Prof Swales
Mrs Coffin
To be aware of these developments.
I produced the 2 page synopsis on blood research and also contacted the College about Wraxton/Watson with nv CJD blood.

To: Mr Kenny PPS/SofS

From: Christine Corrigan HSD1C

Date: 1 October 1997

GRO-C

7/10.

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FRENCH IMPORTS OF BPL ALBUMIN AND new variant (nv) CJD

1. You are aware that an issue arose yesterday regarding the above and that CMO called a meeting this morning to ascertain, as far as possible, the facts of the situation and to determine what action was required. This note is to alert Secretary of State to the current position and action in progress.

<u>The issue</u>

2. The Bio Products Laboratory (BPL) met yesterday with representatives of Pasteur Merineux Connaught (PMC) when the latter informed BPL that they were discontinuing with immediate effect the contract under which BPL had supplied albumin to be used in the manufacture of a range of blood products. PMC claimed that this was, in part, related to a new restriction which the French authorities are expected to impose shortly on the importation into France of any plasma product derived from UK donors, citing concern about the risk of transmission of nvCJD in the UK.

3. We have since confirmed that, although no such advice has, as yet, been given to the French authorities, one of the two viral safety sub-committees advising the French Agence de Medicaments (the French MCA) is about to make this proposal. As the licensing and sale of blood products is a EU competence, and subject to the Committee of Proprietary Medicinal Products (CPMP) recommendations, the next step would normally be for this matter to be put to CPMP. However, it is understood that, if it follows the advice from the viral safety sub-committee, the French Government may take action unilaterally on the grounds of the national protection of public health. This approach would be based on France's policy on extreme caution when it comes to any risk of infection transmission by blood or blood products, which is hardly surprising in view of the difficulties they had over HIV in the '80s.

4. The announcement is likely to be in the form of a decree from the French Ministry, on the advice of the Agence de Medicaments. It is not clear exactly when this will take place, but we understand that it will be "shortly". These are still proposals but if implemented, would not be applied retrospectively (ie. products already made from British plasma would not be recalled). As PMC have been given early warning of this, it is highly likely that a number of other pharmaceutical companies will already be aware of this development.

Scientific Background

5. The French authorities have been voicing concerns about the possible transmission of sporadic CJD by blood and blood products for some time. They have been arguing in the Biotech Working Party of CPMP that Europe should follow the FDA and remove from distribution any blood products which have been implicated as a result of a donor, who subsequently developed CJD, contributing to a plasma pool. CPMP, however, have taken the view that there is no scientific justification for such a recall.

6. French concern has grown, however, following the advent of nv CJD. (A background note detailing the current state of play on scientific research on CJD and blood is attached - but Secretary of State is aware that the science magazine "Nature" will tomorrow publish the results of two studies which effectively confirm that nvCJD is caused by the same agent that is responsible for BSE in cattle.) Of the 22 confirmed cases of nvCJD, only one was outside the UK (and was in fact in France).

7. Although there is no verified epidemiological evidence of transmission of CJD by blood or blood derivatives anywhere in the world, we could not deny that there is a risk, albeit on present evidence remote. Animal data suggest that transmission by blood is possible.

8. There is, however, no test currently available which enables infection with CJD to be identified in the blood of living persons, nor is there a current technique sensitive enough to enable prions to be detected in human plasma (although a significant amount of research is currently being undertaken in these areas). Our current knowledge is based on the study of sporadic CJD and it would not be wise to assume a direct comparison

with nvCJD about which much less is known.

9. In view of the theoretical risk, the guidelines issued by the National Blood Service exclude from giving blood individuals who, as a result of personal health factors or treatment received, may be at risk of developing CJD. Relatives of CJD sufferers are also excluded from giving blood. This is in line with the Council of Europe guidelines and with the advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) who keep the safety of blood under review, and SEAC.

10. The latest Council of Europe guidance on the matter (issued by the Committee of Experts on Blood Transfusion and Immunohaematology - September 1997) recommends increased worldwide surveillance, significantly enhanced research efforts in this area, and the application of strict donor selection criteria. The Department is taking action in all three areas.

Political/public health implications

11. BPL anticipate that some other countries could well follow the French lead. BPL currently export about 20% (in cost terms - £10m) of their products. Only a very small amount however goes to the EU (including the Swiss Red Cross), the rest (mainly albumin sales) goes to the Middle and Far East and Central and South America. The main concern however is not of course the financial loss to the NHS in terms of sales abroad, but the impact such action might have, if this is given significant coverage, on the public perception in the UK on the safety of blood and blood products. The juxtaposition of the French action with the forthcoming Watchdog programme on CJD and blood (due to be shown on Thursday 9 October) is not helpful.

12. In commenting on the French actions, we must emphasize that protection of public health must always take precedence over commercial considerations. We must also acknowledge that transmission of CJD by blood products is a possibility and in this context the UK has the additional problem of the nvCJD cases, where the natural history is unknown.

Action taken

13. Discreet enquiries have been made of the French position and Dr Jones (CE of the MCA) has spoken in confidence to his opposite number in the French Agency, who has confirmed that these are still proposals. It has been pointed out that, so far as the transmission of sporadic CJD is concerned, the French position is no different from the UK. Dr Jones has also drawn attention to regulation of blood products being the responsibility of the CPMP.

14. We have confirmed with the CJD Surveillance Unit and with colleagues in the relevant research fields that there is at present no test or technique at a sufficient stage of development which might be deployed to provide evidence to disprove the theoretical

risk. However, Professor Collinge has indicated that he is prepared to carry out his immuno blotting test on blood samples taken from nvCJD patients to see if PrP^{sc} (the abnormal form of prion protein associated with transmissible spongiform encephalopathy - TSE) can be detected. We have therefore arranged for Professor Collinge to contact Dr Will at the CJD surveillance unit about the supply of the necessary blood samples.

Recommended Line to take

15. We could in theory mount a strong official protest against the proposed French action to try and persuade them to shift their ground. We do not, however, believe that this would be likely to succeed. More importantly, it would raise the public awareness of the issue at precisely the wrong time, that is just before the Watchdog programme, which will in any case raise public concern and sensitivity to the subject.

16. In the circumstances, given that there is no new evidence and there has been no official notification of the action, we would recommend that the Department maintain a watching brief for the time being and adopt a low key response to the French action. We would suggest that the following Departmental line be taken:

"The European Commission on the advice of the Committee of Proprietary Medicinal Products (CPMP) has responsibility for the licensing and distribution of blood products in the European Union. We have not heard directly what the French authorities intend to do, but are making further enquiries."

17. Meantime, we are arranging for members of MSBT and SEAC to meet, hopefully early next week, to discuss preparation of a joint statement. We will also maintain a close watch on the situation in Europe and continue to monitor research and developments in this area. We will of course keep you advised of any new developments, and in particular, of the outcome of Professor Collinge's experiment (para 14).

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