Annex A

FIBRIN SEALANT CONTRACT: BACKGROUND

BPL's Current Situation

1. During 1997, the last full year prior to the decision to switch BPL production from UK plasma to US plasma, BPL fractionated approximately 640,000 litres of plasma. During 1999, BPL will begin to regain UK and overseas market share lost during the transitional period, and the volume of plasma to be fractionated is expected to be around 440,000 litres. BPL's plant at Elstree has the capacity for 750,000 litres with the potential to increase this, with relatively minor investments, to approximately 1 million litres.

2. The UK market for plasma products has changed substantially with the introduction of recombinant (ie synthetic) clotting factors and a reduction in albumin usage. The UK demands for products likely to be placed on BPL are too low to sustain the Elstree factory. At present, BPL exports product which is surplus to NHS requirements but, in order to break even, BPL's exports would need to exceed 50% of total output. Downsizing would be very uneconomic. The aim of the current review is therefore to find ways – probably involving public private partnerships – to address this under capacity problem.

Proposed Contract

3. If BPL is to maximise its value to the NHS it must utilise its spare capacity to reduce unit costs and maximise revenue. Even with the most optimistic forecasts on UK sales and exports over the next 5 years, BPL will still have hundred of tonnes of spare fractionation capacity. BPL has therefore been seeking contract fractionation opportunities, and has identified an opportunity to manufacture a Fibrin Sealant product for a substantial profit. This will be of direct benefit to the NHS by reducing BPL's current dependence on Vote 1 central funding (£15 million in 1999/2000) to support its income and expenditure deficit.

Fibrin Sealant

4. Many companies, including BPL, are working on the concept of producing a fibrin sealant. Fibrin sealant is a plasma-based product which is effective in reducing or eliminating blood loss during surgery. The market potential for such products in the developed world is estimated to be in the order of $1 billion. However, only three fibrin sealant products are currently licensed worldwide. The US Food and Drugs Administration (FDA) regard fibrin sealant as the gold standard to alternative approaches to wound closure.

Haemacure

5. Haemacure, a Canadian venture capital company set up specifically to exploit the fibrin sealant maket opportunity, acquired full rights to one of these products – Hemaseel APR – in the US in 1997. This followed the acquisition of the pharmaceutical company Immuno by the US firm Baxters. At the time of the acquisition both companies had a fibrin sealant product well advanced in the registration process in the US. Approval of both products would have given Baxter/Immuno a major monopolistic position in the US market. Consequently, as a condition of approving the take over, the Federal Trade Commission (FTC) insisted that Baxter/Immuno sold rights to one of these products. However, a condition of the licensing agreement between Baxter/Immuno and Haemacure is that Haemacure manufacture the product themselves as soon as possible. Haemacure therefore approached BPL as one of the few fractionation companies with the capacity to manufacture the sealant.

6. The deadline which FTC gave Haemacure to obtain a manufacturing agreement for Hemaseel APR has now expired. The FTC are therefore under pressure from Baxter/Immuno to withdraw Haemacure's license unless they can demonstrate that BPL have Ministerial approval to sign the contract subject to the contingent liabilities issue being placed before Parliament.

Copies:

Mr Ferrero PS/SofS
Ms Fretten PS/MS(H)
Mr Murphy Sp Ad
Mr Stevens Sp Ad
Ms Jarvie PS/CE
Mr Kerr Ops
Dr Adam HSD
Mr Hewlett HSD1
Dr McGovern HSD1
Ms Harrison SOL Commercial
Mr Palnoch EOR
Mr Miller EOR
Mr Paley FPA-FAS2
Ms Skinner HSD1