REVLON HEALTH CARE (UK) LIMITED

Formerly Now known as
Armour Pharmaceutical Company Limited

B0000120/2

BERK Pharmaceuticals Ltd.

INTER OFFICE MEMORANDUM

R. B. C. - 5 NOV 1985

TO : L. Lucas

DATE: 4th November 1985.

FROM : C.R. Bishop

REF: CRB/BAK

SUBJECT : DR. PETER KERNOFF - THE ROYAL FREE HOSPITAL, LONDON

COPIES TO :

A. Sheppard
R.B. Christie
M. Rodell
A. Bessler
J.D. Michelmore
C. Schott**
C. Swartz
I. Regier
Master
Day
File

Claudia, Please ring me urgently to discuss French Study.

Dear Lofty,

Further to our telephone discussion on the 31st October, I am confirming to you the various points made at the long meeting I had with Dr. Kernoff this week.

Future Business

Peter confirmed that he will not be placing any further orders for the current Armour material, despite the weakness of the preliminary communication on the Alpha product printed in The Lancet recently. On the basis of actual published evidence, the Alpha product is still considered to be a safer product than dry heated materials.

We are now aware in the U.K. of litigation being prepared against Doctors who have been shown to prescribe "less-safe" materials in the light of evidence available at that time and we are thinking here particularly of Clinicians who have prescribed non-heat treated material when heat treated material was available.

Clinicians are, therefore, now becoming much more aware and "frightened" of similar action and are now taking all precautions possible.

ALT Testing

We are advised that Alpha will be introducing a product which has been ALT tested with effect from the 1st January 1986.

There is a fear among U.K. Clinicians that the U.K., U.S. and perhaps other markets will get German "reject" batches as, as you know, their products supplied into Germany now has to be tested for ALT as well as HTLV III. It is felt that this for the German market and not for the rest of the markets must increase the chances of "questionable" batches entering these other markets.

We, therefore, make the strongest recommendation possible that as soon as possible ALL material supplied by Armour should be ALT, as well as HTLV III, tested. Perhaps you could advise me of the Company's feelings in this respect. If we do not do it, it will be another plus for Alpha and a further negative for Armour, irrespective of the actual clinical validity of such testing.

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Non-A Non-B

Despite the recent articles by Mannucci and Aledort et.al., the U.K. Clinicians are still convinced that NANB is a long term problem and ,on a personal level, Peter is extremely perturbed that Armour haven't been able to demonstrate even one clean virgin patient treated with heat treated Factorate who has stayed clean and free of NANB. At least Travenol in the Mannucci Study and Alpha in the Kernoff Study have been able to demonstrate clean virgins who have stayed clear. Could you please advise whether you have any data from any other markets, including the States, that we can quote.

By copy of this memo I am asking Claudia Schott to update me on the French study.

Half-Life and Recovery

We are sending Peter Kernoff unpublished information from Inga Marie Nilsson (we have had permission), in which she compares heat treated and non-heat treated products and in which she postulates denaturation of the Alpha molecule after heat treatment. He is very interested in this information as he has had reports of problems on half-life and recovery with the Alpha product compared with ours, which is "excellent". We are working hard on this apparent advantage, although an apparent advantage at this stage is still secondary to the safety factor related to viral contamination.

GRO-C

C.R. Bishop.