Perhaps it is just my lack of knowledge of the medical profession that prompts me to ask these questions, but I think it is a fair question to ask on the basis of these presentations.

Mr. GOODRICH. What the panels are saying to us is not that it is somewhat effective or slightly effective, what they are saying is that the scientific evidence available to support the claims is not of the type required by law, but there is some evidence that the drugs are probably effective, or that there is a little bit of evidence that the product is effective in the case of the possibly effective drugs. And rather than move at once to suspend the drugs from the market because there is not the type of evidence required by law to support the claims, they have been allowed 12 and 6 months for the development of that initial evidence. But there has been no compromise with the standard of effectiveness.

Mr. DUFFY. Did I understand you to say that the panel was making legal judgments?

Mr. GOODRICH. No; they were making judgment on the adequacy of the medical evidence.

Mr. DUFFY. They were saying these were not in keeping with the standards required by law?

Mr. GOODRICH. The panels were measuring the medical evidence by the standards required by law. And they found that the evidence did not meet the standards, but nonetheless there was evidence to show that the drug was either probably effective or possibly effective, and recommended that the companies be allowed 12 or 6 months additional to supplement the medical evidence.

Mr. DUFFY. Thank you.

Dr. LEY. As if these four categories were not sufficient, during the course of the study it proved necessary to add two additional categories. One of these, "effective, but," was added to accommodate those drugs which presented special problems such as products which were found effective for the indications listed, but which included ingredients, represented as active, which were concluded to be ineffective, and for products that were effective but required labeling revisions of a major sort. The second category added was "ineffective as a fixed combination," a classification I will discuss in greater detail a little bit later.

In support of each category assignment, panels were expected to present a justification citing the scope of the evidence evaluated and, where appropriate, how this evidence supported the decision. It was evident that these justifications would be of great value to FDA in effecting by regulatory action the recommendations of NAS/NRC. It should be noted that NAS/NRC committees were not charged with the review of safety of the products.

To enable NAS/NRC to proceed with its task, it was necessary to provide the panels with the basic informational material on each drug to be evaluated. On July 9, 1966, the FDA published an order in the Federal Register calling for each holder of a New Drug Application approved between 1938 and 1962 to submit specified information on each drug, preferably on forms prepared by NAS/NRC. The information requested included an identification of the product, copies of the labeling to be reviewed, and a list of literature references most perti-