

mg/kg per day at any time during the course of said study, and had not been administered the dose of 20 mg/kg per day for the time specified but for a less time, to wit, approximately seven months and 26 days;

(b) monkey designated as No. 35 had been a control monkey for the entire period of the study and had been administered placebos for the entire 16 months, which was false, fictitious and fraudulent, as the defendants well knew, in that said monkey No. 35 had been administered another drug which was an analogue of MER/29 for the first six months of the study and had not been used as a control monkey during that period;

(c) the oral administration of MER/29 to test monkeys had caused no significant effect on the body weights of the monkeys receiving MER/29, which was, as the defendants well knew, false, fictitious and fraudulent, in that test monkeys Nos. 49 and 51 had each suffered significant loss of weight during the latter part of said study;

(d) microscopic examination upon autopsy showed the liver and gall bladder organs of female monkey No. 49 to be normal, which was false, fictitious and fraudulent, as defendants well knew, in that such examination disclosed that monkey No. 49 had an enlarged gall bladder, several small necrotic areas in the liver and many adhesions between the lung and chest cavity;

(e) microscopic examination upon autopsy of monkey No. 51 showed a normal heart organ, which was false, fictitious and fraudulent, as the defendants well knew, in that the said examination of the heart of monkey No. 51 revealed a condition described as possible left ventricular hypertrophy, and

(f) during the aforesaid chronic study, the MER/29-treated monkeys and the control monkeys showed similar hematologic values, and the morphology of the peripheral blood was similar in both the MER/29-treated monkeys and the control monkeys, which were false, fictitious and fraudulent, as the defendants well knew, in that various blood dyscrasias such as vacuolated and binucleated lymphocytes, and lymphocytes with irregularly-shaped nuclei had been observed in the blood smears taken from monkeys receiving MER/29 but not in those taken from the control monkeys.

Second Count

1. At the times mentioned herein, The Wm. S. Merrell Company had submitted to the Food and Drug Administration a New Drug Application, and amendments thereto, for a new drug known as MER/29 (Triparanol), said application stating and representing that attached thereto were full reports of all investigations that had been made to show whether or not the drug was safe for use.

2. During the period from on or about February 17, 1960 to March 31, 1960, within the District of Columbia, the defendants, The Wm. S. Merrell Company, a body corporate, Harold W. Werner, Evert F. Van Maanen and William M. King, 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 a Department and agency of the United States, in that during the period above-mentioned and at the place aforesaid, the defendants caused to be submitted to the Food and Drug Administration of the Department of Health, Education and Welfare, as an amendment to the New Drug Application of The Wm. S. Merrell Company for MER/29 (Triparanol), a new drug then subject to the provisions of section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355) and which was then a matter within the jurisdiction of the Food and Drug Administration of the Department of Health, Education and Welfare, certain reports purporting to be full reports of the results of all investigations which were made by The Wm. S. Merrell Company to show whether or not said drug was safe for use, said defendants knowingly and wilfully withholding, and omitting to include therewith, reports of the results of certain investigations, and data and information obtained therefrom, which had been made to show whether or not the drug was safe for use, and failing to disclose the fact that certain investigations had been made, and that adverse and toxic effects had been observed in animals to which the drug had been administered, said investigations being more particularly described as follows:

A. An investigation made by The Wm. S. Merrell Company, begun on or about June 23, 1959 with three female monkeys, to study the effect of dosages of 10