

2. Require that the efficacy of anorectics be based on substantial evidence that the use of these drugs results in achievement and maintenance of weight loss, with improved morbidity or mortality.

Approved _____ Disapproved _____.

3. Approve anorectics based on short-term trials, but simultaneously require long-term studies.

Approved _____ Disapproved _____.

B. With respect to amphetamines, including oral methamphetamine: (These alternatives are mutually exclusive.)

1. Label amphetamines to exclude use in obesity.

Approved _____ Disapproved _____.

2. Label amphetamines for restricted use in obesity, e.g., for patients refractory to other drug therapy.

Approved _____ Disapproved _____.

3. Continue current labeling for amphetamines, i.e., for narcolepsy, for minimal brain dysfunction, and for short-term adjunctive use in obesity.

Approved _____ Disapproved _____.

C. With respect to abuse potential: (These alternatives are mutually exclusive.)

1. Recommend that all anorectics *except* fenfluramine be placed in Schedule II of the Comprehensive Drug Abuse Act, fenfluramine to be placed in Schedule IV.

Approved _____ Disapproved _____.

2. Recommend that all anorectics including fenfluramine be placed in Schedule II of the Comprehensive Drug Abuse Act.

Approved _____ Disapproved _____.

3. Recommend that some or all the currently unscheduled anorectics be placed in Schedule III and/or IV, (the amphetamines and phenmetrazine remaining in II).

Approved _____ Disapproved _____.

4. Recommend no changes in the current scheduling of these drugs.

Approved _____ Disapproved _____.

D. With respect to possible further testing: (These alternatives are not mutually exclusive; only #1 is recommended.)

1. Require further testing of some or all anorectics with respect to abuse potential.

Approved _____ Disapproved _____.

2. Require further testing of some or all anorectics in long-term prospective trials.

Approved _____ Disapproved _____.

3. Require epidemiologic surveys relevant to how anorectic drugs are used or abused.

Approved _____ Disapproved _____.

E. Other requirements (All but #5 are recommended):

1. Eliminate parenteral amphetamines.

Approved _____ Disapproved _____.

2. Withdraw approval for all currently marketed combination drugs containing amphetamines.

Approved _____ Disapproved _____.

3. Require anorectic drug labeling describing the reservations many experts have with regard to use of anorectic drugs. Draft wording is attached (Tab "C" of attached memo.)

Approved _____ Disapproved _____.

4. Require fenfluramine labeling to include reference to the possibility of unusual adverse effects.

Approved _____ Disapproved _____.

5. Require anorectic drug labeling for the consumer.

Approved _____ Disapproved _____.

F. Certain ancillary or implementing actions (These are all recommended.)

1. Publish an article on anorectics in the *Drug Bulletin* (See draft, Tab "A" of attached memo.)

Approved _____ Disapproved _____.

2. Publish a *Statement of Policy and Interpretation* on anorectics (See draft preamble to SPI, Tab "B" of attached memo.)

Approved _____ Disapproved _____.