ANORECTIC DRUGS

The successful treatment of obesity requires only one essential therapeutic measure—that the patient take in fewer calories than he or she needs for a given level of exercise so that the stored fat in the body is gradually lost as it is burned as body fuel. All supportive 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, that is, loss of appetite, and thereby to assist the patient in restructuring his or her dietary habits.

There are currently 12 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, chortermine 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, individual States have passed laws and regulations governing abusable drugs. The FDA controls the approval of new drugs for marketing, regulates initial and revised labeling, and recommends to the DEA the selection of an appropriate schedule for a drug under the Controlled Substances Act—CSA. In addition, the FDA provides to DEA information on legitimate medical usage of schedule II drugs which DEA uses in setting production quotas. While the placing of a drug into a particular category under the CSA is the ultimate responsibility of DEA, it is done only on recommendation from FDA after careful review by the FDA scientific staff, consultants and the Controlled Substances Advisory Committee.

The DEA has the ultimate authority to schedule drugs under the CSA, to establish quotas on those drugs in schedules I and II, to monitor the domestic production and distribution of controlled drugs, to regulate their importation and exportation, and to enforce the provisions of the CSA. In selected cases, DEA can act against the prescribing and dispensing of controlled drugs by physicians by invoking penalties against those who are acting outside the legitimate practice of medicine.

The National Institute on Drug Abuse—NIDA—and, in some areas, DEA fund programs to study the potential and actual abuse of drugs, including anorectics. NIDA also funds programs to treat and prevent