

for both drug and placebo subjects and tended to decrease in succeeding weeks.

Four, the natural history of obesity is measured in years, whereas the studies cited are restricted to a few weeks duration; thus the total impact of drug-induced weight loss over that of diet alone must be considered clinically trivial.

The limited usefulness of these agents must be measured against any possible risk factors inherent in their use.

Five, the amphetamines including methamphetamine have been widely abused in numerous populations. It is thus in the best interests of the public health to limit the use of amphetamines as far as is compatible with adequate therapy. This is both to minimize the risk of dependence in susceptible patients being treated and to decrease the amount of drugs being distributed, since widespread prescription of a dependence-producing drug inevitably increases the possibility for diversion to nonmedical use and abuse.

Six. Evidence presented for newer "anorectic" congeners of the amphetamine family and nonamphetamine drugs do not set them apart as having higher benefit or lower risks than older available drugs.

Seven. There was no evidence in the data reviewed which showed that combination of an antiobesity agent with other drugs increase the benefits or reduce the risk of the antiobesity agent.

Eight. Obesity is not an indication for the parenteral use of these agents. The principal recommendations of that committee were:

One. That all antiobesity agents reviewed be placed in schedule II on the basis of abuse potential.

An exception was made for fenfluramine which was a new drug and about which little was known at that time.

Two. That combinations of antiobesity drugs with other drugs be removed from the market.

Three. That parenteral amphetamines may not be approved for use in the treatment of obesity.

Four. That the single-entity oral antiobesity preparations including the amphetamines be permitted to be labeled for restricted use in obesity provided that they are used in association with a specific weight reduction program and that the clinically trivial contribution of these drugs to the overall weight reduction is properly emphasized and that the limited usefulness of these agents must be measured against any possible risk factors such as nervousness, insomnia, and drug habituation that might be inherent in their use.

Moreover, these agents can only be recommended for use in the treatment of obesity in a carefully monitored and specified weight reduction program under the care of a physician.

What to do about these drugs has troubled the medical officers of the FDA for quite some time. For example, Drs. Elmer Gardner and Barrett Scoville, Director and Deputy Director, respectively, of FDA's Division of Neuropharmacological Drug Products, stated in 1972 at a symposium:

Ultimately, we must all weigh the potential benefits of these drugs against the risks of the drugs. Here we hope that in giving your opinion, you will consider risk in its largest sense—not simply the innate clinical toxicity of the anorectics, but the risk to the public health of potential abuse. We do want to hear what these drugs mean in medical practice. But we also must think in