ANNEX B

DNV RISK ASSESSMENT - LINES TO TAKE

What does this report tell us?

A risk assessment is a "what if" picture, not real facts. The report does not give us new scientific evidence about nvCJD. It acknowledges that we know very little about nvCJD and its transmissibility, and makes no firm predictions or conclusions. It gives us useful background against which scientific information can be judged as it emerges, and action taken.

Leucodepletion

The report says that leucodepletion may have significant benefit in reducing risk of nvCJD through blood transfusion. [Leucodepletion is already standard practice in some countries as it has wider benefits, for example preventing infections in young babies and avoiding fever in patients with leukaemia and other cancers who need repeated transfusions.]

Elimination of UK plasma products

The report says that the importation of non-UK plasma for the manufacture of blood products is prudent in the absence of better information. [This measure was taken on the advice of the Committee on Safety of Medicines, which acknowledged that the theoretical risk of nvCJD through blood products could not be discounted].

"Every unit of blood could infect about 3 patients" (The report estimates that an infected donation could result in up to 2.6 new infections, of which 0.8 are predicted to live long enough to develop nvCJD, and that about half of the new infections could be due to blood transfusions and half to plasma derivatives (blood products))

These are not actual figures or firm predictions, and there is no evidence that nvCJD is transmitted in blood. The risk assessment rightly makes **assumptions** to give a "what if" picture, including a worst case scenario. It says that **if** nvCJD can be transmitted through blood then for each donation of infected blood about three new infections might result. It is simply based on the fact that a donation of blood goes to more than one person.

Other risk reduction measures considered in the report

Reduction in blood usage - seen as possibly moderately effective. Action already in hand - Health Service Circular "Better Blood Transfusion" issued 11 December 1998.

Preventing donations from past recipients of blood - the report says that this would possibly result in a moderate risk reduction. However, it recognises the need to balance theoretical risk against overall blood supply. A balance needs to be struck between the theoretical risk of nvCJD transmission and the real immediate risk of losing lives if there is not enough blood.

Use of whole blood rather than separating donations into components - the report says that this would have small and uncertain benefit - the benefit of separating blood into components is that more than one patient can benefit from each valuable donation.

Maximising autologous transfusions could lead to a small risk reduction - action has already been taken - HSC on "Better Blood Transfusion" gives advice on how this might be put in place and the way forward.

Use of imported pooled plasma -

The report says that even if nvCJD is very uncommon in UK blood donors, the pooling of their plasma to make blood products could increase the risk of transmission to patients needing such treatment, especially if the agent proves very infectious. This would support the decision to import plasma from donors who live in countries where there is no BSE and no cases of nvCJD.

Use of high purity Factor VIII - the report acknowledges that the uncertainties are too great for valid estimates.

Prophylaxis treatment against nvCJD - the report says that there is reasonable evidence to suggest that some new treatments can reduce susceptibility to infection in animal models, and their effectiveness is worth investigating further. The Committee on Safety of Medicines is considering the position on Pentosan.

Length of time taken to publish risk assessment

The draft report was given to SEAC in June, and it was re-presented to the committee in January after review by external experts. The data were complex and the whole report required peer review to ensure the reliability of the assumptions.

Validity of spending money on leucodepletion and importation of non-UK plasma

The safety of the blood supply is paramount and, given the prospect of nvCJD, it is better to be safe than sorry. Leucodepletion costs about £80 million a year and has wider benefits, such as reducing fever in babies and patients such as those with leukaemia and cancer who require repeated transfusions. The importation of non-UK plasma for the present time follows the advice of the Committee on Safety of Medicines, and again reflects the need to protect the public health.

Adequacy of precautionary measures

Against the background of no firm evidence about nvCJD transmission, the report acknowledges that leucodepletion may have significant benefit and that the use of non-UK plasma for the manufacture of blood products is prudent. On top of that we have taken steps to encourage better blood transfusion practice in our hospitals.

Doesn't the report in fact say that patients receiving red cells could be exposed to infectivity?

There is no evidence that nvCJD is transmitted by blood. The report makes a range of **assumptions** about transmission. Experts took the view that if infectivity was present, it would most likely be in the white cells, and hence our decision to introduce leucodepletion as soon as possible. Also on expert advice we decided to produce all blood products from non-UK plasma.

Why have you not taken precautionary measures for red cells?

It would be impossible to obtain red cells from elsewhere because we use a lot of them. (2.5 million units a year for 1 million patients.) There is a balance to be struck between the theoretical risk of nvCJD transmission and the real risk of death or harm through lack of blood for transfusion.

Why is Anti D still being issued from UK plasma?

To ensure that there could be action to prevent the real risk of harm to babies and mothers, supplies of UK plasma derived Anti-D continues to be available to meet need. Until now there has been only one licensed Anti D product using non-UK plasma and supplies have been less than plentiful, but they are now being boosted. A further non-UK plasma derived Anti-D product has just been licensed and supplies will be available soon. Supplies of Anti D from the Bio Products Laboratory using non-UK plasma will be available in April/May.

Availability of other blood products using non-UK plasma

All mainstream non-hyperimmune plasma derived products are now made from non-UK plasma.

When will leucodepletion be completed?

October 1999. It involves changes to the service which cannot be achieved overnight but which are being taken forward as quickly as possible and on schedule.

Will the infection be passed on in blood products, as HIV and hepatitis C were?

There is no evidence that nvCJD is transmitted through blood. I am advised that information available on those patients who have already developed nvCJD suggests that transmission of the agent may be more complex than HIV or hepatitis viruses.

Progress on developing test for nvCJD

Research is under way to develop sensitive and specific diagnostic tests for the detection of nvCJD in blood, urine and tissue samples. It is too early yet to be able to forecast when these will be available.

Other research

The Department of Health has a comprehensive research programme in place to address the unknown issues relating to possible infectivity of blood and blood products.