Mr. GORDON. What do you plan to do about the "probably effective" drugs? For example, do you see any reason for using a "probably effective" drug if there is an alternative drug known to be effective?

Dr. STEINFELD. This is a real problem. In the NAS–NRC review they found, as you know, many studies which were really not too well carried out. They were not certain that the drug was really effective for the indication for which it was proposed. So that what we are requiring for the probably effective drugs is that the companies, if they propose to continue manufacturing them, provide use data, good data, which would demonstrate the drug is indeed efficacious for the indication for which it is proposed. They have a year in which to either provide that data or provide protocols showing that the data will be forthcoming.

Now, I can conceive of instances where a patient may be allergic to an effective drug for a particular complaint and that therefore the physician may have to use a probably effective drug. I could conceive of some instances of cost differentials, perhaps, some instances where a physician is convinced that something really does work, and has a great deal more experience with what is called a probably effective drug than with an effective drug, and thus might continue using it—so that I can see instances where probably effective drugs would continue to be used until such time as we have adequate data to determine either that it is effective or it is not.

Mr. GORDON. But they will be used except when you know that an effective drug is available and the patient is not allergic to it, and so forth?

Dr. STEINFELD. Ideally the physician would use the effective drug. I think the panel felt probably effective drugs most likely with some additional information would fall into the effective category. In earlier years the companies did not have to demonstrate effectiveness in the way they do now, so a number of the studies on which approvals were based, we would now fault in terms of present knowledge and present scientific criteria; these will have to be brought up to date or the drugs will then be placed in another category.

Mr. GORDON. Now, the HEW task force report gives as one example of irrational prescribing—this is on page 24 of the task force report—the use of a costly duplicative or "me-too" product when an equally effective but less expensive drug is available. You probably heard this morning that AID will no longer finance such drugs. Dr. Edwards told us when he was here on January 18 that—

> The Government as a major purchaser of drugs should and must insist on the least expensive of equivalent drugs and upon rational choices among different drugs which satisfy the same medical needs.

I am quoting him.

What do you plan to do about this form of irrational drug usage and purchasing?

Dr. STEINFELD. You are raising here for the non-Federal direct programs, the whole question of the formulary, which is certainly one of the things we have under intensive consideration as one of the parts of the overall health program which the President will cover in his message, but I do not think I can address that issue now. I think that is the formulary issue.