NDA 16-618, PONDEREX, A. H. ROBINS CO., INC.

Investigator	Average total weight loss, pounds		Net weight loss, pounds	Duration, weeks	Dose, milligram per day	Fenfluramine patients completing the study
	Fenfluramine	Placebo				
Adult:						
1. Hollingsworth [1]	13.8	2.9	15.9	8	120	14
2. Roginsky	14.1	4.4	9.7	12	60	28
3. Roginsky	11.2	4.4	6.8	12	40	27
4. Hollingsworth [2]	7.6	12.8	+3.2	8	120	10
5. Roginsky	7.0	4.0	4.0	12	80	30
6. Fisch	4.8	.3	4.5	4	60	15
7. Rosenberg	4.7	1.7	3.0	1-12	120	29
8. Rosenberg	3.6	1.7	1.9	4-8	60	
9. Stern	3.0	.4	2.6	8	80	20
10. Fisch	2.6	.3	2.3	4	120	14
11. Oren	Ineffective			2	40	12
Pediatric:						
12. Andersen	5.7	+.7		3	90	20
13. Bacon [1]	4.8	+.7	3.5	4	20-60	
14. Bacon [2]	2.2	+.7	2.9	4	20-60	20

[1] Crossover, giving fenfluramine first.
[2] Crossover, giving placebo first.

MEMORANDUM

APRIL 9, 1971.

To: Barrett Scoville, M.D., Deputy Director.
From: Robert Knox, M.D.
Subject: Notes on the panel discussion on anorexic drugs held April 6, 1971.

SUMMARY

Dr. Prout, Chairman
Dr. Goldberg
Dr. Crowell
Dr. Christakis
Dr. Bray
Dr Reidenberg
Dr. Rogers
Dr. Hollingsworth
Dr. Herting, Abbott Labs
Dr. Scoville

Dr. Prout reviewed the agenda which had been previously distributed by the FDA, and then called on Dr. Herting to present the industry's view of the matter. Dr. Herting discussed the pharmacology of the amphetamines and their clinical uses. He stated that there does seem to be some definite evidence for the fact that the value of an appetite suppressant is that it gives you about two times the rate of weight loss that diet alone does. That seems to hold up whether you give placebo or not. The duration of these studies was 12 weeks up to 20 weeks; 24 weeks was about the longest but it didn't have placebo. Intermittent and continuous treatment were compared with Tenuate Dospan being used. The actual total weight loss on intermittent was a little greater—but the continuous therapy actually did a little better (sic). Regarding tolerance, he said that there is some evidence that at least it is not a 2–3 week effect. In the literature, a really good program reaches 85 percent of target weight in females in a 12-week period, and 37 percent of the placebo groups arrived at a desired weight loss at the end of the 12 weeks. Males 50–55 percent with drugs; 25 percent with placebo. (When questioned by Dr. Prout as to what constituted "target weight," Dr. Herting replied that in general the target weight was the "Ideal weight as listed in the Metropolitan Tables.) There is little or nothing to prove the long-term efficacy of these drugs. The suspicion is that most of the patients are fat again. The question is whether they would have been fatter without the drugs. Dr. Herting went on to compare the situation to that of the anti-coagulants—does the drug have to be proven to do any real good?

Dr. Prout stated that you obviously can't ask the drug ot do anything in the long range. He asked Dr. Herting to sent a copy of his bibliography to Dr. Scoville (this was in relation to Dr. Herting's claim that 55 percent of ideal weight had been achieved using these drugs for 12 week). Dr. Reidenberg pointed out the importance of realizing the obese patients, are terribly hetrogeneous as to their characteristics, and said we should define the groups in which