company wanted it. She named other former Merrell employees who were familiar with this experiment, particularly Bruce I. Umberger.

I interviewed Mr. Umberger that night of March 12–13, 1962. Since his recollections substantiated Mrs. Jordan's to a considerable extent, they were prepared in affidavit form. I again interviewed Mrs. Jordan on March 13, and her recollections were also prepared in affidavit form.

Following this, I attended a conference in Washington, D.C., to plan further investigation. It was decided to send a three-man inspection team, consisting of a medical officer, a pharmacologist, and me, to inspect the firm and review the raw data from the chronic studies on rats, dogs, and monkeys, and to get up-to-date information on adverse effects to humans.

I made the inspection on April 9 and 10, 1962, with Dr. John O. Nestor and Dr. Edwin I. Goldenthal, from FDA Headquarters.

During this inspection, discrepancies were found between the raw data notebooks and charts kept by the firm with respect to the monkey chronic oral toxicity studies and the data and charts on these studies which had been submitted to FDA by the firm in support of the MER/29 NDA. For example, as submitted in the NDA, monkey M51 was reported as having received 40 mg/kg body weight MER/29 for six months and 20 mg/kg for ten months. The NDA data showed no weight loss at the end of the experiment. The raw data showed that monkey M51 was started on MER/29 about half way through the experiment and was placed on 20 mg/kg body weight of MER/29 for only about eight months. There was a significant weight loss toward the end of the experiment.

Monkey F49, according to the NDA submission, showed a wieght gain in the last month of the experiment, but the raw data showed a significant weight loss from 9.9 kg to 7.5 kg—a loss of 2.4 kg (5.3 lbs) in this last month.

Furthermore, discrepancies were found between the NDA submission and raw data in the dates of autopsies of the monkeys. In particular, no record of any autopsy on drug monkey M34 was found in the raw data.

The charts showing discrepancies with the NDA submission were copied, but the firm refused to permit us to take the raw data notebooks the evening of April 9, although promising to make copies of the pages we wanted. No one at the firm was able to explain the discrepancies noted. We returned to the firm on April 10, 1962, and still no one could explain the discrepanies. They did not have the copies of the pages of the raw data notebooks as promised. However, they assured us that copies would be made available as soon as possible.

On April 12, 1962, I called Mr. E. R. Beckwith. Executive Vice President of Merrell, because we still had not received the promised copies. He said they were trying to get a complete picture of the situation, but because of changes in personnel during the time the data was compiled, information was scattered. He told me it was taking time to get the pieces of information together. He again assured me he would get me the copies as soon as possible.

On April 17, 1962, I paid another visit to the firm because we had still not been supplied with the copies of the pages from the raw data notebooks. At the same time, we discussed the details and status of the firm's recall of MER/29, which was by then, underway. At this time, I was told by Mr. Fred Lamb, attorney for the firm, that he could not give me copies of the requested pages because the notebooks had been sent to an attorney for the firm in New York City for examination. He said it was up to this attorney, dealing at the Washington level, to decide whether the pages would be made available.

I understand that copies of the requested pages were finally turned over to a Food and Drug Inspector in New York on April 19, 1962.

On April 24, 1962, I interviewed Dr. King at his home, accompanied by Mr. T. C. Maraviglia, Director of FDA's Cincinnati District.

At this time, Dr. King told us that a control monkey, M35, had actually been on an analogue of MER/29, known as compound 5066, for a time prior to being used as a control animal. He also stated that his findings from the autopsy of monkey F49, which had received MER/29, indicated morphological changes in the ovaries. He said that it was Dr. Van Mannen's decision to omit this information from the second edition of the MER/29 brochure so that the investigators supervising clinical studies on MER/29 wouldn't know about it.

I again visited Mr. Umberger the night of May 3 and 4, 1962. He reviewed copies of pages from the bound raw data notebooks which had been supplied to me by this time. From these, he was able to recall that the sick test monkey was number M34. He recalled that at autopsy he was told that the monkey,