

February 12, 1970

Dr. Edward Woodward, Jr.
A. H. Robins Company
1407 Cummings Drive
Richmond, Virginia 23220

Dear Dr. Woodward:

The fenfluramine-behavior study (#0761) was undertaken following our observation that the EEG profile was more like amobarbital than dextro-amphetamine. Since we had no prior experience with studies of weight reduction and anorexia, we proposed a study to observe the behavioral effects of fenfluramine and placebo. Since this was not feasible without a protocol, one was filed.

The study was double-blind, with neither the subjects nor the observer aware of the medication given.

In the first few subjects, sedation and somnolence occurred during the initial 2-4 days of drug trial, and did not with placebo, i.e., by the reports of the subject we were able to discern which medication they received. We confirmed this after 7 subjects by breaking the first 7 codes.

An analyses of the behavioral data indicated that sedation was indeed the most prominent symptom.

At this point, we continued the study and with succeeding cases, found only one reporting stimulation.

Since we were ill-equipped to answer the many relevant questions of weight reduction, we had problems in managing this difficult group of subjects.

In a telephone discussion, I indicated that I was satisfied with the behavioral data, remarked on the difficulty with the weight reduction aspects, and recommended the study be discontinued.

With this background, the following are specific answers to the questions:

1. Study was double-blind.
2. Crossover resulted from a desire to assess the differences, if any, in behavior. Also, since the subjects signed a permit that included "placebo", at the end of the study they inquired whether they had received "drug" or "placebo". For the patients who received placebo, a trial of active drug was offered.

3. FDA: see notes this letter.

4. Supplies: see attached.

I trust this is responsive and useful.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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