

13624 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

The Committee on the Care of the Diabetic has repeatedly protested the partisanship of government agencies in this controversy. The release to the press of the UGDP study before its scientific presentation triggered a storm of controversy. Our criticism of multiple flagrant defects in the UGDP study was and still is, apparently, considered a challenge to the National Institutes of Health which expended over \$7.7 million for a study which neither tested oral hypoglycemic therapy as it is practiced nor provided any insights into insulin therapy.

- For years patients were carried in a study monitored by NIH personnel--a study which has become the subject of severe criticism by many of the leading diabetologists in the United States.

- Other agencies in HEW, such as the FDA, have entered the scene and, despite the clear existence of valid scientific controversy, the government has to this day sought to impose its will by excluding from oral hypoglycemic package inserts the very "fair balance" required by its own regulations. When challenged in the courts, it seeks by regulatory means to exempt itself from the preexisting requirement of fairness.