

care. I believe, and I have often stated, that he who controls the economics will control the quality of care. The quality of drugs is inescapably a vital part of the quality of care.

Now, there is growing clamor to make the price of drugs the primary consideration in their selection to relegate quality to secondary consideration. Any such approach could not fail to adversely affect the quality of care. It would not, as I have tried to show, appreciably lower the nation's health care bill. It could do irreparable harm to the nation's health care system. I present this statement to you because I am anxious to do my small part in alerting you to this peril.

Our present balanced and flexible health care system is the wonder of the rest of the world. As you proceed with your inquiry, I sincerely hope you will conclude that it is in the best interests of all concerned to keep it that way, and that you will summarily reject demands for such chancy experiments as the imposition of controls over the prescribing of drugs for economic, not health reasons.

APPENDIX V

THE MER-29 CASE

STATEMENT BY THOMAS M. RICE, ACTING CHIEF INSPECTOR, BUFFALO DISTRICT, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman, it is a pleasure to appear before you today to discuss my part in the investigation of MER/29.

During the time of the field investigation of MER/29, from 1961 to 1963, I was employed as a Supervisory Inspector at FDA's Cincinnati District Office. I was the principle field investigator in the MER/29 case.

In early 1962, there was considerable publicity in the Cincinnati area, as a result of the drug warning letter mailed by the William S. Merrill Company to all physicians, the previous December. This warning letter informed physicians of the incidence of cataracts, hair changes, ichthyosis, and other skin changes, depression of adrenocortical function and other side effects associated with MER/29 therapy.

This publicity was the topic of a conversation in my Cincinnati car pool in February 1962. One of the car pool members, Mr. Carson Jordan, who knew that I was employed by the Food and Drug Administration said that his wife had been involved in animal studies on MER/29 during the time she worked at Merrell, when this drug was being developed. His wife, he said, suspected the records on the animal studies had been falsified to make the reports look good. He told me that Mrs. Jordan later resigned her job in the animal testing laboratory, where she was employed under the supervision of Dr. William M. King, because she was dissatisfied with the way Dr. King was directing the work. He said she felt very strongly that Dr. King would have no qualms about "doctoring" the results of the studies.

Recognizing the importance of what Mr. Jordan had said, if true, I reported this incident to our Bureau of Field Administration. At the request of our Bureau of Field Administration, I interviewed Mrs. Jordan on the evening of February 26, 1962. She told me that she had the responsibility of dosing and weighing both the test monkeys and the control monkeys during a toxicological study of MER/29. Mrs. Jordan said that at the end of the study, which took a number of weeks, she worked up charts depicting the observations and weights. Three or four monkeys were on MER/29 and a similar number were in the control group in the study, she said.

Dr. King and his superior, Dr. Evert F. Van Maanen, were not satisfied with the charts, Mrs. Jordan said. She said one test monkey on the drug, MER/29, had been sick and doing very poorly; its eyes "did not look right." This monkey subsequently was not autopsied with the rest. In addition, her superiors decided to substitute a control monkey in its place. Because of this decision, Mrs. Jordan said it was necessary for her to rework the charts three different times. She believed that the results on the charts would have been very unfavorable if the sick monkey had been left in the test group. She stated that she was told never to mention this substitution of data on the charts because this was the way the