I believe the conclusions should be discussed within FDA before any possible uncritical release of them to the public.

BARRETT SCOVILLE, M.D.,
Deputy Director,
Division of Neuropharmacological Drug Products,
Office of Scientific Evaluation, Bureau of Drugs.

Those present at meeting: George J. Christakis, M.D.; Edward P. Crowell, D.C.; Leon I. Goldberg, Ph. D., M.D.; Dorothy Hollingsworth, M.D.; Daniel M. Rogers, M.D.; Thaddeus E. Prout, M.D.; Marcus Reidenberg, M.D.; George Bray, M.D.; Robert Herting, M.D., Ph. D.; and Barrett Scoville, M.D.

MEMORANDUM

APRIL 19, 1971.

To: Dr. Marion Finkel, Department Director, Bureau of Drugs.
From: Leszek Ochota, M.D., D. Sc., DNPDP.
Subject: IND 420 for Stimsen (thozalinone) Lederle Labs. Dr. Finkel's memo of April 8, 1971.

SUMMARY

Dr. Finkel: Since you may have been possibly misinformed about the discussion of the guidelines for antiobesity agents by the Committee that met at the FDA on April 6, 1971, I would like to call your attention to the following facts:

The Chairman of the Committee, Dr. Thaddeus Prout rather forcefully proposed a minimum of 12 weeks for the study of the anorexigenic agents, with additional 2 weeks for "followup".

While other members of the Committee did not comment on this problem, I did amplify Dr. Bray's position by citing several unpublished, well controlled studies which showed that adequate decision as to the effectiveness may be made after 4 to 8 weeks of study.

N.B: I personally believe that there is no scientific rational for the 12-week studies of the antiobesity agents, and agree with Dr. Bray that 4 to 8 weeks studies are entirely satisfactory.

LESZEK OCHOTA, M.D., D. Sc.,
Supervisor, Medical Office,
Division of Neuropharmacological Drug Products.

MEMORANDUM

SEPTEMBER 22, 1971.

To: The Commissioner.
From: Henry E. Simmons, M.D., M.P.H., Director, Bureau of Drugs.
Subject: Neuropharmacology Advisory Committee Meeting, September 13–14, 1971.

PURPOSE

The following is an abstract of the issues considered and the recommendations made by the Neuropharmacology Advisory Committee at their meeting on September 13–14, 1971.

TEXT OF THE INFORMATION

A. Parafon Forte I and Paraflex

1. The firms can make only these claims for which they have shown sufficient data. It was generally agreed that Parafon showed statistical superiority over placebo with respect to low-back pain; however, there was lack of evidence that the improvement was due to a specific muscle relaxant effect.

2. Other suggestions to be communicated to the firm include:

a. Evaluation of these drugs with standard treatments (sedatives and analgesics).

b. Testing of other specific syndromes (cervical pain, etc.).

c. Optimization of dosage schedules and correlation with blood levels.

d. There should be continued efforts for definition of criteria for improvement.

e. Relationships between statistical significance and clinical significance should be clearly defined.