Bacon No. 2055–B: No figures given ("data shows fenfluramine equal to placebo in effectiveness; however, subjects lost more weight in first period of the study regardless of drug (fenfluramine or placebo) used. Therefore design of study not good to detect weight loss effect. Also, study periods too short."

Stern No. 2060:	*Pounds per week*
Ponderex	−0.34
Placebo	+0.20

The actual total weight lost for 3 studies was as follows:

Average total cumulative weight loss

Fisch:	*Pounds*
40 mg	2.6
20 mg	4.8
Placebo	0.3

	Completions only	All patients
Roginsky:		
40 mg	−11.2	−7.0
60 mg	−14.1	−11.0
80 mg	−7.0	−5.0
Placebo	−4.0	−3.0
Stern:		
80 mg	−3.0	−1.5
Placebo	−.5	−.3

Since the duration of these 8 trials varied from about 2 to 12 weeks, more commonly 4 to 8 weeks, the studies submitted do not provide data for long term therapy.

The above 8 controlled studies were completed between March 1967 and January 1968 and were not submitted until November of 1968. They were all designated as Phase 2 studies on the summary sheets.

In addition, there were 5 "special studies": No. 1001 Fred, H.; No. 1002 Arson, E.; No. 1006 Itil, T.; No. 2051 Cagnon, M.; and No. 2063 Fink, M.

These studies were not primarily concerned with weight loss but with interaction between the fenfluoramine and methamphetamine; effect of fenfluramine on reaction time and EEG; a study of its central action through its effect on sleep; and effect on behavior, etc.

The paper by Cagnon is the only one which does not have a summary by the sponsor. It is significant that Dr. Cagnon concludes that fenfluramine disturbs sleep and therefore has a CNS stimulating action, He further states that it is questionable whether daytime drowsiness is a manifestation of a truly sedative effect of fenfluramine or rather a symptom of fatigue following primary excitation.

The group of non-controlled clinical trials are all designated as Phase 3 studies. The duration is from one week to approximately a year. There are no tabulations of the actual weight loss but only of the rate of weight loss. When the individual results are tabulated, it appears that the patients on 2 months' treatment did just about as well as those on 3 months' treatment so that results are not proportional to duration of therapy. Dr. Berman voiced the opinion that the drug was a poor one for general anorexigenic use. Dr. Araujo of Mexico achieved no less than 36.5 lbs average weight loss perperson. The marked variation in results demands an explation other than merely differences in population.

Finally, there are two "Other Clinical Studies", one from Dr. Daneman. Sponsor has not included his work in their statistics because no weights were recorded. The second study by Dr. Feldman, #3025, was terminated due to his death.

VIII. *Literature reviewed*

1. Fazekas, J. F. Anorexigenic agents. N.E.J.M. 264:501–503, 1961.

2. Harris, S. C. et al. The mechanism of amphetamine-induced loss of weight. J.A.M.A. 134:1468–75, 1947.

3. Thorn, G. W. and Bondy, P. K. Obesity, p. 398. In Harrison's Principles of Internal Medicine (5th ed.) 1966.