

Senator NELSON. I might say to the Senator that all of the findings and recommendations of the National Research Council of the National Academy of Sciences have been made public, have been filed in the Federal Register. We have invited Dr. Ley of the FDA and we have invited all the drug companies whose drugs are affected, to appear before the committee to present their side.

Thank you very much, Dr. Kirby.

Our next witness is Dr. Eichenwald. Doctor, the committee is very pleased to have you here this morning. As I said to Dr. Kirby, if there is any aspect of your testimony on which you would like to elaborate extemporaneously, feel free to do so. I assume you do not mind being interrupted with questions.

Go ahead, Doctor.

STATEMENT OF DR. HEINZ F. EICHENWALD, WILLIAM BUCHANAN PROFESSOR AND CHAIRMAN, DEPARTMENT OF PEDIATRICS, UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL SCHOOL, DALLAS, TEX.

Dr. EICHENWALD. Thank you, Senator, and Senator Dole.

As you gentlemen are aware, the National Academy of Sciences-National Research Council undertook a drug efficacy study in 1966 under contract with the Food and Drug Administration. Essentially, the organization agreed to review the claims for effectiveness of drugs approved between 1938 and 1962. The study was conducted by a group of 30 panels, each consisting of a chairman and five additional members. Five of the panels concerned themselves with antimicrobial agents and each had occasion to consider the claims for efficacy of several products containing fixed combinations of antimicrobial drugs. I was chairman of the Antibiotics Panel No. 1.

It is of interest that all five panels, consisting of a total of 30 recognized experts in the field of antimicrobial therapy, concluded unanimously that there was no place in the medical armamentarium for fixed antimicrobial drug combinations or for products consisting of antibiotics combined with other pharmacologically active drugs. There are few instances in medicine when so many experts have agreed unanimously and without reservation.

The panel chairmen felt it to be desirable to inform the medical profession of the facts on which the unanimous recommendations were based. Accordingly, a scientific paper entitled "Fixed Combinations of Antimicrobial Agents," was written for publication in the New England Journal of Medicine. At the time of my statement, the article has not appeared. A copy of the manuscript has been supplied to this committee. It will be generally available as soon as it has been published.

Senator NELSON. I understand that Dr. Inglefinger of the New England Journal of Medicine has accepted the article?

Dr. EICHENWALD. Yes.

Senator NELSON. And plans to publish it in an early journal.

Dr. EICHENWALD. I think within the next month, May 22.¹