with whom, I am sure, you are acquainted as being an eminent scientist and clinician, and others stated that phenformin has no role in the treatment of diabetes mellitus. Do you agree with Dr. Winegrad?

Dr. SCHMIDT. Well, Dr. Crout and I have been discussing this for some time. And with your permission, I will let him describe our feelings on this.

Dr. CROUT. Let me wear two hats. The first hat is as a physician. And I agree with him. The second hat, Director of the Bureau of Drugs, where we have to deal with the issue of action on that point.

Let me state the reason why the benefit to risk for phenformin is less than for the other drugs. This drug may cause lactic acidosis, a potentially fatal complication in patients who take it. So, there is a clear added hazard, in addition to what it does to cardiovascular mortality.

Now, the incidence of that lactic acidosis has in the past been thought to be quite low. As more and more information comes along, it looks like it is higher than we had anticipated. And that issue of lactic acidosis was brought before our Metabolic and Endocrine Advisory Committee more than a year ago.

At that time they recommended that a warning be placed on the drug, but that it stay on the market. We are going to take the issue back to that committee and take up that issue again. But, it is a separate issue, it is a separate issue from the labeling on cardiovascular mortality. On that, as far as we know, phenformin is the same as the sulfonylureas. We are dealing here with two adverse effects. And it is the sum of those two that I think is the important issue.

Mr. GORDON. As a medical scientist, could you tell us what the medical justification is for having this drug on the market?

Dr. CROUT. What my personal opinion is?

Mr. GORDON. Yes.

Dr. CROUT. I would support Dr. Winegrad. I personally would not use the drug.

Mr. GORDON. Then you see no reason for this drug to be on the market. Is that correct?

Dr. CROUT. You are asking me as a medical scientist?

Mr. GORDON. As a medical scientist.

Dr. CROUT. As a medical scientist, yes, I don't see any such reason.

Mr. GORDON. Well, then, why is it not being taken off the market? Why aren't steps going to be taken to take it off if there is no medical justification? After all, is that not the purpose?

Dr. CROUT. As I point out, we will take that back to our advisory committee. It is hardly a universal opinion. And neither I nor anybody else in the Federal Government that I am aware of has the power to simply exercise his personal opinion in the drug regulation business.

If I may wear that hat of the Director of the Bureau of Drugs, we will take that back to our advisory committee. We will attempt to see what support there is for a position that phenformin should not be marketed. We will take appropriate action after that.

That is a separate issue from this labeling.