Senator NELSON. In the letter dated May 9, 1972, Mr. Heller, the Associate Director of the GAO states: "As of May 1, 1972, regulations have not been issued to implement the revised Federal drug policy for medicaid."

Do you have any comment to make on that?

Mr. SEGGEL. Yes, sir. As I mentioned, for medicare we have issued a notice of rulemaking, and are evaluating comments on that notice. With regard to medicaid, SRS has actually developed a similar notice of rulemaking. But we have, at the Department level, been studying this with particular reference to how we would administer it, how we would actually get enforcement of that through the reimbursement mechanism.

It is a very complicated thing. We have no way, obviously, of controlling what the doctor prescribes except by means of our regulatory process of taking things off the market, or by our educational process of informing him of the classification. And we have no way through the fiscal mechanism of determining exactly what drugs are prescribed to what patients. We don't know quite how we would deal with that kind of thing, except with some kind of post audit that we might make on a sample basis. And that would be somewhat less than effective enforcement, doing it by post audit.

And also we are concerned about the question of whether, if the doctor prescribed a drug that we wouldn't pay for, the burden would fall on the patient rather than on the Federal Government.

We are emphasizing the twin strategies, I would say, of our regulatory process of vigorous enforcement through regulation and our regulatory process of vigorous enforcement through regulation and our education process.

In the meantime, we are trying to study ways and means by which we could actually get some enforcement of this if we decide to go forward with it.

We have comments, as I have mentioned, on the SSA proposal.

Mr. GORDON. Comments from whom?

Mr. SEGGEL. From manufacturers and others.

Mr. GORDON. They don't want you to do this at all, do they?

Mr. SEGGEL. That is right in many cases. As I understand it, some of them point out the inconsistency of, on the one hand, being given the opportunity to provide further evidence on the efficacy of their products, yet, on the other hand, Federal funds to purchase those drugs are turned off before that evidence is provided. I think that is one of the main concerns. However, we are committed to this policy of trying to cut out the national support for these drugs. Certainly, as Dr. Finkel has indicated, as we get them off the market. The question of reimbursement becomes moot in any event.

The "possibly effectives" are a little bit tougher problem. There, how we would audit, for example, the question of a doctor prescribing a drug which he says is the appropriate therapy for that patient I don't know. At any rate, I want to say that we have this under study trying to determine how we could enforce it through the reimbursement machinery.

Mr. GORDON. This "possibly effective" business disturbs me. I have read the Food, Drug and Cosmetic Act, and I don't see any reference to "possibly effective" at all. Any drug that is on the market is