CHAYET & FLASH,
Boston, Mass., October 7, 1971.

COMMISSIONER OF FOOD AND DRUGS,
Department of Health, Education, and Welfare,
Washington, D.C.

DEAR SIR: I am herewith transmitting a petition relative to the Food and Drug Administration's actions based on the agency's acceptance of and extrapolations from the conclusions of the University Group Diabetes Program.

I would appreciate a prompt reply to this petition and would hope that in any case, one could be received within 30 days.

I anticipate that the petition will be printed in the Federal Register in the usual course. Kindly address your reply to me at the above address.

Very truly yours,

NEIL L. CHAYET.

PETITION OF COORDINATING COMMITTEE OF THE COMMITTEE ON THE CARE OF THE DIABETIC TO COMMISSIONER OF FOOD AND DRUGS

(From the office of Neil L. Chayet, Esq., Chayet & Flash, 15 Court Square, Boston, Mass.)

COMMISSIONER OF FOOD AND DRUGS,
Department of Health, Education, and Welfare,
Washington, *D.C.*

DEAR SIR: This petition is submitted with respect to (1) the issuance of recommendations contained in the October, 1970 FDA Current Drug Information Bulletin entitled, "Diabetes Prescribing Information" and (2) the recommended changing of the INDICATIONS AND WARNINGS section of the labelling of all sulfonylureas as stated in the June 23, 1971, FDA Drug Bulletin.

Attached hereto, in quintuplicate and constituting a part of this petition are the following:

A. The FDA Current Drug Information, October, 1970 (marked Appendix A).

B. Relevant excerpts from FDA Drug Bulletin dated June 23, 1971 (marked Appendix B).

C. Written communications of Robert F. Bradley, M.D. and the Committee on the Care of the Diabetic to the FDA. (marked Appendix C).

D. A statement of the grounds upon which your petitioner relies for the action requested herein (marked Appendix D).

The recommendations which are the subject of this petition have been made by the Food and Drug Administration (FDA) as a result of the report of the University Group Diabetes Program (UGDP). This report has been the subject of intense controversy since its conclusions were made known both because of the unprofessional manner in which the conclusions originally became known, in the lay press, as well as the irreparable flaws of its methodology, and the major inconsistencies in the conclusions. The report, which suggested that tolbutamide is no more effective than diet alone in the treatment of mild adult-onset diabetes, is insupportable in the light of impartial scientific inquiry, and the Food and Drug Administration, by embracing its conclusions, has intruded into the practice of medicine, placing the physician who continues to prescribe tolbutamide for the treatment of maturity-onset diabetes in jeopardy and causing great concern on the part of more than a million diabetics and their physicians who have regularly used this drug.

This petition is grounded in three fundamental principles:

1. Regardless of the validity of the UGDP study, it is the contention of your petitioners that the Food and Drug Administration's legal mandate is solely the regulation of drugs as to safety and efficacy and not the control of medical or scientific practices; furthermore, the FDA should not engage in the establishment of an official governmental policy in respect to the practice of science or medicine. We believe this to be as true for the treatment of diabetes as it would be in relation to such procedures as cardiac surgery or kidney and heart transplants.