upon us to exercise when we make statements which can be interpreted by others or would have the effect of promoting these drugs.

So, in that sense their responsibility goes beyond those of others who have been critical of the use of these agents and who have been proponents of the UGDP conclusion.

Such a statement can be divorced entirely from the UGDP study. It should be noted in this regard that the critics of the UGDP study often emphasize the limited indications and rarity with which they employ oral agents in their own practices. However, so long as such statements are immediately followed by a statement attacking or discrediting the UGDP, the end result is a perpetuation or exaggeration of the abuse of these agents which characterizes current medical practice.

Two: Emphasis should be placed on dietary management rather than oral agents in the instruction of medical students and in postgraduate medical courses on the treatment of diabetes.

Three: Research should be undertaken on developing improved methods of assuring patient compliance and success in adhering to weight-reducing diets.

Four: Most importantly, the labeling of oral hypoglycemics should be changed to include: (*a*) a warning that evidence has been reported that these agents may increase cardiovascular mortality; and (*b*) that use of these agents should be restricted to adult-onset diabetes in whom dietary measures have failed and insulin is refused or impractical.

I might just digress for a moment to indicate that the question of the patient's refusal becomes a difficult one. It is almost analogous to the question of informed consent. It has been said that any physician can probably convince any patient to do anything. In the same way, I am quite certain that every patient I see would refuse to take insulin depending on the way in which I present the alternatives. If I say, would you like these nice tablets or this medicine that has to be injected with a needle, I think we can all predict what proportion would refuse having to take a painful injection every day. So, I think we have to couple with this the clear implication of the physician's responsibility to advise the patient in the context of that decision of the implications of the findings of the UGDP study. Only in that way can we have patient refusal that represents a decision on both the physician's and the patient's part which is made from some knowledge.

Mr. GORDON. The Commissioner of the Food and Drug Administration stated, and I think it is also in the proposed labeling, that the patient should participate, that the physician should inform the patient of the side effects, and so forth. The patient should participate in the prescribing and use of these drugs.

Now, what do you think of the idea of having a document for getting informed consent? The form, which would be signed by the patient, would state that he had been told what the risks are, the advantages, if any, that he is aware of all this, and he wants to use the drug.

What do you think of that idea?