

14644 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

measures for the management of obesity -- including group therapy (e.g., Weight-Watchers), special diets, jogging, and drugs -- have as their sole purpose assisting the patient to eat less or to increase his or her level of exercise or both. The pharmacological action of drugs in the anorectic class is to produce anorexia, i.e., loss of appetite, and thereby to assist the patient in restructuring his or her dietary habits.

There are currently twelve drug entities approved for prescription use in the United States for the treatment of obesity. Three of these, d,l-amphetamine, dextroamphetamine, and methamphetamine, have been in clinical use since the 1930's. Six additional anorectic drugs were introduced in the period between 1935 and 1962 before the Kefauver-Harris Amendments: benzphetamine, phenmetrazine, phendimetrazine, phentermine, chlorphentermine, and diethylpropion. The remaining three -- fenfluramine, clortermine and mazindol -- were approved for marketing by FDA in 1973. All of these, except mazindol, are related in chemical structure, all have central nervous system effects, and, today, all are scheduled under the Controlled Substances Act.

REGULATION OF ANORECTIC DRUGS

Before highlighting the major past actions of the FDA, it is worth emphasizing that the powers and responsibilities of the Federal Government to regulate anorectic drugs are shared by the Drug Enforcement Administration (DEA) and FDA. In addition,