

The New York Times

Section 1; National Desk

A Company Stops Making A Child Drug

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786 words

24 February 1996

03:49

The New York Times

NYTF

Late Edition - Final

English

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WASHINGTON, Feb. 23 -- Doctors say they can no longer get supplies of a drug that is the primary treatment for a severe seizure condition in infants because the manufacturer unexpectedly stopped making it.

Specialists around the country said that there was a critical shortage of the medication, called ACTH gel, for several weeks and that there were few available alternatives, none of which were as effective.

The manufacturer, Rhone-Poulenc Rorer, based in Collegeville, Pa., a unit of the French company Rhone-Poulenc S.A., said production of ACTH was suspended after an inspection by the Food and Drug Administration late last year found violations of manufacturing standards.

But spokesmen for both the company and the agency said today that they were discussing the problem and that a tentative solution had been found.

"We have been talking to the company and are doing everything we can to make supplies of this drug available again," said the F.D.A. spokesman, Don McLearn. "We and R.P.R. have essentially agreed to a solution and I think we will have the problems solved in a few weeks."

Bob Pearson, a spokesman for Rhone-Poulenc Rorer, said, "Our goal is to get back to manufacturing the product and making it available in the United States."

ACTH gel, which is injected into muscles, is the first choice therapy used by doctors treating **infantile spasms**, a potentially devastating seizure condition sometimes known as West's syndrome, specialists said. **Infantile spasms** usually occur between birth and the first year of life, and about 3,000 children are affected each year in the United States, they said.

The condition, a leading cause of epilepsy in children, is characterized by sudden jerks followed by stiffening. In some cases, a patient's arms are thrust forward as the body bends backwards, resulting

in so-called jackknife seizures, and in others, there are more subtle movements limited to the neck and other body parts.

Infantile seizures, which often result in retardation and physical impairment, are only partly responsive to Valproic Acid and other anticonvulsive drugs. ACTH, a hormone derived from the pituitary glands of pigs or cows, has some beneficial effect in up to 80 percent of cases, experts said.

Dr. W. Edwin Dodson, a child neurologist at Washington University in St. Louis and president of the Epilepsy Foundation of America, said the shortage of ACTH surprised doctors, who were not told by the company or the F.D.A. that the manufacturer had halted production.

In a letter last week to the F.D.A. Commissioner, Dr. David Kessler, Dr. Dodson asked for agency intervention to get more of the drug. "Remaining supplies are rapidly dwindling and are already unobtainable in some parts of the country," he wrote.

"Since there is no adequate substitute for ACTH gel, loss or long-term interruption of this agent would be a catastrophic situation and would undoubtedly doom some infants to a lifetime of disability that they otherwise might not have experienced," Dr. Dodson said.

Dr. Wendy G. Mitchell, a professor of neurology and pediatrics at Children's Hospital Los Angeles and the University of Southern California Medical School, said doctors were unaware that Rhone-Poulenc Rorer had stopped making ACTH, sold under the brand name **Acthar**, until spot shortages arose.

Mr. Pearson, the spokesman for the manufacturer, said he could not supply details as to why the production of ACTH at a plant in Kankakee, Ill., failed the F.D.A. standard for good manufacturing practices. "There are no safety issues with the drug, the production of which hasn't changed since the 1950's," he said. "However," he added without further explanation, "the regulatory standards have changed."

In his letter to the F.D.A., Dr. Dodson cited unspecified problems with the bioassays, or tests, used to monitor the quality of batches of the drug during manufacturing. Mr. Pearson said he had no comment about the bioassays, which are part of the manufacturing practices monitored by the F.D.A.

Mr. McLearn, of the F.D.A., said officials were unaware of any changes in agency inspection standards regarding the drug.

Rhone-Poulenc Rorer said it was trying to find supplies of ACTH in Canada and other countries where the drug has been shipped, and looking for other stocks of the drug while it worked to restart production. "Our focus is to try to keep the drug on the market," Mr. Pearson said.

Specialists in **infantile spasms** said they would be forced to rely on less effective treatments if no more ACTH can be found.

04:49 EST February 24, 1996

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