were made by the UGDP using the methods that have come under heavy criticism when applied to tolbutamide."

A similar implication of absence of criticism of the UGDP with respect to phenformin appears at the end of section 3.1 (Findings) of the Biometric Committee's Report published in the February 1975 issue of the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION.

We believe it is necessary to dispute any implication that the criticisms leveled against the UGDP study are concerned with the drug, tolbutamide, alone. To the contrary, the substantive criticisms made, although perhaps naming tolbutamide specifically, apply equally with respect to phenformin inasmuch as the structuring of the two trials under the UGDP was nearly identical. Further, it should be pointed out that because of the nature of phenformin, the rather late introduction of its trials, and a variety of other material factors, the phenformin portion of the UGDP necessarily becomes the subject of <u>additional</u> criticisms.

There are several reasons why criticism of the UGDP study most generally is publicized in terms of tolbutamide. Tolbutamide was the first of the two drugs to be studied by the UGDP - in fact, tolbutamide preceded phenformin in the study by 18 months. Likewise, the first data generated by the studies were those on tolbutamide. Second, and just as importantly, the final Report of the UGDP on phenformin had yet not been published as of the date of the Biometric Committee's review. Since it is not generally recognized as scientifically proper to comment upon, or criticize, work presented only in preliminary form, it is natural that there had been less formal criticism on the phenformin aspect of the UGDP