

MATERIAL FROM FOOD AND DRUG ADMINISTRATION FILES ON CLORTERMININE
(TRADE NAME: VORANIL)

BENJAMIN SIMKIN, M.D.
Los Angeles, Calif., February 1, 1968.

WILLIAM S. WESTLIN, M.D.,
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DEAR DOCTOR WESTLIN: I was very disturbed to receive your letter of January 23, 1968, suggesting immediate termination of the SU-10568 study, particularly since it followed hard on the heels of a most extraordinary session that I had with your ——— some two or three weeks ago. I was quite surprised that you made such a recommendation (which, incidentally, was also suggested by ——— during our interview), without first personally discussing the matter with me. I consider your failure to directly communicate with me, and your formulation of a decision concerning this study based upon a secondhand report by a non-medical monitor without any kind of a report from me, a breach of your professional responsibility to your clinical investigators.

Furthermore, I would like to assert, that: (1) from my vantage point, the prevailing tone that seems to stem from your group is that of an employer to a paid employee, rather than the mutually respectful professional relationship of a Director of Clinical Research to a carefully chosen clinical investigator; and (2) from my point of view, ——— is not a satisfactory project monitor, and cannot take the place of a medically qualified representative of the Clinical Research Section.

Allow me to complete these prefatory remarks (before getting down to specifics) by re-informing you that, prior to the present CIBA study, I have successfully and fully completed 6 anorectic drug evaluations for 4 different pharmaceutical manufacturers since 1956, the last two conducted during the past two years. Six published papers in established medical journals have emanated from these studies. The average length of time for completion of each of these studies (embracing comparable number of patients as the present CIA study) was 9 months, varying from 6 to 12 months as conditions allowed ——— was given all of this information in our first meeting last spring. Furthermore, I had the honor of having been contacted by the FDA approximately three or four years ago, to testify in their behalf in a Court case in Chicago; they were particularly interested in my presentation of my published placebo data in publications of 1960-61. Unfortunately, I could not oblige them at that time. In view of the preceding, I feel a sense of insult and consider it a blemish on my past record when you informed me that "it appears that you will be unable to meet your commitment". How, so? It is particularly disturbing to me, since I have just this month turned down a request to do a study for the Upjohn Company, because I felt that I could not do full justice to my commitment to you by taking on another study at this time.

As for your statement that I received drug supplies in July, 1967, true, but I should remind you that I did not receive the first check from you until the end of September, whereupon the study was immediately launched. My records show that I deposited your check for ——— on September 28, 1967. You will note from the case report forms that the first patient entered the study on September 26, 1967. In my past experience, no study has ever been begun prior to receipt of the first installment of the grant.

As I have already indicated, I had previously told last spring that three months was not a realistic time for the performance of this study, in view of my past experience of a nine-month average for comparable studies, as well as the restrictions of the present protocol ruling out patients with Hypothyroidism, Diabetes, and Hypertension. If there is to be an onus for this situation, it will have to be ——— since he apparently did not take sufficient notice last spring of my statement to him that I was an Internist subspecializing in Endocrinology which includes some obese patients. I am not a bariatric specialist.

First of all, as already indicated, he either does not or chooses not to remember things that I have previously told him. Second, in my opinion, he knows very little about the subject of obesity and consequently fails to comprehend much of what