Dr. LEY. A broadly representative forum was held on the guidelines prior to their adoption by the PAC. Among the other matters covered, the guidelines provided that—and these are the three points that I mentioned earlier:

> The judgments of the panels will be based on the following criteria: (1) Factual information that is freely available in the scientific literature, (2) factual information that is available from the FDA, from the manufacturer or other sources, or (3) on the experience and informed judgment of the members of the panels.

Operating with in these criteria, the panels were asked originally to classify claims for drugs into one of four categories:

(a) Effective.—For the presented indication, the drug is effective on the basis of the criteria which the panel has established for its review.

(b) Probably Effective.—For the indication presented, effectiveness is probable on the basis of the operative criteria, but additional evidence is required before it can be assigned to category (a).

(c) Possibly Effective.—In relation to the indication in question, there is little evidence of effectiveness under any of the operative criteria to support claim effectiveness.

(d) Ineffective.—In relation to the indication in question, the panel concludes that there is no acceptable evidence under any of the operative criteria to support a claim of effectiveness.

Mr. DUFFY. Doctor, if I may interrupt you for a minute, I would be very interested to hear Mr. Goodrich's interpretation of the first three categories. It would seem to me that among the first three we have a question of relative effectiveness, is that not correct?

Mr. GOODRICH. No, I don't think so. The first of course is that the claims are fully supported. The second is "probably effective," that there is some evidence to support the claim, but more research is required before there can be a conclusion of the type required by law that there is adequate well-controlled evidence to support the claim.

The third, "possibily effective," is that there is little evidence of effectiveness. Now, these second and third categories were adopted by the agency to give the companies even additional time after receiving the NAS–NRC report within which to produce the kind of evidence called for by the law. It was pointed out in the hearing recently before the Fountain committee that if we found the product either effective or ineffective, under the law we should proceed immediately to take the drug off the market or leave it on. We as an agency adopted these middle two categories, "probably effective" and "possibly effective," to allow a period of 1 year for the "probably effectives," and 6 months for the "possible effectives, for the development of evidence that would keep the drugs on the market or show in a definitive way whether they were ineffective.

Mr. DUFFY. Is it necessary to develop new evidence, or would it merely be necessary, let's say, to limit the claims? Would either of those two have the result of making the drug "effective."

Mr. GOODRICH. The company can do either. If it wants to abandon the claim we cheer them and encourage that.

Dr. LEY. May I respond to this question too? I have already responded to a similar question in many public statements.