PAPER III

Implications for UK imports of new FDA requirements

1. Dumping

There are presumably large stocks of Factor VIII concentrates in the USA prepared before the 23 March guidelines came into force. It is possible that concentrates made from the "safer" plasma may be retained for use in the USA while the older stocks may be dumped on export markets such as the UK. MB4 advises that the manufacturers are certainly able to identify those batches of plasma collected after 24 March 1983 and are therefore able to identify batches of concentrate made from such plasma Whether or not they would be prepared to release this information is another matter.

Should we now initiate new requirements to make it mandatory for the date the plasma was collected to be on the product label?

2. Should we accept only 'post 24 March' products? Would there be adequate supplies? MB4 advise that all FVIII concentrates are subject to full "Stop Orders", which require the manufacturers to submit protocols and samples from every batch they propose to sell in the UK, to Dr Duncan Thomas's department at NIBSC. The content of an individual manufacturer's protocol is very much a matter for agreement between Dr Thomas and the company. Date of plasma collection is thought not to be a requirement at present, but probably could become so if it were thought desirable. The Licensing Authority would then, on the advice of Dr Thomas, be able to reject those batches which did not comply.

The practical and legal aspects of this suggestion would, of course, have to be checked beforehand, but even the threat of such action might be sufficient to persuade the manufacturers to comply voluntarily. There are probably large stocks of FVIII waiting for batch clearance by NIBSC and this almost certainly includes material made from pre 24 March plasma.

3. Possibility of obtaining concentrates from plasma which does not come from "epidemic" centres

Plasma taken from high risk donors has to be labelled as such but the products derived therefrom do not. MB4 advise that exclusion of suspect plasma could only be achieved by voluntary action by the companies themselves, since although the source of all plasma is known to the manufacturers, unless they take a specific decision to segregate the plasma on geographical grounds, it is likely that the huge pools employed would contain everything available. Travenol have closed down their downtown New York City Plasmapheresis Centre and they and the other three companies may be giving thought to doing the same thing to centres in San Francisco, Florida, etc.

4. Could we obtain from sources other than the USA sufficient material derived from European plasma to supply up to 30 million i.u. of FVIII concentrate should it prove necessary to withdraw some or all of the American products? MB4 advise that the European manufacturers would have no chance at all of producing this amount from European plasma, for sale in the United Kingdom. The Swiss are said to have a small surplus of "home grown" concentrate but the amounts involved are nothing like 30 million i.u.

However, Dr Gunson has discussed the situation with Dr Hassig, Director of the Swiss Red Cross Blood Transfusion Service and it would appear that Switzerland has no surplus either of plasma or of products.