under the Federal Food, Drug, and Cosmetic Act, section 505 for the FDA to assure efficacy as well as safety of a drug, I believe that the FDA has a responsibility to make such indications, since they affect the relative efficacy of a drug. Considered alone a drug might be rated as effective, but if a superior alternative becomes available, its relative effectiveness is changed. Since the types and stages of diabetes vary, it seems to me appropriate for the FDA to suggest priorities for the use or non-use of drugs at these various stages. The physician retains the ultimate responsibility of deciding how his particular patient relates to the general guidelines. He should not be medicolegally vulnerable for electing any particular option provided that he can justify his decision and also makes his patient an informed partner in the choice, whenever possible.

SUGGESTED CHANGE IN PROPOSED LABELING FOR SULFONYLUREA DRUGS

In line with the above considerations I suggest that the section on Indications for the use of sulfonylurea drugs submitted for the Federal Register (page 40 of the copy available for the hearings) be modified as follows. (Changed wording is underlined).

Diabetic patients with non-insulin-dependent diabetes who are overweight commonly exhibit insulin resistance and have elevated fasting insulin concentrations and increased, though relatively inadequate insulin response to glucose. Such patients can frequently be rehabilitated and their overt diabetes reversed by a vigorous and comprehensive regimen of dietary restriction, increased physical activity and weight loss. Thus neither treatment with (drug) nor insulin is indicated, unless application of such measures is totally impractical. (Drug)is indicated in maturity onset non-ketotic diabetics of normal or subnormal weight whose hyperglycemia*cannot be controlled by carbohydrate restriction and increased activity and