E.14

BLOOD TRANSFUSION SERVICE

(EDINBURGH AND SOUTH-EAST SCOTLAND REGION)

Tel. Nos
Laboratory: 031-229 7291-4
Reg. Director: 031- GRO-C

REGIONAL BLOOD TRANSFUSION CENTRE,
ROYAL INFIRMARY,
EDINBURGH 3.

JDC/LSW

16th April 1971.

Dr. J.A. Holgate,
Dept. of Health & Social Security,
Queen Anne's Mansions,
LONDON, W.C.1.

Dear Dr. Holgate,

During the final planning phase of a large project here in Edinburgh, designed to investigate the use of various approaches to the prophylaxis of post-operative thromboembolic disease, I drew my colleague's attention to the potential hazards (viral hepatitis) of the currently available preparations of 125I-labelled human fibrinogen, supplied by the Radiochemical Centre, Amersham.

Since November, 1970, we have made repeated attemps to obtain advice on this matter from both the Medical Research Council and the Radiochemical Centre. As no assurances have been given that all possible means are being used to ensure that this reagent is safe, with regard to transmitting viral hepatitis, we have concluded that it is unethical to proceed with our proposed research project and it has, therefore, been abandoned. It is our view that the current safety provisions which may have been satisfactory 2-3 years ago are now manifestly inadequate. We appreciate that ever when all the necessary techniques at our disposal are employed, complete safety will not be achieved, but at least we can assure the volunteer that while a risk still exists, all possible precautions have been taken to eliminate it.

I think as a result of our enquiries to the M.R.C., Dr. R. Bangham very kindly invited me to a meeting (concerned with this problem) at Mill Hill on 25th January. During the course of this meeting, I asked on several occasions, who or what body was respon- for (a) defining accredited fibrinogen and (b) controlling the use of currently available material until fully accredited reagents are available. Once again, no answers were forthcoming from the distinguished members at this meeting and I could not escape the conclusio that these problems were not being considered by the central authorities.

Despite this, I understand that significant sums of money have already been released, presumably from the D.H.S.S., to provide additional staff at the Edgeware Blood Transfusion Centre to enable Dr. Cleghorn's group to gather together a group of accredited donors. Dr. Cleghorn is working up to an accreditation scheme which, with certain modifications, we regard as quite excellent. However, subsequent conversations with him have revealed that this accreditation system is his own personal one and has not been formally considered by D.H.S.S.S., let alone the Dunlop Committee. We are bound to enquire who was responsible for the release of funds to establish an accredited panel of donors at Edgeware, when as far as I can ascertain, the basic United Kingdom definition of accreditation has not been established? Moreover, are the activities at Edgeware and Elstree confined to responsibilities in England and Wales, or has the Central Consultative Committee of the Scottish National Blood Transfusion (S.N.B.T.A.) been consulted and given agreement to these plans? If not, is it understood that the S.N.B.T.A. must make its own arrangements?

You will, I am sure, appreciate the reasons for the strong feelings here in Edinburgh. We believe it is important that the problem is clearly and speedily defined and clarified. I am now under heavy pressure to pursue the matter further by an open letter to the Lancet, particularly as my colleagues now know that those responsible for the M.R.C. Aspirin Trial have abandoned the use of labelled fibrinogen derived from Kabi sources on the grounds of safety and would appear to have made their own arrangements to secure the relatively safe product originating from Edgeware.

In an effort to be as constructive as possible, I enclose separately, suggestions for the satisfactory definition of an accredited donor at this moment of time, along with a phased programme leading to the introduction of this material.

Yours sincerely,

John D. Cash, Ph.D. F.R.C.P.E.
Deputy Regional Director.

c.c. Dr. I.S. McDonald.