Drug Administration has requested that we bring to your attention an advertisement for Zorane tablets that was considered misleading. The F.D.A. states that, for example:

"The advertisement implied the elimination of the risk of stroke with the Zorane formulation, the F.D.A. is not aware of any proof that these Zorane products are free from risk of strokes."

The Zorane tablets contain relatively small doses of the female hormone estrogen. The F.D.A.'s basic objection was that the company was making unwarranted special claims for safety because of the low estrogen level. The corrective advertisement said the F.D.A. believed the earlier versions implied a direct relationship between estrogen dose levels and ill-effects related to that hormone. The correction said the F.D.A.'s position was that the implication was not supported by substantial evidence.

In a statement released after the seizure, Lederle said, "This action comes as a complete surprise to the company."

In March, during negotiations over the advertisements, an officer of Lederle wrote to the F.D.A. saying it was the concern's intention to send the Government agency advance copies of advertisements to give it a chance to review and comment. An F.D.A. official said today, however, that advance copies of this sort were not sent to the agency by the Lederle concern.

An F.D.A. memornadum summarizing a meeting between the agency and the drug maker later in the year said an official of the agency asked a Lederle officer why the implied promise of the letter in March had never been fulfilled. The memorandum said the officer replied that this was a matter of intention, not a pledge, and that the company's intentions changed.

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