2nd May 1990

Our ref: RJP/AWM

Professor J.D. Cash
National & Scientific Medical Director
S.N.B.T.S.
Livingstone House
39 Cowgate
Edinburgh
EH1 1JR

Dear John,

ACVSB

Somewhat belatedly I enclose some scribbled notes of a recent ACVSB meeting.

With kind regards.

Yours sincerely,

Dr. R.J. Perry
Director

Encl.

NOTES OF ADVISORY COMMITTEE ON VIRUS SAFETY OF BLOOD

1. EC DIRECTIVE ON BLOOD PRODUCTS

Blood product annexe to E.C. Directive 75/318 (draft) is now in Brussells for discussion by Working Party.

Has also been approved (U.K.) that the Directive will be supported by Guidelines document which basically consists of relevant chapters of UK/BTS document with UK references omitted. This UK initiative has been approved by "policy side of D.O.H." - whatever that means.

Draft directive attached.

2. HIV 1 + 2

Approval to proceed with combi-test confirmed June 1st to date for blood issues to be HIV 1/2 tested and thus introduction of testing before that date is requested.

2 centres in E+L (N. London, Oxford) already commenced testing as 'extended pilot study' using Welcome tests. Report expected in May (iu 20,000 donations).

Status of pre-existing plasma stocks discussed in light of previous experience with HIV-1. D.O.H. have agreed that plasma stocks collected before 1 June will continue to be acceptable for fractionation - no requirement to retrospectively test for HIV-2. R.S. Lane suggested that H.M. Government should state that all products will be derived from HIV 1/2 tested plasma from April 1991. Strongly resisted by R.J.P. D.O.H. also unhappy about specific dates and agreed that statement should be 'as soon as practicable'.

Report in Clinica (March 28 1990) that U.S. F.D.A. will not require HIV-2 testing as a routine screening procedure for blood on plasma!

3. HTLVI

Draft study/trial protocol ready for submission to D.O.H.

4. HCV TESTING

Main agenda item - dominated by reports and discussion by academic virologists!

RPAM3004.90R

General Comments

- tests do not have adequate specification for routine BTS use and there remains no effective confirmatory test.

- preference to recommend implementation once confirmatory test is in place and we have better understanding of the science.

  (ARC, AABB)

- U.S. have developed a set of guidelines for implementation once the test is F.D.A. approved.

- recent U.S. meeting concentrated on issues of litigation/liability and implications for donors.

- HCV testing in place in France, Belgium, Luxembourg, Finland and Australia.

- NIBSC reported that U.S. have not decided yet on whether HCV +ve donations will be included or excluded from plasma pools.

- U.S. will not give up ALT/HBc testing in event of HCV test.

- despite ill defined science of test, high false positive results, lack of correlation of test postivity with infectivity and confirmatory test there is good evidence in the U.S. that testing prevents 50% of P.T.H. NANB - compelling reason to introduce test.

CONCLUSION

Absence of F.D.A. approval, confirmatory test and unequivocal science led to conclusion that UK should not yet proceed with HCV testing at present time.

However it was agreed that Gunson, Tedder, Mortimer and Mitchell would organise a full trial of c 100,000 donors to gather more information on such matters as donor positivity and predictive value of HCV Ab with regard to infectivity.

H.G. and R.J.P. felt that there was sufficient data to justify testing now (based on U.S. data suggesting 50% reduction in PTH) but the majority and D.O.H. preferred more cautious approach.

More details from R.M.

GRO-C

Dr. R.J. Perry
30th April 1990

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