those that would believe that the regulation of blood sugar, in the absence of symptoms, might be an indication. But I would prefer to see, based on the available evidence, a comment in the labeling that this would be primarily for the symptomatic diabetic patient, because it is only in that circumstance that we really have evidence of the benefits. There is a lot of evidence of the risk, but we are concerned with risk-benefit ratios and we ought to emphasize the utilization of these drugs only in situations where one can provide evidence of benefits. Symptomatic relief would be considered a benefit, without any question, and that is why I would favor a labeling which emphasizes the importance of restricted utilization to the symptomatic diabetic patient—clearly, where diet has failed and where insulin is refused by the patient.

Mr. GORDON. Incidentally, we will send a copy of your comments to the Food and Drug Administration to be included in their record before they issue the final order.

Dr. Larner?

Dr. LARNER. Well, in general, I am very pleased that the movement to insert the labeling is now going on, and it presumably will be consummated, and I, in general, agree with the labeling as it is written up.

I would feel a little bit more comfortable if perhaps something specific could be said in the labeling about warning physicians administering these agents to patients who have demonstrated cardiac problems, for example, with abnormal electrocardiagrams and so forth. I would like to see a little bit more of that type of warning.

Mr. GORDON. Dr. Chester.

Dr. CHESTER. I agree in general, but there are two things that disturb me, and one, on page 29, the very first sentence: "The Commissioner also concludes that a patient population exists for which these drugs, properly labeled, can be considered as safe and effective."

I would take issue with "safe" and would indicate that the effectiveness is limited.

And the other thing that bothers me—and I cannot find in this document—is how the patient will ever see the label. Will it be on the bottle with a skull and crossbones?

Mr. GORDON. Maybe that should be made more explicit in the proposal.

Dr. CHESTER. I would think so.

Mr. GORDON. We shall send that on to the FDA.

Dr. Sims?

Dr. SIMS. I have already described some ways in which the labeling could be modified to include mention of other preferable options for treatment. The question has been raised as to whether the FDA has the right to dictate to the physician how he will manage his particular patient. Another question is whether, if specific priorities and options are outlined, the physician would then become medico legally liable to suit if he does not follow them. I believe that these fears are a distortion. The FDA, in section 505 of the Food and Drug and Cosmetic Legislation, is given the responsibility to determine, to insure, rather, the efficacy of a drug. Now, efficacy is a relative thing, and if there are other options which are better, the drug