

United States District Court for the District of Columbia

Holding a criminal term

Special July 1963 Grand Jury sworn in on July 2, 1963

THE UNITED STATES OF AMERICA

v.

THE WM. S. MERRELL COMPANY, RICHARDSON-MERRELL, INC., HAROLD W. WERNER,
EVERT F. VAN MAANEN, WILLIAM M. KING

Criminal No. 1211-63; Grand Jury No. Original; Violation: 18 U.S.C. 1001

The Grand Jury charges:

On or about July 24, 1959, within the District of Columbia, the defendants, The Wm. S. Merrell Company, a body corporate, Evert F. Van Maanen and William M. King, wilfully and knowingly made and used, and caused to be made and used, in a matter within the jurisdiction of the Food and Drug Administration of the Department of Health, Education and Welfare, an agency and Department of the United States, a false writing and document knowing the same to contain false, fictitious and fraudulent material statements and entries, in that the defendants knowingly and wilfully filed and caused to be filed, on or about July 24, 1959, with the said Food and Drug Administration, in Washington, D.C., a new drug application, designated as NDA 12-066, 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 said Food and Drug Administration, containing certain reports of investigations made to show whether or not the said MER/29 (Triparanol) was safe for use, that is, the results of toxicity studies in animals, in which the defendants knowingly made and caused to be made false, fictitious and fraudulent material statements and entries, to wit:

1. The report of the six-week subacute toxicity study in rats on 37.5 and 75 mg/kg per day regimen of MER/29 contained statements and entries that four out of eight female rats on a daily regimen of 75 mg of MER/29 per kilogram of body weight had survived six weeks of experimentation and study, and it set forth figures and amounts showing the body weights and organ weights of said four surviving rats, their food consumption during the six-week study period and statements and entries showing that the hematologic values of rats administered MER/29 during the six-week study period were within normal limits and similar to the hematologic values of the control rats (i.e., rats which were a part of the study but not administered any of the drug MER/29), all of which statements and entries the defendants knew to be false, fictitious and fraudulent in that all of the female rats on the 75 mg/kg per day regimen of MER/29 had died before the completion of the six-week study and no final organ weights, body weights or blood values were obtained covering the entire six-week period, and that in certain of the remaining rats adverse blood effects consisting of changes in leukocytes, granulocytes and lymphocytes had been observed but were not reported.

2. The report of the twelve-week chronic toxicity study in rats on 25 and 50 mg/kg per day regimen of MER/29 contained statements and entries showing that hematologic and blood determinations were within normal limits, said statements and entries being false, fictitious and fraudulent in that, as the defendants well know but did not report, a marked increase in leukocytes and reticulocytes and a number of vacuolated and binucleated forms of lymphocytes had been observed in rats to which MER/29 had been administered.

3. The report of the chronic study in monkeys covering the period from on or about September 9, 1957 to on or about March 15, 1959 contained statements and entries that

(a) rhesus monkey designated as No. 51 in the study had been administered MER/29 at a dosage of 40 mg/kg per day for a period of six months and thereafter at a dosage level of 20 mg/kg per day for an additional ten months, which was false, fictitious and fraudulent, as the defendants well knew, in that rhesus monkey No. 51 had not been administered a dose of 40