Association, the German Ministry of Health, the German Diabetic Society, and the Swedish government.

Failure to grant petitioner's requests will result in a continuance and aggravation of damage which has already been perpetrated by the dissemination of these recommendations already made and the suggested labelling changes. As a result of actions taken by the Food and Drug Administration, an undetermined number of patients stopped taking medication on their own or were taken off the medication by their alarmed physicians and subsequently became symptomatic.

Failure to grant these requests will cause further irreparable harm to more than a million patients, particularly to their relationship with their physicians and to their personal psychic stability so essential in a disease such as diabetes.

Failure to grant the request will perpetuate the unjustified damage done to a large number of physicians and research scientists in the field of diabetes with respect to their standing in the public view as well as in the medical and scientific communities.

The Food and Drug Administration has taken a partisan position in an area of valid and continuing medical and scientific discussion and debate. This is a serious error both in principle and in fact. The Food and Drug Administration identification with a controversial study which has been subject to extensive criticism is particularly unfortunate.

It must clearly be recognized that the government has no role as a partisan in valid continuing scientific controversy.

Your petitioners, in reliance on the statement contained in Appendix D of this petition, respectfully request that the following steps be taken immediately:

(1) That the recommendations contained in the October 1970 Food and Drug Administration Current Drug Information Bulletin, entitled "Diabetes Prescribing Information" be immediately rescinded and that notice of such rescission be distributed in exactly the same manner as the Bulletin was distributed.

(2) That the recommendations which would change the Indications and Warnings section of the labelling of all sulfonylureas as stated in the June 23, 1971 Food and Drug Administration Drug Bulletin be rescinded and that notice of same be distributed in exactly the same manner as the Bulletin was distributed.

(3) That the Food and Drug Administration use its best efforts to restore the confidence of patients in their physicians who use tolbutamide and the sufonylureas generally.

(4) That pending corroboratory studies the Food and Drug Administration refrain from making any further recommendations related to hypoglycemic substances based on the University Group Diabetes Program and that any actions related to the UGDP studies avoid debatable extrapolations and clearly indicate the study's deficiencies and the controversial nature of its implications. And that any references be made in the context of fair balance as above stated.

(5) That the Food and Drug Administration repudiate all other recommendations, statements, mailings or communications of any kind which have been distributed to the medical and scientific communities, to the lay press, or to the general public based on the UGDP study and that the Food and Drug Administration use its best efforts to widely disseminate such repudiation.

(6) That the Food and Drug Administration make available to your petitioners and other qualified researchers the baseline data of the University Group Diabetes Program; such baseline data shall include the total patient record of each patient included in the study.

(7) That in accord with its policy of fair balance, the Food and Drug Administration disseminate with equal effort, emphasis and frequency, the results of all other studies reported by qualified researchers as well as clinical opinions of outstanding diabetologists which disagree with or controvert UGDP study and the conclusions extrapolated therefrom.

(8) That your petitioners be provided with full and complete answers to the following questions:

(*a*) By virtue of what statute, regulation, rule, or other legal authority does the Food and Drug Administration establish therapeutic regimens by stating preferences—i.e., first, diet; second, insulin and third, oral agents—in its Bulletins marked Appendix A and Appendix B of this petition?

(*b*) Why did the Food and Drug Administration ignore the views of the majority of its own Advisory Committee on Diabetes, a committee that was composed of four diabetologists, two biostatisticians and a biochemist? That majority was not willing to accept the conclusions of the UGDP report.