which stimulate release of insulin promote fatness.

III. Intense preoccupation with one aspect of the UGDP study has blurred our perceptions of other vitally important data in the study. These data indicate adverse effects of therapy both with sulfonylureas and with insulin in promoting further development of obesity. This is a recognized risk factor for cardiovascular disease.

IV. One should not go on writing package labeling recommendations based on data comparing the five treatment modes chosen by the investigators of the UGDP in the 1960s, when these options are now out of date. They do not include preventive and rehabilitative measures available in 1975.

V. Lifestyle changes in eating and in physical activity are essential components of the management of non-insulin-dependent diabetes, as well as of cardiovascular disease and are often sufficient in themselves to restore near normal function. Initiated early they may provide effective prevention.

VI. The proposed FDA package labeling for oral agents should reflect these considerations. They should also be written in a form conducive to the education of the patient.

VII. The schedule of peer review and publication of the results of randomized prospective clinical trials requires modification, if the results of future studies are to be accepted by interested parties.

VIII Efficacy of a drug must be considered in the light of other available options for management. On this basis there is little evidence of acceptable efficacy of the sulfonylureas, except under special circumstances which preclude other therapeutic options. In the case of phenformin the efficiency:efficacy ratio is not acceptable.