

which it was observed that there was a reduced conception rate among rats receiving doses of 25 mg/kg per day of MER/29 during pregnancy, the size of the litter was reduced and there was an increase in rate of the deaths of the young during the 24-hour period after delivery.

Said concealment and covering up being effected by the trick and scheme of submitting to Dr. Frank J. Talbot, Medical Officer of the Food and Drug Administration, a letter dated October 7, 1960, from The Wm. S. Merrell Company in response to his request set out in paragraph 1, in which letter it was stated that "while high doses of MER/29 interfere with conception in rats there is no evidence that this is a clinical problem," and by substantiating this statement with memoranda and references to studies and medical literature which showed that other well known and widely used drugs had similar effects upon rats, but wilfully omitting and failing to disclose and make known the existence of the aforesaid MER/29 animal studies and the results thereof.

Tenth Count

From on or about October 26, 1961 to on or about December 1, 1961, within the District of Columbia, the defendants, Richardson-Merrell, Inc., a body corporate, Harold W. Werner, Evert F. Van Maanen and William M. King, for the purpose of and with the intent to influence the Food and Drug Administration of the Department of Health, Education, and Welfare, an agency and Department of the United States, in the exercise of its function of passing upon and approving the issuance of a warning letter by said Richardson-Merrell, Inc., to the medical profession concerning MER/29 (Triparanol), a new drug subject to the provisions of section 505 of the Food, Drug, and Cosmetic Act (21 U.S.C. 355), and its function of determining whether administrative action calling for the suspension of the effectiveness of the New Drug Application for MER/29 should be instituted, knowingly and wilfully concealed and covered up, and caused to be concealed and covered up, by trick and scheme, material facts in a matter within the jurisdiction of said Food and Drug Administration, in that, following the receipt, on or about October 18, 1961, from said Richardson-Merrell, Inc., of a report that MER/29 had caused eye injuries to humans, the Food and Drug Administration requested said Richardson-Merrell, Inc., to furnish complete data in its possession concerning adverse and toxic reactions resulting from MER/29 therapy in humans and animals, including all information concerning eye changes in humans and animals with reference to both corneal and lenticular changes; that thereafter between on or about October 26, 1961 and on or about December 1, 1961, certain officers and employees of said Richardson-Merrell, Inc., met from time to time with representatives of the Food and Drug Administration at Washington, D.C., to discuss the safety of MER/29, the preparation of the warning letter and the question of whether the drug should be withdrawn from public use; that during the course of the aforesaid discussions and by means of letters addressed to said Food and Drug Administration at Washington, D.C., said defendants did present and submit, and cause to be presented an submitted in purported compliance with the aforesaid request, certain data, reports of investigations and other information pertaining to adverse and toxic reactions of the said drug in animals and humans, including information concerning eye changes in animals and in humans, which said defendants falsely and fraudulently led the Food and Drug Administration to believe constituted all of the aforesaid reports of investigations, data and information pertaining to eye changes in humans and animals possessed by defendant Richardson-Merrell, Inc., said defendants well knowing that they had failed and omitted to report and make known the following material facts, to wit:

1. That said defendant Richardson-Merrell, Inc., had in its possession data and information obtained by its former subsidiary, The Wm. S. Merrell Company, from an investigation which that company had conducted as to the safety of the drug between on or about October 26, 1959 and on or about November 1, 1960, during which period said drug was administered to rats at 20 mg/kg and 40 mg/kg per day and which rats developed eye opacities in a quantity and degree greater than those reported to the Food and Drug Administration on February 17, 1960;

2. That said defendant Richardson-Merrell, Inc., was then conducting an investigation, which began on or about April 19, 1961, to determine the effect of MER/29 upon the eyes of rats, during the course of which MER/29 and MER/29 plus Vitamins and Cholesterol was being administered to rats at a dosage of 40 mg/kg per day and in which eye opacities were observed first to