

Table C

Only one table is presented for the two week interval. The data for males were so skimpy that they were not tabulated. Please note the suggestion of greater weight loss with increasing dosage.

Tables D and E

In addition to failing in providing chronologically comparable data between placebo and drugs, these tables and weights changes are based on only a few subjects. Please note the small numbers in parentheses. This highlights the fact that relatively few subjects have been studied on this drug. Even with pooling the numbers are often too small.

Of even greater concern to me is the fact that the weight changes shown in these tables are based on differences between two numbers. There is very little supporting or intermediate data to indicate that there is actually a trend in decreasing body weights.

It can be noted again how body weight loss appears to be linked with the dosage level trend. Consider, too, the relationship between this trend and that seen in Tables A and B.

Because of these imbalances and other sources of variation it is difficult to judge the degree of superiority, if any, of the drug groups over the placebo. Is there actually a built-in bias in these data? Is the superiority of drug groups or a single drug group as consistent and marked as it appears to be in these tables? In attempting to assess these questions and others fairly, I have re-assembled the data in these tables into sub-groups that provide data for all pertinent clinical and dosage comparisons. Certain studies and data were rejected since they provided no information for judging relative effectiveness with an acceptable control.

This procedure appears justified on the basis of common sense, the requirements of the law and the tenets of valid experimentation. In summary these adjustments produced the following actions and sub-groups:

1. All studies without a placebo control were not used; these were study numbers 1, 2, 6, 7, and 9.

2. Study number three was not used since it had a few subjects only on placebo.

3. Study number 10 (Finnerty) was eliminated for the following reasons:

(a) Gross differences between the starting weights; the placebo subjects averaged 171 pounds, the drug group averaged 233 pounds.

(b) Imbalances in sample size and study groups composition. There were only 10 placebo subjects (males and females) and 18 in the drug group, of these none were females.

(c) The percentage of overweight average over twice as much in the drug group. Placebo subjects were only 18 % overweight; those on the drug were 39% overweight.

(d) The drug dosage used in this study was 80 mg/day. It was an odd dosage regimen since its use was limited to only this study.

(e) From the above it appears that the study was not well planned or controlled and, very likely, not double blind.

4. The number of subjects and studies which could provide direct comparison between placebo and one or more drug groups were reduced to only 174 and 7, respectively. Not all of these were comparable to each other. The following distribution of subjects shows the possible comparisons:

Subgroup	Drug group				Total
	Placebo	40 mg	60 mg	120 mg	
I. 3-group comparison (2 studies only, Nos. 4 and 5).....	57	23	76	16	174
II. 3-group comparison (4 studies, Nos. 11, 12, 13, 14).....	17	-----	16	16	48
III. 2-group comparison (studies 4, 5, 8, 11, 12, 13, 14).....	24	23	50	-----	107
	57	-----	78	-----	135

The above counts indicate that two studies provide 48 subjects with which to evaluate the relative effectiveness of the placebo, the 60 mg/day dosage and the 120 mg/day regime. Only 10 were males. These are maximum counts. Not all subjects had data for the 2, 4, and 6 week study durations.

Four studies provide 107 subjects to evaluate the placebo, 40 mg and 60 mg dosages. Again these are maximum counts not always represented by data in