Dr Smithies A633 AFH

I am sending you a copy of a paper submitted by NIBSC to the Biologicals Sub-Committee and CSM this month. The pink sheets comprise the paper which is an attempt to control performance of tests for hepatitis antigen and HIV in commercial blood products. This should not pose any problems for BPL since all their blood products would be tested with the well controlled Wellcome kit.

Some of the products which hold commercial licences obtain their plasma from a wide variety of sources and currently the only evidence of testing we have is a certificate, sometimes even in a foreign language. We are hoping that the need to provide some quality assurance evidence on the protocols for batch release will make the manufacturers a little more circumspect about the sources of their plasma.

The paper still has to go before CSM and I will not be writing to any manufacturers until sometime in June.

GRO-C

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18 May 1987

