

day or two before the autopsy. This could establish which is the correct date of autopsy because samples of blood are not taken after autopsy. He explained that Mary Ann Stevens learned under Mr. Knox Smith and that she was the type of employee that would not make any false entries as to dates that was taken from animals on any data she helped to prepare. Umberger stated that Mr. Smith had told all technicians that if they were always truthful in their entries, they had nothing to worry about when they signed their names to a report. Knox Smith had always emphasized that only the truth should be recorded.

5. Umberger said that monkey # 35 was used as a drug monkey on 5066 according to the notebook data at the beginning of the study. He said this animal could have been used as a control for the 5052 study later in the study as it appears on the graphs and charts. He said that since it is recorded on the charts, it must have been used starting 6/12/58 as a control. Umberger further stated that this information should have been shown in the raw data notebook as a control, but that whoever made the entry for # 51 as a test animal on 5052 must have simply overlooked entering monkey 35 in the book as a control.

6. Umberger was unable to explain why no autopsy information was recorded for monkey 34 and monkey 35 in the raw data notebook. He believes the only explanation is that Dr. King may have had the data. He noted that in the raw data notebook for monkeys number 51 and 53 such an entry was made that Dr. King had the data. Later on entered in the notebook for animals 51 and 33. Umberger felt that in the case of monkeys 34 and 35 for some reason their entry into the raw data notebooks had been overlooked.

Following our interview with Umberger, a three page affidavit was prepared attesting to the above information. This was signed by Umberger after he swore with his right hand raised that the information contained in the affidavit is "the truth, the whole truth, nothing but the truth, so help me God." The oath was administered by Inspector Rice and witnessed by Inspector Brodsky.

Umberger was asked if he would be willing to testify to the above statements if the need should ever arise. He stated that he would be willing to testify to anything he had signed his name to, but only to the true facts. He then asked us what he should do if he were contacted and questioned by representatives of Merrell. We told him that while it would be up to him to use his own judgment, we strongly suggested that he holds completely to the truth. We indicated that if he were contacted by any representative of Merrell, we would appreciate his contacting us. He indicated that he would do this.

One final interesting point should be reported in connection with monkey 34 as follows. Mr. Umberger told us that monkey #34 for which no autopsy result appears in the raw data notebook was in fact autopsied. He remembers this because he asked at the autopsy why the monkey behaved abnormally; i.e. why did it miss the box at the time it attempted to jump when being weighed. Umberger told us that he was advised that the monkey had a "reverse heart attack." Umberger could not further explain or elaborate on what this meant.

This may be significant since clinical studies in the NDA mention that in several instances, patients died, but this was attributed to the type of patients being given the drugs. These were explained away because they felt the patients such as had heart conditions would have died any way.

Note that the autopsy report on monkey 34 submitted with the NDA indicated nothing abnormal about the heart whatsoever.

PHILIP BRODSKY,
THOMAS M. RICE,
Inspectors.

Enclosure—Affidavit.

AFFIDAVIT

STATE OF OHIO,
County of Franklin:

Before me, Thomas M. Rice, an employee of the Department of Health, Education, and Welfare, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803 (5 U.S.C. 521); Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953, to administer or take oaths, affirmations, and affidavits, personally appeared Bruce I. Umberger in the county and State aforesaid, who, being first duly sworn, deposes and says: