

Witness Name: Katherine Victoria Burt

Statement No: WITN6392001

Exhibits: WITN6392002 - WITN6392267

**INFECTED BLOOD INQUIRY**

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**WITN6392212**

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RESTRICTED TO EXECUTIVE COMMITTEE

Blood Resources Working Party

Wednesday 3 February 1988

Blood Products Laboratory: Norman Pettet

Armour Pharmaceutical (UK): Chris Bishop

Haemophilia Society: Ken Milne

The Revd Alan Tanner

In attendance, David Watters

Chris Bishop outlined progress with MONOCLATE. The FDA have granted a full product licence in the USA and this has also now been achieved in Holland. The full UK application was lodged in mid-January 1988 and France has indicated, by granting their equivalent of a Clinical Trial Certificate (CTX) that a licence will be forthcoming. Armour state that there is strong evidence to support monoclonal products as the state of the art product for the moment. Virgin patients have been on the product for some two years and show no signs of HIV or NaNb (or any other form of) hepatitis. It is commonly accepted that the pasteurisation process dispels HIV and that the real problem for all production of concentrates is no NaNb.

Patients with HIV antibody and declining 'T' counts have shown recovery or stabilisation after treatment with Monoclote with the bonus of no hepatitis infection and low protein contact. The likely cost of Monoclote is 35-40p per unit.


The recent FDA meeting in Atlanta had decided against dry-heat-treated product. Cutter and Travenol were applying for a FDA licence. This would leave BPL as the sole dry-heat-treated product manufacturer in the world and Alpha with its current neo-wet-state product.

Norman Pettet felt that the BPL 80/72 product was still safe although there had been no independent clinical trial results. He agreed to look into the possibility of conducting a 'T' count trial, possibly along with Monoclote. Current production at the new Elstree plant is 19-20m units pa: It is hoped that this will increase to the maximum capacity of 75m units by October.

It was reassuring that there was no evidence of HIV or hepatitis infection in patients on 8Y. It was also noted that there was no evidence of HIV infection through donor-screened and heat-treated product anywhere in the world. Where this had happened there were found to be other-risk-behaviour involved.

The 1986 statistical returns are awaited with interest since they will be an accurate indicator of demand up to December 1986. It was estimated that Scottish/Northern Ireland consumption accounts for approximately 12m units pa. Norman Pettet estimated that current total UK consumption was approximately 107m units - 85m units being consumed in England and Wales: A shortfall of 10m units on the estimated current consumption.

A short discussion also took place on ALT testing of donors: It was generally agreed that this had no benefit for concentrates in view of the apparent success of BPL pasteurisation.

 Ken: Please amend or verify for distribution 