

What U.S. Drug Company Pleaded Guilty to 10 Charges of Concealing Evidence from the F.D.A.?



Eli Lilly & Co. released and kept on the market the arthritis drug Oraflex, despite knowing about numerous deaths and illnesses resulting from its use. Lilly failed to report to the FDA the known dangers of the drug.

- A report from the Justice Department disclosed that in January 1982, one of Lilly's top medical officers and other officials received a document listing 25 deaths associated with Oraflex in the UK.

- On April 7, 1982 Lilly received a detailed report on three deaths associated with Oraflex in Denmark.

- On April 19, 1982 the U.S. Food and Drug Administration approved use of Oraflex in the U.S., having received few reports from Lilly on the known dangers.

- In May 1982 Lilly began heavily marketing Oraflex in the U.S. Business Week stated "Eli Lilly & Co.'s Oraflex was the miracle drug of 1982." A Lilly researcher implied that Oraflex not only reduced the symptoms of arthritis, but could also arrest the disease itself.

- Responding to Lilly's marketing promises, after about 30 days on the market

approximately 500,000 American citizens were using Oraflex.

- On August 4, 1982, Health Authorities in Britain ordered a suspension of Oraflex from the market, citing reports of more than 3,500 adverse reactions and 61 deaths in the UK associated with Oraflex.

- The same day, after meeting with Food and Drug Administration officials Lilly "voluntarily" agreed to suspend sales and distribution in the U.S., saying that it was confident Oraflex would eventually be returned to the market: "An objective review of all data

concerning Oraflex will confirm that (it) is safe and effective when used as directed."

- But the growing number of deaths and reports of negative reactions proved that Oraflex was far from safe and effective. Federal authorities in the U.S. found evidence linking the drug to over 100 deaths.

- On August 22, 1985, Lilly pleaded guilty to criminal charges that it failed to report the known deaths and illnesses linked to the drug as required under federal drug laws. The company was fined.

Look for the special advertising supplement on TIME magazine appearing June 14 in USA Today.

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