

# THE RHEUMATOID DISEASE FOUNDATION

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May 21, 1985

JOHN R. A. SIMOONS, Ph.D.  
President

Robert A. Turner, M.D.  
Professor of Medicine and  
Chief, Section on Rheumatology  
Bowman Gray School of Medicine  
Winston-Salem, N.C. 27103

Dear Bob:

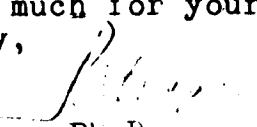
Re: Clotrimazole Study R-1120-A

In my letter of yesterday I expressed our disappointment of the fact that you enrolled only 9 patients into the study during the period of 5 months but I would kindly call your attention to a more serious matter, viz., the high drop-out rate at the start of the study. If we assume that 5 patients of the total of 9 were on Clotrimazole it could probably indicate a 100% drop-out rate! Wojtulewski had a 29% drop-out rate at a much higher dosage of 80mg/kg/day (every day) for 7 weeks versus our 20mg/kg/day for only 2 days per week. Ms. Crater listed the reasons for drop-out as:

- a) one patient with extremely high liver enzymes
- b) one patient had pain on micturition
- c) one patient had stomach problems
- d) one patient had lung problems
- e) one patient requested to proceed with Gold

From data reported in the Wojtulewski study (page 471) and often experienced by our physicians, we believe that patients, b, c and d responded favorably to the drug with the Herxheimer reaction, a prerequisite for a good prognosis and that they should have been encouraged to complete the study. Please inform me if these five drop-outs will be replaced (less than one month in the study) or are they considered completed patients? You stated in your letter of May 9 to me and Dr. Pybus that the study is not designed to determine the severity of the Herxheimer reaction but that you will again alert your staff to carefully record the symptoms. I am afraid that this is not sufficient to avoid a complete failure and that the patients should be informed that these symptoms are transient and can be expected to diminish if the patient continues with the treatment. I sincerely hope that you will consider this request because I know that you are also anxious to obtain good results. Would you kindly send me a confidential (no names) report of the patients on a monthly basis in order to keep our board physicians informed about the progress of the study.

Thank you very much for your kind attention and understanding.  
Yours sincerely,

  
John R.A. Simoons, Ph.D.  
CC: Drs. Pybus, Regelson, Blount,  
Prosch and Bingham  
Mr. Perry Chapdelaine.

THE RHEUMATOID DISEASE FOUNDATION IS A PROJECT OF  
THE ROGER WYBURN MASON & JACK M. BLOUNT FOUNDATION  
FOR THE ERADICATION OF RHEUMATOID DISEASE

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