

# THE RHEUMATOID DISEASE FOUNDATION

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## Distribution:

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## Dear Colleagues:

I have kept you informed of my recent correspondence and telephone calls with Dr. Turner concerning our double-blind clinical study of Clotrimazole in rheumatoid arthritis which officially started on December 19, 1984. I expressed our dissatisfaction with the slow rate of admissions of patients into the study and the high incidence of drop-outs so early in the study. I enclose copies of Dr. Turner's response dated May 23, 24 and 29, 1985 for your information. The letter of May 29, 1985 is of particular interest because we agreed that our Foundation will NOT pay for drop-outs prior to one month in the study and that these patients will NOT be calculated in the results and will be REPLACED. Dr. Turner agreed to inform his staff that patients should be encouraged to complete the course even if they encounter the various manifestations of the Herxheimer reaction. Since we can expect a Herxheimer reaction within 2 or 3 weeks (or earlier) in the treatment, I believe that patients who stay longer than one month will continue whereas those that cannot cope with these reactions will drop-out before one month. It is obvious that we can expect more understanding from those in charge of the patients evaluation after our expressions of dissatisfaction and the fact that it will cost them money! Dr. Turner agreed to try his utmost to accelerate the admissions and I know that he will. He is very cooperative and will send me weekly reports which I will review and distribute to you. I had also written to Dr. Bradley Wells, the Biostatistician of Bowman Gray who will also monitor the study.

I can inform you that I will watch very carefully how the study is progressing but that I have confidence that the results will be satisfactory if we can only keep the patients on the treatment long enough to improve their conditions. Dr. Turner also indicated that the exclusion criteria in the protocol, especially # 5, "patients treated or have been treated in the last three months with immunomodulating agents (gold, penicillamine, antimalarials, corticosteroids or cytotoxic agents)" leaves us with a rather small patients population but that he still hopes to finish on time. I will keep you fully informed.

Yours sincerely,

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

TAX EXEMPTION APPROVED BY THE UNITED STATES INTERNAL REVENUE SERVICE  
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*P.S. DR TURNER JUST CALLED ME AND SAID THAT HE NOW BELIEVES IN  
THE HERXHEIMER REACTION AFTER A PATIENT COMPLAINED OF BURNING OF  
URINATION FEW DAYS AFTER STARTING THE DRUG. HE ENCOURAGED TURNER  
TO STAY ON IT AND IT DISAPPEARED WHILE THE PATIENT IMPROVED  
WE ARE GETTING THEM!*