

risk to society from the abuse of some of these drugs do not present all-or-nothing alternatives; the questions do not simply involve questions such as—is it beneficial for the obese to lose weight and do drugs help in weight reduction for a sizeable proportion of any population group than would diet, exercise, counseling, and so forth without medication. The other questions which must be asked are:

1. Do some of the drugs represent a public health risk and, if so, are there alternative drugs with equal efficiency and less or no public health risk?

2. Are the anorectics being used largely in weight reduction programs for populations with medical disability or increased risk of morbidity and mortality, or is the great bulk of utilization for esthetic purposes—for example in women with mild to moderate obesity.

3. If there is a public health risk due to medical misuse and due to illicit diversion with "street abuse", are we talking about reasonable and legitimate prescription and utilization of these drugs or are we, in fact, dealing with an abundance of drugs which are manufactured in amounts well beyond that needed for any treatment of obesity,—with overprescription and loose or careless utilization? Let me in this respect give you figures on amphetamines and methamphetamine production.

Regardless of whether the anorectics are misused by medical users of these drugs or abused by non-medical users—psychopathic or otherwise—is there a public health risk and, if so, do overprescription, careless prescription, overproduction, and the use of drugs with greater abuse potential than others contribute to such a risk, what can be done? Will more intensive medical education campaigns help? Would greater peer review and/or control through medical societies be beneficial? Must some drugs be placed under prescription and record keeping control—as in Schedule II? Must production controls or quotas be maintained for some drugs? When there is a public health risk, these questions can't be ignored and the best information and opinion currently available is needed to make what are obviously complex, multifaceted social as well as scientific judgments and decisions.

FINAL REPORT TO THE DIRECTOR, BUREAU OF DRUGS, BY THADDEUS E. PROUT, M.D.,
CHAIRMAN, CONSULTANTS ON ANORECTIC DRUGS

On June 27 and July 25, 1972, a group of clinicians and statisticians met under my chairmanship to review data compiled by FDA Staff on the safety and efficacy of anorectic drugs.

After careful review of clinical trials and of pharmacologic data the following conclusions were reached and recommendations made:

CONCLUSIONS

1. Adult obese subjects instructed in dietary management and treated with "anorectic" drugs on the average tend to lose more weight than those treated with placebo and diet in relatively short-term trials.

2. The amount of weight loss associated with the use of an "anorectic" drug varies from trial to trial. The possible origins of the increased weight loss due to the various drug effects are not established. The increased weight loss appears to be related to variables other than the drug prescribed, such as the physician-investigator, the population treated, and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

3. The magnitude of increased weight loss of drug treated patients over placebo treated patients was (only a fraction of a pound a week). The rate of weight loss was greatest in the first weeks of therapy for both drug and placebo subjects and tended to decrease in succeeding weeks.

4. 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.

5. The amphetamines including methamphetamine have been widely abused in numerous populations. It is thus in the best interests of the public health