R v North Derbyshire Health Authority ex p Fisher (Kenneth Graeme)

Queen's Bench Division
Dyson J
11 July 1997

A public body which fails to implement national policy contained in a circular from the Secretary of State because it considers that the policy is wrong, fails to have regard to the policy and, accordingly, acts unlawfully.

Facts

On 15 November 1995 the NHS executive issued executive letter EL(95)97 ('the circular') to, among others, all health authorities. The circular asked:

> *. . . purchasing authorities and providers to develop and implement local arrangements to manage the entry of [Beta-Interferon] drugs into the NHS in consultation with other key interests . . . and, in particular, to initiate and continue prescribing Beta-Interferon through hospitals . . . the drug will – in line with the commitment of Ministers that patients should receive the treatments which they clinically need – become available for NHS prescription, subject to . . . clinical decisions about the appropriateness of treatment in individual cases.*

The respondent health authority was not convinced that Beta-Interferon was an effective treatment, or had been sufficiently tested, and decided to adopt what it described as 'creative constraints' on its use.

By January 1996 the respondent health authority had adopted a policy to fund Beta-Interferon treatment only for patients participating in a randomised control trial but:

a) no trials were currently being undertaken (all trials were subsequently postponed indefinitely), any trial that was undertaken would take years to generate results and the NHS executive made it clear that it expected health authorities to follow the guidance in the circular on the basis of information currently available and not wait for trials;
b) although the respondent health authority contended that its 'within-a-trial' policy only operated to deny additional funds to the trust with which it contracted, and that nothing prevented the trust from buying Beta-Interferon with money ear-marked in the block contract sum for neurological services generally, in the real world, without additional funds, the effect was that there was a blanket ban on Beta-Interferon treatment – due to its relative expense, on the evidence, Beta-Interferon treatment would not be dispensed by hospital pharmacists/trusts, even if prescribed by clinicians, without additional funding.

On 10 October 1996 the NHS executive wrote to all health authorities stating that as all randomised control trials had been postponed indefinitely there was now no excuse for delaying the introduction of local purchasing policies in line with the circular. The respondent health authority did not, however, adopt a new policy and in particular did not make additional funding available for the prescription of Beta-Interferon. There was a sum of £50,000 which had been allocated within the respondent health authority's budget as an extra-contractual referrals budget for neurologists, which could according to one of the respondent's minutes have been released as additional funding for Beta-Interferon, but was not. One reason given was that the respondent health authority considered it to be inequitable to make

money available to be allocated on a 'first come first served' basis until it ran out, and that it did not have the resources to enable a more equitable assessment of patients' needs to be carried out, but that it would consider (undefined) 'special cases'.

Held:

1 The circular contained guidance to which the respondent health authority had to have regard and not directions with which the respondent was required to comply by virtue of National Health Service Act 1977 s13. If the Secretary of State for Health intended to give directions then s/he should have made that clear. However, executive letter EL(95)97 did not refer to itself as 'directions', did use the word 'guidance' on several occasions and used words such as 'asks', 'suggested' and 'taking into account' rather than words such as 'shall'. The circular was 'strong guidance' rather than mandatory directions.

2 The respondent health authority had to have regard to national policy set out fully and firmly in the circular. It was not obliged to follow the policy, but if it decided to depart from it, it had to give clear reasons for doing so and those reasons would be susceptible to a *Wednesbury* challenge. Moreover, if the respondent health authority failed to understand the circular properly then its policy would be as defective as if no regard had been paid to the policy at all. It was under a duty to give serious consideration to each aspect of the circular.

3 The respondent health authority's policy was plainly not in accordance with the circular which exhorted health authorities to make 'local arrangements to manage the entry of [Beta-Interferon] into the NHS . . . and in particular to initiate and continue prescribing Beta-Interferon through hospitals . . .' in order to 'target the drug appropriately at patients who were most likely to benefit . . .' The primary purpose of trials is not to prescribe drugs in order to treat patients but to test their efficacy. It could not, therefore, be fairly said that a policy of funding Beta-Interferon only within trials was a reasonable way of giving effect to the circular. Further, in effect, as the respondent health authority must have known, its policy amounted on the facts to a disingenuous disguise of a blanket ban on Beta-Interferon. This was not a case of a public body deciding to depart from a national policy because there were special features which justified departure, nor did the respondent health authority take the circular into account and then decide exceptionally not to follow it. The respondent health authority failed to implement any aspect of the circular, in effect instituting a blanket ban on the use of Beta-Interferon, the very antithesis of national policy, principally because it disagreed with it altogether. In effect, therefore, the respondent health authority disregarded the circular because it was opposed to it and its policy was accordingly unlawful.

4 In any event the respondent health authority's policy became unlawful when in late 1996 it became apparent that trials had been postponed indefinitely. Once that point had been reached the truth was that the respondent health authority had no policy at all in relation to the implementation of the circular. Reliance on sums of money already included in block contracts was not a reasonable response to the circular because on the facts an expensive drug such as Beta-Interferon would not be dispensed by hospital pharmacists/trusts, even if prescribed by clinicians, without additional funding. Accordingly there remained, in effect, a blanket ban on Beta-Interferon.

5 The respondent health authority's failure to release the sum of £50,000 included in the extra-contractual referrals budget to neurologists specifically for Beta-Interferon was irrational. The reasons given – that money could only be allocated

A on a 'first come first served' basis, which was unfair, while the respondent health authority did not have the resources to enable a more equitable assessment of relative needs to be carried out – would, if correct, justify refusing to make any expensive treatment available in almost all circumstances. Clinicians routinely have regard to many factors, including resources and needs, when prescribing
B and it was absurd to suggest that all potential patients had to be surveyed before any patient was prescribed expensive treatment.

Cases referred to in judgment:

Associated Provincial Picture Houses v Wednesbury Corp [1948] 1 KB 223; [1947] 2
C All ER 680; 45 LGR 635, CA.

Grandsden (E C) & Co and Falkbridge v Secretary of State for the Environment and Gillingham BC (1987) 54 P&CR 361; [1987] JPL 365; (1985) 54 P&CR 86, CA.

R v Cambridge District Health Authority ex p B [1995] 1 WLR 898; [1995] 2 All ER 129; [1995] 1 FLR 1056; [1995] 2 FCR 485; [1995] 6 Med LR 250; [1995] Fam Law
D 480; (1995) 145 NLJ Rep 415; (1995) *Times*, 15 March; *Independent*, 14 March, CA.

Legislation/guidance referred to in judgment:

National Health Service Act 1977 ss1, 2, 8, 13, 18 and 97 – National Health Service
E and Community Care 1990 ss3 and 4 – Department of Health Circular HC(91)25 – NHS Executive Letter EL(95)97.

This case also reported at:

(1997) *Times*, 2 September, QBD.

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Representation

J Grace QC and J Galbraith-Marten (instructed by Irwin Mitchell) appeared on behalf of the applicant.

A Seys Llewellyn (instructed by Wansbroughs Willey Hargrave) appeared on behalf
G of the respondent.

Mr Elvin (instructed by the Treasury Solicitors) appeared on behalf of the Secretary of State for Health.

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Judgment

H **MR JUSTICE DYSON:**

Synopsis of the Case

In December 1987 the applicant was diagnosed as having the relapsing/remitting form of Multiple Sclerosis. He has at all material times lived in the area for which
I the respondent authority is the health authority. The authority cannot itself provide appropriate neurological services to treat the applicant but is able to purchase such services under the internal market established pursuant to sections 3 and 4 of the National Health Service and Community Care Act 1990 from a provider. The relevant provider in the instant case is the Central Sheffield University Hospital's National Health Service Trust, one of whose hospitals is the Royal
J Hallamshire Hospital at Sheffield. This hospital does provide neurological services. The respondent could purchase neurological services from the Trust either by an NHS contract under section 3(2) of the 1990 Act or by what are called Extra Contractual Referrals or ECRs under section 3(5) of the Act.

K On 15th November 1995 the NHS executive issued an executive letter EL(95)97, ('the Circular') to, amongst others, all health authorities. It asked

purchasing authorities and providers to develop and implement local arrangements to manage the entry into the NHS of a new drug for Multiple Sclerosis called Beta-Interferon.

In January 1996 the applicant was referred to the Royal Hallamshire Hospital where Dr Petty, a consultant neurologist, assessed him as suitable for Beta-Interferon therapy. Dr Grunewald, Dr Petty's successor, was of the same view. No funding was made available for the treatment. It will be necessary to examine in some detail what happened between January and November 1996. The applicant seeks judicial review of the respondent's decision, which was communicated to him by the letter from the Trust dated 18th November 1996, to decline to fund the treatment of the applicant with Beta-Interferon.

The Statutory Framework

The key statutory provisions are to be found in the National Health Service Act 1977 ('the 1977 Act') as amended. Section 1(1) imposes a duty on the Secretary of State to provide:

> *. . . a comprehensive health service designed to secure improvement –*
> *(a) in the physical and mental health of the people [of England and Wales]; and*
> *(b) in the prevention, diagnosis and treatment of illness,*
> *and for that purpose to provide or secure the effective provision of services in accordance with this Act.*

Section 2 provides:

> *Without prejudice to the Secretary of State's powers apart from this section, he has power–*
> *(a) to provide such services as he considers appropriate for the purpose of discharging any duty imposed on him by this Act; and*
> *(b) to do any other thing whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of such a duty.*

Section 8(1) of the Act requires the Secretary of State to establish Health Authorities. Section 13(1) empowers the Secretary of State to direct a Health Authority:

> *. . . to exercise on his behalf such of his functions relating to the health service as are specified in the directions, and . . . it shall be the duty of the health authority . . . to comply with the directions.*

Section 18 provides:

> *(1) Any directions by the Secretary of State in pursuance of sections 13 to 17 above shall be given either by regulations or by an instrument in writing. . . .*

The Circular EL(95)97 includes the following provisions:

> *1. EL(94)72 asked purchasing authorities to focus on a number of key prescribing objectives for 1995/1996, including the effective management of new drugs into the NHS.*
>
> *2. In that context, EL provides information in connection with the possible marketing authorisation, in the near future of Beta-Interferon drugs for multiple sclerosis. It asks purchasing authorities and providers to develop and implement local arrangements to manage the entry of such drugs into the NHS in consultation with other key interests, especially GPs and patient interest groups; and in particular,* to initiate and continue prescribing Beta-Interferon through

A hospitals. *In doing so, they are asked to take account of the checklist of issues in the Annex, and of the attached clinical advice on Beta-Interferon*.*

*3. [*I omit the first part*] . . . if authorisation is granted, the drug will – in line with the commitment of Ministers that patients should receive the treatments which they clinically need – become available for NHS prescription, subject to any conditions which may be attached to the marketing authorisation and to clinical decisions about the appropriateness of treatment in individual cases. As with other drugs, prescribing the drug outside licensed indications is not encouraged . . .*

Clinical issues

5. Decisions about the treatment of individual patients are, of course, for the clinical judgement of the doctor concerned and no doctor is prohibited from prescribing Beta-Interferon drugs. However, in view of the clinical consideration as set out in the advice of the Standing Medical Advisory Committee, it is suggested that GPs should be encouraged not to prescribe Beta-Interferon drugs themselves and instead to refer patients who apparently fulfil the indications for this form of treatment to a hospital neurologist for specialist assessment (or reassessment). *Where the treatment with Beta-Interferon is appropriate, it is suggested that treatment should be initiated and the drug prescribed by the specialist. . .*

6. . . . In order to maximise opportunities for monitoring and evaluating the effectiveness of treatment, it will usually be appropriate for clinical responsibility for prescribing Beta-Interferon to remain with the hospital consultant.

Clinical objectives

7. Key aims of the above approach are to:–

- *target the drug appropriately at patients who are most likely to benefit from treatment;*
- *develop a consistent approach to patient education and training in the use of the drug;*
- *provide structured opportunities to monitor and evaluate the treatment, including side-effects, and compare its effectiveness between patients;*
- *help inform decisions about when it is appropriate to withdraw treatment in individual cases.*

8. Whilst it is suggested that GPs should be encouraged not to prescribe Beta-Interferon themselves in accordance with the above guidance they will retain a key role in: . . .

Managing the introduction of Beta-Interferon

9. Purchasing authorities and providers are asked, as part of their existing arrangements for managing the introduction of new drugs (discussed in EL(94)72) to work with other local interests – notably GPs, FHSAs, neurologists and patient interest groups – to develop and implement a prescribing approach for Beta-Interferon through hospitals, as outlined above . . .

Resource implications and funding

10. Further consideration is being given to the funding consequences on HCHS of the introduction of Beta-Interferon for 1996/1997 and beyond. In the meantime, it will be necessary to assess current resource implications locally. In particular, providers will need to consider workload and manpower implications – eg for hospital neurologists and out-patient departments. Patients who

apparently fulfil the indications for treatment with Beta-Interferon are likely to seek an early opportunity for assessment and diagnosis: providers are asked to give sympathetic consideration to such GP referrals, taking account of local priorities. As funding for Beta-Interferon will fall on HCHS budgets, there should be little or no impact of FHS drugs budgets, though we shall be monitoring this carefully . . .

Further guidance and information
12. This guidance will be updated and amplified as necessary when decisions about marketing authorisation are known.

The Principal Issues

(1) Whether the Circular constitutes directions which the respondent authority is under a duty to apply, or merely guidance which it is required to take into account in performing its statutory functions.
(2) Whether the respondent has acted unlawfully in adopting a policy not to fund the treatment of relapsing remitting Multiple Sclerosis with Beta-Interferon.
(3) Whether the applicant has a legitimate expectation of treatment with Beta-Interferon, based on a decision communicated to him by a letter dated 19th February 1996, the effect that whether he received treatment would be a clinical decision, that decision already having been made in his favour.

The Circular EL(95)97 directions or guidance?

For the applicant, Mr Grace QC submits that paragraph 3 of the Circular makes it clear that, if authorisation is granted, the drug will became available for NHS prescription, and that paragraph 2, which is the principal operative paragraph, is expressed in the language of requirement, that is, it is mandatory. The use of the 'asks' in paragraph 2, which is repeated in paragraph 9 shows, he submits, that the Circular is imposing duties and not merely giving guidance.

For the Secretary of State, Mr Elvin, whose submissions are adopted by Mr Seys Llewellyn, submits that it is clear on the face of the Circular that its function is to provide guidance to help authorities which they should take into account in the discharge of their functions, and not to impose mandatory requirements which they are absolutely obliged to follow. If it is the intention of the Secretary of State to give directions which attract a statutory duty of compliance, then he should make it clear that this is what he is doing. The difference between a policy which provides mere guidance, and one in which the health authority is obliged to implement is critical. Policy which is in the form of guidance can be expressed in strong terms and yet fall short of amounting to directions. There is no reference in the Circular to the word 'directions', and read as a whole there is no indication that the Circular is intended to trigger the statutory duty of compliance to be found in section 13(1) of the 1977 Act. The Circular includes words such as 'asks', 'suggested', 'taking into account'. It does not include the word 'shall' or any of the other badges of mandatory requirement.

In my judgment Mr Elvin and Mr Seys Llewellyn are right. If the Circular provided no more than guidance, albeit in strong terms, then the only duty placed upon health authorities would be to take it into account in the discharge of their functions. They would be susceptible to challenge only on *Wednesbury* principles if they failed to consider the Circular, or they misconstrued or misapplied it whether deliberately or negligently: see *Grandsden & Co Ltd and Another -v- Secretary of State for the Environment and Another* (1985) 54 P&CR 86, 93–94.

If the Circular gave directions, then the health authorities would have an absolute duty to comply. I agree that it is important that the court should be slow to construe a document as a direction in the absence of clear words that that is what it is intended to be. The language of the Circular is very far from clearly demonstrating an intention to give directions. It is, of course, important to examine substance rather than form. The substance here is to be found in the language of the Circular. The absence of the word 'direction' and the use of the word 'guidance' in paragraph 8 and in particular in paragraph 12, are highly significant. It is also revealing that the last three paragraphs of the Circular are prefaced with the heading 'further guidance and information'. This implies that what has gone before is itself guidance. The nearest the Circular gets to the language of direction is in the use of the word 'asks' in paragraphs 2 and 9. In my view, however, in the context of the Circular as a whole, 'asks' is the language of strong guidance rather than mandatory requirement. I conclude, therefore that the Circular was guidance and not a direction.

Before I turn to the other issues I need to set out the history in some detail.

The History

On 4th January 1996 the applicant was admitted to the Royal Hallamshire Hospital. Dr Grunewald prescribed Beta-Interferon for him, but made it clear that he was uncertain as to the position as regards funding for what was a new and expensive drug since it was the first time he had prescribed it. The prescription was sent in the usual way to the hospital's pharmacy for the pharmacist to process and dispense. By reason of its expense the drug was red-lined in the hospital's pharmacy records. Drugs are red-lined *inter alia* where they are costly. The policy of red-lining is a means of ensuring as far as possible that drugs and treatments are prescribed within the total budget available to the Trust.

In view of the fact that Beta-Interferon had been red-lined, the pharmacist blocked the prescription and referred the matter to the Neuro-Sciences Clinical Directorate, with a view to determining whether the funding of the applicant's treatment with Beta-Interferon could be met within the block contract of funds allocated by the respondent to the Trust.

A decision was taken by the chief executive of the Trust in conjunction with clinical colleagues not to authorise treatment of any North Derbyshire residents with Beta-Interferon in the light of lack of funding for this drug therapy.

Dr Grunewald was told by the pharmacy that the Trust was unable to fund Beta-Interferon as there were insufficient funds. He was told that the hospital would need to contact the respondent to negotiate additional funding. This was the first time in his clinical experience that he had been unable to prescribe a drug to a patient because of insufficient funding.

He explained to the applicant that the hospital was unable to treat him with Beta-Interferon. Understandably the applicant was disappointed. Meanwhile the respondent had been considering what to do about the Circular. Dr McConville (Director of Public Health to the respondents) and others in the Trent region were unconvinced about the effectiveness of Beta-Interferon. They felt that it had not been sufficiently tested. Nevertheless as early as 5th December 1995 a minute of one of the respondent's meetings records:

> *However, the government had now issued guidelines, and health authorities could not refuse to purchase courses of treatment with the drug, but it could only be prescribed by neurological centres.*

Despite this, by 8th January 1996 the respondents were writing to the Trust

saying that they had adopted a policy 'that funding will only be considered for patients who are participating in a randomised control trial'. On the same day Mr Dorrell, who was the Secretary of State for Health, delivered the millennium lecture in which he said:

> *There should be no clinically effective treatment which a health authority decides as a matter of principle should not be provided; there will always be the exceptional case where treatment is clinically justified. To ban treatment in such circumstances would be inconsistent with the principles on which the NHS is established and I do not believe that they represent acceptable practice.*

This was picked up at this meeting of the regional directors of the Trent region, which included the respondent authority in the following way:

> *It was noted in the light of Stephen Dorrell's speech, that blanket bans were not acceptable. However, it would be possible to have creative constraints. Performance Managers at Region would be picking up on this issue and it may be difficult to hold the North Derbyshire line if there was no imminent prospect of a trial.*

Sometime in February, the NHS executive wrote to the Directors of Public Health in the Trent region including Dr McConville, saying that any new clinical trials that might be undertaken in the UK would take several years to generate results, and that, for the time being therefore, purchasers must make decisions on the basis of knowledge now available. To hold back on the grounds that the evidence did not conclusively indicate a sufficiently large health gain to justify the costs would be at variance with the national and regional guidance that had been issued.

The applicant had enlisted the support of his Member of Parliament, Mr Harry Barnes, who had written to Mr Fewtrell, the chief executive of the respondent. On 19th February 1996 Mr Fewtrell replied to Mr Barnes in the following terms:

> *There is widespread concern in the medical profession about the way Beta-Interferon has been introduced in the treatment of multiple sclerosis. The possible benefits appear quite limited, the side effects potentially severe, and until more experience is gained both the risks and benefits of the treatment cannot be readily assessed. The only way the value of this drug can be assessed would be to undertake randomised controlled trials to compare how patients with the treatment fare as against those who do not receive it. Introduction into routine clinical practice without such a trial would mean there would never be any reliable evidence of the benefits of the drug. Specifically there is no evidence that Beta-Interferon reduces handicap or extends life expectancy amongst sufferers of multiple sclerosis, and it is unfortunate that expectations have been raised as in this case.*
>
> *It has now been determined nationally (EL(95)97) that the drug may only be prescribed through neurology centres, and in line with this guidance, but against the consensus of medical opinion in North Derbyshire, the Health Authority is discussing the contractual arrangements with local neurology provider units. Priority for use of the limited funds available will be determined by the neurologists at the specialist centres and whether Mr Fisher receives this treatment will be a clinical decision.*

In fact however the respondent was not having discussions with the Trust about contractual arrangements to implement the Circular. It continued to hope that Beta-Interferon treatment could be limited to patients who participated in a trial.

A They were told in March that a national trial was planned to start within nine to 12 months co-ordinated from Edinburgh. On 22nd March at a meeting of the Directors of Public Health in the Trent region the directors recommended that all districts in Trent support the use of Beta-Interferon only in the context of the proposed trial. On 16th April the respondent accepted the recommendation of B the directors of public health and agreed to identify a sum within the ECR budget for that purpose. Arrangements would be made to inform GPs and consultants of the policy but it was felt that a public statement on the subject would be inappropriate.

The respondent's policy, however, became public knowledge and was featured C in the News at Ten on 11th May 1996. The NHS Executive was contacted by the News At Ten for comment. On 2nd May the Executive wrote to the respondent saying:

> *Our view, as part of the NHSE is, of course, that we expect Health Authorities in* D *Trent to work within the national guidance. The national R&D directorate have had to make it clear through the media that no firm decision has yet been made to fund further trials.*

The Executive had, in fact, issued a press release on 1st May which included the following:

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> *2. No firm decisions have yet been taken by RDD to launch such a trial. In any event, as the aim of the trial would be to evaluate Beta-Interferon for a different purpose than that for which the current drug has been licensed [ie the licensed drug aims to reduce the frequency and severity of relapse in relapsing-remitting* F *MS patients], the approach being recommended by Trent DPH's will – if it is followed – have the effect of cutting across the NHS Executive's suggested prescribing policy [in EL(95)97] and effectively denying eligible MS patients the opportunity of receiving treatment now.*
>
> *3. Dr Winyard has been in contact with the Region to discuss the position, and* G *agreed the following line, which is being issued to News at Ten:–*
>
> > *The NHS Executive is currently developing a possible national trial with experts, including neurologists, to measure the effects of Beta-Interferon on disability for people with Multiple Sclerosis. Any decision on whether such a* H *trial would proceed is some way off. The NHS Executive issued guidance last year to all Health Authorities in the NHS, which expected them to follow, to help them plan locally for the prescribing of Beta-Interferon for patients who would appear to benefit from treatment at the present time. There is no question of a blanket ban on treatment with Beta-Interferon.*

I Despite this the respondents did nothing to implement the Circular, but continued to see the solution to the Beta-Interferon issue in a trial. Thus although a meeting of the directors of 24th May was told that the Department of Health was not going back on the original decision laid out in the Circular and that a blanket ban on Beta-Interferon was not possible, on 29th May Dr McConville wrote:

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> *1. North Derbyshire health authority has resolved that Beta-Interferon will only be prescribed in accordance with the regional and Pharmaceutical offices protocol as part of the controlled randomised control trial.*
>
> *2. £50k has been allocated for Beta-Interferon in the 1996/7 Health Investment* K *plan.*

In line with this, on 30th May she wrote to the Trust saying that the respondents

were willing to purchase Beta-Interferon as part of the proposed Edinburgh randomised control trial, and that of the £50,000 in the 1996/7 health investment plan for Beta-Interferon, a maximum of £40,000 may be available within Sheffield.

By 26th June two possible trials were being investigated: one national (the Edinburgh trial) and one within the region. The respondents were still refusing to consider any treatment outside a trial. During the Summer, representations were made on behalf of the applicant to the Prime Minister. On 3rd September Mr Major wrote a letter which included the following:

> *Quite separately, the Department of Health's Technology Assessment Programme had been considering a possible national clinical trial of Beta-Interferon drugs, specifically to measure the impact of treatment of disability and earlier this year, some health authorities, particularly in the Trent Region, decided to wait for a decision on this trial before finalising their own arrangements for purchasing and prescribing Beta-Interferon.*
>
> *However, following further consideration, I understand that the Trent health authorities have recently reviewed their position and are making arrangements for the treatment to be prescribed in appropriate cases. The proposed national trial has been postponed indefinitely.*
>
> *[*He concludes*] I hope that this is helpful in explaining the situation and that given the revised position of health authorities in the Trent region, it may now be possible for Kenneth to be treated with Beta-Interferon.*

Whatever may have been the position with other Trent Health Authorities, the respondents were not making arrangements for the treatment to be prescribed in appropriate individual cases. By mid-September the respondents had become aware that any randomised control test was at least 18 months away. They decided to reconsider their trial only policy. At a meeting held on 17th September, three options were considered. These were:

(a) *Release of £50K in the ECR budget for neurologists specifically for Beta-Interferon.*
(b) *Increasing the value of neurological contracts by the amount identified in the ECR budget, and asking neurologists to use it, on the basis of clinical priority, for new drugs and treatments in neurology.*
(c) *Maintaining our current policy of funding only as part of the proposed national trial.*

Dr McConville's memorandum goes on:

> *The Professional Advisory Team recommended that the Health Authority maintain its current position, option c, until the contents of Dr Winyard's letter are known. Once this is no longer sustainable, they recommend option b.*

On 17th September it was decided by the respondent:

> *. . . to maintain the Authority's current policy of funding Beta-Interferon only as part of a proposed national trial for as long as possible. When this position was no longer sustainable neurologists would be asked to use their discretion, on the basis of clinical priority, for new drugs and treatment in neurology within an overall contract sum.*

On 10th October Dr Winyard, who had been the author of the Circular, notified all health authorities that the randomised control trials had been postponed indefinitely. In his letter he stated that:

There was now no further reason for delaying the introduction of local purchasing policies in line with the circular.

This caused the respondents to look at their policy again. On 29th October Mr Fewtrell and Mr Whitney of the Trust met. The substance of the decision taken by Mr Fewtrell, on behalf of the respondents, was recorded in Mr Whitney's letter to the applicant's father dated 1st November 1996 which includes the following:

At the beginning of 1996, they had thought that there was to be a further national clinical trial on Beta-Interferon; they are now aware that this will not take place in the foreseeable future. However, they do not believe that the use of Beta-Interferon is cost effective and therefore would not advocate its use particularly within the finite financial resources which they have available to them. On this basis, therefore, they have told me that they will not support the treatment of North Derbyshire residents using Beta-Interferon for this particular condition, although they accept they cannot ban its use given that the drug has been licensed. In the light of this, I am afraid that I cannot endorse any decision of my own Consultant Neurology colleagues from within this Trust for treating North Derbyshire residents with Beta-Interferon for this particular condition without additional resources becoming available from North Derbyshire Health Authority. We have been reminded by North Derbyshire Health Authority that they do not wish us to overspend at the end of the current financial year.

On 14th November Mr Whitney, Mr Fewtrell and Dr McConville met the applicant's father and explained the respondent's policy. That explanation was confirmed in Mr Whitney's letter to the applicant's father dated 18th November 1996 in the following terms:

Mr Fewtrell confirmed that the policy of North Derbyshire Health Authority was that they could not support, in cost effective terms, the use of the drug Beta-Interferon for relapsing multiple sclerosis patients and also they could not identify any new money to give priority to the use of this drug. This was based on the unanimous views of their professional advisers. However, they also made it clear that they could not restrict clinicians, such as Dr Grunewald, prescribing this drug where appropriate based on individual patient need and within existing contracts. (It is not North Derbyshire's policy to contract for individual drugs.)

A meeting of the respondents held on 19th November records:

The Authority's policy on the use of Beta-Interferon had been fully explained and a meeting had been held with the individual to discuss the matter. Both Dr McConville and Mr Fewtrell confirmed that as the clinicians had not accorded the patient priority for the use of Beta-Interferon within the existing contract they could not recommend a change of policy.

It was RESOLVED to note the situation.

The respondent's evidence as to whether it did change its policy at this time, and what considerations it took into account, is far from satisfactory. Dr McConville says at paragraph 15 of her affidavit that, following receipt of Dr Winyard's letter of 10th October, she gave consideration to whether or not the respondent should change its policy. She continues:

The alternatives that were available to the Authority included a release of the £50,000 allocated in the Authority's budget as part of the Health Investment Programme. This could only be allocated on a 'first come, first served' basis until the money ran out. This would mean that those who may have the greater

clinical need or greater potential to benefit who presented to clinics later in the year would be later denied treatment. Accordingly, the authority resolved that it was reasonable for them to maintain their current policy so as to avoid the iniquities of prescribing on a 'first come first served' basis, rather than clinical need or an ability to benefit, a feature of NHS purchasing which Mr Fewtrell has described in his Affidavit.

A change such as I described was potentially very inequitable. Alternatively, the Authority, but for the fact it had no funds available, could have requested 'within the contract' with its providers that neurologists assess all potential recipients, assess their clinical need and ability to benefit and prioritise that need across all North Derbyshire residents with MS. This would have involved the 3 'regional' neurology departments, an increase in the number of clinics and a corresponding increase in the number of staff the costs of which the authority would not have been able to meet within its allocated budget for the year. There was no evidence from the literature that would suggest the need for the Authority to review the clinical and cost effectiveness information upon which the authority's original decision was founded. Indeed the SCHARR report strengthened the evidence against purchasing Beta-Interferon.

In my judgment it is clear that she is saying that there was no change in policy following the receipt of Dr Winyard's letter. At paragraph 27 of his affidavit Mr Fewtrell says that:

At the meeting of the Board on 19th November 1996 it was reported that the estimated outturn of overspending for the year would be £1,185,000.

Accordingly, there were no additional resources to fund the applicant's treatment. It is suggested by Mr Seys Llewllyn that Mr Fewtrell's affidavit implies that there was a change of policy, but that the respondents had no new funds to make available for Beta-Interferon treatment; and the question whether any money available to the Trust within the so-called block contract should be applied in providing Beta-Interferon treatment remained a matter for the Trust.

On instructions, that is what Mr Seys Llewllyn says the policy was. He also told me on instructions that £50,000, which had been described in Dr McConville's memorandum of 17th September 1996 as 'in the ECR budget to neurologists specifically for Beta-Interferon', and the release of which Dr McConville had said in her affidavit was an available alternative, had not been 'ring fenced', and did not in fact exist. I shall return to this when I deal with the issues.

I can complete the narrative quite shortly. The contract agreed between the respondents and the Trust for 1997/1998 includes a statement that in relation to Beta-Interferon the respondents will consider 'special cases' as ECRs. I have not been told what 'special cases' are. It seems that the respondents have made something of a move away from their original policy of treatment only within a trial, but I do not find it possible to assess the extent of that move.

Dr McConville records in her report dated 1st April 1997, that:

The position reflects an impasse and is probably not sustainable. It is out of line with other North Trent purchasers who appear to have allocated a budget for Beta-Interferon to the Royal Hallamshire Hospital, leaving clinicians to prioritise which patients receive treatment.

Finally, although this is not in evidence, Mr Seys Llewellyn told me, again on instructions, that it is now agreed in principle between the respondents and the Trust that the 1997/1998 block contract sum for neurological services generally

A will be increased by £40,000.

I now turn to the issues.

Was the respondents' policy in relation to the Beta-Interferon treatment up to November 1996 lawful? What was the policy?

B In my view the within-a-trial-only policy was maintained throughout 1996. It is submitted on behalf of the respondents that (1) the policy only operated to deny additional funds to the Trust and not to prevent the Trust from using money earmarked in the block contract sum for neurological services generally, and (2) in any event the policy changed in November 1996.

C As regards the scope of the policy, in the real world, without additional funds, there was bound to be a *de facto* ban on Beta-Interferon treatment. This was well understood by everyone, and explains why the within-a-trial-only policy was regarded as a blanket ban: see the press release dated 1st May 1996 and Dr McConville's memoranda of 29th May and 5th July.

D If in practice the block contract sums would be able, subject to clinical judgment, to fund Beta-Interferon in appropriate cases, it is difficult to see why the respondents' within-a-trial-only policy generated the reaction that it did from the NHS Executive.

E The fact is that the block contract sums had been agreed before the Circular was issued. Beta-Interferon is an expensive drug. The respondents would have known, or at least would not have been surprised, that it was the type of drug that would be red-lined and would not be dispensed unless additional funding was provided. Thus when Mr Fewtrell wrote in his letter of 19th February 1996:

F *Priority for use of limited funds available will be determined by the neurologist at the specialist centres and whether Mr Fisher receives this treatment will be a clinical decision.*

He must have known that, unless additional funds were made available, this was simply not true. No doubt that is why he said in his letter that he was:

G *Discussing the contractual arrangements with local neurology units.*

Although the evidence does not disclose that any such discussions took place. The suggestion that Beta-Interferon treatment may be available within the block contract was impliedly repeated in the letter of 18th November 1996, viz:

H *They made it clear that they cannot restrict clinicians such as Dr Grunewald prescribing this drug where appropriate based on individual patient need and within existing contracts.*

I Of course, they could not stop clinicians writing prescriptions, but the respondents knew that, at any rate within the Trust hospitals, those prescriptions would not be dispensed and treatment would not be given unless additional funds were made available. It is pointed out that one of the respondents' residents did in April 1996 receive Beta-Interferon treatment from a hospital in Manchester. It is suggested that this shows that the respondents' policy did not amount to a blanket ban on Beta-Interferon treatment. The evidence does not

J indicate how this patient came to receive the treatment. The respondents were clearly surprised and Dr McConville's note of 1st August 1996 says:

As they made the decision to treat without reference to us I am not convinced that we should pick it up this year.

K This single exceptional case concerning a different Trust does not persuade me

that it was part of the respondents' policy that Beta-Interferon treatment should be given in appropriate cases funded by the sums available for neurological services generally within the block contracts.

Did the policy change in November 1996?

I have already referred to the evidence. The affidavit of Dr McConville is quite clear. There was a review of the policy following receipt of Dr Winyard's letter of 10th October and, for the reasons she gives, it was decided not to change the policy. Nor do I read paragraph 27 of Mr Fewtrell's affidavit as saying, in effect, that there was a change of policy. It would have been very surprising if he had said that the policy changed in November, because as the minutes of the meeting dated 19th November record:

> *Both Dr McConville and Mr Fewtrell confirm that as the clinicians had not accorded the patient priority for the use of Beta-Interferon within the existing contract they could not recommend a change of policy.*

Was the policy lawful?

Its lawfulness must be judged in accordance with *Wednesbury* principles against the background of national policy which was set out fully and firmly in the guidance to be found in the Circular. The respondents had to have regard to that national policy. They were not obliged to follow the policy, but if they decided to depart from it, they had to give clear reasons for so doing, and those reasons would have been susceptible to a *Wednesbury* challenge: see generally *Grandsden* (supra). Moreover, if the respondents failed properly to understand the Circular, then their policy would be as defective as if no regard had been paid to the policy at all. It is accepted on behalf of the respondents that they were under a duty to give serious consideration to each aspect of the Circular. Mr Seys Llewllyn submits that the respondents' policy was an honest and conscientious way of managing the introduction into the NHS of the new drug, and was at least consistent with the Circular.

In my judgment the policy was plainly not in accordance with the Circular. The Circular asked for purchasing authorities and providers:

> *. . . develop and implement local arrangements to manage the entry of such drugs into the NHS . . . and in particular to initiate a continued prescribing Beta-Interferon through hospitals.*

One of the key aims was to 'target the drug appropriately at patients who were most likely to benefit from treatment'. In other words, the Circular was giving guidance as to how most effectively Beta-Interferon could be introduced into the NHS as a drug to be prescribed to treat patients. The primary aim of a trial is not to prescribe drugs in order to treat patients, but to test their efficacy. I do not consider that the respondents' policy could at any time have fairly been described as a reasonable way of giving effect to the Circular. The respondents, like others, no doubt honestly and conscientiously believed that the efficacy of Beta-Interferon had not been sufficiently tested. The assumption that underpinned the Circular was that it had been sufficiently tested. A possible outcome of a further trial would be to demonstrate that Beta-Interferon should cease to be a drug prescribed on the NHS. This merely serves to underline how far away the respondents' policy was from an implementation of the Circular. This is not a case in which a health authority departed from the national policy because there were special factors which it considered exceptionally justified departure. The respondents failed to implement any aspect of national policy, principally

because they disagreed with it altogether. They now seek to argue that at least they acted consistently with that policy, although for the reasons that I have given that is plainly not the case. Accordingly, they do not seek to justify their policy as a rational exception to the national policy. That is hardly surprising, since I expect that the situation in which the respondent found themselves when the Circular was issued was not materially different from that faced by most other health authorities. The respondents did not take the Circular into account and decide exceptionally not to follow it. They decided to disregard it altogether throughout 1996, because they were opposed to it. That is something which in my judgment they were not entitled to do.

I conclude therefore that at no time was the policy a proper application of the Circular and that the respondents did not properly take it into consideration.

If I am wrong about that, then the policy became unlawful in about September 1996 when the respondents became aware that any trial had been postponed 'indefinitely' (the Prime Minister's letter from 3rd September); or 'for at least 18 months' (Dr McConville's report of 17th September). The matter was put beyond doubt by Dr Winyard's letter of 10th October which said that the trial had been postponed 'indefinitely' so that, as he said, there was no longer any reason for delaying the introduction of policies in line with the Circular. The respondents' policy had, to use their own word, become well and truly 'unsustainable'. Once there was no trial in prospect, in truth the respondents had no policy at all in relation to the implementation of the Circular, and yet they continued to maintain this unsustainable position. For the reasons given earlier, reliance on the block contract sum was not a reasonable response to the Circular.

I must now return to the £50,000. On the material before me, £50,000 had been included in the ECR budget to neurologists specifically for Beta-Interferon: see Dr McConville's memorandum of 17th September. As I said earlier, Mr Seys Llewellyn told me on instructions that by November, when the estimated overspend for the year was put at £1,185,000, the £50,000 did not exist, because it had not been 'ring fenced'. Evidence as to the financial arrangements between the respondents and the Trust is almost non-existent. But what is clear is that Dr McConville swore an affidavit, on 29th May 1997 saying that 'an alternative available to the respondent when it considered its policy in late October 1996 was to release the £50,000 allocated in the respondent's budget as part of the health investment programme'. The affidavit of Mr Fewtrell which was sworn on the same day does not expressly deal with the £50,000, but in my view it is not inconsistent with the evidence of Dr McConville.

The fact that, in November 1996 it was estimated that at the end of the financial year the respondents would have overspent by more than £1,000,000, is consistent with there being available at that time a sum of £50,000 for the ECR budget allocated specifically for Beta-Interferon.

I am bound to express surprise that the respondents' case on this important aspect of the dispute should have been dealt with in this unsatisfactory way. No explanation has been given as to why, if paragraph 15 of Dr McConville's affidavit was in error, the true position has not been explained in a further affidavit. I am not willing to accept what I have been told on instructions. I shall proceed on the basis of Dr McConville's affidavit, which is entirely consistent with the contemporary documents in relation to the existence of £50,000. The situation was therefore that part or all of the £50,000 could have been released to the Trust, so that the policy embodied in the Circular could have been implemented. That policy was to target Beta-Interferon appropriately by the exercise of clinical judgment, having regard to local resources. If that step had been taken, it is

difficult to see on what basis the respondents could have been have criticised, save for the delay in taking it.

Why was this not done? The reason given by Dr McConville is that the money could only be allocated on a 'first come first served' basis, which was unfair, and that the respondents did not have the resources to enable a more equitable assessment of clinical need of patients across the whole North Derbyshire area to be carried out. I regard this as an irrational reason. If correct, it would be a reason for refusing to make any expensive treatment available in almost all circumstances. When deciding whether to prescribe treatment to a patient, a clinician has to have regard to many factors, including the resources available for that treatment and the needs of and likely benefit to that patient, as compared with other patients who are likely to be suitable for that treatment during the financial year. It is absurd to suppose that, before any patient is prescribed any expensive treatment, a survey must be made of all patients who are, or might be, in need of the same treatment in the area. I do not accept that this was a rational justification for not releasing additional funds.

Indeed, I have considerable doubts as to whether it was the true reason. It is striking that this was not the reason given at the time. In the letter of 18th November 1996 a different reason was given. It was said that the respondents 'could not identify any new money to give priority to the use of this drug'. That was simply not true. They could identify new money, namely the £50,000 referred to by Dr McConville, but decided not to release it. It is implicit in the reasoning now advanced by Dr McConville in her affidavit that she accepts that funds were available at the time. Internally the respondents gave yet another reason. The minutes of the meeting of 19th November state that 'as the clinicians had not accorded the patient priority for the use of Beta-Interferon within the existing contract they could not recommend a change of policy'. I regret to say that I regard that as disingenuous. The patient who was being referred to was, of course, the applicant. It has never been suggested that the reason why the applicant had not been accorded priority for the use of Beta-Interferon was because of an exercise of clinical judgment by the clinicians, and a refusal on their part to make use of the block contract sum for that purpose. I find it most surprising that this excuse (for that it is what it was) was put forward by Dr McConville and Mr Fewtrell in justification of their inability to recommend a change of policy. I therefore reject each of the three reasons variously relied on in justification of the refusal to abandon the policy which had become admittedly unsustainable. None of them could reasonably be relied on.

Mr Seys Llewellyn emphasised two points. First the respondents were under a statutory duty not to overspend: see section 97(1)(a) of the 1977 Act and the Department of Health Circular HC(91)25. Secondly, clinical decisions must always be taken with due regard to the resources available: see, for example, *R -v- Cambridge Health Authority* [1995] 1 WLR 898. I unreservedly accept both propositions as correct. But on the facts of this case, they do not assist the respondents. The respondents had funds available, but chose not to allocate them. As for clinical decisions, they were not for the respondents to take, and it is no part of the applicant's case to suggest that they were.

I conclude therefore that the policy was unlawful because it was not a proper application of the guidance contained in the Circular, and the respondents did not properly take into account the essential requirements of the Circular in adopting and maintaining their policy. In my judgment, the respondents were aware from an early stage that they were not properly applying or taking account of the Circular. They knew that their own policy amounted to a blanket ban on

Beta-Interferon treatment. A blanket ban was the very antithesis of national policy, the aim of which was to target the drug appropriately at patients who were most likely to benefit from treatment. They knew from as early as 12th January 1996 that, if there was no imminent prospect of a trial, it might be difficult to 'hold the line'. Most revealingly of all, the note of the meeting of that date spoke about the possibility of 'creative constraints'. This is surprising language to find in the context of health care.

What they had in mind at this early stage was using the possibility of a trial as a creative means of avoiding the implementation of national policy. The reason was plainly that the respondents disagreed with that policy. I fear that 'creative' is a euphemism for 'disingenuous'. The prospect of a trial served its purpose as a creative constraint until that prospect disappeared. Thereafter the respondents resorted to other unacceptable and inconsistent excuses in seeking to hold the line, and hang on to their unsustainable position. My conclusion on this issue, based on the reasons that I have given, is sufficient to dispose of this application, subject to questions of relief.

Other arguments

Mr Grace advanced a number of other arguments. These included the submission that since the respondents' policy involved a blanket ban, it amounted to an unlawful fetter of its discretion to make funds available for Beta-Interferon treatment. He also submitted that the respondents acted unfairly in writing the letter of 19th February 1996, which concealed the true nature of their policy, thereby denying the applicant the opportunity of making representations about the appropriateness of the policy, whether to the respondent, the department, ministers or others. This was and is a high profile case, and pressure might have been brought to bear if the applicant had known the true position.

I also heard arguments that the letter of 19th February 1996 gave rise to a substantive legitimate expectation that the question whether the applicant received Beta-Interferon treatment would be a clinical decision, made by neurologists at the specialist centre, taking into account the limited funds available; alternatively that the letter gave rise to a procedural legitimate expectation that, before the respondents decided to implement a policy which was materially different from that which was represented by the letter, they would give the applicant the opportunity to make representations as to why such a policy should not be implemented. Having regard to the clear conclusion that I have reached on the main *Wednesbury* unreasonableness point, it is unnecessary for me to lengthen this long judgment still further and deal with these other issues. Accordingly, I do not propose to do so.

Relief

If I were satisfied that the respondents now had in place a policy which does reasonably apply national policy, I would not have been minded to grant relief. The present position however is far from clear. As I said earlier, the report of Dr McConville of 1st April 1997 refers to the fact that the 1997/1998 contract includes a statement in relation to Beta-Interferon that the respondents will consider 'special cases' as ECRs, but that the position reflects an impasse, is probably not sustainable and is out of line with other purchasers who appear to have allocated a budget for Beta-Interferon to the providers.

It is not clear what is meant by 'special cases' or why Dr McConville is of the view there is an impasse. As for what Mr Seys Llewellyn told me about an agreement 'in principle' between the respondents and the Trust that the 1997/1998 block contract sum for neurological services generally will be increased by

£40,000, I would comment that this is not evidenced by any affidavit still less by any document. For that reason alone, given the unfortunate history of this matter, it would, in my view, be quite wrong to refuse relief merely on the basis of what I have been told.

In my judgment the appropriate relief to give effect to my judgment is:

1. To grant a declaration that the policy adopted by the respondents during 1996 in relation to EL(95)97 was unlawful;
2. To order certiorari quashing the decision reported in the letter dated 18th November 1996 from the Trust to the applicant's father; and
3. To make an order of mandamus requiring the respondents to formulate and implement a policy which takes full and proper account of national policy as stated in EL(95)97.

Mr Grace submits that I should also order that the applicant's case be reconsidered in the light of the lawful policy that will be implemented by the respondents. I do not consider that it is appropriate to make such an order, since it would lie against the Trust who are not parties to this application. However I have no reason whatsoever to doubt that if, as I would expect, the respondents fall into line with the other North Trent purchasers and allocate to the Trust a budget for Beta-Interferon, then the applicant's case will be reconsidered, and that subject to clinical judgment and availability of resources he will receive the treatment.