labeling for oral hypoglycemic drugs. The group included some of the country's leading diabetologists.

In October 1971 the Committee on the Care of the Diabetic petitioned the Commissioner to rescind his position that labeling for oral hypoglycemic drugs must contain a warning of associated cardiovascular hazards. The committee maintained that the UGDP study constituted an improper basis for the agency's decision, because it had been criticized on scientific, clinical, statistical, and other grounds. The Committee on the Care of Diabetes cited "controverting data," particularly the studies of Keen et al. (ref. 13 through 15) and Paasikivi (ref. 16), which, it contended, demonstrated the safety of oral hypoglycemic therapy. The committee also insisted that labeling for these drugs must reflect a "fair balance" of scientific opinion and cite the alleged deficiencies of the UGDP study and the controversial nature of its conclusions as well as the data in controversy.

After thorough evaluation of all the materials submitted to the agency, the Commissioner formally replied to counsel for the Committee on the Care of the Diabetic on June 5, 1972. The Commissioner's letter responded to each of the criticisms raised by the committee concerning the UGDP study and the agency's position. The Commissioner reaffirmed the position of the Food and Drug Administration that an undiluted and unencumbered warning in the labeling of the oral hypoglycemic drugs regarding cardiovascular hazards was fully warranted by the available evidence.