

NDA 11538
LOC 656 1295Panel on Psychiatric DrugsINDICATIONS

- I. Biphentamine-T is indicated for exogenic obesity.

EVALUATION: Possibly effective.

COMMENTS: The amphetamines have been evaluated as "Effective, but . . ." as anorectic agents in obesity. The Panel evaluates methaqualone as "Probably effective" as a daytime sedative, similar to such daytime sedatives as barbiturates in the treatment of anxiety. The utility of the combination in the treatment of either condition or both concurrently has not been determined. The drugs might antagonize each other's effects.

In the total absence of positive controlled studies, the combination is evaluated as "Possibly effective." Basic studies, beginning in the animal, of the interaction of the anorectic and tranquilizing effects of the two drugs in this combination are necessary to begin to clarify the issue.

A majority of the Panel evaluated the sympathomimetic stimulants as "Effective, but . . ." as anorectic agents, with the following comment. Sympathomimetic stimulants as a class have been shown to have a generally short-term anorectic action. Anorectic agents suppress appetite. They are not a treatment of obesity in themselves and should be used primarily as an adjunct to a total program of weight reduction for obese patients that includes patient education, motivation, calorie restriction, and exercise. The anorectic effect of anorectic agents often plateaus or diminishes after 4-6 weeks (1-4). The dosage of drug must be individually titrated and given at least 1 hr before meals.

Clinical opinion as to the contribution of the sympathomimetic stimulants in a weight-reduction program varies widely. Most studies of these preparations are for short periods. The Panel suggests that controlled studies of the long-term effects of the sympathomimetic stimulants in weight-reduction programs be conducted. These preparations have a significant potential for drug abuse.

A minority of two of the Panel members agreed with the above comment of the majority of the Panel, but evaluated the sympathomimetic stimulants as "Probably effective" as anorexiant. Their reasoning for the "Probably effective" evaluation was that: (a) most studies of these preparations have been for short periods, (b) there is no available evidence that the use of these anorexiant preparations alters the natural history of obesity, (c) there is some evidence that anorectic effects may be strongly influenced by the suggestibility of the patient, and (d) there are reservations about the adequacy of the controls in some of the clinical studies. The minority suggested that controlled studies on the long-term anorectic efficacy of the sympathomimetic stimulants be conducted.