

The major complications and life-threatening disorders associated with diabetes are heart disease, kidney disease, blindness, and limb gangrene. There is no evidence that sulfonylureas ameliorate or prevent these disorders. While in many instances in medicine the physician must prescribe for overt symptoms, we all prefer to correct the underlying problem if possible. Unfortunately, this is not presently possible with diabetes without additional basic and clinical investigation. There is no evidence that sulfonylureas will assist in the underlying problem. Since these agents would appear to relieve primarily the symptoms of hypoglycemia, one should restrict their use until less costly and perhaps safer measures have been used—diet with or without insulin.

For this reason, I feel that there should be stronger labeling of the oral hypoglycemic drugs in the package insert. With regard to the nature of the labeling, I feel that the stronger 1972 FDA draft is preferable to the weaker 1974 draft for the reasons just discussed.

Mr. GORDON. Dr. Lerner, this is a question actually for the panel rather than for you alone, but I would like you to take the lead in this.

Yesterday the Commissioner of the Food and Drug Administration acknowledged that phenformin has even a more unfavorable benefit to risk ratio than the other oral hypoglycemics. In an article that appeared in *Controversy in Internal Medicine* Dr. Albert Winegrad and two others wrote that the biguanides have no role in the treatment of diabetes mellitus. In addition, the Director of the Bureau of Drugs, Dr. Crout, yesterday could see no justification for this drug to be on the market. That's phenformin.

How do you feel about this?

Do you find any medical justification for that particular drug to be on the market?

Dr. LARNER. Well, I would generally agree that probably there is no—at the present time—medical indication for phenformin that I can think of. That would be my feeling.

I do not see any justification for phenformin being prescribed at all.

Mr. GORDON. Dr. Chester?

Dr. CHESTER. I would agree. It is not only hazardous, but it is almost totally ineffective.

Mr. GORDON. Dr. Sims?

Dr. SIMS. I think that first of all we ought to speak specifically about phenformin and not the biguanides as a group.

Mr. GORDON. I am talking about phenformin, which is the only biguanide on the market now.

Dr. SIMS. There is a tendency to condemn the whole group. Phenformin does some very interesting things and some of them resemble the effects of exercise lowering insulin, and whatnot. Further research may develop new drugs of this class which will do what one wants without the side reactions. So, I would not say that it should be a blanket condemnation of all of that type of drug. But, on the other hand, my own feeling about phenformin is that the labeling should be shortened to four words: Not for internal use.