

Our Ref: MG/hd/195

19 January 2001

Dr Julia Anderson
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Haemophilia Centre
Royal Victoria Infirmary
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Bio Products Laboratory

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Dear Dr Anderson

Further to your conversation with Mrs Jane Martin, please find enclosed copies of the letters sent to the Royal Victoria Infirmary on 14 December 2000.

As you are aware, this notification was sent to all customers who had received batches manufactured from plasma in 1996/97 where a donor had subsequently been diagnosed as suffering from vCJD.

Prior to the letter being sent, Frank Hill, Chairman UKHCDO, was consulted regarding the situation and was provided with a copy of the letter.

If I can be of any further assistance, please contact me on **GRO-C**.

Yours sincerely

GRO-C

Marc Greenwood
Senior Product Manager/Sales Manager
Coagulation Factors

Encs: Letter 14/12/00 - Audrey Savage - ATIII
Letter 14/12/00 - Dr J Anderson - Replenine-VF

Our Ref: SJ/ac

14/12/00

Dr J Anderson
Centre Director
Comprehensive Care Centre
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Dear Dr Anderson

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

Bio Products Laboratory (BPL) currently sources plasma from the United States. However, until 1998 plasma was sourced from donors of the United Kingdom (UK). BPL has received notification that a UK donor has been diagnosed as suffering from variant Creutzfeldt-Jacob disease (vCJD). Plasma from the donor 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 and the appropriate regulatory body of such products. The affected batches that have been supplied to you are listed below.

Replamine PJM 4596

There is no evidence that the vCJD agent has been transmitted by blood products and therefore it is still considered a theoretical risk.

We can confirm that since 1998 BPL has been fractionating plasma solely sourced from the US and therefore this issue does not affect current supplies of BPL product.

If you have any queries regarding the above please ring Customer Services on 020 8258 2342.

Yours sincerely

GRO-C

SJ Jenkins
Quality Assurance Manager

Our Ref: SJ/ac

14/12/00

Ms A Savage
Chief MLSO
Blood Bank
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Dear Ms Savage

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

Bio Products Laboratory (BPL) currently sources plasma from the United States. However, until 1998 plasma was sourced from donors of the United Kingdom (UK). BPL has received notification that a UK donor has been diagnosed as suffering from variant Creutzfeldt-Jacob disease (vCJD). Plasma from the donor 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 and the appropriate regulatory body of such products. The affected batches that have been supplied to you are listed below.

AT III ATA 4535

There is no evidence that the vCJD agent has been transmitted by blood products and therefore it is still considered a theoretical risk.

We can confirm that since 1998 BPL has been fractionating plasma solely sourced from the US and therefore this issue does not affect current supplies of BPL product.

If you have any queries regarding the above please ring Customer Services on 020 8258 2342.

Yours sincerely

GRO-C

SJ Jenkins
Quality Assurance Manager