NIBSC LIAISON GROUP ON THE VIROLOGICAL ASPECTS OF THE SAFETY OF BLOOD PRODUCTS

At a meeting of this group on May 2nd, 1986, with representatives of the National Institute for Biological Standards and Control, Hampstead, the Blood Products Laboratory, Elstree, and the Protein Fractionation Centre, Edinburgh, the safety of immunoglobulins was considered. After full discussion, the group concluded that:

1. There is no epidemiological evidence associating the administration of intramuscular immunoglobulin with seroconversion for antibodies to LAV/HTLV III or the subsequent development of AIDS, and there is no reason to believe that intramuscular immunoglobulin, both normal and specific, is anything other than a safe product. Furthermore, several studies have now shown that patients who received immunoglobulins containing anti-LAV/HTLV III antibodies have not subsequently seroconverted (e.g. Tedder et al., Lancet 1985, 1: 815; Bremard-Oury et al., Lancet 1986, 1: 1090).
2. While the epidemiological evidence for the safety of intravenous immunoglobulins prepared by conventional Cohn fractionation is somewhat less secure, there is no convincing evidence that such preparations transmit LAV/HTLV III infection. However, certain products have been demonstrated to transmit non-A, non-B hepatitis.
3. Current evidence suggests that the LAV/HTLV III virus does not survive cold ethanol plasma fractionation during the preparation of immunoglobulins. At least six laboratories have demon-

strated, in spiking experiments, that the virus is inactivated or removed during Cohn fractionation for immunoglobulins.

4. The group did not consider that the recall of distributed batches of immunoglobulins for intramuscular use prepared from unscreened donors was warranted on the basis of the available evidence.

The group also noted that the National Blood Transfusion Service, as an added safety measure, has adopted a policy of not issuing immunoglobulins manufactured from a plasma pool to which a donor contributed who subsequently developed anti-LAV/HTLV III antibodies.

Currently, all immunoglobulins (both i.m. and i.v.) that are subject to batch release by NIBSC under the Medicines Act are examined by immunoblotting, and any batch that is positive is not released for distribution. All licensed immunoglobulins will be prepared from plasma derived from screened donors by the end of June, 1986.