

labeling must be investigated and reported within 15 days after such knowledge is available to the producers.

No one has a greater interest or responsibility in the safety and effectiveness of a drug product than the manufacturer, who can ill afford to market a drug that will demonstrate a toxic response not commensurate with its effectiveness. To insure the continuing flow of all essential information in respect to an FDA approved drug product the pharmaceutical manufacturers support the Armed Forces Institute of Pathology in its investigation of tissue reaction to possible toxic drug effects and the American Medical Association's Council on Drugs and its panel on hematology of the registry on adverse reactions.

More than 700 doctors of medicine are engaged full-time by PMA member firms. There is a grave responsibility in the overall development of a new prescription drug product. Less than an honest appraisal of the product and constant surveillance of the claims made for it by its marketers could destroy a scientific reputation that was not obtained without great effort.

Senator NELSON. Thank you very much, Doctor. We certainly appreciate your taking the time to come here and present your very valuable testimony to the committee. We regret the great imposition on your time.

(The complete prepared statement and attachments submitted by Dr. Van Riper for presentation on November 16, 1967, follows:)

STATEMENT OF DR. HART E. VAN RIPER, VICE PRESIDENT, GEIGY PHARMACEUTICALS

THE CLINICAL EVALUATION OF NEW DRUGS

Mr. Chairman and members of the committee, I am Hart E. Van Riper, M.D., Vice President for Medical Affairs of Geigy Pharmaceuticals, Division of the Geigy Chemical Corporation, Ardsley, New York. I was graduated from the University of Pennsylvania, being awarded a bachelor of arts degree in 1926 and a degree of doctor of medicine in 1930. After an internship and residency in pediatrics, I was certified by the American Board of Pediatrics and practiced my specialty in Madison, Wisconsin from 1933 to 1941. From 1941 to 1944, I served as Assistant Director for Maternal and Child Health, The Children's Bureau, at that time a bureau in the Department of Labor. From 1944 to 1945, I was Medical Director of the Jackson Memorial Hospital, Miami, Florida. From 1945 to 1956, I was Medical Director at the National Foundation for Infantile Paralysis, and during this period was concerned with the research that culminated in the field trials that established the safety and efficacy of the Salk poliomyelitis vaccine. Since 1956, I have been associated with Geigy Pharmaceuticals and for seven years, as Medical Director, I have been responsible for the clinical investigation of new drugs and the filing of new drug applications with the Food and Drug Administration.

In my statement I would like to outline briefly some of the activities of the research-oriented companies in the pharmaceutical industry in preparing safe and effective medicines for the treatment, cure or prevention of disease. I hope to give you some idea of the vast amount of time, effort, talent and money expended in the clinical phases of drug research.

In an article entitled, "The Evaluation of New Drugs", which appeared in The Archives of Internal Medicine, Volume 119, June, 1967, scientists not associated with the pharmaceutical industry presented in considerable detail the steps that must be taken in the evaluation of a chemical compound from the chemist's laboratory to the finished pharmaceutical product on the pharmacist's shelf. Drs. Barron and Bukantz, authors of this scientific paper, state that "it is presently estimated that approximately four years will elapse between the time a