A drug is not a simple matter of effective or ineffective. A drug has claims. And it is the claims we are judging effective or ineffective. Drugs may have a half dozen claims included in the labeling that was current at the time the Kefauver-Harris amendments were passed. Where a drug has half a dozen claims, the Academy finds three claims effective, one claim probably effective, and let's say two claims ineffective, I have pleaded with the firms in public speeches that they simplify the matter by reducing their claims to only those that the Academy finds effective without question and delete the others for the time being.

Certainly the "ineffectives" must be deleted. But it is not a simple matter. This is something that is very difficult to convey to the general public. A drug by itself is neither effective nor ineffective. A drug is effective or ineffective only in terms of the indication for which the physician uses it, and the manufacturer promotes it.

Mr. DUFFY. Mr. Goodrich, can you tell us as a matter of law, when you say a drug is "probably effective," you are not saying that to some degree this drug is "effective."

Now, where do we transcend this question of effective versus probably effective, and what is the legal standard we use in judging this?

Mr. GOODRICH. The legal standard was provided by the Congress in a quite careful definition of what was substantial evidence, that is, evidence obtained from adequate, well controlled studies, including clinical studies, on the basis of which it can reasonably and responsibly be concluded that the drug will have the effectiveness claimed. Now, literally, if we apply that standard today to any of these drugs classified "probably effective" or "possibly effective," they would fail to meet the defined standard, and the department would be authorized to remove them from the market as of now. Because we are getting back judgments from the expert panels of "probably effective" and "possibly effective," we decided as an administrative matter to allow the 12 months and the 6 months additional for the accumulation of scientific evidence. We did that in the expectation that most drugs should either stand or fall, die, or survive on their scientific merit, and that rather than going ahead with initiating a large number of administrative proceedings to withdraw the drugs from the market, we should encourage, as much as we could, the development of evidence that would prove effectiveness.

But if it was not available, if it was not developed within 12 months for the probably effective or within 6 months for the possibly effective, we have let the industry know that we intend to move resolutely ahead to apply the standard that Congress wrote for us.

This, I say, is a legal situation. But we were given the discretion of how quickly to proceed with the implementation of the efficacy requirement. And it was an administrative judgment made by Dr. Goddard, Dr. Ley as a medical director, and by me as the legal counsel, that this was a proper and permissible way to move ahead with the effectiveness review.

Mr. DUFFY. I don't want to belabor this point, but what troubles me is that perhaps we are saying here that these drugs are effective, but they are not effective enough. And the moment we say that, then, query, whether or not we are introducing an element of relative efficacy here.