Witness Name: Katherine Victoria Burt

Statement No: WITN6392001

Exhibits: WITN6392002 - WITN6392267

INFECTED BLOOD INQUIRY

WITN6392249

The Bulletin

1993 – No 3

MAJOR CHANGES AT THE SOCIETY'S NATIONAL OFFICE

The Society has undertaken a major restructuring exercise to shape it for the challenges of the year 2000 and beyond.

This has taken place as a result of the Society's work in implementing its Strategic Plan. The planning began over two years ago when priority areas were identified. Having identified the priorities, the Executive Committee considered the structure of its own internal working procedures and reviewed its national office staff and premises.

At the same time an extensive needs assessment exercise involved the membership in identifying the changing requirements of people with haemophilia.

The Executive Committee has now implemented the restructuring of the national office organisation in line with the needs of the Strategic Plan.

The national office now operates with two departments which reflect the new Executive Committee structure. The Services Department, under Graham Barker handles the core work of the Society. This work includes such items as services to individual members and groups, campaigning and government and public relations. The Resources Department under Susan Archer deals with the day to day running of the Society office, such as office management, finance and membership administration. Graham and Susan should now be your main points of contact at the national office.

"The two department format, with each dealing with separate aspects of the Society's work is the outcome of the review of our approach," said Haemophilia Society Chairman, the Revd Alan Tanner.

"The new structure will enable us to continue to be at the forefront in matters that affect the lives of people with haemophilia and yet have a greater flexibility to involve a wider cross section of the membership in the operation of the Society." Having the two departments, providing mutually complementary services, means that the Society has greater depth of resource available to provide services for people with haemophilia."

The new structure has meant that the Society has had to lose some existing posts, while creating two new positions at the national office. One of the posts that has been lost is that of General Secretary of the Society.

"David Watters, gave the Society sterling service over the years and successfully led the organisation through a critical period when the campaign for compensation was high on our agenda," said the Revd Tanner. "We wish him every success in the future."

Two new posts have already been advertised and appointments are expected soon. The posts are Member Services Officer and Head of Fundraising. Both are seen as crucial to the success of the new structure. The Member Services Officer will support the work of the Services Department, allowing a greater depth of resource to be available. The Head of Fundraising will also have a vital role to play. The Society will need to at least double its annual revenues by the year 1995 to finance its planned expansion in services.

KEN MILNE

It is with the deepest regret that we report the death of Society Vice Chairman Ken Milne.

Ken was a long serving and staunch supporter of the Society and he will be greatly missed.

A full tribute to Ken will appear in the next edition of The Bulletin.

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THE HAEMOPHILIA SOCIETY

123 Westminster Bridge Road, London SE1 7HR

Tel: 071 928 2020
Fax: 071 620 1416

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LOOKING TO THE FUTURE

by Andy Cowe, Editor of The Bulletin

The Haemophilia Society has achieved great things in the last ten years. We have grown in membership, expenditure and professionalism. The timing of our growth was fortunate - more fortunate than we could have known in the early 1980s - because the demands and challenges have grown immeasurably.

As a Society we have become stronger and better equipped to deal with new problems. We have learned how to make our voice heard, how to influence the events that shape our lives, and we are always learning about our members' needs. Most importantly we have learned that to be effective we must be able to identify our goals and plan our activities to achieve our targets.

Like all voluntary organisations we are learning that generating the income that we need to support our programmes of help for people with haemophilia is becoming more difficult. We must be able to demonstrate that our own organisation is geared to meeting the challenge of the future.

The Strategic Planning process and the Organisation Review referred to on page one are an essential part of this process. It can be hard to look at our activities and to ask whether we are doing the right things. Those who carry the responsibility of managing the Society do not treat this obligation lightly. The officers and members of the Executive Committee have worked long and hard to prepare the Society for the next decade. Preparing for the future involves learning from the past, but it also involves new ways of working for the future.

The Haemophilia Society has grown into a strong, effective organisation. All who serve it are committed to one aim. As one year draws to a close, and as we move from one era in the Society's life to the next, let us pledge ourselves to working together in a spirit of unity and cooperation to achieve our common purpose – improving the quality of life for people with haemophilia.

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BIO PRODUCTS LABORATORY

We extend our grateful thanks to the Bio Products Laboratory who have kindly donated a sum to pay for the publication of The Bulletin throughout 1993

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SELF HELP WEEKEND

The Birchgrove Group is a self-help group set up by HIV positive people with haemophilia for HIV positive people with haemophilia, partners and parents.

As you may be aware the Birchgrove Group recently held a National Self-Help Weekend in London, which was attended by over ninety people living and working directly with haemophilia and the HIV virus. The intention was to introduce people who were feeling isolated after all these years to others who were in the same situation as themselves.

People were introduced to the benefits that can be obtained from the various alternative therapies. The alternative therapies on offer were: reflexology, chinese herbs and acupuncture, homeopathy, shiatsu, there were also sessions on safer sex and alternative opportunities. Among those attending the weekend were medical professionals from the field of haemophilia, HIV and AIDS and representatives from the Macfarlane Trust, Haemophilia Society, Terrence Higgins Trust and the National Body Positive Group.

One of the aims of the weekend was to set up a network of self-help groups across the UK, to be run by HIV positive people with haemophilia for HIV positive people with haemophilia, partners and families. The Birchgrove Group is now able to put you in touch with a person with haemophilia in your region who is in the process of establishing a local group. If you are interested in being involved locally, contact the Birchgrove Group on Cardiff (0222) 373560 for further information.

The weekend was a great success and there are hopes that some more permanent developments will be formed as a result. A full report of the conference is available together with a discussion document proposing the help that should be on offer from the Birchgrove Group.

Some comments received from people attending the weekend. "We had a great weekend and it helped to know others who are in the same situation and to discuss problems with people who want to help." - A mum of an HIV positive boy with haemophilia.

"The friendship gained over the weekend is so strong, very supportive and deeply caring. Feelings that have never been allowed to be shown or talked about before, could be, knowing that they would be understood by all those attending. My most profound thanks to all in the Birchgrove Group. Long may we all live and prosper. - An HIV positive person with haemophilia.

"I don't think anyone knew what that weekend would hold for them, or what they would find when they got there. Well, if I said it was an outstanding success, that would be the understatement of the decade. Thank you to everyone concerned who did all the hard work to make a HOPE into REALITY." - An HIV positive person with haemophilia.

NEW SERIES TO START

A new series on von Willebrand's disease will be starting in the next edition of the Bulletin. The series will build up into a handy reference booklet about the condition.

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VIRAL TRANSMISSION OF HEPATITIS C AND HIV IN PARTNERS OF PEOPLE WITH HAEMOPHILIA

Heterosexual partners of haemophilia patients do not carry an exaggerated risk of HCV infection.

This, the principal finding of a study carried out at the Royal Free Hospital, largely confirrns what has been observed in earlier investigations

Dr Telfer revealed the findings of research designed to determine the risk of heterosexual transmission of HCV and HIV in partners of anti-HCV-positive haemophilia patients 'Quite a lot is known about the hetero-sexual spread of HIV infection,' he said, 'but not so much about the heterosexual spread of HCV.

Although most studies suggest a low level of risk, a recent US study on the incidence of non-A, non-B hepatitis showed that in six per cent of new cases the principal risk factor was exposure to a sexual partner

The Royal Free team tested the partners of 53 HIV-seropositive haemophilia patients, and the partners of 60 HCV-seropositive patients. Since 1983, couples attending the Royal Free have been advised to use barrier methods of con-traception to reduce the risk of viral transmission. But median exposure to the virus was found to be 10.6 years in the case of the HIV patients and 17.3 years in HCV patients. 'This indicates,' said Dr Telfer, 'a long period when partners would have been exposed to the virus before we began to counsel them about the use of condoms.'

Four of the 53 partners (75 per cent) of HIV-seropositive haemophilia patients tested seropositive for HIV themselves. Only one partner of the 60 HCV-seropositive haemophilia patients (1.7 per cent) was found to be HCV seropositive.

Dr Telfer concluded that:

i) There is a low prevalence of HCV infection in partners of haemophilia patients.

ii) HIV is more prevalent than HCV in partners of patients with both infections - a finding that is in keeping with the fact that their partners have had prolonged exposure to hepatitis C and are mostly HIV seropositive.

He reported that the Royal Free is continuing to advise both their HCV- and HIV-seropositive patients to use barrier methods of contraception.

THE NATIONAL BLOOD AUTHORITY – BUILDING THE FUTURE FOR THE NATIONAL BLOOD TRANSFUSION SERVICE

by John F Adey, NBA Chief Executive

On 1 April 1993 the National Blood Authority (NBA) was created and charged with managing all parts of the National Blood Transfusion Service (NBTS). My objective is to share with you my preliminary thoughts on how the formation of the NBA will help maintain the highest levels of patient care and service as the NBTS faces the challenges of the next decade.

Background

In April of this year, the NBA assumed the responsibilities of the Central Blood Laboratory Authority and the national Directorate of the NBTS. As of April 1994 the NBA will assume the responsibility for managing the thirteen regional transfusion centres, thus creating a truly national blood transfusion service.

NBTS Principles

At this early stage in the organisation's development, there are a number of issues confronting the NBTS to which we don't yet have specific answers. As we address these issues and build a unified national vision, we will, however, be guided by some strong principles. First and most important, the NBTS is concerned with providing outstanding patient care. We see our role as accomplishing this by effectively providing the bridge between the patient and the generous and much valued network of voluntary donors.

We remain committed to providing an ample supply of blood and blood products to meet local patient needs. The progress the English service has made toward meeting the domestic demand for blood and blood products with domestic resources is exemplary within Europe. This is increasingly important in the light of recent EC regulations like 89-381 which call for self-sufficiency in blood products across the EC.

Unfortunately, the exact definition of EC self-sufficiency is unclear and is understandably causing some speculation and anxiety among patients in England. While I don't know exactly how self-sufficiency will ultimately be defined, I do know that, whatever the outcome, patient care in England will not be jeopardised to meet self-sufficiency objectives. We will make every effort to continue progress toward self-sufficiency, but we will also ensure that the best products and treatments are made available to the patients in England, whether they are sourced domestically or not.

The supply of blood and blood products must also be timely. The logistics required to collect, process and distribute the huge amount of blood and blood products needed each day are challenging. Our ability to make quality products must be complemented by the ability to provide them where and when patients need them.

The supply of blood and blood products must be of the highest quality. Quality assurance begins with donor education and recruitment and continues with blood testing and stringent process and product quality controls. One of the most important elements of our quality control programme is the strong local relationships between donors and NBTS staff which ensure the English service continues to benefit from voluntary, unpaid donations. Any changes we make to the blood transfusion service must not jeopardise these important relationships.

Lastly, the blood supply must be cost-effective. This is in line with our patient focus. Every pound saved in the NBTS goes directly into improving patient care in other NHS services. New ways to operate more efficiently must continuously be sought out whilst ensuring that patients' needs remain fully satisfied and that the safety and soundness of the system is upheld.

Challenges

As we look forward to the next decade, the demands placed on the NBTS are numerous and changing rapidly. The primary role of the NBA in this challenging environment will be to co-ordinate our national resources, including research and development, and to allocate them in the manner that provides the highest level of patient care possible.

Specifically, there are a number of forces driving change in fractionated plasma products, like factor VIII which is used in the treatment of haemophilia. One issue affecting the potential demand is the emergence of new treatment philosophies which may dramatically increase the usage of many fractionated plasma products. Another issue driving change in coagulant factor demand is the development of recombinant products. Longer term, advancements in gene therapy may have a dramatic impact both on achievable levels of patient care, and on the shape of the fractionated products marketplace.

We at the NBTS welcome these changes and the Bio Products Laboratory (BPL) is working to determine the best way to meet the challenges of the next decade in plasma fractionated products.

Likely Improvements

I believe that the formation of a truly national blood service should assist us in meeting the challenges of the next decade and in providing real benefits in patient care. One of the internal improvements that we are working to achieve is increased co-ordination between each of the organisations involved in blood services, particularly between the RTCs and BPL, and between BPL and the clinicians treating patients. We also hope to identify and implement opportunities to improve testing and quality control procedures within each of the RTCs and at BPL, through enhanced experience-sharing and, where appropriate, increased standardisation.

Obviously, at this early stage in the NBA development, there are still many unanswered questions. These questions require each of us in the transfusion service to keep an open mind. We must strive to preserve the best of the existing system while at the same time creating a culture that is capable of changing to improve patient care.

John Adey

I want to stress that the future development of the NBTS is an on-going process. Each of us, in the centre and in the regions, depend on your feedback and support. I believe the formation of truly national service provides a historic opportunity. I know I speak for all those throughout the service when I say I'd like to make the most of that opportunity.

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A PROFILE OF DR ELIZABETH MAYNE

A profile of Dr Elizabeth Mayne verges on being a concise history of haemophilia treatment during the past three decades.

She began her haematology career in 1963 when there was "no effective treatment for people with haemophilia and they dreaded hospital admission."

She has welcomed treatment breakthroughs and been saddened by its setbacks during her long career.

Today, as Director of the Northern Ireland Regional Haemophilia Centre, Consultant Haematologist, member of the Haemophilia Society's Medical Advisory Panel and outgoing Chairman of the Haemophilia Centre Directors' Organisation, she believes people with haemophilia can "look forward positively to a better and brighter future.

"With its ups and downs, treatment has seemed like a seesaw during my career," she says. "There has been a long learning curve to achieve the present-day better treatment, but the problems that have been experienced over the years have yielded many positive results and lessons for the future." Dr Mayne remembers when simple dental extractions could mean many days, even weeks, for people with haemophilia in hospital.

However, in the late 1960's, when the first effective treatment utilising cryoprecipitate became available, for many it seemed as if a miracle had occurred. "Doctors and patients both became full of optimism and hope."

In the early 1970's a downside started to appear when some patients developed hepatitis. However, during the mid and late 1970's, home treatment programmes were introduced with a resultant change in lifestyle.

The boy with haemophilia was now able to attend school regularly, without long absences on account of bleeding episodes. Similarly, they were able to obtain training and consequently to secure jobs. Marriage and the raising of families was approached with increasing confidence. In the 1980's the impact of HIV infection was a tragedy for the haemophilic community worldwide. It brought home the essential lesson that blood products needed to be rendered safe from viral contamination.

"The present decade, the 1990's, are indicative of a new upswing in treatment," she said.

"Safer high purity concentrates are available, prophylactic treatment regimens are in progress and there is the future prospect of the introduction of gene therapy.

"When it becomes available, it should eradicate the most severe and crippling form of haemophilia."

Dr Mayne considers it has been a privilege to look after people with haemophilia.

"The majority of haemophilic patients have a great depth of understanding of their condition and to this end, they have been helped by their own patients' support group, the national Haemophilia Society.

"No other medical condition has had or has the benefit of such a well informed and helpful support group."

During her Chairmanship of the UK Haemophilia Centre Directors' Organisation, several changes relevant to haemophilia care have evolved.

These include: the publication of guidelines on the choice of therapeutic blood products; the introduction of cross-regional Haemophilia Centre audit; and in association with the Society, the compilation of the Health Service Circular HS30(93).

The latter sets out the aims and objectives for haemophilia care, particularly the need for comprehensive care centres and the availability of comprehensive care for all patients with haemophilia.

Dr Mayne acknowledges the outstanding help of her fellow colleagues from other regional Haemophilia Centres in achieving these results.

Dr Mayne has served as a member on the Committee on Safety of Medicines and has been a past member of the Northern Ireland Statutory Advisory Commission on Human Rights.

Her other main research interest is diabetes mellitus and the subject of her Doctorate thesis at Queens University Belfast examined the thrombotic complications of that condition.

Her personal interests include sports, cooking, gardening and she is an avid reader of novels and biographies.

Dear Doctor...

Our question this issue is "Why can't we have factor VIII as a tablet or patch?"

Molecules of factor VIII and IX are quite large, much larger than simple antibiotics which are readily absorbed across the lining of the gastrointestinal tract or skin. A further problem is that they are protein molecules, made of chains of aminoacids. The juices released into the gastrointestinal tract during digestion contain substances called enzymes whose very purpose is to break down proteins in our food for absorption. Any factor VIII or IX swallowed would be broken down into much smaller fragments, just like the proteins in our food. Unfortunately, the resulting pieces of the factor VIII molecule would be of absolutely no value as they do not retain the activity of the original large and complex molecule. Similarly, there are enzymes around the tiny blood vessels under the skin which would destroy any coagulation factor injected under the skin.

Attempts to wrap up molecules of factor VIII or IX in protective coats ("liposomes") which would protect the molecule from the action of the digestive juices or enzymes under the skin have so far failed, although research in this area continues.

Although factor VIII cannot be absorbed across the lining of the stomach or skin, the chemical DDAVP may be. This substance is often of value to people with von Willebrand's disease or mild haemophilia A (with a baseline factor VIII level of around 10%). A preparation of DDAVP in the form of a nasal spray is available, and this may be of clinical use in certain circumstances.

Giving coagulation factor concentrates by intravenous injection does actually offer some advantages over oral administration. Whenever any medication is given by mouth there is always some delay before the drug is absorbed and the benefit is felt. By contrast, after injection there is no such delay and the benefit is immediate. Giving factor concentrate by injection thus acts on the blood immediately, hopefully minimising the pain and discomfort caused by a joint bleed. This may even eliminate the need for further doses of concentrate.

Another problem associated with drugs in tablet form is that it is difficult to know how much has been absorbed from the gastrointestinal tract. A definite advantage of injection is that patients and doctors can be absolutely certain of the number of units that have got into the circulation. This is of particular importance in the setting of surgery or serious bleeding episodes, where we wish to be sure of the maximum value of a dose of concentrate.

Dr.P.L.F. Giangrande, Consultant Haematologist, Oxford Haemophilia Centre, Churchill Hospital, Oxford OX3 7LJ.

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HAEMOPHILIA AND HEPATITIS C

from the British Society for Haematology annual scientific meeting

While the treatment of haemophilia patients has been revolutionised by the judicious use of clotting factor concentrates, inability in the early years to effect viral inactivation has had fatal consequences.

Thus, while spontaneous bleeding can now be treated effectively, and while surgery has become a safer procedure, as many as 60 per cent of patients who contract hepatitis as a result of blood transfusion go on to develop chronic hepatitis. Some 20 per cent of these patients develop cirrhosis over the course of a decade, often with resulting liver failure and hepatocellular carcinoma.

It was against this bleak background of chronic viral infection - notably HIV and non-A, non-B hepatitis - that Dr Paul Telfer, from the Royal Free Hospital, London, detailed a study looking at haemophilia patients treated with blood products.

"Potentially, this is a very large problem - but we really don't know very much about the natural history of non-A, non-B hepatitis; in particular, whether every patient with chronic hepatitis is likely to develop complications, and over what time period this may develop". In 1989, the virus responsible for most cases of post-transfusion hepatitis was identified as hepatitis C.

The Royal Free study looked at 1,220 patients with congenital coagulation factor deficiencies, of whom 269 were anti-HCV seropositive. The median age of the patients investigated was 32 (range seven to 82) Some 74 per cent had haemophilia A, 17 per cent haemophilia B six per cent von Willebrand's disease. Of the remaining three per cent, six patients were carriers, and one patient had Factor XI deficiency. Bleeding was classified as severe in 67 per cent and mild or moderate in 33 per cent.

HIV status was sero positive in 42 per cent and negative in 58 per cent. Eight patients (three per cent were hepatitis B surface antigen (HBsAg) positive Median duration of exposure to concentrates was 15.2 years (maximum 28 years, minimum three years).

Some 224 patients (83 per cent) had evidence of chronic hepatitis, eight (three per cent) had portal hypertension, nine (three per cent) had liver failure, while one (0.4 per cent) had hepatocellular carcinoma and 47 patients died.

The study revealed that patients older than the median, those who had been exposed to HCV for more than 15 years, and HIV seropositivity were all independent risk factors for chronic hepatitis. The severity of haemophilia, however, was not independently associated with an increased risk.

Dr Telfer concluded that

i) There are a large number of haemophilia patients who are anti-HCV seropositive as a result of blood product therapy

ii) Chronic hepatitis is present in 83 per cent of these patients - a higher percentage than has been reported in post-transfusion hepatitis C

iii) 68 per cent have been exposed to hepatitis C for at least a decade, and 12 per cent for more than two decades

"This is a disease that is still early in its evolution," he warned. Over the next two or three decades we may be seeing many more patients presenting with liver failure."

He urged that treatment should be directed towards such patients, and towards those who are also HIV seropositive.

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DR RIZZA RETIRES FROM OXFORD HAEMOPHILIA CENTRE

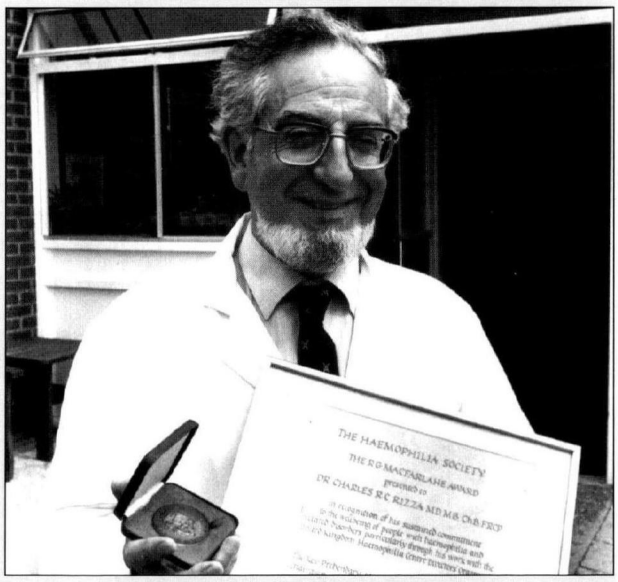
Dr Charles Rizza has retired after more than thirty years at Oxford Haemophilia Centre.

He took over as Director of the Oxford Centre from Rosemary Biggs in 1977. Over the years his major area of interest has been in HIV and hepatitis and he has been involved in the development of safer concentrates.

Very popular with his patients, Dr Rizza has always been ready to put himself out if there is a need. His popularity is shown by the fact that he is a past recipient of the Macfariane award for outstanding service to people with haemophilia.

Three events were held in Dr Rizza's honour to mark his retirement in October. There was a staff party at the hospital attended by his colleagues. An international symposium held at Wolfson College, Oxford, attended by an international audience; and a party held by past and present patients, with over two hundred present. At these events he received gifts including a video camera and binoculars.

Married with four children, Dr Rizza will have plenty to keep him busy during his retirement. He will continue to work on research projects at the Centre and is currently writing a book on the management and treatment of haemophilia.



Dr Ruzza with the Macfarlane Award.

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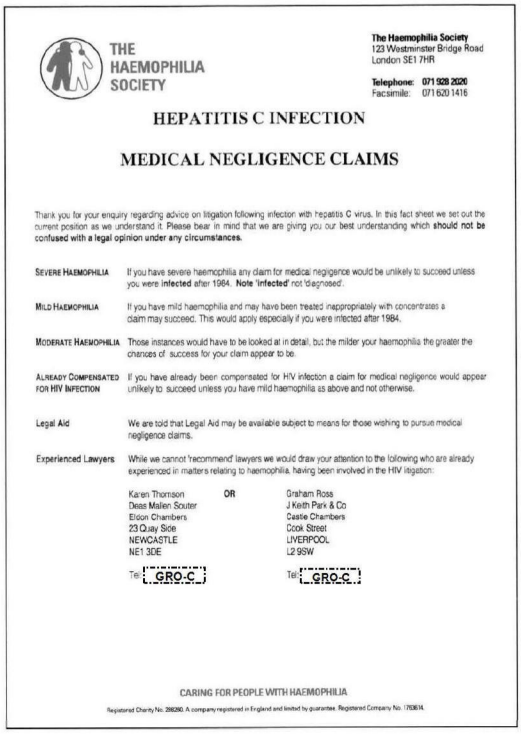
HEPATITIS C INFECTION

The Society receives a number of enquiries about what people should do about litigation concerning Hepatitis C.

The advice that the Society gives is printed below. If you require further details contact the Society national office.



THE HAEMOPHILIA SOCIETY

The Haemophilia Society
123 Westminster Bridge Road
London SE1 7HR

Telephone: 071 928 2020
Facsimile: 071 620 1416

HEPATITIS C INFECTION

MEDICAL NEGLIGENCE CLAIMS

Thank you for your enquiry regarding advice on litigation following infection with hepatitis C virus. In this fact sheet we set out the current position as we understand it. Please bear in mind that we are giving you our best understanding which **should not be confused with a legal opinion under any circumstances.**

SEVERE HAEMOPHILIA If you have severe haemophilia any claim for medical negligence would be unlikely to succeed unless you were **infected** after 1984. **Note 'infected'** not 'diagnosed'.

MILD HAEMOPHILIA If you have mild haemophilia and may have been treated inappropriately with concentrates a claim may succeed. This would apply especially if you were infected after 1984.

MODERATE HAEMOPHILIA Those instances would have to be looked at in detail, but the milder your haemophilia the greater the chances of success for your claim appear to be.

ALREADY COMPENSATED FOR HIV INFECTION If you have already been compensated for HIV infection a claim for medical negligence would appear unlikely to succeed unless you have mild haemophilia as above and not otherwise.

Legal Aid We are told that Legal Aid may be available subject to means for those wishing to pursue medical negligence claims.

Experienced Lawyers While we cannot 'recommend' lawyers we would draw your attention to the following who are already experienced in matters relating to haemophilia, having been involved in the HIV litigation:

Karen Thomson
Dees Mallen Souter
Elcon Chambers
23 Quay Side
NEWCASTLE
NE1 3DE
Tel: GRO-C

OR

Graham Ross
J Keith Park & Co
Castle Chambers
Cook Street
LIVERPOOL
L2 9SW
Tel: GRO-C

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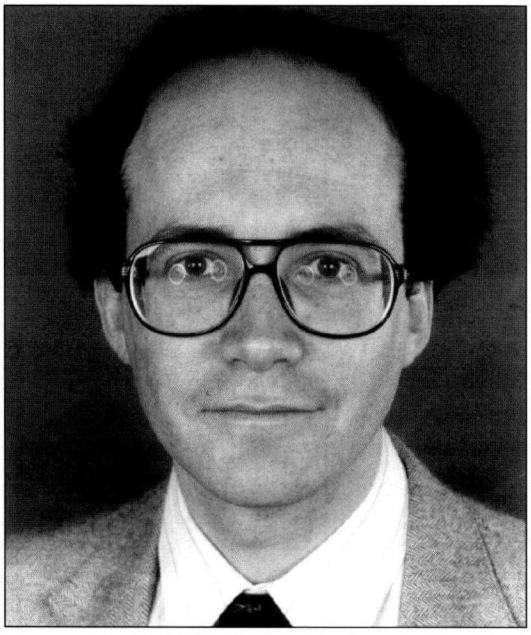
NEW APPOINTMENT

Dr Paul Giangrande has been appointed as Centre Director of the Oxford Haemophilia Centre at Churchill Hospital. The Society welcomes Paul to his new post and wishes him every success.



Dr Paul Giangrande

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HEPATITIS

The Society is currently making plans for a series of Hepatitis Awareness sessions in the UK.

Plans are still at an early stage, but it is likely that there will be six sessions held next year, where people will be able to receive advice from Society officers and health professionals.

Look out in the next edition of the Bulletin for details.