

6. Evidence presented for newer "anorectic" congeners of the amphetamine family and non-amphetamine drugs do not set them apart as having higher benefit or lower risks than older available drugs. The risk potential of Fenfluramine may be an exception to this general statement.

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

8. There are no clinical data which support the parenteral use of these drugs in the treatment of obesity. Obesity is not an indication for the parenteral use of these agents.

RECOMMENDATIONS

On the basis of the data reviewed and from all evidence at hand, the following actions are therefore recommended:

1. That all "anorectics" reviewed (dl-amphetamine, d-amphetamine, methamphetamine, benzphetamine, phentermine, chlorphentermine, clortermine, phenmetrazine, phendimetrazine, fenfluramine, mazindol, and diethylpropion) with the exception of fenfluramine, be placed on Schedule 2 on the basis of abuse potential.

2. That combinations of "anorectics" with other drugs be evaluated in accordance with the policy of the FDA on combination drugs, that each constituent of the drug combination contribute to the total effect claimed for the combined drugs, and that the present available and proposed drug combinations be handled in this manner in view of the lack of demonstrated efficacy for each of the constituents of the drug combinations reviewed.