We are very pleased this morning to have before the committee two very distinguished doctors, Dr. William M. Kirby, professor of medicine, University of Washington School of Medicine, Seattle, and Dr. Heinz Eichenwald, William Buchanan professor and chairman of the Department of Pediatrics, University of Texas Southwestern Medical School, Dallas.

Our first witness will be Dr. Kirby. Dr. Kirby, the committee is very pleased that you have been willing to take the time from your busy schedule to come here today and present your viewpoint and the viewpoint of the Panel on Antibiotics of the National Academy of Science-National Research Council to this committee.

You may present your testimony, Doctor, however you wish. If at any time you would like to elaborate on anything you have said in your statement, just feel free to do so. Your statement will be printed in full in the record.

Dr. Kirby, the committee welcomes you here this morning.

STATEMENT OF DR. WILLIAM M. M. KIRBY, PROFESSOR OF MEDICINE, UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE, SEATTLE, WASH.

Dr. KIRBY. Thank you, sir.

As chairman of one of the five anti-infective panels for the National Academy of Science-National Research Council Drug Efficacy Review I should like to present the reasons for the recommendations made by the panels concerning fixed combinations of anti-infective drugs. Fixed combinations refer to mixtures of antibiotics, or of an antibiotic with another drug, in the same package. They were first marketed during the period 1938–62 when the FDA was charged with passing upon the safety of drugs but not on their efficacy. The Kefauver-Harris Amendments of 1962 specified that efficacy should also be evaluated, and the drug efficacy review was the mechanism chosen to implement this requirement.

The drug amendments of 1962 provide that a drug must have "the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." For use of the drug efficacy review panels this wording was translated into a guideline specifying that for combinations of drugs "each active ingredient must contribute to the effect of the combination as claimed." The law further requires that there be "substantial evidence" in support of all claims made for therapeutic efficacy.

In reviewing claims of efficacy made for the various antibiotic combinations, the anti-infective panels found that they did not meet the above requirements and they were, therefore, given the evaluation "ineffective as a fixed combination."

Senator NELSON. Excuse me, Doctor. Would you identify the panel—did your particular panel of which you were chairman have a specific title?

Dr. KIRBY. It was called Anti-infective Panel Number 3.

Senator NELSON. I see. And that panel was assigned a certain number of drugs?

Dr. KIRBY. Yes.