

Perm Sec  
Mr E Waterhouse  
PS (Perm Sec)

From: Mr J Canavan  
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505 Eileen House  
Ext **GRO-C**

19 July 1990

cc: Mr Heppell DS HSS)  
Mr Dobson EHF1 )  
Mr Powell SOLB3 ) Minute  
Dr Rejman MEDISD) only  
Ms Bendall SOLC5 )  
Mr Gutowski MCA )

*I have signed, and am  
grateful for the careful way  
in which new papers have  
been prepared.*

**GRO-C**

### Haemophilia/HIV Litigation

1. We are asking the Permanent Secretary to sign a certificate (Annex A) objecting to the disclosure of certain documents in possession of the Department, the Medicines Licensing Authority and CSM which are relevant to this litigation. We are asking the Permanent Secretary rather than a Minister as the documents span two Administrations.

#### BACKGROUND

2. Some 1,000 haemophiliacs are suing the Department, Licensing Authority and CSM for damages for having acquired HIV infection through NHS treatment with blood products. A large number of documents relevant to the litigation have been listed for discovery by the plaintiffs. However we have been advised by Counsel that nearly 600 documents in five categories can be protected from disclosure in the public interest.

#### PUBLIC INTEREST TO BE PROTECTED

3. In relation to the Department's documents the interest we are seeking to protect are the inner workings of Government mainly in the formulation of policy. In the case of the Licensing Authority and CSM documents we wish to protect our voluntary reporting system for adverse reactions. This relies on the willingness of practitioners to provide information about their patients on assurance from the CSM that the information will not be passed on to others in a form by which they or their patients can be identified. The Licensing Authority and the CSM believe that if this confidentiality is breached doctors would be unwilling to submit further reports. This would jeopardise the monitoring of medicines in the UK and could lead to failure in identifying drug safety hazards with serious implications to the safety of patients.

4. The normal method of ADR reporting is by a "Yellow Card" report which provides information on a patient who has suffered a possible reaction to a medicine. Details of the medicines received by the patient, the reactions experienced and the relevant clinical information are provided on the report. In this instance there have been no specific "Yellow Card" reports on infected Factor VIII. However the Licensing Authority has received a number of letters from doctors detailing patients' reactions to Factor VIII which the Licensing Authority consider fulfil the same function. The Licensing Authority and CSM recognise that these letters could be important to the plaintiffs in the preparation of their case. They are only willing to divulge their contents in an anonymous form that is with the doctors and patients names blocked out.

#### CLAIM FOR PUBLIC INTEREST IMMUNITY

5. Counsel has sifted through almost all the documents and advised on the claim for protection from disclosure. He cleared this advice with Treasury Counsel. Where documents are protected by public interest immunity, Departments have no discretion but are under a duty to claim the privilege. The plaintiffs have the right to challenge the claim and it is then a matter for the Court to decide whether the balance of the competing public interests lies in favour of, or against disclosure.

6. In the view of Counsel our claim is stronger in relation to some documents than others. In particular the judge may well decide that the balance of public interest favours disclosure of categories 2 and 4. However, Counsel takes the view there is nothing in any of the documents he has seen that would have any significant adverse effects on our defence in the litigation. Indeed many of the documents may be helpful in showing the careful consideration given to various matters at the time.

7. In the expectation that the plaintiffs will wish to challenge our claim in this case a hearing has been set for 25 July. A signed certificate will have to be produced to the judge at the hearing. If the judge decides that all the documents are covered by PII a decision may be given at that hearing. However, it is more likely that the judge will reserve his decision until September in order to study the documents.

#### DOCUMENTS/CERTIFICATE

8. The Permanent Secretary will wish to examine a representative selection of documents in each category and these are attached (Annex B). The others are readily available should he wish to see more.

9. If there any changes of emphasis that the Permanent Secretary wishes to make he should do so since the certificate is to reflect his considered opinion of the public interest. Once content we would be grateful if he would sign the certificate.

GRO-C: J Canavan

J CANAVAN