

M34 had had a "reverse heart attack," when he asked why this sick monkey behaved abnormally—for example, missing a box it attempted to jump into after being weighed. He could not explain why there were no autopsy results recorded in the raw data notebooks for M34. The autopsy report submitted with the NDA on this monkey indicated nothing abnormal about the heart. After reviewing the raw data, Mr. Umberger signed another affidavit reaffirming the affidavit of March 13.

On May 30, 1962, I interviewed Mrs. Jordan again. This time, she was shown copies of the pages from the raw data notebooks and charts which she had helped prepare, including Figure 7 submitted with the NDA. She now was able to recall that the sick monkey she referred to in her earlier affidavit was M34, which agreed with Mr. Umberger's recollection, and that this monkey did not lose a dramatic amount of weight, but did poorly.

She confirmed the fact that M34 was the monkey that was mean, withdrawn, and couldn't see properly, missing the box when he tried to jump into it. She also recalled that monkey, M34 was not autopsied in her presence, which was the reason no record was in the raw data book. She advised us that Dr. Van Mannen was the one that told her to falsify the chart (Fig. 7) turned in with the NDA. He supplied the weights to be used for the curve on monkey M34, which did not agree with those in the raw data notebooks, and insisted on the other changes which: (1) showed M51 as being on MER/29 during the entire experiment rather than the last eight months only; (2) showed monkey M35 as being a control monkey for the entire time, though she knew it was on 5066, another test drug, during the first part of the experiment; and (3) eliminated weight figures for the closing weeks of the study—figures which would have shown the dramatic weight loss of F49 and the weight loss of M51.

She also knew there were some suspicious looking rats on MER/29 studies and that about one-third of the MER/29 rats died.

On June 19, 1962, I interviewed Dr. K. S. Grady. He had been a consultant veterinarian for Merrell since about June 1961. He said he had made specialized examinations on dogs' eyes once a week for three or four months for Merrell and noted abnormalities which developed slowly until some were diagnosed as cataracts. Some of the dogs' eyes showed fingernail-like opacities. He also noted dermatological problems in the dogs. These findings were reported to the firm, primarily to Dr. King. Dr. Grady later found that these dogs were being dosed with MER/29.

On June 20, 1962, I interviewed Frank A. Nantz, M.D. He is an ophthalmologist and had done some examinations of dogs' eyes for Merrell on November 9, 1961. These dogs had developed cataracts while on a high-level MER/29 study. He later made about six trips to the firm over a four-month period to examine these dogs. In addition to cataracts, he noted that these dogs developed skin rashes.

On June 22, 1962, I interviewed Dr. Irvine H. Page, M.D., Director of Research, Cleveland Clinic, at the request of our Bureau of Enforcement. A dog study on MER/29 which had been performed by his group and which had been completed about two years previously, had shown results which were unfavorable to Merrell. This was submitted for publication in the Archives of Pathology, but Dr. Page decided to withdraw publication after he had sent his manuscript to Merrell and they urged him to delay publication. I understand that the paper eventually was published in June 1962.

This was the final field investigation I made of any significance in respect to this case.

If you have any questions, I will try to answer them for you.

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STATEMENT BY EDWIN I. GOLDENTHAL, PH. D., ACTING DEPUTY DIRECTOR, OFFICE OF NEW DRUGS, BUREAU OF MEDICINE, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman, I appreciate the opportunity of appearing before you today to discuss my involvement with the drug triparanol, or MER/29, with regard to (1) the initial review of the pharmacological and toxicological data submitted in support of safety of the drug, and (2) the investigation at the William S. Merrell Company and the subsequent review of some of the raw data upon which the reports submitted to FDA were based. MER/29 is a drug formerly marketed by the William S. Merrell Company for lowering cholesterol levels.