combination. Now, I am aware that in certain other areas which do not involve systemic use of an antibiotic the recommendation of the Academy will be more favorable, and for very good reasons. And that is an issue aside from the topic we are discussing here. To the best of my knowledge, the systemic antibiotics as fixed combinations have been considered inappropriate in every case that has been received and reviewed by our agency.

Senator NELSON. We will take a 5-minute recess.

(Short recess.)

Senator NELSON. We will resume the hearings.

Dr. Ley, as I recall, you were on page 8.

Dr. LEY. Yes, sir. I was going into the details of the organization of the study, Mr. Chairman.

The study was carried out under the direction of the division of medical sciences of the NAS–NRC. This Division's Drug Research Board, with additional representatives to cover all appropriate medical specialties, made up the Policy Advisory Committee (PAC), which we will refer to subsequently, that established guidelines for the review.

In the development of guidelines for the study, the Academy and the PAC made an effort to involve the pharmaceutical and medical communities to the greatest possible extent.

Senator NELSON. May I interrupt for a moment there?

Dr. LEY. Certainly.

Senator NELSON. At the time Dr. Goddard established this procedure for evaluating the efficacy of these drugs, did the industry itself approve or disapprove of this method?

Dr. LEY. We met subsequently with the members of industry, the members of the Policy Advisory Committee, and the panel chairman. Industry did actively participate in the discussion that established the categories of evaluation which were selected for reporting effectiveness. In general I saw and heard of no serious disagreement on the part of industry with the procedures as they evolved. Industry was largely represented by PMA in many of these policy discussions that established the guidelines for the efficacy review.

Mr. Goodrich was here at that time. I was not. He may wish to add a few additional comments on this matter.

Mr. GOODRICH. Only to say that, as Dr. Ley has, I have heard no objection from the pharmaceutical industry or any of its members to this method of review. And indeed Mr. Stetler did attend and participate in meetings before the Policy Advisory Committee. And there are two people from the drug industry—one with Hoffman La Roche, and the other with Merck and Co.—who serve on the policy advisory board of the NAS–NRC.

Senator NELSON. So the procedure for evaluation was participated in by the industry, and you are not aware of any criticism of the procedure?

Mr. GOODRICH. That is right. The opposition comes when an economically important drug is involved, and is coming in the legal contest to the removal of such a drug from the market.

Senator NELSON. You may continue.