Witness Name: Charles Hamilton Massey
Statement No.: WITN3365011
Exhibits: WITN3365012-WITN3365031
Dated: 30 August 2019

INFECTED BLOOD INQUIRY

EXHIBIT WITN3365023 OF MR CHARLES HAMILTON MASSEY

WITN3365023 – Exhibit: Complaint by Mrs GRO-A (on behalf of her deceased husband Mr GRO-A against Dr Ian Thomas Gilmore (1504220) & Dr Charles Hay (2310390). GMC Case Reference: 2004/0781

Case Examiner Decision Form

GENERAL MEDICAL COUNCIL
Protecting patients, guiding doctors

Investigation Officer: Tim Cox-Brown

File Reference No 2004/0781/1 Date 140205

Dr's Name Charles HAY Reg No 2310390

Part 1.

Nature of Allegations

Date complaint first received by the GMC: 220304

Year alleged events took place: 1990

The following are the allegations raised by the complainant and/or employer: (TO BE NUMBERED)

That Dr Hay;

1. Failed to diagnose liver disease in GRO-A
2. Failed to test for Hepatitis C
3. Failed to refer to hepatologist
4. Failed to communicate the clinical condition of "liver failure" to the patient
5. Failed to refer or recommend liver transplant
6. Refused to refer to specialist Dr Gilmore
7. Failed to diagnose and treat liver cancer early enough
8. Prevented full liver tests being undertaken

Nature of Allegations: presumption of impaired FTP

1.1 Do the allegations fall within one of the categories where there is a presumption, if proven, of impaired fitness to practise to a degree justifying action on registration?

Sexual Assault or indecency	**Yes**	**No**
a. Indecent behaviour	☐	☒
b. Indecent assault	☐	☒
c. Rape/attempted rape	☐	☒
d. Female circumcision	☐	☒
e. Child pornography	☐	☒
Violence		
f. Assault	☐	☒
g. Attempted murder	☐	☒
h. Firearms offence	☐	☒
i. Murder/manslaughter	☐	☒
j. Robbery	☐	☒
Improper sexual/emotional relationship	☐	☒
Dishonesty		
k. False claims to qualifications/experience	☐	☒
l. Financial fraud/deception	☐	☒
m. Forgery/improper alteration of documents	☐	☒

n.	Research misconduct	☐	☒
o.	False certification, false reporting	☐	☒
p.	False claims about effectiveness of treatment	☐	☒
q.	None of the above dishonesty allegations	☒	☐

Part 2.

Nature of allegations: Good Medical Practice

2.1 Do the allegations relate to one or more of the principles of Good Medical Practice set out below? If yes, please tick and cite the relevant paragraph in the right hand column then go to Part 3.
If no, please tick ' None of the above' then go to Part 3.

(For more detail on the principles of GMP, refer to the GMP booklet and the guidance provided.)

			Para(s) in GMP
a.	Good Clinical Care	☒	2, 3
b.	Maintaining Good Medical Practice	☐	
c.	Teaching and Training	☐	
d.	Relationships with patients	☐	
e.	Working with colleagues	☐	
f.	Probity	☐	
g.	Health	☐	
i.	None of the above GMP allegations	☐	

Part 3

Criteria for assessing the seriousness of allegations

Questions 3a to 3g will help to identify whether the allegations are sufficiently serious to meet the Investigation stage test: 'Is there a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on registration?'

Please tick yes or no in each section

Do the allegations indicate that:

	Yes	No
a. the doctor's performance has harmed patients or put patients at risk of harm?	☒	☐
b. the doctor has shown a deliberate or reckless disregard of clinical responsibilities towards patients?	☒	☐
c. the doctor has abused a patient's right or violated a patient's autonomy or other fundamental rights?	☐	☒
d. the doctor has behaved dishonestly, fraudulently or in a way designed to mislead or harm others?	☐	☒
e. the doctor's behaviour is such that public confidence in doctors generally might be undermined if the GMC did not take action?	☐	☒
g. the doctor's health is compromising patient safety?	☐	☒

Part 4

Realistic prospect test

4.1 Is there a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration

Yes ☐

No ☒

4.2 Please give reasons for your decision

1. GRO-A widow has investigated a civil action for damages and the expert opinions are included on file. They do not support her allegations and accordingly her solicitors dropped the action. Dr hay was closely monitoring liver function tests. Cirrhosis of the liver was diagnosed in 1992 following knee surgery. There is nothing to indicate that this surgery was contraindicated or had any adverse effect on GRO-A liver disease. GRO-A own expert hepatologist confirms that this is the case and that earlier diagnosis via biopsy would *have been very unusual practice at the time. Fails realistic prospect test.*

2. The hepatitis C test only became available in late 1991 and Dr Hay began testing in early 1992. This is not an issue to justify action on a Dr's registration - fails realistic prospect test

3. In this context Dr Hay was an experienced consultant and it was reasonable for him to manage GRO-A care himself. The independent expert view was that the liver disease was appropriately managed with very effective treatment of the patient's oesophageal varices. No action on registration indicated as fails realistic prospect test

4. GRO-A liver function was regularly monitors and discussions about the diagnosis documented. There is no evidence that any information was deliberately withheld so no action on registration indicated as fails realistic prospect test

5. At the time it is clear liver transplantation was a last resort measure, particularly with the increased morbidity and mortality associated with patients who had haemophilia. When his liver function deteriorated GRO-A was referred. Unfortunately this deterioration coincided with the diagnosis of a malignant liver tumour so removing transplantation as an option

6. GRO-A was referred to Dr Gilmore. Unfortunately it was at a stage when the hepatoma was diagnosed. There is no evidence that Dr hay or any other Dr failed to act on evidence that would have led to an earlier diagnosis

7. The blood test result indicating a possible hepatoma was 1st recorded in excess of 9000 in July. By August it was greater than 1000000. This is a large rise in a short space of time and occurred in combination with the patient's worsening clinical condition. It was not routine accepted practice to "screen" patients with cirrhosis for liver cancer and Dr Hay's management is what might reasonably have been expected. No issue indicating action on registration – fails realistic prospect test

8. "A full liver work up" may have involved risk laden procedures such as liver biopsy, the complications from which are multiplied in patients with a bleeding disorder such as haemophilia. Professor Shields discussed the pros and cons with the haemophilia specialist

– Dr Hay, who can be said to have been acting in his patient's best interests. No issue justifying action on registration – fails realistic prospect test

Part 5

Undertakings

5.1 Do you consider that this is a case where undertakings should be offered to the doctor?

Yes ☐

Case Examiner Referral Form

Section 1: Case Details

See Notes on Completion at end of form

FPD reference **RG/FPD/2004/0781**

Doctor's name **HAY, Charles**

Registration no. **2310390**

Date **140205**

Investigation Officer Richard Grumberg

File location: E:\.... **Not Relevant**

Section 2: Previous History

See Note 1

Previous history? Yes

FPD Reference	Nature of complaint	Outcome/current status
2003/0206	Substandard clinical practice	Open

Section 3: Index complaint – background and summary

The complaint is made by the widow of Mr. GRO-A, a haemophiliac who died of liver cancer in September 1994.

Flag 1 is the case against Dr. Hay as set forth by GRO-A. In essence the allegations can be summarised as follows:

1. That Dr. Hay was fully aware of the prevailing issues facing the haemophiliac community in the period 1975 – 1994 and in particular the presence of progressive liver disease that affected haemophiliacs but did not foresee, or even recognise, the clinical manifestations of liver disease in GRO-A
2. Dr. Hay did not conduct any testing for Hepatitis C on GRO-A even though he knew, or should have known, that GRO-A was in a high-risk category for infection of that virus. This failure to test GRO-A meant that his hepatitis C positive status was not discovered until January 1992 when the virus had progressed unchecked to the point where he was suffering from cirrhosis of the liver, with Dr. Hay estimating that he only had 2½ years left to live.
3. Dr. Hay did not refer GRO-A to a Hepatologist, even when it was clear that he was Hepatitis C positive and suffering from cirrhosis of the liver.
4. Dr. Hay did not iniform GRO-A that he was in the clinical phase known as liver failure.
5. Dr. Hay did not recommend GRO-A for a liver transplant.
6. Refused to refer to specialist Dr. Gilmore
7. Failed to diagnose and treat liver cancer early enough
8. Prevented full liver tests being undertaken

The following points should be noted and correspond numerically to each point above:

1. GRO-A widow has investigated a civil action for damages and the expert opinions are included in the file. They do not support her allegations and accordingly her solicitors dropped the action. Dr. Hay was closely monitoring liver function tests. Cirrhosis of the liver was diagnosed in 1992 following knee surgery. There is nothing to indicate that this surgery was contraindicated or had any adverse effect on Mr. GRO-A liver disease. GRO-A own expert hepatologist confirms that this is the case and that earlier diagnosis via biopsy would have been very unusual practice at the time.
2. The hepatitis C test only became available in late 1991 and Dr. Hay began testing in early 1992.
3. The independent expert view was that the liver disease was appropriately managed with very effective treatment of the patient's oesophageal varices. Dr. Hay was an experienced consultant and it appears that it was reasonable for him to manage GRO-A care himself.

4. GRO-A liver function was regularly monitored and discussions about the diagnosis documented. There is no evidence that any information was deliberately withheld.
5. At the time it is clear liver transplantation was a last resort measure, particularly with the increased morbidity and mortality associated with patients who had haemophilia. When his liver function deteriorated Mr. GRO-A was referred. Unfortunately the reason for the deterioration, a malignant liver tumour meant that transplantation was not an option.
6. GRO-A was referred to Dr. Gilmore. Unfortunately, it was at a stage when the cancer was diagnosed. There is no evidence that Dr. Hay or any other Dr. failed to act on evidence that would have led to an earlier diagnosis.
7. The diagnosis of GRO-A liver cancer was made following his transfer to Newcastle in August 1994. This followed deterioration in his liver function tests and clinical condition, which had previously been stable. It was not accepted practise to screen patients with cirrhosis for liver cancer and there is nothing to suggest that earlier diagnosis or treatment could reasonably have been expected.
8. A 'full liver workup' would have involved invasive and risky procedures. Prof. Shields deferred to Dr. Hay's greater expertise in the treatment of haemophilia and the risks compared to the benefits given the other clinical information available on GRO-A condition. There is nothing to suggest that Dr. Hay was doing other than acting in what he felt to be his patient's best interests.

Section 4: Additional information

None but for the previously mentioned expert opinions in the file.

Section 5: Performance Assessments/Health Examinations

None.

Section 6: Summary of Allegations

See Note 5

A	B	C	D
No	Allegation	Presumption of impaired FTP?	Breach of GMP?
1	Failed to diagnose liver disease in GRO-A	No	Yes
2	Failed to test for Hepatitis C.	No	Yes
3	Failed to refer to hepatologist	No	Yes
4	Failed to communicate the clinical condition of "liver failure" to the patient.	No	Yes
5	Failed to refer or recommend liver transplant.	No	Yes
6	Refused to refer to specialist Dr. Gilmore.	No	Yes
7	Failed to diagnose and treat liver cancer early enough	No	Yes
8	Prevented full liver tests being undertaken	No	Yes

Other relevant guidance? No

See Note 6

Section 7: Charges

None.

Section 8: Conclusion/Suggested Action

It does not appear from the above that the realistic prospect test can be satisfied, however I welcome the medical case examiner's view on the issue.

Casework Screening Memo and Screening Decision Form
Part 2 – Screeners to complete

Section 7: Conduct

Medical Screener's decision on each allegation *(Note, it is possible that whilst individual allegations do not raise issues of SPM/SDP the totality of 2 or more allegations may do so. Record such instances in the reasons section)*

Dr ____Hay_____

No	Allegation	Category *[drawn from Annex A]*	SPM by definition?	Part 1 screening test met?	If part 1 is met, is part 2 also met?
1	Dr Hay failed to diagnose liver disease in GRO-A GRO-A	Substandard treatment	Discretion	N	
2	Dr Hay failed to test for Hepatitis C	"	"	N	
3	Failure to refer to hepatologist	"	"	N	
4	Failure to communicate clinical condition to patient ("liver failure")	"	N	N	
5	Failure to refer or recommend liver transplant	"	Discretion	N	
6	Refusal to refer to specialist, Dr Gilmore	"	"	N	
7	Failure to diagnose and treat liver cancer early enough	"	"	N	
8	Prevented "full liver work up" i.e. proper investigation	"	"	N	

Reasons

Allegation number	Reasons
1	Dr Hay was clearly aware of the issues affecting haemophiliac patients and monitored GRO-A condition (clinically and via blood tests regularly). It is accepted that GRO-A blood tests were stable prior to his knee operation
2	Testing for hepatitis C was not widely available until late 1991. The issues of prognosis were not fully understood, so treatment options limited
3	Dr Hay had wide experience of patients with hepatic complications of blood disorders and worked with Professor Shields, a surgeon specialising in the treatment of liver problems, such as the oesophageal varices which GRO-A had
4	Whilst failure to tell a patient about a condition they were suffering from is clearly not good practice, there is no evidence to suggest that Dr hay failed to advise GRO-A about his liver problems. Consequently I do not feel that this is properly arguable as SPM. GRO-A was having regular monitoring including blood tests for liver function
5	The prevailing opinions at the time were conflicting. A liver transplant was clearly highly risky, more so in a patient with Hepatitis C. It is clear the option was considered, but unfortunately by the time it was indicated Mr GRO-A had developed a rare complication of hepatoma. I do not think that failure to refer can be said to represent SPM. Most forms of more conservative treatment (e.g. medication, sclerotherapy) are used to try to avoid surgery for as long as possible
6	Mr GRO-A was referred to Dr Gilmore. Unfortunately it was at a stage when the hepatoma was diagnosed. The case for SPM cannot be properly argued as there is no evidence that Dr Hay or any other Dr failed to act on any evidence that would have led to a significantly earlier diagnosis
7	The blood test result indicating a possible hepatoma was 1st recorded in excess of 9,000 in July. By August it was >100,000. This is a large rise in a short space of time. In combination with the patient's worsening clinical condition, with ascites the patient was transferred. Screening is controversial and the management of Dr Hay was what might reasonably have been expected at that time
8	Failure to conduct a "full liver work up" meant preventing Mr GRO-A from having potentially risky invasive procedures performed. Whilst with hindsight it may have been useful it is not properly arguable that this was done in anything other than consideration of the patient's best interests

Comment

The case has been considered outside the 5 year rule because of the wider public interest prevailing with a series of Haemophilia and hepatitis C cases. However I do not feel that given the responses of Dr Hay and consideration of specific allegations that the case should go before the PPC. The case will now be considered by a lay case examiner.

Section 8: Performance

This/these allegations raise issues of seriously deficient performance *for the following reasons*:

Dr _____

Reasons

Section 9: Summary and Decision – Medical Screener

Copy this page for each doctor named in this complaint

To be completed by the Medical Screener:

In my view this case raises:

Tick one box only

a. Issue(s) of spm (only) and should be referred to the next available PPC	☐	*Sign, date below and return to the CW*
b. Issue(s) of sdp (only) and a performance Rule 6 letter should be sent	☐	*- ditto -*
c. Issues of **both** spm and sdp	☐	*go to 9e*
d. No issues of spm **or** sdp	☑	*Sign, date below and return to the CW*

e. In my opinion this case should be considered in accordance with:

Tick one box only

1. *The conduct procedures*	☐	*Refer to next PPC*
2. The performance procedures	☐	*Performance R6 letter*

Signed Sarah Whiteman (Medical Screener)
Date 16.8.04

Action	Draft Charges	Closure letters
Approve		
Amend (discuss with CW)		
Re-Draft (discuss with CW)		

Section 10: Conduct

Lay Screener's decision on each allegation *(Note, it is possible that whilst individual allegations do not raise issues of SPM/SDP the totality of 2 or more allegations may do so. Record such instances in the reasons section)*

Dr Hay Consutant Haemotologist

No	Allegation	Category *(drawn from Annex A)*	SPM by definition?	Part 1 screening test met?	If part 1 is met, is part 2 also met?
1	Failure to diagnose liver disease in high risk patient	Substandard treatment	By Discretion	Yes	no
2	Failure to test for Hep C	Substandard treatment	By Discretion	No	
3	Failure to refer to Hepatologist	Substandard treatment	By Discretion	No	
4	Failure to communicate clinical condition to patient	Substandard treatment	By Discretion	No	
5	Failure to refer for transplant	Substandard treatment	By Discretion	Yes	no
6	Refusal to refer appropriately to Dr Gilmore	Substandard treatment	By Discretion	Yes	no
7	Failure to diagnose & treat liver cancer early enough	Substandard treatment	By Discretion	Yes	no
8	Prevention of proper investigation ie by Prof Shield	Substandard treatment	By Discretion	Yes	no

Reasons

Allegation number	Reasons
1	This case concerns GRO-A a haemophiliac who died of liver cancer in Sept 1994. He had been infected, probably in 1981, with hepatitis C from infected blood products used in the treatment of his haemophilia, which directly increased his risk of liver disease. His widow makes a number of allegations about the quality of the treatment her husband received and believes that Dr Hay, his haematologist, failed to monitor or adequately treat her husband's liver disease. She has investigated a civil action for damages and the expert opinions she obtained are included on the file. They do not support her allegations and accordingly her solicitors dropped the action. It is clear in respect of this particular allegation that Dr Hay was

	closely monitoring GRO-A via liver function tests and that Cirrhosis of the liver was diagnosed in early 1992 following his knee surgery. There is nothing to indicate that this surgery was contraindicated or had any effect on the progress of GRO-A liver disease. GRO-A own expert Hepatologist, Dr Mervyn Davies confirms that this is the case and that earlier diagnosis via biopsy would have been very unusual practice at this time. There is therefore no properly arguable case that SPM/SDP occurred.
2	The test for Hepatitis C only became widely available in late 1991 and this allegation cannot therefore reach the threshold of SPM/SDP as Dr Hay began testing GRO-A in March 1992 i.e. within a short time of the test becoming available.
3	As Dr Hay was very experienced and knowledgably about the development of liver disease in this context it was reasonable for him to manage GRO-A care himself .The independent expert view is that the liver disease was appropriately managed with very effective treatment of (his) varices.' This allegation does not therefore reach the threshold of SPM/SDP as given the treatment being provided referral was not necessary at this stage.
4	GRO-A was clearly aware that he was being monitored for liver disease and once a diagnosis of cirrhosis was made this was fully discussed with the patient and his wife. There is nothing to suggest that any information was deliberately concealed from the patient and the exact terminology used in discussion with *patients of a diagnosis may vary between clinicians. This allegation does not* reach the threshold of SPM/SDM.
5	This issue is addressed at length in expert reports and it is clear that the indications for transplantation at the time were ones of last resort particularly given the additional morbidity associated with Haemophiliac patients GRO-A GRO-A was referred at the point when his liver function tests showed a severe deterioration. Unfortunately the reason for the deterioration, a malignant liver tumour meant that transplantation was not an option. There is however no properly arguable case that SPM/SDP has taken place.
6	The referral to Dr Gilmore was made at the point when the cancer was diagnosed but there is nothing to suggest that there were earlier indications, which would have made such a referral imperative, or that it would have altered the course of events. SPM/SDP is not therefore properly arguable.
7	The diagnosis of GRO-A liver cancer was made following his transfer to Newcastle in August 1994.This followed deterioration in his liver function tests and clinical condition, which had previously been stable. It was not accepted practise to screen patients with cirrhosis for liver cancer and there is nothing to suggest that earlier diagnosis or treatment could reasonably have been expected. There is not therefore a properly arguable case that SPM/SDP has taken place.
8	There was clearly a disagreement between Dr Hay and Prof Shields about the timing of a 'full liver workup', which would have involved invasive and risky procedures. Prof Shields deferred to Dr Hay's greater expertise in the treatment of haemophilia and the risks compared to the benefits given the other clinical information available on GRO-A condition. Whether this would have changed the later course of events is debatable and there is nothing to suggest that Dr Hay was doing other than acting in what he felt to be his patient's best interests. There is no therefore a properly arguable case that SPM/SDP has occurred.

Section 11: Performance

This/these allegations raise issues of seriously deficient performance for the following reasons:

Dr _____

Reasons

Section 12: Summary and Decision – Lay Screener

To be completed by the Lay Screener

a: Do you agree with the Medical Screener's decision at 9d. above?

Yes ☑ ∏ *Sign, date and return to the CW*

No □ ∏ go to b below

GRO-C

Signed (Lay Screener)

Date 17/8/04

b: Please state briefly why you do not agree with the Medical Screener's decision at 9d.

Sign, date and return to the CW

Signed (Lay Screener)

Date

Casework Screening Memo and Screening Decision Form
Part 1 – Caseworkers to complete

NOTE:

Sections 1-6 of this memo should be completed by caseworkers for every case referred to screeners for a decision, except cases involving a criminal conviction. Where a case has multiple doctors, they can be included on this form. However, where we receive adverse information from Drs' employer(s) which raise separate issues for consideration by the screener, a separate form must be completed.

Sections 7-9 should be completed by the medical screener. Sections 10-12 should be completed by the lay screener in cases where the medical screener seeks to conclude the complaint. On completion of the relevant sections the form must be returned to the caseworker for final action.

Draft charges, Rule 6 or closure letters should be attached to the file by the CW in all cases where a recommendation is made to close or proceed. The screeners should comment on these at section 9 & 11. Drafts should not be attached in cases where no recommendation is made.

Section 1: Case details

FPD complaint reference | 2 | 0 | 0 | 4 | 0 | 7 | 8 | 1 | 0 | 1 |

Date | 1 | 6 | 0 | 8 | 0 | 4 |
D D M M Y Y

Dr's name HAY

Reg no | 2 | 3 | 1 | 0 | 3 | 9 | 0 |

Complainant no | 2 | 6 | 0 | 6 | 7 |

Insert a new line for each Dr subject to this complaint

Section 2: Previous History

NOTE: List below any previous complaints against each doctor. State clearly the date, nature and outcome of the case.

Where there is no history write NONE in the box below

Dr. Hay

FPD ref	Date of complaint and brief outline	Outcome and stage closed
	NONE (but see below)	

Insert a new previous history record for each Dr subject to this complaint

Section 3: Current Case Background

NOTE: Include a brief history of this case, noting significant events, times and dates. This should be cross-referenced to documents on file as necessary, using clearly marked tabs.

1. Dr. Hay has been identified. He has not been the subject of any previous complaints, but there is a current complaint about him, from a haemophiliac, which is attached for your attention (2003/0206). You will see that that complaint is to be closed with no further action. Mrs GRO-A complaint has already been considered by a Medical Screener, who was asked to decide whether the public interest required that we consider this complaint, despite the events leading to it having taken place over five years ago. The Medical Screener confirmed that we should consider only the complaint about Dr. Hay GRO-A also complained about Dr. Gilmore - see memo at Flag A below; this complaint has been closed). We have dealt with this complaint in the usual manner, including disclosure to Dr. Hay. At Flag B below is a copy of our Standards guidance issued in 1988 regarding the testing of patients for hepatitis C and HIV in the 1980s.

2. Mrs. GRO-A initial complaint is at Flag 1. At Flag 2 is a summary of Mrs. GRO-A complaint about Dr. Hay, and a similar summary regarding Dr. Gilmore is at Flag 3. At Flag 4 is a statement which outlines details of Mr. GRO-A treatment, and further general information is at Flag 5. Mrs. GRO-A has also provided copies of Mr. GRO-A medical records, which are voluminous and are held separately from this file but which are available should you require them.

3. Dr. Hay's initial response to this complaint, provided by the MPS, is at Flag 6, and Mrs GRO-A comments thereon are at Flag 7. Dr. Hay's further comments are at Flag 10. Mrs. GRO-A has sent copies of expert opinions she obtained during the course of the aborted litigation referred to in her final comments, which are at Flags 8 and 9.

4. Mrs. GRO-A husband was a haemophiliac who was infected with hepatitis C probably as a result of receiving infected blood products during an operation to repair a duodenal ulcer in 1981. He died in September 1994 as a result of hepatocellular carcinoma, cirrhosis of the liver, hepatitis C, and haemophilia A.

Section 4: Summary of allegations

NOTE: Summarise all the complainant's / referrer's allegations against the doctor concerned (extend the table as necessary). In cases where there is more than 1 Dr include a table for each Dr showing the Dr's name.

If it is impossible to summarise allegations, please note that in the table and summarise at section 6. This will be particularly relevant in cases where there are performance concerns.

Dr Hay

No.	Allegation	Category *[drawn from Annex A]*	SPM by definition?	Part 1 screening test met?	If part 1 is met, is part 2 also met?
1	Dr. Hay was fully aware of the prevailing issues facing the haemophiliac community in the period 1975-1994, and in particular the prevalence of progressive liver disease as it affected haemophiliacs, but did not foresee, or even recognise, the clinical manifestations of liver disease in GRO-A	Sub-standard treatment	SPM by discretion	Yes	Yes
2	Dr. Hay did not conduct any testing for hepatitis C on GRO-A, even though he knew, or should have known, that GRO-A was in a high-risk category for infection with that virus. This failure to test GRO-A GRO-A meant that his hepatitis C positive status was not discovered until January 1992, when the virus had progressed unchecked to the point where he was suffering from	Sub-standard treatment	SPM by discretion	Yes	Yes

No.	Allegation	Category *[drawn from Annex A]*	SPM by definition?	Part 1 screening test met?	If part 1 is met, is part 2 also met?
	cirrhosis of the liver, with Dr. Hay estimating he only had 2.5 years left to live.				
3	Dr. Hay did not refer GRO-A to a hepatologist, even when it was clear that he was hepatitis C positive and suffering from cirrhosis of the liver.	Sub-standard treatment	SPM by discretion	Yes	Yes
4	Dr. Hay did not inform GRO-A that he was "in the clinical phase known as 'liver failure'."	Sub-standard treatment	SPM by discretion	Yes	Yes
5	Dr. Hay did not recommend Mr. GRO-A for a liver transplant.	Sub-standard treatment	SPM by discretion	Yes	Yes
6	Dr. Hay "Vehemently protested" against GRO-A eventual referral to Dr. Gilmore claiming that he did not consider that Dr. Gilmore could achieve any more for GRO-A than Dr. Hay had done.	Sub-standard treatment	SPM by discretion	Yes	Yes
7	Dr. Hay was responsible, jointly with Dr. Gilmore, for failures in Mr. GRO-A treatment between June and September 1994. This includes an alleged failure by Dr. Hay to detect a large cancerous tumour in Mr. GRO-A liver, and a subsequent	Sub-standard treatment	SPM by discretion	Yes	Yes

No.	Allegation	Category *[drawn from Annex A]*	SPM by definition?	Part 1 screening test met?	If part 1 is met, is part 2 also met?
	attempt by Dr. Hay to deny that the tumour existed when he had examined Mr. GRO-A				
8	Dr. Hay "wilfully obstructed a full liver work-up" from being conducted on GRO-A	Sub-standard treatment	SPM by discretion	Yes	Yes

Section 5: Relevant GMC / other Guidance

NOTE: Note here all GMC guidance relevant to any of the allegations above. In the vast majority of cases, you should refer to and state the relevant paragraph(s) of Good Medical Practice. Include any relevant guidance offered by other organisations, such as the Medical Royal Colleges. State clearly the publication, paragraph / page and content.

Section 6: Summary & Conclusions

Including concerns which raise issues of seriously deficient performance

Mrs. GRO-A has made some serious allegations which clearly reach the threshold of SPM, and which are properly arguable. I feel, therefore, that this complaint should be referred to PPC for further consideration. I have not drafted charges, however, as I should be grateful for your advice on this case.

I should also be grateful if you would confirm that the public interest requires that Mrs. GRO-A complaint about Dr. Hay should be referred to PPC despite the events giving rise to it occurring over five years ago.

I look forward to receiving your advice.

GRO-C

Tim Cox-Brown
Caseworker, Fitness to Practise Directorate
Direct Line: GRO-C ; Fax: GRO-C
E-mail: tcoxbrown@ GRO-C

Now pass this document to the screeners to record their decision.

A

Tim. 26.4.04. I agree with your assessment about the issue raised against Dr Hay are generic, and hence of public interest. These concerning Dr Gilmore are specific and not of public interest.

Memorandum **To** **Dr. Brian Keighley**

Date 8 April 2004 ✝ see below

2004/0781: GRO-A **v. Dr. Charles Hay and Dr. Ian Gilmore**

1. I wonder if you would be kind enough to consider this complaint which we have received from the widow of a haemophiliac, given that you have seen the last three we have received.

2. GRO-A complaint concerns events which are over five years old. At Flag A below is a copy of our Standards guidance issued in 1988 regarding the testing of patients for hepatitis C and HIV in the 1980s.

3. Mrs. GRO-A husband, GRO-A, who was a haemophiliac, died in GRO-A 1994. Mr. GRO-A had been infected with hepatitis C through contaminated blood products used in the treatment of his haemophilia. GRO-A's initial complaint is at Flag 1. A statement made by GRO-A in 1997 (in support of litigation) is at Flag 2, which describes the background to this complaint. Further information is at Flag 3. GRO-A has helpfully provided detailed accounts of her complaints about Drs. Hay and Gilmore, which are at Flags 4 and 5. At Flag 6 is an article by Dr. Hay entitled "Haemophilia and Liver Disease" and at Flag 7 is a paper (published in The Lancet in 1985, which Dr. Hay co-authored) entitled "Progressive Liver Disease in Haemophilia: An Understated Problem?". Please note that GRO-A has also sent copies of medical records and correspondence with the NHS which are so voluminous that I have not added them to the file, but which are available should you wish to see them.

4. Mrs. GRO-A alleges that Dr. Hay:

a) Was fully aware of the prevailing issues facing the haemophiliac community in the period 1975-1994, and in particular the prevalence of progressive liver disease as it affected haemophiliacs, but did not foresee, or even recognise, the clinical manifestations of liver disease in GRO-A
b) Did not conduct any testing for hepatitis C on GRO-A even though he knew, or should have known, that GRO-A was in a high-risk category for infection with that virus. This failure to test GRO-A meant that his hepatitis C positive status was not discovered until January 1992, when the virus had progressed unchecked to the point where he was suffering from cirrhosis of the liver, with Dr. Hay estimating he only had 2.5 years left to live.
c) Did not refer GRO-A to a hepatologist, even when it was clear that he was hepatitis C positive and suffering from cirrhosis of the liver.
d) Did not inform GRO-A that he was "in the clinical phase known as 'liver failure'."
e) Did not recommend GRO-A for a liver transplant.
f) "Vehemently protested" against GRO-A eventual referral to Dr. Gilmore claiming that he did not consider that Dr. Gilmore could achieve any more for Mr. GRO-A than Dr. Hay had done.
g) Was responsible, jointly with Dr. Gilmore, for failures in GRO-A treatment between June and September 1994. This includes an alleged failure by Dr. Hay to

✝ The issues re Dr Hay are 4 a) - d) & e) now separated.

GRO-C

detect a large cancerous tumour in GRO-A liver, and a subsequent attempt by Dr. Hay to deny that the tumour existed when he had examined GRO-A.

5. Mrs. GRO-A alleges that Dr. Gilmore:

a) Did not warn GRO-A that a bout of encephalitis in August 1994 was potentially a sign that his liver was failing.
b) *Did not note that* GRO-A *was suffering from a cancerous tumour (7cms in* diameter) which rendered a planned liver transplant impossible, despite extensive testing, and allowed GRO-A to be transferred to Newcastle Freeman Hospital for said liver transplant. It is alleged that he has not admitted that this tumour was present when GRO-A was transferred to Newcastle (13 August 1994), but has claimed that the tumour developed between the date of transfer and GRO-A return to Liverpool (18 August 1994), a matter of five days.
c) Did not urgently a bed for GRO-A on his return from Newcastle Freeman Hospital, and did not arrange chemotherapy for him as a matter of urgency, but rather conducted non-urgent varices reparation treatment instead. This further delayed the start of vital chemotherapy, and GRO-A sadly died from the effects of a burst tumour days before his first planned chemotherapy appointment.
d) Did not show any urgency regarding GRO-A treatment during the period 19 August 1994 to GRO-A 1994.

6. It appears to me that GRO-A complaint about Dr. Hay raises some serious issues which, although they focus mainly on treatment afforded to one person, have wider implications, and which could therefore require us to pursue this matter in the public interest despite the age of the events complained about.

7. GRO-A complaint about Dr. Gilmore, on the other hand, does not appear to raise any issues such that the public interest requires that we consider it despite its age, as it seems to mainly focus on specific treatment issues in a limited time frame.

8. Please advise (only) whether the public interest requires that we pursue Mrs. GRO-A complaints about Drs. Hay and Gilmore through our Screening procedures despite the events giving rise to them occurring over five years ago. If you do consider that we should pursue any of GRO-A complaints I should be grateful if you would indicate on what basis we should do so.

GRO-C

Tim Cox-Brown
Caseworker, Fitness to Practise Directorate
Direct Line: GRO-C
E-mail: tcoxbrown@ GRO-C

RECEIVED
22 MAR 2004

GRO-A

16/3/04

Dear Mr Cox-Brown,

I am enclosing the following for your attention:

1) My Statement and Guide to Appendices
2) Letter to Professor Preston from C.R.M Hay
3) Letter to C.R.M Hay to Professor Preston
4) Letter from A. McKernan to Professor Preston
5) Letter from Professor Bassendine to I.T. Gilmore
6) Letter from I.T. Gilmore to Professor James
7) Liver transplant assessment

I would appreciate any comments you may have after reading the contents of the above, as I firmly believe that my husband was a victim of medical negligence.

yours sincerely

GRO-A

RE . J

2 6 May 2004

GUIDE TO APPENDICES

i) "Haemophilia and liver disease". Article written by Dr. C R M Hay. Haemophilia Society bulletin (May 1991).

ii) Royal Liverpool University Hospital medical references No 1382. Letter from Dr C R M Hay dated (7.10.91) to Professor L Klennerman requesting consideration for knee replacement operation. Statements from Dr Hay " that there are no haemotological problems " .

iii) Occasional Survey : " Progressive liver disease in Haemophilia - an understated problem?". The Lancet (June 1985).

iv) Royal Liverpool University Hospital medical reference No 724. First recorded note of existence of " liver failure " (16.1.92).

v) Royal Liverpool University Hospital medical reference No 841 . Further recorded note of existence of " liver failure " (5.5.92)

vi) "Hepatitis C: The facts" . Produced by the Haemophilia Society, in conjunction with Professor Mike Makris, of the Royal Liverpool University Hospital. Lists the timescale for consideration of liver transplant.

vii) Royal Liverpool University Hospital, medical reference No 1425. Letter from Mr. Mark Hartley, Senior Surgical Registrar, to Dr. Ian Gilmore, hepatologist, requesting his involvement with my Husband (8.6.94).

viii) Newcastle Freeman Hospital medical records, clinical record by Professor M. Bassendine, ruling out possibility of transplant. (18.8.94).

ix) Newcastle Freeman Hospital medical records, letter from Professor M. Bassendine to Dr. Ian Gilmore, confirming the existence of cancer prior to Liverpool's referal to Newcastle. (19.8.94)

x) Royal Liverpool University Hospital medical reference No. 1061. Relevant blood count test prior to Liverpool's referal to Newcastle, confirming the existence of cancerous tumor via Alpha Feto Protein reading of 9280. (15.7.94).

xi) Newcastle Feeman Hospital medical records, clinical details showing increase in cancerous tumour since Liverpool's failure to recognise it via alpha Feto Protein reading of 10,000 (23.8.94)

xii) "Hepatitis C - The facts ". Produced by the Haemophilia Society in conjunction with Professor Mike Makris of the Royal Hallamshire Hospital stating that patients with cirrhosis should be recommended for alpha feto protein test readings at four monthly intervals.

xiii) Royal Liverpool University Hospital medical reference No. 373. Original ultra sound report following liver scan in Liverpool stating existence of " Well- defined round mass (6.5cm in diameter) ". (20.7.94).

xiv) Newcastle Freeman Hospital medical records, MRI liver scan dated 16.8.94 confirming 7cm mass. likely to represent hepatoma (cancer).

xv) Royal Liverpool University Hospital medical reference No. 194. Dated (18. 6.92) - clinical confirmation listing Dr. Hay's refusal for liver work -up.

xvi) Royal Liverpool University Hospital medical reference No. 191. Discharge summary (18.6.92) detailing further refusal for liver work-up as vetoed by Dr. Hay due to "limited likely benefit".

xvii) Royal Liverpool University Hospital medical reference No. 1433/1434 letter from Dr. Hay to Professor E. Preston. Department of Haemotology, Royal Hallamashire Hospital, confirming Liverpool's failure to recognise cancerous tumour. Statement that "Alpha feto proteins have been negative" when in fact the opposite was the case.

xviii) Statement by my late Husband in his own handwriting detailing the deteriorating quality of his life in January 1994 for Social Security purposes.

xix) Royal Liverpool University Hospital medical reference No. 1409. letter of support from Dr. Hay, again for Social Security purposes, confirming poor quality of life.

xx) Letter of support from Royal Liverpool University Hospital Social Worker, Mrs. Linda Smith, confirming poor quality of life.

xxi) Personal correspondence from Dr. I. Gilmore to myself passing his condolences on my Husbands death. Statement to the effect that my Husband's "hopes were raised" by the late referral to transplant.

xxii) Correspondence between Dr. I Gilmore and Dr. C R M Hay refering to myself and my family's visit to Dr. I. Gilmore.

xxiii) Pesonal correspondence from Dr. Hay to myself.

RECEIVED
22 MAR 2004

STATEMENT

From myself, Mrs GRO-A , regarding my late husband, Mr GRO-A GRO-A (Date of Birth GRO-A 34 / Date of Death GRO-A 94) a haemophiliac, who died at the Royal Liverpool University Hospital as a result of:

i) **Hepatocellular carcinoma.**
ii) **Cirrhosis of the liver.**
iii) **Hepatitis C**
iv) **Haemophilia A.**

This statement has been made to support my pursuance of a medical negligence claim, through Irvings Solicitors, Liverpool, against the Royal Liverpool University Hospital.

After examining my late husband's medical records in detail, I wish to emphasise that it is my conviction that he was the subject of compounded medical negligence over a period of not less than 2 years and 10 months encompassing December 1991, to the date of his death, GRO-A 1994.

I have restricted details to the above period for the purposes of this statement only. I have done this both for ease and with a firm conviction that, although I am convinced my husband had certainly been the subject of medical negligence prior to December 1991, the clinical events in the last period of his life alone should provide enough evidence to substantiate my claim.

Although my statement concerns the 1991-94 period as stated, I have, as a matter of necessity, included occasional history and back-up references from prior to that period.

I base my statement around four key areas:

i) How was my husband allowed to undergo a knee-replacement operation in December 1991 when his haemotological / hepatological state clearly made him unfit for such a procedure ?

ii) Why, after diagnosis with cirrhosis of the liver in January 1992, followed by periods of oesophageal bleeding (varices), which are known indicators of the recognised medical state known as "liver failure" - which is one of the recognised starting points for consideration of liver transplantation - was all mention of such a possible procedure withheld until June 1994, when he was finally referred to a liver specialist ?

iii) Why, in July 1994, when preparations were underway to send my husband to the Freeman Hospital, Newcastle, for further tests re: a liver transplant, was the existence of cancer not noted at the RLUH ?

It is medically known that the hopes for a liver transplant are seriously undermined, if not eradicated, by cancer. My husband's cancer, as can be proved, was in existence in July 1994 in the form of a 6.5cm (diameter) tumour with an Alpha-fetoprotein reading of 9280. Liverpool's failure to spot this crucial indicator was duly noted by the clinicians in Newcastle.

iv) Why, on return to Liverpool on August 19 1994, with said tumour likely to be in excess, at that stage, of 7cm (diameter), was chemotherapy treatment not due to be administered until September 6 1994, which, as it transpired, proved to be three days after his death ?

This represents an unacceptable waiting period of 19 days for a patient with seriously defined cancer. My husband was actually discharged from the RLUH following treatment for varices just four days before his death.

---

1)

How was my husband allowed to undergo a knee-replacement operation in December 1991 when his haemotological / hepatological state clearly made him unfit for such procedure ?

In January 1992, as the medical records confirm, my husband was a patient at the Royal Liverpool University Hospital recovering from a knee-replacement operation, necessitated by his basic condition as a haemophiliac.

At this stage, and indeed for several years previously, I was inclined to believe, in the absence of information to the contrary, that my husband was free from infection due to contaminated NHS administered blood products.

We had known for some time that he was HIV negative, unlike his two haemophiliac brothers, who had both died of AIDS-related illnesses in 1989 and 1990.

We had previously been alerted to another possible blight on the haemophiliac community, known as *Hepatitis Non-a Non-b*. The existence of this disease, later to be medically defined as Hepatitis C, was brought to our attention through an article in the *Haemophilia Society* bulletin of May 1991. Ironically the article was written by Dr Charles Hay the haematologist attending to my husband.

The article (enclosed) was entitled Haemophilia and Liver Disease and was by-lined to Dr C.R.M. Hay, Director of the Mersey Region Haemophilia Centre.

The central thrust of the article, is to the effect that research, conducted over a number of years, had led to the medical conclusion that a serious hepatological problem lay in store for haemophiliacs, who had been injected with infected blood products.

The author clearly makes the distinction between NEWER and OLDER haemophiliacs. Clearly my husband fell into the OLDER category, especially as it was known that he had suffered from 'transfusion hepatitis' in the late 1970s and then again in November 1981, following transfusions accompanying a duodenal ulcer at the Royal Liverpool University Hospital.

There had clearly been some concern about the likelihood of a newer hepatological problem for haemophiliacs for some years and as Dr Hay noted in his 1991 article:

"Increasing awareness of transfusion hepatitis during the 1970s led to the universal adoption of hepatitis B testing of all blood donations and the closure of American skid-row blood banks. This greatly reduced the frequency of hepatitis B after transfusion, but had little impact on the prevalence of transfusion hepatitis as a whole, since it was usually caused by non-A non-B hepatitis.

"The hepatitis C test is only now becoming widely available after the discovery of the virus in 1989 and all blood donations will be tested for this virus within the next few months."

The article later concludes by stating:

"For newly diagnosed haemophilic patients, haemophilic liver disease is of historical interest only, since current licensed concentrates are virologically safe. For older patients, it is usually not an active concern since most will have recovered or will have mild liver disease.

"A minority of patients are at risk from more serious problems and may require treatment with alph-interferon (sic) however, even though the role of such treatment is still under investigation.

"Certainly, it is one of the functions of every haemophilia centre to monitor all patients for evidence of chronic liver disease and the clinical problems that can result from this."

Therefore, with some justification, my husband and I safely assumed, prior to his admittance for the 1991 knee operation, that such monitoring had been ongoing and in the absence of information to the contrary, that he was a suitable candidate for major surgery.

The dangers of major surgery in haemophiliacs are well known and it could be sensibly assumed that such dangers would only be compounded, especially in a haemophiliac suffering from chronic liver disease.

My husband's admittance for his knee operation is, I believe, proof that he was judged to be in an adequate hepatological state.

Medical record sheet No. 1382 (enclosed) dated October 7 1991 would appear to back this up.

A letter from Charles Hay, the Consultant Haematologist, to Prof. L Klennerman of the RLUH Orthopaedic Dept, refers specifically to the prevailing conditions governing my husband's admittance for a knee-replacement operation.

Dr Hay clearly states: "**There are no haemotological problems other than his haemophilia, so the whole thing should be very straightforward...**"

To be totally accurate there probably weren't any haemotological probelms but there most definitely were hepatological problems in existence and these most certainly were detectable.

The operation, finally carried out on December 6 1991 had clearly run into complications as early as the mid-point of January 1992.

It is now clear that those complications surfaced because such a complex operation had been carried out on a patient suffering from Hepatitis C.

Naturally extensive testing was carried out in January 1992 and on the 14th of that month, I was informed, by the RLUH, that my husband was suffering from CIRRHOSIS OF THE LIVER and it was explained to me that this had been the result of ongoing Hepatitis C (formerly non A non B), most likely the result of infected 'preheat treatment era' blood transfusions during his duodenal ulcer operation at the same hospital in November 1981.

At that point I was told that my husband's condition was terminal. His condition also explained as to why the knee-replacement had not been the success expected, and indeed I was told, that if it had been known, prior to the operation, that my husband was suffering from Hepatitis C / cirrhosis, then most certainly he would not have been allowed to undergo surgery.

I find this explanation difficult to reconcile with the extensive medical research into the likely incidence of complicated liver disease, especially in patients such as my husband.

It is difficult to accept that my husband's condition had not been monitored, especially when the haematologist in charge of him, namely Dr Hay, had carried out such extensive research and stated publicly that "it is one of the functions of every haemophilia centre to monitor all patients for evidence of chronic liver disease and the clinical problems that can result from this."

Indeed to compound the dissatisfaction with the explanation given me the RLUH, the contents of an article in *The Lancet,* of June 29 1985 (enclosed), to which Dr Hay was one of four contributing haematologists, make it doubly unsatisfactory that I learned about my husband's terminal condition at such a late stage.

The introductory summary of the article clearly states that:

"It is anticipated that liver disease in haemophiliacs will become an increasing clinical problem in the future."

It goes on to say that:

"Although few reports of death attributable to liver disease in haemophilia have appeared, we predict that this will become more common.

"The introduction of virus-free or synthetic factor VIII concentrates cannot be expected to make a significant impact for several years."

It is my contention therefore, especially in the light of such knowledge, that my husband's condition had not been monitored satisfactorily.

The key-point of proof here, I believe, was his admission for knee surgery in December 1991. Given that he was deemed to be suffering from chronic liver disease in the December, it is hard to believe that advanced cirrhosis had developed by the following 14 January - a little over a month.

Therefore it is my contention that his hepatological monitoring was grossly inadequate and as such, in my opinion, was a contributing factor in ongoing medical negligence.

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2)

Why, after diagnosis with cirrhosis of the liver in January 1992, followed by periods of oesophageal bleeding (varices), which are known indicators of the recognised medical state known as "liver failure" - the recognised starting point for consideration of liver transplantation - was all mention of such a possible procedure withheld until June 1994, when he was finally referred to a liver specialist for the first time in 2.5 years?

Having accepted, in good faith, in 1992 that my husband was suffering from cirrhosis of the liver, I enquired as to how long he would have to live. I was told by Dr Hay that his life expectancy would be "maybe 2 weeks, 2 months or 2 years - in fact, he may never leave this hospital."

No mention was ever made of a transplant or any other avenues of hope.

I was not given any supplementary information relating to the manifestations of his condition. Therefore, it was something of a shock, when the first bout of oesophageal bleeding (varices) occurred in April 1992.

My husband was admitted to the RLUH with the condition which is a known indicator of 'liver failure'. He was admitted to a high dependency unit and was in a life threatening condition for three days.

Only after he rallied and was discharged,was it that we were informed of the nature of VARICES and it was explained that from then on, he would need to undergo surgical treatment, on a regular basis, to counteract the spontaneous oesophageal bleeding.

We were, at no stage, informed that he was in the medically defined state known as LIVER FAILURE. However medical record sheet No. 724 (enclosed) dated January 16 1992, just two days after I was informed that he had Hepatitis C / cirrhosis of the liver, clearly states "liver failure".

Another sheet, No. 841 (enclosed) dated May 5 1992, again clearly lists "liver failure"

Yet not only was no mention of a liver transplant mooted, my husband incredibly was still not referred to a hepatologist.

It is my contention that clearly my husband should have been referred to a hepatologist quite some considerable time before December 1991. If not, however, then surely such action should have been taken in January 1992 following the diagnosis with Hepatitis C / cirrhosis. In the event of the abject failure to refer on either of those two occasions then quite clearly he should have been referred at the latest by April 1992 following the first varices attack.

It is known that varices is one of the classic indicators of 'advanced liver failure' and indeed the document *Hepatitis C - the facts* (enclosed) produced by the Haemophilia Society, in conjunction with Prof. Mike Makris, from the Royal Hallamshire Hospital, Sheffield, states thus.

Under the sub-heading *'Liver transplantation - when is a liver transplant considered ?'* the document states:

"Once there is advanced liver failure. Your doctor will discuss this with you if it is present. Features of liver failure include swelling of the abdomen (ascites), dilated veins (varices) in the gullet (oesophagus) which can rupture and cause vomiting of blood, or confusion (encephalopathy)."

It really is quite astonishing now to consider that my husband had reached such a stage and the possibility of a transplant was never mentioned. However it did not seem so to us at the time as the idea of a transplant had never crossed our minds as being even the remotest possibility in a haemophiliac.

It is even harder in retrospect to accept that my husband underwent two further very serious varices attacks - later on in April 1992 and then again in May 1992 and still the possibility of a transplant failed to materialise.

It is obvious to us now that such a possibility was not mentioned for the simple reason that my husband had not been referred to a hepatologist.

Only in the period after May 1992 were my husband's varices attacks controlled, by means of vein-strengthening injections (sclerotherapy), a procedure repeated at regular and frequent intervals until just 4 days before his death.

In the period between May 1992 (the control of the varices) and June 1994, in excess of two years, my husband's condition visibly deteriorated to the point where his quality of life was *nil*.

His medical records show repeated problems with a hernia, itchiness, leg ulcers, spontaneous and embarrassing tongue bleeds, ascites, acute digestive problems and chronic fatigue. All are known symptoms of advanced liver failure.

On a personal level, it was distressing for me to witness that by May 1994 my husband was longer able to wear formal clothes such was the distention of his abdomen. His only comfortable attire was loose-fitting leisure wear.

His social life, as a consequence, was completely indoors and was blighted by the tongue-bleed episodes. As a result, by that stage my husband and I were at a very depressed level such was his ongoing rapid debilitation and deterioration.

In June 1994 his condition had visibly worsened to the point where a referral to a liver specialist was medically inescapable.

It is to be noted though that medical record sheet No. 1425 (enclosed) dated June 8 1994, shows that Dr Ian Gilmore was consulted only on the advice of Mr Mark Hartley, a Senior Surgical Registrar in the RLUH Gastro' unit and not by the hematology department.

Pointedly Mr Hartley requests of Dr Gilmore:

"I would appreciate it if you could see him fairly soon in your clinic because of his discomfort."

It is important to stress here that at that point, it had not occurred to me or my husband that such, now seemingly obvious action, should have been taken at least two years earlier.

To our amazement and without any form of medical examination, Dr Gilmore immediately raised the idea of a liver transplant. In fact, Dr Gilmore, before even taking so much as my husband's temperature, informed us of exactly which hospital he wished my husband to attend - namely the Freeman Hospital, Newcastle. Consequently the process to transfer my husband to the north east began immediately.

It is my contention, that given that my husband was deemed a possible liver transplant candidate just four months before his death, that surely he should, in light of all the medical knowledge available at that time, have been considered for a transplant in January 1992.

I believe that the failure to refer my husband to a liver specialist for **TWO AND A HALF YEARS** is considerably evidential of medical negligence, especially when the idea of liver transplant was raised almost immediately upon doing so.

Serious questions must be asked as to how a University Teaching Hospital failed in such basically stark terms to a refer a patient, patently suffering with chronic liver disease, to a liver specialist for two-and-a- half years, when such a course of action would have seemed obvious even to the non-medically qualified.

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3)

Why, in July 1994, when preparations were underway to send my husband to the Freeman Hospital, Newcastle, for further tests re: a liver transplant, was the existence of cancer not noted at the RLUH ?

It is medically known that the hopes for a liver transplant are seriously undermined, if not eradicated, by cancer. My husband's cancer, as can be proved, was in existence in July 1994 in the form of a 6.5cm (diameter) tumour with an Alpha-fetoprotein reading of 9280. Liverpool's failure to spot this crucial indicator was duly noted by the clinicians in Newcastle.

After consultation with our daughter and son, my husband decided, with some degree of heightened anticipation, to undergo preliminary tests for a liver transplant.

It needs to be stressed here that the whole idea of a transplant came as a complete shock to all of the family. Essentially though, it raised all our hopes by no inconsiderable measure. Not only would it have meant that my husband's life might be prolonged, maybe for another 10-15 years but also that such a life extension could be haemophilia free, thanks to a new liver.

The massive psychological leaps here cannot be understated. The feelings of euphoria were difficult to suppress although we knew we must do so, in case our hopes were dashed. Nevertheless, we had our own confidences that, at last, our hopes and prayers were being answered and the end to my husband's suffering could well be near.

It was therefore with some anticipation that we waited for transference to Newcastle.

Shatteringly though, in early August 1994, my husband underwent a serious bout of HEPATOLOGICAL ENCEPHALOPATHY. In much the same way as I was not informed back in April 1992 about the varices attacks, I was again subjected to a quite frightening episode, whereby my husband slipped into encephalitic coma overnight, without me realising or even suspecting a problem until a very advanced comatose state had developed.

At no stage since cirrhosis was diagnosed in January 1992 were my husband and I warned about the dangers of encephalitic coma episodes.

My husband's medical records confirm that his life was seriously threatened for several hours, until the coma was eventually treated at the RLUH following his admittance to the Accident & Emergency unit.

The hospital's records will confirm that in August 1994 the A&E dept was undergoing extensive reconstruction and was in a quite chaotic state. My husband, a haemophiliac, suffering from cirrhosis of the liver, and, unknown to us at that time - the end stages of liver failure - was left on a trolley for almost six hours, whilst myself and my family were asked rudimentary questions about his health, such as "is an asthmatic ?"

Had we have been informed of the likely incidence of coma, we would have been able to inform the overstretched A&E dept staff of the true nature of my husband's condition.

Once my husband's condition eased the next day, we were left to consider what remained of the transplant possibilities.

We were informed, rather confusingly, that my husband was now in the FINAL PART of the END STAGES of LIVER FAILURE. As far as we were aware, up to that point, my husband had not even entered liver failure.

It is clear to us now that liver failure had been in existence prior to the first varices attack in April 1992. From that point onwards, his liver had entered the "end stages" process - as highlighted by varices. Indeed those end stages were now coming to a conclusion with the onset of coma. Yet my husband had only been recommended for a liver transplant five weeks earlier.

Within five days of the coma episode, my husband and I were transferred, via hospital limousine, to the Freeman Hospital, Newcastle. It is fair to say that upon leaving Liverpool, facing the unknown in strange surroundings, that we were both in quite an emotional state.

It must also be stressed that a journey, which later proved to be utterly pointless, was a very tiring endurance for my husband. It is also distressing now to reflect that it was a sheer waste of precious days.

Tests with a view to a liver transplant started immediately and were progressing well on the following Tuesday, when the transplant coordinator explained to my husband, myself and our children, who had travelled north that day, the precise details of the operation.

We were given a step-by-step introduction to the whole process, even down to the point where we were told we would be receiving a bleep in order to let us know that a donor liver had been found.

Although it would have been quite impossible for my husband to have even considered a holiday abroad - it is interesting to note that the plans for a transplant had reached such a developed stage in Newcastle that we were told that under no circumstances must my husband leave the country.

It is fair to say then that the process of preparing for a transplant had reached an advanced and very detailed stage and it was accepted by all that if a donor organ became available then my husband would undergo procedure.

The whole family was very optimistic.

It was therefore with a sickening shock, the extent of which I cannot emphasise adequately, that my husband and I learned, just hours after watching our elated children return to Liverpool full of hope, that that transplant was an impossibility because a liver scan had revealed a tumour some 7cm in diameter.

It is important to record here that when the Newcastle staff were breaking the news to us, they pointedly asked my husband how long it had been since his last liver scan. When they learned that it had only been three weeks earlier in Liverpool, they seemed more than a little surprised.

However before breaking the shattering news to us, the clinicians at Newcastle had obviously discussed the likely impact. Quite naturally they were concerned about how we would react to such news so far away from home.

As shown in the Newcastle medical records Nos 1 and 2 (enclosed), dated August 18 1994, the clinicians in Newcastle at a prior stage deliberated as to whether they should inform us of the cancer.

It is clear from the clinical notes that Newcastle had decided to discuss the findings with Dr Gilmore at Liverpool and "we will simply say we have finished assessment and will let him know outcome."

However, it is clear that this decision was reversed at some stage during the day and later notes state that "COR has informed patient and his wife," and "suggested that surgery was probably not now and option..."

It was fortunate for us that Newcastle reversed their decision and informed us, as it is quite possible that my husband and I would never have discovered that the cancer was already in existence at the time of the previous liver scan in Liverpool.

The day following Newcastle's discovery, Prof. Bassendine's letter to Dr Gilmore (enclosed) dated 19 August 1994, confirmed the existence of the tumour during the Liverpool scan.

Detailing that my husband, as part of his work-up, had an NMR scan, Prof. Bassendine reports that Newcastle had discovered "a lesion of approximately 7cm in the left lobe, possibly penetrating the capsule".

Prof. Bassendine goes on to state: "On review of his Liverpool medical records we unearthed an alpha-fetoprotein from blood taken on 15th July of 9280, confirming that he has developed a hepatocellular carcinoma on the background of his Hepatitis C cirrhosis."

Interestingly I find that Prof. Bassendine's letter revealing Liverpool's failure to spot cancer was not in the medical records file submitted to me by the RLUH. My only access to this information came via the submission of records from the Freeman Hospital.

One is left to wonder why such an important document is missing. I also find curious the remark made by Dr Hay (August 26 1994) upon my husband returning to Liverpool, insisting that there was no cancer prior to Newcastle. Indeed Dr Hay, obviously referring to the gap between the Liverpool and Newcastle scans went on to say that "a lot can happen in three weeks."

However in the records submitted from Liverpool, Sheets 106 and 373 (enclosed) confirm Prof. Bassendine's report. Sheet 106 (a blood test, taken on 18 July 1994 - 20 days prior to the encephalopathy episode) clearly shows the Alphafeto Protein level of 9280. The only medical conclusion here is that my husband was suffering from cancer.

The consultant named was C.R.M. Hay.

It must be stressed also that in the document referred to earlier Hepatitis C - The Facts, it goes on to state (enclosed): **"For people with cirrhosis, an abdominal ultrasound examination and alpha-fetoprotein determination are recommended at approximately four month intervals."**

Worse though, is the liver scan result (Sheet 373, July 20 1994 - enclosed. i.e. subsequent to the revelation of the AFP level):

Dr D.F. Walters, the Senior Registrar, reports to the named clinician, Dr I.T. Gilmore that the ultrasound has revealed "a very well defined round-mass (6.5cm in diameter) in the left lobe of the liver. This has no characteristic appearances and it is not possible to differentiate between a regenerative nodule and tumour."

At face value, this would appear to suggest that the RLUH is incapable of diagnosing cancer ? Even given the apparent identification problems, three things, in my opinion, point towards medical negligence / incompetence.

Firstly, given the medical knowledge available, the likelihood that the "very-well defined round mass..." (appearing on the the liver of a Hepatitis C suffering haemophiliac, with cirrhosis of the liver) was cancer must have been very high indeed and certainly worth consideration.

It is my firm conviction that the failure to refer my husband to a hepatologist until June 1994, the omission to explain about encephalopathy, the failure to diagnose cancer and the earlier refusal of a work-up, are all examples of ongoing medical negligence.

It is important to note that medical records 1433 and 1434, (both enclosed), which form a letter from Dr Hay to Prof. E. Preston at the Royal Hallamshire Hospital , dated 19 August 1994: Dr Hay concedes that my husband had undergone varices treatment for the last 18 months.
However, he goes on to report that my husband's "AFP have been negative and ascitic tap showed no abnormalities suggestive of underlying carcinoma". This was clearly not the case.

Interestingly Dr Hay then reports that "we have been considering hepatic transplantation with our hepatology for 2/3 months" and the delay in submission to Newcastle was down the the hepatologists "dragging their feet a bit".

It is difficult to understand as to what the purpose of this letter was, yet it clearly indicates that my husband's transference to Newcastle was too late.

Another record from my husband's file, medical record No. 1437 (enclosed), a letter from Dr Gilmore to Dr Hay, dated 20 October 1994, six weeks after my husband's death is difficult to comprehend.

Apart from the fact that it was Dr Gilmore who suggested that myself, my daughter and my son should meet him - the letter seems to indicate otherwise - it is difficult to see as to what purpose Dr Gilmore is pursuing. However, as with Dr Hay, Dr Gilmore seems to indicate that the timing of the decision to consider was husband for transplantation was far from satisfactory.

---

4)
Why, on return to Liverpool on August 19 1994, with said tumour likely to be in excess, at that stage, of 7cm (diameter), was chemotherapy treatment not due to be administered until GRO-A **1994, which, as it transpired, proved to be three days after his death ?**

This represents an unacceptable waiting period of 19 days for a patient with seriously defined cancer. My husband was actually discharged from the RLUH following treatment for varices just four days before his death.

Following my husband's return to Liverpool, after being diagnosed with cancer, it was accepted that chemotherapy would need to be administered as soon as possible.

It is unacceptable that my husband returned on 19 August 1994 and by the date of his death on 3 GRO-A 1994 he still hadn't received treatment. In fact his first chemotherapy session was not scheduled until 6 September 1994 - and may I stress that it was most disturbing to receive a telephone call from the RLUH on that day, informing me that my husband had failed to appear for his appointment.

It is difficult to accept that Newcastle were willing to keep my husband at the Freeman Hospital and commence chemotherapy treatment immediately whilst the RLUH did not consider it necessary for a further 18 days.

In Dr Hay's letter to Professor Preston (Medical Record No. 1433) , he refers to the "urgency" in sending my husband to Newcastle for transplant assessment. However, no such urgency is sensed in treating my husband for cancer, the eradication of which was the condition for a return to transplant assessments.

It is particularly unacceptable that on the Monday before my husband's death he was admitted to the RLUH for his varices to be treated. I was informed that it was the variceal check-up that forced the delay in chemotherapy as the oncologist only visited the RLUH once a week on a Tuesday.

A likely appointment for the commencement of chemotherapy on the Tuesday before my husband's death was cancelled by the variceal check-up which revealed no change in condition.

As the reports state, my husband had a level of AFP sufficient to suggest a serious cancerous growth on July 19th. yet by September 3 he had still not received any chemotherapy - a period touching on SEVEN WEEKS.

That seven week figure (at the inside) depends on my husband having achieved an AFP level @ 9280 in just one day, namely July 19. However, the likelihood is that my husband had started to develop cancer considerably earlier, which means that for the whole of the last three months of his life - and probably more - he was suffering from Hepatocellular Carcinoma and subsequently died without the relevant treatment.

I find that difficult to accept in the case of my husband, a patient who was so obviously in need of constant monitoring and who, ironically, spent most of that time in hospital.

I would refer you to the last appendices (enclosed) namely a copy of a letter, in my late husband's handwriting, detailing his general quality of life for Department of Social Security purposes and also supplementary letters of support for the authenticity of his condition from Dr Charles Hay and Mrs Linda Smith, Social worker for the RLUH.

I would stress the date of Dr Hay's letter particularly. December 1993 was still six months prior to any mention of a possible liver transplant. Yet the haematologist treating him lists all of the factors mentioned throughout this statement that are known prime indicators of liver failure.

Dr Hay makes a general point that my husband was in **"poor general health"**. To say that was an understatement is an understatement in itself.

I also refer you to the significant correspondence (enclosed) from Dr I Gilmore to myself, 9 September 1994, following my husband's death, who when referring to the late possibility of a liver transplant, states that **"it was particularly disappointing that his hopes were rasied."**

I refer also to further correspondence from Dr Gilmore, this time to Dr Hay, 20 October 1994 (enclosed)in which he seems at pains to assert that the **"timing"** of the transplant would have been **"much easier"** had we have had a (liver) centre in Liverpool.

My contention is what difference did it make to the timing of a liver transplant whether we had a centre in Liverpool ?

I also refer you finally to the correspondence from Dr Hay to myself, 21 November 1994, (enclosed).

GRO-A

May 1997.

RECEIVED
- 2 APR 2004

Tim Cox-Brown,
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General Medical Council,
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53 Fountain Street,
Manchester,
M2 2AN.

GRO-A

Liverpool,
GRO-A

Tel: GRO-C
E: GRO-C

31 March 2004.

Your reference: TCB/FPD/2004/0781

Dear Mr Cox-Brown,

Re: Dr. Charles Richard Morris Hay (and Dr Ian Gilmore).

Thank-you for your letter of 29 March 2004, detailing the requirements for pursuance of complaint. You will also note that in addition to Dr. C.R.M. Hay, I have broadened the scope of this case to include also Dr Ian Gilmore, who in 1994 was a hepatologist at the Royal Liverpool University Hospital.

Accordingly, I enclose (by hand at Fountain Street) the following relevant documentation.

1. A completed, signed, consent form, referring to Drs Hay and Gilmore, giving my approval for the GMC to disclose matters of this case to those involved.

2.1 An outline summary of the case against Dr Hay.
2.2 An outline summary of the case against Dr Gilmore.

3. A broader summary, with relevant appendices, of the scenarios relating to the treatment of my husband (GRO-A) by Drs Hay and Gilmore, particularly relating to, but not restricted to, the period of December 6 1991-September 3 1994. This document was originally written in 1997, and was used as a statement of complaint as part of a medical negligence case, conducted through my solicitors (Irvings, Liverpool) at that time.

4. Copies of all my husband's medical records.

Yours sincerely,

GRO-C

GRO-A

Enc. All above.

GENERAL MEDICAL COUNCIL

Protecting patients, guiding doctors

GMC Case Reference Number: **2004/0781**

Name of correspondent: **Mrs.** GRO-A

- Are you willing to identify the doctor? YES ☑ NO ☐
- Are you willing to allow us to disclose your letter to the doctor? YES ☑ NO ☐
- If necessary, would you be willing to be a witness at a public inquiry? YES ☑ NO ☐

Name of doctor/(s)

Dr. Charles Richard Morris Hay

DR. IAN GILMORE

Declaration

I have provided the GMC with details of the doctor(s) about whom I have written and confirm that the GMC may disclose to the doctor(s) my letter, including any supporting documents, and any further information I may send to the GMC in connection with this matter.

I understand that if I have answered no to any of the questions above, it is unlikely that the GMC will be able to take the matter forward.

Name (please print)... GRO-A .....

Signature GRO-C ..... **Date** 2.4.04

1

The case against Dr C.R.M. Hay:

There is enough empirical evidence, stretching back to at least 1985, to suggest that Dr Hay was more than fully aware of the prevailing issues, that had faced, and were facing, the haemophiliac community in the UK from the period 1975-1994. Particularly, there is precise evidence to indicate that Dr Hay had a strong knowledge of one of the headline issues, namely the prevalence of progressive liver disease as it affected haemophilic patients, which, in 1985, he queried as to whether it was actually an 'understated' matter.

I contest, therefore, that a professional, operating with the benefit of such a solid base of clinical knowledge, should not have failed to foresee, or certainly recognise, the clinical manifestations of liver disease in my haemophilic husband (Mr GRO-A as they presented themselves - often visibly - throughout the period whilst he was under the haematological care of Dr Hay.

Throughout my husband's medical history from 1978 onwards, the instances of hepatic irregularity were writ large in his records. While it is accepted that Hepatitis C was not formally identified until 1989 - but had hitherto existed under the ambiguous heading of 'Hepatitis non-A, non-B' - it could be assumed, from my husband's medical notes prior to that date, that he was in a high-risk category of having been exposed to the virus through infected NHS blood products as administered to him at NHS hospitals in Liverpool. It is the case though that a test for Hepatitis C certainly existed from the mid part of 1991 - and most definitely prior to my husband's admission to the Royal Liverpool University Hospital (RLUH) for a knee replacement operation on December 6 1991. Such a test was never conducted on, or even considered for my husband, prior to that date, despite the extreme likelihood, certainly as far as the more knowledgeable members of the medical community would have undoubtedly suspected, that he would indeed have the virus.

It was only in the prolonged and confused aftermath of my husband's knee replacement operation, wherein his progress was minimal, that such a test was undertaken (and then only after my husband had to undergo another corrective procedure in mid-January 1992) to identify the source of his problems.

From about 18 January 1992, no later, it was identified that not only was my husband suffering from Hepatitis C (most likely contracted after being treated with contaminated NHS blood products at the RLUH during a duodenal ulcer repair operation in November 1981) but that the virus had progressed, unchecked, to the point where he was also suffering cirrhosis of the liver and, at this point, according to Dr Hay verbally, he only had some 2.5 years left to live (a remarkably accurate estimation given the eventuality).

Whilst I do maintain that Dr Hay had been negligent, in the round, to this point, for failing to assess the ongoing and indeed visible deterioration of my husband's health, especially in light of the expert knowledge and suspicions that he had long since externally professed, I hold that he was pointedly negligent thereafter.

Dr Hay should, at this point, at least have: 1) referred my husband to a hepatologist; 2) helped, either solely or in conjunction with a fellow professional, to prepare my husband and I for the likely manifestations of his hepatic state (such as varices episodes, which were first terrifyingly experienced, without preparedness, in April 1992); 3) unequivocally have informed my husband and I that he was already in the clinical phase known as 'liver failure'; and 4) recommended my husband for a liver transplant.

None of the above was achieved. Consequently, my husband and I were completely unaware what was happening, even as late as August 7 1994, when he underwent an, again unprepared for, hugely traumatic episode of encephalitis.

In eventuality, my husband was NEVER referred by Dr Hay to a hepatologist - at any point, which is both astonishing as well as being grossly negligent. My husband was only finally referred to such a professional - who transpired to be Dr Ian Gilmore - by a Dr Hartley, not Dr Hay. Subsequently, I was made privy, via a third party, who can be named if so desired, that Dr Hay vehemently protested against this referral to Dr Hartley, saying (although this might not be a verbatim account) 'what do you think you can achieve for this patient that I have already failed to?'

My husband was duly referred on to Dr Gilmore and, up until this point, I hold Dr Hay solely responsible for the negligence meted out to my husband over several years at the RLUH.

From that referral point on, I hold that Dr Hay was jointly responsible, with Dr Gilmore, for the calamities that ensued between the period June 20 1994 - September 3 1994, that saw my husband - as well as suffering that encephalitis episode - be referred to the Newcastle Freeman Hospital for a prospective liver transplant, only to be returned to the RLUH as an impossible case because tests had proved that he was already suffering from cancer (with an alpha feto protein level of 100,000), and also callously disregarded for emergency treatment in the final two weeks of his life.

Although it was barely believable that my husband had been sent to Newcastle for work-ups ahead of a liver transplant when he was clearly, according to his notes, suffering from obvious cancer, no time was wasted in directing him back, in NHS transport, without delay, to the care of RLUH, where my husband presented himself on Friday 19 August 1994 - as per instructions sent from Newcastle to RLUH - only for him to learn there was no bed for him. He was dispatched home.

Whilst visiting an oncologist (Dr Smith) on Wednesday 23 August 1994, I encountered Dr Hay in the corridors of RLUH, whereupon he expressed his sympathy to me regarding me husband's state but immediately and without request defended his position to me stating categorically that 'he certainly didn't have cancer when he left here (on Saturday 13 August 1994)'.

I found this self-serving, and unsolicited, defence of his, especially at a time when vital days at the end of my husband's life were being squandered, unpalatable and negligent in their tone, intent and delivery.

An ultimately pointless varices reparation procedure was then arranged, by both Dr Hay and Dr Gilmore, for my husband on Tuesday 30 August 1994, which frustratingly meant that any administration of chemotherapy could then not be undertaken until Tuesday 6 September 1994.

My husband then died from complications arising from the bursting of his tumour on GRO-A 1994, some two weeks and one day after he had been despatched from the Newcastle Freeman Hospital for emergency treatment. I hold both Dr Hay and Dr Gilmore negligent for the inertia demonstrated in this latter period.

My pain at that time was cruelly compounded on Tuesday September 6, when Dr Smith, unwittingly, contacted me to ask me where my husband was as he had not arrived for his chemotherapy appointment.

MEDICAL PROTECTION SOCIETY

Direct Line GRO-C
Direct Claims Fax GRO-C
Secretary Nicola Oliver (9.00 – 5.30pm)

Mr Tim Cox-Brown
Caseworker
Fitness to Practise Directorate
5th Floor St James's Buildings
79 Oxford Street
Manchester M1 6FQ

Our Ref: CL/GB/540234
Your Ref:TCB/FPD/2004/0781

28th May 2004

BY FAX AND POST – GRO-C

Dear Mr Cox-Brown

Re: Dr CRM Hay

I have been instructed by Dr CRM Hay to respond to your letter of 30th April 2004.

It appears that the General Medical Council has received a complaint from Mrs GRO-A GRO-A in respect of medical treatment received by her husband between December 1991 and his death in GRO-A 1994. In a letter to the Council dated 16th March 2004 GRO-A raises allegations of "medical negligence" against Dr Hay in relation to this treatment.

On the basis of these facts alone it is submitted that this case may not be referred to the Preliminary Proceedings Committee, as more than five years have elapsed since the events in question. I refer to Rule 6(7) of the General Medical Council *Preliminary Proceedings Committee and Professional Conduct Committee* (Procedure) Rules Order of Council 1988 (as amended) which clearly states that:

"An allegation of misconduct in a case relating to conduct may not be referred to the Preliminary Proceedings Committee under this rule if, at the time the complaint was first made to the Council, more than five years had elapsed since the events giving rise to the allegation".

The purpose of the five year rule in conduct cases is understandable - to avoid prejudice to the parties and to ensure fairness in the proceedings. It is recognised that a delay in bringing a case can have a significant detrimental effect on the cogency of the evidence available; there is an inevitable dimming of the memory so that a witness's recollection of events may become less reliable with the passage of time; contemporaneous documentary evidence may be lost or no longer available several years after the event. The intention of the five year rule therefore is ultimately to uphold the integrity of the Council's own investigations and procedures.

In this case the events in question took place over 10 years ago; the case comes firmly within the five year rule and therefore, according to the Order of Council, it may not proceed.

If, contrary to Rule 6(7) this matter were referred to the Preliminary Proceedings Committee it is submitted that Dr Hay's ability to conduct his defence would be severely prejudiced by the delay. When he received the Council's letter Dr Hay called for copies of the patient's hospital records. So far only a few have been produced but having reviewed those documents Dr Hay already suspects that some of the original records have now gone missing or are lost. This is unfortunate but not entirely surprising from a document management perspective. The patient's records were voluminous. He was a haemophiliac who had contracted Hepatitis C; he suffered from numerous medical problems and was under the care of a number of specialists at more than one hospital. The matter is still under investigation but it appears quite possible that a complete set of this patient's hospital records are no longer available, which would obviously prejudice Dr Hay in his defence.

In order to defend this case Dr Hay may also need to interview and obtain evidence from the other practitioners who had responsibility for the patient during the period in question. He will have to overcome firstly the hurdle of trying to locate and identify those practitioners (who may have left the hospitals concerned and moved on). Then he will be prejudiced by the fact that those witnesses' recollection of events will inevitably have faded over the intervening 10-13 years.

As regards his own evidence Dr Hay has some recollection of this patient but freely acknowledges that his memory of events which took place over 10 years ago will not be perfect. It is similarly submitted that the Complainant's recollection of events will have dimmed over time. Sadly, it may also inevitably be the case that Mrs GRO-A memory has been influenced by her husband's subsequent demise and possibly tainted by the "conviction" she now has, that he was the victim of medical negligence.

In the circumstances, I submit that Dr Hay's ability to conduct his defence would be severely prejudiced by the delay in bringing this complaint, and it would be inappropriate and inequitable to allow the matter to proceed.

The medical screener may wish to consider whether there is an argument that this case should proceed to the Preliminary Proceedings Committee on the grounds that "public interest requires this in the exceptional circumstances of the case", pursuant to Rule 6(8). In my submission, no such argument exists in this case. The complaint concerns the management and treatment of one patient only, and concerns specifically:

- Management of the patient's knee replacement operation in December 1991,
- Management of his liver cirrhosis from January 1992,
- Management of a hepatocellular carcinoma diagnosed in 1994.

On any view these matters are private and unique to the patient in question. They do not raise wider matters of public interest. Further, whilst the circumstances of GRO-A GRO-A death were no doubt sad, they were by no means exceptional.

In my submission there could be no justification for an exceptional referral of this case to the Preliminary Proceedings Committee under Rule 6(8).

Finally, the screener should take into account the facts that:

- As far as Dr Hay is aware, the Complainant did not pursue a complaint through the hospital complaints procedure at the time,
- The Complainant has already attempted legal action in respect of these events, which failed in the late 1990's.

The statement which GRO-A has provided in support of her complaint to the Council was originally made in 1997 in support of a claim for damages for medical negligence. Dr Hay understands that GRO-A had the benefit of legal advice and assistance in investigating that claim and that an independent expert report was obtained on her behalf. That expert report was never disclosed but it must be presumed that it was unsupportive of the Complainant's case because shortly afterwards the claim was discontinued. In fact formal civil proceedings were never issued.

It is noted that the Complainant has chosen not to share a copy of that independent expert report with the Council, presumably because it does not support her position.

Thus it appears that the Complainant has already had the opportunity fully to explore the issues in this case, and she has the benefit of an independent expert report (which she has not disclosed). GRO-A is now trying to open the same allegations and explore the same issues, through the General Medical Council. It is submitted that this is inappropriate and an unreasonable waste of the Council's time.

Dr Hay would like to make it clear that he firmly refutes all the allegations and criticisms made by the Complainant, and reserves all his rights to provide comments on the substantive issues if this proves necessary. As a preliminary issue however it is submitted that the screener should have regard to the five year rule and properly conclude that no further action can be taken, and this enquiry should be brought to an end.

Yours sincerely

GRO-C

Catherine Longstaff
Solicitor
Claims and Legal Services Division

RECEIVED

15 JUN 2004

Reference: TCB/FPD/2004/0781

Mr Tim Cox-Brown,
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GRO-A

Liverpool,
GRO-A

Tel: GRO-A

15th June 2004

Dear Mr Cox-Brown,

Re: Dr CRM Hay

I thank-you for your correspondence of 2nd June 2004 informing me of, and enclosing, the response of the Medical Protection Society, written 28th May 2004 and received by you on June 2nd 2004, in relation to the above doctor.

I acknowledge also your invitation to respond to that response by June 16th 2004 and confirm that this letter will form the structure of my comments. I understand that, subsequently, Dr Hay's counsel will be invited to comment further.

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1. By way of explanation as to the structure of this letter, I wish to stress that, purely for cohesiveness, I will respond to the points raised by Dr Hay's counsel, Ms Longstaff, only in the order she presents and in no way should it be interpreted that I have addressed matters in order of priority.

Ms Longstaff states at the start of her response that my complaint is in respect of treatment received by my late husband 'between December 1991 and his death in GRO-A 1994'. Whilst I broadly agree with this, I do wish to emphasise that those bookended dates are purely for simplicity, in a massively complex wider matter, as I submit that the events within that period and the evidence that exists as confirmation, are sufficient enough to support my contention of medical negligence on the part of Dr Hay against my husband.

However, you will note from my earlier submission, and indeed on several occasions in this response, that it is often necessary to refer back to before that period, in order to contextualise matters. I reserve my right to do this, where it is both necessary and appropriate, and I do not wish it to be assumed that I am only to mention events between 1991 and 1994 to the exclusion of all else.

2. Ms Longstaff states:

On the basis of these facts alone it is submitted that this case may not be referred to the Preliminary Proceedings Committee, as more than five years have elapsed since the events in question. I refer to rule 6(7) of the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988 (as amended) which clearly states that:

"An allegation of misconduct in a case relating to conduct may not be referred to the Preliminary Proceedings Committee under this rule if, at the time the complaint was first made to the Council, more than five years had elapsed since the events giving rise to the allegation".

The purpose of the five year rule in conduct cases is understandable - to avoid prejudice to the parties and to ensure fairness in the proceedings. It is recognised that a delay in bringing a case can have a significant detrimental effect on the cogency of the evidence available; there is an inevitable dimming of the memory so that a witness's recollection of events may become less reliable with the passage of time; contemporaneous documentary evidence may be lost or no longer available several years after the event. The intention of the five year rule therefore is ultimately to uphold the integrity of the Council's own investigations and procedures.

In this case the events in question took place over 10 years ago; the case comes firmly within the five year rule and therefore, according to the Order of Council, it may not proceed.

While I can entirely understand Ms Longstaff's recourse to the 'five year rule', which she seeks to do throughout her response, as reason for non-referral - indeed I fully expected her to cite such, which was first drawn to my attention by yourself in your correspondence to me of 29th March 2004 and again on 30th April 2004 - I rather feel this is attempting to force the matter back a few steps.

I fully understood your explicit reference to the possibility that the five year rule might be invoked when it was first made by you and I appreciated also that the lengthy and comprehensive submission that I hand-delivered to your office, on March 31st 2004, might ultimately be in-vain, if the medical screener were to block its passage. As such, I was fully prepared up to that point to invest time in what I knew may eventually prove to have been a wasted exercise.

Consequently, you will appreciate how re-assured I was, following your correspondence on 30th April 2004, informing me that the medical screener, no doubt fully in possession of the rules governing referral, had, as quoted, decided that 'involvement is merited regarding your complaint about Dr Hay'.

To this end, I would now be very disappointed, especially after the formulation of this considered response to Ms Longstaff's submission, to learn that the matter is to stop here.

Furthermore, I can only assume the decision to approve referral of my case against Dr Hay to the next stage was made by the screener following an in-depth consideration of the evidence, particularly as the screener had, at the same time, decided that the extent of the investigation

must be narrowed to Dr Hay (you will recall my initial request that this matter be wider). Therefore, it would be reasonable to assume that the screener has made a fully lucid decision to approve involvement so far in the case against Dr Hay.

Although I am not familiar with the rules of the General Medical Council, it is my lay assumption that this, no doubt necessary, hurdle has now been cleared; although, of course, I stand to be corrected. Therefore, my understanding is that Ms Longstaff's repeated appeals for the five year rule to be invoked are after the matter.

Nevertheless, regardless of whether my understanding is misplaced or not, it is my submission that whatever conclusion the screener initially reached, by agreeing to further the case against Dr Hay, should continue to prevail and influence the progress of this matter further, as I can only conclude that the considerable evidence I supplied was substantial enough to merit the case progressing thus far.

While I therefore reject Ms Longstaff's attempted invocation of the five year rule, I share her view that 'the purpose' of it is 'understandable' - as it seeks to 'avoid prejudice' and 'ensure fairness in the proceedings'. I wish to assure you, and, by proxy, Ms Longstaff and Dr Hay, that I too wish to avoid such prejudice and achieve such fairness. It is my view, though, that there is enough documentary evidence alone to ensure that, even if the five year rule were to be waived, a non-prejudicial and unquestionably fair investigation can easily be conducted.

Furthermore, I reject, completely, Ms Longstaff's contention that the 'delay' (although I suggest 'time lapse' is a more appropriate description) in bringing this case would have a 'significant detrimental effect' on the cogency of the evidence available. I can assure you that the powerfully convincing nature of the documentary evidence is such that it cannot be diminished, even minutely, let alone to any significant detriment, by any passage of time.

Equally, I wish to stress that there is no 'inevitable dimming of the memory' as far as my recollection of events is concerned; and in no way has the passage of time rendered my recollection of events any less reliable now as a decade ago. However, if Ms Longstaff is alluding to the possibility, but certainly not an 'inevitability', that witnesses other than myself may experience 'dimming of the memory', then again I can assure you the cogency of the documentary evidence available is more than enough to compensate for any human failings that may, or may not, occur.

Similarly, Ms Longstaff's, understandable, concerns that 'contemporaneous documentary evidence may be lost or no longer available several years after the event,' can easily be allayed. For, even if Dr Hay has struggled so far to obtain certain documents, it is somewhat of a relief, especially in light of the need to achieve a fair and unprejudiced investigation, to remind you that a full set of my husband's medical records does exist, a copy of which is currently in your stewardship at Manchester, as obtained by me several years ago.

Nevertheless, Ms Longstaff makes a valid point, for I have always been able to ascertain, rather than merely suspect, that some documents were indeed missing from my husband's files - even at such a relatively early stage of acquisition by me. But these were so few as to be actually

more conspicuous by their absence rather than their absence blurring the overall picture of my husband's case. For example, the results of repeat liver function tests and of an alpha feto protein test, requested on March 10th 1993, by a medic other than Dr Hay (namely Prof. Shields), which may have proved my husband had cancer far earlier than suspected (see several later references in this letter) have never appeared in my husband's files, despite my relatively early acquisition of his records. Nevertheless, it has always been something of a relief to me - and to Ms Longstaff and Dr Hay now, no doubt - that a fully illustrative picture of the management of my husband can still be drawn from the copious notes that do remain.

Having said that, it was a deep concern to me several years ago that those few certain documents relating to my husband were clearly missing and it is even more disconcerting now to learn, from Dr Hay's experiences, that the reverse is actually now true and so few of them remain lodged where they should be.

So, whilst I support Ms Longstaff's reported view, if it is correct and I have no reason to doubt it, that the 'intention' of the five year rule is to 'uphold the integrity of the Council's own investigations and proceedings,' I wish to assure you that the waiving of the rule, in this instance, is entirely safe, especially based on the cogency of the documentary evidence still available.

I note with interest, though, the absolute tone of Ms Longstaff when she submits that this case, according to the Order of the Council, 'may not proceed'. If this matter were as *fait accompli* as is presented by Ms Longstaff, then I would have fully expected her to end her submission there and then. However, I note that Ms Longstaff continues her submission to quite some considerable length and I am left to query as to why. I can therefore only assume that the rules of referral are not as absolute as Ms Longstaff makes out and a facility to override the five year rule, when it is deemed appropriate, does exist.

I wish to re-affirm my contention, then, that this is just such a case in point and re-iterate that, whatever judgement was made earlier by the screener, in order to let the matter proceed thus far, should continue to prevail and influence its progression.

3. Ms Longstaff states:

If contrary to Rule 6(7) this matter were referred to the Preliminary Proceedings Committee it is submitted that Dr Hay's ability to conduct his defence would be severely prejudiced by the delay. When he received the Council's letter Dr Hay called for copies of the patient's hospital records. So far only a few have been produced but having reviewed those documents Dr Hay already suspects that some of the original records have now gone missing or are lost. This is unfortunate but not entirely surprising from a document management perspective. The patient's records were voluminous. He was a haemophiliac who had contracted Hepatitis C; he suffered from numerous medical problems and was under the care of a number of specialists at more than one hospital. The matter is still under investigation but it appears quite possible that a complete set of this patient's hospital records are no longer available, which would obviously prejudice Dr Hay in his defence.

I can only assume that the considerable continuation of Ms Longstaff's response is an indicator

that she is fully aware that the matter can progress and, indeed, her view that it could be referred despite, in her words, being 'contrary' to Rule 6(7), is a further implicit indicator, not only that such a facility exists, but that she is also aware it does.

Again Ms Longstaff suggests that Dr Hay's 'ability to conduct his defence would be severely prejudiced'. Whilst I can certainly appreciate Ms Longstaff's anxieties, I can only again emphasise that evidence exists of such a magnitude that it would eradicate any concerns that the unfortunate time lapse - but certainly not a delay - might diminish fairness.

It is re-assuring to learn that Dr Hay sought recourse to my husband's medical notes; I would expect this to be so. Having said that, I find it wholly inadequate that Ms Longstaff has felt it appropriate, *at this point*, to submit Dr Hay's, presumably considered, submission, having only read 'a few' of the documents that 'have been produced'. As is learned later in Ms Longstaff's response, Dr Hay is refuting all the allegations made against him. Whilst this comes as no surprise to me, it is a standpoint which I find impossible for him to maintain and, in any case, one which he would readily abandon as, despite any 'dimming of the memory' that he may or may not experience, documentary evidence will show his position to be baseless. Therefore, I find it shocking that Dr Hay is content enough to continue his intransigence having admitted to only reading 'a few' of the documents, as though that were enough to trigger Ms Longstaff's response. I can only interpret this most negatively. I find it arrogant. It is clear to me that Dr Hay does not think this matter serious enough to warrant further investigations *prior* to his counsel submitting a response. It rather smacks of hoping a swift response ensures the matter gets swept under the carpet before tedious concerted efforts are expended.

I would have hoped, at this stage, that I would not be having to address half-measures or conjecture; so it is with some frustration that I learn that not only has Dr Hay made his response on the reading of a only 'a few' documents but that he 'already suspects' that some are 'missing' or 'lost'. The realm of suspicion is not something I regard appropriate to a case of such import and I find it insulting that Dr Hay sees fit to deal, even at this point, in speculation. At this point in proceedings, it is my submission that to merely 'suspect' documents are missing is not adequate enough. On what grounds are such, quite disconcerting if true, suspicions made? Are there some documents missing or aren't there? Which documents are they? How can Dr Hay possibly identify them in their absence - especially after such a passage of time? What is it that leads Dr Hay to form his suspicions?

I agree, once again, with Ms Longstaff's view that it is 'unfortunate' that, as it appears, at least based on mere suspicion anyway, that some documents are missing; and I can only again re-assure you that such fears can immediately be allayed. However, I find it deeply disconcerting, on a broader point, how easily and blithely Ms Longstaff seems to accept the assumption that some documents are missing and I find it disturbing that her viewpoint, whether formed through instinct or experience, of the document management procedures at the NHS, is clearly so dim.

I wonder how it is, though, that Ms Longstaff *knows* my husband's medical records were 'voluminous', when, in fact, only 'a few' have been produced? I can only assume it is instinct - perhaps based on the complexities of my husband's condition - which tells Ms Longstaff that my

husband's records were likely to have been voluminous; for, of course, she couldn't know this as fact from knowing that only a 'few' have been produced. It is her factual statement, despite suspicions that some documents are missing, that they were indeed so voluminous, which I find curious. Either she knows them to be voluminous or she doesn't? Surely it should be more a case that she can only 'suspect' them to be voluminous? It appears though that Ms Longstaff *knows* them to be voluminous - and it is indeed a correct assertion - but I find it somewhat contradictory that she can factually reach this conclusion in light of only 'a few' records having been located.

I also find it not a little disingenuous of Ms Longstaff to state that my husband was 'under the care of a number of specialists at more than one hospital'. Aside from the fact that I don't understand how she can make such a statement on the basis of only 'a few' documents having been located (and as Ms Longstaff has stated, we are referring, in the main, but not exclusively to, the period 1991-94), this is a gross distortion of facts.

It had been the case from the middle of the 1980s, almost exclusively, that my husband was under the care of Dr Hay at the Royal Liverpool University Hospital (RLUH) only. Indeed, since my husband was referred from Broadgreen Hospital, in November 1981, to the RLUH, for an operation to repair his duodenal ulcer (during which, it is roundly suspected, he contracted Hepatitis C from infected NHS blood products), he was never again an in-patient at another hospital until three weeks prior to his death - and then only for five days.

Furthermore, aside from necessary instances during the period immediately following his knee repair operation, in December 1991, in the aftermath of which his Hepatitis C positive status and his cirrhosis of the liver were diagnosed, for example the temporary involvement of orthopaedic professionals, my husband was under the constant care of Dr Hay from the mid-1980s to April 1992. Only then, in April 1992, when my husband suffered his first bout of varices - which, despite the existence, in any case, of cirrhosis, are a recognised indicator, certainly in someone like my husband, of liver failure - was my husband managed by someone other than Dr Hay, namely the gastro unit at the RLUH. Then, aside from recorded episodic instances of varices repair treatment, between April 1992 and June 1994, my husband was in the continuous and arch care of Dr Hay, until, at evidently too late a stage in June of that year, Dr Ian Gilmore was brought in.

As I have submitted in earlier correspondence, Drs Hay and Gilmore could then be assumed to be in the joint care of my husband, certainly only at the RLUH, until he was dispatched to the Newcastle Freeman Hospital - despite evidence to prove that he was already suffering from cancer, with an alpha feto protein taken three days later showing a reading of >100.000 micrograms per litre - for work-ups ahead of a prospective liver transplant. As stated, my husband was in the care of the medics at Newcastle for only five days until he was dispatched back to the RLUH as being so evidently unfit to travel, let alone to undergo a liver transplant.

Therefore, to put things into clearer perspective than Ms Longstaff does, my husband was under the care of the RLUH from the mid-1980s until his death in GRO-A 1994, except for a five day period. Also, within that period, my husband was unquestionably in the care of Dr Hay. Dr Hay also held a veto on the management of my husband. An example of this veto is

given by Dr Hay's overriding of Professor Shields, in June 1992 - some six months after Hepatitis C and cirrhosis of the liver were diagnosed and within two months of my husband's first varices episode - when he actively blocked elective tests, as suggested by Professor Shields, to conduct a 'full liver work-up'. This episode even saw my husband actually being admitted to the RLUH on June 7th only to be sent home the next day after receiving apologies from Prof. Shields' team for the inconvenience caused. My husband's medical notes show that Dr Hay was not happy for this liver work-up to be conducted, despite the known extent at that time of my husband's worsening liver disease.

Only in the final three months of my husband's life could Dr Hay realistically contend that he shared care responsibility with another specialist and that was Dr Gilmore.

Therefore, Ms Longstaff's contention that my husband was under the care of specialists other than my husband - which although it could be borne out on a pedantic technicality if Dr Hay sought to be so obstructive - is a tenuous submission and far removed from the reality of the situation.

Dr Hay knows that my husband was almost constantly under his care for a significantly prolonged period from the middle of the 1980s until his death in 1994 and to suggest otherwise - especially 'at more than one hospital' - is a gross distortion which is obviously borne out of an intention to deflect blame; a tactic which, as you will see later in this response, in the shape of his letter to Prof. Preston, Dr Hay has arguably sought to use before.

The inherent irony in Ms Longstaff's statement is such that I could only have wished that my husband were indeed in the care of more than one specialist, as it may have ensured that his hepatic state wasn't allowed to deteriorate to the state of cirrhosis, varices and beyond, before he was finally referred to a hepatologist and then not even at the behest of Dr Hay.

May I just again, at this point, re-emphasise these incontrovertible facts; namely that: between 1989 and 1992 Dr Hay failed to monitor my husband's hepatitis status; also that, after overseeing the diagnosis of Hepatitis C and cirrhosis of the liver on my husband, in January 1992, Dr Hay singularly failed, at any point prior to his death 33 months later, to refer his patient to a liver specialist; during this period, Dr Hay also wilfully obstructed a full liver work-up from being conducted on my husband; also the fact that my husband was finally referred to such a liver specialist (Dr Gilmore) in June 1994 was only at the behest of another medic.

Had it simply not occurred to a man who was internationally recognised as an expert in haematology and the hepatic irregularities that had beset the haemophiliac community, that his patient, whose notes, stretching back several years, confirmed bouts of Hepatitis A and B and a recording of Hepatitis Non-A, Non-B, who, in any case, went on to be diagnosed with Hepatitis C, then to develop cirrhosis of the liver, varices, and pronounced aescites, and many other complications besides, was in the need of a liver specialist? It simply didn't occur to him? A trained medical professional? Really? Sadly, it would appear so and I readily submit these base facts alone as among the central tenets of my submission of sustained medical negligence on the part of Dr Hay in his care of my husband.

I am at least re-assured that the apparent disappearance of my husband's medical records is 'still under investigation' but wish to stress that there need be no further fear that a complete set of my husband's records are no longer available. In any case, a full set of these records is held at your offices and therefore any anxieties Ms Longstaff has that Dr Hay's defence would be prejudiced on the grounds of lost evidence can, fortunately, be allayed.

4. Ms Longstaff states:

In order to defend this case Dr Hay may also need to interview and obtain evidence from the other practitioners who had responsibility for the patient during the period in question. He will have to overcome firstly the hurdle of trying to locate and identify those practitioners (who may have left the hospitals concerned and moved on). Then he will be prejudiced by the fact that those witnesses' recollection of events will inevitably have faded over the intervening 10-13 years.

I would not dispute that Dr Hay may need to interview and obtain evidence from other practitioners - however any emphasis that they would have held 'responsibility' for my husband is entirely rejected. This is purely a matter for Dr Hay and his counsel to decide. However, it would be my instinct that such practitioners, given the time passage that Ms Longstaff is so acutely aware of, would immediately seek recourse to my husband's medical notes as evidence. I have stressed earlier that this body of documentary evidence is of such quality that it would render any personal recollections as purely supplementary. However, if Dr Hay is keen to acquire such evidence then that, of course, is his right, to which I have no objection.

Nevertheless, I feel it to be rather overstating the case, to some significant degree, to allege that Dr Hay will have to 'overcome...the hurdle' of contacting and identifying those practitioners. I would submit that, in a highly networked world, with a rich choice of communications tools at our disposal, there will be little trouble in locating these practitioners and any assertion that there would be is wholly rejected. In any case, the matter of 'identification' is easy, as the case notes of my husband clearly name the practitioners who were party to - but by no means responsible for - my husband's care. I would indeed be very much surprised if some of the practitioners hadn't moved-on, as Dr Hay himself did very shortly after my husband's death, but again I submit that it is a relatively straightforward exercise, and certainly not a hurdle to overcome, in order to locate these people.

I also dispute the absolute tones of Ms Longstaff when she submits that Dr Hay will be prejudiced by 'the fact' that those witnesses' recollection of events 'will inevitably have faded'. It is neither fact nor an inevitability that these witnesses will experience memory 'fade'. They might. They might not. It is not, though, a fact that they have or will. In any case, it is again my submission that this concern too can be easily allayed given the quality and the extent of the materials available as evidence.

5. Ms Longstaff states:

As regards his own evidence Dr Hay has some recollection of this patient but freely acknowledges that his memory of events which took place over 10 years ago will not be perfect. It is similarly submitted that the Complainant's recollection of events will have dimmed over time. Sadly, it may also inevitably be the case

that GRO-A *memory has been influenced by her husband's subsequent demise and possibly tainted by the "conviction" she now has, that he was the victim of medical negligence.*

It is deeply disappointing to learn that Dr Hay only has 'some recollection' of my husband, a man who, after all, was in his care for so very long, and suffered a multitude of traumatic complexities at a time when the events that were unfolding throughout the haemophiliac community were truly shocking. Nevertheless, I have to accept that such is the case, and that the gravity and tragedy of my husband's suffering were not of such depth that they became indelible in the memory of his carer. I am, at least, grateful that Dr Hay, despite the evidently erosive effects of a decade, has 'some recollection' of my husband.

Accepting that reality, however reluctantly, in no way indicates that I too am suffering from faded memory concerning the events that led to my husband's untimely death. I emphatically reject, and am deeply insulted by, Ms Longstaff's submission that my recollection of events has dimmed over time. I can assure Ms Longstaff that the tragedy that lay behind my husband's death was of such magnitude and distress that even the minutiae of events between 1991 and 1994, if not earlier, are seared into the memory of myself and my two children, who were grown adults at the time.

For a decade now, I have had little choice but to regularly revisit the precise details of my husband's case - and indeed was doing so very shortly after his death - and so I can assure Ms Longstaff that my recollection and knowledge of those events has actually deepened rather than shallowed. I utterly reject Ms Longstaff's iteration that my recollection 'will' have dimmed. It is another instance of Ms Longstaff passing conjecture off as absolute fact. Yet even were it the case that Ms Longstaff had modified her language to instead submit that my recollection 'may' have dimmed, I can assure you, most categorically, that it has not.

Insulted as I am by Ms Longstaff's earlier phrase, it is nothing compared to the repugnance I feel at her clumsily phrased submission that my memory may inevitably have been influenced by my husband's 'subsequent demise' (read death) and 'possibly tainted by the "conviction",' I have that he was a victim of medical negligence.

I wish to stress at this juncture, to the parties involved in this case, that they should not lose sight of the tragedy and trauma I have had to endure for over a decade now. Ms Longstaff's choice of language and questionable punctuation emphases are unwarranted in this case. Aside from the fact that I reject her crass submission - again if only because the medical evidence is sufficient to back up my claims even were my lucidity to be questioned - I would request that whichever way this matter progresses, a degree of tonal respect is appropriate in general submissions.

6. Ms Longstaff states:

In the circumstances, I submit that Dr Hay's ability to conduct his defence would be severely prejudiced by the delay in bringing this complaint and it would be inappropriate and inequitable to allow the matter to proceed.

I believe I have amply outlined that any such fears Dr Hay has about his ability to conduct an unprejudiced defence can be completely allayed. Furthermore, I reject Ms Longstaff's assertion of inappropriateness and inequitability and submit that it actually would be inappropriate and inequitable for this matter not to proceed.

7. Ms Longstaff states:

The medical screener may wish to consider whether there is an argument that this case should proceed to the Preliminary Proceedings Committee on the grounds that "public interest requires this in the exceptional circumstances of this case", pursuant to Rule 6(8). In my submission, no such argument exists in this case. The complaint concerns the management and treatment of one patient only, and concerns specifically:

- *Management of the patient's knee replacement operation in December 1991,*
- *Management of his liver cirrhosis from January 1992,*
- *Management of a hepatocellular carcinoma diagnosed in 1994.*

On any view these matters are private and unique to the patient in question. They do not raise wider matters of public interest. Further, while the circumstances of GRO-A *death were no doubt sad, they were by no means exceptional.*

I was not surprised that Ms Longstaff recoursed to the 'public interest' and 'exceptional' requirements of the Council's rules on referral. You will recall that in your correspondence of March 29th you enclosed a general synopsis of the Council's scope of powers and interest. Aside from the fact that I will go on to demonstrate the exceptional nature of my husband's case, if, in fact, I haven't already done so, it was the fulfilment of 'public interest' that I paid particular attention to.

Consequently, I gave due and appropriate consideration to this aspect before furthering my submissions to you. Subsequently, I made reference to the fact that Dr Hay, since the mid-1980s at least, has been held in high regard across the international haematological community for both his perceived expertise in this field and also where it has tragically overlapped, over the last two decades, with the hepatological field, most specifically because of the consequential hepatic irregularities experienced by haemophiliacs in the wake of being infected by contaminated NHS blood products.

To substantiate this submission I use two examples.

Firstly, you have in your possession a copy of a medical paper, written for The Lancet, 19 years ago by Dr Hay, in a period when the medical realities of HIV, let alone HCV, were still emerging. It was even less appreciated, in the round anyway, how these diseases would affect the haemophiliac community. Regardless of the nascent general understanding of such matters at that time, Dr Hay, when writing for The Lancet, demonstrated considerable foresight, knowledge and expertise, not only in the field of haematology but also in hepatology with particular reference to haemophiliacs and the likelihood that many of them will have contracted HCV as a result of treatment with contaminated products. In fact, as you will see,

Dr Hay further demonstrates his awareness and concerns of this matter to the extent that he saw fit to title-headline the article with the query that the problem, as it was perceived in 1985, was actually an 'understated' one.

It is reasonable to assume that in the wake of this article, if not before - which in actual fact has proved remarkably, if tragically, prescient - Dr Hay's adjudged standing in his respected field rose considerably.

It is therefore with a sense of deep irony, frustration and no little concern, that I now am forced to review Dr Hay's management of my husband, from some six years after that article was written, and in a period which post-dated, by two years, the clinical identification of Hepatitis C, as opposed to its previous ambiguous standing as Hepatitis Non-A, Non-B. How, if it wasn't an oversight on a scale of such frightening magnitude that it could only constitute negligence, did a respected expert such as Dr Hay fail to notice, under his own care, a manifest portrayal, in the shape of my husband's complexities, the very things that he had forewarned of some six years earlier?

This alone merits an inquiry into negligent management. Also, it singularly demonstrates, not only the need for such an investigation on the grounds of both equitability and appropriateness, but also that the public interest demands it, so exceptional were the circumstances of my husband's fatal decline over a period of not less than 35 months leading up to September 1994.

Did it simply not occur to this leading field expert, that his patient, of whom he now only has 'some recollection', might be suffering from chronic liver disease? How, also, is it that, six years after Dr Hay wrote that article, he could also write, in my husband's medical notes - in the wake of his Hepatitis C and cirrhosis of the liver being diagnosed following his knee repair operation in December 1991 - that had he known of the 'severity' of my husband's hepatic state that he wouldn't have considered him suitable for such surgery?

Following this, how, also, was it that such a professed expert, then knowing his patient to be suffering from both Hepatitis C and related cirrhosis of the liver, singularly failed to refer him to a liver specialist at any point? Further, how was it that, as is shown in the case notes, this expert, being fully cognisant of his patient's chronic liver deterioration, which had further manifested itself in the shape of varices and aescites, wilfully obstructed the acquisition of advanced hepatological information, even when this was recommended by his collegues as being appropriate in the shape of a full liver work-up in June 1992, some two years before my husband was eventually referred, evidently too late, for a liver transplant?

Even further, how was it that such an expert, even knowing his patient was suffering so much that he was eventually, and terrifyingly, rendered comatose - without any forewarning as to the possibility - due to an episode of encephalopathy, failed at least once, and possibly twice, to recognise clinical indicators in the shape of positive alpha feto protein readings which clearly showed him to be suffering from liver cancer and therefore so obviously unfit for a liver transplant?

It is my submission that Dr Hay failed at every single critical juncture in the management of my husband. He either did so wilfully, in which case negligence would be starkly clear, or he did it out of incompetence, which again would lead to negligence. There can be no other conclusions. For such an esteemed expert to oversee even one of the above related episodes, before then correctly seeing his error and referring his patient to an appropriate specialist, would be considered negligent. But for it to happen repeatedly, even when there was a chance to refer him on, thanks to a colleague's recommendations, over such a protracted period of time, would defy belief were it not true.

The case for this matter to be referred on the basis of it being 'in the public interest' is therefore clear.

Among questions that must be asked are:

Was Dr Hay's management of my husband typical of his care of others? If it wasn't, then why was my husband so unequivocally overlooked time and again? Further, although he has only 'some recollection' of this patient - which I simply believe not to be true - would Dr Hay manage him so again, given the chance? If not, then why was my husband managed so?

Secondly, I make reference to the book 'A Case of Bad Blood' (Author - Rosemary Daly; Poolbeg, published 2003) which examined the tragedy that befell the Irish haemophiliac community following treatment with contaminated health service blood products.

Referring to the ongoing efforts of campaigners, particularly the Irish Haemophiliac Society (IHS) for whom the author worked, to raise public awareness of this tragedy, the book states on Pg 83-84 of the 2003 paperback edition:

In 1989, the Non-A Non-B virus was finally isolated and identified. As they already had hepatitis A and hepatitis B, the scientific community named it hepatitis C. We were taking more of an interest in it by this stage and seeking information where we could. In October 1989, we used our AGM as an opportunity to invite a UK expert on hepatitis (sic), Dr Charles Hay. He said, in his view, the hepatitis C virus was so closely associated with concentrated clotting-agents that most people with haemophilia had contracted it after their first injection.

I can only assume, although I stand to be corrected, that this is the same Dr Charles Hay as is being referred to in my submission.

It is clear then that, in the years since he wrote his paper for The Lancet, in 1985, Dr Hay was still not only taking a sustained and studied interest in the hepatological state of haemophiliacs but that his public reputation as an expert on such matters, both in the UK and beyond, was strengthening.

At the time of his attendance at that AGM in Ireland in 1989, if the author's version is accurate, my husband was under the direct care of the esteemed Dr Hay. Instead of finding himself fortunate to be in the care of such an expert, it would appear that my husband failed to benefit, repeatedly, from his carer's, presumably considerable, expertise.

It is clear then that either Dr Hay, given his management of my husband, didn't warrant to be held in such high esteem - in which case the public interest demands an explanation; or, in fact, Dr Hay was indeed deserving of such stature but he somehow failed to translate his knowledge into care regarding my husband. Either way, it is clear that an investigation is warranted on the grounds of public interest.

As an adjunct at this point, it is also interesting to note that the paragraph immediately subsequent to the referral to Dr Hay in 'A Case of Bad Blood', relates how the IHS 'brought in another expert', Prof. Eric Preston, to discuss developments. I only make reference to this as it was ironic that it was to Prof. Preston that Dr Hay pointedly wrote, on 18th August 1994, a day after my husband had been diagnosed with liver cancer at the Newcastle Freeman Hospital, and also, no doubt, as my husband and I were having to travel south, back to the RLUH trying in vain to absorb the devastation of the previous 24 hours. I include, for your ease of reference, the full transcript of Dr Hay's letter.

(19 August 1994) *Dear Eric,*

Re: GRO-A

Diagnosis - *Severe haemophilia*
Hepatitis C
Decompensated cirrhosis of the liver
Oesophageal varices
Hepatocellular carcinoma

I am just writing to you about this patient for information. GRO-A *is one of three haemophiliac brothers, the other two of whom were HIV positive and died of AIDS.*

GRO-A *has been known to have cirrhosis for some time, and we have been injecting his varices quite successfully for the last 18 months.*

His aescites has developed over the last year, and was quite easy to control until very recently.

Alpha feto proteins have been negative and an aescitic tap showed no abnormalities suggestive of underlying carcinoma.

We have been considering hepatic transplantation with our hepatologists for two or three months in view of his deteriorating quality of life, and my general feeling that his prognosis was poor and they had been dragging their feet a bit.

He was admitted with his first episode of hepatic encephalopathy only 10 days ago and his aescites was even more difficult to keep under control, at which point (I was on holiday), they finally sent him up to Newcastle for urgent assessment for liver transplant.

They have just sent him back and tell us that he has hepatic cellular carcinoma. We are planning cytoreductive chemotherapy, following which they will reconsider him for transplantation.

I am sure this is a complication we shall see more of, but since the numbers are currently low I felt I should let you know.

It is ironic that I received this bad news while going through Mike Makris' thesis!

With best wishes - yours sincerely

Charlie

pc: Dr P Giagrande, Oxford.

You will note that Dr Hay, understandably, places my husband in the immediate context of being one of three haemophiliac brothers - all of whom were cared for by Dr Hay, and all of whom were wiped out through either AIDS or HCV following treatment with contaminated blood products. It is no surprise that Dr Hay should contextualise as such. At the time, the tragedy of my husband and his brothers, as their deaths unfolded over a five year period from 1989, was a well referenced case in the medical community. Since the death of my husband, the case of 'the three brothers', as it is often referred to, has been quoted across many national media outlets and indeed has been referred to in both Houses of Parliament. I only make this reference to put further into perspective Ms Longstaff's contention that Dr Hay only has 'some recollection' of my husband, which I don't believe to be the case.

You will also note that Dr Hay asserts that my husband's alpha feto protein levels 'have been negative'. Given that my husband had already been dispatched back to the RLUH from Newcastle Freeman Hospital with an alpha feto protein reading of >100.000 micrograms per litre, I find it incredulous to read Dr Hay's assertion. I also wonder what his motivation was for saying so, at that time, especially only some 24 hours - at the very most - after he had learned that my husband had cancer? Surely it would have been more useful for Prof. Preston to be informed of my husband's current alpha feto protein levels, rather than the totally ambiguous assertion that they 'have been negative'? What timescale is Dr Hay putting on this? Is he, in fact, still asserting that they 'have been negative' up to the point of writing?

In actual fact, my husband already had an alpha feto protein reading of 9280 over a month before Dr Hay wrote that letter, as the medical notes will confirm.

As you will also see from another transcript of a verbatim letter that I am enclosing in this submission, the alpha feto protein level reading of 9280 was only first unearthed by the medics at Newcastle, after it had lain unnoticed in my husband's file for five weeks. By any standards this is incredible, and it is especially so considering that, even after learning my husband had cancer, Dr Hay was still asserting that my husband's readings 'have been negative'.

I have emphasised before, in my earlier submissions, that shortly after returning from Newcastle, Dr Hay verbally informed me that my husband 'didn't have cancer when he left here' (the RLUH, on 13th August 1994). No doubt Dr Hay will have no recollection of such a conversation, although I can assure him that it took place in the corridors of the RLUH. Furthermore, any dispute that this conversation ever took place would likely be an issue to

which Ms Longstaff would no doubt readily cite in support of her contention that Dr Hay's defence would be prejudiced on the grounds of 'dimming of the memory', consequent to a time lapse of 10 years.

Similarly though, it is also an evidential point to emphasise that such, in this case accurate, recollections only need be supplementary, simply because enough documentary evidence exists to show that Dr Hay, in the shape of his letter to Prof. Preston, was clearly at pains to let it be, falsely, known that my husband's alpha feto protein levels were negative around the time of his transfer to Newcastle.

I submit that this is just one of scores of vignettes relating to my husband's case that can adequately demonstrate how the continuing cogency of documentary evidence, over and above personal recollections, flawed or otherwise, will certainly ensure a non-prejudicial and fair investigation.

To shed some further, but admittedly limited, perspective on Dr Hay's assertion that my husband's alpha feto proteins 'have been negative', as at 16th August 1994, it is a fact that an alpha feto protein test was earlier requested by Prof. Shields' team on my husband in March 1993 (some nine months after Prof Shields was blocked by Dr Hay in the conduction of a full liver work-up) as his medical notes show. Unfortunately, despite such a request having been made by Prof Shields' team, no such documentary evidence has ever been within my husband's files to show not only the results but actually whether the test even took place. Obviously, if my husband's records did contain a positive reading of alpha feto protein levels from that 1993 test, it would demonstrate that Dr Hay had actually overlooked this clinical data on two occasions. Nevertheless, the existence of a single overlooked reading, on July 15th 1994, of 9280, and a later assertion by the team at Newcastle that those levels were >100.000 micrograms per litre, circa 16th August 1994, would perhaps be enough for a specialist to put some time length on the likely development of cancer within my husband.

Even if this were not possible, it still remains a fact that Dr Hay was, at best, being evasive to inform Prof. Preston that my husband's alpha feto protein levels 'have been negative'. They hadn't been for *at least* five weeks up the date of that letter, a fact of which Dr Hay would have been well aware had his care of my husband reached even the minimally accepted standard.

It is also a point of interest to note that Dr Hay, in his letter to Prof. Preston, is willing to place some timescale on all my husband's other complexities; such as: in references to cirrhosis, varices and aescites, he is confident and detailed enough to record, fairly accurately, the varying timescales of 'some time...the last 18 months...over the last year.'

The only matter that Dr Hay rather leaves dangling in time-scale ambiguity is when he refers to alpha feto proteins. How long, for instance, had they been negative until? Unfortunately, the only real value of Dr Hay's assertion is to say that, at some indeterminate point in my husband's medical history, his alpha feto protein levels 'have been negative', which I am sure is the case for the majority of people.

I wonder what Prof. Preston would have made of the matter, were he to have learned that, in

actual fact, my husband's alpha feto protein levels, at the time of his writing, were >100.000 micrograms per litre, having been 9280 five weeks earlier and that only six days earlier, Dr Hay was still under the impression that my husband could be considered for a transplant?

It is clear to me that Dr Hay is trying to influence Prof. Preston that my husband's alpha feto protein levels had been negative up to the point of his travel to Newcastle and it was, tragically, while he was at the Freeman Hospital that the cancer first manifested itself. I also submit that this was the gist of what Dr Hay told me in the corridors of RLUH after my husband had returned from Newcastle.

Dr Hay also refers to my husband's deteriorating quality of life. He was right to do so. However, the appalling reality of my husband's deteriorating quality of life which eventually reduced him to tears - spontaneous, profuse and socially embarrassing oral bleeds, persistent styes, a hernia, leg ulcers, physically incapacitating aescites which eventually prevented him from even getting dressed, deep fatigue, insufferable and persistent itchy skin flakiness that wouldn't yield to creams, the list could go on - was such that it had been allowed to decline to almost nil long, long before a transplant was recognised, but even then not by Dr Hay, as being a possibility for my husband. In fact, almost from the time of his first varices episode, in April 1992, my husband was largely housebound, such was the unpredictability of his condition.

Given this perspective, it is has to be asked why, if he believed 'quality of life' eventually to be a factor to bear in mind when considering transplantation, Dr Hay, seemingly arbitrarily, actively blocked hepatological involvement in my husband's case during 1992 when, as notes show, he refuted Prof. Shields' submission that liver work-ups were necessary?

I submit that the value of these tests, conducted just six months after my husband was diagnosed with Hepatitis C and cirrhosis of the liver, and a full two years before he was eventually, far too late, considered for a transplant, may have hastened the decision not only to refer my husband to the joint care of a hepatologist but also to consider him for transplantation. When these major decisions were finally made some two years later, it is clear that my husband was by then facing imminent death, as occurred less than three months later.

I therefore find it utterly repugnant that Dr Hay can write that he believes the hepatologists were 'dragging their feet a bit' concerning my husband's transference to Newcastle for pre-transplant tests 1994. It is clear here that Dr Hay is attempting to lay blame (rather similar to Ms Longstaff's earlier submission that my husband was under the care of a number of specialists at more than one hospital). Therefore, he clearly believes that blame does exist. He was correct. However it is my submission to you that an overwhelmingly large portion of that blame can only be attributed to Dr Hay and that, as such, he was clearly negligent in his management of my husband.

Dr Hay also seeks to lay further blame when, after making it clear that he was on holiday at the time of my husband's encephalopathy episode, he informs Prof. Preston that it was only after this event that 'they...finally' sent my husband to Newcastle. Dr Hay is presumably referring here to the hepatological team at the RLUH. Again, it is clear here that Dr Hay believes that

somewhere along the line, to someone, blame must be attributable for lessening my husband's chances.

You will note that Dr Hay concludes his letter to Prof. Preston by again demonstrating his study of haematological matters as they overlapped with hepatological issues in the wake of treatment of haemophiliacs with infected blood products, as he was confident enough to assert that he 'feels sure' that 'more cases' like my husband's will be witnessed. Again, just like he had been nine years earlier through his article in The Lancet, and no doubt in his address to the IHS in 1989, Dr Hay is remarkably prescient.

I include here Prof. Preston's response to Dr Hay, some four months later, and three months after my husband had died (and it is clear that Prof. Preston did not know Dr Hay had since left RLUH) if only to demonstrate how precious time was. I also include the RLUH's response, in the new year of 1995, to Prof. Preston just to complete the correspondence.

(19th December 1994)

Dear Charlie,

Re: GRO-A *DOB unknown.*

You may recall that a few months ago you wrote to me about the above named patient of yours with the hepatocellular carcinoma.

I am now trying to pull together as much information as possible about this particular problem and I would be grateful, therefore, if you could find time to let me have some further details of your patient.

These are:

1) Type of bleeding disorder and severity; 2) Method of HCC (sic) diagnosis and age at diagnosis; 3) Year of HCC (sic) diagnosis; 4) Date (if known) of first exposure to clotting factor concentrate; 5) HCV antibody status; 6) Hepatitis B status; 7) HIV status; 8) Alcohol intake (if known); 9) Presence or absence (if known) of cirrhosis; 10) Alpha feto protein levels; 11) It would also be useful to know whether the patient is still alive or whether he has died.

I appreciate that this might be a bit of hassle, but I am sure you will agree with me that we ought to do it.

I look forward to hearing from you,

Kindest regards,

Eric

(6th January 1995) From RLUH to Professor Preston at the Royal Hallamshire Hospital.

Dear Prof. Preston

Re: GRO-A

Here is the information you requested on GRO-A

He has (sic) severe haemophilia A. HCC was diagnosed in 1994 GRO-A *He is (sic) anti-HCV positive, Hepatitis B surface antigen negative (anti Hepatitis B surface 268), HIV negative, alcohol intake unknown, cirrhosis present, alpha feto protein levels in August 1994 was 10,000 (sic).*

GRO-A *died on the* GRO-A *1994. It is assumed he bled into his hepatoma or had a* retroperineal bleed as he was shocked when admitted, however a post-mortem was not carried out.

Yours sincerely,

Angela McKernan
Locum Consultant Haematologist

At this point in my submission, I think it also appropriate to include a verbatim transcript of the letter that was sent from Prof. Bassendine at Newcastle to Dr Gilmore on 19th August 1994, the very same day that Dr Hay was writing to Prof. Preston.

(19th August 1994)

Dear Mr Gilmore,

Diagnosis - 1) Haemophilia A; 2) Cirrhosis secondary to chronic hepatitis C with portal hypertension; 3) Hepato cellular carcinoma

Thank you very much for asking us to assess this charming 59 year old man for liver transplantation. As discussed on the phone, we were all optimistic that he would be an ideal candidate, as transplant would not only cure his liver disease, but also his haemophilia.

As part of his work up he had an NMR scan (copy enclosed) which confirmed a small shrunken liver with splenomegaly and aescites, but unfortunately also revealed a lesion of approx. 7 cms in the left lobe possibly penetrating the capsule. On review of his Liverpool medical records we unearthed an alpha feto protein from blood taken on 15 July of 9280, confirming that he has developed a hepato cellular carcinoma, on the background of his Hepatitis C cirrhosis.

GRO-A *and his wife have been told that he has developed a growth within his liver and that this alters our decision to recommend transplantation and probably other surgery.*

They know that on his return to Liverpool, treatment options will be discussed with you, and the ones that I have mentioned are of chemotherapy and/or intrahepatic injection of alcohol directly into the growth.

GRO-A *and his wife asked whether a transplant would be reconsidered if the tumour shrank and I indicated that we would happily re-discuss this with you but emphasised that he should not hold out too much hope for this, as in the past, I had had patients turned down at the assessment meeting despite some improvement in the growth.*

However, it may be that we will shortly adopt a protocol using intravenous adriamycin pre-operatively during the anti-hepatic phase and post-operatively, as good results have been obtained in tumours of this size using this regime in the United States.

Certainly if his alpha feto protein falls, reflecting response to medical therapy, I would be very keen to re-discuss this option with you.

MF Bassendine
Prof. of Hepatology / Consultant Physician

A point to note is how quickly Prof. Bassendine stresses that a liver transplant for my husband would not only have cured his liver disease but also his haemophilia. Given that Dr Hay should have visibly been able to see - one would assume - the sheer deterioration of my husband before him, it again has to be asked as to why my husband wasn't considered for a transplant much, much earlier? Why did Dr Hay block the involvement of hepatologists in 1993, as evidenced in my husband's notes, when it was recommended by Prof. Shields?

The lesion that Prof. Bassendine refers to in my husband's liver was some 7cms in diameter. In mid-July it had been 6.5cms. I find it impossible to understand how Dr Hay or Dr Gilmore could have failed to note this before sending my husband to Newcastle. Either it was seen and it was ignored, in which case this was clearly negligent, or neither Dr Hay or Dr Gilmore had the expertise to be able to notice such and were therefore incapable of managing my husband, with the ensuing fact that they continued to do so itself being clearly negligent.

As you will have noted, Prof. Bassendine refers to the unearthing of an alpha feto protein reading of 9280 in my husband's notes from July 15th 1994.

Reading the transcript of Prof. Bassendine's letter, it should be clear to you how distressing the whole scenario surrounding Newcastle was for my husband and I. To have needlessly had our hopes raised to such an undreamt of extent, only then to have them not just dashed but effectively coupled with an almost certain prognosis of imminent death, is a trauma that is etched forever in my mind. They are still singularly the most distressing few days of my life and it further bolsters my submission to you that my memory of those events simply isn't capable of fading, despite Ms Longstaff's assertions to the contrary.

Quite obviously, my husband was in no fit state to even travel to Newcastle let alone undergo the physical pre-transplant work-ups and the psychological trials he endured; he should have been in his fifth week, at the very least, of chemotherapy back at RLUH, had the fact that he was even suffering from cancer been correctly interpreted.

To have allowed him to go when there was such overwhelming evidence to demonstrate that, at a stroke, it would be a wasted journey was gross negligence. If this aspect alone is not exceptional enough to justify the furthering of my husband's case, then I have to query as to what is considered exceptional or, more worryingly, the norm?

Therefore, I find it indigestible to read another absolute assertion of Ms Longstaff, when she states that no such argument exists in the case of my husband to fulfil either of the requirements of being in the public interest or being exceptional enough.

Surely an expert in his field, so evidently not applying his knowledge and his expertise to the benefit of his patients, for whatever reason, merits an investigation, on the grounds of public interest in order to ascertain as to why this was allowed to happen? Either Dr Hay deserved his reputation or he didn't? Surely the public interest is served if only to establish that there weren't other cases handled like my husband's? Surely all the evidence surrounding my husband's case bears all the hallmarks associated with being exceptional?

Rather than Ms Longstaff dismissively asserting that 'no such argument' exists to support referral of my husband's case, on the grounds of it not being either in the public interest or exceptional enough, it is my submission that the matter is evidently riddled with justifiable arguments as to why if fulfils all the onward referral requirements.

I therefore reject, unequivocally, Ms Longstaff's submission and submit that my husband's case can clearly proceed.

Ms Longstaff then goes onto state, somewhat superfluously, that this case concerns 'the management and treatment of one patient only'. I cannot see what point she is trying to make here. Naturally my case refers to only one person, my husband. But surely one of the matters to establish from investigating my husband's case is that it wasn't part of a wider standard concerning other patients? Again, if Dr Hay's management of my husband was indicative of his wider standards, then surely negligence applies. Conversely, if it was just an isolated case of negligent management - and my submission to you is that negligence is beyond dispute - then it has to be asked, again, as to how my husband was so unfortunate, at best, to be treated such over a sustained period?

Ms Longstaff also seeks to reduce my husband's clearly sizeable case to just three bullet points. Whilst I can appreciate her attempts at shorthand, at least for ease of reference, I regard this as a rather belittling diversionary tactic, presumably hoping to gloss over many crucial elements of my husband's treatment. My husband's case simply cannot be boiled down in such a manner - if only it were so - whilst also reflecting the sheer gravity of the consequential episodes. Either Ms Longstaff seeks to veil certain aspects of my husband's suffering or she is displaying her lack of knowledge surrounding the case. Either way, Ms Longstaff's admirable shorthand references are not an adequate reflection of reality, especially in a case of such magnitude.

There were scores of key milestone events that unfolded between the bullet point junctures that Ms Longstaff uses to boil down my husband's suffering. In many instances, these episodes were far bigger and far graver than the neutralised headlines that Ms Longstaff has employed.

For instance, between bullets 2 and 3 - i.e. *Management of his liver cirrhosis from January 1992* to *Management of a hepatocellular carcinoma diagnosed in 1994* - there could be several quite stark headlines that could be inserted to give a truer picture as to the gravity of this case. For example *'Continuing failure to refer patient to a liver specialist'* to *'Deliberate veto of liver specialist involvement even when it was suggested'* to *'Failure to correctly identify patient was suffering from cancer'*. The list could go on, but I submit to you that Ms Longstaff's breezy and rather disingenuous reference to some, or what she presumably believes to be the key, events in my husband's case, is insubstantial and can be disregarded as an adequate overview of the pertinent facts and episodes.

Ms Longstaff's emphasis that my husband's matters are 'private' is also another deflection-attempting irrelevance. Of course his matters are private but, as his surviving spouse, it is clear that I am again surrendering my long-abandoned preference to keep such matters private. If only I still had that refuge. As I have stated, my husband's private suffering has been publicly aired across several media channels for many years now, particularly in relation to the ongoing and quite arduous campaign to have the British government address the bereaved families of deceased HCV haemophiliacs. Whilst I do appreciate the apparent concerns that Ms Longstaff seems to have for the sensitivities surrounding my husband's suffering, I can assure you that, out of necessity, I have long-since had to abandon this privilege and quite obviously I am doing so again.

Furthermore, as to Ms Longstaff's assertion that the matters surrounding my husband's case are 'unique', then, I would have to say, it must be hoped that they are. In any case, whether they were unique or not is an irrelevance. If they were unique, then it has to be determined as to why my husband was allowed to suffer so; if they were not unique, then obviously the gravity of that matter also demands exploration.

Further, whilst I am at least assured that Ms Longstaff appreciates that the circumstances of my husband's death 'were no doubt sad' - and she is right - they were self-evidently exceptional, at least it is hoped that they were and not reflective of the norm.

I therefore reject all of Ms Longstaff's submissions recommending no further referral of my husband's case on the grounds of it neither being in the public interest, nor exceptional enough, or relating only to one patient, or being too private, or unique. My husband's case can clearly proceed.

8. Ms Longstaff states:

Finally, the screener should take into account the facts that:

> *•As far as Dr Hay is aware, the Complainant did not pursue a complaint through the hospital complaints procedure at the time,*
> *• The Complainant has already attempted legal action in respect of these events, which failed in the late 1990's.*

Ms Longstaff is correct in her tentative assertion that 'as far as Dr Hay is aware,' I did not

pursue a complaint through the hospital complaints procedure at the time. I did not do so for several reasons.

Firstly, in the immediate aftermath of my husband's death, I not only had to contend with the considerable grieving process ahead of me, but the issue of financial redress for the bereaved families of Hepatitis C-infected haemophiliacs, as consistent with the reparation made to the bereaved families of HIV-infected haemophiliacs, including, of course, the families of my husband's other two haemophiliac brothers. This matter was suddenly propelled into the national media spotlight within weeks of my husband's death and, as his case was infamously part of the previously referred to scenario of the 'three brothers', it immediately became something of a test-case and consequently much of my time was swallowed in preparing relevant submissions in relation to this. I am sure that you and Ms Longstaff can appreciate how arduous and traumatic this was for me at the time, swallowing much of the first year after my husband died when clearly I should have been allowed to grieve without resorting to such campaigns.

Furthermore, it was not until Christmas 1996 that, after many requests, I was finally able to access my husband's medical records, the reading of which was, given how voluminous they were, as painstaking as it was traumatic.

It was only after reading these notes, over two years after his death, that I was finally able to confirm my increasing suspicions that my husband had in fact been negligently managed. The decision I then faced was which way to best pursue a case of medical negligence. Considering that I was already involved in the formation of a case against the British government - which still exists to this day - I had to make a pragmatic decision as to how best to pursue a parallel submission of medical negligence regarding the specifics of the management of my husband at the RLUH.

Several events over the course of a period, stretching from immediately after my husband returned from Newcastle to 11 weeks after his death, influenced my eventual decision not to pursue a complaint through the hospital complaints procedure, if in fact it wasn't already too late for me to be able to do so by the early part of 1997.

Firstly, there were two conversations I had with Dr Hay in that period. I have earlier related the first of those occasions, which took place in the corridors of the RLUH immediately following my husband's return from Newcastle after being diagnosed with liver cancer. Dr Hay arrogantly and, without solicitation, tersely informed me that 'he never had cancer when he left here.' You will recall from earlier in this submission that Dr Hay was also at that time writing to Prof. Preston to this effect by stating that my husband's alpha feto protein levels "have been negative".

A second conversation with Dr Hay then took place in the corridors of a hotel in Coventry in November 1994, 11 weeks after my husband's death, where he, like I, was an attendee at the UK Haemophilia Society's AGM. Again without solicitation - in fact I did not want to speak to him - Dr Hay, in an unduly dismissive way, especially considering I had only been a widow for such a short period, informed me that 'I did all I could' for my husband. I had no choice but to

accept this and although my suspicions about negligence were only just beginning to crystallise, I was immediately sceptical about Dr Hay's continuing and unsolicited stance, especially in light of the earlier conversation he had with me at the RLUH.

However, I recalled Dr Hay's words, on both of those occasions, when I read my husband's medical notes some two years later and realised the depth of the negligence he experienced and that it most certainly was not the case that my husband didn't have cancer when he left Liverpool for Newcastle. It was also clear that Dr Hay had not done all that he could for my husband.

Another matter influencing my decision not to pursue matters through the hospital complaints procedure was my rather naive acceptance, in October 1994, of Dr Ian Gilmore's verbal assertions to me, and my two children, that nothing more could have been done for my husband considering how 'late in the day' he had been referred to the hepatologist unit at the RLUH.

Dr Gilmore spoke to me and my two children in his office at the RLUH during a meeting that he himself had prompted, for which I was grateful for at the time. Still in a deep sense of grief at that point, I did not realise the significance of what Dr Gilmore said to me regarding the tardiness of my husband's referral to the hepatologists at RLUH (this was similar to my naive acceptance, during the course of my husband's decline, when I never queried Dr Hay's inactivity in not referring my husband on - instead having complete, but eventually wavering, faith in an expert who I believed to have my husband's best interests at heart).

Instead, I paid more attention to Dr Gilmore's assertion that, as he put it, under the circumstances, everything that could have been done for my husband was done. At this point, it must be remembered, I had absolutely no idea that my husband had cancer before he went to Newcastle. Instead, influenced by Dr Hay, I believed, right up to my husband's death, and beyond, that he had just been so extremely unlucky to have developed cancer in the few days whilst he was actually at Newcastle. My husband and I were actually under the impression that we were lucky that Newcastle had detected it so early. Ironically, this even gave my husband false hope that his chances with chemoptherapy would be at the maximum because cancer had only just surfaced. Therefore, given my understanding of matters at the time I spoke to Dr Gilmore, in October 1994, I had no reason to think more deeply about his words and accepted his assurance, which although untrue, was delivered rather more gently than Dr Hay's abrasive assertions that everything that could have been done for my husband was done.

You can imagine my utter shock when eventually I read my husband's medical notes, to realise that not only had my increasing suspicions about his treatment been borne out, but that they had been magnified massively. I could only recall the words of both Drs Hay and Gilmore with utter contempt as it was clearly untrue that everything that could have been done for my husband was done.

Consequently, I judged that any chances of success I would have in pursuing a case of medical negligence against the RLUH and/or Dr Hay and/or Dr Gilmore would be best served in a route other than the hospital complaints procedure, as I had no faith that the investigation

would be objective, especially given the already demonstrated stances of both Drs Hay and Gilmore.

While Ms Longstaff is correct in her assertion that I have already attempted legal action in respect of this case, she is quite incorrect to say that it 'failed'. She is correct though to refer to this action as having been 'in the late 1990s' which underlines how long it took for me to be able to formulate that case.

You will have known, in my earlier submissions to you, that I have not hidden the fact that I have already tried to pursue this matter through legal avenues - I have not hidden this. As I have stated earlier, my immediate priority - the timescale of which was rather forced on me, as my husband was deemed to be part of that 'test case' involving his three brothers - was to formulate a case against the British government for compensation for bereaved families of Hepatitis C haemophiliacs, as consistent with that of bereaved families of HIV haemophiliacs.

Naturally, this necessitated the seeking of legal advice and the requested access to my husband's medical records. Before I could even progress down this road though, I had to pursue a claim for legal financial aid as I had not the funds to progress such a matter on my own. The approval of my legal finances itself swallowed up much of the immediate period after my husband's death. Only after I was able to establish that I could support such a case did I learn that I would have to initially bring a case against the health authority in the first instance before then being able to bring matters against the British government.

For this course of action to proceed, of course, I had to gain access to my husband's medical records. Although these records were, in the first instance, accessed to support a case against the health authority and the British government, it was also my intention to scrutinise these materials to establish the true facts surrounding the specific management of my husband, primarily by Dr Hay, with a view to seeing if they supported the now considerable suspicions that I then had that he was negligently treated.

Naturally, though, I could not progress on any front until those records were obtained. An anxiety of mine though was that I knew in order to progress any case of medical negligence that I would have to initiate proceedings within three years of my husband's death - i.e. by GRO-A 1997. Despite repeated requests from my counsel, the procedure of this case was stifled through inexplicably long delays by the RLUH in their release of my husband's medical notes. In the end, I only achieved access to those files at Christmas 1996, over two years after my husband's death.

You will immediately appreciate that this left only nine months, and in reality much less than that, in order for this case to proceed. Alongside this, I was still having to formulate a case against the British government.

As my records, if you require access to them, will show, the period between Christmas 1996 and GRO-A 1997 was also beset by further delays, particularly regarding the identification of independent experts who were both competent enough and willing enough to pass judgement in the case of medical negligence experienced by my husband.

Identification of such experts took many months and the situation was not at all helped by the fact that, after initially promising his assistance, one of the experts suddenly informed us, with only a few months remaining before deadline, that he would no longer be able to help. He gave no reason for this unexpected withdrawal. Naturally this impacted the timely development of the case to some significant degree.

Another significant setback was that, even after the panel of experts had been finalised, the length of time before their submissions were actually received saturated much of the remaining time; although to an extent this was inevitable considering how voluminous my husband's medical records were.

In eventuality, it prevented my counsel from formulating its case until during the Bank Holiday period of August 1997 - as my records, if you require them, will show - and it inevitably meant that we would not be able to initiate proceedings within the strict timetable.

Furthermore, the legal financial assistance I had benefited from, for some two and a half years at that point, reached a finite point in terms of costs already incurred.

On two fronts therefore, I was prevented from furthering my proceedings regarding medical negligence against the RLUH and/or Dr Hay and/or Dr Gilmore.

I am sure you will appreciate the frustration I felt at that time when, after three years of trying I was simply unable to press proceedings any further. As Ms Longstaff has correctly asserted, therefore, the matter did indeed reach the late 1990s, however she is quite wrong to say that legal action 'failed'. It did not fail because it was never given the chance to either fail or succeed. I do find Ms Longstaff's statement, that it 'failed', somewhat curious given that she later goes on to point out that proceedings never materialised. If she knows that proceedings never materialised it is hard to see how she can conclude that they 'failed'.

It did not fail because it was never allowed to. However, it my submission to you that, had I have had the opportunity to progress matters further, then my action would, in fact, have succeeded.

It is also difficult to reconcile Ms Longstaff's earlier submission that Dr Hay only has 'some recollection' of my husband with the fact that he seems to be able to recall specifics such as me not pressing a case through the hospital complaints procedure and that I also attempted legal action in the late 1990s. Either he can substantively recall my husband's case - and it my submission to you that he most certainly can - or he can't.

Nevertheless, I trust I have clarified the reasons as to why I didn't progress matters through the hospital complaints procedure and also why formal legal proceedings - which most emphatically did not fail - were prevented from progressing.

9. Ms Longstaff states:

The statement which GRO-A *has provided in support of her complaint to the Council was originally made in 1997 in support of a claim for damages for medical negligence. Dr Hay understands that* GRO-A GRO-A *had the benefit of legal advice and assistance in investigating that claim and that an independent expert report was obtained on her behalf. That expert report was never disclosed but it must be presumed that it was unsupportive of the Complainant's case because shortly afterwards the claim was discontinued. In fact formal civil proceedings were never issued.*

Ms Longstaff is correct to state that one of the statements I have provided to you in support of my claim against Dr Hay was originally made in 1997 during the preparation of the legal action referred to above. In fact, I made it clear to you that such was the case in my earlier submission. However, I also, in my earlier submission to the Council, made a newer submission to you entitled 'The Case Against Dr CRM Hay' - as I was requested to. I note that Ms Longstaff has chosen to overlook this statement in her response to you and chooses only to cite the existence of the previous, seven year old statement. In any case, I would submit to you that both statements are in fact complementary and whether one of them is seven years old is an irrelevance.

Further, given Ms Longstaff's repeated references to the passage of time and her anxiety that it could render memories unreliable, I would submit that the statement I made in 1997 - less than three years after my husband's death - should at least be regarded by her as a reliable statement.

Although Dr Hay only has 'some recollection' of my husband, he is right to understand - however he has reached his belief - that I did indeed have the benefit of legal advice in 1997 and that an independent report was produced on my behalf. I trust, though, that I have already clarified the matters surrounding this actuality, and stress further that I have made no attempt to hide such facts from you, simply because I have no need to.

Ms Longstaff then enters the realm of conjecture again by 'presuming' - even though it was never disclosed - that the independent expert report was 'unsupportive' of my case, chiefly because my claim was shortly afterwards discontinued.

I have made it clear as to why these matters were reluctantly discontinued and would caution Ms Longstaff against her presumptions. As I have indicated, I would have welcomed the ability to progress my case further in the wake of receiving that independent report but unfortunately I was only prevented from doing so by chronological and financial factors.

So while Ms Longstaff is correct to say that formal proceedings were never issued - which Dr Hay would surely be aware of - I submit to you that it is nevertheless dangerous for her to presume that I did not do because the independent report did not support my claim.

10. Ms Longstaff states:

It is noted that the Complainant has chosen not to share a copy of that independent expert report with the Council, presumably because it does not support her position.

It is quite wrong of Ms Longstaff to state that I have not 'chosen' to share a copy of that independent report with you. You will know that in previous submissions I have drawn your attention to my previous legal activities regarding this matter. Had you have requested a copy of any materials supplementary to that activity, such as the independent report, I would gladly have shared them with you - as is still the case. Nevertheless, I judged that these documents could in fact prejudice your investigations, insofar as I assumed you would wish to maintain objectivity in order to reach your conclusions, free of the earlier judgements of others.

I therefore interpreted, rightly or wrongly, the fact that you did not request any materials relating to my previous legal activities between 1994 and 1997 as an indication that you did indeed wish to proceed unprejudiced by the conclusions of earlier enquiries. While I would certainly support this as the most appropriate approach, I equally would not wish to presume any aspect of the Council's correspondence with me so far and I would readily concede, if appropriate, that I may unwittingly have misinterpreted any non-requests of materials. To that end, I am fully prepared, if you so wish, to let you see copies of the independent expert reports - to which Ms Longstaff alludes - that I possess.

It is, though, incorrect, of Ms Longstaff to say that I have 'chosen' not to share these materials with you and it is misguided of her to presume their contents.

11. Ms Longstaff states:

Thus it appears that the Complainant has already had the opportunity fully to explore the issues in this case, and she has the benefit of an independent expert report (which she has not disclosed). GRO-A GRO-A *is now trying to open the same allegations and explore the same issues, through the General Medical Council. It is submitted that this is inappropriate and an unreasonable waste of the Council's time.*

While it may appear to Ms Longstaff that I have already had the opportunity 'fully to explore the issues in this case' it is in fact incorrect of her to say so.

The fact that I was frustratingly prevented from progressing my previous legal activities, through no fault of my own - especially after obtaining independent expert reports - itself underlines that I did not 'fully' have the chance to explore this matter.

It is my submission to you that I still wish I were able to have progressed matters further in order to have 'fully' explored the issues but I was unfortunately prevented from doing so. Therefore, I completely reject Ms Longstaff's assertions on this point.

Ms Longstaff is right to say that I am 'trying to open the same allegations and issues,' through the Council. Of course I am. Moreover, the allegations and issues can only remain the same,

regardless of the passage of time. It has been a lasting frustration of mine that I was never able to fully explore the matters of this case and I felt that I reluctantly had no choice but to accept this reality.

However, I was encouraged when I first learned, some 10 months ago, about the possibility of re-attempting an exploration of these issues through the channel of the General Medical Council. Had I have known about this channel, I would have sought recourse to it a long time ago. Sadly I did not and I can only submit to you that the reason I am now doing so after so long a time is that I simply wasn't aware of it as a viable option.

I can assure you that I would have liked to have explore these issues through the General Medical Council many years ago and so avoid the pain of still having to revisit my husband's case so many years later, especially with the added poignancy that we are now upon the 10th anniversary of learning that he was a 'suitable' candidate for a liver transplant.

I reject Ms Longstaff's dismissiveness that my submission is now 'inappropriate' and especially her rather arrogant assertion that it is 'an unreasonable waste' of time. I also detect, rightly or wrongly, a note of inferred tedium from Ms Longstaff behind this statement. Whilst I submit to you that, given the circumstances - however long it is since they occurred, it is most certainly not 'inappropriate' to further this matter and certainly not 'an unreasonable' waste of your time, and that it is much more than a case of mere tedium for me. It is deeply traumatic and time-consuming for me to have to do this and I would trust that the fact I am having to do so - especially at so poignant a time - is self-evidence of the depth of injustice I feel.

Rather than it being an unreasonable waste of the Council's time, it is my submission to you that I trust it does not become an unreasonable waste of my time, coupled with further injury, especially after going to the lengths I already have, particularly the preparation of this response which has been traumatic in itself.

12. Ms Longstaff states:

Dr Hay would like to make it clear that he firmly refutes all the allegations and criticisms made by the Complainant, and reserves all his rights to provide comments on the substantive issues if this proves necessary. As a preliminary issue however it is submitted that the screener should have regard to the five year rule and properly conclude that no further action can be taken, and this enquiry should be brought to an end.

I have said earlier that I am not surprised to learn that Dr Hay refutes all of the allegations against him. However I am surprised that he is so trenchant in his position based not only on the evidence I have shared with you, but also based on the fact that he has only read 'a few' of the documents that he has been able to access.

I would submit that before Dr Hay fully refuted all the allegations against him, he should have consulted a complete file of my husband's records. This is especially so considering that he also only has 'some recollection' of my husband. I therefore cannot see how Dr Hay arrived at his position. Furthermore, in Dr Hay's situation, especially after electing to allow his counsel

to respond to you at this immature stage in his investigations, I would have thought a few cautionary noises would be more appropriate pending the release of further materials.

I submit that Ms Longstaff's response is therefore ill-considered and ill-formed, especially on the basis of so little evidence, apparently, having been read. I also submit that it is my conviction that, on reading all the evidence available, Dr Hay must ultimately conclude that he at least has to modify his position, if not totally abandon it, and offer an adequate explanation, perhaps containing an apology, twinned with recognition of undue suffering, as to why he managed my husband so.

I fully respect Ms Longstaff's submission that Dr Hay reserves all his rights to provide comments on the substantive issues, which I indeed would welcome, although I reserve judgement as to what Ms Longstaff's interpretation of 'substantive' is. As I have emphasised several times earlier, I believe that there is more than enough justification for the screener to disregard the five year rule in this instance, on the very safest grounds.

Further, I would regard it as an improper conclusion if the screener were to recommend no further action, particularly in the light of the case having reached thus far. It should be starkly clear to you that the management my husband received - according to the documentary evidence available - was at best sub-standard. There are a myriad instances that can be pointed to in order to support my submission of negligence on the part of Dr Hay.

My husband suffered dreadfully and it must be established as to why he did so, particularly in so exceptional a way, no matter how long it has been since. It must also be established that others did not suffer in a similar way.

The tragedy meted out to the haemophiliac community in general - as so starkly illustrated by the events within my husband's own family - was hard enough to bear in itself in the wake of being infected with contaminated NHS blood products. But, in my husband's instance, to have such pain compounded by further inestimable injury in the shape of the treatment I have described was simply unacceptable and fully merits investigation.

My husband was an utterly helpless, extremely vulnerable man - desperate for any respite offered him - and both he and I trusted implicitly the medics appointed to care for him over several years. It is starkly clear to me that such trust was hideously misplaced and I submit to the Council that an investigation as to how and why this was the case must be conducted.

This case must progress.

I anticipate your considered response in due course,

Yours sincerely,

GRO-C

GRO-A

15th June 2004

MEDICAL PROTECTION SOCIETY

RECEIVED
12 2004

Direct Line: GRO-C
Direct Claims Fax: GRO-C
Secretary: Helen Huby (9.30am ~ 5.30pm)

Mr Tim Cox-Brown
Caseworker
Fitness to Practise Directorate
5th Floor St James's Buildings
79 Oxford Street
Manchester M1 6FQ

Our Ref: CL/HH/540234
Your Ref:TCB/FPD/2004/0781

9th July 2004

BY FAX AND POST – GRO-C

Dear Mr Cox-Brown

Re: Dr. C.R.M. Hay

I refer to your letter to Dr Hay of 21st June 2004, and our subsequent telephone conversation in which you reported that:

- You were not willing to disclose copies of the correspondence referred to in the second page of the Complainant's letter of 15th June 2004, and
- A medical screener had already considered the issue of the five year rule in isolation, and determined that the enquiry should proceed.

As indicated, I was surprised and concerned to receive this information and submitted that the Council was guilty of a grave error of procedure. Any decision involving an exercise of discretion on the part of the Council should be transparent and cannot be made without the benefit of submissions on the part of both parties.

In the circumstances, you have agreed that the case will be submitted to the next available medical screener, so that it can be considered with a fresh pair of eyes. It is important however that the correct procedure is complied with. On behalf of Dr Hay I would submit that the new medical screener should not be provided with any documents which have not been seen by Dr Hay; nor should he/she be provided with any material relating to the previous (invalid) decision.

The purpose of this request, as I am sure you will appreciate, is to uphold the rules of natural justice, and to protect the Council from any allegations of abuse of process.

Thank you for sending me a copy of the Complainant's letter of 15th June 2004. This does not add greatly to the preliminary point of principle which falls to be determined but I would like to make the following points:

1. The Complainant confirms that this is a "massively complex" case, and that the events in question took place over ten years ago. In fact it is suggested that it will be necessary to refer back to before that period in order to contextualise matters. GRO-A also asserts that her own recollection of these events is entirely reliable, although clearly she is unable to speak for any other witnesses. The medical screener must appreciate that all these assertions go to support the contention that at this stage it would be extremely difficult to conduct a non-prejudicial inquiry, and to ensure fairness in the proceedings.

2. The Complainant also confirms that the medical records are voluminous and that certain notes are missing; she refers in particular to an alpha feta protein test requested in March 1993. I would point out that this report was not requested by Dr Hay, but by another specialist. If this case were referred forward it would be a great injustice to Dr Hay if he were asked to comment on the absence of medical records not actually commissioned by himself. This is another example of the way in which Dr Hay might find himself severely prejudiced if this matter were allowed to proceed.

3. The Complainant has taken issue with the suggestion that a number of different practitioners were involved in this patient's care and yet it is clear, even from the limited extracts from the records attached to the initial letter of complaint, that the patient was under the care of a number of treating consultants during the period in question. I understand that the screener may even have access to a complete set of the records (which have apparently been lodged at the Council's Manchester office by Mrs GRO-A from which it will be clear that from 1992 the patient was under regular review by Professor Sir Robert Shields, Head of the Academic Surgical Unit specialising in management of liver disease, especially cirrhosis. Dr Hay is not seeking to attribute blame whatsoever but would like to make it clear that he would have some difficulty addressing the principal allegations in this case, because they appear to relate to a time when the patient's liver disease was predominantly managed by Professor Sir Robert Shields. Ultimately it is not clear what the exact allegations are and to whom they should properly relate.

4. The Complainant has suggested that the public interest argument comes into play because Dr Hay is a renowned expert. In the first instance, I would submit that it seems manifestly unfair that a practitioner with particular expertise should not have the proper protection of the five year rule, in a case where events in question occurred over 10 years ago, where any other practitioner would. Furthermore, as previously expressed, while the circumstances of GRO-A death were no doubt sad they cannot be described as exceptional and it would be an illogical extrapolation of Rule 6(8) to suggest that the death of any patient of an eminent medical professional should automatically lead to an investigation by the General Medical Council. GRO-A argues strongly and at length that her husband was managed negligently but the medical screener must not lose sight of the fact that Dr Hay firmly refutes these allegations, and believes they are unfounded.

5. The Complainant confirms that she never made a complaint through the NHS complaints system, but that she did attempt to make a civil claim for damages in 1996/97, which was not pursued. She also confirms that she obtained independent expert reports in relation that claim, but has not produced copies of those reports, and has remained silent on the question of whether they supported her case.

6. The Complainant implies she was partly prevented from commencing legal proceedings by chronological factors, and the expiry of the three year limitation period. However this argument does not convince. By August 1997, according to the Complainant's own account, the medical records were available, independent expert reports had been obtained and legal Counsel had advised. GRO-A was certainly in a position to issue proceedings prior to the 3rd September 1997. If Counsel was unable to formulate detailed particulars of claim immediately, then it was open to GRO-A solicitors to issue protective proceedings, and it would still not have been necessary to serve the detailed case for another four months. After that GRO-A solicitors could have applied for an extension of time for service of the formal proceedings. All of these are common proceedings in civil litigation and should not prevent a Claimant with a meritorious case from pursuing their claim.

7. In the circumstances it is open to the Screener to conclude that the expert evidence was not supportive of the case and that GRO-A was advised by her lawyers not to pursue a claim, which would need to be established on the balance of probabilities (where her allegation to the GMC would need to be established to the higher, criminal standard).

8. The Screener may wonder why this particular complaint has been re-opened at this stage. By way of explanation, GRO-A has said that she only first learned about the possibility of reattempting an exploration of these issues through the channel of the General Medical Council some ten months ago. This may well be the case, but the Screener may wish to consider whether a more comprehensive answer lies in the wider issues for the haemophilia community. The Screener is probably aware that ten months ago, the Department of Health launched a compensation scheme whereby £20,000 is awarded to any patient who contracted hepatitis C from contaminated blood products, and £45,000 for the families of any patients who died after September 2003 from liver disease caused by contaminated blood products. However, the dependants of patients who died prior to September 2003 do not receive anything and therefore individuals such as GRO-A are excluded from this scheme.

For the record, Dr Hay would like to make it clear that he appreciates that some families within the haemophiliac community must feel great resentment, and he understands why campaigning groups have made representations to the Department of Health arguing for a change in the scheme. He has made similar representations himself. However it is possible, and it will be put no higher than that, that a concern about the compensation scheme is in part the precipitating cause for GRO-A

present complaint. If this should be the case then the medical screener should have regard to the wider issues, and question whether further investigation of this complaint could be justified as an appropriate use of the Council's resources.

In conclusion, it is submitted that the medical screener should have regard to the five year rule which clearly states that, pursuant to the rules of Council, this allegation may not be referred to the Preliminary Proceedings Committee. For the avoidance of doubt, I would like to make it clear that any decision concerning discretion can only be made at this stage, by the medical screener, and that it is not a decision which can be passed on to the Preliminary Proceedings Committee.

If, despite these submissions, a decision is made to refer this case to the Preliminary Proceedings Committee, I specifically request that reasons for such referral are provided.

Yours sincerely

GRO-C

Catherine Longstaff
Solicitor
Claims and Legal Services Division

In reply please quote: RG/FPD/2004/0781

30 March 2005

GRO-A

Liverpool
GRO-A

GENERAL MEDICAL COUNCIL
Protecting patients, guiding doctors

Dear GRO-A

I refer to our previous correspondence regarding your complaint about Dr. Hay.

In accordance with Rule 8 of the General Medical Council (Fitness to Practise) Rules 2004, the Case Examiners have considered your complaint. They have concluded that we do not need to take any further action on Dr. Hay's registration, in respect of this.

When making their decision, the Case Examiners must consider whether there is a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on registration. In doing so, they must have in mind the GMC's duty to act in the public interest, which includes the protection of patients and maintaining public confidence in the profession.

They first consider the seriousness of the allegations and then whether the GMC is capable of establishing that the facts demonstrate the practitioner's fitness to practise is impaired to a degree justifying action on registration.

The Case Examiners concluded in this case that, whilst the allegations were serious, there was no realistic prospect of establishing that Dr. Hay's fitness to practise is impaired to a degree justifying action on his registration.

In your complaint you alleged that Dr. Hay failed to diagnose liver disease in GRO-A GRO-A failed to test for Hepatitis C, failed to refer to a hepatologist, failed to communicate the clinical condition of "liver failure" to GRO-A failed to refer for or recommend a liver transplant, refused to refer to specialist Dr. Gilmore, failed to diagnose and treat liver cancer early enough, and prevented full liver tests being undertaken.

Specifically, with respect to the allegation that Dr. Hay failed to diagnose liver disease in GRO-A you instigated a civil action for damages and we have copies of the opinions on file. They do not support your allegations and accordingly your solicitors dropped the action. Cirrhosis of the liver was diagnosed in 1992 following knee surgery. There is nothing to indicate that this surgery was contraindicated or had any adverse effect on GRO-A liver disease. Your expert hepatologist confirms that this is the case and that earlier diagnosis via biopsy would have been very unusual practice at the time.

Regarding the allegation that Dr. Hay failed to test for Hepatitis C, the Hepatitis C test only became available in late 1991 and Dr. Hay began testing in early 1992. This is therefore not an issue to justify action on Dr. Hay's registration.

As to the allegation that Dr. Hay failed to refer to a hepatologist, Dr. Hay was an experienced consultant and it was reasonable for him to manage GRO-A care himself. The independent expert view was the liver disease was appropriately managed with very effective treatment of the patient's oesophageal varices. No action on Dr. Hay's registration is therefore indicated.

Pertaining to the allegation that Dr. Hay failed to communicate the clinical condition of "liver failure" to GRO-A, GRO-A liver function was regularly monitored and discussions about the diagnosis documented. There is no evidence that any information was deliberately withheld and therefore no action on Dr. Hay's registration is indicated.

Regarding the allegation that Dr. Hay failed to refer for or recommend a liver transplant, at the time it is clear that liver transplantation was a last resort measure, particularly with the increased morbidity and mortality associated with patients who had haemophilia. When his liver functioned deteriorated, GRO-A was referred. Unfortunately, this deterioration coincided with the diagnosis of a malignant liver tumour so removing transplantation as an option.

With respect to the allegation that Dr. Hay failed to refer GRO-A to Dr. Gilmore, GRO-A was referred. Unfortunately it was at a stage when the hepatoma was diagnosed. There is no evidence that Dr. Hay or any other doctor failed to act on evidence that would have led to an earlier diagnosis.

As regards the allegation that Dr. Hay failed to diagnose and treat liver cancer early enough, the blood test result indicating a possible hepatoma was first recorded in excess of 9000 in July. By August it was greater than 1000000. This is a large rise in a short space of time and occurred in combination with GRO-A worsening clinical condition. It was not routine accepted practice to "screen" patients with cirrhosis for liver cancer and Dr. Hay's management is what might reasonably have been expected.

The last allegation was that Dr. Hay prevented full liver tests being undertaken. A full liver work up may have involved risk-laden procedures such as liver biopsy, the complications from which are multiplied in patients with a bleeding disorder such as haemophilia. Professor Shields discussed the pros and cons with the haemophilia specialist – Dr. Hay, who can be said to have been acting in his patient's best interest.

I acknowledge that this may be disappointing news for you but hope that given our explanation you understand the reasons for our decision.

Yours sincerely,

GRO-C

Richard Grumberg
Investigation Officer
Fitness to Practise Directorate
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