Mr. GORDON. Are you saying we should have a formulary for Government purchasing?

Dr. STEINFELD. No.

Mr. GORDON. You say it is a formulary issue. What are you saying?

Dr. STEINFELD. I am saying this is one of the things we have under discussion and that I cannot say what the Government's position will be at this point. I am sorry.

Mr. GORDON. Now, Dr. Steinfeld, as you know, neither the USP nor the National Formulary recognizes sustained release preparations as being reliable dosage forms. Expert testimony before our subcommittee has confirmed this view and Dr. Edwards told us on January 18 that the majority of those currently on the market have not provided adequate evidence, and in general, they appear to be quite unreliable.

These are generally expensive drugs on which the Federal Government has been spending considerable funds. Do you think the use of these drugs by the Government is rational?

Dr. STEINFELD. Well, let me tell you what our policy has been. The NAS–NRC did not look at sustained release drugs; they looked at the individual drug in its regular form. So as a matter of policy, the FDA put the sustained release version of any compound in a lower category from the rating given the regular form.

For example, if a drug was "effective," the sustained release one would be rated "probably effective." If it was "probably effective," the sustained release form would be rated "possibly effective," a "possibly effective" would be rated "ineffective" and the manufacturers would then be required to provide us with adequate information showing that in fact the sustained release compound did do what it was supposed to do—provide a concentration over a period of time.

They are, as you pointed out, erratic, difficult to standardize with different people, and I think very likely we would find fewer uses for such compounds. Where they can be shown to work, I can conceive of places where they would be useful—nursing homes, for example. Rather than having somebody distribute drugs four or five times a day, the sustained release compound would be extremely useful, if indeed it works.

So I think there are places where it would be useful but we are going to have to require evidence that indeed they do perform as advertised.

Mr. GORDON. But until they show that they cannot perform, what do you recommend the Government do?

Dr. STEINFELD. We are going to proceed as we have with the classification I just described. We are going to——

Mr. GORDON. Do I understand you recommend the Government not buy such drugs until they are proven to be effective, reliable, et cetera?

Dr. STEINFELD. Mr. Gordon, those which are in the ineffective or possibly effective category we would not buy. Those that are probably effective we could buy now. None of them would be "effective" because all of the sustained release drugs are one category lower in the NAS–NRC scale than the regular dosage forms.