The way this was done was that—let's assume that we had about 10 preparations to consider for our panel, of which there might be 20 or 30 different brand names. Each panel member was assigned the job of reviewing, say, two of these, with all the variety of preparations by many manufacturers. They went over every claim. They brought this out in long hand and prepared it and presented it to us as a group. Then we met together and went over individually every consideration that each individual brought up. We did have staff assistance in the sense of the assistance to find out where we were going to meet and to take care of our travel, and to perhaps help us with a reference or two. But basically this was work done by the members and prepared by the members.

These white papers were prepared by the members of the committee, not by the staff—we were the staff.

Senator DOLE. I think that is interesting for me to know, and I am certain the chairman is aware of it.

Then based on your statements, and the statements of the other experts in this field, what do you recommend now as far as what this committee might do? I understand now everything is being reviewed by the FDA. Is there anything you feel that the committee should be doing, or should we wait and see what happens at the FDA level?

Dr. KUNIN. Well, I personally believe that the members of the panel and the medical community should be made aware of the valuable work of the Food and Drug Administration, and particularly the pressures and strains that Dr. Ley is undergoing at this time. I believe personally that Dr. Ley has taken these recommendations extremely seriously, and that he is a very responsible official. I believe that the process that he is going through is very appropriate. It is more important that the sentiment among physicians and the population should be in support of Dr. Ley's activities.

From time to time he may judge that he would permit a company to provide more evidence, and give them a little time to bring forth some evidence. This is based perhaps upon some new evidence that a company may come up with. Dr. Ley should be entitled to have some flexibility. But I am thoroughly convinced, after discussing this with him, and watching his performance, that he will see to it that the judgments of the panels are carried through. I am sure he is dedicated to that position. I think what your committee can do and what the physician can do is support the Food and Drug Administration and give it the backbone it needs.

Senator. DOLE. But I understand you are not critical of the FDA?

Dr. KUNIN. No, sir.

Senator DOLE. The only thought I have, I wonder if we are sitting in judgment or whether the FDA is sitting in judgment, because there appears to be rather complete unanimity with reference to the subject matter. And I would guess in accordance with the 1962 act, the FDA is acting efficiently and properly, in making a determination. You are not critical of the speed or what they are doing?

Dr. KUNIN. Absolutely not. The FDA is perfectly aware of the fact that there are certain procedural problems that they have to go through. It is true that if Dr. Ley felt that the drugs were extremely