in the treatment of obesity in a carefully monitored and specified weight reduction program under the care of a physician.

5. That future approval of all "anorectic" drugs prepared for future use be based on demonstration of efficacy as measured by statistical superiority of the drug over placebo in trial using FDA recommended protocols. These protocols should include provisions, among others, for the testing of a specific target population, specification of a minimum duration trial to assure clinical relevance of the study and give consideration to the handling of patient drop-out.

6. Further, that appropriate summary data derived from efficacy studies be presented in labeling and in all promotional material to indicate the degree of weight loss that was found. For this purpose the guidelines noted in (4) above should be supplemented by the addition of the specific facts found for the specific drug under consideration.

Only part of these recommendations have been put into effect. The amphetamines and some, but not all, of the related drugs reviewed were placed in Schedule 2. For those in Schedule 2, quotas for production were established as required by law. The remaining drugs were placed on Schedule 3 or 4 without production quotas. As predicted, there was a shift from the Schedule 2 to the drugs in Schedule 3 and 4 which require very little change in the prescribing habits of the physician. Extraordinary production and sales have been realized by certain companies to meet this increased usage. Pennwalt, producers of Ionamin, a resinated preparation of phentermine, has been cited as one of those companies with unusual sales. We must express serious concern that the