study. Under these circumstances, it was to be expected that criticism of the UGDP study was more likely to be framed in terms of tolbutamide; however, this should not, in our opinion, be interpreted to mean that as to phenformin, the results of the UGDP study "have been accepted by medical scientists."

The Biometric Committee obviously considered important the fact that the final UGDP Report on phenformin had not yet been published and, in fact, the Committee did not consider the basic data on the effects of phenformin treatment. This is clearly reflected in the following quotation from Section 1 (Introduction) of the Biometric Committee's Report:

> "The preliminary report on phenformin was considered in September of 1973, but in view of the fact that the final report on that subject was still unpublished, the Committee did not request the basic data on the effects of this treatment."

In addition, the Biometric Committee recognized in its Report that the introduction of phenformin to the UGDP ..."greatly complicated an already difficult study." [See Section 7.1 (Conclusion, Protocol)].

Based upon these and other factors, it is our conclusion that the Report of the Biometric Committee does not resolve the controversy surrounding the UGDP study. It does not resolve the general criticisms of the UGDP study set forth in our letter of October 21, 1974, nor does it resolve the specific issues relative to phenformin.

We greatly appreciate this opportunity to present these