



DEPARTMENT OF HEALTH AND SOCIAL SECURITY

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From the Minister for Health

The Rt Hon Sir Geoffrey Howe QC MP
 Lord President of the Council
 Privy Council Office
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NBSM

PRC 27/10

19 OCT 1989

Dear Lord President,

COMMUNITY CARE: LEGISLATION

Further to your recent meeting with Ken Clarke on the NHS Review Bill I am writing at his request to alert you and colleagues to our policy proposals on community care which will need legislative cover, and on which my officials have provisionally instructed Parliamentary Counsel. As you know we hope the provisions will form part of the NHS Review Bill which means that we need to prepare legislation as soon as possible. Colleagues will have an opportunity to consider our proposals in detail when we circulate our draft White Paper in the near future. Meanwhile if there are any significant reservations about our legislative proposals I would be grateful for an early indication.

In the main we think we can rely on existing provisions - enabling local authorities to arrange the provision of social services with voluntary and private contractors and to pay for them - to carry forward our main proposals that authorities should act as enablers of community care provision. All that is needed here is some tidying up and amendment to enable local authorities to arrange the provision of nursing home care. Local authorities will not be able to provide nursing home care themselves. Neither will they have any power or duty to provide services to, or top up, people enjoying preserved entitlements to income support under the social security system. I have recently written to Tony Newton and Nick Scott on this matter.

The position is similar as regards charging for services. Again we shall rely on existing legislation which means that local authorities will have a duty to charge for residential and nursing home care, in accordance with national rules embodied in regulations. We shall be able to consider the rules in more detail later. Local authorities will retain their present power to charge on a less formal basis for domiciliary and day care. Again only tidying up amendments will be needed.

Our intention is that local authorities should negotiate with voluntary and private providers of services and by arranging bulk provision secure competitive prices. We feel that any attempt to set a limit on what authorities could pay would disturb the working of what we intend should be a competitive market and could be counter-productive. We therefore do not intend to seek a power to set such limits.

Local authorities will be required to carry out assessments of client needs before awarding services. They will also need to ensure that disabled people are given every opportunity to exercise their statutory rights and that the authority itself acts in accordance with its statutory duties towards them. Within this context we intend to frame legislation so that local authorities will be able to decide whether and in what form assessment should take place; carry out one assessment to cover all statutory purposes so long as they inform the client of this; and inform the client of his rights if he is known to be a disabled person or if over the course of the assessment process it becomes clear that he is a disabled person. We intend to issue guidance to the effect that assessments should specify the period they cover, and that authorities should have arrangements for considering representations and complaints from clients (including those refused services). In view of this we do not propose to make any provision for clients to appeal against the findings of an assessment.

We propose that the arrangements for monitoring local authorities performance should be made more robust. Here we intend that local authorities should be required to prepare and publish plans for the development of community care services. We propose that the Secretary of State should have power to call for reports and statistical returns, to hold enquiries and carry out inspections across the whole range of personal social services provision and to issue directions and guidance. We propose to replace the present default powers, again on the lines of the Children Bill. Although these will be slightly less formal than existing provisions (which empower the Secretary of State to take over local authority functions) we feel that coupled with the proposed complaints procedures and the improved arrangements for central monitoring they give us more practical scope to deal with failures in performance.


There remains a financial provision which my officials have been unable to agree with the Treasury but which we think should be included in the legislative package.

This is a general power to make specific grants. At present we have only very limited powers to make specific grants for certain training purposes. At a minimum we shall need to frame a new power to disburse the agreed grant to provide social care to mentally ill people. However, there is a strong possibility that we shall, in the future, want to press our case at least for a number of targeted specific grants. There is also an administrative case for consolidating our current grants under a general power. It would make no sense to legislate and it seems sensible to take a general power at this stage. Any new grants would of course be subject to Treasury approval.

E.R.

As explained earlier I should be grateful to know as soon as possible whether you have any reservations about these proposals. If your officials need more details on our legislative proposals they should contact Mr M T Skinner (Room B1611, Alexander Fleming House GTN 3915 Extn 6829).

Copies of this letter go to members of H and E(A) Committees, Sir Robin Butler and First Parliamentary Counsel.



PP DAVID MELLOR

(Approved by Mr Mellor
and signed in his absence)

*Rick
Gyestron*

FACE THE FACTS

BBC RADIO 4

18th October, 1989

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JOHN WAITE:

In today's programme we investigate the medical furore over the government's decision to pump millions of pounds into a controversial treatment for cancer, a treatment some doctors say they personally wouldn't undergo. The decision to go ahead with the treatment has been condemned by many of Britain's cancer

experts, who say they were not consulted and that their warnings about the risks to patients have since been ignored. Sir Raymond Hoffenberg is the immediate past president of the Royal College of Physicians and Chairman of the United Kingdom Coordinating Committee on Cancer Research.

SIR RAYMOND HOFFENBERG:

The UKCCCR represents the overwhelming majority of medical scientists concerned with cancer research and treatment, and the view of the UKCCCR is unanimous at the project should not go ahead a; on the grounds that the treatment itself has not been proved to be beneficial and b; on the grounds, on the more serious grounds, that it may in fact be harmful.

JOHN WAITE:

The treatment, personally supported by the Prime Minister is called fast neutron radio therapy. In a video just produced, it's protagonists claim thousands of patients will benefit. It's critics, including some of the most senior figures British cancer medicine, say the benefits though have not been sufficiently proven, and they fear the possible consequences. Consequences of the sort endured by 60 year old Burt Child, now facing a lifetime of pain and hardly able to speak after suffering radiation damage.

BURT CHILD:

If the people involved could see me, I think they might have second thoughts in spending this money. Because what's happened to me, I don't want to happen to anybody else, I just don't want anybody else to have the problems I've had, the side effects are so bad. I wouldn't wish it on my worst enemy, put it that way.

JOHN WAITE:

The history of neutron therapy, the treatment Burt Child received, goes back to the 1930's when it was suggested the neutron particles, produced when atoms are split, might be used to attack cancer tumours. In 1955 work began on building a machine called a cyclotron at the Hammersmith hospital in London, which was capable of focusing a beam of neutrons at malignant cells.

In 1969, clinical trials began, aimed at finding out whether neutrons represented an advance on conventional X-ray treatment. Doctor Alan Goulden was then a consultant radio therapist working with conventional X-rays at the Hammersmith.

ALAN GOULDEN:

In order to find out whether a new method of treatment has advantages or not, a group of patients is given standardised conventional treatment in this case treatment with X-rays, and the result of this treatment is compared with the results of the new method of treatment, in this case neutrons, which was under investigation. We thought that there might be radio biological reasons why it might be superior to X-rays, but that obviously had to be put to the test.

JOHN WAITE:

Word soon spread that the results from the Hammersmith trial headed by a consultant called Mary Catrell were extremely promising.

Doctor Sidney Arnott was sent by the Medical Research Council to the Hammersmith cyclotron unit to observe what was being viewed on both sides of the Atlantic as a major breakthrough in the treatment of cancer.

DR SIDNEY ARNOTT:

I think in 1974 when I went to Hammersmith hospital, I was on the crest of a wave. The Americans were very enthusiastic, and the early reports which Doctor Catrell had produced from Hammersmith were enthusiastic and seemed to indicate that it was indeed true that tumours which were very large and unlikely to respond to conventional treatment. Tumours which had previously been treated by numerous other methods of either surgery, radio therapy, chemotherapy, all seemed to respond well to fast neutron therapy.

JOHN WAITE:

That year 1974, Doctor Catrell produced a report which said that neutrons from the cyclotron at Hammersmith, had been almost twice as effective at controlling certain advanced head and neck tumours, as had the X-rays used on the comparison group of patients. Medical scientists were impressed but cautious and the Medical Research Council decided on a second major trial, this time at the Western General Hospital in Edinburgh to see if Doctor Catrell's successes in London could be repeated. Among the consultants involved in the Edinburgh trial was Doctor Hugh McDougall.

DR. HUGH MCDUGALL:

Well we're all very excited of course about the original results from Hammersmith, but nevertheless when we looked at the reports it became evident that their trial, comparing standard X-rays with neutrons was flawed in two ways. Firstly, the group given standard X-ray treatment were treated in different institutions throughout London and the southern area. In other

words, they weren't treated all in the same way in the same centres. Secondly, when you look at the results, [word unclear] given to the group with standard X-rays were lower and in fact not uniform. There were a variety of doses used in the standard X-ray group.

JOHN WAITE:

In order to irradicate what they saw as the flaws in the Hammersmith trial the Edinburgh doctors set up strict controls, to ensure, as far as possible that when they compared patients receiving X-rays with patients receiving neutron treatment, they would be comparing like with like.

DR. HUGH MCDUGALL:

All the patients were recruited from within the one area and all were treated within this institution. All patients were recruited with formal consent and either drew standard X-rays or neutrons. They were all worked up in exactly the same fashion. Investigations were identical, the planning procedures were identical, the patients were nursed by the same nurses, they were looked after by the same group of doctors.

JOHN WAITE:

But well before the Edinburgh trial got under way, consultants in the radio therapy department back at Hammersmith were growing increasingly worried.

Doctor Sidney Arnott and his colleague Alan Goulden were seeing some of the long term side effects of neutron treatment.

DR. SIDNEY ARNOTT:

When I was in the follow-up clinic reviewing patients who had been treated previously, I began to see patients who had gross

thickening of the tissues of the part that had been irradiated. So that for example, they had difficulty opening their mouths or difficulty turning their heads from side to side. I also began to see patients who were developing persistent ulcers in the treated area, where the skin never healed and a number of patients had to in fact undergo quite major plastic operations, to reconstruct the area that had been so adversely effected by fast neutron therapy.

DR. ALAN GOULDEN:

Most of us in the radio therapy department I think became very sceptical about the results. But Doctor Catrell was clearly convinced as a result of her studies, that neutrons were superior to conventional radio therapy, so patients continued to be treated.

JOHN WAITE:

Doctor Catrell had every reason to carry on using the neutron treatment. Her own research, the best and available suggested that in many cases, neutron treatment gave patients with advanced cancer, a better chance than X-rays. That was to change though, with the results from Doctor Hugh McDougall and the team, at the Western General Hospital in Edinburgh.

DR. HUGH MCDUGALL:

We launched the trial in 1977 and between 1977 and 1984, 185 patients were recruited. The initial experience was that the tumour control rate appeared almost identical.

JOHN WAITE:

In other words, neutrons appeared to have no advantage over X-rays in terms of tumour control. Worse was to follow, for although the doctors at Edinburgh had been aware of the side

effects reported at Hammersmith, and had therefore reduced the dose of neutron radiation given to patients, the consequences were tragic.

DR. HUGH MCDUGALL:

We began to see increasingly severe late complications to the neutron therapy. There are a variety of late effects of course, some of these quite trivial, like thickening of the skin. But some of them sadly more severe. And these varied from superficial ulceration of the lining of the mouth, of the tongue, to severe necrosis, that's death of the tissue and death of the bone, particularly of the mandible, the jaw bone.

And sadly 6 of the patients treated by neutrons had severe late radiation damage in the area treated with neutrons. Such that they consequently died due to the side effects of the treatment.

JOHN WAITE:

By this time the Medical Research Council was faced with the situation in which one set of trials at Hammersmith showed neutrons were far more effective than X-rays at controlling tumours, while the other at Edinburgh showed no such benefit and 6 deaths due to radiation.

The MRC's response was to order a comparative study of the two trials. The report that followed came to no further conclusions, but it did reveal that out of 52 patients studied from the Hammersmith trial, 10 had died as a result of neutron radiation. A death rate from side effects of approaching 20%. Doctor Goulden and other radio therapy consultants were appalled.

DR. GOULDEN:

This was the first occasion in which I had seen a detailed

account of the radiation damage caused by neutrons, and as far as I'm concerned that was the first time it had really been comprehensively documented. This amount of damage and this, the number of people dying as a result of the treatment, is something which I think most of my colleagues and I would regard as quite unacceptable in radiation practice.

JOHN WAITE:

Though by the early 80's, many doctors who had been initially excited by neutron treatment, had become deeply sceptical. It's protagonists, led in this country by Doctor Mary Catrell from the Hammersmith, argued that newer high energy cyclotrons, then being developed, would provide a better targetted dose of radiation, thus reducing the side effects.

The Medical Research Council, along with cancer charities agreed to fund further trials using a new cyclotron, at the Clatterbridge hospital on Merseyside.

Meanwhile, Doctor Catrell had helped set up a charitable organisation called the Cyclotron Trust, aimed at raising money for a new facility in London on which neutron therapy could be continued. But though Doctor Catrell remained convinced, many others weren't, though they did accept there might be a case for neutron treatment in a very small number of rare tumours, and notably cancer of the salivary gland. Even so, a number of hospitals turned down suggestions that they might house the proposed cyclotron. Among them the Royal Marsden, where the Professor of radiology at the Institute of Cancer Research was Michael Peckham.

MICHAEL PECKHAM:

We examined the status of neutron therapy and the British and European experience in terms of cure, local cure, patient survival, normal tissue damage and so on. We also reviewed the American data that was available at that time, and it was our conclusion at the end of that, and following discussions in the department that the Royal Marsden should not be involved in neutron therapy, because we felt that on the evidence available, it was unlikely to constitute a significant contribution, a significant advance to curative radio therapy of human cancer.

JOHN WAITE:

In 1984, neutron therapy, using the ageing prototype cyclotron at Hammersmith came to an end, and for several years radio therapists assumed there would be no further work on neutron radio therapy in Britain outside the Clatterbridge hospital on Merseyside.

But then in June last year, the Government rocked the scientific world with a sudden and unexpected announcement that it was to give a £6 million grant to the Cyclotron Trust, to set up a cyclotron at St. Thomas's hospital in London. The decision was taken without consulting external experts on cancer treatment and research, notably the United Kingdom Coordinating Committee on Cancer Research.

SIR RAYMOND HOFFENBERG:

There are mechanisms for making decisions about scientific grants, and there is an elaborate system of review of scientific projects and one hopes they are given, that grants are made on the

basis of scientific merit. In this case, the scientific merit itself is dubious. And [word unclear] procedure just wasn't followed.

JOHN WAITE:

If the Government had asked Sir Raymond Hoffenberg and his colleagues on the Coordinating Committee, it would have been told it was wasting it's money and possibly endangering patients with an unproven treatment. It then emerged that the grant had been made after a conversation between the Prime Minister and the surgeon who carried out her eye operation in 1983, Mr. Richard Packard.

Mr. Packard is a trustee of the Cyclotron Trust and put the trusts plans to the Department of Health. In answer to a Parliamentary question, the health minister, Mr. David Mellor explained that ministers understood neutron therapy gave relief from certain cancers, and that they wanted the treatment more widely available to NHS patients. But, in January this year, the United Kingdom Coordinating Committee on cancer research dispatched a high powered delegation to protest to Mr. Mellor. It included the most senior representatives of the main cancer research charities, and doctors were quick to note the distinguished figure of Professor Norman Blehan, honorary director of the Medical Research Council's clinical cancer unit, and as consultant adviser to the government's chief medical officer effectively the government's own expert on the subject. The protestors, led by their chairman, Sir Raymond Hoffenberg, then president of the Royal College of Physicians suggested that Mr. Mellor should wait for the results of existing trials before

funding further neutron treatment.

SIR RAYMOND HOFFENBERG:

He listened very sympathetically to what we had to say, and he asked for further information about two aspects, and one of them was the reported increased hazards associated with the treatment, and we provided that information. Including the the latest results of the Edinburgh trial and some of the results published by the proponents of cyclotron therapy, which show increased death rates. We gave him that information, and we made the point that it would be irresponsible to enter patients into treatment and to have them pay for treatment which might be harmful, perhaps even fatal.

JOHN WAITE:

Before making a decision, Mr. Mellor wanted to know what doctors abroad thought about neutron therapy, so the committee dispatched Doctor Sidney Arnott, who worked in at both Hammersmith and Edinburgh, and was head of radio therapy at St. Bartholomew's in London, to America to find out.

SIR RAYMOND HOFFENBERG:

He came back and reported that they were very unenthusiastic about it, they were very worried about the morbidity, the side effects associated with that form of treatment, and that federal funding for it was being withdrawn, it would be totally withdrawn within another couple of years. And I submitted this evidence to Mr. Mellor, and I got a letter back saying that neither pieces of evidence was sufficient to make him change his mind.

JOHN WAITE:

What did you make of that?

SIR RAYMOND HOFFENBERG:

Well one can't help feeling that Mr. Mellor might not be a free agent, that he might be having pressure put on him from above.

JOHN WAITE:

Since Sir Raymond's exchange of letters with Mr. Mellor in the middle of this year, the Cyclotron Trust has been pressing ahead with its plans. It needs to raise an additional £4 million from charitable donations before the cyclotron can be built, and has produced a fund-raising video to be distributed to businessmen and others in a position to contribute. The video suggests up to five thousand patients a year could benefit.

Doctor Mary Catrell, now retired and the driving force behind the trust, says that's because neutron therapy is established as the first choice treatment for a range of advanced and inoperable tumours. In her own work she says, 60% of patients suffering from hopelessly advanced cancers, survive for an average of thirty months, compared with up to 30% treated with X-rays.

MARY CATRELL:

I think people who advocate delay have not had personal experience of the daily hell suffered by patients with some types of cancer. More the curative effects of neutrons on those cancers, and you can cure a patient in 60% of cases.

JOHN WAITE:

What is the proof, what is the evidence that neutron therapy is any better than X-ray therapy?

MARY CATRELL:

There is scientific proof, which has been obtained in many

centres throughout the world, and there are the results of treatment from Hammersmith and from the Americans, from Japan and they, and there are plenty of other non trial results. Now these, the international agreement, on the superiority of neutrons is in the advanced large cancers of the face, the mouth, the glands in the neck, the salivary glands, sarcomas, melanomas and those that have recurred after X-ray treatment or surgery. But every new treatment in medicine has, at least most new treatments in medicine, have been opposed by carping criticism, and in this country the carping criticism of some medical experts is very much more strong than in other countries.

JOHN WAITE:

What you are advocating Doctor Catrell, this cyclotron at St. Thomas's, you seem to be standing alone here, opposed by, if I may say so Doctor, the vast majority of your proprofession?

MARY CATRELL:

Well that is not true. It maybe the vast majority, but they haven't seen the patients and they do not know what they are talking about. Most of them have never seen advanced cancers of the type I'm talking about, and they have never seen high energy neutrons.

JOHN WAITE:

Doctor Catrell, how do you assess the risk of side effects that seem to so worry many of your professional colleagues?

MARY CATRELL:

That again is a terribly complex question.

JOHN WAITE:

But very important?

MARY CATRELL:

Yes, but the side effects with the high energy neutrons, which will be used at St. Thomas's are 30% less frequent than they were with the lower energy ones.

JOHN WAITE:

There is a great antagonism which we have detected amongst your cancer colleagues that the funds that have come to your project could have gone elsewhere, and could have been better spent, what do you think of that?

MARY CATRELL:

I think they are wrong.

JOHN WAITE:

The cyclotron for St. Thomas's is also backed by the hospital's local health authority, west Lambeth, which says the hazards of neutron treatment have been grossly over stated, and the proposed centre in south London will provide many more facilities than simply neutron therapy.

Across the Thames in Downing Street, a spokesman confirmed that the Prime Minister had taken a personal interest in the scheme, but added that the decision to provide a grant had been the department of health's. Mrs. Thatcher has however, according to the trust made a personal donation.

There is support to from Doctor Douglas Errington, one of the consultants involved in the clinical trials on the new high energy cyclotron on Merseyside. He believes that neutron treatment is beneficial for certain rare tumours, and argues that because the Merseyside cyclotron is principally for research, patients would

benefit from the neutron treatment proposed for the capital.

DR. DOUGLAS ERRINGTON:

The problem is with just one facility, with the capacity perhaps of not being able to treat more than two 240 patients a year, but at present we can only treat patients from within our own Mersey region, who present with locally advanced cancer, where neutrons are known to be of benefit. This is somewhat of a dilemma as clearly a machine funded for research should not be directly involved in treating patients, where neutrons are recognised of being of benefit without patients being in a study.

It is for this reason that a second cyclotron will be helpful to these patients and also of course to continue with aspects of research in neutron therapy at other sites.

JOHN WAITE:

Despite the arguments you have heard in favour of neutron therapy and the support it enjoys from the British Government, the National Cancer Institute in the United States has confirmed this week that it has no plans to fund further trials once existing commitments come to an end in 1993. A similar lack of enthusiasm is reported in Europe. The reasons are simple - funding bodies are not convinced neutron treatment represents a significant advance in the treatment of cancer, and they are worried about the side effects, worried that others could suffer like Mr. Burt Child from Marlow in Buckinghamshire. Mr. Child underwent neutron treatment at the Hammersmith hospital in 1981 suffering from cancer of the tongue. Though the tumour was irradiated and has not recurred, two years ago he began to suffer late radiation damage. Today the muscles and glands in his neck are useless, his jaw is rigid and

locked just two millimetres open. The jaw bone is crumbling away and he knows his condition can only get worse. His daily meal consists of liquids pumped into him through a hole in his chest.

BURT CHILD:

I have a drip feed [inaudible word] into every night when I go to bed and I have a machine that pumps it in for 8 hours during the night. And in the daytime, I have a build up of liquid that I have poured down my throat, I open my throat and pour it straight down, I don't swallow but that makes up the food that I have.

JOHN WAITE:

It's the plight of people like Burt Child and the fact that side effects from neutron radiation may take years to surface, that worries many of those who criticise the Government grant to St. Thomas's. But though some of the most distinguished individuals and authoritative bodies in cancer research have urged the Department of Health to wait for the results of existing trials, the Government says they have produced no evidence to make ministers change their minds.

Prospective patients are therefore left in an unenviable position, in which the Government is making available a treatment which consultants like Hugh McDougall from Edinburgh say they wouldn't personally undergo.

HUGH MCDUGALL:

They would have to persuade me of some new evidence that I'm not aware of had become available. I'm certainly unaware of any evidence that would make me accept neutron therapy at present.

I would be very concerned if patients were treated with neutrons in an uncontrolled fashion, outside a proper medical

scientific experiment and without full and formal consent from the patients.
