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Statement No: WITN6392001

Exhibits: WITN6392002 - WITN6392267

INFECTED BLOOD INQUIRY

WITN6392234



THE BULLETIN

CAMPAIGN ADVANCES ON THREE FRONTS

Encouraging progress continues to be made in the Society's new proactive campaign strategies. We have achieved a major step forward in organising the way the Haemophilia Society lobbies government on its campaign aims, with the registration of a new All Party Parliamentary Group on Haemophilia in the Houses of Parliament. This group is made up of members of parliament and peers from all political parties.

We have also created another new group – a Hepatitis C Think Tank – to help strengthen the campaign for financial recompense for people with haemophilia who have been infected with hepatitis C. The members of this Think Tank are experts in

legal, actuarial, medical and government relations. They will be working together to investigate a range of financial models that could be used to release funds to the HCV infected haemophilia community.

Meanwhile, the Carpet of Lilies campaign to highlight the number of people with haemophilia who have died, or are still suffering as a result of HIV or hepatitis passed on through contaminated blood products, is rapidly spreading across the UK. We currently have 153 parliamentary supporters committed, with news of more coming in all the time.

See pages 5-7 for more about the campaign.

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CONTENTS

Society News 2 – 4

Campaign News 5 – 7

GMTV 'Get Up and Give' 8

Other Fundraising News 9

Hepatitis - self-management special 10 – 11

Red Ribbon Page 12

AGM & National Conference 13

Children & Families Page 14

News Round-up 15 – 16

MAGAZINE OF THE HAEMOPHILIA SOCIETY

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Copies of the Haemophilia Society's commercial funding guidelines are available on request.

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LORD OWEN SPEAKS OUT

Former Minister of Health, Lord David Owen, has added his voice to the campaign calling for the government to pay compensation to haemophiliacs infected with potentially lethal viruses from contaminated NHS treatment. It was the first time the cross-bencher has spoken about his own work, more than 25 years ago, which should have safeguarded their health.

Interviewed on BBC Radio 4's Face the Facts programme on 3 August, Lord Owen described how, from the early 1970s, he grew increasingly worried about blood products Britain was importing from America to treat people with haemophilia. He had been aware that Americans were paid for giving blood and, consequently, donors included prisoners and occupants of 'skid row' who were at the highest risk of carrying viruses.

"I decided that if we invested enough, we could become self-sufficient so our blood would come only from British sources and we felt we would then be able to be more confident that it would not have

contaminated blood in it", Lord Owen said. "The decision was to invest enough money to become self-sufficient, which was several million pounds, and I announced the news publicly and I also announced it in parliament."

It was only years later, as people with haemophilia were being diagnosed with HIV in the 1980s, that Lord Owen realised his plans had not been carried out and the millions he had earmarked had not reached their destination. "I was very upset that the decision I'd taken in 1975 had not been fulfilled. There was resistance at the Department of Health at the time to putting in the money. I think some people felt this was an unproven danger, that we were putting money in without knowing what the viruses were, but then prevention is everything in health. The government should make a generous increase in the compensation pool of money available for these cases and accept some degree of responsibility - moral if not anything else."

MAKING A STRONG CASE

The Hepatitis C Think Tank is a new initiative, set up to research and provide necessary data to underpin our campaign for financial recompense for people with haemophilia infected with hepatitis C. The Society is keen to ensure that opportunities to press for financial recompense are not lost due to a lack of information on how many people might qualify for money; the future progression of hepatitis C in people

with haemophilia; or estimates of likely cost to the Government. We believe that this group will formulate a strong case for the practical workings of any recompense scheme.

The legal, actuarial, medical and government relations experts who form the Hepatitis C Think Tank will be working together to investigate a range of financial models that could be used to release funds to the HCV infected haemophilia community. The first meeting took place in June, when each member had the opportunity to request the information needed to consider the

issue, with these initial analyses being developed at the second meeting in September.

Important 'snapshot' survey

The Think Tank is currently in the process of collating data, including a survey of the impact of hepatitis on people's lives, which is being run through two Haemophilia Centres. Ultimately, the group will structure and cost a proposal for presentation to the Government, after a full discussion within the Society. We shall keep you updated as the project continues.

Spreading the carpet further

The AGM in Solihull was the first opportunity for members to see how far the Carpet of Lilies has spread across the UK. Progress to date shows the campaign has 153 parliamentary supporters, and news of more supporters keeps coming in. It's a great reflection of all the work being done across the UK by members. So remember, if you've recently been in touch with your MP to sign them up as a supporter, please let Jo at Weber Shandwick or **GRO-D** at the Haemophilia Society know about it!



CAMPAIGN AIMS

The Carpet of Lilies campaign asks parliamentary supporters to sign up to the Haemophilia Society's campaign aims:

- * the provision of recombinant for all, children and adults alike, throughout the UK and regardless of postcode, to avoid the risks of future blood-borne infections
- * a public inquiry into the tragedy of contaminated blood products that caused mass infection of people with haemophilia with the HIV and hepatitis C viruses through their NHS treatment
- * financial recompense through a hardship fund for those people with haemophilia infected with the hepatitis C virus, in addition to the financial assistance scheme established by Government in 1987 for those infected with HIV (The Macfarlane Trust)

MPs WILL WEAR A WHITE LILY TO SHOW SUPPORT

In October, we have plans to make our 'Carpet of Lilies' even more visible. On the day of the first Prime Minister's Question Time after the summer recess, we will be asking all our parliamentary supporters to wear a white lily badge and ribbon, particularly in the Chamber of the House of Commons during the Prime Minister's Question-time session. We are hoping that this show of support will remind both the government and the media that the importance of this campaign is paramount.

We shall also be asking all of our parliamentary white lily-wearers to attend a photo call at Westminster, which we will be inviting national and regional media to attend. Please let Ben at Weber Shandwick know if there's a local journalist you think would like a photograph, and he will arrange to get a picture to them.

PLAY YOUR PART IN OUR CAMPAIGN

As part of the development of the Society's media relations programme, we have now introduced an easy way for you to assist the Society at local level, using template local press releases. Press releases issued by the Society nationally are being adapted to allow members to add a local slant, or simply to add your name as a local representative. Having filled in your details, all you need to do is pass the story to your local newspapers and television/radio newsdesks.

If anyone would like to play a more active role in promoting the Haemophilia Society's messages at the local level, or would be willing to act as a spokesperson and/or case study, please contact **GRO-D** or

GRO-D at the Haemophilia Society Press Office on **GRO-C** or by e-mailing

GRO-C

Campaign resources...campaign resources...campaign resources...

Thanks to an excellent suggestion from a member of the Haemophilia Society (thank you, **GRO-D**), Weber Shandwick have prepared a short briefing note for members meeting their MP as part of the Carpet of Lilies campaign work. It consists of a key message sheet, some fast facts and a checklist.

If you would like a copy, please get in touch with Jo at Weber Shandwick on

GRO-C

or on e-mail at

GRO-C

and we will put one

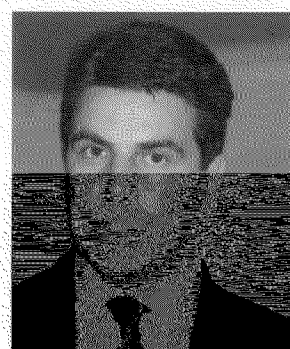
in the post to you!



QUESTIONS AND ANSWERS ABOUT THE CAMPAIGN

Q Why is the Society campaigning for a 'hardship fund'?

A The Society's communications and public affairs advisors have chosen the term 'hardship fund' as a means of conveying the message that infections passed on through contaminated blood products are causing actual hardship. And at the same time, that some sort of special fund needs to be set up for the purpose of providing financial help. The Society does not rule out other forms of financial help – including compensation, of course. However, we are aware that the normal route to compensation is through the courts of law and legal process. The setting up of a special fund would be a very different process, involving a political decision by government and MPs – as happened when the Macfarlane Trust was created as a special political initiative with all-party support. Our message is that the tragedy of contaminated blood products needs to be addressed now, with funds made available as a matter of urgency to enable those affected to have the best possible quality of life.



Weber Shandwick director, David Peel, fielding questions about the campaign at the Society's Annual Conference

Q Would any fund be means tested?

A The Society accepts that the use of the phrase 'a hardship fund based on evidence of need' has caused some confusion. The 'need' referred to in this phrase is clinical need, just as is used in applying for money from the Macfarlane Trust. The Haemophilia Society has been careful to note the objections from our membership concerning means testing and stresses that we have no intention of proposing a means tested scheme to government.

Q Why would an application for financial help need to be assessed at all?

A All recompense schemes operate on a framework that judges, amongst other things, medical condition. This is particularly important with hepatitis C, which affects individuals very differently. If a scheme were to be established to provide financial assistance for people with haemophilia affected by HCV, medical criteria would need to be established to determine eligibility and assess the appropriate level of awards.

Q What is the campaign's position on the current recombinant shortage?

A The Society believes that the current recombinant shortage should not prevent the government from making a policy commitment to providing recombinant for all, regardless of postcode. We are continuing to lobby hard for this assurance from the Department of Health.

No justification in excluding people with haemophilia from settlement

Scottish Health Minister Mrs Susan Deacon AM announced on 29 August that negotiations will begin shortly on compensation pay-outs to Scottish patients who contracted Hepatitis C during routine operations. This follows the recent English High Court ruling by Justice Burton, who determined that under the Consumer Protection Act 1988 compensation should be paid to a number of patients who had been infected through blood transfusions and other treatments.

In line with the approach set by that ruling, the Scottish initiative will only apply to people infected after the Consumer Protection Act came into force in 1988. This means that haemophiliacs who contracted deadly viruses

during blood transfusions in the 1970s and early 1980s will continue to receive nothing.

In a press release reacting to this announcement, Karin Pappenheim, Chief Executive of the Society, welcomed the acceptance that it is right to compensate Scottish Hepatitis C victims infected by NHS blood; but deplored "the continued refusal to extend the same justice to the haemophilia patient group. The Haemophilia Society has long argued that the Government has a moral obligation to provide recompense to people with haemophilia who contracted terrible diseases through products supplied to them by the NHS. The public will pass its own judgement on the morality of the Scottish Executive's refusal to do so."

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8

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SELF-MANAGEMENT SPECIAL

Anyone with a bleeding disorder can 'get the most out of life!'

Self-management for people living with long-term conditions will form a central part of the Government's Expert Patients Programme – promised in the NHS Plan as a means to improving health service provision for people with chronic illness – in recommendations coming out this month. The Haemophilia Society (along with seven other national voluntary organisations) has played an important role over the past two years by organising self-management courses as part of the Living with Long-term Illness project, which has fed into the Expert Patients Report.

Haemophilia Society courses

The Haemophilia Society has run eight self-management courses so far under the title **Get the most out of life!** Two of our tutors talk about their involvement and help to explain what the courses are about. Telling someone what the course is like is actually very difficult – self-management is very much about participants taking control of their condition and acting to positively improve their life. Take our word for it, it works! Come along to one of our next courses or ring **GRO-D** if you would like one run in your area.

GRO-A

GRO-A is one of a growing number of people living with a long-term medical condition to be trained to deliver a self-management course to others in a similar situation. He now co-ordinates the Society's 'Get the most out of life!' programme. Babs Evans finds out more.

GRO-A

GRO-A tell me a bit about yourself

I'm 42, I have haemophilia and I've been HIV and hepatitis C (HCV) positive for at least 20 years. This said, I'd characterise myself as pretty healthy, in that each of my conditions seems to be relatively controlled at the moment. More important than the health stuff is the real me. I'm happily married and live in the West Country. I retired from full time employment as an NHS finance manager some years ago and now spend my time learning to garden organically and, increasingly, in self-management, working with people suffering from a wide variety of conditions.

What is self-management?

In a sense self-management is something everyone does all the time – it's planning for the future and dealing with problems that come up along the way. The training that I'm involved in recognises that people with long term illnesses have additional problems and seeks to teach them skills to overcome these. The groups learn life planning and problem-solving techniques, then apply them to issues such as communicating with others about our conditions, dealing with anger, fear and frustration, eating well, dealing with medications and talking to health professionals. In addition we learn skills for ameliorating symptoms and relaxation. Obviously a course like ours doesn't replace treatment. What it does is give us skills to better deal with whatever life throws our way.

How did you become interested in it?

I've always been interested in non-medical ways of dealing with my conditions - at first because there wasn't much in the way of treatment available and later because I realised that they helped. I've always used complementary therapies and been interested in personal development.

What motivated you to become a tutor?

I chanced on a Haemophilia Society advert wanting tutors at a time when I was keen to find new roles in life (in common with many people with HIV, combination therapy changed my expectations and meant I felt the need to do something). It seemed an ideal way to develop something I'd already done and to help others. Initially I was sceptical about self-management on the basis that "I'm doing well, it can't help me", but I rapidly became a convert. It's helped me and I've seen it help most of the people who've participated in the groups I've worked with.

What impact has being a tutor had on you?

I've learned so much from working with the groups - about the similarity of the issues facing all people with long term conditions, about how amazingly strong they are and about how to manage my own life.

What happens on the course and how long is it?

The courses run once a week over a six-week period for roughly three hours a session. There's a certain amount of work to carry out between the sessions - but we don't set and mark homework! The learning is very interactive - you need to come willing to talk. We take advantage of the fact that every group is made up of experts on living with a long-term condition. Most people are shy at first but the groups are very supportive and the course is designed to involve everyone.



What sort of people come on the courses?

All sorts. On the courses I've been involved in, the age range has been between 17 and 70. They've had a wide range of conditions including haemophilia, HIV, HCV, ME, non-viral liver diseases, arthritis, heart disease and depression. We've had representatives from many ethnic groups and have also managed when English isn't the first language of some group members.

Which work best, courses where everyone has the same condition or a mixed group?

I personally like mixed groups, because it allows us to bring out the similarities between the problems facing us regardless of condition. This stops us feeling that our condition is 'special' and it stops the group getting bogged down in the medical details of their condition, rather than focussing on the personal issues that result from it. However, single condition groups can work too. It's a matter of preference.

Do men and women respond differently to the idea of 'self-management'?

I'm not sure. However, women are generally more able to talk about their conditions and willing to accept that learning new skills can help than men are. I've been involved in some groups that were mostly men with haemophilia and they were harder to 'get going'.

What do people get out of the course?

It varies. Some people begin to make really major life changes; most enjoy it and learn new skills; a few hate it. Evaluation work carried out in America (where the course originated) and more recently in Britain suggests that people feel more in control of their conditions and adopt more healthy behaviours after the course. The evidence also supports the lasting effect of the courses.

Babs Evans
HIV/HCV worker

GRO-A

GRO-A

is our newest recruit to the Society's team of four self-management tutors. Being himself in his late twenties, he is especially interested in getting people with haemophilia who are under thirty involved with the programme of courses. Some of you will have met him at the Young Persons' Manchester Weekend in September; and he will be at the Living with Hepatitis C Weekend in November.

"I have severe haemophilia A, HIV and HCV and I'm gay, so managing all that has always been a bit tricky for me. I do voluntary work in Liverpool and in the past have done talks to small and large groups on coping with haemophilia and co-infection. When I first heard about self-management I didn't know what it was. But after being encouraged to train as a tutor this May I saw what it was all about – and realised I could have been doing something positive about my conditions had I done this sort of course earlier in life.

My vision for the under-thirty age bracket is for them to be able to feel more comfortable about what and who they are, and to be given ways of managing their own conditions. I find it hard to describe the positive feeling I got whilst I was training; but I hope others will share it when I train them on the Birmingham and future courses."

W W W . H A E M O P H I L I A . O R G . U K

FORTHCOMING COURSES

Nailsworth (near Stroud, Gloucestershire)
Six Mondays beginning **1 October 2001**,
Birmingham (city centre)
Six Wednesdays beginning **24 October 2001**,
London (Angel tube)
Six Wednesdays beginning **31 October 2001**.

A course in **Bournemouth** is also planned for this winter. Contact **GRO-D** on **GRO-C** or e-mail **GRO-C** if you would like to join these courses or would like more information.

LIVING WITH HEPATITIS C WEEKEND

9-11 November

Hothorpe Hall, Nr Market Harborough, Leics.

Self-managing your life will be a theme throughout this weekend. The Society's four tutors will be working with you to help you to take charge of your condition and/or the way your life is affected by it. You'll also be able to hear the latest about HCV treatments and learn about all aspects of HCV healthcare from a leading expert. You can choose to explore alternative therapies or simply relax in your own way in the beautiful setting of the Georgian Manor. It's a chance to meet others affected by HCV and there will be a special focus for partners. A booking form is available from **GRO-D** but be quick! Places are going fast.

C ISSUES

C ISSUES is a quarterly newsletter for people affected by haemophilia and HCV. It covers news and developments in greater depth than space allows in *The Bulletin*. If you would like to receive regular copies, please phone John Morris at the Society or e-mail

GRO-C



GRO-A

GRO-A self-management tutor



CO-INFECTION SEMINAR REPORT

A total of 122 people attended the one-day seminar on HIV and Hepatitis C co-infection held at BMA House in London on 29 May. The event was organised as part of a project (primarily funded by the Department of Health) to improve the quality of treatment, care and support for people with haemophilia who are co-infected with HIV and hepatitis C (HCV). The greatest number of delegates were nurses, HIV consultants, representatives of HIV voluntary organisations and people living with haemophilia and/or HIV/HCV co-infection.

GRO-D

A wide-range of expert speakers, including people living with haemophilia and HIV/HCV co-infection, discussed topics that included epidemiology and the natural history of co-infection; provision of care in the UK; treatment issues and guidelines for the treatment of people living with co-infection. The following key points were raised:

Epidemiology

- A UK-wide HCV screening programme is needed to determine numbers of those with HCV. A national programme of research into the epidemiology of co-infection is also needed
- Funding for good quality data collection in the NHS is essential – or it won't happen
- The rate of sexual transmission of hepatitis C needs to be clarified

Provision of care in the UK

- Audit and accreditation of all Haemophilia Centres is needed
- Information to patients and their carers should be improved
- Designation of those particularly qualified to manage HIV/HCV co-infection is needed
- Co-ordinated care delivery must be achieved (this is a possible role for specialist nurses)
- Treatment needs are not the only issues that must be addressed in delivering care for people with co-infection

Treatment issues

- A very individualised approach to care and treatment of people with HIV/HCV co-infection is needed. Treatment should be managed only by those with clear

expertise and experience – joint clinics with HIV and HCV specialists are essential and smaller centres without experience must refer on.

- Important research questions have to be addressed: interactions between HIV and HCV and their treatments, whom to treat, who will respond, what is a cure, does treatment failure result in resistant viruses, does interferon reduce viral load/ improve CD4 count?
- A test that can be done early in the HCV treatment period should be developed, to identify people who will have an undetectable viral load at the end of treatment, but whose viral load will then break through during the next twelve months
- Alcohol reduction for those with HCV is crucial
- Better information is needed for treatment providers, individuals with HCV and their families
- The issue of funding for the provision of interferon and ribavirin needs to be addressed

Guidelines for the treatment of people living with co-infection

- There is a need for official guidelines for treatment and care of people with HIV and HCV co-infection
- The implementation of NICE guidelines should be reviewed

View the full report at www.haemophilia.org.uk or contact Babs Evans at the Society if you would like a copy by post or e-mail.

INFORMATION, ADVICE & SUPPORT

By phone:

Babs Evans at the Haemophilia Society **GRO-C**
9.00am – 4.30pm
The AIDS Treatment Project Helpline 0845 9470047
Mondays and Wednesdays 3pm – 9pm, Tuesdays 3pm – 6pm
The National Birchgrove Group 0345 697231
The Terrence Higgins Trust Helpline 020 7242 1010
12 noon – 10pm
The National AIDS helpline
0800 567123 - 24 hours

On the Internet

www.haemophilia.org.uk
www.aidsmap.com
www.birchgrovegroup.org.uk
www.tht.org.uk
www.positivenation.co.uk
www.hivandhepatitis.com

If you would prefer not to give other organisations your details we can get information on treatments or any issue and forward it on to you via post or e-mail.
Please contact Babs on the above telephone number or e-mail **GRO-C**

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GLOBAL FACTOR VIII RECOMBINANT SHORTAGE: LATEST

Dr Charles R M Hay, vice chairman of the UK Haemophilia Centre Doctors Organisation (UKHCDO) explains the current situation.

As you know, Bayer has encountered severe manufacturing problems since late last year leading to a very severe shortage of Kogenate and Helixate. Very little of either of these products has been released anywhere in the world since the beginning of the year. These products account for about half the recombinant factor VIII normally used in the UK. The other manufacturers had 'little or no' surplus supply and were unable to plug the shortfall. The UKHCDO, working with The Department of Health and The Haemophilia Society, acted to rationalise the use of recombinant factor VIII to make the most of those supplies that were available to us.

Action taken

Following policies similar to those being adopted throughout the western world, adults, and, in many cases, older children, were taken off recombinant factor VIII, some elective surgery was cancelled and many patients were taken off prophylaxis. Some older children were faced with the choice of prophylaxis with plasma-derived factor VIII or recombinant treatment on demand. UKHCDO also redirected recombinant from some adult centres to other centres for the treatment of small children who would otherwise have had to change to plasma derived factor VIII. The supply situation is now relatively stable and it is hoped that it should not be necessary to take any more patients off recombinant factor VIII.

Alternative treatments

The shortfall in supply has been made up using high purity plasma derived factor VIII, usually virally inactivated using two methods. These products have an excellent safety record over a period of more than 15 years. Although Monoclate is in short supply, there are generally adequate supplies of plasma-derived factor VIII.

Reasons for the shortage

To fully understand the complex reasons for the current shortage one has to recognise that the manufacture of factor VIII is very heavily regulated. Every detail of manufacture must be documented and must be conducted in a consistent way, as laid down by the regulatory authorities. Deviations from the usual 'recipe' are not permitted, even if they have no effect on the final product.

Bayer had been found to have altered some minor details of their process; had excess bacteria in some of the water at an early stage in the process and were

found not to be documenting various stages of manufacture adequately. Each batch of product generates several thousand documents recording every conceivable aspect of manufacture. None of these deviations from good manufacturing practice adversely affected the safety of the product but they had to be corrected anyway. This has caused massive disruption of manufacture and has lengthened the time it takes to manufacture a batch of Kogenate to six months. This has been very damaging for Bayer, which has announced two profit warnings in the last year, as a result.

In July, Bayer announced that they should not be regarded as a regular supplier of recombinant factor VIII until further notice. They held a meeting at the International Society of Thrombosis and Haemostasis to present the current supply and production situation and their forecast for a return to normal supply.

Outlook for supplies

Bayer are 're-engineering' their workforce, many of whom have been replaced or retrained. They estimate that they will not return to regular normal supply until the third quarter of 2002. Although Kogenate and Helixate will be released during the intervening period, there has been no prediction of the amounts that will be available.

Our best information at the present time indicates that, from September, there will be a modest increase in the supply of Baxter's Recombinate. From November, some supplies of Kogenate are expected, though the amounts are uncertain. It is expected that the supply of Helixate may be slower to pick up. Early in 2002, Wyeth hope to open their new Refacto plant and that should also lead to an improvement in supply. Supply should therefore begin to pick up in the autumn but may not normalise completely until next summer. New supply will be allocated to the youngest children first, and consideration must also be given to restarting prophylaxis amongst those small children who have gone onto treatment on demand. This will be co-ordinated by UKHCDO, to try to achieve some degree of equity of supply.

UPDATE: RECOMBINANT AND THE EUROPEAN COURT OF HUMAN RIGHTS

Many of you will remember from the AGM the question of a test case being taken to the European Court of Human Rights (ECHR) over the current system of provision of recombinant. The Haemophilia Society has sought legal advice on this issue, and the case is now being considered by ECHR legal experts. A formal legal opinion on progressing the case is expected soon. We will update you as soon as we have new information.

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Dr Rosemary Biggs, Haematologist
Died 29 June aged 89

(this obituary appeared in The Times on 9 July)

"Rosemary Biggs was internationally renowned for her work on the diagnosis and treatment of haemophilia. As a medical student at the Royal Free School of Medicine she helped with casualties in the streets of London during the Blitz. In 1944 she moved to the pathology department at the Radcliffe Infirmary in Oxford, where she spent the rest of her professional life. As well as contributing to the understanding of haemophilia, she helped to develop preparations of antihaemophilic factor for treatments. She strongly believed that there was no point in laboratory research, unless it was translated quickly into benefits to patients.

In the 20 years from 1950 she wrote a string of research articles, and in 1953 she and Gwyn Macfarlane published *Human Blood Coagulation and its Disorders*. Biggs took over the Medical Research Council's blood coagulation research laboratory from Macfarlane in 1967, and also became director of the newly established Oxford Haemophilia Centre. She was also editor of *The British Journal of Haematology and Thrombosis and Haemostasis* and a founder member of British and international societies in the field. She was awarded the James F Mitchell Foundation International Award for Heart and Vascular Research in 1971 and the Macfarlane Award of the Haemophilia Society in 1978."

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