Public Citizen

June 10,1975

Alexander M. Schmidt, M.D.
Commissioner,
Food and Drug Administration
Federal Building 8
200 "C" St. S.W.
Washington, D.C. 20204

Dear Dr. Schmidt:

This letter is to urge immediate publication of a warning to patients and doctors about all oral drugs used to treat diabetes. New evidence from four previously unreported studies combined with previous evidence demands this action to prevent the unnecessary death of thousands of diabetics and waste of more than 100 million dollars a year on these drugs.

It is now five years since the University Group Diabetes Program (UGDP) reported that there was a significant excess cardiovascular mortality in patients taking an oral diabetes drug (tolbutamide-ORINASE). Although promulgation of an FDA-proposed warning label for all such drugs[1] was enjoined in 1972 by a Federal District Court, this was reversed in July, 1973 by the U.S. Court of Appeals. Thus, the FDA has delayed for almost two years the

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1. "Although the specific sulfonylurea drug studied by UGDP was tolbutamide, the conclusions apply equally to all sulfonylureas--Diabinase, Orinase, and Tolinase--because of their close chemical relationship." "...the conclusions apply to DBI and Meltrol as well" (FDA Drug Bulletin, May 1972).

LEADING ORAL "ANTIDIABETES" DRUGS
TOTAL PRESCRIPTIONS PER YEAR FOR U.S.[1]

	1972	1973	%CHANGE
Diabinase (Pfizer)	5,845,000	6,201,000	+7.8%
Orinase (Upjohn)	5,290,000	4,998,000	-5.5%
DBI (Geigy)	4,035,000	4,282,000	+6.1%
Dymelor (Lilly)	1,553,000	1,462,000	-5.8%
Tolinase (Upjohn)	1,468,000	1,975,000	+34.6%
Total Prescriptions (including all oral drugs)	18,369,000	19,381,000	+5.5%

(National Disease & Therapeutic Index, 1972 & 1973, LEA Inc., Ambler,PA.)