they began to take them. But what did they do? They took their tolbutamide but now they did not think that they needed to diet. And this is very sad. It is a poor outcome of this business we are talking about.

The CHAIRMAN. Thank you.

Dr. Zelen, did you have a comment?

Dr. ZELEN. Yes. There have been some who suggest that another UGDP-like trial be mounted.

The CHAIRMAN. I am sorry. I did not get the first part.

Dr. ZELEN. There have been some individuals who suggest that another UGDP-type trial be mounted. Judging from the experience with this one, it is likely to take 6 to 10 years before any conclusions will be reached.

Furthermore, with the recent change in patient consent, people face the following situation. If an individual comes to a clinician who is participating in such a trial, the physician, by law, has to inform the patient of the risks involved. The scenario would go something like this. The physician would state:

> There are a large group of people in the country who believe that tolbutamide may be dangerous. A study has been completed purporting to show this. However, there is conflicting evidence to believe that the interpretation may be in doubt. Consequently we are going to try again.

Well, I think most people would not like to be part of such a scheme, and it might be very difficult to enlist patient volunteers.

The CHAIRMAN. Well, was there anything in evaluating the UGDP study that would indicate some necessity for repeating the same study?

Dr. ZELEN. In my opinion, no!

Mr. GORDON. May I ask a question at this point?

Dr. MEIER. I would just like to clarify my own position. I have not taken a position on whether there should be restrictions on tolbutamide. What I have said is that if it is to continue to be widely used, then I think it imperative that another study be mounted. I hope I make that clear. It is now being widely used long after the UGDP report was published and discussed. If that situation is to continue, then I would see no ethical choice for those who use it but to mount another study.

Mr. GORDON. But what are they going to do in the meantime? Are they going to keep on using it widely while the 6- or 8- or 10-year study goes on?

Dr. MEIER. That is a matter that I presume the FDA is actively studying right now. The report of the UGDP appeared, received commendation from the ADA and the AMA, but as a matter of fact, the community continued to use the drug. Barring administrative action, I presume they would still continue to use the drug, and I am saying that if there is no action to prevent that, then I think there should be action to further study the matter.

Mr. GORDON. How about the newer drugs that have not been released yet?

Dr. MEIER. I would hope that they would be studied. If they are to be released, I would hope that proper studies would be initiated immediately.