

115
REVION HEALTH CARE (UK) LIMITED

INTER OFFICE MEMORANDUM

HT Fortula Ltd
A Armour Pharmaceutical
Company Limited

B0000052

BERK
Pharmaceuticals Ltd.

TO : Dr. P. Harris

DATE: 27th February, 1986.

FROM : C. R. Bishop

REF: CRB/PSB

SUBJECT : ANITA BESSLER : TELECALL 26TH FEBRUARY

R. B. C.

27 FEB 1986

COPIES TO :

R. B. Christie
A. Sheppard
J. Michelmore
K. W. Fitch

Positions statement

1. M. Rodell and C. Schwartz visited Dr. Aronson of the F.D.A. and presented the Meloiy and Paul-Erlich data.

2. Aronson concluded that the Meloiy data shows a 5.5 log reduction of HTLVIII for Factorate Gen 1.

Although we are showing detectable virus after "high spiking" if you kill 5 logs it is the maximum you could statistically find in any batch of contaminated untested material, (Petrocceni).

3. Aronson's summary:-

a) There are no cases reported of clear cut conversion due to heat treated products only.

b) The titre of the virus varies from batch to batch.

c) The sero conversion could represent immunisation with the killed virus.

d) No one knows the incubation period for sero conversion or AIDS due to either killed or live virus.

e) Competition only states non-detectable levels in their products, because of insufficiently sensitive tests at their disposal. (We have the most sensitive tests apparently on the market).

4. Summary:-

a) 5 logs of virus is the maximum considered to be possible in an unscreened product.

b) 2-3 logs is the maximum considered to be possible in a screened product.

c) Our procedure produces a 5.5 log reduction.

d) Even though we meet the arbitrary 5 log reduction criteria, we still show detectable levels of virus live or killed in our product.

GRO-C

C. R. Bishop

ARMOUR002794

ARMO0000491_0001