

Senator NELSON. Well, was any data of value on which the panel could make a judgment not furnished by the FDA?

Dr. KIRBY. No. Nothing was withheld.

Senator NELSON. So, all the material that the FDA had to support the efficacy of the drug was available to the panel?

Dr. KIRBY. Was available to the panel, yes, sir.

Senator NELSON. Then the panel explored the literature on the drug also.

Dr. KIRBY. Also. Yes. In addition to the FDA supplying material, the panel made its own individual search of the literature to find all the articles bearing on the subject.

Senator NELSON. Thank you.

Dr. KIRBY. Panalba is only one of more than 80 fixed antibiotic combinations reviewed by the five anti-infective panels, and they all received similar comments and evaluations.

Senator NELSON. Eighty fixed antibiotic combinations were reviewed and the judgment of lack of efficacy was found on each one of the 80?

Dr. KIRBY. Yes. I believe that is true. It is more than 80—83 or 84, I believe.

Senator NELSON. Have the five panels completed their review of antibiotics?

Dr. KIRBY. Yes, they have.

Senator NELSON. Does that number that they have reviewed cover all the antibiotic combinations in the market?

Dr. KIRBY. Yes, it does.

Senator NELSON. Did the panel find that any one of the antibiotic drug combinations met the appropriate standards of efficacy under the law?

Dr. KIRBY. I do not believe they did. I cannot answer that categorically, because I was only involved with some of them but I do not believe so.

Senator NELSON. How many antibiotics were reviewed by panel 3? That is your panel, is it not?

Dr. KIRBY. Yes. I am sorry, I cannot give you that figure right off, either.

Senator NELSON. But every one of those reviewed by your panel was found to be—

Dr. KIRBY. Oh, yes, was judged ineffective. Every one by our panel, and I think perhaps we had the largest number, just about the largest number, at least, of the fixed combinations.

Senator NELSON. Were the findings of your panel on each antibiotic combination unanimous?

Dr. KIRBY. Yes, they were.

Senator NELSON. Go ahead.

Dr. KIRBY. A curious paradox has been the continued widespread usage of these fixed combinations despite the fact that the experts, without exception to my knowledge, have opposed them. In April of 1957 nine leading infectious disease authorities, concerned about the increasing number of fixed combinations being marketed, signed an editorial in a prominent medical journal that stated the following:¹ And this incidentally, was the Archives of Internal Medicine, the issue of April 1957, and in an editorial—

¹ See Appendix I, pp. 5251-5252, *infra*.