

Yesterday's women

The story of R.A.G.E.

Researched and written by
Bec Hanley and Kristina Staley,
TwoCan Associates

This story is dedicated to all those who have supported the R.A.G.E. campaign over the past 15 years. We'd like to particularly mention Liz Gebhardt, Carole Hunter, Valerie Eldridge and Lorna Patch, R.A.G.E. Committee members who sadly have passed away and for whom *Yesterday's Women* has been written too late.

Yesterday's Women is a report commissioned by Macmillan Cancer Support and researched and written by TwoCan Associates. It aims to tell the story of R.A.G.E. (Radiotherapy Action Group Exposure), drawing on interviews with R.A.G.E. members and other people who played a part in their history, as well as a review of the documents kept by the people who were interviewed.

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Contents

Foreword	7
Executive Summary	9
Chapter 1: Introduction	14
Aims of this report	14
Structure of this report	14
The personal stories of R.A.G.E. members	15
Chapter 2: Our approach	21
How we selected and recruited people for interview	21
How we carried out the interviews	22
How we ensured ethical practice	22
The limitations of our approach	24
Chapter 3: Background	25
Radiotherapy treatment for breast cancer	25
Lady Ironside's case	29
The establishment of R.A.G.E.	32
Chapter 4: The R.A.G.E. story	34
Aim 1: Raising awareness of injuries and campaigning for sympathetic medical care in the NHS	34
Aim 2: Campaigning for national standards in radiotherapy	45
Aim 3: To seek compensation – via DH and through litigation	59
Aim 4: To provide mutual support	89
Chapter 5: Reflections	92
What were R.A.G.E.'s greatest achievements?	92
What can we learn from R.A.G.E.'s story?	93
Chapter 6: Conclusion and recommendations	97
Afterword	100
List of abbreviations	102
Appendices	103

Foreword

People who have cancer want to be cured. Radiotherapy cures more cancer than any treatment other than surgery. The women in this story are still alive 20 years after their treatment. But for them, and several hundred others treated at that time, the consequences of treatment have ruined their lives. Their problems become more of a burden with each passing year, yet they become increasingly invisible – yesterday's women.

But is this yesterday's problem? The particular set of circumstances that led to this story may never happen again. But complex cancer treatment is not risk-free. From time to time clusters of treatment-related problems are inevitable.

By 2020 there will be over 2 million people alive in the UK who have received cancer treatments. These treatments may affect their health in a range of different ways – from the trivial to the catastrophic. Yet, until recently, there has been little research on the measurement or management of 'chronic survivorship illnesses'. There is no national system to record outcome for those who have received radiation therapy or chemotherapy, and so no way of allowing national trends to be studied or clusters of problems to be spotted early. And meanwhile, new equipment, surgical techniques and drugs are being introduced at an ever-increasing rate.

Health professionals have developed hospital based follow-up systems to monitor people who have been treated for cancer. However, it might be more effective to educate people who are treated for cancer to recognise, record and report problems rather than to rely on the hospital systems. This would make it easier for problems to be picked up earlier.

If a medical treatment were found to have serious consequences, what would people receiving the treatment reasonably expect? They would expect to be warned of what might happen. But they would also expect that if problems arose, their needs would be recognised and appropriate help would be made available. They would expect to be given information to help them to help themselves manage changes in their health and social circumstances, and they would expect support to navigate the complexities of health and social care systems.

Sadly, when a treatment does result in a serious side effect, the NHS does not routinely move to provide this kind of support to those affected. Instead, there is a requirement that fault is allocated to individual people or organisations and tested in court. Yet many patients in this situation just want access to services to which others with equivalent disability are entitled. The women in this story found that an illness without a label made (and continues to make) every request for help a potential battle – and some felt forced to resort to litigation.

In the specific case of late effects of cancer treatment, what most people want (in common with people with other chronic conditions) is information and support for self-management. They need face-to-face access to specialists relatively infrequently. A few survivors, like the women in this story, need ongoing help from a multidisciplinary team. Here the need is not just for such a team to assess them and clarify what interventions might help, but also to support them to access the services they need locally, where there may be no expertise or interest. A link oncologist in each cancer centre is helpful. But he or she can only deliver what is required by mobilising local services. The failure to implement guidelines produced by the Royal College of Radiologists (in partnership with R.A.G.E. - Radiotherapy Action Group Exposure) for those with radiation-induced injuries following treatment for breast cancer illustrates this challenge.

Nobody wants a system that makes a bad situation worse. Yet the R.A.G.E. story shows how this could still happen. No one emerges unscathed from this story: doctors, politicians or lawyers. Yet all meant well.

Radiotherapy for breast cancer is very much safer than it was – in no small way due to R.A.G.E.'s campaign. Macmillan Cancer Support hopes that this report will stimulate more discussion about chronic survivorship conditions in general and the late effects of radiation treatment in particular. Macmillan Cancer Support will be working on others to focus on six areas:

- the need for a national register of consequences of cancer treatment
- the need to support patients to recognise & understand changes in their health after cancer treatment, to provide the information and help they need to manage these and to understand when and from whom they should seek help, including appropriate face-to-face, written and web based information.
- the need to improve communication between primary and secondary care
- the need to develop innovative ways to bring multidisciplinary specialist expertise to patients with rare, severe treatment related chronic illness
- the need for innovative commissioning models to help people with severe chronic survivorship illnesses get the care that they need
- the need to develop an expert patient programme for chronic treatment related survivorship conditions.

Jane Maher,
Chief Medical Officer, Macmillan Cancer Support

Executive summary

This report aims to tell the story of R.A.G.E. (Radiotherapy Action Group Exposure), drawing on written material and interviews with a number of people who were part of their history. R.A.G.E. is a group of women who experienced terrible long-term side effects as a result of radiotherapy treatment for breast cancer. Radiotherapy works by destroying cancer cells in the treated area. Long-term effects after treatment for breast cancer are relatively rare, but can be severe. They begin months or years after treatment, tend to persist and get worse rather than better. They include loss of use of an arm, chronic uncontrollable pain, fractured ribs, difficulty with breathing, severe burns to the skin, digestion and circulation problems.

It seems that during the late 70s and early 80s, within a particular group of hospitals in the UK, a number of factors combined to result in an increase in radiation-induced injuries. These risk factors are well understood today and are now carefully avoided. But it took a very long time for this understanding to become public knowledge. The R.A.G.E. women initially found it very difficult even to get their problems recognised, let alone to gain an understanding of how and why they had been damaged.

It wasn't until as late as 1991, when one of the women, Lady Ironside, took her doctor to court, that the women realised that there were others like them. Although Lady Ironside had to discontinue her case because of costs, her case was crucial to the development of R.A.G.E.

Lady Ironside met up with the other women who had experienced similar damage, including Jan Millington, and together they set up R.A.G.E. As an organisation, R.A.G.E. has four key aims:

- to raise awareness of the injuries and campaign for sympathetic medical care within the NHS
- to campaign for national standards in radiotherapy
- to seek compensation commensurate with the injury
- to provide mutual support.

The work that R.A.G.E. has taken forward to achieve each of these aims is summarised below.

Raising awareness of the injuries and campaigning for sympathetic medical care within the NHS

R.A.G.E.'s early campaigning on this issue was extremely successful in gaining support from MPs and the leading cancer experts. In 1994, in response to lobbying from R.A.G.E., the Royal College of Radiologists

(RCR) set up the Maher Committee. This committee was tasked with considering how the NHS should manage the treatment of women with radiation induced injuries and published its report in 1995. The report recommended a multidisciplinary approach to the care of the women, with a focus on symptom control. Perhaps most importantly, the committee recommended that there should be one oncologist in every cancer centre with responsibility for women with radiation induced injuries, who would act as the link person and co-ordinate each patient's care.

Although highly valued on its release, in the longer term this report had very little impact. One of the key lessons for those involved was the importance of focussing on the implementation of guidelines, as well as their development.

Based on their experience of using cancer centres over a number of years, the R.A.G.E. women have concluded that they need a specialist national centre, staffed by professionals with an understanding of their injuries and the skills to help them manage their symptoms more effectively. Although there have been a number of promising offers and initial plans, no national centre has yet been established and many R.A.G.E. women still aren't able to access effective treatment.

R.A.G.E. has also instigated and supported research to find new ways of treating the women's symptoms. In 1996 they secured funding for a trial to look at whether there were any benefits from hyperbaric oxygen – a treatment that had shown promise in treating people with multiple sclerosis. Regrettably, this trial showed no benefit for women with radiation damage.

Campaigning for national standards

After extensive lobbying by R.A.G.E., the Department of Health agreed to fund an audit to investigate how the R.A.G.E. women's radiotherapy treatment had led to such serious injuries. Thelma Bates, who had been the Senior Vice President at the RCR was asked to lead the audit.

The Bates and Evans report, published in December 1995, identified the common factors in the treatment of 126 women who took part in the audit. The main finding was that moving women in between treatments greatly increased the risk of injury. High dose techniques also increased the risk. Based on these findings, the report made a number of recommendations to help improve radiotherapy practice.

Views about the impact of the report are divided. But disappointingly again for the R.A.G.E. women, it was of little help in gaining compensation for the injuries they had suffered.

Seeking compensation commensurate with the injury

The lives of all of the R.A.G.E. women were profoundly affected by their radiation-induced injuries. Like many people who feel they have been harmed in some way as a result of medical treatment, they wanted an apology and an appropriate level of compensation.

In 1993 R.A.G.E. appointed a legal adviser, who worked for Russell, Jones and Walker (RJW). She led the women to believe that they had a strong legal case for compensation.

Some R.A.G.E. members did not want to follow the legal route – they were more in favour of pushing the Department of Health for a public enquiry that might lead to compensation. But others felt they really had no choice. Government officials told them repeatedly that the only way they would ever gain compensation was by going through the courts. This led to a great deal of tension amongst members of the R.A.G.E. Committee.

By 1995, the women's concerns about the legal action had reached such a peak that they decided to separate themselves from the litigation and focus on seeking compensation through other means. They then concentrated their efforts on lobbying MPs, the House of Lords and government ministers. This led to Early Day Motions, as well as questions in the House of Commons and House of Lords. But the answer from ministers was always the same - that compensation would only be payable if negligence could be shown through legal means.

In the meantime, the litigation did proceed but without the support of R.A.G.E. RJW took forward a group action involving over 130 women (only half of whom were R.A.G.E. members). They gained Legal Aid assistance for 125 of these. The group action was a big risk – very few have been successful in this country. But the fact that Legal Aid had been secured made the women believe there was some hope of winning, but also made it very difficult for them to go elsewhere for legal advice.

In 1995, 10 test cases were selected to represent the 130 women, and RJW initially identified nine principal issues, which they believed underpinned their case. But after the defence team's experts pointed out serious flaws in their arguments, RJW concluded that the nine principal issues could no longer be supported, and reduced them to one.

In December 1997 the litigants were summoned to a meeting and advised that only three of the original ten lead cases could proceed. This was a devastating blow for the women whose cases were dropped.

Almost on the eve of the trial, the defendants offered to settle for £2 million. But the women weren't told how this sum would be divided and realised there would be little left over after covering their costs. So they decided to proceed to trial.

The trial took place in early 1998. Only two of the original test cases were tried, and neither of these women had been treated at a hospital where there had been high rates of radiation induced injury. The central legal question was whether the doctors had been negligent. In her summing up, the judge said that she found the case to be of exceptional difficulty, and commended the women for their courage in coming to terms with their condition. But she found in favour of the defendants, concluding that the doctors' practice had not been negligent and consistent with the standards at that time.

Losing the case was a huge blow for the women involved and for some resulted in great financial loss. Even though R.A.G.E. had long since distanced itself from the case, the judge's conclusions seriously undermined their attempts to gain compensation by other means. The Government has since stated that R.A.G.E.'s claim for compensation has effectively been fought and lost in the courts. However, the R.A.G.E. women still believe there are strong moral arguments for compensating them for their suffering.

Providing mutual support

One of the experiences shared by many R.A.G.E. members was a deep sense of isolation. After years of wondering and worrying, R.A.G.E. helped hundreds of women to finally find out what had caused their injuries. These women also found much-welcomed practical and emotional support and benefited greatly from the understanding of others who shared their experience. In addition to providing practical advice on how to cope with daily living, some R.A.G.E. members have acted as advocates for their peers. This mutual support has been an essential lifeline for many R.A.G.E. members. Throughout its history, R.A.G.E.'s work has therefore involved much more than its activity around campaigning.

R.A.G.E.'s achievements

Although R.A.G.E. has not yet achieved all its aims, it has still achieved a great deal. Many people, professionals and patients alike, believe that R.A.G.E.'s greatest achievement has been to improve the standards of radiotherapy treatment for breast cancer in the UK. For R.A.G.E. members, it is particularly important that other women are prevented from going through the same experience and that women today are able to make better informed choices about their treatment.

Lessons

R.A.G.E.'s story offers a number of important lessons. A very widely held

view is that legal action is not the best way to resolve the issues for people damaged by medical treatment. Many believe that the vast amount of public money wasted in legal fees could have been better spent in providing the women with compensation.

It is also clear that more should have been done when the women first raised their concerns. This could have avoided costly legal action. Some health professionals have commented that most of the problems arose because at the time no one was willing to take responsibility for what had happened.

The story also highlights the need for better follow-up of patients after any form of cancer treatment or therapy, especially if any aspect of a treatment is changed. Such a system could have identified the problems experienced by the R.A.G.E. women much earlier and perhaps prevented some of the women's injuries. Once a problem is found, it is also important that there are better ways to support the people with injuries, to help them manage their symptoms and improve their quality of life.

We are now entering an era where people with cancer are living longer after treatment – by 2020 there will be over two million people alive in the UK who have been treated for cancer. Quality of life is therefore becoming an increasingly important issue. Yet, until recently, there has been little research on how many people suffer long term damage after treatment, or how best to care for them. And there is no national system to record what happens to people after they receive radiation therapy or chemotherapy.

The lessons from R.A.G.E. are therefore still very relevant today, in helping us to remember the importance of living well after surviving cancer.

In response to this report, Macmillan Cancer Support will be working with others to focus on six priorities:

- a national register of consequences of cancer treatment
- support and information for patients after cancer treatment
- improved communication between primary and secondary care
- the development of innovative ways to bring multidisciplinary specialist expertise to patients with long term effects of cancer treatment
- the development of innovative commissioning models to help these patients get the care that they need
- the development of an expert patient programme.

Chapter 1: Introduction

Aims of this report

This report tells the story of R.A.G.E. (Radiotherapy Action Group Exposure) – a group of women who experienced terrible long-term side effects as a result of radiotherapy for breast cancer. R.A.G.E. was set up in 1991 and at its most active from 1993 to 1998. The group continues to exist and still offers support to nearly 250 members.

R.A.G.E.'s experience offers useful lessons for different groups – other patient groups who feel they have been harmed by the NHS; health professionals who provide treatment which can have damaging long-term side effects; and government ministers and officials who are faced with demands from patients who believe they may have been harmed by medical treatment.

Yet R.A.G.E.'s story has never been written down. Different papers are held by various members of the group and by others who were involved in R.A.G.E.'s campaign. R.A.G.E. members are getting older and frailer. So with help from Macmillan Cancer Support they have decided to create a record of their experience – before more key members of the group, and others who played an important part in R.A.G.E.'s story, die or become too unwell. R.A.G.E. members feel they are 'yesterday's women' as their story seems to have been forgotten. They are anxious to ensure that no one has to learn the same lessons all over again.

This report therefore aims to tell R.A.G.E.'s story – where possible in the words of people who were part of the story at the time.

Structure of this report

At the beginning of this report, you'll find the stories of three R.A.G.E. members, that they have written themselves. We hope this will set the rest of the report in some context.

We then describe the methods we used to put this report together. In chapter three, we offer some background to the development of R.A.G.E. – in particular the history of radiotherapy over this period, and then details of a legal case that led to the establishment of R.A.G.E.

Chapter four forms the bulk of this report, as it tells the story of R.A.G.E., using the group's four key aims as a structure. In chapter five we reflect on the impact of R.A.G.E., as well as the problems the group faced and the outstanding issues for its members.

Finally, in chapter six we offer some conclusions and recommendations for the future.

This report has been written for the layperson. We have not referenced every point, as we believe this would make the report hard to read. However, we have listed all of the documents we referred to in Appendix 1. Most of the report is based on what people told us during interviews. Copies of the interview tapes are held by Macmillan, where interviewees agreed to this. Some people's names have been changed to protect their anonymity.

The personal stories of R.A.G.E. members

This report is the story of R.A.G.E. – but to understand the story of the group, it's important to understand the experience of the women who are R.A.G.E. members. Below, you can read the stories of three R.A.G.E. members, in their own words. Each of the stories is anonymised.

Story A

At Christmas 1981 I felt as though I was on the crest of a wave. I had completed my first term at law school and had done very well in the Christmas exams. Then I read in Michael Baum's *Breast Cancer – the facts* that the typical breast cancer patient was '51, fat, childless and hypothyroid'. As I had all these risk factors, I went to my GP to ask for a mammogram. His reaction was typical, 'You women, you read all these books and then come down here imagining you've got everything'. He changed his tone when he discovered a slight thickening in my left breast and proposed to send me to a general surgeon at the local hospital. I asked instead for referral to a specialist breast unit at X hospital, and thereby possibly signed my own death warrant.

I was seen immediately and within a week had a small lump removed. It was, I understand, at a very early stage and the lymph nodes were not affected.

I was then given an appointment for radiotherapy. There was no discussion on alternatives or possible risks, just an appointment. I had radiotherapy every other day for 6 weeks. I did not know at the time that this would involve a higher dose of radiotherapy at each session than if I had attended every day and that this higher dose involved a greater risk of injury.

In August 1982 (about four months later), I began to have very severe tingling all along my arm, followed by pain, then complete loss of feeling in the arm, even though the pain persisted. In December, I told the surgeon about this. He just barked, 'You are absolutely A1,' and rushed out of the room. Loss of feeling could be associated with a number of

serious problems and he would have been careless had he not arranged for these to be checked out. He didn't of course, because he must have realised it was radiotherapy damage. At subsequent 'check ups' he diagnosed I was suffering from arthritis. My GP sent me to a number of doctors to investigate. This of course involved more scans and X-rays. Worst of all was the terrible anxiety that this was a recurrence of cancer. It was useless to tell me that nothing was wrong because I knew it was.

I arranged a private appointment at another hospital, eventually reaching an eminent neurologist. He wrote to my surgeon in 1986, '*She must be suffering from radiation damage, which is likely to progress*'. I was recently shocked to discover that X hospital had themselves acknowledged to my GP in that same year that I had brachial plexus neuropathy (BPN). Nevertheless, the hospital kept denying to me that there was any problem at all. My request to see a radiologist was refused – 'There was no point'. The consultant almost reduced me to tears. I was 'neurotic, arthritic' and it was 'all in my mind'. My husband was advised to 'trade me in for one that doesn't moan'!!

In all this time, the pain had become unbearable and the arm progressively weaker and the dreadful anxiety of recurrence remained.

In 1991, I read of Lady Ironside's action (see page 29). She had been treated on a very similar protocol to mine. It was admitted that her treatment (part of a cost cutting exercise) had unfortunately resulted in a higher than expected incidence of injury and had been discontinued. Quite clearly then, the hospital knew that I was radiotherapy damaged, yet they took no action at all, apart from one X-ray in 1982 and mammograms. I had no tests whatsoever until 1999.

In 1994, I suddenly became breathless. I had tried everything possible to keep fit, in spite of my pain and had swum 3 times a week. Suddenly, I could hardly manage one width. The neurologist I had seen before carried out extensive tests to discover that my left diaphragm was elevated and paralysed. He said this might be due to radiotherapy damage, or possibly a recurrence and referred the problem to X hospital who denied the diaphragm was paralysed. I had 'gas in the stomach'. It was however conceded that the other symptoms were caused by radiation damage - the first time the hospital had admitted after 12 years of denial. Had it been admitted earlier, I might have had a decompression operation or specialised pain relief.

Searching my medical records, I discovered that mention had been made of the pain clinic at X hospital, though no one had thought to tell me that such a clinic was available. I went there, and was given nerve blocks and acupuncture. What blessed relief after all those years of pain; I was able to sleep at night. It beggars belief that doctors, who are supposed to be so concerned for the patient's welfare, could just sit back and watch for 12 years, knowing that I was desperately anxious about the cause of my

problems and suffering pain that could have been relieved. Yet they have the nerve to recommend a 'positive attitude'.

In September 1997, I drew attention to extremely severe stabbing pains in my neck and to the fact that when I did my neck exercises, I could feel something pulling in the middle of my chest. Both these were quite new problems and clearly distinct from the previous radiation problems. At my next appointment, I asked to see the consultant and explained the symptoms. A junior doctor was instructed to get scans from the neurologist, investigate the problem and call me in for an MRI at X hospital. No progress of course. So I asked the neurologist to carry out an MRI, which showed in January 1999 that I had a recurrence of malignancy!! This time X hospital flew into action, prompted no doubt by their knowledge that I had taken full detailed notes of all my interviews. The tumour was completely separate from the breast cancer and life threatening - it was a sarcoma induced by radiation!!

The support of the R.A.G.E. committee members was I am sure, invaluable. As well as their personal support and comfort to me, X hospital would know that I was not going to sit down and die quietly!!

The operation to remove the sarcoma left me very, very breathless, and I cannot walk far or bend down at all. I also have a painful lymphoedema. There was of course the dreadful fear that the sarcoma might have spread elsewhere, particularly considering the long delay in diagnosing it.

I try to push this to the back of my mind, but it comes back when I cannot sleep. Almost every day it is the first thing on my mind on waking. It has of course cast a great cloud of anxiety over our last years. Had this been inevitable I should have found it easier to bear, but it was not inevitable. It was caused first of all by excessive radiation, but most of all by the refusal of X hospital to admit the problem or follow me up.

I am now under the care of a very understanding consultant for whose support and meticulous monitoring I am most grateful. But we are now left in a state of great anxiety, particularly as chemotherapy would not be effective against any recurrence. I have constant severe pain and we must have lost thousands of pounds in lost earnings and all because of a treatment that might not have been necessary.

Story B

My breast cancer was diagnosed in May 1990 and probably like many others before me, I found the news that I had the disease almost unreal in that it was conveyed to me in a few short sentences.

Treatment to that date had been surgery (lumpectomy). This was then to

be followed by radiotherapy and here my problems really started. I was sick almost every day, suffered a severe shoulder and arm pain and could not swallow. I was also exhausted.

The radiotherapy doctor had warned me about the swallowing problem. No one however, advised me of any other difficulty. The exhaustion lasted for several months and I felt permanently tired, although could not sleep in spite of this.

I returned to work in October on a part-time basis. Agreement was reached that I should return to full time work in November. We also discussed my plans to continue in employment until the age of 63 years. I thoroughly enjoyed my work, which was as PA/secretary to a director at one of the major UK banks.

But my plans to continue in employment to the age of 63 were short lived. During one Saturday and prior to returning to work full time the following Monday, a sudden onset of severe chest pain which travelled to my throat and into my jaw, had me convinced that I was suffering a heart attack. I was taken to the local hospital's emergency department where, after many hours of exhaustive tests, I was advised that I had a "lung blood clot". I was admitted, but much later was told that I was suffering a chest infection. This was all very confusing, but at that time I felt too ill to raise any questions.

A scan carried out on my last day in hospital revealed 'severe internal bruising' and my consultant asked me whether I had 'been involved in a major accident'. So lacking in knowledge were my husband and I that we did not at this stage attribute my internal injuries to the radiotherapy treatment and we were both astonished by the 'major accident' question. The following year one of my lungs was found to be 'scarcely working'. The year after that, three of my ribs fractured, my left arm ceased to function properly and my diaphragm was elevated (paralysed). And so the catalogue of disasters continued. I was passed from clinic to clinic at the hospital and was becoming increasingly unwell with absolutely no idea of the cause of my problems.

My husband and I eventually, and very much later, concluded that my problems had to be connected with radiotherapy, but we also thought that there had probably been an 'accident' with the radiotherapy. The further consultation with a radiotherapy doctor left me so distressed that I was never to return to that clinic – he had commented, "It is not cancer, it is still all there – but I cannot help you". When I asked what the problem was, he said that he "did not know". He then left the room, leaving me with a nurse. She commented that I appeared distressed and could she "reassure me by pointing out that there were many grey areas in medicine". I was not reassured. I felt very ill and did not know why.

After many more months, my husband concluded that my continuing

health problems had to be a "radiotherapy accident". I put in a claim to my personal accident insurers. That company eventually received a report from the hospital, which said that I had "radiation changes to the lung and chest wall". This was my first real knowledge and the information had obviously been forced out of the hospital by my placing a claim for what I eventually concluded had been an 'accident'.

My experiences were so distressing that I eventually refused to return to the hospital which had administered my radiotherapy treatment.

My life now revolves around morphine for severe pain. I seldom leave my home; any exertion leaves me breathless and the pain quickly breaks the control barrier with the minimum exertion. Sometimes I have to spend day after day in bed. I find that complete rest seems to be the partial answer to comfort. At least it helps to keep the pain under control for most of the time.

The pain is always there, but bearable provided there is no exertion. To exert oneself is a recipe for chronic pain. It is so very bad that one feels at times almost close to death. This feeling, I am sure, has to be experienced to be understood.

Story C

This R.A.G.E. member had a successful business career until 1986, when she had to give up her job because of the impairments caused by late radiation damage. She has not been able to work since, and has had to give up her house. Her hobby was fine needlework, which she has not been able to do since 1986. This letter was drafted to the chair of X hospital in November 1993, but never sent.

'I was diagnosed in early 1985 as having bilateral breast lumps. Within a week the surgeon at X hospital had performed the necessary operations. As I had always had regular check-ups, the two growths were detected in their very early stages. One was malignant. I was advised in the days following my operations that three courses were open to me: To do nothing, and hope for no recurrence of the disease – this was felt to be risky. To have total mastectomies – this was considered to be far too drastic in the circumstances. Or to have a course of radiotherapy treatment – this was the strong recommendation.

Neither then nor at any other time, either before or after the surgery, or before or during the radiotherapy, was I given any counselling whatsoever. The only comment made about radiotherapy was that some patients sometimes felt a little tired after the treatment.

Since early 1986 I have been in constant pain and have now lost the use

of my right arm and hand. On my visits to X hospital, I tried to bring my increasing pain and disablement to the attention of my radiotherapist, and in every case I was treated as if I were a troublemaker. There are several occasions, but the following particularly come to mind. In the early stages, I detailed my symptoms to my radiotherapist and he said he had arthritis too. On a later occasion when attending the hospital for occupational therapy, for which my condition soon became too severe to be of benefit, I arrived in great pain and distress. The therapists were instantly helpful and sympathetic, and telephoned for a doctor. I was seen by my radiotherapist. He said there was nothing he could do. He said I should just tuck my arm in my coat, like Napoleon or Nelson and he didn't remember who.

Were you aware that women were being damaged by incorrect or incorrectly administered dosages of radiation in your hospital? That when it was brought to the attention of your radiotherapist, he always gave the impression that in some way it was the women's fault? If you were aware, why did you not immediately form a committee of neurologists and other disciplines to try to help us in our plight? If you were not aware, how could that possibly be other than by a watertight conspiracy? These are questions that will not go away'.

This R.A.G.E. member adds:

Many years after the above operations and radiotherapy to my right breast area, during a regular check-up, my cancer specialist found abnormalities and he said that a mastectomy must be performed without delay. This cancer was a direct result of the over dosage and careless placement of my original radiotherapy. I am left deformed and disabled by gross medical mistakes and can only function at all on a regime of quantities of medication, prescribed by a pain clinic.

There are now known to be hundreds of cases of serious post breast cancer radiotherapy injury. Many women have had amputations. All of us are in constant pain.

Chapter 2: Our approach

Our approach involved carrying out a literature review as well as interviewing key people from R.A.G.E.'s history. We first read through essential background documents selected by Jan Millington, R.A.G.E. member and Jane Maher, the Chief Medical Officer at Macmillan Cancer Support. The people we interviewed also provided us with additional documents and papers from their personal records, which we included as part of the literature review.

How we selected and recruited people for interview

We drew up a long list of potential people to interview, based on recommendations made by Jan Millington and Jane Maher and through identifying key people in the background papers. The list of people we interviewed (who also agreed to be named in this report) can be found in Appendix 2, along with a brief biography.

A short-list of twenty individuals was agreed with the Project Steering Group (Steering Group members are listed in Appendix 3). This included eight R.A.G.E. members and twelve professionals. These people were selected because individually they each played an important role in R.A.G.E.'s history and as whole they included people with a diverse range of perspectives.

Recruiting R.A.G.E. members

Jan Millington sent a letter of invitation to the relevant R.A.G.E. members asking if they would be willing to take part in the project (Appendix 4). The letter introduced the researchers, and briefly explained the project. We also offered to meet with individuals or to talk to them on the phone to provide more details about what taking part would involve. We spoke to everyone who agreed to take part, before sending them a detailed information sheet (Appendix 5) and subsequently setting up a time and place for interview. The interviewees were able to choose a time and place that most suited them.

Recruiting professionals

We sent the professionals a letter of invitation (Appendix 6) and a detailed information sheet about the project (Appendix 7). Again we offered to speak to individuals on the telephone to address any queries they had before making their decision about whether to take part. Interviews were again arranged at a time and place to suit the people who agreed to be interviewed.

How we carried out the interviews

At the beginning of each interview, we introduced ourselves and explained the aims and objectives of the project. We then explained the issues around confidentiality (see 'Ensuring Confidentiality'), asked the interviewees if they had any further questions and finally asked for permission to record the interview before starting the tape recorder.

During the interview, we based our questions on a semi-structured interview schedule, previously agreed with the Steering Group. This included questions about:

- how the person had been involved in R.A.G.E.'s story
- what they thought R.A.G.E. had achieved over the years relating to the four main aims of:
 - raising awareness of the injuries and campaign for sympathetic medical care within the NHS
 - campaigning for national standards in radiotherapy
 - seeking compensation commensurate with the injury
 - providing mutual support
- what lessons they thought had been learnt through R.A.G.E.'s experience
- what they would like to see happen to the report.

Each individual was also asked specific questions relating to their particular expertise. For example, R.A.G.E.'s parliamentary officer was asked questions about R.A.G.E.'s lobbying and campaigning, while the lawyers were asked about the details of the trial.

At the end of each interview, we asked the interviewee to sign a consent form (Appendix 8) (see 'Obtaining Consent' below). We also asked whether they had any other relevant articles, photographs or newspaper cuttings. We photocopied these documents and returned the originals by registered post within 7 days of the interview.

Immediately after each interview, we made brief written notes of the key points and our overall impressions. We then made detailed notes from the tapes, which were only shared between the two researchers.

How we ensured ethical practice

We initially sought advice on how to select and approach interviewees from an expert in oral history. We then drafted invitation letters and information sheets and developed a detailed proposal of how we would recruit people and conduct the interviews. We sent the draft documents

and proposal to two researchers with extensive experience in this area and made amendments in light of their comments. The final versions were then agreed by the Steering Group.

Providing support for interviewees

We did not expect the interviews to cause anyone any distress. However, because we were concerned that talking about the past might be upsetting for some people, we arranged for a counsellor to be available, to offer short-term help after the interview. The R.A.G.E. interviewees were given contact details of the counsellor so they could make an appointment themselves if they wished to do so.

Ensuring confidentiality

We explained to the interviewees that during the project it would only be the researchers who would have access to the tapes and written notes from the interviews. We also informed them that the notes would be stored on personal computers, so that no one else would be able to access those files.

At the end of the project, rather than destroying all the material, we asked the interviewees if they would be willing to allow Macmillan Cancer Support to keep the tapes as a historical record. We explained that Macmillan might refer to the tapes in future projects, and that the individual could specify who could have access to their tapes. We also gave people the option to have the tapes returned to them. Similarly, we explained that computer files would be erased, unless they specifically asked for Macmillan to keep them for possible follow-up work.

We also explained that the interviewees need not be identified in the final report, or could choose to be recognised for their contribution without having any of the information attributed to them. We checked with each person at the end of each interview, which information they wanted to be kept confidential (ie not included in the report) or which information they wanted anonymised (ie included in the report but not linked to them).

All of the people we interviewed were given an opportunity to review early drafts of this report, before the final version was made publicly available. This step ensured that they were happy with all of the information that had been attributed to them. This does not mean that they necessarily agreed with everything that has been said by other people.

Obtaining consent to use the information from the interviews

At the end of each interview, we asked the interviewees to sign a consent form (Appendix 8) in which they:

- agreed that they had read the information and understood what the project was about

- agreed to the notes from their interview being used for this report
- described what they wanted to happen to the tapes and computer files from their interview.

R.A.G.E. members were also asked if they agreed to being contacted by Macmillan about any follow-up work and if they were happy for their contact details to be passed to Macmillan.

The limitations of our approach

We recognise there are many limitations to our approach and do not claim that the story we are presenting is 'the absolute truth' about what happened. This story is based on people's recollections of events, some of which took place over twenty years ago. Inevitably, over this length of time some of those memories will have faded. It is also likely that they will have been altered in the intervening years; people often avoid the trauma from remembering distressing or even shameful times by finding a 'story they can live with'.

We have tried to find out how people were thinking and feeling in the past by referring to papers and letters that were written during that period. However, the written records have not always been complete and we have mostly relied on what people have been able to tell us. It is important to remember that many of the R.A.G.E. women only have the use of one arm and are often in constant pain – so writing, filing and maintaining records was not only very difficult but understandably may not have always been the highest priority.

Sadly, some people we have interviewed are now quite elderly and frail and expressed some difficulty in recalling precisely when and where certain events took place. This highlights the importance of carrying out a project like this early on in any story.

In spite of these limitations, we believe this report brings a new and valuable perspective on what R.A.G.E. achieved. Not only is this the first time that the views of R.A.G.E. members and the various professionals have been brought together, but it has also provided an opportunity to find out more about where people agreed about what happened, where they had different opinions and why those differences exist.

We believe there are important lessons from R.A.G.E.'s story – we hope it will inspire people to take some action, or at the very least, help others to avoid repeating the same mistakes.

Chapter 3: Background

In this chapter, we describe some of the background to R.A.G.E.'s story. This includes background information on radiotherapy, in particular how it was used to treat breast cancer in the late 70s and early 80s at the time when the R.A.G.E. women received their treatment. We go on to describe how that differs from treatment today and why those differences exist.

We also provide details of a landmark court case that brought radiation damage to everyone's attention for the first time. This was Lady Ironside's court case in 1991. Lady Ironside attempted to sue the doctor who had given her a course of radiotherapy for breast cancer which had resulted in severe and permanent damage. It wasn't until her case was publicised that the R.A.G.E. women began to realise that there were other people with similar injuries to themselves. It was therefore pivotal to R.A.G.E. coming together.

Finally, we provide some background information on how R.A.G.E. was initially established and how their early work gained them increasing numbers of members.

Radiotherapy treatment for breast cancer

What is radiotherapy and why is it used?

Radiotherapy involves using radiation to treat disease. It is most commonly used to treat cancer – sometimes to cure people, sometimes to reduce the chances of the cancer coming back and sometimes to help reduce the symptoms.

Radiotherapy works by destroying cancer cells in the treated area. Although normal cells are inevitably damaged as well, they usually repair themselves more effectively. The problem with radiotherapy has always been getting the balance right – giving enough radiation to deliver the benefits without damaging too much healthy tissue. Historically, there was a trend towards higher doses. Doctors assumed that the risks of any radiation-induced damage were insignificant when compared to the risks of not giving a high enough dose – which might result in the return of the cancer and possibly death.

Like all treatments, radiotherapy has both short-term and long-term side effects. The short-term effects begin during or shortly after treatment and usually don't last for more than a month. Following breast radiotherapy, they include tiredness, reddening or blistering of the skin, loss of appetite, nausea and vomiting and temporary difficulty swallowing. Not everyone experiences side-effects and those who do don't necessarily experience

all of these problems.

The long-term effects following treatment for breast cancer are rare, and can be severe. They begin months or years after treatment, tend to persist and get worse rather than better. They include loss of use of an arm, chronic uncontrollable pain, fractured ribs, difficulty with breathing, severe burns to the skin, digestion and circulation problems (see below 'What long-term damage did the R.A.G.E. women experience?'). It seems that during the late 70s and early 80s, at a particular group of hospitals in the UK, the way women were treated for breast cancer resulted in an increased incidence of this type of long-term radiation-induced damage.

What radiotherapy treatment had been given to the R.A.G.E. members?

The R.A.G.E. women had all been given radiotherapy treatment for breast cancer. Although there were huge variations in their individual treatments, typically they were given radiotherapy to their affected breast and to their armpit on the same side.

Breast cancer cells can migrate through the body via the lymphatic system (part of the circulation). If caught early on, they will have only migrated as far as the nearest lymph nodes (glands) in the armpit. At the time when the R.A.G.E. women were being treated, if nearby lymph nodes tested positive for cancer cells, they were usually removed and the surgical site then treated with radiotherapy. The armpit region was sometimes treated even if there wasn't any evidence of the cancer spreading – just as a precautionary measure. The goal was to kill off any possible remaining cancer cells, and so reduce the risk of the cancer coming back.

What long-term damage did the R.A.G.E. women experience?

Some years after their radiotherapy, usually between 2 and 5 years later, the R.A.G.E. women started to suffer serious long-term side effects. For many, this was due to damage to the brachial plexus, known as radiation induced brachial plexus neuropathy (BPN). The brachial plexus is a bundle of nerves in the region of the shoulder that supplies power and sensation to the arm. The precise cause of the injury is unknown. It could result from direct damage to the nerve or could be caused by a build-up of scar tissue compressing on the nerve. Either way, the injuries were severe and irreversible. They began as tingling and numbness in the thumb and forefinger, weakness of the hand and pain in the shoulder. Over the years the symptoms got much worse. Many women eventually lost the use of their arm and continue to live with chronic excruciating pain.

Although not all the R.A.G.E. women had this brachial plexus injury, the radiation damage they experienced was just as severe. Some had brittle bones, leading to fractured collarbones and ribs. These fractures were slow to heal or never healed and sometimes ulcerated through the skin. Others experienced damage to their chest muscles causing difficulty breathing, which in some cases was fatal. Many had skin burns and rashes, and experienced swelling of the arm (lymphoedema) more frequently than other women treated for breast cancer. They also had digestive and circulation problems. The long-term pain and increasing disability has in many cases led to clinical depression and other stress-related illnesses.

Why was there an increase in radiation-damage at the time the R.A.G.E. women were treated? – A brief history of radiotherapy.

Radiotherapy is extremely complex and historically it used to be much more of an art than a science. With hindsight, it seems that a number of factors all combined at the time the R.A.G.E. women were being treated to result in an increase in radiation-induced injuries. These factors are outlined below:

A limited understanding of how to calculate the 'right' dose

Rather than being given all in one go, radiotherapy is usually split into chunks, known as fractions. This maximises the damage to cancer cells and minimises the damage to normal tissue. When the R.A.G.E. women were being treated, the biological effects of radiotherapy were thought to depend on the following factors: the total number of fractions, the size of the individual fractions, the intervals between the fractions (ie the number of fractions per week), the overall treatment time and the total dose of irradiation. Doctors used a formula that was based on this understanding, to work out what the 'right' dose should be. What this formula didn't take into account was the fact that different tissues vary in their sensitivity to radiation eg nerve cells are more sensitive than skin. A better formula, the linear quadratic equation, wasn't used routinely in clinical practice until the end of the 1980s.

Limited understanding of 'good' technique

The risk of harmful effects in normal tissue can also be reduced by aiming the radiation beam from a number of different directions over the course of the treatment. This means that the total dose delivered to the tumour is far greater than that delivered to any of the surrounding tissue. But when giving the treatment from different directions, the radiologist has to be careful about areas of overlap – as these can turn into 'hotspots' that have the potential to cause damage. It is notoriously difficult to plan the radiation treatment of breast cancer to avoid any hotspots, because there is so much variation in the shape of women's breasts.

At the time the R.A.G.E. women had their treatment, doctors were routinely giving radiation to the breast from the front and back as well as irradiating under the arm to treat the lymph nodes. But what they weren't aware of was the fact that this combination was creating hotspots at the level of the brachial plexus. They may not have had any concerns anyway, because they also mistakenly believed that nerves were resistant to radiation. Nowadays, most centres no longer routinely carry out such treatment. The lymph nodes are only treated if there seems to be a high risk of the cancer coming back. Radiotherapy is often avoided altogether, particularly in cases where breast cancer is detected very early.

In the years since the R.A.G.E. women were treated, new techniques have also been developed to improve the targeting of the radiation beam, including the use of ultrasound and IT. This means that it is now possible to plan radiotherapy treatment more effectively, to only treat the site of the tumour and reduce the irradiation of the surrounding healthy tissue. However, these techniques are not yet being used routinely.

Lack of consistent standards

In the late 1970s and early 1980s, there was little consistency in how radiotherapy was delivered in different departments, or even between consultants in the same department. Each individual developed their own approach – usually based on a mixture of what they had learnt wherever they trained and what they had observed during clinical practice. In the UK, there were two major approaches, one from The Manchester School of Radiotherapy, which dominated the North of England, and another that relied on international protocols was used in the South of England and Scotland. The variation in approach may not have been a problem in itself, since most of the treatment regimes being used were probably achieving a similar result. But problems probably did emerge when clinicians who moved jobs started to use new and different equipment – while still relying on old and now inappropriate techniques from their previous departments.

Lack of manpower and machines

During the time the R.A.G.E. women were treated, many radiotherapy centres in the UK were also seriously troubled by an ever-increasing caseload combined with a lack of staff and/or lack of equipment. This caused them to start reducing the number of daily radiation treatments they gave to each woman with breast cancer, to try to increase the number of people they could treat. According to the formula they were using, this meant increasing the size of each fraction (each chunk of radiation) at the same time as reducing the total dose (the total sum of all the individual chunks). But because they were using the 'wrong' formula (the improved formula, the linear quadratic equation was not in routine use until the late 80s – see above), some doctors didn't reduce the total dose far enough. Combined with overlap between fields of treatment, this may have been enough to cause the increase in late radiation damage.

The risk of injuries could not have been foreseen at the time and because of the delay in seeing any late effects, doctors only became aware of the damage resulting from changes to the system after 1984.

Changing technology

New developments in radiotherapy technology resulted in machines producing more powerful beams, which pass through the skin leaving it more or less undamaged. These also produce higher doses at the internal site of a tumour. Two major incidents occurred in the UK between 1988 and 1991 where it was discovered that patients had received the wrong dose from high-powered machines. Problems were found in the way the machines had been calibrated, which led to an audit of all radiotherapy departments and the introduction of new professional guidelines and regulatory standards. But these standards only related to checking that the machines were delivering the right amount of radiation – including standards linked to inspection and testing, internal audits and training. They had no bearing on the question of whether the planned radiation dose was the right one or whether the right technique was being used. The problems with the new technology were not a factor in explaining what happened to the R.A.G.E. women.

The only difference that the new equipment made in the R.A.G.E. story was to reduce the incidence of short-term skin reactions. Because the new beams passed through the skin more easily, they didn't cause as much damage on the skin surface. These effects, more commonly seen with the older equipment, had actually proved useful, as they quickly alerted the radiotherapists to places where there was overlap between fields of radiation. They could then adjust the treatment regime accordingly. Without these early warning signs, they were less likely to be aware of overlaps at a deeper level inside the tissue.

In summary, there were very many factors that could have contributed to the injuries the R.A.G.E. women received and each case might have had a slightly different cause. These risk factors are well understood today and are now cautiously avoided. However, it took a very long time for this understanding to become public knowledge. The R.A.G.E. women initially found it very difficult even to get their problems recognised, let alone to gain an understanding of how and why they had been damaged. It wasn't until as late as 1991 that the women even found out there were a number of them who had been injured in the same way. When one of the women, Lady Ironside, took her doctor to court, they became aware for the first time that they were not alone – this was ten years after they had first been injured.

Lady Ironside's case

Lady Ironside's case was crucial to the development of R.A.G.E. Before the case was publicised in the media, women with late radiation damage

thought they were the only ones who had this problem. When they heard about Lady Ironside, it was an immense relief to find there were others like them.

Lady Audrey Ironside was first treated for breast cancer in 1982. She underwent a lumpectomy at that time (and following further operations underwent a mastectomy much later in 1997). She has described what happened with her initial treatment as follows:

'I was very fortunate, I was operated on by a specialist breast surgeon who assured me that he was very content in his mind that he had got rid of the cancer as it was at a very, very early stage, and... he said he would like me have radiotherapy purely as an extra precaution... The radiotherapist told me it was standard routine treatment. My husband said "Are you sure?". "Yes", he said, "Don't go round looking for trouble".'

Her radiotherapy treatment began in November 1982. She was treated as a private patient. She experienced serious side effects from the radiotherapy immediately:

'I was very badly burnt, but they told me not to make such a fuss. I had great big open weeping blisters. I thought this can't be right'.

Two years later she began to have other problems.

'I started dropping things. I had continuous pins and needles. I went to my GP and he said "You must have tennis elbow". I had cortisone injections, but it got worse. All this went on for nearly a year. Then a doctor friend took me off to see a neurologist and he said straight away "You've got radiation neuritis", which I'd never heard of. I said "What do you do for that?". And he said "There's nothing you can do". I went back to my specialist and said, "There's something terribly wrong with my arm", and he said, "Not you too". He said, "There's been some trouble with the radiotherapy and I was hoping you were alright".'

Lady Ironside's symptoms gradually became worse – her pain was incessant.

"In 1987 my specialist told me the only way to restore my arm was a decompression operation. He did it – that was 5 years after the treatment. I was told later by a lot of people that that's only any good if it's done 3 years after. I think that made me worse. I've slowly deteriorated all the time. In about 1989 my specialist announced I wasn't going to get any better. Before that they'd told me that I should be patient – that the nerves would regrow".

Believing that the doctors had been negligent in their treatment, Lady

Ironside decided to sue her consultant. She was not eligible for legal aid, and therefore funded the cost of the action herself. She was advised she had a good chance of winning. The case came to court in March 1991, and attracted a lot of press attention.

However, it seemed as if the odds were stacked against her. Lady Ironside had an expert solicitor and barrister, but she couldn't afford a QC or a legal team of the size taken on by her opponents. The doctor in question was backed by one of the two defence bodies that cover doctors against negligence claims, and so could afford a QC as well as a junior barrister and a number of solicitors.

Faced with mounting legal bills, Lady Ironside continued with the case for as long as she could, without risking losing everything. She says that during the trial:

'Twice I was rung up in the evening and threatened. I was told that if I didn't drop the case they would go on until they bankrupted me. It cost me over £100,000. I couldn't risk losing the house. I withdrew on the last day where I could get out without paying their costs, which were then running at over half a million pounds. So they went laughing on their way'.

When the case was dropped, the defence team accepted that Lady Ironside had suffered radiotherapy damage, and that this was 'a tragic error'. However, they argued that this was not negligence, as the risks could not have been foreseen. The doctor involved in the case said, 'It was the worst experience of my life'. He is also convinced that the treatment he gave was the best he could have given at that time:

'At the time, the treatment we gave was considered correct. In no way was it thought to be negligent. We were trying to spare these ladies from having a breast removed. At that time, thousands of other women were cured of their breast cancer and the radiotherapy had helped with that'.

Lady Ironside felt the whole process had failed her. Shortly after the trial had ended, she told a reporter at *The Guardian*:

'I've been left with no compensation, I've lost the money I put up, and I'm worse off than before. It doesn't seem like British justice'.

The establishment of R.A.G.E.

Throughout the entire time leading up to her court case, Lady Ironside believed she was the only person to have experienced such terrible injuries. However, there were women all over the country reading the articles in the press about her court case with surprise and recognition. Lady Ironside returned home to hundreds of letters from people who had suffered similar damage. Most of these women were also under the impression that their experience was unique. Some had received no diagnosis.

One of these women was Jan Millington. Jan had her breast operation in 1982 and was then prescribed a course of radiotherapy in 1983. Like Lady Ironside, Jan began to experience problems of tingling and numbness in her arm. This started in 1985, and by 1989 she had lost the use of her right arm and hand and was in constant pain.

'I'd already had a diagnosis of my problem in the late 1980's. I thought it was a pretty rare problem. I also thought the problem could be improved. I think by then I was told that it probably couldn't, but it wouldn't get much worse'.

Like Lady Ironside, Jan Millington was told by her doctor that the effects she experienced were extremely unusual and that he didn't know anyone else who had them. Jan was on holiday during the Ironside trial, but friends phoned to tell her about the reports they had seen in the press. Jan was one of the many women who wrote to Lady Ironside. Lady Ironside replied, and suggested a meeting. Every woman who had been in contact was invited, although not all were able to attend.

This first meeting of what was to become R.A.G.E. took place in July 1991, at the home of Liz Gebhardt. Liz, an actress, had also experienced radiotherapy damage. She died in August 1996, aged 51. About 18 people came to this first meeting – including a man from the BBC, and a woman involved in an action against the Christie Hospital in Manchester, where a number of women had suffered terrible injuries after radiotherapy treatment for gynaecological cancer. Most of the women at the meeting had been treated at one particular hospital.

Writing about this first meeting a few years later, Jan Millington remembered:

'It was at the same time sad and exhilarating to meet others who shared such strange experiences. We were all suffering varying degrees of pain and paralysis although not all had been told the cause of the problem. Not one of us had been forewarned of any risk of permanent injury. We all had problems coping with everyday life, cooking, cleaning, sewing, dressing'.

'We all got extremely indignant. We were all telling each other these

stories of what we'd been told and going along for this decompression operation and not having any good from it. There was a lot of emotion there, it was quite heavily charged'.

After the meeting, the women contacted Clare Dyer. Clare was a legal correspondent at *The Guardian* newspaper who had reported extensively on the Ironside case and continued to follow her story. The R.A.G.E. women sought her advice about what they should do next. She advised them to form a pressure group – and R.A.G.E. was born. As Jan Millington recalls:

'At the outset the aims of R.A.G.E. were clear and simple. We wanted an enquiry into the delivery of radiotherapy for breast cancer in order to establish the incidence and cause of the injuries. All agreed that it was unacceptable that a patient be left to face what could be a full lifetime with such a poor quality of life. If there was ANY risk of injury, full information should be given ahead of treatment so that the patient may give informed consent. We wanted medical, practical and emotional support for those of us already injured'.

These aims were later adopted as part of R.A.G.E.'s constitution, and printed as follows on their publicity leaflet:

- to raise awareness of the injuries and campaign for sympathetic medical care within the NHS
- to campaign for national standards in radiotherapy
- to seek compensation commensurate with the injury
- to provide mutual support.

We describe R.A.G.E.'s activity under each of these aims in Chapter 4 of this report.

Chapter 4: The R.A.G.E. story

Aim 1: Raising awareness of the injuries and campaigning for sympathetic medical care within the NHS

Getting their injuries recognised

One of the problems faced by many R.A.G.E. members was that their injuries were not recognised by their doctors. Many women weren't given an explanation of how their injury had occurred, or what could be done to help. Some were told they were the only patient their doctor had seen with this type of damage. It was only the publicity about R.A.G.E. that helped the women find one another and gain a better understanding of what had happened.

Following the media coverage of the Ironside trial in 1991, the R.A.G.E. women continued to raise awareness of their injuries through telling their stories to the newspapers. In February 1993, the *Mail on Sunday* published an article describing the experiences of Margaret Forrest, another early R.A.G.E. member. As a result of this article, about 200 more women joined the group. Jan Millington recalls:

'In the same year, the issue of disparity in cancer treatments between the North and the South hit the news... R.A.G.E. was literally under siege and articles appeared in the press under such headlines as CANCER VICTIMS MAY SUE and CANCER WOMEN'S RADIATION AGONY. Literally hundreds of women came forward thinking that they were suffering similar injuries and regional newspapers were constantly ringing for details of women prepared to give interviews. R.A.G.E. was given TV and radio coverage nationally and locally'.

This press coverage meant that R.A.G.E. continued to grow – at one stage to over 1,100 members. Many of these women had experienced damage to their brachial plexus. Others had different symptoms – including brittle bones and scars that would not heal. What they all had in common was a deep frustration at not having been given any explanation about their injuries and real anger at not having been forewarned of the risks of their treatment.

The lack of support and information made the women's situation much worse. As highlighted by the Maher Committee (see page 36), who looked in depth at the women's injuries 'One of the worst deficiencies was the denial that there might be a problem, which compounded the real anger they felt at not being warned of possible dangers of radiotherapy treatment'.

An important aim for R.A.G.E. was therefore to make women in general more aware of the risks of radiotherapy, so that they would be fully informed before consenting to treatment.

The need for improved care

Many of the R.A.G.E. women also faced extreme difficulties in getting any form of treatment for their injuries at any stage of their condition. Nor were they offered any psychological support or counselling. The various doctors who saw them didn't appear to communicate with each other and the treatments that they did offer proved ineffective. When the women spoke to their doctors, whether they were GPs or cancer specialists, they felt fobbed off or let down. As Jan Millington describes:

'When I thought I was going to lose all use of my arm, I couldn't believe this was going to happen to me. I went for this decompression operation that clearly didn't work, and I thought they'd pull something else out of the bag. And the doctor said "I'm sorry this operation hasn't worked", and he got up and walked towards the door with me, and said "I'm truly sorry there's nothing more we can do for you – we can't see you again".'

The women were desperate for anything that could relieve their constant pain or put a stop to their decline. As Jan explains:

'I've spent so much money on alternative therapy, because you're desperate for relief. I did the lot. Different acupuncturists. Went to a healer. Different nutrition therapies, massage, aromatherapy. And it costs every time you go. But you hang on in there because you're so convinced something's going to make a difference. Private pain clinics, kinesiology, cranial osteopathy, chiropractic, homeopathy. The guy who was Princess Diana's homeopath, he did dowsing. He told me I'd got to put pills on my head. I did it. I'd have done anything. You're so desperate, you think something's got to make this stop'.

There was unanimous agreement amongst R.A.G.E. members that one of their key aims should be to get better treatment and support through the NHS.

Early campaigning

One of the early steps that R.A.G.E. members took was to write to the MP, Jack Ashley, who had a reputation for campaigning for disabled people. They hoped he might be able to offer advice about how they might achieve their aims. He responded positively and invited them to meet with him in 1992 as Jan describes:

'Instead of the usual polite, not-to-worry letter there was a phone call inviting R.A.G.E. to a meeting with him in the House of Commons. Sir Geoffrey Johnson Smith (an MP who had experience with the HIV infected haemophilia sufferers) also attended. Jack told the group to conduct a polite methodical campaign but to expect minefields. He agreed to ask pertinent questions of the then Secretary of State for Health, Virginia Bottomley... Jack Ashley said that it was important to gain wide publicity to discover how widespread the injuries were and where they were clustered in order to strengthen the campaign'.

In the same year, the group gained the support of Professor Karol Sikora, a cancer specialist. R.A.G.E. approached him because he was seen to be 'on the side of the patient' and had been involved with the Bristol Cancer Support Group. (This was a group of women affected by breast cancer, who had attended the Bristol Cancer Support Centre, and then challenged some flawed research that had been carried out to assess the impact of the Centre.)

R.A.G.E.'s early campaigning was therefore extremely successful in gaining support from MPs and the leading cancer experts. This enormous investment of time and energy finally resulted in a pivotal meeting on 22 February 1994 between Lord Ironside and Jan Millington from R.A.G.E., the Chief Medical Officer from the Department of Health, Chris Paine (then President of the Royal College of Radiologists - RCR) and Karol Sikora. It was at this meeting that the Royal College agreed to commission two important pieces of work – the first was to carry out an audit of the radiotherapy treatments received by the R.A.G.E. women to investigate the cause of their injuries (see page 48) and the second was to set up a committee to consider how women with radiation induced brachial plexus nerve injury should be managed by the NHS. Baroness Cumberlege made a public announcement about the committee during a debate in the House of Lords in May 1994 in response to a question tabled by Lord Ironside asking the government 'in what ways they expect to improve diagnosis and surgical treatment of breast cancer and avoid hazards in radiotherapy treatment of this condition'.

The Maher Committee

The committee set up to investigate possible treatments for the R.A.G.E. women was chaired by Jane Maher, a consultant oncologist from Mount Vernon Hospital in Middlesex (who already had some experience of working with patient groups). It became known as the Maher Committee. R.A.G.E. was represented by Jan Millington and Margaret Forrest. Although R.A.G.E. had asked for four places, it was decided that only two would be offered. However, Jane Maher did meet with the whole of R.A.G.E.'s committee to listen to their views and concerns. As a result of this meeting, the Maher Committee recruited additional people with expertise in areas identified as a concern for R.A.G.E.

The Maher Committee had its first meeting on 30 August 1994. Its terms of reference were to investigate the problems the women were experiencing and to produce a set of guidelines on 'best treatments'. However, one of the biggest problems the committee faced was that there was 'no solid research' in this area and therefore no evidence on which to base any guidance. No one knew how best to treat brachial plexus nerve injury or any other type of radiation damage. Nor had anyone in the UK, including the RCR collected figures on the extent of the problem. One of the Committee's final recommendations was therefore that there should be more clinical trials in this area, to help build up the evidence base on how best to manage these types of injury.

Because of the lack of research evidence, R.A.G.E. agreed to undertake a survey of their membership to find out more about their symptoms and the impact that radiation damage was having on their lives. Questionnaires were sent out to 640 women and 180 replied. In their responses the women described their main symptoms as being unrelieved pain, paralysis of the hand or the whole arm, severe fibrosis, lymphoedema, respiratory problems, chronic skin conditions and digestive problems. Sixty percent of these women had previously received a diagnosis of radiotherapy damage.

The survey also asked women how their symptoms were being treated. A wide range of treatments were reported – ranging from amputation of the damaged arm or surgery on the nerve through to prescription of opiates, acupuncture, massage or paracetamol. Twenty-five percent of the women had attended a pain clinic, and almost all of these had found this helpful. Only 5% of respondents had received any psychological support. Overall the results of the survey showed that what most respondents wanted was: (1) an expert diagnosis, (2) a more honest prognosis and (3) more effective pain control.

The Maher Committee's final recommendations therefore stated that what was needed was:

'A collaborative multidisciplinary approach with honest explanation and communication with the patient, as well as all health care professionals involved'.

The committee also concluded that 'In the absence of definitive treatment, management should be directed towards optimising symptom-control and function to maintain as good a quality of life as possible. This should be combined with careful surveillance to detect and treat recurrent cancer, particularly in the first two years after presentation'. Symptom management was agreed to include assistance with daily living and psychological support.

Perhaps most importantly, the committee recommended that there should be one oncologist in every cancer unit/cancer centre who would act as

the link person for women with radiation induced injuries, and ensure that each patient's care was co-ordinated.

Looking back, Jane Maher believes that the involvement of R.A.G.E. members in the committee had a major impact on the committee's recommendations:

'Doctors essentially are interested in diagnosis and treatment – as are patients – but patients are also interested in management. So it changed the whole tenor of the thing, to a much more practical approach'.

Publication of the Maher Committee's guidelines

The Maher Committee presented their guidelines to the Royal College of Radiologists in February 1995. It was sent to all directors of public health at district and regional level, and to all the medical directors at NHS Trusts with a covering letter from Dr Graham Winyard, the Deputy Chief Medical Officer, in October 1995. There was huge demand and copies soon ran out. Jane Maher reflects:

'When the report first came out it felt as if clinicians saw it and said, "We can go with this". And it was what the patients wanted... I got a ton of letters from people saying what a valuable document it was'.

The College admitted it had not anticipated such high demand and wrote to the Department of Health in January 1996 to request funding for a reprint:

'The College underestimated the demand for the report when we set the print run. This demand, which comes not from our Fellows but (i) from patients making contact with R.A.G.E. complaining of a wide variety of symptoms and (ii) from the various health care professionals involved in this area, reflects the need for good quality information about these problems. It would be very unfortunate if the report were to go out of print while R.A.G.E. are still lobbying Parliament for investigations of radiotherapy injury, as they value it highly'.

In a subsequent letter to the Department of Health, the College also argued that 'the work of the Maher Committee was never properly funded'.

The impact of the Maher Committee's guidelines

Although highly valued on their release, in the longer term the Maher Committee's guidelines had very little impact. Jane Maher described how she consulted large numbers of women with BPN about two years after the guidelines were published to find out whether they had noticed any difference in their treatment. She found that:

'The women were more sympathetically handled, but that was it. Some of

them had found good people... but the report hadn't achieved what they would have liked'.

Jane Maher believes there are a number of reasons for this:

'The doctors who see people with non-specific symptoms, ie GPs, knew nothing about radiation damage, so when people came with their symptoms the GPs didn't know what to do with them. Also, BPN was so rarely heard about once the original publicity had died down. The specialists, who people found helpful, didn't necessarily work with any others as part of a specialist group. So you couldn't form proper specialist teams. For a multi-disciplinary team to work together they have to have some relationship and work together on a regular basis – so without good teams the guidelines couldn't be enforced... If a specialist moved on a new specialist wasn't identified... So when people had forgotten about it and it was off the agenda, you had no levers for implementation'.

The Maher Committee did try on a number of occasions to get the guidelines on to the agenda of the Department of Health Clinical Outcomes Group – a precursor to NICE. This would have encouraged clinicians to use the guidelines by making them standard NHS practice. But the Clinical Outcomes Group refused to accept them because of the lack of an evidence base. By this time the whole culture of the health profession had undergone a major change in favour of evidence-based medicine. So the fact that the guidelines were not informed by clinical trials reduced their credibility and gave clinicians little impetus to act on them.

For the R.A.G.E. women this seemed doubly unjust. In the 70s and 80s they had received inappropriate treatment apparently because doctors were free to base their practice purely on clinical experience, but by the 1990s they were being denied any help with their medically-induced injuries, because doctors were now insisting on basing their practice on research evidence.

For Jane Maher, the lessons were clear:

'It's not the creation of guidelines that's important. It's the implementation that you need to focus on. You can't just create them and go away. You have to work at what the levers are for keeping people interested. And you have to engage with GPs'.

Written information for radiotherapy patients

One of the issues raised by the R.A.G.E. members on the Maher Committee was the huge public demand for information about the risks of

late radiation damage. R.A.G.E. was finding it difficult to keep up. The Committee therefore recommended that new written information for radiotherapy patients should be produced.

After the work of the Committee had finished, Jane Maher, Jan Millington and others worked with CancerBACUP, Breast Cancer Care and CancerLink to produce three new leaflets about radiotherapy. This was the first time that the cancer charities had collaborated successfully in this way. However, the response was again somewhat disappointing. Although the Department of Health paid for the leaflets to be produced and they were made available through voluntary organisations, there was no systematic dissemination across the NHS. It seemed that the health professionals were reluctant to give out the information, in case it worried people unduly.

Jane Maher recalls:

'I got Macmillan to agree that their breast care nurses would distribute the leaflets. But what I learned was that distribution of information is an incredibly value-laden thing. And whereas nurses are the gatekeepers of information within a hospital, they take their lead from the doctors, and if the doctors don't prioritise that information, and the patients aren't clamouring for it, it won't get given out'.

R.A.G.E. members are therefore still concerned that women receiving radiotherapy for breast cancer aren't being adequately informed about the risks.

The need for a specialist clinic

As the years progressed, R.A.G.E. members became increasingly frustrated by what Margaret Carling, a R.A.G.E. member, described as 'The disparities in care between what we aimed for in the [Maher Committee] Guidelines and the realities of today'. She explained:

'I saw a very pleasant breast cancer surgeon who clearly had no expertise in brachial plexus nerve injury, he did not even examine my arm. He enquired about pain management but agreed with me entirely that most medication for severe chronic pain is normally only meant for short term acute situations and accepted that I felt I had exhausted the armoury of pain killers'.

The R.A.G.E. women came to the conclusion that cancer centres were no longer the right place for them to go. As Jan Millington describes:

'Some [R.A.G.E. members] go to pain centres, but most go to cancer clinics... But I can't see they've got the discipline... They have a different

mind set. And for us, we're cured, or at least we're walking about. So it's a different feeling towards you. And I don't really like going there, I don't want to take up their time. And it brings back horrible memories... and I don't want people to look at me and think they might end up like this'.

They felt the medical profession were always letting them down, as Jan explains:

'They (doctors) might think it's their problem for a little while, but then they leave you. It's like being in a pen, like the elephant man. Everyone comes along with cameras and notebooks, and you think perhaps someone might say I can help you. But they come along, they walk round and in the end they walk away. They always do'.

Karol Sikora believes this is because doctors are poorly equipped to help, because there is nothing that can be done medically – 'just occupational therapy and physiotherapy'. However, doctors are the only professionals with a knowledge and understanding of radiation damage. Occupational therapists and physiotherapists may have the appropriate skills, but have little awareness of how the women's problems have been caused or how they might develop. R.A.G.E. women were rarely offered this kind of support anyway. As Jan describes:

'I've never been offered any occupational therapy, gadgets for the kitchen or anything like that... I went back to the physiotherapist and she said there's absolutely nothing I could do to help you. And I went all the way to X hospital for that'.

The R.A.G.E. women realised that they needed a specialist clinic, one that was staffed by professionals with an understanding of their injuries as well as all the right skills to help them manage their symptoms more effectively. But because late radiation damage is rare, there were simply not enough women to justify the provision of specialist services at a local level. R.A.G.E. therefore lobbied for a national centre. They wanted the centre to provide treatment on an ongoing basis, offering:

'An assessment from someone who understands the ramification of the injury, what the prognosis is... who can understand thoroughly what expertise you need, by the way of physio, if you can have any massage. Sometimes it's counselling, and occupational therapy... or what you shouldn't do'.

Attempts to establish a specialist clinic

In 1998, it seemed there might be an opportunity to establish a specialist clinic opening at Guy's & St Thomas' Cancer Centre in London. Given its central location, the R.A.G.E. committee members hoped their members

would be willing and able to travel at least once to the clinic for a proper assessment. In November 1998 Dr Adrian Timothy, a consultant clinical oncologist at the Centre wrote to Valerie Eldridge, a R.A.G.E. Committee member:

'You are correct that at St Thomas' we have a real interest in providing a 'one-stop clinic' facility for patients who have suffered late effects from breast radiotherapy. I think we are ideally placed since we have the Chronic Pain Unit... and an Orthopaedic Surgeon with a particular interest in nerve and upper limb problems, together with a whole range of diagnostic facilities from MRI to PET scanning'.

However, two years on, there had been little progress. Dr Timothy wrote again in September 2000:

'I have had some difficulty in identifying both clinicians and funding to establish the sort of clinic we had envisaged. I am rapidly coming to the conclusion that we may need to do this in some form of trial whereby any intervention we are able to offer can be properly evaluated, and in this way, we may be able to obtain suitable funding to put in the sessions that we need from the various clinicians involved'.

This option was felt to be untenable by R.A.G.E. members – if the clinic was to form part of a trial, then there would presumably need to be a control group of women who would not be allowed to use the clinic. And who should be denied access to this treatment? Since all of the women lived with damage, it was felt that all of them should be given a chance to access any services offered. Whilst this debate was going on, Valerie Eldridge, the R.A.G.E. Committee member who had been pursuing this possibility, became very ill and later died. The project was not progressed any further.

But R.A.G.E. did not lose hope and decided to lobby again for specialist services. This included lobbying government ministers. Lady Ironside, Pam Pond, Margaret Carling, Christina Rogers and Jan Millington met with Hazel Blears, Under Secretary of State for Health, in the spring of 2003 and received a fairly positive letter after the meeting. The letter stated:

'It would appear that much of your drive for compensation has been fuelled by the problems your members have experienced in accessing NHS services which may be able to help your condition. Improving access to these services is something I believe the Department can genuinely help with. In order to proceed on this front it would be helpful if you could discuss with your members the types of services you have found most beneficial and those which you have found particularly difficult to access and write to me with the details'.

However at this point in time, the R.A.G.E. Committee could not face

running yet another survey. One of the problems was that however well-meaning politicians and health professionals were, they didn't provide any form of support to carry out this kind of research. Each request required a mass mailout – and because almost all R.A.G.E. members only have the use of one arm, it is a huge undertaking both to carry out the survey and for individuals to complete the questionnaires. Given their previous experience, R.A.G.E. Committee members were cynical that anything would happen as a result of yet another piece of research. They therefore decided not to follow-up this course of action.

In October 2003 Jan Millington wrote again to Melanie Johnson (who had taken over from Hazel Blears) requesting a meeting to explain R.A.G.E.'s concerns. However, the Minister's reply did not take them any further forward:

'You were asked to write with details of the services causing concerns if you wanted the Department to follow this up. I am not aware of any such letter... If you wish to write to me about the services that are vital to the group and that you find it difficult to access, I will look into this. I do not believe that meeting with me would take this matter further'.

Jan Millington approached Jane Maher, by now the Chief Medical Officer for Macmillan Cancer Support, to ask her to explore the possibility of establishing a specialist clinic. In February 2003, motivated by the promise of real action from Jane, the R.A.G.E. committee did write again to all of its members to try to assess how many of them had brachial plexus nerve injury. The results of this survey were analysed by R.A.G.E. and passed to Macmillan.

In 2005 Jane Maher began discussions with R.A.G.E. members about the possibility of setting up a 'virtual' specialist clinic. Since a relatively small number of women experience severe radiation damage, setting up a clinic at a local or even regional level is not really practical. Jane Maher is therefore exploring the use of telemedicine to connect up a multi-disciplinary team of professionals, ranging from neurologists to benefits advisers, who could all contribute to a combined package of therapy. R.A.G.E. members are keen to be the first group of people with late radiation damage to be treated by such a team. If this idea receives funding, pilots should begin in 2006.

Research into new treatments for radiation induced injuries

Given the lack of research evidence to support any particular treatment for women with radiation damage, R.A.G.E. members have over the years, shown a keen interest in taking part and supporting any research in this area. They have been instrumental in taking forward two clinical trials – a trial for hyperbaric oxygen (HBO) treatment and a trial of radiotherapy for breast cancer (see page 56).

Jan Millington first heard about the potential benefits of HBO for treating nerve damage from the Multiple Sclerosis Society. Since HBO had been used to alleviate the symptoms of nerve damage in other situations, it seemed reasonable to hope that it might help relieve the symptoms of brachial plexus nerve injury. Jan discussed the idea with Jane Maher, who in turn discussed it with John Yarnold, a Professor of Clinical Oncology at The Institute of Cancer Research. They began to consider the possibility of running a trial.

John Yarnold met with the R.A.G.E. Committee to start planning the work, and two members of the committee, initially Jan Millington and Margaret Forrest, agreed to join a steering group. At the instigation of Lady Ironside, Jan Millington successfully applied to the National Lottery Charities Board for a grant to support the trial. R.A.G.E. was awarded £117,620, to be administered by John Yarnold's research department.

But recruitment to the trial proved difficult. In February 1997 letters were sent to 766 R.A.G.E. members, asking if they would be interested in taking part in the trial. Two hundred women responded positively. Unfortunately, only 26 of these women were considered eligible to join.

Joyce Pritchard, a R.A.G.E. Committee member who took over from Jan Millington on the trial steering committee and became centrally involved in the trial, recalls:

'Most of our people were turned down because they were too badly damaged, they'd been damaged for too long'.

The trial involved women staying in Portsmouth for six weeks, but they willingly came and took part from all over the country. For R.A.G.E. members, this trial represented a possibility that something might be found to alleviate their symptoms. Jan Millington commented:

'You can only tolerate this thing with the feeling that one day it's going to end. Not by dying, but with the feeling that one day somebody somewhere is going to find something. So you pin a heck of a lot on these trials or whatever. To think that anyone even wants to trial something that could be of use... If it's likely to be of any benefit I'll give it a go... You say I'll accept the risks because you're so desperate for something that's going to work'.

Disappointingly the trial did not show any benefits in terms of treating brachial plexus nerve injury. However, unexpectedly it did seem to suggest that HBO might help women with lymphoedema. As Jan describes:

'There was a great deal of excitement because one particular lady with lymphoedema appeared to have been helped, and then there was talk of

a trial for that. And we were upset and hurt by that because we know lymphoedema is awful, but it is recognised and there is a certain amount of treatment for it. It felt that brachial plexus nerve damage had been pushed aside again'.

The HBO trial was therefore yet another frustration for the R.A.G.E. women. They had worked hard to raise the money, and were actively involved in supporting it, to the extent that Joyce Pritchard was named as first author on the paper reporting the results. But it came to nothing. The research carried out to date has only led to disappointment, as Pam Pond describes:

'I have tried any thing they have wanted to test... but it never seems to go anywhere. You go up there, you give up your time... it doesn't matter how hard we have tried to help ourselves by letting them experiment on us... you feel they aren't getting anywhere... They need to come up with something else. They can send a rocket to the moon – but can't do something to make this [her arm] look nice – not even proper bandages. It may seem cosmetic – but it affects my quality of life'.

Aim 2: Campaigning for national standards in radiotherapy

Gathering evidence of what had happened

From the beginning, the R.A.G.E. women were convinced that something had gone seriously wrong with their radiotherapy treatment, but it proved hard to find any information or evidence to support this conclusion. Initially, they carried out their own research into what had happened by surveying their members (see page 61). This research revealed a concentration of injuries at particular hospitals, which suggested that faulty procedures were involved. They also knew just from talking to each other just how much variation there was in the treatments given to women with breast cancer at that time. As Jan Millington describes:

'One lady and I compared notes about our treatment plans. HERS was totally different to mine. She had four fields of treatment to my three. She was treated daily, me every other day and we went to different machines... I asked my surgeon why the disparities in treatment? Was her disease less rampant, was the tumour a different type? Bless his dear honest heart, my surgeon said 'The treatment would have nothing to do with her condition, more to do with the clinicians' preferences'. He implied that as there was no agreement on the best way to treat breast cancer, and basically it was all a bit muddled'.

Lady Ironside's trial had also provided R.A.G.E. with a lot of valuable

evidence. They knew from the trial in the late 70s and early 80s, that many radiotherapy departments had developed new treatment regimes because of a lack of staff and equipment (see page 27). These new techniques, which combined high doses and large fraction sizes, seemed to be responsible for greatly increasing the risk of injury.

The leading cancer specialists at that time had reached similar conclusions. For example, Professor Karol Sikora wrote an article for the *BMJ* (published in January 1994) that said:

'There seems to be a considerable clustering of affected patients to certain hospitals and year of treatment, suggesting that technique rather than individual radiation sensitivity is the problem. Furthermore, there is an association with the use of high treatment doses and large fraction sizes. I believe that the culprit is overlap between fields.

British radiotherapy services are overstretched. Staffing and equipment shortages are well documented. There is also good evidence of wide variation in the doses and technique used to treat many patients. Such variation does not make sense. Why should one hospital use 15 fractions and another 30 to treat exactly the same disease? Either one is using suboptimal treatment or the other is wasting resources'.

He concluded that there was a need for an urgent and comprehensive review of Britain's cancer services.

In the early days, R.A.G.E. repeatedly pushed for a full investigation into precisely what had happened to them during their treatment – not only for their own peace of mind but also, and more importantly, to stop it from happening again. Lobbying for an independent enquiry was a major feature of their early campaigns (see page 62).

Lobbying the Department of Health

On 13 September 1993, acting on the advice of Julie Turner, who was their legal adviser at that time (see page 61), R.A.G.E. drafted a formal letter to Virginia Bottomley, then Secretary of State for Health, calling for a full public inquiry into radiotherapy for breast cancer. They knew there were no centrally held records of the outcome of breast cancer treatments – the Royal College of Radiologists had freely admitted as much. R.A.G.E. therefore presented evidence of the problem in the form of data gathered from its own membership records.

R.A.G.E. gave the Department of Health, on a privileged basis, a list of 525 members with their places and years of treatment. This showed that out of the 53 radiotherapy treatment centres in the UK there were:

- 10 or more injuries at each of 12 of the centres

- 20 or more injuries at each of another five of the centres
- 59 injuries at one of the centres
- less than 10 at any of the remainder.

The letter, drafted by Julie Turner and signed by Jan Millington, stated:

'You will be concerned to hear that the number of women throughout the United Kingdom who have now contacted us complaining of severe radiation injuries to their shoulders, arms, hands, lungs, chests and breasts on the irradiated side, exceeds 1,000 and the number is increasing daily.

We write to you today with three purposes: firstly to object strenuously to any inquiry chaired or controlled by the Royal College of Radiologists; secondly to press in the strongest possible terms for a fully independent public inquiry and thirdly to make the strongest representations to you regarding the terms of reference and preferred procedures for that inquiry.

Clearly public confidence in the provision of breast cancer treatment in the UK is shaken and only a public inquiry in which the public can have complete faith can address that concern'.

They also requested that the terms of reference for the public enquiry include:

'The thorough review of the history and efficacy of radiotherapy both in the past and now in the treatment of breast cancer;

The drafting of guidelines or further regulations to prevent the occurrence of these injuries in future;

The development of a consent form designed to ensure that women about to undergo radiotherapy have full information about their disease;

The provision of counselling and medical services for those already injured;

The provision of adequate compensation to women who have been injured by radiotherapy treatment'.

The letter also threatened that they would go to the press if they didn't receive an adequate response. Julie Turner anticipated that the Department might not respond, and hoped to use this to fuel the argument for litigation. R.A.G.E. wasn't entirely convinced by this approach. In the end, the Department of Health refused to co-operate, but no further action was taken.

Agreement to carry out an audit

R.A.G.E. then took matters into their own hands and sent another letter to the Department of Health. This time they wrote it themselves. It had much more of an impact and resulted in a meeting on 22 February 1994 between Lord Ironside and Jan Millington from R.A.G.E., the Department of Health and RCR officials, and Kenneth Calman, the Chief Medical Officer at that time. It was at this meeting that the Department agreed to fund an audit to investigate the treatments received by R.A.G.E. members with brachial plexus nerve injuries. At the same time they agreed to set up a committee to look at how these injuries could be treated (see page 36).

Thelma Bates, who had just stepped down from being Senior Vice President of the RCR, was asked to lead the audit. She believes she was invited to take on this role because:

'Previously I had been involved in an enquiry into radiotherapy practice, an investigation of underdosing... So I knew how to go into people's departments and find out what happened without upsetting people'.

The R.A.G.E. women believed she would do the job well, because 'Kenneth Calman had said he trusted her to do it'. They met with her early on and found her very encouraging. As Jan Millington describes: 'Thelma Bates said if we leave it with the lawyers it could be years. She did imply that there could be a global settlement – but she didn't put it in writing'.

Thelma Bates' impressions from that first meeting were that 'Most of the women were in a great deal of pain and were very angry. They kept using the words "Now listen" which meant they hadn't been listened to before then'. She thought that the R.A.G.E. women '...were wanting to understand what had happened and wanting to make sure it didn't happen again, but that throughout the whole thing there was also hope for compensation, as an undercurrent – not upfront'.

However, not everyone was convinced by the RCR's proposal. Julie Turner, in particular, was very concerned. She questioned whether the audit could be truly independent when the RCR were effectively investigating themselves. She wrote to R.A.G.E. in October 1994 saying:

'The difficulty with the audit is that by sheer weight of numbers of the hospitals concerned, any positive conclusion on the part of the Royal College of Radiologists will necessarily involve criticism of a substantial and influential number of its own members'.

She also advised that '...the diagnosis of radiation-induced injury is in fact quite complex and we are devising our own sophisticated criteria for dealing with this problem. We are concerned that the Audit Committee

does not appear to have settled on any such criteria before embarking on its investigation. If the Royal College has decided upon such criteria, participants in the exercise should be entitled to see them so that they can query, if necessary, the finding made in their individual cases'.

As adviser to the litigants, she said she was also '...extremely concerned about the potential for damage which would inevitably be inflicted on the litigation by a less than objective Audit Report'.

By this time, R.A.G.E. was trying to separate itself from Julie Turner, who had been developing a legal case (see page 64), and the women therefore decided to co-operate with Thelma Bates and the RCR. Although they recognised that the audit would be far from perfect, they seized on it as an opportunity to achieve their goals at the same time as avoiding any lengthy and costly litigation.

The Bates audit

The scope of the audit was limited to 15 of the 51 cancer centres in England and Wales and to R.A.G.E. members who were treated at these centres during a 14-year period, 1980 to 1993. R.A.G.E. was happy with this decision because 'They chose the hospitals that had had the most injuries, and they confined it to a period of time, which is what we wanted'.

There were 249 R.A.G.E. members who had received treatment at these centres during the 14-year window and all were invited to take part in the audit. R.A.G.E. had no direct role, other than sending out letters of invitation. Joyce Pritchard and Thelma Bates believe that some women were advised by Julie Turner not to take part in the audit because of the potential threat to any future litigation. Of the 126 women who did finally agree to co-operate, only 48 were found to have brachial plexus injuries. The remainder all had other types of radiation-induced injuries.

The audit involved visiting each of the 15 cancer centres, consulting staff, inspecting equipment and viewing patients' medical records to build up a detailed picture of the treatment received by each of the 126 women. The data from R.A.G.E.'s own research was also considered. The work took over a year to complete and the final report written by Thelma Bates and RGB Evans was published in December 1995.

Thelma Bates was satisfied with the report at one level because:

'We had a lot of co-operation from every centre, and I cannot criticise any of them. It was easier because we all tended to know each other. They gave access to all their files. There was never any cover-up in any department'.

But she also recognised its limitations:

'With a self-selecting group of patients... it was always going to be a limited study. We were looking backwards and not able to see everybody and every centre. We had to look at their total care – everything that had happened to them – not just the radiotherapy. There were limitations on how many people we could do this with'.

The report therefore came under some criticism, mainly because the sample was heavily biased. It relied on people putting themselves forward and only included a minority of the total R.A.G.E. membership. There were also likely to be other women with radiation damage who had not joined R.A.G.E. and therefore hadn't been included. Nor was any comparison made with the women who had not been injured but had received similar treatment at those centres. This would have been a monumental task as this group of women included another 65,000 breast cancer patients.

In spite of these limitations, the authors were able to draw out the details of the radiation damage experienced by the 126 women who took part and were able to identify factors common to their radiotherapy treatment. Their main finding was that moving women in between treatment to the breast and treatment to the lymph nodes greatly increased the risk of injury. 'High dose techniques' also increased the risk. 91% of the women who were moved whilst being treated with a high dose regime went on to develop a brachial plexus nerve injury.

Based on these findings, the report went on to make a number of recommendations for radiotherapy practice. These were:

- treatment of the lymph nodes in breast cancer patients should not be considered routine – patients should be carefully selected for this treatment based on risk of reoccurrence
- patients should not be moved during treatment
- all cancer centres should have an agreed written protocol for breast cancer management, which is subject to audit and reviewed regularly
- all breast cancer patients should be looked after by a multi-disciplinary team of breast specialists with a wide knowledge of the disease
- health professionals need to be more aware of brachial plexus nerve injuries caused by radiation
- patients need acknowledgement and, when possible, an explanation of their symptoms, whether or not these are thought to be due to their cancer or its treatment.

Notably, the authors said they were unable to advise on an 'optimum

radiotherapy dose and technique'. Instead they recommended that large-scale studies be carried out to identify whether high doses were really necessary to improve patients' survival prospects and also to establish the optimal radiotherapy regime.

But overall, the report was positive about the future, convinced that the advances in treatment, widespread use of chemotherapy and the development of specialist breast care centres, would ensure that radiation induced nerve injuries would 'continue to become even rarer in the future'.

Thelma Bates has commented:

'Even though this wasn't a scientific study – we got the most out of it we could. I think we squeezed the most juice out of that orange'.

How did R.A.G.E. respond?

Their views on the conduct of the audit

R.A.G.E. was somewhat disappointed with the way the audit had been carried out. As Jan Millington describes, 'We weren't consulted as much as we should have been. We did have a couple of meetings with Dr Bates, but she didn't examine anybody. We all thought she was going to look at people'.

Joyce Pritchard remembers that Thelma Bates 'said in the [invitation] letter... she wanted permission to speak to their GPs and bring them in for examination. She never did that'.

Thelma Bates explained why in the end she decided it wasn't necessary to see the women:

'It was because of the quality of the medical records. Many women had been photographed; there were diagrams, descriptions of damage. I saw no reason to doubt what was in the records, because there was so much radiation damage reported.

Some of the women were invited to see a Consultant Neurologist for assessment, because their diagnosis was uncertain. Eight of these eleven women gave their consent to be seen and brachial plexus damage confirmed in four of them. Seeing a neurologist was, in my opinion, more valuable than seeing me'.

As a researcher she was focusing on finding out what had caused the damage. She only wanted to identify which women had been damaged, so she could then go back and look in detail at how they had been treated. She wasn't interested in finding out how badly the women had

been damaged as she explains”

‘It was important for us to find out what went wrong – why did this group have this trouble... if we had lined them all up and listened to every one we might have found more damage than we did – but what we were interested in was marrying the damage to what had actually happened during treatment. We saw a lot of damage anyway and didn’t minimise it.

Some of the R.A.G.E. women could have been worried that their doctor only wrote down half of what they suffered. I could understand that – but it wouldn’t have got us any more answers – it may have muddied the waters’.

Jane Maher believes there were tensions over the amount of evidence that needed to be collected that compromised the audit from the start, ‘There were two somewhat conflicting demands on it. Firstly to get the evidence the women needed for their compensation claims and secondly to draw out the lessons as to what might need to change in radiotherapy practice. You can’t do both at the same time’.

R.A.G.E.’s views on the final report

R.A.G.E. members were also frustrated by the fact they weren’t given an opportunity to comment on the report before it was published. They had expected to be able to comment in detail on a draft version, but were not shown the report until 48 hours before it was released to the press. Thelma Bates recognises that she could have ‘communicated more’. She commented that ‘R.A.G.E. is not an easy group – but that doesn’t mean we shouldn’t have tried harder. I have always taught my students that a difficult patient is a worried patient and needs more of you and needs more time. We could have given more of ourselves instead of concentrating on getting the report as good as we could’.

In spite of their reservations, some R.A.G.E. members were still reasonably happy with the outcome. Jan Millington thought at the time, ‘We knew instinctively that the audit wasn’t a perfect job... but we felt that it was done in the right spirit. We thought it was enough... that it was going to curtail this long costly court business. If the government had then said we’ll do this, this and this for you, it could have all been settled’.

Lady Ironside commented, ‘We thought we were home and dry when the Bates report came out’.

But not all R.A.G.E. members agreed. Some were still concerned that the audit relied too heavily on written medical notes, particularly as they knew their own notes were inaccurate or incomplete. As Joyce Pritchard describes, ‘...my consultant had taken papers out of the file before he

sent it back to X hospital. How could she [Thelma Bates], if she hadn’t seen the records of my injuries, know that I had bone necrosis, nerve damage etc... I would think she took a lot of it from the forms we filled in about our problems. But she couldn’t have checked them all’.

Margaret Carling also commented ‘There were lots of inaccuracies. The audit didn’t paint as black a picture as it should have, as it was based on the hospital notes’.

One woman in particular, Margaret King, wanted to work on developing a full and detailed critique of the audit’s conclusions. She spent the following year carrying out research into members’ experiences with admin support from Joyce Pritchard.

Jan Millington and others felt that Margaret’s work wasted precious time, ‘We were railroaded into that, it went on and on and on. She said she’d spent hours and hours going through this. I couldn’t see the point of it all. I couldn’t get through to Margaret how much we’d put into this and what the intention was’.

Margaret King eventually produced her own report that was made available by the RCR in 1997. But it had little or no impact.

Jan believes the delay in waiting for Margaret King’s report caused R.A.G.E. to lose precious momentum. They also lost opportunities to argue their case. It looked as if they weren’t willing to accept what the RCR had concluded. As Jan describes:

‘We didn’t want too much probing. But as a result of doing that we shot ourselves in the foot. We lost time and momentum... We played right into their hands. We should have taken that [the Bates Report] to another big rally, and then gone straight for it’.

The wider R.A.G.E. membership also lost interest. As a result of the audit, some women had been told they didn’t have radiation damage, which was difficult for them to hear. Jan concluded, ‘I do think that was a retrograde step for us. I think it did dilute us. We had the momentum going at the time, and we should have hung onto that like grim death’.

Joyce Pritchard is also dismissive of the audit. She believes ‘The Bates report was done to appease us, to keep us quiet. I think they loved that year when nothing happened’.

How did the radiotherapy profession respond?

Thelma Bates believes that the audit was very effective in leading to permanent changes in radiotherapy practice as she describes:

'One criticism of the centres was the lack of a protocol – only three of the 15 centres had a written protocol. After the report, everyone had a protocol, and improved their audit. It certainly stopped people moving patients. It stopped people giving mini boosts here and there – it led to clinical trials... So good came out of it'.

But some professionals believe that many in the radiotherapy profession were already aware of the issues raised in the report. Research published by John Yarnold back in 1984 had shown that irradiating the lymph nodes was unnecessary in most cases of early breast cancer. By 1995, when the Bates report came out, it was no longer routine practice.

The profession were also aware of the lack of consensus regarding best treatment and the need for clinical trials in this area. Back in 1989, the Royal College had carried out a survey of all the radiotherapy centres in the UK, which showed that 52 different treatment schedules were being used to treat the same hypothetical case of breast cancer. The study concluded that despite this variation, all the treatments were essentially very similar in their outcome – 'what we are seeing in effect is different clinicians reaching the same biological endpoint by different routes'. However, the report still concluded that there was a need for more consistency in radiotherapy schedules, if only to 'ensure that resources in RT departments are being effectively utilised'.

Nor was the experience of the R.A.G.E. members new to radiotherapists. Lady Ironside's trial and all of R.A.G.E.'s campaigning work had already woken up the health profession to the need to 'get their house in order'. As Karol Sikora describes, 'When the Ironside case fell through in 1991, everyone got more careful. It woke everyone up to the problem. Everyone started recognising it and a lot was written about it. This made people review their technique'.

R.A.G.E.'s exposure in the press in the early years had also prompted Stanley Dische, a nationally respected oncologist, to write a paper in *Clinical Oncology* in 1993, which said 'Clinical oncologists in the United Kingdom must have been considerably embarrassed by the recent discussions in newspapers and on television concerning post-radiation morbidity and the influence of fractionation. Particularly discomfiting must be the confession by a number of eminent oncologists to the insecurity of our knowledge concerning the optimum fractionation of radiotherapy'. He went on to describe what was known about the optimum radiotherapy treatment and advised his peers to become more '...familiar with the data and the evidence to support their practice in radiotherapy'.

So by the time the Bates Report was published at the end of 1995, much of the radiotherapy profession believed they had already moved on. As Karol Sikora commented 'The report didn't have much of an impact because it seemed as if women weren't getting injured anymore... The

general view was that an unusual combination of events had caused the injuries, none of which on their own would have led to damage... This is the Swiss cheese model of accidents... if you put a knitting needle through all the holes in Swiss cheese, now and again it will go through all the holes and come out the other side and that's what happens... now and again all the holes line up – all these things happen at same time which leads to an accident... By the time the report came out we'd all realised this. So there was no real interest in revisiting it'.

The radiotherapy community were also facing far greater pressures caused by the continuing shortage of equipment and manpower. As Karol Sikora described, 'British radiotherapy has never been great – the waiting times were too long. So while that was still happening, it seemed there were far more pressing problems than a few women who got damaged 20 years ago. The question was what were we going to do to benefit the majority of women with breast cancer?'.

Although its impact on radiotherapy practice may not be agreed upon, as John Yarnold describes, 'That was not the only reason it was done... It was documenting what had happened, and why we think it happened and saying this is something doctors have to recognise happened... It was part of addressing what the profession had done – publicly stating that as a group this is what we have been responsible for'.

Jane Maher agrees, 'It brought relief and closure. I think people had already begun to change their practice, but the Bates report confirmed what many people had already decided was the issue'.

However she is also concerned that the 'Radiotherapy profession never fully took on the responsibility for allowing this to happen. Although it did take on the responsibility of sorting out the subsequent problems – producing guidelines and standardising procedures, the emphasis was on defending the profession. The audit made it look as if the Royal College was responding, but they didn't really do enough'.

How did the Government respond?

There was also scepticism about the audit from other quarters, including MPs. Jeremy Corbyn MP, spoke about R.A.G.E. in Parliament on 22 November 1995. In his speech, he raised the following concerns:

'The Department of Health is about to publish an audit conducted by the Royal College of Radiologists on the practices of its own members, to establish how such injuries occurred. R.A.G.E. was denied an independent, multidisciplinary inquiry. I hope that the audit will go some way to supporting the arguments constantly made on causation and for proper compensation. There is strong support for an independent inquiry that is not dominated by the medical profession, but takes evidence from

its members – in the way that a select Committee does’.

However, neither the Bates report nor this support from MPs, helped R.A.G.E. further their claim for compensation (see page 65).

The only comment the Government has made in subsequent years is that it recognises the contribution R.A.G.E. has made to raising radiotherapy standards. In a letter to R.A.G.E. on 8 April 2003, Hazel Blears, then Under Secretary of State for Health, commented:

‘The work undertaken by R.A.G.E. has highlighted the need... for further research on fractionation schedules and the need for standards relating both to radiotherapy and to the provision of supportive care. I am pleased to say that progress has been made in each of these areas’.

The START Trial

The national Standardisation of Adjuvant Radiotherapy (START) Trial was launched in January 1999 with the aim of identifying the optimum radiotherapy treatment for breast cancer – both in terms of reducing the risk of the cancer coming back and minimising the damage to normal tissue. The results of the trial have not yet been reported (the trial was expected to last ten years), but it has already had an enormous impact on breast cancer care in terms of standardising radiotherapy treatment in the NHS.

Professor John Yarnold was the researcher who developed the idea for the trial and has been running it ever since. He described how the trial came about ‘The main scientific reason to do the START Trial came from a pilot study. The pilot study involved 1400 patients and started in 1986. The pilot study confirmed the results from another piece of published research – together they suggested that breast cancer is more sensitive to fraction size than other cancers. That was just amazing. Because it has always been assumed that what really matters to a cancer is the total dose of radiation, so that it doesn’t matter if it’s in a few big doses or lots of little ones... but breast cancer is different. It is more sensitive to fraction size – which means if you give lots of small doses, you may spare the cancer and increase the risk it will come back’.

Professor Yarnold was therefore concerned that the standard radiotherapy treatment for breast cancer was not as effective at eliminating the cancer as people thought – because the size of the individual chunks or fractions was too small. He thought larger doses might be more effective, but that this needed to be tested in a robust clinical trial. As a scientist, he was also interested in finding out what underlying biology might be responsible for these differences between cancers, and if this might lead to a way of testing people to see if their tumour was more likely to respond to small or large fraction sizes.

The idea of using large fraction sizes was of great concern to R.A.G.E. members, because larger doses were believed to be responsible for their injuries. John Yarnold therefore agreed to meet with R.A.G.E. to discuss this issue. The R.A.G.E. Committee concluded that it was unwilling to become involved in supporting the clinical trial as Jan Millington describes:

‘As a group we felt it unprincipled and untimely to add support to a clinician’s research which was going to cost vast amounts of money. It would have meant ‘rubbing salt in the wounds’ of our severely affected members, for whom as yet, NO money could be spared. We felt that fighting the huge battle to have our members’ needs met had to be our priority and it absorbed all our scant resources’.

However, two of the women, Joyce Pritchard and Margaret King, were personally very interested in the trial and subsequently became involved in developing the trial protocol (the plan for the trial), though not as official representatives of R.A.G.E. These two women proved to be key to getting the trial funded as John Yarnold describes,

‘I first submitted an application for funding of the trial in 1996 or 97, but because of the concern about adverse comments from R.A.G.E., the Royal College of Radiologists who had been formally supporting the trial felt they needed to withdraw their support – they were afraid of the publicity.

Over the next 2-3 years I developed the protocol with Joyce and Margaret’s input and when I then submitted another application to the Medical Research Council, it was the letter of support from those two women that was very important to everybody – not only to me personally and the research team but also the funding agencies – with this apparent support from patients they had no reason not to fund it.

Joyce and Margaret saved that whole initiative. Then everyone else jumped into line – including the College. It was very much down to Joyce (Mrs Pritchard) – she was persuaded by the arguments – and even though the other R.A.G.E. Committee members were not convinced – her view was heard’.

Before the START Trial actually began, John Yarnold approached R.A.G.E. again to ask if they would join the Management Committee overseeing the trial. But there were still some concerns, as Joyce Pritchard describes, ‘The answer from the R.A.G.E. Committee was no. They felt that he was going to use protocols that some of the committee members who were badly damaged had had themselves’.

Jan Millington explains ‘We weren’t too sure about the START Trial. We thought it was in many ways a backward step, because it was using fractions that we were worried about’.

A compromise was reached with Joyce Pritchard and Margaret King joining the Management Committee, purely as observers. However, Joyce Pritchard believes they have had more of a positive impact through influencing the design of the trial. She describes how 'Margaret told them one of the dosages they were using was wrong. And they amended it, and Margaret was quite content about it. It was giving a 3rd dose from the back'. John Yarnold has commented that they became 'a really positive force' which he has certainly benefited from.

Some R.A.G.E. members are still fairly negative about the trial. They are concerned that the real interest may not be about finding the most effective treatment regime to treat breast cancer, but rather finding the most economical way to deliver radiotherapy. Jan Millington believes, 'Everybody knows what's a safe and effective dose, but nobody wants to settle for that. They just tinker away with this. If there's a good standard, why not stick to it'.

David Bainbridge, a R.A.G.E. member whose wife experienced late radiation damage in 1998, has also commented, 'The START Trial is designed to show that high doses can be used safely. This would allow people to be treated in half the time. The motivation is not clinical effectiveness – but economic and political. ...Economic because of the extreme shortage of staff, machines and funding – even now in 2006 and political because they won't tell politicians they can't cope without increasing the dose rate given to breast cancer patients. I would be more convinced by the results of the START Trial if they were actually examining patients, in detail, using scanning processes for all of the areas of damage within the treated volume. Particularly the muscles, ribs, lung and heart'.

In contrast, from the professional's point of view the START Trial has been of major significance. As Jane Maher describes, 'The START trial placed rigorous quality assurance demands on centres before they were allowed to take part. Very many centres across the UK took part – it was one of the highest recruiting trials ever. The quality standards for the START Trial thus effectively became the quality standards for radiotherapy in the UK. This is how R.A.G.E.'s experience led to a harmonisation of standards'.

John Yarnold explains how this standardisation was carried out, 'We got half a million pounds from the Department of Health to appoint three experts full-time to do quality assurance. We built a dummy body with properties similar to people – but full of dosimeters and films to measure exactly what dose is being given. We spent the first year driving round radiotherapy centres. Before centres could start work on the trial, they had to show, using the dummy, that they were achieving the right doses. We've also been monitoring a subset of patients during the trial to check they were maintaining the standard. In this way the trial has effectively standardised UK practice... If Joyce and Margaret hadn't supported START, then these improvements across centres wouldn't have happened'.

Aim 3: To seek compensation commensurate with the injury

The case for compensation

The lives of all of the R.A.G.E. women were profoundly affected by their radiation-induced injuries. Many had to give up their jobs because they were unable to use their arm, or because their brittle bones made them too fragile, or they were simply in too much pain. This meant that some women lost their homes. Many suffered a reduced income and consequently were unable to save for a pension. Lorna Patch, who joined R.A.G.E. soon after its inception, describes how her life changed following radiotherapy for breast cancer:

'The radiotherapy happened to me in 1985. I began having problems in 1986. I had to give up my job then. I haven't had a penny in income since then, except old age pension... Having lost my job, I lost my house'.

David Bainbridge describes the situation for his wife, treated in 1998:

'Brenda had a job, she was a deputy headmistress. She lost her job seven years ago and with it her entire income. She has a small pension, but not a lot because she had to retire early. We could have lost our house. She could have found better, less damaging treatment elsewhere if she had known'.

Pam Pond, another R.A.G.E. member, also experienced huge changes in her life following radiotherapy:

'I had a complete life change. I had to give up my lovely job, my 4-bedroom house and bought a mobile home. But because of problems with my chest I had to move again. I was living in an area where they sprayed crops. When I went to the doctor, she said you can't live up there, it's making your chest worse. So now I am renting a much smaller house'.

Many R.A.G.E. members also spend money on complementary therapies, such as massage and acupuncture, which they feel necessary to give temporary relief for some of their symptoms. They also have to buy special clothing, either because of their mastectomies or because their arms are swollen by lymphoedema, and have extra costs because they have lost the use of their arms. As Pam Pond describes:

'If you get your hair done, it's £10. The little money you have goes quickly. But if you've only got use of one arm, you can't do your hair. Little things like that mean such a lot. They really affect your quality of life... Clothes are a problem – to find things with big sleeves... there was someone who made special clothes – but they weren't good quality and were

expensive... but you want to keep your arm covered – so people don't ask about it'.

In March 1995 when Lady Ironside and Jan Millington presented evidence on behalf of R.A.G.E. to the Health Select Committee (which was investigating breast cancer treatment in the UK), they gave a very clear summary of the reasons that they felt compensation was justified. These were stated as follows:

- (a) As a result of injury, entitlements to statutory benefits and state pensions have been eroded
- (b) As the type of injury is not recognised by the Department of Social Security and the consequences are far-reaching for R.A.G.E. members who are suffering a much reduced quality of life, through no fault of their own, R.A.G.E. believes that statutory benefits cannot be regarded as the sole remedy for the state they find themselves in. Also Disability Allowances are discretionary and may become regionally dependent.

They also presented a list of factors they felt should be taken into account when considering their case. These were:

- (a) Women have been forced to give up work and have therefore lost earning power and had to forego pension contributions
- (b) They have had to pay for very expensive mechanical aids in their homes, such as stairlifts and other devices
- (c) They have had to employ domestic help, odd-job men and garden help
- (d) They have had to give up driving and have had to pay for taxis and other forms of transport, thus curtailing their ability to travel freely and move about
- (e) They have had to attend clinics regularly, some of which are difficult to reach
- (f) They have had to forego leisure pursuits.

What were the R.A.G.E. women hoping for?

Most of the R.A.G.E. members were not seeking huge sums of money. Like many people who feel they have been harmed in some way as a result of medical treatment, they wanted an apology and an appropriate level of compensation. As Jan Millington describes:

'All I wanted was for this to be settled, for someone to say "Don't worry about this, we'll look after you", to say "This is awful. But here's some money – invest it so you can get some help in the house". Because

you've lost your job. You lose pretty much everything if you've lost your right arm... We didn't want £400,000... it wasn't realistic. It was a few thousand pounds, whatever the figure is for industrial injury. That's all most people would have been happy with'.

There was a widely held feeling amongst the group that a claim for compensation should be high on their list of priorities. In the first few years, this involved three different areas of intense activity – developing a legal case, campaigning for a public inquiry and lobbying MPs. There was some confusion and disagreement as to which of these activities should become a priority, so initially they were all taken forward in parallel.

Developing the legal case

Not long after R.A.G.E. got started, one of the women brought along a solicitor from the firm Russell, Jones and Walker (RJW) to a R.A.G.E. meeting. This solicitor was Julie Turner. She became R.A.G.E.'s legal adviser at that time, and was to have an enormous influence on the rest of R.A.G.E.'s history.

At the beginning of 1993, Julie Turner advised R.A.G.E. to gather statistics on the women's injuries as evidence to support their case. Every R.A.G.E. member was sent a questionnaire – the first of many. And every woman who contacted R.A.G.E. during that time was asked to take part in the survey and to help with the costs of collecting this information. The initial data confirmed what the women had long suspected – their injuries were clustered around certain hospitals over a specific period in time – at that time 23% of R.A.G.E. members had been treated at one particular hospital.

Over the next few meetings, Julie Turner explained how she thought she could help R.A.G.E. members win compensation for their injuries through legal means. She was very persuasive. The women even agreed to contribute £200-300 each to a 'fighting fund' to help research their case.

Julie Turner sent a letter to everyone who completed the R.A.G.E. questionnaire. It was very encouraging, leading the women to believe they had a strong case. She told them that a QC had advised there were good grounds for seeking legal aid for a group action. She also said they would be able to seek compensation for all types of radiation damage – not just the brachial plexus nerve injuries. She also began to put the pressure on R.A.G.E. members. She warned that legally claims had to be made within 3 years of a woman realising her injuries were due to radiation so that 'if you have any intention of seeking legal redress for your injuries, it is most important that you seek legal advice NOW'.

Jan Millington felt Julie was helping enormously at the time, 'Julie really

revved up our campaign. I can't blame her for doing that as she got an awful lot of publicity for us and brought in a lot of new members... we asked all of them for a contribution to the fighting fund because we trusted her at that time'.

The first rally

Julie Turner's activity certainly helped the early campaigns. It was Julie who enlisted the support of Lynn Faulds Wood, a TV presenter, who helped the group organise a big rally at the London School of Economics in September 1993. Lady Ironside and Professor Karol Sikora spoke at the rally, which was attended by over 500 people. Many of the women had travelled some distance, some in great pain, to attend the event. As Jan Millington describes:

'It was heady stuff, almost exhilarating to have gone from being of absolutely no consequence to such dizzy acclaim'.

The rally led to even more publicity. R.A.G.E. was featured on a number of television programmes, including *The Time and Place* and *The Big Story*. These in turn brought many more members. The media were asking various cancer experts for their opinions. Many expressed surprise at the severity and frequency of injuries, and publicly stated their support for the R.A.G.E. women. For example, on a *Panorama* programme about radiotherapy, Dr David Skeggs, a consultant radiotherapist, commented:

'I feel that somebody in the medical establishment has got to stand up and speak for them. If you realise an injustice has been done to a patient you are morally bound to stand up and support them. It should never have happened in the first place'.

Campaigning for a public enquiry

Unfortunately, Julie Turner's activities soon began to cause great tensions within R.A.G.E. Some members were not at all interested in pursuing the litigation. They were more in favour of pushing for a Department of Health investigation – either through a public enquiry or another type of investigation that might lead to compensation being paid. As Margaret Carling said at the time:

'Access to the Courts is for most of us, out of the question. We have lost health and livelihood. We cannot afford to put our homes at risk by embarking on the lottery of litigation'.

R.A.G.E. members also wanted more than financial compensation – they

wanted to be certain that what had happened to them would not happen to anyone else. They were aware that a public enquiry had the potential to achieve much more than a court case. As David Body and Jonathan Glasson (a solicitor and barrister who were involved in litigation related to Human Growth Hormone and CJD) have described:

'Litigation has a restricted palate of remedies to offer to Claimants, of which damages are the most obvious. If damages are the only remedy sought, then a multiparty action is the most obvious means of redress; if there is a broader agenda of resolution then litigation can only ever be of partial satisfaction. The fact that public inquiries follow a broader remit than litigation is more reassuring to those who say that the events being enquired into "must not happen again". Since the recommendations made by a public inquiry are susceptible to political implementation, the breadth of potential redress is much wider'.

Therefore with the aim of calling for a full public inquiry into radiotherapy for breast cancer (see page 46), R.A.G.E. signed a formal letter that Julie Turner had drafted and sent it to Virginia Bottomley, then Secretary of State for Health. The Department of Health did not respond.

Lobbying MPs

A small sub-group of the R.A.G.E. Committee focused their attention lobbying MPs, the House of Lords and government ministers as a means of seeking compensation. Lorna Patch was a key member of this sub-group, along with Valerie Eldridge and Margaret Carling. Margaret's view, which was shared by many of the R.A.G.E. Committee, was that the women had a strong moral case, rather than a legal one – and that this should be a focus of R.A.G.E.'s lobbying. They began with a successful parliamentary lobby in 1993. This was undertaken in partnership with Northern R.A.G.E. (which later re-named itself COUR.A.G.E.), a group of women who had suffered late radiation damage following treatment for gynaecological cancer.

Tensions increase

At the same time as work on the legal case and government lobbying was moving forward, Professor Karol Sikora was working with another sub-group of the women to push for a Department of Health sponsored investigation. Towards the end of 1993, they were close to agreeing with the RCR that they should carry out an audit of the women's injuries (see page 48). However, this was causing ever increasing tensions between R.A.G.E. and Julie Turner. Things reached a head when RJW refused to share the results of their early survey of the R.A.G.E. members with anyone else, and in particular the RCR. They strongly warned R.A.G.E. against working with any organisation likely to be a defendant in a legal

case. In a letter to Jan Millington on 10 Nov 1993, Julie wrote:

'I understand that the idea has been mooted... that R.A.G.E. apply for a Government grant in order to undertake and complete a survey of R.A.G.E. membership, which will be handed to the Royal College of Radiologists... from the perspective of the legal cases of R.A.G.E. members this would be extremely dangerous. As long as the Defendants are unaware of the extent of the information we have obtained, it is a 'Sword of Damocles' hanging over the health authorities' heads and it is likely to encourage an early settlement...

...It is most important to remember R.A.G.E.'s days "in the wilderness" when no-one from the Royal College, the Government or established cancer charities would give R.A.G.E. the time of day. It was only when litigation on a large scale was mooted that these bodies became interested and it would be sensible to view their current offers with a degree of scepticism and a great deal of consultation with the R.A.G.E. membership as a whole and your legal advisers'.

R.A.G.E. was in a very difficult position. There wasn't strong support for pursuing the litigation – but they also felt that they had no choice. They were told repeatedly by government officials that the only way they would ever get compensation was by going through the courts (see below).

R.A.G.E. separates itself from the legal action

By December 1993, R.A.G.E. was in a state of great conflict. Many members wanted to co-operate with the government and the RCR. At the same time, the litigation seemed to be discouraging people from joining R.A.G.E. Jan Millington was severely criticised for working with RJW. She was so distressed that she even considered stepping down from her role as R.A.G.E. co-ordinator. Julie Turner did resign as legal adviser to R.A.G.E. In a letter to R.A.G.E. in January 1994, she wrote:

'There has been a breakdown in the essential relationship of trust that must exist between solicitor and client, and in these circumstances, it is appropriate that I should now tender my resignation as legal adviser'.

However, she continued to act as the solicitor in the court case, taking it forward independently of R.A.G.E.

R.A.G.E. now began to see its interests as diverging from those of the radiotherapy litigants. They did not respond to RJW's advice and continued to work with other organisations. With hindsight, they're still glad they made this decision. As Jan Millington says:

'Cancer patients, especially those with radiation damage, do not have a

great deal of choice about who they turn to for any kind of support and had R.A.G.E. heeded this advice and not behaved pro-actively, it is likely that the injured women would still be without any acknowledgement'.

Seeking compensation by lobbying Government

Having effectively divorced itself from the legal case, R.A.G.E. now focused all of its efforts on seeking compensation by other means. However, they were always overshadowed by the legal action.

The R.A.G.E. parliamentary sub-committee encouraged the membership to write to their MPs, to ask for their support. Lorna Patch, who led the work of this sub-committee, went to see any MP who agreed to help, accompanied by other R.A.G.E. members. From 1993 onwards there was a great deal of activity, as Lorna remembers:

'About one in 10 MPs responded when we wrote to them. I would then telephone. It isn't just one phone call, it can be as many as five. Then you have to set up an appointment, then it's cancelled – not his fault, he's called away. Then he'd give you a meeting on the one day you couldn't go. It was a very very hard slog'.

Margaret Carling compiled a detailed report on what had happened to R.A.G.E. members. A copy of her report was given to all MPs who expressed an interest as part of an 'information pack' on R.A.G.E. Her report stated:

'The R.A.G.E. case is quite simple. We are the innocent victims of medical procedures – often unnecessary and sometimes experimental. We could do nothing to prevent our injuries. We trusted the medical professional and our trust was betrayed. As a result we are left disabled, in excruciating pain, unable to work, pursue hobbies, to care for ourselves or our families.

As Lady Ironside has commented, "Before our *purely precautionary* treatment, we had two good arms. As a result of that *precautionary* treatment we now have one".

Nothing can restore our lost health but as our injuries have been caused by errors and sometimes experimentation in the medical procedures to which we were subjected without our consent, there is a MORAL obligation on the government to make an ex-gratia payment as a partial compensation for our loss.

Payment to us would not set a precedent. Our claim for compensation is unique in that the risks of treatment, though known, were not disclosed to us. Nor was the treatment necessary to preserve life'.

This campaigning proved very successful. At one point, over 100 MPs were publicly supporting R.A.G.E.'s claim for compensation.

One of the MPs who offered support was Jeremy Corbyn, a Labour MP for Islington North (although support for R.A.G.E. cut across political party lines). He raised the need for compensation for R.A.G.E. members during a House of Commons debate in November 1995:

'All the work of R.A.G.E. has been done by women in constant and dreadful nerve pain, whose personal and professional lives have been shattered. Some members of R.A.G.E. have had their limbs amputated and almost all have been left with only one usable arm. For the rest of their lives, in addition to being under the cloud of the possible recurrence of cancer, they will become progressively disabled...

The government should give urgent consideration to what is happening to those women and to giving them the compensation that they so desperately need and deserve.

The government's present position is that victims must seek compensation through the courts... That is unacceptable, because one must be very rich to pursue compensation that way. It costs around £200,000 to mount an effective case to prove medical negligence in the High Court, which is totally beyond the means of almost everyone in this country. It would certainly be beyond the means of an individual who has suffered as a result of breast cancer, lost her income and, more importantly, forgone any prospect of future income... The Government must instead produce a compensation package... The least we can do is to ensure that women who have suffered so grievously in the past receive proper compensation, ensure that such suffering does not recur and try to conquer that awful illness".

Mr Corbyn, along with a number of others MPs including Charles Wardle and Alice Mahon, continued to raise questions in the House of Commons on behalf of R.A.G.E. But each time, they were told that compensation would not be paid by government:

'The government's policy is clear: that compensation will be paid when negligence is established in court. That, we believe, is the right way in which to protect patients, and to safeguard the precious resources of the National Health Service for patient care'.

The second parliamentary lobby

R.A.G.E. organised a second lobby of parliament in December 1996. This was chaired by Lynn Faulds-Wood. Lady Ironside welcomed everyone to a full lobby room. Karol Sikora and David Skeggs (both oncologists)

spoke, as did MPs Jeremy Corbyn, Liz Lynne, and Charles Wardle. Baroness Cumberlege, Parliamentary Under-Secretary of State for Health, attended the lobby to respond to the question R.A.G.E. had posed:

'Will the Secretary of State for Health consider the award of compensation to those women suffering permanent, progressive and disabling injury after radiotherapy for breast cancer?'

All the speakers, except for Baroness Cumberlege called for compensation to be paid to R.A.G.E. members. Yet again, the response from the government was negative.

Early Day Motions in Parliament

MPs continued to raise the case for compensation through Early Day Motions (EDMs). In 2001, Edward Davey, Liberal Democrat MP put forward an EDM that stated:

'This House believes there is a moral obligation for the government to provide an ex gratia payment for women who have been injured by their radiotherapy treatment; recognises that in the past women were not warned of the dangerous risks before their radiotherapy treatments, were not given counselling after them and that the treatment was administered without informed consent being sought or given; understands radiotherapy injuries can include painful, uncontrollable and permanent injuries such as the paralysis of an arm or spontaneous bone fractures; notes that no compensation has been paid since EDM 512 (COUR.A.G.E. campaign for patients with radiotherapy damage) was tabled in December 1997; asks the Secretary of State for Health to empower the Health Service Commissioner to recommend the award of ex gratia payments in appropriate circumstances, as proposed by the Health Select Committee in 1999; and urges the Department of Health to look again at the provision of an arbitration system to provide no-fault compensation for exceptional cases where the NHS is responsible for non-negligent harm'.

The impetus for this EDM was that haemophiliacs who received blood transfusions infected by the hepatitis C virus had won their case for compensation in court – and the government had chosen not to appeal. The R.A.G.E. women – and many of their supporters – felt that there were a number of similarities between these two groups. However, nothing happened as a result of this EDM, and R.A.G.E. felt that Edward Davey lost interest after he had tabled the Motion.

Lobbying of ministers continued

Alongside the work to lobby MPs and House of Lords members, R.A.G.E.

continually lobbied government ministers. The R.A.G.E. Committee and other R.A.G.E. members wrote to a succession of Secretaries of State for Health asking for help and compensation. MPs also wrote on behalf of their constituents who were R.A.G.E. members. But it came to nothing, and R.A.G.E. simply felt they were fobbed off. As Jan Millington reflects:

'Once you get into the Department, they write these letters saying we have every sympathy, but how are they showing that sympathy? It's just words, they're not doing anything. They're quite prepared to spend all that money sending off all those reams and reams of letters rather than sorting it out'.

The answer from ministers was always the same, typified by this letter written by Lord Hunt, Parliamentary Under-Secretary of State on 25 October 1999 to Valerie Eldridge, a R.A.G.E. Committee member:

'We fully acknowledge and sympathise with the women who have suffered severely as a consequence of the radiotherapy treatment they received for breast cancer. However, the government's position has been consistent that compensation should be payable only if negligence can be shown'.

The other commonly offered response was that there was provision for individual NHS Trusts to make one-off payments. Baroness Jay, Minister of State, wrote to Lorna Patch, R.A.G.E. Committee member in January 1998:

'With regard to ex gratia payment, NHS bodies already have the authority to consider whether such a payment should be offered in individual cases. Decisions to do so for those suffering adverse effects from medical treatment are a matter for the individual Trust, after careful appraisal of the facts. However, I should point out that it is unlikely an ex-gratia payment would be made whilst legal action is pending'.

The R.A.G.E. women felt trapped – as a committee, they had disassociated themselves from the legal action – but the legal action was going ahead anyway. Even more frustratingly, it was still being seen as R.A.G.E.'s action by the Department of Health – and the Department was using the court case as a reason not to consider compensation through any other means.

Once the legal battle had been lost (see page 78), the government then argued that the trial had demonstrated that R.A.G.E. had no case for compensation. For example, in 1999 Lord Hunt of King's Heath, then Parliamentary Under Secretary of State wrote to Lord Ironside:

'The NHSLA¹ is not able to settle any case where evidence of negligence cannot be shown and so no compensation is payable'.

¹The NHS Litigation Authority (NHSLA) was set up in 1995 to handle negligence claims made against NHS bodies in England.

And in October 2003 Melanie Johnson, Parliamentary Under-Secretary of State for Public Health wrote to Jan Millington:

'Compensation for injury or damages as a result of clinical negligence can only be obtained through the civil justice system, where legal liability must be established and where it is necessary to prove fault on the part of the defendant. R.A.G.E. made such a case and I understand that given the state of knowledge and techniques used at the time that there was no evidence of negligence on which to base a claim for compensation'.

What were the barriers to R.A.G.E.'s campaign for compensation?

One of the problems for the R.A.G.E. women involved in lobbying government was that every time they seemed to make progress with a minister at junior or senior level, there was a re-shuffle and the process had to start all over again. Lady Ironside comments:

'We were so near victory so many times, when the minister says, this is disgraceful. Then two or three days later you pick up the paper and they've been moved. Very convenient... Every time a minister said something must be done, they were moved'.

There was also a change of government during the campaign. Originally when the Labour Party came into power in 1997, R.A.G.E. members were optimistic that progress might be made, as many Labour MPs had expressed support for them whilst in opposition. But this changed once they were in government.

For example, Tessa Jowell (at that time an opposition MP) met with R.A.G.E. members in April 1996 and was 'plainly prepared to help'. But as Minister for Public Health she announced in the House of Commons that compensation would not be offered unless negligence could be established in court – and rebuked the MP who raised the issue. Hazel Blears was very active in the EDM that sought compensation for C.O.U.R.A.G.E. (see page 63). But when she became Under Secretary of State for Health, whilst remaining sympathetic to the women's plight, she refused to consider compensation.

Whichever party was in government it seemed that the overriding concern was that a payment to R.A.G.E. members would set a precedent. For example, Lord Hunt, Under Secretary of State for Health wrote to Valerie Eldridge in October 1999:

'I hope you will appreciate that our position has to remain the same in that we can only compensate patients where there has been negligence.'

We cannot pay for events during the evolution of medicine when treatments were not as well understood as now. Unfortunately, R.A.G.E. is not the only group of patients who have suffered non-negligent harm and the potential implications of no-fault compensation for the provision of NHS services today are immense'.

R.A.G.E. members were also challenged by the fact that their injuries had made them sick and disabled. As Jan Millington describes:

'When I saw my MP, Geoffrey Johnson-Smith, he said it's a minefield, you've just got to stick at it. You've got to keep going back. But as an ill person, you don't always feel up to that. And you just think you'll settle for the rest of your life. Because that's how it makes you feel, as if as an individual you're worthless.'

Efforts to gain other types of financial support

The R.A.G.E. Committee tried other ways to access financial support for R.A.G.E. members. In 1999 Jan Millington approached Macmillan Cancer Support, to see whether the charity could offer any help to R.A.G.E. members. Macmillan replied:

'Macmillan recognises that those individuals who have experienced disablement and other health problems associated with radiation damage are a special case. It has therefore been agreed that individuals with a specific diagnosis of Brachial Plexopathy or Radiation Enteritis, may be considered eligible for the whole range of Macmillan grants. Eligibility would of course still be dependent upon meeting our usual financial criteria. We are not able to award ongoing help or assist with treatment costs, education or training courses, special diets or supplements, daily living expenses, telephone bills or items of major expenditure such as structural alterations'.

Macmillan therefore ruled out offering help in precisely the areas where R.A.G.E. women most needed assistance – complementary therapy and daily living expenses. And the requirement for R.A.G.E. women to meet 'the usual financial criteria' presented them with yet another hoop to jump through. But this they did and some members successfully applied for grants.

R.A.G.E. Committee members have also worked hard to help members obtain (and retain) welfare benefits. For example, their understanding from the then Chief Medical Officer, Kenneth Calman, was that those with brachial plexus injury should receive Disability Living Allowance. However, over the years R.A.G.E. members have had these benefits withdrawn, and have had to repeatedly challenge this action.

What could R.A.G.E. have done differently?

With hindsight, some R.A.G.E. members wonder if they were simply too nice, and that this meant that their claims could be ignored. They felt they could have been more aggressive, and put the Department of Health under more pressure.

Other members felt that they should have pushed for more public sympathy, and gained more public support this way. As Margaret Carling describes:

'It's not strictly comparable, but the war widows got money because they got sympathy. The suffering of R.A.G.E. women over the years should have generated sympathy'.

Although the work to gain compensation has not yet succeeded in accessing any financial support for R.A.G.E. members, many of the R.A.G.E. Committee do not see it as a failure. Margaret Carling also commented, 'This area of work wasn't a failure. The compensation claim was a means of hanging on to all of our other aims... It wasn't a waste of time because it raised the level of awareness'.

The court case

In the early years, the R.A.G.E. women felt they had little choice other than to pursue a legal case for compensation (see page 67). As Jan Millington describes:

'We had no cause at the beginning not to support the legal route, we had a very, very reputable firm... and the Government said the same, they said the same all along, they said medical negligence has to be proved in court'.

They were also hugely influenced by Julie Turner. The R.A.G.E. women had no reason to doubt her. She came from a well-respected firm recognised by the authorities as a specialist in medical litigation. Julie Turner was personally very motivated by the case, and her enthusiasm did much to persuade some of the R.A.G.E. members.

Getting legal aid to fund the case

At the beginning, Julie Turner told the women she would aim to win 'out of court settlements' in just one or two 'good' cases. By the time, RJW applied for legal aid in January 1994, this plan had changed. Based on the advice of the very eminent QC, Dan Brennan, they were now proposing to proceed with a group action with over 130 women. As Ian Walker from RJW describes:

'The decision to go for a multi-party action was made by RJW – based on advice from Dan Brennan. Because Dan felt so strongly that this was a case that could succeed – he was one who initially said go for a multi-party action. So when someone like him says that, you tend to go with it. As he was the one who was going to be standing up in court to fight it'.

RJW were successful in their application. One hundred and twenty-five of the litigants received legal aid assistance, although the remainder were faced with paying privately. Getting this funding was crucial for RJW as Ian Walker describes:

'We were very keen to take on this case because we believed in it... we certainly don't do legal aid cases for the money – it was a very high profile case potentially – we believed we had the expertise to do it properly. But it would not have got off the ground at all without legal aid'.

The Legal Aid Board supported the proposal for a group action – so as to reduce the amount of court time required to try the case and so reduce the overall costs. RJW had also argued that because the cases were so complex, they would need to be tried by a single high court judge, who could gain a deep understanding of all the issues and so make a better informed decision. As Ian Walker describes: 'If 100 women used 100 different solicitors to fight 100 cases - it would have been mayhem – someone had to control it – and if it wasn't brought together then 100 different judges would make different decisions... There were also benefits to the women agreeing to share costs. Lady Ironside lost £100,000 on fighting her case alone. If 200 women had brought individual cases the overall cost (using Lady Ironside's figures) would have been £20 million'.

Jan Millington has commented, 'I don't think there would ever have been lots of individual cases... it seemed to me as if many of the women wouldn't have considered litigation if it hadn't been for the class action'.

However, taking this approach was a big risk. Group actions are less likely to succeed than individual cases and very few have ever been successful in this country. They also require a lot more investigation, as Gillian Solly from RJW describes: 'In a group you have to not only assess what happened to each individual, but also to make comparisons across a group and try and work out similarities and differences... so it raises a lot more complex issues than if it were just an individual on her own. The benefits are that if you win on one aspect you win for everybody – but a lot more work has to be done'.

Ian Walker has also commented: 'In my view it's important not to forget the very complex nature of this litigation. This was a huge legal undertaking for the claimants and for us, and was no where near the same as a single-party accident case'.

Some people have commented that the decision to go with a group action effectively diluted the women's case. Initially the focus was clusters of injuries at a small number of hospitals over a limited period of time. Adding the other claims not only increased the number of defendants but also increased the period of time over which the claims were being made. This made it even more difficult to prove negligence because of the broader historical context. It also reduced the number of common elements shared by the cases in the group action, since many more factors had to be taken into consideration. Some people have questioned whether taking this approach was the right decision.

There were radiotherapy experts who were also seriously concerned about the decision to go ahead with a group action. Professor Stanley Dische commented: 'The decision to go for a group action was a very serious move. It was unusual in being a group action against a large proportion of a profession. Most others involve a single product – a drug or device. But when a high court agreed to a group action against half the radiotherapy departments in the country, this was unprecedented. It had enormous implications not only for oncologists but for medicine as a whole'.

R.A.G.E. members also had their concerns, as it seemed as if the issues they believed to be important had been lost. But the fact that legal aid had been secured made it difficult for them to go anywhere else for legal advice. As Steve Walker, chief executive of the NHS Litigation Authority explained, 'They couldn't go elsewhere and retain the legal aid. If they had gone elsewhere they would have had to apply again and the Legal Aid Board might say this is being managed by someone else'.

The legal aid funding also meant that any woman pursuing her own case had to put her legal action on hold. Some were even taken to court by Julie Turner to put a stop to their cases. She had the support of the legal aid system to do this – the whole point of funding the group action was to reduce the costs from having lots of individual trials all going ahead at the same time.

R.A.G.E. separates itself from the case

By the end of 1994, tensions within R.A.G.E. had reached breaking point. There was considerable opposition to the group action which led R.A.G.E. to completely separate itself from the litigation (see page 64). Some of the women who were now part of the group action were still R.A.G.E. members, but they made up less than half the total number of litigants. It was understood that these women were now acting independently of R.A.G.E., effectively pursuing their individual claims.

Over the years R.A.G.E. of course kept an eye on the proceedings but became more and more concerned. To them it seemed as if the case

was being fitted around all the people who wanted to sue, whatever their reason. They felt the original purpose of the case had been lost. As Margaret Carling describes, 'The injuries that went to court were not typical of R.A.G.E. members' injuries'.

In 1996, the R.A.G.E. Committee made a formal decision to no longer tell new members about the case, unless specifically asked.

Pulling together the group action

On 8 March 1995, RJW attended a case management hearing at the Royal Courts of Justice. This involved presenting their proposal as to how the action should be fought. The judge, Mr Justice May accepted their proposal, which was based on selecting 10 test cases that would represent the whole group. If the 10 were then successful, the other 121 cases would be judged along similar lines to resolve them relatively quickly. Mrs Justice Ebsworth was appointed as the judge for the trial. Ian Walker comments: 'It seemed an oddly structured multiparty action – but quite sensible'.

Some women thought that Mr Justice May would have detected the weaknesses in the group action, and perhaps stopped it from going ahead. However, at such early stages it is uncommon for a judge to read deeply into the issues surrounding a case. He or she is more likely to accept it at face value, basing his or her decision on the representations from the lawyers.

RJW therefore went on to develop nine 'principal issues' which they believed underpinned their case. These were the things they believed had gone wrong with the radiotherapy treatment the women had received, based on the advice they had been given and the research they had carried out. As Ian Walker describes:

'In the beginning it looked as if the correct view was that all these women had been damaged for nothing. Some shouldn't have had it [radiotherapy] at all – but then if they had had it – did they have it properly? The other expert advice was that the science of radiotherapy was not well controlled...there was a view that the radiotherapy profession was a dustbin profession – so the picture was that women were being given dangerous, harmful treatment by people who weren't that well-qualified, who weren't being properly controlled. So it seemed as if things were going desperately wrong'.

The nine principal issues were presented and accepted by the courts in May 1996. But by this time these principal issues had little support from elsewhere.

Professor Karol Sikora had initially provided expert advice and supported the case. However, he was not convinced by the principal issues and tried to advise Julie Turner of the problems. He explains, 'If she pursued her line, the whole [radiotherapy] community would end up being sued by every patient... she would be saying that all the doses we'd been using had been incorrect - which couldn't be right'.

He believed the arguments were over simplistic '...because they wanted to make out that treatment within a certain dose range was negligent... when other people had been using higher doses and not seen any injury. We couldn't get it over to the lawyers... they refused to accept it'.

He made it clear that he couldn't 'Stand up in court or write a report... because the defence would say 'Sikora – YOU were doing it' – and we'd all be stuck.'

Jane Maher agrees, 'Because it could have been anyone who did this – any individual would have been 'torn to shreds', in order to defend the community'.

After withdrawing his support, Professor Sikora received no further correspondence from Julie Turner about the case. He described how 'They moved on without us and we weren't informed about what was happening... If you told her what she didn't want to hear – she didn't like you. She antagonised a lot of consultants'.

It seemed to him as if 'The lawyers kept turning to more and more doctors to find someone who would agree with them.' In his view, 'A lawyer can't control how good a case is, but they can decide to stop if it's no good'.

Other radiotherapy experts were also sceptical about the nine principal issues as Professor Dische describes:

'Here were nine different things that could have gone wrong – but they were all very different. They went from irradiating people who shouldn't have been irradiated through to technical errors when giving treatment - having overlapping fields or giving too high a dose. With such variation, it was extraordinary that they agreed this was suitable for a class action'.

Although some of the litigants were also worried that the case was going in the wrong direction, they had little option other than to put their trust in the legal system. As Jan Millington (one of the R.A.G.E. members who remained a litigant) describes:

'It seemed to me as if none of us knew what was going on. We were all very concerned. But we thought the Legal Aid Board is bound to be overseeing this because they're spending such a lot of money. They're

bound to watch carefully what's going on... we had a top firm of city lawyers... with a very good name.. they couldn't be more prestigious. So at the end of the day we thought ours is not to question, they must know what they're doing'.

Pulling together the defence

With large numbers of women now involved in the group action, large numbers of radiotherapy centres were forcibly drawn into the case. Beachcroft Stanleys, a firm of solicitors based in London were given the role of co-ordinating the solicitors representing all the different Trusts. The defence team was led throughout by Stephen Miller QC. He brought together a wide range of experts to work on the case – including Professor Charles Joslin and Professor Stanley Dische – the two most eminent and respected experts in radiotherapy in the UK. Charles Joslin played a major role in helping to select other defence witnesses as and when was needed to address the varying claim. This included an expert in the effects of radiation on nerve tissue who came from overseas.

According to Professor Dische, the strength of the defence's team was key to their success. He describes how 'We all got on very well together. We were a good team. Their team went through difficulties. Our team was good and we didn't change anyone.'

In contrast to the defence, the RJW team found themselves in serious trouble. In 1997 Dan Brennan left the case to defend a new case abroad. There was also the added complication in trying to find UK experts to support RJW's case. As Stanley Dische describes:

'No one was willing to act against their colleagues. At the time, clinical oncology was a small specialty so most people knew each other. No one could claim to be an independent witness when giving evidence against so many friends and acquaintances'.

RJW were forced to rely on the evidence of a retired oncologist and radiologists from abroad. As Ian Walker describes:

'We knew that we could not hope to fight the case without very heavyweight expert witnesses because what you've got to get is a high powered expert to say everything that was done was wrong. To begin with we had a lot of people who were prepared to say that – but we had to travel the world to get them. We were very worried because it looked as if going to have experts from outside the UK all saying 'Do you know how bloody backward you lot all are?' which is not an attractive way to put it to a judge'.

It did seriously weaken their case in the eyes of the trial judge (see page

84), while the strength of the defence team had a very positive influence.

In Stanley Dische's view, 'The problem with the litigation is that it became a battle between two teams. Our team was more successful. When you look at the result I think the better team won – which doesn't mean to say that their case was better... it seems to me that the other side started off with the wrong proposition and went to the wrong people'.

The group action collapses

In the months leading up to the trial, the defence experts were given an opportunity to examine each of the ten women in the group action and prepare their own detailed reports. In May 1997, they handed over their report to the plaintiffs. This delivered a devastating blow to the group action. As Ian Walker describes:

'What happened was our experts changed their view... We ended up with a team of four who were all prepared to say things were wrong - but the experts for the defence thought something totally different and when they swapped their expert reports – our experts start to think about it – it's easy for one expert to say something in a report and in counsel with you because no one is batting against them – then suddenly there are fast-bowls from the opposition – and one by one they all began to say 'I may have been a bit bullish on this one' – which meant that one by one the generic issues were no longer supportable.

In the beginning it was very tempting once an expert says what you want to hear and backs it up with what appears to be good science – you think well that's great... but I've learnt you really have to challenge them a good deal more – but as a lawyer you can't necessarily see past the science. If they come up with the right literature that seems to back up what they're saying – it's very hard to say we think you're talking rubbish. Because that's the definition of expert'.

There were other problems in the RJW team. With Dan Brennan's departure, RJW needed to appoint another QC. They finally recruited Adrian Whitfield to help rethink the case, as Gillian Solly describes:

'He was an eminent clinical negligence QC – equivalent in standing and status to Dan Brennan – the two of them were involved in most of the leading cases at the time. He was very heavyweight and it was very desirable to have him acting for you'.

The defence team's expert report had pointed out serious flaws in RJW's arguments. In July 1997, Adrian Whitfield spent four days in consultation with three experts to discuss these issues in depth. They agreed that there were serious discrepancies between the two sides. What they

realised was that each side had used different formulas to calculate the doses of radiotherapy that the women had received. What this meant was that the nine original principal issues could no longer be supported.

Soon after in the summer of 1997, two of the ten cases settled because both the litigants and the defence agreed these individuals had received inappropriate treatment. However, for the remaining cases, the nine principal issues had to be cut down to one. This single issue now simply stated that some women had received too high a dose of radiation. This of course made the women's case much more vulnerable. It cast serious doubts on their credibility. However, there was still some hope. Adrian Whitfield believed the single issue could stand. His advice was that they had about a 50-60% chance of success.

However his main concern was the women who were privately funded. If they lost, they were likely to have to pay even higher costs – because the defence would claim for time wasted investigating issues that had then been abandoned. He wrote to the remaining women saying:

'We would be entirely sympathetic to any private claimant who took the view that she did not wish to remain on the register with the prospects of success which we have identified'.

Some people have commented that at this stage the lawyers had every reason to press ahead with the case, because within the rules of the legal aid system they were guaranteed to get paid whatever the outcome – win, lose or draw.

From Ian Walker's perspective: 'By the time the generic issues collapsed – we'd already had five years of litigation so it would have been wholly wrong to have dropped it. We had produced six-monthly reports to the legal aid board – huge detailed reports which they had gone through with a fine tooth comb and then said they were happy to support this... When Adrian Whitfield realised we were in deep trouble – he wrote a very long advice which we sent to the legal aid board and we had a meeting with them. We said 'We can stop but we don't think we should – because some individual cases will succeed. We think we should bat on'.

The trial proceeds

In December 1997, the remaining litigants were summoned very hastily to meetings at the lawyers' offices. They were told, by Adrian Whitfield QC, that because of all the changes only three of the 'lead' cases out of the original 10 could proceed to trial. They were told one at a time, as Jan Millington describes:

'The people who were the ten lead cases got called up... and they were

told, they were called in one by one and told by the QC their cases had failed. They weren't allowed in the room with the rest of us, they were just ushered out'.

This was devastating for the women whose cases were dropped. As Jan says: 'When the cases tumbled... we were all absolutely distraught... everyone knew the case was a shambles. Everyone was sitting around waiting for their destiny. To see whether they'd been thrown out. That was a shock'.

Soon after, Julie Turner resigned from RJW. From NHSLA Chief Executive Steve Walker's point of view, this was evidence of the weakness of the plaintiff's case:

'When partners who've been taking a high profile and saying 'I'm going to make new law, I'm going to make my name', when they resign - defendants normally think they're on a winner'.

It was at this point that Ian Walker took over the case. In contrast, he remained convinced there was still a chance of success:

'By that point I was managing it and I was pretty sure we were going to get an offer. And we did – we thought this was vindication of our position'.

A few weeks later, almost on the eve of the trial, the women were summoned again to a meeting with the QC. About 20-30 claimants attended. This time there was an offer of £2 million on the table from the defendants. This offer had come from the NHSLA. The NHSLA inherited the case late in 1997. As Steve Walker describes:

'This was the first group action that we inherited. A series of health authorities had been running it, all using their own lawyers. Then we took it over and made the offer'.

He explains why, 'The offer was made very, very late. It was cheaper to give them something, to buy off the risk, than to risk losing it... We knew there were some cases that would probably win – a very small number. There were others where there was a small risk but we thought we'd be OK. But the overwhelming majority we thought we should win... but you never know what the judge is going to do. So we made the offer that we thought would be attractive to them, that might persuade them to think we could live with this and take it, and avoid the trial, because the costs of the trial were going to be horrendous'.

With a case funded by legal aid such as this one, the defendants have to pay their costs whether they win or lose. Most will try to avoid going to court. From the NHSLA's point of view 'It's all about money, it's all about avoiding paying £1,000's a day on either side to have your case talked

out. The sooner you can talk about your case outside the court the better, cheaper for both sides, and as long as the claimant gets what he or she might have got in the high court, we feel that's fair'.

The £2 million offer from the NHSLA was to be shared between all the litigants. This was either to be shared by everyone, which would just about have covered all their legal costs, or it was to have been distributed amongst the 'strong' cases. But the women weren't told who the strong cases were. They were only told that the defendants knew and refused to say. It was suggested there were about forty, which meant that minus costs they would have each received about £25,000. None of the women felt they were given enough time to think about this, or that they had been given sufficient advice.

R.A.G.E. member Christina Rogers recalls, 'On the Friday afternoon I got a call saying there was an offer on the table. I got a call from another woman who was so excited, saying there was an offer. I said don't get excited, we haven't got it yet. At that point I thought there was something funny going on... chaotic was the only word you could use to describe it'.

Jan Millington was also there and from her point of view it was 'Another Alice through the Looking Glass thing... we'd got absolutely nothing on which to make a decision. Some of the litigants were just in tears. You can imagine after all these years thinking they were going to get money'.

Her case had been funded by her husband's trade union and a representative of her funder was there. He confirmed that he would continue to support her case and advised 'rather than accept settlement, the cases, such as they are, should be tried'.

Ian Walker also remembers the meeting: 'We had a meeting in the RJW office... overwhelmingly they all said to stuff the offer – even though the advice we gave was that there was a good chance we could lose. From our point of view – what were we supposed to do with two million pounds? How were we to decide who should get the money?...And unless you get every member of the group agreeing this is how you should do it – you can't do it – which is great weakness of a multi-party action. There's not just one client, but 150. There was a small group who were very vociferous, very angry, and who wanted to go ahead – thinking 'We've got this far - let's see what the judge says'.

The women decided to proceed to trial. Steve Walker said 'If I'm honest I was flabbergasted'.

The trial of the three remaining cases began on Monday 12 January 1998 and ended on 5 February 1998. One case settled during the course of the trial. So only two of the original 10 test cases were eventually tried. Neither of these women had been treated at a hospital where there had been high rates of injury.

Mrs Justice Ebsworth handed down her written judgement on 8 May 1998. She ruled in favour of the defendants.

Why the women lost

The central legal question in the trial was whether the doctors had been negligent in their treatment. In order to prove negligence, the litigants had to show that the doctors had treated the women in a way in which no other 'reasonable' radiotherapist would have done at the time - or in a way that would not have been accepted as proper by a 'responsible' body of radiotherapists. In such cases the judge can also reach a decision on whether the practice considered 'proper' by a 'responsible' body is defensible. If the professional opinion is not logical, for example because they're sticking to out-of-date ideas, this can also be considered as negligent action.

The two women in the trial – Mrs Robb and Mrs Unitt - had been treated in 1979 and 1980. So the judge was trying to assess whether their treatment was appropriate given the state of medical knowledge at that time. The key questions that the court needed to address were: (a) should doctors have known about the risks of radiation-induced injury at that time and tried to avoid them? (b) had the women been given the proper radiotherapy treatment – in terms of the dose and technique? (c) should the women have been given radiotherapy at all?

The court's discussions around these questions will be considered in turn.

(a) Should doctors have known about and avoided the risks of radiation-induced injury?

There had been several scientific reports of injuries to the brachial plexus caused by radiation years before either of the two women had received treatment. The litigants therefore argued that the doctors should have known about the risks and tried to avoid them – especially as one of the doctors had come from a large teaching hospital supposedly at the forefront of medical research. Adrian Whitfield QC, acting for the litigants, also pointed out that it might be reasonable to expect any consultant who became aware of "a bad result from comparable treatment to that provided by his hospital" to ask himself 'Could this apply to me?'. The litigants argued that the doctors seemed to have ignored what the literature was saying.

In their defence, the opposition argued that the literature wasn't important and for lots of different reasons. They said that no doctor could be expected to read everything that is published in an international field. They also argued that because the papers only suggested there were risks in extreme conditions – the aver.a.g.e. doctor who had treated hundreds of patients successfully, and never seen any serious injuries,

would have no reason to be concerned or to change what they were doing. As Stanley Dische said, 'You do not change an established regime on the basis of one paper reporting a problem encountered at one centre'. They also stressed that the medical literature tends to be unbalanced – people shout more about sudden disasters than about long-term successes.

The defendants also explained how in the 1980s doctors hadn't been familiar with the concept of evidence-based medicine. It was then considered the norm for doctors to base their practice on what they had been taught wherever they had been trained, or had subsequently learned through many years of experience. In some radiotherapy departments, a 'strong' head would dictate the policy and insist that everybody followed it. Doctors saw no reason to change what they were doing unless they were alerted to problems by their patients. Since injuries to the brachial plexus nerve are so rare, the defence argued that doctors couldn't have been expected to know about it.

The judge was persuaded by the defence's arguments – accepting that at that time more weight was given to doctors' informed opinions than the results in the medical literature.

Stanley Dische, while agreeing with the judge's conclusion says 'I was concerned through the trial that the clinicians should have been more familiar with radiobiological science and more prepared to relate it to their practice'.

(b) Had the women been given the proper radiotherapy treatment – in terms of dose and technique?

There was much debate during the trial about what should have been considered a proper radiation dose in the 1980s. The litigants had originally claimed that a treatment regime of a total of 50 Grays (the unit for measuring radiation) in 25 lots of 2 Gray fractions should have been recognised as the international standard. They later changed their minds about this and said it should have been a total of 60 Grays in 30 lots of 2 Gray fractions. The defence didn't argue against this being an appropriate dose – but simply argued that there hadn't been any recognised standard. There hadn't been a clinical trial to determine the most effective regime for radiotherapy treatment. And in the absence of such evidence, neither side was in a position to say whether the dose the women had received had been inappropriate.

At the time the women were being treated (see page 27) radiotherapy in the UK was undergoing massive changes. New and more powerful machines were being introduced at the same time as there were huge problems with staffing levels. To make sure that they could treat everyone who needed it, doctors changed the way they delivered the radiotherapy. The litigants argued that doctors should not have changed the treatment regime without first trialling its effects.

In turn the defence argued that the doctors had simply done their best, under what were very difficult circumstances. They had treated as many women as possible in the only way they knew how. In the 80s, the effects of radiation on cancer cells versus normal cells were far from being understood. The doctors used academic physicists to calculate the right dose and regime – and as long as they were within the confines of that formula, the doctors believed the dose they were giving was safe. So every department - and even doctors within the same department - were giving different treatments, none of which had been effectively compared with each other. But what they all believed was that they were essentially doing the same thing.

The defence experts were still critical of the treatment that the women had received. Charles Joslin spoke frankly, saying that he would have, even in 1980, questioned the dose in use at the hospital where one of the women had been treated. But he didn't go as far as saying he thought that treatment was irresponsible, only that he would have questioned how they managed to achieve so little radiation damage.

The other key factor was that in the 1980s, doctors weren't aware of the sensitivity of the brachial plexus. In fact it was generally thought of as one of the structures most resistant to radiation. So none of the doctors took into consideration what was happening to the brachial plexus when they calculated their doses – which certainly isn't the case now.

So what the defendants were able to conclude was that even though the treatment the women had received differed considerably from their own practice, and would never be considered acceptable now, it was still within the limits of what any reasonable consultant would have prescribed at the time. They were able to say that the doctors hadn't been guilty of negligence - because they couldn't have known that their treatment carried unacceptable risks.

Others have since concluded that what the doctors were guilty of was allowing a state of ignorance to be maintained – but this was never a matter for the courts to decide.

(c) Should the women have been given radiotherapy at all?

Doctors were still taking a 'belt and braces' approach to treating breast cancer when the two women in the trial were treated. They typically prescribed radiotherapy on top of surgical removal of the tumour and the lymph nodes - as they thought this was necessary to eliminate all the cancer cells. They also tended to err on the side of caution – favouring larger doses to reduce the chances of the cancer coming back. Nowadays, radiotherapy is given much less often. It tends to be avoided in cases of early breast cancer, since surgical removal of the tumour is often 100% successful. But back in the 80s, doctors recommended - and women often preferred - to do 'everything that we can to fight the cancer'.

Which arguments persuaded the judge?

In her summing up, the judge stated that she had 'found this case to be of exceptional difficulty'. She commended the two women in the trial for 'what can only be regarded as remarkable and courageous efforts to come to terms with their painful and disabling condition'.

She also made clear how she had 'found the defendant's witnesses more convincing and relevant than those called by the plaintiff'. This had very much influenced her opinion. In particular, she found 'Professor Dische confronted the problems caused by the passage of time more acceptably than Dr Halnan [an expert for the litigants] and was better able to distinguish his own views from what would have been a respectable alternative view 17/18 years ago'. She "could detect no professional defensiveness in his approach'.

She 'reached the firm conclusion that there was more than one view of proper radiotherapy treatment up to 1980 and beyond' and was 'impressed by the fact that in 1995 the Royal College of Radiologists, felt itself unable to advise on an optimum treatment regime'. Professor Joslin had persuaded her to keep in mind that she was "not conducting a comparative review of optimum techniques of treatment, but considering the reality of routine standard treatment in the context of heavy caseload'.

She was also unsympathetic to the litigants' case because so much of it seemed to be based on American research and international practice. As she said, "It does not follow... that a particular technique is negligent simply because it can be shown that things were done differently elsewhere...".

Dr Orton [called by RJW] was used as a vehicle to introduce the literature in the case and to place non-controversial material before the court. He is substantially criticised by the defendants... on the basis that his experience is essentially American and therefore arises from a social and cultural background to treatment, which is not appropriate to the issues in these *English* cases...

In cases where... heavy emphasis is placed upon the weight to be placed upon contemporary medical literature, I was frankly troubled by the extent to which reliance was placed upon a radiation physicist from the United States to set out the literature and its claimed significance for United Kingdom clinicians".

Overall she felt the women's case should not have been tested in the way that it had. She concluded by saying 'I regard it as unfortunate that litigation in terms of medical negligence was felt to be the only mechanism available to obtain the answers. Because medicine is constantly developing, there are obvious problems inherent in allegations of negligence directed to the choice of a method of treatment used many years ago'.

What happened after the trial?

Some cases dragged on over the following year. These were cases that were deemed to be outside of the findings of the judgement. Jan Millington believes that 'Fifteen out-of-court settlements were made and £1,800,000 paid out in compensation. One quarter of this went to an individual whose case was never part of the group action'.

Steve Walker, Chief Executive of the NHSLA believes that offers were made to twelve women - not necessarily those who were in the court case. In almost all of the cases he says the settlement was "a fraction" of the amount asked for by the lawyers.

The women who had been part of the group action were subsequently presented with huge legal bills by RJW. The case had proved to be extremely expensive. The total bill was £3.3million including counsel's fees, expenses and VAT, although much of this was covered by legal aid. The case had been expected to be costly because the legal team had invested so much time in researching, pleading and preparing for the trial. But some of the women who were privately funding their case were still alarmed at how much they were being charged. As Jan Millington describes: 'The people who had to pay their own bills were appalled when they got this great big bill of costs, which had to itemise all the expenditure, because they weren't consulted. Other people were faced with bills of around £25,000 each despite their cases never reaching court'.

Three of the privately funded women decided to challenge the bill, with the help of solicitor Richard Stockdale, from the Brooke North firm in Leeds. Christina Rogers was one of these women.

The appeal was successful. The bill for the private fee-paying clients was reduced by over one million pounds, and the Legal Aid Bill reduced by just over £750,000. It was thanks to Christina Rogers that the legal fees were reduced. As Jan Millington commented, 'If it hadn't been for Christina, that money would still have been with RJW'.

In a letter to the journal *Medical Litigation* in May 1999, Richard Stockdale condemned the trial for being such a terrible waste of public money. He believed, as did many others, that the money could have been used far more effectively if it had been given directly in compensation to the women:

'This case will also add to the debate as to whether society is best served solely by a system of fault-based compensation. The £3.3 million claimed by the law firm when added to the estimated £1.5 million costs of the various NHS defendants could have been used much more productively to found a structured settlement for the 132 women who suffered injury. It is ironic that the bulk of the actual expense of the case

has come from the public purse, but has instead been spent on an unproductive legal battle of titanic proportions’.

Jan Millington responded in the same journal agreeing with his conclusions, and adding, ‘The failed litigants would say that added to their financial costs are those of huge stress, frustration, anger and demoralisation generated by protracted litigation over which they had no control. They would agree with Mr Stockdale that the costs vastly outweigh the benefits one hundredfold’.

A solicitor from RJW also responded in the journal, defending their involvement in the case. She concluded ‘We believe that the legal action... has led directly to improving standards in medical treatment. Guidelines are in force now involving radiotherapy treatment for women with breast cancer that were not in place, and had no signs of being in place, before the litigation started’.

Ian Walker’s reflections on the case were: ‘I think that from a lawyer’s point of view – it was very difficult to litigate on a large group of people who were as angry as these ladies were. For many of them we didn’t feel that what we were saying to them about the difficulties was going in. If you have clients who aren’t listening to your advice – it makes it very difficult to continue acting for them. I think the way we managed the case here was actually was very good. Julie had a grip of iron on the facts of each case. We maintained meticulous records. We had a detailed analysis of every case. We actually controlled the thing as well as could be done – but what can you do when the experts walk away from you?’

If we went back in time - we would probably do it still – on the basis of what we thought we knew then. It was an action that had to be fought’.

What was the impact on the women involved in the case?

‘After the court case I think people lost heart’. Christina Rogers said.

Losing the case was clearly devastating to those who had been involved in the litigation, as their hopes had been built up over a period of several years.

Ian Walker thought it must have been terrible for the litigants: ‘The impact on individual ladies must have been devastating... By running any litigation for any person you give them hope, because they say ‘You wouldn’t be running this if you didn’t think it would win’. When the case is lost and there’s no suggestion the NHS will make it up in other ways... they get devastated. It must be adding insult to injury – a ghastly experience for them’.

The R.A.G.E. women feel they had been forgotten through all of this, as one of the women described in an article in *Clinical Oncology* in 1999: ‘All that palaver about us. All that court stuff, the telly, the papers... Parliament... It’s all been about us but at the end of the day nothing relates to us, like we don’t exist’.

Much of what had happened in the lead up to the trial had not been in the public domain. After the trial the women began to feel that involving the legal profession had made things worse for them. They felt that the law firm had encouraged them to pursue a claim that only had a remote chance of success and that they should have been made more aware of the problems.

Some time after the case, another medical negligence lawyer called and asked to meet a few of the failed litigants. He was curious as to how their case had been presented to the Legal Aid Board. He appeared very interested in the R.A.G.E. story, but it turned out that this was only so as to inform his own work. This meeting didn’t lead to any further legal help for the R.A.G.E. women.

The women feel very angry about the whole experience - another group of professionals had let them down. And it seems as if R.A.G.E.’s case for compensation has suffered as a result. As Pam Pond describes, ‘Now every time these legal cases get thrown up as if we’ve had a fortune – but we’ve had nothing’.

How did the government agencies respond?

A few years after the trial, Jan Millington met again with Steve Walker from the NHSLA to discuss pursuing R.A.G.E.’s goal for compensation. After that meeting Steve Walker wrote to Yvette Cooper, Health Minister, on 21 March 2001 and explained how ‘We ended up knowing more about the background and motivation for the action in the hour we spent talking to Jan Millington than we had over the last five years trying to engage with the solicitors’.

Therefore some government agencies did recognise that R.A.G.E. had effectively divorced itself from the case very early on. However, other Government agencies and professional bodies continued to see R.A.G.E. and the court case as one and the same thing. While R.A.G.E. continued to lobby for some kind of compensation, time and again the trial was brought up as a reason why their claim was invalid. The Government continued to refuse payment to the women with severe injuries on the grounds that negligence had not been proved. For example Hazel Blears responded in a letter to R.A.G.E. on 8 March 2003:

‘In your case, an action was taken through the civil justice system and the judge decided in favour of the defendant. In these circumstances it is

not possible for me to offer compensation of patients, such as yourselves'.

This is a source of continued frustration on the part of R.A.G.E. members, as Margaret Carling describes, 'Some individuals chose to pursue a legal action for negligence. Some of those were, or had been members of R.A.G.E. but the majority were not. It is absurd to attempt to classify this as 'an action by R.A.G.E.' on the grounds that some of the litigants may also have been members of R.A.G.E. Would a legal action, in which some litigants were members of the Labour Party, be classified as an 'action by the Labour Party?'

How did the radiotherapy profession respond?

Jane Maher felt that when the legal case got started it was 'a wake-up call' to the radiotherapy profession. She believes that 'People who'd had the odd case thought that this was just one of those unfortunate things. And then when they saw it being taken to court, there's a sudden thing, 'It might be me'. At that time there were only about 200 radiotherapists in the country. It's a small world. People would have started to reflect on it and talk about it before it got to court'.

John Yarnold has commented that the final judgement was still a concern to the profession, even though negligence hadn't been proved, 'Everybody realised something had gone badly wrong no matter what the courts had said. There was sense of collective shame. But it must have been worse for the patients because they were humiliated, they didn't get any money and were still left with the injuries. That was a very, very deep hole to have been left in'.

Professor Stanley Dische thought there were some very important lessons for the profession that came out of the trial. He concluded that: 'Radiotherapists were wrong to have been much more influenced by training than by the new knowledge that was coming through. But clinicians were sceptical about the basic science. They tended to think - I know what I can see and that's what matters. Although nothing is more important than listening and observing and seeing patients - with quantitative issues you've just got to have research data'.

Professor Dische wrote a report of the trial that was published in the journal *Clinical Oncology*. He thought this was important to do because he was concerned that 'People tried to not know about it – to avoid anything uncomfortable or bad news'.

He was amazed about how ignorant the profession was about the case. He says 'They didn't want to know'. Professor Karol Sikora came to a similar conclusion, 'It's an episode of British radiotherapy that no one really wants to remember'.

Aim 4: To provide mutual support

Overcoming isolation

One of the experiences that many R.A.G.E. members shared was a sense of isolation. Many were told that they were the only person who had this type of injury. Margaret Carling, who went to one of the first R.A.G.E. meetings, describes how vulnerable she felt before joining the group, 'The pain was absolutely excruciating. And of course the worry of it too. You were thinking, my God, I've got the cancer again. It's hard to put into words. You feel so vulnerable'.

Christina Rogers, another early R.A.G.E. member, describes the sense of isolation felt by many of the women: "About two years after I had my radiotherapy I had pain again and my arm swelled... I went back to X hospital and was referred to the lymphoedema clinic. That's how it all began... I never met a soul. Nobody said that anyone else was suffering from such a thing'.

After years of wondering and worrying, R.A.G.E. helped the women to find out what had caused their injuries. They were also able to find much welcomed support and understanding from others who shared their experience. Christina Rogers describes what this felt like:

'I was so relieved that I wasn't isolated. The first meeting I went to was a big meeting, because after the newspaper article we all came out of the woodwork... I felt, at last I'm not the only one. Because you wonder what's going to happen to you. It was a total wall of silence at X hospital. Then I went to this rally with all these people. It was a relief – thank God for that, I'm not on my own, at least I'll be able to get some help'.

Margaret Carling shared these feelings when she attended her first R.A.G.E. meeting: 'It was a blessed relief that something was happening, that we're going to get to the bottom of this, and also that they're not going to get away with this. You think, thank God somebody understands, somebody has the same thing. It was nice just to talk to other people, swap experiences... It was the comfort of having the mutual support'.

This mutual support was a lifeline for many R.A.G.E. members.

Providing support by telephone

For some women meeting others whose injuries were further advanced came as quite a shock. Margaret Carling recalls that at her first meeting 'One of the depressing things was seeing how progressive it was. That was one of the downsides'.

For this reason and because they sometimes found it difficult to travel, some women chose not to attend meetings and gained their support by phone instead. Jan Millington describes how people would call 'All day every day. Some days the phone just didn't stop ringing'.

Even today, providing telephone support continues to be seen as crucial by members of the R.A.G.E. committee. Pam Pond explains: 'The telephone advice is really important because many women can't talk to their GP or practice nurse – but they can talk to R.A.G.E. members knowing that they are going to get the most up to date advice – hints and tips. We always put a note that it [the advice] is based on personal experience. Telephone help has done a lot of good'.

These days people who believe they may have been damaged by radiotherapy can get help and advice from R.A.G.E. members, whilst people who are about to undergo radiotherapy can call to talk about their fears.

Whenever there has been a discussion about dissolving R.A.G.E., it is the role of providing mutual support, particularly by phone that has motivated members to carry on. As Lorna Patch describes: 'It cheers people up. And if you've only done that – at least you've done something'.

Keeping in touch

Some long-standing members still speak to each other regularly, and have developed very strong friendships. As Jan Millington describes:

'There are people you'll always be friends with. It's almost spiritual, the kind of bonding you have with them'.

This strong connection has developed because of all that they have been through. As Pam Pond describes: 'If you just met Jan or Margaret at a party and they became your friend at that level, you'd never have the same automatic built-in feeling of sympathy and understanding for them, and admiration for each other'.

Over the years R.A.G.E. has produced (and continues to produce) a regular newsletter for its members. This contains practical suggestions about coping with everyday tasks with the use of only one arm, and details of complementary therapies that members have found helpful. It provides another forum for R.A.G.E. members to exchange experiences and offer encouragement to one another.

Providing practical support

The support provided by R.A.G.E. has therefore been practical as well as emotional. In addition to the advice on daily living, some R.A.G.E. members have acted as advocates for their peers, by going to tribunals and hearings with members whose entitlement to Disability Living Allowance has been challenged. This has helped some women access the benefits they are entitled to.

Throughout its history, R.A.G.E.'s work has therefore involved much more than its activity around campaigning. The vital role that R.A.G.E. played in providing support to its members was recognised by the Maher Committee (see page 36). They recommended that 'The supportive as well as the campaigning role of R.A.G.E. should be acknowledged'.

A lot of people said that without R.A.G.E. they simply would have been lost.

Chapter 5: Reflections on R.A.G.E.'s story

As part of the interviews with R.A.G.E. members and professionals, we asked everyone to reflect on the whole of R.A.G.E.'s story to draw out the lessons that might be useful to others.

In this chapter, we report on what people concluded. As far as possible we have tried to do this in people's own words.

What were R.A.G.E.'s greatest achievements?

There was almost unanimous agreement that R.A.G.E.'s greatest achievement was to improve the standards of radiotherapy treatment for breast cancer in the UK.

'R.A.G.E.'s biggest achievement – to raise awareness and to improve radiotherapy standards'.

Margaret Carling, R.A.G.E. Member

'Thanks to the row R.A.G.E. has made, standards are much better... They say it was R.A.G.E. that forced annual audits, that forced hospitals to keep records'.

Lady Ironside, R.A.G.E. President

'The most important thing that happened as result of the R.A.G.E. experience was the START trial. It became clear that there had to be some sort of standardisation of radiotherapy treatment... So they introduced a really rigorous quality assurance system to enter the trial. And nearly everyone entered the trial. It was one of the fastest recruiting trials because everyone wanted to know the answer. So the Quality Assurance programme became the standard for every department'.

Jane Maher, Oncologist

'It was R.A.G.E. alone that really has improved radiotherapy treatment in this country. That alone is wonderful. Anyone walking into hospital has a better chance of having non-damaging radiotherapy'.

Lorna Patch, R.A.G.E. Member

'Through our campaigning we've made sure it doesn't happen again... I don't know that we could have done any more – we got the Maher work done, we frightened the radiotherapists and got them to change things, we've lobbied parliament til we're sick of lobbying... we've done the Early Day Motions – I don't know that we could have done more as we're only a group of women'.

Pam Pond, R.A.G.E. Member

'Their achievements have been a massive improvement in British radiotherapy – people woke up in response to R.A.G.E.... There are no more cases of BPN due to radiotherapy, so they have achieved the long-term goal of changing practice. They may not see that they were responsible. That has been a major problem. The success of R.A.G.E. got no recognition from anyone - professional, political or legal'.

Karol Sikora, Clinical Oncologist

They also set a precedent as being one of the first cancer patient groups to be established and helping to ensure that other patients were better informed of the risks of radiotherapy:

'At the beginning we were the only cancer lobby, there wasn't the networking. And we've achieved more in the way of informed consent'.

Jan Millington, R.A.G.E. member

'There are now lots of patient pressure groups all of which have played their part in improving medical treatment. R.A.G.E.'s unique place is as a forerunner of all of these groups... R.A.G.E. helped serious late-effect radiation injuries to be discussed in public for the first time and brought to the attention of the country, the lack of uniformity in treatment and the variance in the knowledge and understanding of the science of radiotherapy... This was possibly the first time, in the history of the NHS that a patient group had confronted, in the nicest possible way, such an established body of medical opinion'.

David Bainbridge, R.A.G.E. member

What can we learn from R.A.G.E.'s story?

Lesson 1: Legal action is not the way to resolve the issues for people damaged by medical treatment

Many people concluded that going to court had simply been the wrong way to address the women's concerns.

"This is not a good way to sort things out. That's a message to everybody".

Jane Maher, Oncologist

'Some public action was required, but it would have been better to have an independent public enquiry to look into it and devise compensation if necessary. But with litigation it turned into a battle. So it became tactical... which fogged the issue'.

Stanley Dische, Clinical Oncologist

'The court case made relationships worse between the professions and the patients. It was an expensive legal disaster without any real conclusion. It was a real mess – that was a low point for everybody. No one came out well. Court cases force people to be confrontational. That can't possibly work well – it isn't a therapeutic process – it only brings out the worst in both sides'.

John Yarnold, Clinical Oncologist

The way the case was constructed was also thought to be a major problem:

'Poor technique [in radiotherapy] led to a lot of the women's problems – but I didn't think people should have been had up in a court for that. So though I had misgivings, I felt it appropriate to act for the defence. The case was constructed in such a way as to hold up whole profession... the women would have done very much better if they had sued particular hospitals and if they had done so, they might have got experts in this country to act on their behalf'.

Stanley Dische, Clinical Oncologist

Many believe that more should have been done when the women first raised their concerns. This could have avoided all the costly legal action.

'If the hospitals involved had taken responsibility for sorting this out – if that had been done earlier, it would have been very different. The women wouldn't have got so cross... If a clinic with a relevant team had been got together, it would have probably solved the problem and stopped the legal case'.

Karol Sikora, Clinical Oncologist

'The great lesson – when something goes wrong it is best to be completely honest and open – and involve the people who think they've been aggrieved in the process of trying to resolve it– resolve the problem in dialogue not in confrontation'.

Karol Sikora, Clinical Oncologist

'The best thing to do if you make a mistake is to say you're sorry and make sure you don't do it again. If you said 'I'm sorry we didn't realise' – that would solve the problems for most patients. But many doctors find it very difficult to cope with problems and won't see the patient - which makes it far worse'.

Stanley Dische, Clinical Oncologist

The health professionals recognise that most of the problems arose because no one was willing to take responsibility for what had happened:

'Whenever you saw six of the women in a row, all with the same injury, you could see they weren't nuts, there was clearly a problem. But no one felt responsible – the women couldn't speak to anyone... it was really only the clinicians who could have come clean about what really happened... But because it seemed to have been a technical problem with the treatment, no one else, including the Chief Medical Officer or the Royal College of Radiologists, saw it as their responsibility. They saw their role simply to be to lean on the individual hospitals to carry out an independent enquiry'.

Karol Sikora, Clinical Oncologist

Many people also expressed a great deal of frustration that so much money was wasted in legal fees which could have been given to the women in compensation.

'Instead of spending money on the doomed legal case, it could have funded clinics for the women – a centre with a multidisciplinary team with a consultant for assessment. The money would have easily paid for that'.

Karol Sikora, Clinical Oncologist

'That sum [the amount spent on the case] tells you how wrong it was to go through litigation. Most money went to lawyers and experts... But is that the way society should spend its money to solve problems?'

Stanley Dische, Clinical Oncologist

Lesson 2: Time and resources need to be invested in establishing a new group and maintaining its effectiveness

'The journeys we've had should provide lessons for some people. Anybody setting out on this trip could find the same pitfalls'.

Jan Millington, R.A.G.E. member

Their lack of experience when the R.A.G.E. committee first formed caused many tensions, as Jan Millington describes:

'To be honest I think that was a turning point, a cracking point. That [establishing a committee] didn't work to our advantage, because nobody was that experienced. Already people were taking different angles... New people were sounding off when they had no real background'.

There were additional tensions created when new members came on board and expressed concerns that the original members held on to too much power and information. This was a major issue for Jan as she describes: 'They felt I wanted to do too much myself - that I wanted to keep possession of things - which I didn't. My only intention was to try and keep things on an even keel. I had the history, I'd had the meetings and in my head I knew where we were going. But you get career campaigners who want to make a meal of it... I just thought you can't

have too many voices. It's not that you think that your voice is the most important, but in meetings, somebody can get on their hobbyhorse then the next 15 minutes have gone, and you've only got an hour'.

At a more emotional level, there were also differences between the levels of passion and anger felt by different members of the committee.

Margaret Carling observes: 'People say R.A.G.E. is such an angry sounding name, but we were angry. Now we're quite respectable, but we were angry. We had a right to be angry, we had a moral case'.

These views are quite distinct from those of Joyce Pritchard, another member who joined at the group in 1993, and remembers her first meeting: 'It was terrifying. The anger, you could smell it, you could taste it, you could feel it... The R.A.G.E. members there, some were very, very angry, you could feel the anger in the room. This anger. I wouldn't bring people together unless there was enough people who are not angry to keep it all under control. That's how we cope in committee. Some of us don't have this destructive anger'.

These tensions were never completely resolved and so re-emerged repeatedly to cause some disagreement and ill-feeling amongst R.A.G.E. committee members. With hindsight, they recognise it would have been helpful to invest time and resources in settling these disagreements right at the beginning, and to have worked on clarifying the motivations and aims that committee members could have collaborated on. As Jan Millington reflects: 'I can see now that it's a huge mistake involving anybody who doesn't feel exactly the same. You've got to feel huge passion and indignation, and that's got to be the unifying thing'.

Lesson 3: It's important to keep up pressure on government and not to lose focus

In hindsight some of the R.A.G.E. members felt that they allowed themselves to be sidetracked at some stages of the campaign. For example, after the Bates Audit, campaigning for compensation ceased whilst some members spent time challenging the detailed findings of the audit. Jan Millington reflects: 'I do think that was a retrograde step for us. I think it did dilute us'.

Some R.A.G.E. members also feel that, because they were women, they were not aggressive enough in their campaigning. As Jan Millington observes: 'As women you're scared aren't you? You have this protective feeling towards people, you don't want to add to their distress and worry'.

And as Margaret Carling reflects: 'I would advocate being more aggressive, much more assertive, flood *The Sun* and *The Daily Mail* with complaints'.

Chapter 6: Conclusions and recommendations

Conclusion 1: There is a need for better monitoring of cancer patients

The main conclusion that emerged from the interviews is that patients need better follow-up after any form of cancer treatment or therapy, especially if an aspect of that treatment is changed.

'If you introduce a new intervention, however small, you need to be aware that this can have untoward effects. If you change a small thing you have to reflect very carefully and treat it as a major change in behaviour. So you need to get radiotherapists to reflect on their practice, because radiation therapy is a complex intervention'.

Jane Maher, Oncologist

'All doctors must be trained to monitor to see if problems are arising – they should realise when problems occur and do something about it... Not everything can be answered by a randomised controlled clinical trial – sometimes follow-up and careful observation of patients is better'.

Stanley Dische, Clinical Oncologist

'We put all this effort into things after something's happened – look at the amount of effort the lawyers went through to sort out all the details – compared to the little effort we put into the follow-up of individual treatments – it's skimpy compared to the legal efforts'.

Karol Sikora, Clinical Oncologist

Better monitoring and longer term follow-up of the R.A.G.E. women could have:

- alerted the health professionals more quickly to the late radiation damage
- allowed quicker identification of the treatment regimes causing damage
- helped identify and share 'good' clinical practice
- provided more in-depth information for other patients on the risks of radiotherapy.

Recommendations as to how people might be better followed-up in the future included:

- Ensure that all professionals and patients have their say and are listened to.

'Patients with radiation damage should be followed up at the Centre where they were treated. Patients should be listened to and their damage spotted early. Serious side effects following radiotherapy are rare and the only way to spot unusual morbidity [damage or side-effects caused by a treatment] is through regular multidisciplinary audit. A nurse could be the first to comment on the unusual... Nothing is more important than careful follow-up, audit and quality assurance in oncology.'

[Thelma Bates, Clinical Oncologist](#)

- Pay more attention to people's quality of life after cancer treatment and don't just focus on mortality statistics.

'Everyone wants to cure people and no one wants to talk about the dark side of the coin. Oncologists are caring and want to do their best for their patients. But they still have a blindspot – they don't face the damage caused by their treatment... If I had my way, as well as gathering statistics on waiting times and mortality rates we should also collect statistics on morbidity... if you look at the medical literature – it's amazing how morbidity of treatment is given very little space.'

[Stanley Dische, Clinical Oncologist](#)

'In 2001 we spent a lot of time and effort getting assessments of my wife's condition all over the country – not enough to make a case – but along the way we gathered a lot of evidence that there is a serious disquiet among oncologists. They are muddling along as best they can. The worst thing for an oncologist isn't that the patient is damaged but that the patient dies. But there are currently a lot of people with recent damage from radiotherapy.'

[David Bainbridge, R.A.G.E. Member](#)

Conclusion 2: There is a need for better systems to support people who are damaged by medical treatment

R.A.G.E. members were one of the first groups of people who had been damaged by medical treatment to join together in a campaign. Jan Millington comments,

'We've been pioneers. It was uncharted territory. It was a minefield – every step, something's blown up in our faces. If we can chart a course, so that people who follow us can avoid the minefields, it will make it a lot easier.'

Many people thought there could be better systems put in place to provide compensation for people damaged by medical treatment, without them having to prove negligence and at the same time providing them with better psychological support.

'The minute you involve the legal profession you're in it up to your neck. I don't think it's appropriate. Courts of law feel like a criminal thing. You think, what on earth has my experience got to do with that?'

[Jan Millington, R.A.G.E. Member](#)

'The public purse compensates innocent victims of crimes of violence when there is no civil claim through the Courts (the Criminal Injuries Compensation Appeals Authority). The compensation is modest compared to what can be achieved through a Court but at least it is something. Why can't there be something like this for patients seriously damaged by medical treatment?'

[Thelma Bates, Clinical Oncologist](#)

'We need to have a mechanism for dealing with situations where things have gone wrong, without resorting to the law.'

[Jane Maher, Oncologist](#)

Conclusion 3: The lessons from R.A.G.E. must not be forgotten

'Now they think they've got clever and it doesn't happen anymore – they think they don't need to listen to us. But as new people come in – are they even told about BPN?'

[Pam Pond, R.A.G.E. Member](#)

Afterword

When R.A.G.E. was founded most members appeared to be surviving cancer and were generally aware of the open-ended prognosis. One never forgets the possibility of a return of the disease even though years may have elapsed. Many of us initially thought that the symptoms of radiation damage were signs of returning cancer. It was a shock to learn that a treatment aimed at the control of the disease could lead to a lifetime of pain and disability and that the body had no natural ability to cope with excess radiation.

Once our campaign was under way it was equally shocking to discover we were virtually 'out in the cold' encountering a good deal of indifference and even denial of the fact and ramifications of our injuries. Our idea that cash payments would be appropriate – not so much as 'compensation' but as a good will gesture to help us to care for ourselves – seemed to exacerbate those indifferent attitudes.

Yesterday's Women is a skilfully compiled account of our complex struggles. The authors, by some means, have managed to extricate the most relevant threads of our campaign from a massive pile of documentation covering fifteen years of disjointed and spasmodic activity with government, press, The Royal College, charities, lawyers and many other agencies. Ill-health has frequently affected continuity in our campaign. We are grateful to have our story published in this way.

Nobody has ever actually questioned the validity of R.A.G.E.'s aims and objectives. It is a matter of much dismay and concern that our best efforts, self-funded and with very limited physical resources have attracted the media and appeared to interest Parliament, but have failed to change attitudes and policies in any material way. We *are* assured that radiotherapy standards have improved and there is more opportunity for informed consent for patients – but hopefully medicine would evolve in this way naturally.

We do not see how we could have been more co-operative with the Department of Health, yet in terms of our own wellbeing we are no further forward. It is still the support - emotional, moral and practical – that we give each other that we rely on, though as individuals we have so little to spare. When one of our members dies we feel a profound loss as one would for a family member. Our advancing years and cash strapped NHS Trusts mean that we have to fight for a place in the queue for care – or fund it privately, which few can do now.

In spite of what our efforts have achieved for future breast cancer patients, virtually nothing has been done to alleviate the suffering of those already injured. Millions of pounds can be spent on legal costs, but we are almost forgotten. We are expected to be grateful for any medical attention, yet, as proposed in the NHS Redress Bill, remedial treatment should be a right,

and an integral part of any redress package. Radiation damage is a potentially fatal condition, yet there seems to be no effective mechanism (or research) to cope with it. If one is to have confidence in any medical treatment, then those suffering injuries from it cannot be simply abandoned.

Although we may be perceived as 'yesterday's women', R.A.G.E. is still very much alive. Thanks to R.A.G.E., radiation injuries on this scale are unlikely in the future – so 'today's women' and 'tomorrow's women' should never have to go through our experience.

Margaret Carling and Jan Millington
R.A.G.E. Committee Members

April 2006

List of Abbreviations

AVMA	Action against Medical Accidents
BBC	British Broadcasting Corporation
BMJ	British Medical Journal
BPN	Brachial Plexus Neuropathy
CJD	Creutzfeldt-Jakob Disease
DH	Department of Health
EDM	Early Day Motion
GP	General Practitioner
HBO	Hyperbaric Oxygen
HIV	Human Immunodeficiency Virus
MP	Member of Parliament
MRI	Magnetic Resonance Imaging
PET	Positron Emission Tomography (a type of scan)
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NHSLA	National Health Service Litigation Authority
QC	Queen's Counsel
R.A.G.E.	Radiotherapy Action Group Exposure
RCR	Royal College of Radiologists
RJW	Russell Jones and Walker Solicitors
START	Standardisation of Adjuvant Radiotherapy Trial
UK	United Kingdom

Appendix 1: Useful reading

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Appendix 2: The people who were interviewed and agreed to be named in this report

David Bainbridge

David Bainbridge is a retired commodity broker and farmer who joined R.A.G.E. in 2001 to campaign for improved standards of radiotherapy treatment and the provision of successful repair strategies for radiation damage. His mother, treated with radiotherapy for early breast cancer in 1961, died in 1988 from the late developing radiation injuries, including ischemic heart disease. His wife Brenda, treated in 1998, was significantly damaged by sub-optimal treatment. Dismayed by the lack of safe standard treatment for early breast cancer, staff shortages and the gross under-funding of many NHS Radiotherapy Departments, David sees the development of the continuing R.A.G.E. campaign as essential for future generations of radiotherapy patients.

Anthony Barton

Anthony Barton is a solicitor and medical practitioner specialising in clinical negligence and pharmaceutical product liability.

Thelma Bates

Thelma Bates is a Consultant Clinical Oncologist. She is co-author with Dr RGB Evans of the report commissioned by The Royal College of Radiologists 'Brachial plexus neuropathy following radiotherapy for breast carcinoma'. At the time of the review she was Director of the Clinical Oncology Department at St Thomas Hospital and was an officer of the General Medical Council. She had just finished her term as Senior Vice President of The Royal College of Radiologists. Today she has retired from the NHS but continues as a medico-legal expert and as a Founding Trustee of the Princess Alice Hospice in Esher.

Margaret Carling

Margaret Carling has been an active member of R.A.G.E. since 1992.

Stanley Dische

Stanley Dische was a Consultant Clinical Oncologist in the Cancer Treatment Centre at Mount Vernon Hospital from 1965 to 1992. He was Clinical Director and Head of Clinical Research from 1984 to 1992. He is a Life Fellow of the Cancer Research Campaign and Visiting Professor at University College, London. Since 1992 he has had a continued interest in cancer research, morbidity of cancer treatment and medico-legal aspects of oncology.

Lady Ironside

'I was fit and active when I contracted breast cancer aged 51. Before the radiotherapy no mention was ever made that I would suffer injuries from

a paralysed arm, lymphoedema, severe constant pain and bone necrosis. Up to the present date I have had a broken collarbone, four broken ribs, and five breaks in my arm. I have been in this state for a third of my life now, and am still deteriorating; all due to the radiotherapy treatment, which I was later told I did not need anyway. The hospital has never given an apology to me'.

Lord Ironside

Lord Ironside was an active member of the House of Lords and had a career in industry. He has been a prominent supporter of R.A.G.E. since its inception.

Jane Maher

Jane Maher is a Consultant Oncologist at the Mount Vernon Cancer Centre, a senior clinical lecturer at University College, and a Visiting Professor, at the Centre for Complexity Management at Hertfordshire University. She has been Medical Advisor at Macmillan Cancer Support since 1999. In 1995 she chaired the Maher Committee investigating the management of adverse effects associated with radiotherapy and she also led the 1998 audit of late consequences of pelvic radiotherapy (for cancer of the cervix).

Jan Millington

Jan Millington is a 66 year old retired primary school teacher, as well as a mother and grandmother. Her symptoms of radiation injury began in 1985, two years after treatment, just as she and her husband had purchased a preparatory school as a retirement project. As her symptoms progressed in terms of pain and disability, the project was abandoned in 1990, as was an associated property in France. Jan joined Lady Ironside to form R.A.G.E. in 1991. For her, the most devastating effect of her injury was the inability to cope with her very sick husband, now in a nursing home with advanced dementia.

Pam Pond

Pam's career in the newspaper industry involving extensive travel to Europe and the USA ended with the injuries caused by her radiotherapy treatment given in 1982. Pam has BPN, fibrosis of the lung and very severe lymphoedema. She has undergone trials for lymphoedema and done a lot of research into treatment for the condition in the UK and Australia. She feels very upset that she has given a great deal of time and energy in trying to help R.A.G.E. members to give them some kind of relief from the quality of life they have all been reduced to, without any kind of consideration of their plight from the people who should have been helping.

Christina Rogers

Christina Rogers is a 67 year old retired nurse and proprietor of children's homes, as well as a mother and grandmother. Her symptoms of radiation

injury began in 1985, three years after treatment, which was to change the quality of her life forever.

Karol Sikora

Karol Sikora believes the R.A.G.E. saga is a sad piece of history in British radiotherapy. It reflects the Cinderella nature of the specialty and the failure of institutions to listen to their customers. He is now Medical Director of Cancer Partners UK, an independent consortium creating a novel cancer network with the aim of increasing the capacity of the NHS to treat cancer more effectively. He is Dean of the University of Buckingham Medical School. He was Professor of Cancer Medicine and Honorary Consultant Oncologist at Imperial College School of Medicine, Hammersmith Hospital, London.

Gillian Solly

Gillian Solly qualified as a solicitor in 1981 and has been specialising in Claimant personal injury and clinical negligence cases since 1983. She is an original AVMA Referral Panel Member and former treasurer of the Association of Personal Injury Lawyers.

Ian Walker

Ian Walker is a partner in Russell, Jones and Walker solicitors and was part of the legal team that dealt with the R.A.G.E. litigation in the High Court.

Steve Walker

Steve Walker is Chief Executive of the NHS Litigation Authority.

John Yarnold

John Yarnold is Professor of Clinical Oncology at the Royal Marsden Hospital and the Institute of Cancer Research, where his main clinical interests are the management of women with breast cancer. His research interests focus on late normal tissue responses to radiotherapy. In relation to the R.A.G.E. story, he is chief investigator of clinical trials testing: i) the benefits of fewer, larger fractions of radiotherapy (Royal Marsden Hospital/Gloucestershire Oncology Centre Breast Radiotherapy Fractionation Trial and the NCRI Standardisation of Radiotherapy Trial) and: ii) the effects of hyperbaric oxygen in women with radiation-induced brachial plexopathy.

Appendix 3: Steering Group Members

Jane Bradburn, User Involvement Adviser, Macmillan Cancer Support

Margaret Carling, R.A.G.E. member

Jim Elliot, Head of Research, Macmillan Cancer Support

Jane Maher, Chief Medical Officer, Macmillan Cancer Support (Chair)

Jan Millington, R.A.G.E. member and Co-founder

Lorraine Sloan, Medical Strategy Development Manager, Macmillan Cancer Support

Appendix 4: Letter of invitation to R.A.G.E. members

Dear [Name],

Telling R.A.G.E.'s story

Jan Millington from R.A.G.E. has kindly passed your name to me and sent you this letter. She has told me that you might be willing to talk with me about your experience as a R.A.G.E. member.

I'm working with my colleague on a project which has been funded by Macmillan Cancer Relief [now Macmillan Cancer Support]. Our aim is to pull together the story of R.A.G.E.'s experience, by talking to a number of people who were involved, either as members of R.A.G.E. or as other key stakeholders – for example, doctors and solicitors. At the end of the project we'll produce a written report of all the different strands of the story, based on what people tell us.

A steering group, which includes two R.A.G.E. members (Jan Millington and Margaret Carling) is overseeing the project and will decide who should receive the report, and what should happen as a result. We're hoping that at the very least this project will provide R.A.G.E. with a clear summary of where they've got to, and what might be possible in the future. Everyone who takes part in the project will receive a copy of the report.

The project is at a very early stage – we're currently reading relevant documents. But a really important part of the project will be to listen to the experience of some R.A.G.E. members, and to ask them what they'd like this project to achieve. Jan Millington thought you would be a good person to talk to and I'm writing to ask you whether you would be prepared to meet with me to share your story. This would involve talking with me for maybe two hours, at a time and date to suit you. I can come to your home, or I can meet you at Macmillan's offices in London, or elsewhere if that's easier for you. With your permission, I would like to tape record our conversation, but would check this with you before we began talking. I would not share anything you tell me with anyone else except my colleague without your permission.

I hope very much that you'll agree to talk with me, but appreciate that you may want to hear a bit more about the project, or about me, before you agree. You might also want to talk more about what you'd like from the project before agreeing to take part. So I'd be very happy to come and see you, or to talk with you over the phone, before you tell me your story.

Perhaps you could let me know what you'd prefer. Please could you fill in the attached slip and return it to me in the stamped addressed envelope enclosed? Then I'll get in touch with you. You're of course free to decline to talk with me at all if you wish.

Do feel free to ring me or email me if you'd like to talk about this before you decide. My phone number and email address are at the bottom of this letter.

Thank you, in anticipation for your time.

All best wishes,

Appendix 5: Information sheet for R.A.G.E. members

What is the aim of this project?

The aim of this project is to pull together the story of R.A.G.E.'s experience from when it was first formed through to the present day. We are planning to talk to a number of people who were involved either as members of R.A.G.E. or as other key stakeholders, including doctors and solicitors. At the end of the project, we will write a report that pulls together all the different strands to produce a single, coherent story that makes sense to all the people who were involved. We are expecting to find out where people agree about what happened, where people have different opinions about the story and why those differences exist.

The report will describe the key events that took place, include some of the most memorable images and explore what lay behind critical moments along the way. It will also draw out general lessons for different stakeholders – Macmillan, other patient advocacy groups, the medical profession and the Department of Health. We hope that others may then benefit from the lessons that R.A.G.E. has learned.

A steering group, which includes two R.A.G.E. members, is overseeing this work. This group will decide what happens to the final report and what other action might be taken at the end of the project. Jane Maher, the Chief Medical Officer at Macmillan, is Chair of the steering group.

Who is funding the project?

The project is being funded by Macmillan Cancer Support [formerly Macmillan Cancer Relief].

When and how is it being done?

The project is taking place between January and July 2005 and will involve:

- finding and reading the major documents and producing a timeline of the key events
- interviewing R.A.G.E. members
- interviewing other key players including doctors and lawyers
- producing a report of the R.A.G.E. story that will include all the different perspectives. We may also produce short summaries of the main report, targeted at different audiences.

Why have I been chosen for interview?

You are one of eight R.A.G.E. members who have been invited to take

part. You have been chosen because Jan Millington has suggested you as someone who it would be helpful to talk to.

Do I have to take part?

It's up to you to decide whether or not to take part. If you do decide to take part one of the researchers will arrange to interview you. You are free to change your mind at any time without giving a reason.

What will be involved if I agree to take part?

Kristina/Bec will arrange to meet with you at a time and place that suits you. She will chat with you for 1-2 hours, asking you about your views on what happened during the R.A.G.E. campaign. She may make a few written notes during the interview. If you're happy for her to do so, she will also tape record the conversation. Only the researchers, Bec and Kristina will listen to the tapes. They will use the tapes to make more detailed notes of what's been said.

At the end of the interview, you will be asked to sign a consent form to say that you agree to the notes from your interview being used in the report. You will also be able to comment on the report before it is published.

Kristina/Bec will also ask you if you have any papers, photos, newspaper cuttings or any other written material that you think would be useful for the report. If you're happy for her to do so, she will take photocopies of your papers. She'll return all the original documents to you by registered post, within a week of your interview. She can also send you a copy of the tape recording of your discussion.

What kind of questions will I be asked?

Kristina/Bec will ask you about:

- what led up to the formation of R.A.G.E. and why you got involved
- your views on what R.A.G.E. has achieved over the years around its four main aims:
 - to raise awareness of the injuries and campaign for sympathetic medical care within the NHS
 - to campaign for national standards in radiotherapy
 - to seek compensation commensurate with the injury
 - to provide mutual support

Kristina/Bec will ask you to describe in your own words what you thought were the most important events and decisions along the way. You won't be expected to remember everything given that so many things happened a long time ago.

Kristina/Bec will also ask you for your views on the future of R.A.G.E. and what you would like to see happen to the final report – in particular what outcomes you would like from this project.

Please remember you don't have to answer any questions that you don't want to.

What will happen to the information I give?

The information you give will be used to help write the final project report. Macmillan and R.A.G.E. may use the project report as a basis for further action. So there may be other work that follows on from this project. For example, one suggestion has been to produce a play about R.A.G.E.'s experience.

Will my information be kept confidential?

Only Bec and Kristina will have access to the tape recording and written notes from your interview. The notes will be stored on personal computers at their homes, so no one else will be able to access those files. At the end of the project, when the final report has been written and published, and with your permission, the tapes of all the interviews will be kept by Macmillan. Macmillan will release a tape only to those people they feel have a legitimate reason to listen to it. You can say if you'd like Macmillan not to allow anyone to listen to the tape of your interview. You can also say if you'd prefer the tape of your interview to be returned to you. Computer files will be erased, unless you specifically ask that these are kept by Macmillan for possible follow-up work.

If you wish, you do not need to be identified in the final project report. No one other than Bec and Kristina need know that you have been interviewed. The information that you give can be included in the report without referring to you.

However, you might want to be recognised for your role in the project. If you are happy for us to do so, we can attribute quotes to you. We would also very much like to acknowledge your contribution to the report.

At the end of your interview, Kristina/Bec will check with you which bits of information you want to be kept confidential (ie not included in the report) or anonymous (ie included in the report but not linked to you). They will also discuss whether you want to have your name included in the report.

What happens if I get upset?

We do not expect the interviews to cause anyone any distress. However, we realise that talking about what happened during the R.A.G.E. campaign may be upsetting for some women, given all that they've been through. If you do get upset during the interview, we will of course stop the interview and give you time to recover and we'll not start again until you're ready.

If you find that taking part in the interviews has brought up issues that you would like further help with, you can speak with a counsellor, who can offer you short-term help. Call the Lynda Jackson Macmillan Centre on xxxxxxxx, explain you are part of the Macmillan R.A.G.E. project, and the person you speak to will put you in contact with a counsellor. This service is available from 9am to 5pm Monday to Friday.

What happens at the end of the project?

You will automatically be sent a copy of the final report and any other short summaries.

When you sign your consent form at the end of your interview, you will be asked if you would be willing to be contacted about getting involved in any other work that follows on from this project. If you agree to be contacted, someone from Macmillan may get in touch with you again some time after the project has finished.

Even if you do not want to get involved in any further work, Macmillan and/or R.A.G.E. will keep you informed of any further developments.

Thank you for taking the time to read this.

Bec Hanley
Kristina Staley

April 2005

Appendix 6: Letter of invitation to professionals

Dear [NAME],

Documenting the R.A.G.E. (Radiotherapy Action Group Exposure) experience from 1991 to present

I am writing to ask if you would please consider being interviewed to help with a project to document R.A.G.E.'s experience from its formation through to the present day. Jane Maher has suggested we talk to you as one of the key players involved in R.A.G.E.'s history.

I am working on this project, which has been funded by Macmillan Cancer Relief [now Macmillan Cancer Support] with my colleague xxxxx. Our aim is to write a coherent and well-informed account of R.A.G.E.'s experience that makes sense to all of the stakeholders involved. At the end of the project we'll produce a written report pulling together all the different perspectives. We also hope to draw out the lessons for other patient groups, the medical profession and the Department of Health.

A steering group, which includes two R.A.G.E. members and is chaired by Jane Maher, is overseeing the project and will decide what happens to the final report and what other action might be taken at the end of the project.

Further information about what will be involved in taking part is enclosed. If you would be willing to be interviewed, one of us will arrange to interview you at a time and place that is convenient for you. We will seek your written consent to use the notes from your interview in the report, and we will also provide an opportunity for you to comment on the report before it is published.

Please could you let me know by X if you would be willing to be interviewed for this project. My contact details are below. If this is a possibility, we can then arrange a time and place to meet. Of course, if you have any questions or comments, or would like to discuss the project further before making a decision, please do not hesitate to get in touch.

We very much hope that you will be able to take part. Your contribution will be invaluable in telling R.A.G.E.'s story and your participation will be very much appreciated by all involved.

Thank you, in anticipation for your time.

Kind regards,

Appendix 7: Information sheet for professionals

What is the aim of this project?

The aim of this project is to document R.A.G.E.'s experience from when it was first formed through to the present day. The goal is to write a coherent and well-informed account that makes sense to all of the stakeholders involved. We are expecting to find out where people agree about what happened, where people have different opinions about the story and why those differences exist.

The report will describe the key events that took place, include some of the most memorable images and explore what lay behind critical moments along the way. It will also draw out general lessons for different stakeholders – the Department of Health, the medical profession and other patient advocacy groups. We hope that others may then benefit from the lessons that R.A.G.E. has learned.

A steering group, which includes two R.A.G.E. members, is overseeing this work. This group will decide what happens to the final report and what other action might be taken at the end of the project. Jane Maher, the Chief Medical Officer at Macmillan, is Chair of the steering group.

Who is funding the project?

The project is being funded by Macmillan Cancer Relief [now Macmillan Cancer Support].

When and how is it being done?

The project will take a year from January 2005 and will involve:

- locating and reading through the major documents and producing a timeline of the key events and their sequence
- interviewing R.A.G.E. members
- interviewing other key players including radiotherapists, lawyers and consultants
- producing a report of the R.A.G.E. story that will include all the different perspectives. We may also produce short summaries of the main report, targeted at different audiences.

Do I have to take part?

It's up to you to decide whether or not to take part. If you do decide to take part one of the researchers will arrange to interview you. You are free to change your mind at any time without giving a reason.

What will be involved if I agree to take part?

One of the researchers will arrange to meet with you at a time and place that suits you. They will interview you for 1-2 hours, asking you about your views on what happened during the R.A.G.E. campaign. They may make written notes and will also ask for your permission to record the interview. Only the researchers will listen to the tapes to make more detailed notes. At the end of the project, and with your consent, the tape recording of your interview will be passed to Macmillan Cancer Relief [now Macmillan Cancer Support]. They will only allow those with a legitimate reason to listen to the tape. You can stipulate if you wish to limit access to the tape. Or you can stipulate that the tape should be returned to you.

At the end of the interview, you will be asked to sign a consent form to say that you agree to the notes from your interview being used in the report. You will also be able to comment on the report before it is published.

We would also be grateful if you could lend the researchers any papers, photos, newspaper cuttings or other written material that you think would be useful for the report. If you're happy for us to do so, we will take photocopies of these papers and will return all the original documents to you by registered post, within a week of your interview. You can also be sent a copy of the tape recording of your interview.

What kind of questions will I be asked?

You will be asked about how your involvement with R.A.G.E.'s work and your views on what R.A.G.E. has achieved over the years in relation to its four main aims:

- to raise awareness of the injuries and campaign for sympathetic medical care within the NHS
- to campaign for national standards in radiotherapy
- to seek compensation commensurate with the injury
- to provide mutual support.

In particular we would be interested to hear your views on what you thought were the most important events and decisions along the way. We would also like to ask you what you would like to see happen to the final report – in particular what outcomes you would like from this project.

Please remember you don't have to answer any questions that you don't want to.

What will happen to the information I give?

The information you give will be used to help write the final project report. Macmillan and R.A.G.E. may use the project report as a basis for further action.

Will my information be kept confidential?

Only the researchers will have access to the tape recording and written notes from your interview. The notes will be stored on a personal computer at their individual homes, so no one else will be able to access those files. At the end of the project, when the final report has been written and published, and with your permission, the tapes of your interview will be passed to Macmillan Cancer Relief [now Macmillan Cancer Support] for safekeeping. You can stipulate if you wish to restrict access to these tapes. Alternatively you can ask for the tape to be returned to you. Computer files will be erased, unless you specifically ask that these are kept by Macmillan for possible follow-up work.

If you wish, you do not need to be identified in the final project report.

However, if you are happy for us to do so, we can attribute quotes to you. We would also very much like to acknowledge your contribution to this work.

At the end of your interview, the researchers will check with you which bits of information you want to be kept confidential (ie not included in the report) or anonymous (i.e. included in the report but not linked to you). They will also discuss whether you want to have your name included in the report.

What happens at the end of the project?

You will automatically be sent a copy of the final report and any other short summaries. Macmillan will also keep you informed of any further developments.

Thank you for taking the time to read this.

**Bec Hanley
Kristina Staley**

April 2005

Appendix 8: CONSENT FORM

Telling R.A.G.E.'s story

Please initial the box where you agree with the statement:

- I confirm that I have read and understood the information given to me about the project and that I have had an opportunity to ask questions.
- I give permission for the notes from my interview to be used by Macmillan Cancer Relief [now Macmillan Cancer Support] to produce a report on R.A.G.E.'s experience.
- I agree to being contacted about further work arising from this project.
- I agree to my contact details being passed to Macmillan Cancer Relief [now Macmillan Cancer Support].
- I agree to Macmillan holding a copy of the tape recording of my interview.

If you'd like to add any conditions about who should be allowed to listen to the tape once the project is finished, please write them below:

Name of Interviewee _____

Date _____

Signature _____

Name of Researcher _____

Date _____

Signature

Macmillan Cancer Support

Macmillan Cancer Support improves the lives of people affected by cancer. We provide practical, medical, emotional and financial support and push for better cancer care. One in three of us will get cancer. 1.2 million of us are living with it. We are all affected by cancer. We can all help. We are Macmillan.

Web: www.macmillan.org.uk

TwoCan Associates

TwoCan Associates is a small company that promotes and supports user involvement. We carry out research and also provide advice, training and ongoing support to help voluntary and statutory organisations involve service users and carers. For further information visit www.twocanassociates.co.uk or contact us:

Tel: 01273 831043 or 01273 483438

Email: info@twocanassociates.co.uk