MARGARET GHLAIMI
BLOOD POLICY OFFICER
DEPARTMENT OF HEALTH
WELLINGTON HOUSE
LONDON SE1 8UG

FAX COVERING PAGE

(1 + 10 to follow)

To: Dr Philippa Edwards

Message:

As per my answerphone message, herewith the CMO letter.

~~Sean~~ Charles will ring you this afternoon to discuss.

Thanks

Date: 19 September 2001

Phone no: 020 7972 GRO-C

Fax no: 020 7972 GRO-C

URGENT

Charles Lister

Charles

CMO Case PO 116/2001 – Dr J K Wardle

Could Dr Troop have further advice and draft reply, urgently please.

Many thanks.

GRO-C

Rita Culwick
Room 117, Richmond House
Ext GRO-C

18 September 2001

To: Dr Pat Troop, DCMO

From: Lee Morris, PR-OFF(CMO)

Date: 18 September 2001

Copy:

Re: **CMO Case PO 116/2001 - Dr J K Wardle**
Albumin manufactured from a plasma pool which included a donation from a donor now diagnosed with vCJD

Pat

We copied the above correspondence to you when it was originally received in February this year. It was then referred to Charles Lister as a PO case to draft a reply for Liam.

Despite constant progress chasing, we were not supplied with a draft until this month. Apart from being appalled by the length of time it has taken for the draft to be supplied, Liam is questioning whether this response on a safety issue is appropriate in the circumstances.

Would you review the draft reply and let Liam have your view urgently?

Many thanks.

GRO-C

Lee Morris
PR-OFF(CMO)

Encs

Our Reference: **PO116/2001**

September 2001

Dr J K Wardle, Consultant Pathologist
Director
Isle of Man Blood Transfusion Service
Guy Pantin Laboratories
Nobles Hospital
Westmoreland Road
Douglas
Isle Of Man IM1 4QA

Dear

Than you for your letter of 9th February 2001 about albumin manufactured from a plasma pool which included a donation from a donor who was later diagnosed with variant Creutzfeldt Jakob Disease (vCJD). I must first offer my sincere apologies for the delay in replying to your letter.

I am aware that Dr Angela Robinson, Medical Director of the National Blood Service wrote to you on 20th April 2001 in response to her copy of your letter. She explained that the Department of Health was reassessing risk assessment data and that advice updating the letter from Dr Graham Winyard issued in 1998, would be provided once this had been completed.

In August 2000 I set up The CJD Incidents Panel which is an expert panel to provide advice to clinicians and others responsible for healthcare, on what action to take if a patient is diagnosed as having, or develops symptoms suggestive of, CJD some time after having undergone an invasive medical procedure or having donated blood, organs or tissues. I know that The Panel is still working on the assessment of risks from the various components and plasma derivatives prepared from blood donations. I have asked The Panel's Secretariat Dr Phillipa Edwards (Tel: GRO-C) to provide you with advice relevant to your enquiry as soon as possible

Yours sincerely,

PROFESSOR LIAM DONALDSON
CHIEF MEDICAL OFFICER

20th April 2001

Dr J K Wardle
Consultant Pathologist
Director, Isle of Man Blood Transfusion Service
Guy Pantin Laboratories
Nobles Hospital
Westmoreland Road
Douglas
ISLE OF MAN IM1 4QA

Dear Dr Wardle

Re: **Albumin manufactured from a plasma pool which included a donation from a donor now diagnosed with vCJD**

With regard to your letter dated 9th February 2001, firstly please accept my sincere apologies for not responding sooner (on behalf of both myself and Dr John Barbara). I have been waiting for, and still am awaiting, interim advice from the Department of Health on this issue so that I can give you a proper formal response.

I am aware that the Department of Health are re-assessing all the risk assessment data, and will in the near future be providing updated advice from that originally provided in the letter from Dr Graham Winyard in 1998. As soon as I am in receipt of this new advice, I will ensure that you receive it immediately. Until this happens, all I can say is that the 1998 advice remains extant and until that advice is updated, that is the line I am following. I am of course aware that the Haemophilia Directors in the UK have decided that they will inform their patients, and that is allowed for in the letter from Dr Winyard.

I am sorry it has taken so long for this advice to be updated, but it quite complex as at the same time they are considering what advice to give to individuals who might have been exposed to contaminated surgical instruments.

I am sorry that I cannot be more helpful at this stage, but will reply as soon as I have the information you require.

Best wishes
Yours sincerely

GRO-C

Dr E Angela E Robinson
Medical Director

Cc: Dr John Barbara – for information

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HSD 1

Isle of Man Blood Transfusion Service

Urgent to Charles Lister
Copy Dr Troop
Dr O'Mahony
Alan Harvey
Dr McGovern

Guy Pantin Laboratories
Nobles Hospital
Westmoreland Road
Douglas
Isle of Man IM1 4QA

Telephone: (01624) 642152

* Ask Dr Troop to handle as well
* Please keep in B/F and papers close.

Our ref: JKW/SAC

9 February 2001

Professor Liam Donaldson MSc, MD, FRCS(Ed), FRCP, FFPHM
Chief Medical Officer
The Department of Health
Richmond House
79 Whitehall
London SW1A 2NL

RECEIVED IN THE OFFICE
15 FEB 2001

Dear Professor Donaldson

Albumin manufactured from a plasma pool
which included a donation from a donor now diagnosed with vCJD

On 19 December 2000, the Isle of Man Blood Transfusion Service was notified by the UK National Blood Service that plasma-derived products from the Bio-Products Laboratory (BPL), supplied to the Isle of Man, have been manufactured from pooled plasma, including plasma from a UK donor who subsequently was diagnosed with variant Creutzfeldt-Jakob Disease (vCJD). The Isle of Man Blood Transfusion Service was informed, by the enclosed fax, that it had been sent 40 bottles of human albumin (Zenalb 4.5%) from the pool containing that donor's plasma.

The fax quoted advice, originating from your Department, contained in a letter by Graham Winyard to NHS Trust Medical Directors on 6 February 1998. That advice stated that the Department of Health considered that there was no need to inform patients who had received blood components or products collected from donors who subsequently developed vCJD, because:

1. It is thought unlikely that vCJD will be transmitted in this way;
2. There is no diagnostic test for vCJD;
3. Even if a test were available, there is no preventative treatment that could be offered.

National Blood Service,
Mersey and North Wales Centre,
West Derby Street,
Mount Vernon,
Liverpool,
L7 8TW

FAX COVER SHEET

DATE: 19/12/00 TIME: 15:34

TO: Biomedical Scientist i/c Blood Bank

FROM: Hospital Services/ Production PHONE: 0151 551 8800
FAX: 0151 551 8892

RE: BFL NOTIFICATION

Number of pages including cover sheet: 6

Message

The attached pages are for your information.

19 December 2000

To: Blood Bank Managers in hospitals served by the National Blood Service (NBS) Cambridge, Leeds, Liverpool, Manchester and Lancaster Blood Centres by fax. Please inform the Consultant Haematologist with responsibility for the Blood bank is informed.

Dear Colleague,

Re: Product manufactured from a plasma pool, which included a donation from a donor now diagnosed with vCJD

We are writing to inform you that we have been notified by the Bio Products Laboratory (BPL) that plasma from a UK donor who has been diagnosed with variant Creutzfeldt-Jacob disease (vCJD) was supplied to BPL in 1996 and 1997.

The plasma was fractionated into several batches of different products. All of the batches have passed their expiry date. Nevertheless, BPL currently considers it appropriate to notify consignees such as the NBS and the appropriate regulatory body of such products. The affected batches that have been distributed from your supplying Blood Centre are listed on the attachment. As this Centre serves your hospital you may have received this product. We are currently checking our records to confirm which hospitals received these batches of product and we aim to provide this detailed information to you by Thursday December 21st.

There is no evidence that blood products have transmitted the vCJD agent. The risk of transmission is often described as 'theoretical', but current knowledge does not allow exclusion of the potential for the transmission of vCJD by blood transfusion. The advice that DH is providing on this issue is summarised in a letter by Graham Winyard to NHS Trust Medical Directors on 6th February 1998, as follows:-

"The advice that DH has received from ethics experts and other advisory bodies is that there is no need to inform patients who have received blood components or products collected from donors who subsequently developed vCJD, because:-

i) it is thought unlikely that vCJD will be transmitted in this way;
ii) there is no diagnostic test for vCJD;
iii) even if a test was available, there is no preventative treatment that could be offered.

In these circumstances, the general view is that patients will not benefit from this knowledge, and that uncertainty created by informing patients could have the contrary effect causing unjustified worry and creating a permanent blight on their lives in relation, for example, to obtaining life or health care insurance."

Although the advice to you at this time is not to inform patients that they may have received blood products collected from donors who subsequently developed vCJD, we would like to remind you that you should have existing mechanisms for tracing the fate of all blood components and blood products.

You should note that BPL currently sources plasma from the United States and has done so since 1998. However, until 1998 plasma was sourced from donors of the United Kingdom (UK). We can confirm, therefore, this issue does not affect current supplies of BPL product.

If you have any queries regarding the above please contact one of your local Blood Centre's Consultants.

Yours sincerely,

GRO-C

Dr. Mike Murphy
National Medical Lead - Hospital Liaison

GRO-C

Stuart Penny
Head of Hospital Liaison

Product manufactured from a plasma pool, which included a donation from a donor now diagnosed with vCJD distributed from Liverpool Blood Centre

Zenalb 4.5%	500 ml	ADA 0680
Zenalb 4.5%	250 ml	ADB 0681
Replenate	500 i.u.	FHE 4536