I discussed with him, resulting in a considerable waste of my time. Third, and most important of all, in our last meeting he passed some unpleasant and ill-advised remarks, unbecoming to a representative of the Clinical Research Section of a major reputable drug house. After commenting to him that the results of the first 12 patients appeared rather disappointing, and, more importantly, that I had failed to notice any appreciable patient acceptance of SU–10568, he countered by saying that other investigators were getting good results and suggested that my poor results might be due to the bias of the investigator, namely, me. It was after my vehement denial of such a bias that———asked me if I wanted to drop the CIBA project because of my "difficulty" in securing patients. This juxtaposition was most disconcerting to me since it meant throwing out of your clinical evaluation of SU–10568, an investigator who was not seemingly obtaining good results. This is akin to throwing out the bad experiments in a laboratory investigation.

I was so incensed by this interview that I was sorely tempted to call you. Unfortunately, I didn't because of my knowledge of———recent heart attack and his request to me to forget what he said. However, your follow-up letter, released me from any sense of restraint concerning my relations with———.

In summary, I would like to make the following points: (1) your office (unlike all others in the past) has not established a good professional relationship with this investigator; (2) I personally cannot relate to———for the reasons already given; (3) perusal of the 12 enclosed case report forms, as well as my past record and reputation, should answer the question of bias; (4) in view of the unfavorable results to date (although more than half may represent only placebo patients), accuracy would not best be served by haste; and (5) I personally feel that I have been rather shabbily treated with a consequent sense of insult.

Since there is no public honor these days in dispensing anti-obesity drugs from the office, and since there is equally no feeling of honor emanating from your office, I, too, think it best to terminate the study, but not until I have provided you with the data of the 20 patients covered by the grant installment you have already given me. I will give you data on 8 more patients and call it quits. I have at no time stated or indicated that I was unable to fulfill my commitment.

Enclosed you will find the completed case report forms of the first 12 patients.

Finally, I would like to request that you append this letter when you transmit my portion of the data to the FDA.

Very truly yours,

BENJAMIN SIMKIN, M.D.,
Assistant Clinical Professor of Medicine, University of Southern California Medical School; Chief, Endocrine Service, Cedars of Lebanon Hospital.

MEMORANDUM OF TELEPHONE CONVERSATION

CIBA PHARMACEUTICAL CO.,
Summit, N.J. Dec. 30, 1969.

NDA 16–880—AF 20–332

Between Mr. George Ohye, Director of Drug Compliance, Ciba Pharmaceutical Co., Summit, N.J. and William Dworkin, Food and Drug Officer—OND/DND/Med.

Initiated by: Mr. George Ohye.

Subject: Voranil.

Mr. Ohye called regarding the status of his firm's NDA 16–880 for "Voranil". He stated he had received information that all of the reviews were completed and wondered whether I could tell him if we would soon be issuing a letter on the application.

We told Mr. Ohye that we do not know whether or not any of the summaries are completed, but we could tell him that none had reached this office. Therefore,