Neutral Citation Number: [2006] EWHC 171 (QB)

Case No: CO/10217/2005

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 15/02/2006

Before :

THE HON. MR JUSTICE BEAN

- -

Between :

THE QUEEN on the application of ANN MARIE ROGERS	**Claimant**
- and -	
SWINDON NHS PRIMARY CARE TRUST	**Defendant**
- and -	
THE SECRETARY OF STATE FOR HEALTH	**Interested Party**

Ian Wise
(instructed by **Irwin Mitchell**) for the **Claimant**

Philip Havers QC and Matthew Barnes
(instructed by **Bevan Brittan LLP, Bristol**) for the **Defendant**

Eleanor Grey
(instructed by the **Office of the Solicitor for the Dept. of Health)** for the **Interested Party**

Hearing dates: 6th and 7th February 2006

- - - - - - - - - - - - - - - - - - - -

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

THE HON. MR. JUSTICE BEAN

Mr Justice Bean :

1. In this application the Claimant, Ann Marie Rogers, claims that the Defendant, the Swindon NHS Primary Care Trust, has unlawfully refused to provide her with Herceptin to treat her breast cancer. In particular the Claimant claims that:

    a) The Trust has unlawfully failed to act in accordance with what is said to be a Direction of the Secretary of State by providing Herceptin only in exceptional cases;

    b) The formulation and application of the Trust's policy has been arbitrary and irrational, and

    c) The decision of the Trust not to provide Ms Rogers with Herceptin is contrary to her rights under the Human Rights Act 1998 and the European Convention on Human Rights. All counsel made submissions first on domestic law without considering the Convention, then on the impact of the Convention, and I shall follow the same course.

2. The Claimant is 54 and lives in Swindon. She has three adult children and two young grandchildren. Prior to her diagnosis of breast cancer she had run the restaurant side of her sister's public house but since her treatment has been unable to carry on working.

3. Ms Rogers first noticed a lump in her breast in October 2004. She went to her general practitioner the following day and was given an appointment for a mammogram at her local hospital in Swindon which was conducted on 24th November 2004. The mammogram result was initially thought to be normal but subsequent biopsies revealed invasive carcinoma.

4. In January 2005 the Claimant underwent a mastectomy, breast reconstruction and auxiliary surgery. Following a period of recovery from this surgery she commenced chemotherapy in March 2005. This course of chemotherapy lasted until 4th July 2005. She found this treatment very difficult due to its gruelling side-effects.

5. Following the course of chemotherapy she embarked on a course of radiotherapy at the Churchill Hospital in Oxford in August and September 2005. This involved her travelling from her home in Swindon to Oxford every day for 5 weeks. At this time she also had adjuvant hormone therapy.

6. In the meantime the Claimant's son had discovered on the internet that there was a type of breast cancer known as HER2 positive which could be treated by Herceptin. Towards the end of her chemotherapy she accordingly asked her consultant, Dr Cole, if she could be tested for HER2 and on 30th June 2005 was tested positive. In August 2005 Dr Cole wrote to the medical director of the Swindon and Marlborough NHS Trust informing him of the "exciting" results of the Herceptin trials that had been presented to the American Society of Oncology in May 2005 and asked whether Ms Rogers could pay for Herceptin whilst remaining an NHS patient; but the answer was that she could not. In due course Dr Cole agreed to treat the Claimant with Herceptin on a private basis and on 27th October 2005 began treatment at the Ridgeway

Hospital, Swindon. Although Ms Rogers had to pay for the drug she did not have to pay for the medical input as Dr Cole waived his fees.

7. Herceptin is given by a loading dose followed by a further 17 doses given at 3 week intervals. The estimated cost (including VAT) of the course of treatment was £26,328.22. Ms Rogers did not have this money. She borrowed £5,000 from which she paid for her first two treatments each of which cost £1,950. She could not afford to pay for her third course. Given her diagnosis she was unable to re-mortgage her house.

8. It was against this background that the Claimant sought legal advice. Her solicitors sent a letter before claim on 22nd November 2005. The response, the same day, was that, although Herceptin is not prescribed by the NHS in the Swindon area, the Trust would review each individual case. Dr Cole duly applied to the Defendant PCT for funding for the Claimant's Herceptin treatment. As we shall see, the application was rejected.

9. This application was issued on 12th December 2005. On 21st December Charles J granted permission to apply for judicial review and ordered D to fund and provide Herceptin for C from 5th January 2006 (the date of her next course of treatment) until the determination of this application or further order. Ms Rogers duly received treatment on 5th January and again on 26th. In her witness statement she says:

> "It is only now with the Herceptin that I feel that I have been given a small part of my life back and I have been able to start thinking about the future."

10. Breast cancer is the most common form of cancer in women and is the greatest cause of death in the UK for women aged under 65. Traditional forms of treatment for breast cancer have been mastectomy, chemotherapy and radiotherapy. There has been considerable research into treatments for this cancer, the causes of which remain unclear.

11. Breast cancer can occur in a number of forms, including 'HER2-positive' breast cancer. HER2 is a protein found on the surface of certain cancer cells. It is made by a specific gene called the HER2/neu gene. HER2 is a receptor for a particular growth factor called human epidermal growth factor, which occurs naturally in the body. When human epidermal growth factor attaches itself to HER2 receptors on breast cancer cells, it can stimulate the cells to divide and grow. Some breast cancer cells have far more HER2 receptors than others. In this case, the tumour is described as being HER2-positive. It is thought that about 1 in 5 women with breast cancer will have HER2-positive tumours.

12. Tumours that are HER2-positive tend to grow more quickly than other types of breast cancer. A drug called trastuzumab has been developed to be effective against HER2-positive breast cancer. It is a type of monoclonal antibody. Monoclonal antibodies are treatments that can target particular proteins within the body. An HER2 test can assess whether a particular cancer has a specific receptor on the surface of the cancer cells.

13. Trastuzumab attaches itself to the HER2 protein and stops human epidermal growth factor from reaching the breast cancer cells and stimulating their growth. Trastuzumab only works in people who have high levels of the HER2 protein.

14. Herceptin is the trade name given by Roche to the drug trastuzumab. Herceptin was licensed to treat secondary or late stage breast cancer in March 2002 but is not currently licensed for the treatment of early stage breast cancer. The manufacturer has first to obtain a licence from the European Medicines Agency (EMEA); then the drug will be appraised by the National Institute of Health and Clinical Excellence (NICE), which is responsible for providing national guidance on treatments and care in the UK.

15. Adjuvant Herceptin (that is treatment of breast cancer with Herceptin along with other treatments such as chemotherapy) has been the subject of trials in the USA and elsewhere. Results were first presented to the annual meeting of the American Society of Oncology in May 2005 and were published in two papers in the New England Journal of Medicine (NEJM) on 20th October 2005. According to Dr Murray Brunt, a consultant clinical oncologist whose report was part of the evidence before me, the trials showed significant benefits to those patients who had been given Herceptin. Dr Brunt recognises the potential cardiac side effects of Herceptin and notes that of the 1694 patients who received the drug nine developed severe congestive heart failure although there were no deaths.

16. The National Cancer Research Institute (NCRI) is a coalition of cancer charities and research bodies in the UK. On 14th December 2005 it published *UK Clinical Guidelines for the Use of Adjuvant Trastuzamub (Herceptin) Following Chemotherapy in HER2-positive Early Breast Cancer.* This document considered the trial reported in the New England Journal of Medicine and two other trials of Herceptin and concluded: "these trials have all reported considerable therapeutic benefit with around a 50% reduction in the risk of recurrence when trastumazub was given in combination with or following chemotherapy." The NCRI recommended that "women should be considered eligible for adjuvant trastumazub if they fit the following criteria:

    a) Have primary invasive breast cancer that is confirmed as HER2 positive …

    b) Are eligible for and receive adjuvant chemotherapy.

    c) Have normal left ventricular ejection fraction (LVEF) (though particular care was recommended in the case of patients aged over 50 with an LVEF of 55% or less)…

    d) Have none of the [listed] …. cardiac contraindications …

    e) Have an adequate baseline heptatic, renal and haematological function.

    f) Have no evidence of metastistic spread."

I will refer to patients who satisfy all these criteria as "the eligible group".

17. I have already noted that Herceptin is licensed for late stage breast cancer. At that stage Herceptin is given with a range of other treatments. Dr Brunt records that many of his patients who have relapsed received Herceptin for more than two years and he still has survivors from 2001/2002. The cost of treatment (including Herceptin) for late stage breast cancer is considerable and may be in excess of £100,000.

18. There are, however, some who counsel caution, albeit anonymously. On 12 November 2005, an unsigned editorial appeared in the *Lancet*:

> "…it is clear that Herceptin can precipitate severe heart failure in some patients. The best that can be said about Herceptin's efficacy and safety for the treatment of early breast cancer is that the available evidence is insufficient to make reliable judgements. It is profoundly misleading to suggest, even rhetorically, that the published data may be indicative of a cure for breast cancer"

The editorial concluded by warning of the need for caution in the debate about the availability of Herceptin to women with early stage breast cancer. A letter from 19 signatories in the 14th January 2006 edition of the *Lancet*, while accepting the need for caution, criticised the overall tone of the editorial as "inappropriately negative", and urged that women in the eligible group, once fully informed, should have the right of access to treatment if they so choose.

The Defendant's policy and its decision-making process

19. When reaching decisions in relation to the commissioning of pharmaceuticals, the Defendant has two main sources of guidance. The first is NICE. The second is the Swindon Clinical Advisory Forum ("CAF"), a committee with representatives of the NHS agencies providing services to Swindon residents, and including Patient Forum representation. The role of CAF is to review evidence in order to formulate clear health and healthcare priorities and to develop a coherent system for their implementation. In doing so, CAF looks at the absolute merits of a prospective treatment and the relative merits judged against other priorities. The CAF makes recommendations to the Trust's Professional Executive Committee, a subcommittee of the Board..

20. Further advice is received from local Cancer Networks. The Defendant receives guidance on policy making with regard to issues relating to cancer from the Avon Somerset and Wiltshire Cancer Service ("ASWCS"), and, since Oxfordshire is part of the Trust's catchment area, the Thames Valley Cancer Network ("TVCN"). The Defendant adheres to guidance from ASWCS, and takes into account guidance from the TVCN.

21. The Defendant's Service Level Agreements with hospitals and other health care providers do not provide funding for the off-licence treatment of early stage breast cancer with Herceptin. Some drugs <u>are</u> funded for off licence purposes. The example I was given is of drugs used in paediatric medicine, many of which are widely used, have a long safety record, and are licensed for adult use, but have not been licensed

for child use, possibly because of the ethical and practical difficulties in carrying out trials of medicines on children. But these are exceptions to the general rule.

22. At the time when the use of Herceptin for the treatment of early stage breast cancer was first being considered by the Defendant in the summer of 2005, the Trust had no specific policy in relation to it. In the circumstances, the following procedure set out in the Trust's Commissioning Policies document applied:

> "Where Swindon PCT does not have a policy in place for a healthcare intervention, and in circumstances where an individual patient has a special healthcare problem that presents an exceptional need for treatment, Swindon PCT will consider such cases on their own merits. These 'exceptional cases' are considered by Swindon PCT's Clinical Priorities Committee."

23. The Trust's Clinical Priorities Committee ("CPC"), is made up of a range of health professionals, Primary Care Trust managers, a Patient and Public Involvement Forum member, and is chaired by a non executive director of the PCT. It acts as a formal sub-committee of the Defendant's Board, responsible for considering requests for exceptions to the Defendant's commissioning policies. In cases of urgency it acts through an Urgency Panel, and did so in Ms Rogers' case. There is a right of appeal from the decision of the CPC to an Appeal Panel who may make a recommendation to the Board as to the decision which should be taken.

The views of the Secretary of State

24. On 5 October 2005 the Secretary of State for Health, the Rt Hon Patricia Hewitt MP, issued a press release headed "Hewitt fast-tracks cancer drug to save 1000 lives" in which she stated:

> "Herceptin has the potential to save many women's lives and I want to see it in widespread use on the NHS. Today I am asking Professor Mike Richards [the National Cancer Director] to ensure that the facilities are put in place to enable women who require it to be tested. I want the licence for Herceptin to be granted as quickly as possible, without compromising people's safety, and to be available within weeks of the licence being given. I share the huge frustration of many women about the delays in getting Herceptin licensed. I am determined to take action, and this represents a major step forward in our fight against cancer."

25. This press release, especially the headline, must have been very encouraging for early stage breast cancer sufferers, such as the Claimant, who sought treatment with Herceptin.

26. On 25 October 2005 the Secretary of State made a speech on breast cancer which was both more detailed and more nuanced than the press release. It appears to me to have been drafted with great care. She said:

"Any patient diagnosed with cancer wants to know that they will have access to the best possible treatment and care and we are committed to making sure that they get it.

Since I became the Health Secretary I have shared the huge frustration of many women about the delays in accessing new cancer drugs, in particular, Herceptin.

We know that Herceptin has the potential to work for around 1 in 4 women who are diagnosed with early stage breast cancer; those who test HER2 positive. It is important that we and the media do not give the wrong impression that it is suitable for everyone.

Nevertheless, even among those 1 in 4, it has the potential to save as many as a thousand lives a year.

The manufacturers have not yet applied for a licence for prescribing Herceptin for early stage breast cancer and I urge them again to get their application in as quickly as possible.

This leaves us with a difficult dilemma. The drug is already licensed and approved for late stage breast cancer but not for early breast cancer. There are some concerns amongst clinicians that it can cause serious cardiac problems for a small number of women who take it. And yet the early evidence suggests that it can be extremely effective for some early stage cancers which is why it has been fast tracked to NICE. I know that patients and clinicians alike will have seen the evidence presented recently in the New England Journal and will be very keen as patients to discuss the potential benefits of the drug.

As with other unlicensed drugs, it is down to individual clinicians to decide whether or not to prescribe Herceptin for a woman who has tested positive for HER2. The clinician has to make this decision after discussions with the woman about the potential risks and taking into account her medical history. It is the patients and clinicians who are the best people to make that decision. But because it has not yet been licensed or evaluated for early stage breast cancer, PCTs must also be involved and will have to decide whether to support the clinicians' decisions and pay for Herceptin. I want to make it clear that PCTs should not refuse to fund Herceptin solely on the grounds of its cost.

I know that some PCTs are already under financial pressure and may have to make difficult trade-offs in priorities to fund this new treatment for women who want it and whose clinicians want it for them. Although that will not be easy, I believe it is the right thing to do, particularly as they will be managing it over two financial years.

As you know, some weeks ago I have asked Mike Richards, the National Cancer Director, to ensure that testing arrangements are put in place as soon as possible so that patients who may benefit from Herceptin are identified in good time. That is happening.

> And I have asked the National Institute for Health and Clinical Excellence to start on a fast track appraisal of the use of Herceptin in parallel with the licensing process so that they can issue their guidelines to the NHS Herceptin within weeks of the licence being given.
>
> I should stress that the steps I am taking today do not, in any way, replace either the licensing by the European Medicines Agency or the approval process by the National Institute for Health and Clinical Excellence. They are vital and will continue to play the crucial role in ensuring the safety and cost effectiveness of any drug used by the NHS."

27. The Department of Health e-mails a weekly Bulletin to NHS and local authority chief executives and directors of social services. Chief Executive Bulletin Issue 294 for the week 4-10 November 2005 contained the following item:

> ***Herceptin for early stage breast cancer***
>
> On 25 October 2005 the Secretary of State announced:
>
> "It is down to individual clinicians to decide whether…….to prescribe Herceptin for a woman who has tested HER2 positive……after discussions with the woman about potential risks and taking into account her medical history. I want to make it clear that PCTs should not refuse to fund Herceptin solely on the grounds of its cost."
>
> This applies to women prescribed Herceptin for early stage breast cancer ahead of a decision on licensing or NICE appraisal. PCTs should not rule out treatments on principle but consider individual circumstances. Further information: Lindsay Wilkinson, 020 7972 4819."

28. All parties are agreed that this announcement in the Bulletin was intended to be an official communication by the Secretary of State to the Defendant and other Trusts. As will be seen later, there is a disagreement as to whether it amounted to a Direction or merely to guidance. It is also common ground that neither the press release of 5 October nor the speech of 25 October amounted to guidance, still less to Directions. The Bulletin contains extracts from the speech, but the full text of the speech was not distributed to the Defendant and other Trusts.

29. The Secretary of State gave evidence to the House of Commons Select Committee on Health on 6 December 2005, very much on the lines of her 25 October 2005 speech. Again, it is common ground that what she said then cannot constitute guidance, let alone directions; and since her evidence does not in my view add to or subtract from any party's case it is unnecessary to consider whether it is technically admissible. Mr Wise also sought to rely on some answers to oral questions given by the Minister of State for Health, Jane Kennedy MP. I do not think, in fact, that Ms Kennedy's answers take the matter any further: but the courts should in any event be slow, when ascertaining Government policy, to attach weight to oral answers in Parliament to supplementary questions, given in the cut and thrust of Question Time.

The Defendant's decisions on the Claimant's application

30. On 7 November 2005, the ASWCS Commissioning Group met. Among other things, they discussed the off licence provision of Herceptin for early stage breast cancer. Item 7 of the minutes noted that:

> "It was agreed by the SHA's [Strategic Health Authorities] and the PCT's that the Network as a whole will manage the requests for Herceptin from now until NICE approval next July by the use of exceptional funding panels through each PCT when the clinicians put patients forward."

31. The Swindon CAF met on 18 November 2005. Jane Leaman, the Defendant's Director of Public Health, tabled a paper on Herceptin, which set out the background; a review of the evidence; the current licensing position of Herceptin; comment on the articles published in the New England Journal of Medicine and the Lancet; an outline of the Department of Health's position; and what she recommended as the PCT's policy.

32. The documents before the CAF included, among other things, a policy statement from ASWCS, which read:

> "From 5th October 2005, all newly diagnosed women with early breast cancer will be offered HER2 tests. Following this, the routine use of herceptin will be introduced if and when NICE guidance is published in 2006…Until this time, the local NHS will not support the routine use of herceptin in HER2+ve women with early breast cancer. However, a clinician may ask a PCT to approve the use of herceptin in exceptional personal circumstances. All PCT's have well established mechanisms to review such requests on a named patient basis."

Jane Leaman recommended that the PCT should review each patient's case where the managing clinician believed that Herceptin should be considered as part of the patient's treatment to see if there were any exceptional circumstances evident. This was in effect a decision not to treat Herceptin as an exception to the PCT's general policy on off-licence drugs.

33. On 22 November 2005, Irwin Mitchell, on behalf of the Claimant, wrote a letter before action stating that, if the Defendant did not fund appropriate health care treatment, and in particular, a course of Herceptin, they would apply for judicial review. Ms Leaman responded by letter on the same date setting out the Trust's position in relation to Herceptin; and added that although there had been no application on the Claimant's behalf for exceptional funding, the Defendant would be contacting the Claimant's treating clinician, Dr Cole, seeking further information by 2 December 2005.

34. In fact, the Defendant did treat the Claimant's solicitors' letter as a request for exceptional funding. Accordingly, on 23 November 2005 the Defendant sought the information required to consider such an application from Dr Janson, the Claimant's GP, and Dr Cole, and wrote to Mrs Rogers to inform her of the action proposed .

35. Dr Janson responded to the Defendant's request for information by a letter dated 29 November 2005 setting out in brief the background to the Claimant's condition. The letter stated that she had borrowed money from her sister for earlier treatments, and would have to mortgage her house to continue with the course.

36. Dr Cole responded to the Defendant's request for information by a letter dated 30 November 2005, and enclosing a completed application for exceptional funding. Under section 10, dealing with *"Proof of Exceptionality. Rationale for bringing this case to the Clinical Priorities Committee"*, Dr Cole wrote, among other things, *"Mrs Rogers is not an exceptional case."* As he has confirmed in his witness statement, he could not distinguish between the Claimant's case and the 20 or so other residents of the Swindon area in the same position. His view was that all of them who wished to have Herceptin treatment should be funded by the Trust.

37. At around the same time, a request for Herceptin treatment was made to the Defendant on behalf of another patient. In the circumstances, and following further correspondence from Irwin Mitchell in relation to the timing of the hearing of the CPC, dated 1 December 2005, an urgent meeting of the CPC was arranged for 6 December 2005. Irwin Mitchell were notified of this by Ms Leaman by a letter dated 1 December 2005.

38. On 5 December 2005, Ms Leaman spoke directly to Dr Janson about the Claimant in order to obtain as much information as possible. The file note of the conversation reads as follows:

> "Contacted Dr Janson to follow up referral form and discuss if there are any extenuating circumstances that wish to be considered for this case. Dr Janson confirmed that he has spoken to patient about this and discussed possible circumstances such as being a carer but there are none."

39. A note was prepared for the CPC setting out the background, research, and advice given to the Defendant in relation to Herceptin, as well as the relevant policies, including those set out above.

40. The CPC duly met on 6 December 2005, and considered two applications for funding for Herceptin, the Claimant's and one other. Prior to considering these two applications, the panel were reminded that cost should not be a consideration when reviewing applications for Herceptin. Further, the CPC were reminded of their role, which was to consider whether there were any exceptional circumstances surrounding these individual cases that would warrant the provision of Herceptin. Jane Leaman then introduced the cases and presented the evidence available. The CPC considered the question of exceptional clinical or personal circumstances, and concluded that there were none.

41. On 16 December 2005, Irwin Mitchell sent an e-mail to Bevan Brittan, solicitors for the Defendant, informing them that the Claimant would like to appeal against the decision of the CPC, in accordance with the Trust's procedures. The appeal was expedited, and was heard on 20 December 2005. According to their chairman, Mr Fishlock, the panel focussed on four points in particular:

    i) The statement by Dr Cole that *"Mrs Rogers is not an exceptional case"*, together with the fact that she was one of about 20 patients who would stand to benefit from Herceptin per year in North Wiltshire.
    ii) The fact that a member of Ms Rogers' family had died from a similar disease.
    iii) Dr Cole's view that the Claimant had a 43% chance of being alive after 10 years.
    iv) Dr Cole's statement that *"it is likely that she has a greater absolute benefit from Herceptin than somebody with a more favourable prognosis."*

42. The panel concluded that these four points put the Claimant into what they described as "a grey area between unexceptional and exceptional". The terms of reference to the appeal panel required them to refer the case back to the CPC, or on to the Defendant's Board. They decided to refer the case on to the Board so the Board could consider whether the case was exceptional on the basis of the four points the appeals panel had identified.

43. As a result of the decision of the appeals panel, Janet Stubbings, the Defendant's Chief Executive called a Board meeting, which took place on 21 December 2005. She opened the meeting with a summary of the Trust's policy for off licence drugs, and how the Claimant's case had progressed. William Fishlock then summarised the appeal panel's discussion of the case. Ms Stubbings then gave her opinion that when considering exceptionality, the case should be considered against those who could be considered eligible for the treatment. Throughout the meeting, Janet Stubbings referred to *"supporting treatment by Herceptin"* rather than *"funding Herceptin"*. She advised that the Board should not consider the issue of money.

44. In relation to the four points raised by the appeal panel, the Board concluded that: in relation to point (i), exceptionality should be considered in the context of women who met the eligibility criteria, rather than the population as a whole; point (ii) had been taken into account in the assessment of prognosis; as to point (iii), a number of women would have a poor prognosis, and this could not therefore be described as individual exceptionality, but might inform eligibility in any further policy; and, on point (iv), there was insufficient evidence to support the conclusion of Dr Cole that patients with a poorer prognosis are likely to benefit more from this treatment. There was unanimous support for upholding the decision of the CPC.

45. Later on 21 December 2005 the case came before Charles J who granted permission and interim relief and gave directions for the substantive hearing.

46. Many authorities and trusts have taken a different view from the Defendant's and funded Herceptin treatment for all applicants in the eligible group. These include Cheshire and Merseyside; Greater Manchester; Hampshire and Isle of Wight; Leicestershire, Northamptonshire and Rutland; North and East Yorkshire and North Lincolnshire; Northumberland and Tyne and Wear; South West Peninsular; and South Yorkshire Health Authorities, together with Lancashire and South Cumbria Cancer

Network; all Primary Care Trusts in Norfolk and in Northern Ireland; and many PCTs in London, Staffordshire, Cambridgeshire, Somerset and elsewhere.

Legal submissions

The Secretary of State's Bulletin

47. The National Health Service Act 1977 provides:

> "1. It is the Secretary of State's duty to continue the promotion in England and Wales of a comprehensive health service designed secure improvement:
>
> (a) in the physical and mental health of the people of those countries, and
>
> (b) in the prevention, diagnosis and treatment of illness
>
> And for that purpose to provide or secure effective provision of services in accordance with this Act.
>
> 2. 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 purposes 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.
>
> 3. (1) It is the Secretary of State's duty to provide throughout England and Wales, to such extent as he considers necessary to meet all reasonable requirements –
>
> (c) medical, dental, nursing and ambulance services, …….
>
> …….
>
> (f) such other services as are required for diagnosis and treatment of illness"

48. The duties under sections 3 are not absolute: see *R v Secretary of State for Social Services and Others, ex parte Hincks* [1980] 1 BMLR 93, and also *R v North and East Devon HA, ex parte Coughlan* [2001] QB 213 at paras 23-25.

49. Regulation 3 of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002, SI/2002/2375, delegated the general duties of the Secretary of State found in section 2 of the 1997 Act to Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs) as from 1st October 2002.

50. Swindon PCT was established by Order made pursuant to section 16A of the National Health Service Act 1977. The principal duties of PCTs, set out in section 15 of the Act, are "to administer the arrangements made in pursuance of this Act for the provision of primary medical services ….".

51. Directions may be given by the Secretary of State to PCTs (among others) about the exercise of any of their functions, pursuant to section 17 of the 1977 Act. Section 18 requires that "any directions given by the Secretary of State under section …. 17 … shall be given by regulations or by an instrument in writing." Section 126(3C) provides that "any person to whom directions are given in pursuance of any provision of this Act…..shall comply with the directions."

52. The origin of the power to issue guidance is to be found in the general enabling powers of section 2. "Guidance" must be distinguished from "directions". The obligation to take account of guidance is discussed in the judgment of Dyson J (as he then was) in *R v North Derbyshire Health Authority, ex p. Fisher* (1998) 38 BMLR 76 at 80-81, 89 – 90, which all parties accepted as good law. Dyson J said:

> "If the circular provided no more than guidance, albeit in strong terms, then the only duty placed upon health authorities was 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 if they misconstrued or misapplied it whether deliberately or negligently: see *EC Gransden & Co Ltd v Secretary of State* (1987) 54 P&CR 86 at 93-4. 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."

53. Applying these observations to the present case, I have no doubt at all that the relevant paragraph of the Chief Executive Bulletin for 4-10 November 2005 constituted guidance rather than directions. The high point for the Claimant is the use of the word "should" in the injunction that "PCTs should not rule out treatments on principle but consider individual circumstances". However, "should" is not the same as "must"; and there is nothing in the remainder of the Bulletin item to indicate that the draftsman or editor really meant "must", nor (in Dyson J's phrase) to demonstrate clearly an intention to give directions.

54. Mr Wise's next argument was that even if the sentence I have just quoted from the Bulletin was no more than guidance, the Trust failed without good reason to comply with it, since a policy to refuse funding save in exceptional cases amounts to ruling out treatment in principle. But the Bulletin should not be construed as if it were a statute. The qualifying phrase "but consider individual circumstances" makes it clear to me that the guidance was intended to advise against a rigid rule with no exceptions. The full text of the 25 October speech which led to the Bulletin entry makes it clearer

still. If the Secretary of State had intended to issue guidance that pending the verdict of NICE PCTs should (as so many have done) fund Herceptin treatment for all women in the eligible group, it would have been easy enough to say so clearly. But, at least so far, she has not done so. Her position, as communicated by Ms Grey on her behalf, is that Trusts must consider the evidence about Herceptin for themselves; must not refuse treatment solely on the grounds of cost nor maintain a blanket policy of refusal on the grounds of the absence of regulatory approval; but must consider the individual circumstances of each case.

Is the Defendant's policy on Herceptin arbitrary?

55. Mr Wise made four points under this heading. These were that the policy is unclear because it is not in writing; that the definition of an "off-licence" drug is unclear; that it is unclear when a clinician can obtain drugs for a patient simply by prescribing them; and that whether or not the "exceptionality" policy for the funding of Herceptin treatment for early stage breast cancer sufferers is clear, it is arbitrary and unlawful in any event.

56. There is no substance in the first three points. Herceptin treatment for early breast cancer fell within the scope of the Trust's Commissioning Policies document set out at paragraph 22 above. There was no policy that it could be routinely funded once prescribed, nor that its funding was absolutely prohibited, but rather that it could only be funded if the Clinical Priorities Committee considered that the case was exceptional among the eligible group. This appears to have been the usual position for off-licence drugs (those licensed for use by *some* patients, but not for the patient in respect of whom the application is made); but in the field of paediatrics in particular the Trust allows routine prescription and funding of commonly used drugs licensed for use by adults.

57. Mr Wise's fourth point, however, is at the heart of the case. He submits that a policy requiring an applicant for Herceptin to treat early stage breast cancer to show exceptional circumstances (such circumstances not being defined), not among the patient population as a whole but among the eligible group, is arbitrary and unlawful.

58. It is important to emphasise, as both Mr Wise and Mr Havers QC did in their submissions, that this is not a case about the allocation of scarce resources. If it were, the well-known observations of Sir Thomas Bingham MR (as he then was) in *R-v-Cambridge Health Authority ex parte B* [1995] 1 WLR 898, CA would be directly applicable:

> "I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided of doctors were willing to give it, no matter how much the cost, particularly when a life is potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. …. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which

> the court can make. In my judgment, it is not something that a health authority such as this authority can be fairly criticised for not advancing before the court."

59. In this case, by contrast, the Trust have made it clear in both the contemporaneous documents and the submissions of Mr Havers that cost is not the issue in the case. This goes further than the guidance given by the Secretary of State, which is that Trusts should not refuse to fund Herceptin treatment for patients in the eligible group *solely* on the grounds of cost.

60. In a letter to the Department of Health written on Friday 3rd February 2006, the last weekday before the hearing began, Professor Richards, the National Cancer Director, wrote:

> "……my personal view on exceptionality when considering applications to use herceptin [is] that all HER2 positive women who fit the criteria for the HERA trial are in exceptional circumstances compared to other women in the population and indeed to other women with breast cancer. Of course I recognise that this is my personal view and does not constitute DH policy or guidance, and that the PCT was under no obligation to accept or act on this view."

61. The Court of Appeal considered a policy whereby an NHS Trust would only provide treatment in exceptional circumstances in *R v North West Lancashire Health Authority ex p A, D & G* [2000] 1 WLR 977. The respondents were transsexuals who wanted to undergo gender reassignment treatment. The appellant authority refused to fund such treatment save in the event of overriding clinical need, or exceptional circumstances, on the basis that it was low in the list of priorities for public funding.

62. Auld LJ, giving the leading judgment, held that a policy of refusal of funding save for in undefined exceptional circumstances was lawful:

> "As illustrated in the *Cambridge Health Authority* case [1999] 1 W.L.R. 898 and *Coughlan's* case [2000] 2 W.L.R. 622, it is an unhappy but unavoidable feature of state funded health care that regional health authorities have to establish certain priorities in funding different treatments from their finite resources. It is natural that each authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose - indeed, it might well be irrational not to have one - and it makes sense too that, in settling on such a policy, an authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure. Authorities might reasonably differ as to precisely

> where in the scale transsexualism should be placed and as to the criteria for determining the appropriateness and need for treatment of it in individual cases. It is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in "exceptional circumstances" and to leave those circumstances undefined: see *In re Findlay* [1985] A.C. 318, 335-336, *per* Lord Scarman. In my view, a policy to place transsexualism low in an order of priorities of illnesses for treatment and to deny it treatment save in exceptional circumstances such as overriding clinical need is not in principle irrational, provided that the policy genuinely recognises the possibility of there being an overriding clinical need and requires each request for treatment to be considered on its individual merits."

63. The Court of Appeal were considering North West Lancashire's policy on the prioritisation of treatment because of scarcity of resources: and in that context it is to be noted that, as most people would expect, they gave the treatment of cancer as an obvious example of a top priority. But Mr Havers submitted, and I accept, that the same principle applies to a policy based on the absence of regulatory approval. Accordingly, to decide that unlicensed use will not be funded save in undefined exceptional circumstances is not of itself unlawful.

64. Mr Wise submitted that such a policy is arbitrary here because, unless one agrees with Professor Richards that all eligible cases are exceptional, there is no rational basis for deciding on exceptionality. The eligible group are already pre-selected for medical suitability, and any attempt to distinguish between them is impermissible. I have already noted that Swindon had two applications, Ms Rogers and one other, neither of whose cases was regarded as exceptional. Another Trust, Somerset Coastal PCT, agreed to fund Herceptin for one eligible patient: she had a child whose expectation of life was seriously diminished. Swindon do not have to justify that decision – though Mr Havers did not seek to criticise it, and neither would I. They are, however, entitled to rely on the authority of Lord Reid in *British Oxygen Co Ltd v Board of Trade* [1971] AC 610, Lord Scarman in *Re Findlay* [1985] AC 318 and Auld LJ in the *North West Lancashire* case, and say: "if anyone comes forward with an argument that her case is exceptional, we will listen to it; but we will not define in advance what an exceptional case would be".

65. Mr Wise referred me to the observations of Lord Halsbury LC in *Sharp v Wakefield* [1891] AC 173 at 179:

> "……discretion means, when it is said that something is to be done within the discretion of the authorities, that that discretion is to be done according to the rules of reason and justice, not according to private opinion:….according to law, and not humour. It is to be not arbitrary, vague and fanciful, but legal and regular. And it must be exercised within the limit, to which an honest man competent to the discharge of his office ought to confine himself."

66. These dicta, though not often cited these days, are still good law, and no one could quarrel with them. But Swindon are not in breach of them in the present case.

67. Another way of putting the argument on arbitrariness is, as Mr Wise put it, that the Defendant has drawn the cohort or pool among whom the Claimant was required to be exceptional so narrowly as to make the outcome inevitable, and that the selection of that pool (the 20 or so eligible patients in Swindon) is arbitrary or irrational. I confess to having started this hare running, by asking whether an analogy could be found in discrimination law. But on reflection I do not think that the analogy is valid. The Defendant's policy decision is not to fund Herceptin treatment for early stage HER2+ breast cancer sufferers unless individual exceptional circumstances can be shown. Unless that decision is itself irrational, which is the next question, the choice of pool is not arbitrary: it is all those in Swindon affected by the policy.

Is the Trust's policy, or its application in the Claimant's case, irrational?

68. The evidence before me shows that many areas fund Herceptin for all women in what I have described as the eligible group. Their reasoning may be the same as Professor Richards' (in his letter of 3rd February 2006) or not. Neither the Defendant Trust nor the Secretary of State suggests that such a policy is irrational or otherwise unlawful. But there can of course be more than one lawful answer to a policy question. Some may criticise the present state of affairs as a "postcode lottery": others will defend the principle of local autonomy in decision-making. In any event, Mr Wise rightly accepted that what other PCTs do cannot be determinative of Swindon's policy, nor of its lawfulness. Even if Swindon are now in a minority among PCTs (and the evidence is not clear about that), rationality in law is not determined by counting heads.

69. Ms Rogers' case is that her cancer is life-threatening; if she waits for EMEA licensing and NICE appraisal of Herceptin, it may be too late; she is aware of the risk of side effects, but as an intelligent adult she is willing to take the chance. The Defendant's case, on the other hand, while taking the Claimant's arguments into account, is that the system of licensing and appraisal of drug treatments is essential and should not be bypassed; that medical opinion may be moving in the Claimant's favour, but it is not yet unanimous; and that in the absence of unequivocal guidance from the Secretary of State that PCTs should (or a direction that they must) fund Herceptin treatment for all the eligible group, they are entitled to be cautious and wait for EMEA's licensing decision and NICE's appraisal.

70. Many people will think that the more generous policy of authorities such as those listed in paragraph 46 above is a better one than Swindon's. Which is the better policy is a matter for political debate, but it is not an issue for a judge. The question for me is whether Swindon's policy is irrational and thus unlawful. I cannot say that it is.

71. I emphasise, however, that in my view decision-makers in this difficult field must continue to keep their policy under review in the light of the up-to-date evidence and any further guidance from the Secretary of State. If the verdicts from EMEA and NICE are unequivocally favourable the position would plainly be transformed. Even in the meantime, if medical opinion in the UK moves towards a consensus in favour of using Herceptin to treat early stage HER2+ breast cancer sufferers, that is something to which Trusts should give careful consideration.

Have Ms Rogers' Convention rights been infringed?

72. In the Strasbourg case of *Nitecki v Poland* (21 March 2002, Application No 65653/01) the applicant was an elderly man suffering from a life-threatening condition known as amyotrophic lateral sclerosis (ALS). He was prescribed the drug Rilutek to treat the disease but could not afford to pay for it. His complaints to the European Court of Human Rights under Articles 2, 8 and 14 of the Convention were found to be inadmissible. The Court held that:

> ""*an issue may arise under Article 2 where it is shown that the authorities of a Contracting State put an individual's life at risk through the denial of healthcare which they have undertaken to make available to the population generally…*"

The same wording was used in *Pentiacova v Moldova* (4 January 2005, Application No 14462/03).

73. In oral argument Mr Wise conceded that in the light of these observations he could only succeed in the Article 2 claim if I found that the Secretary of State's Chief Executive Bulletin was a direction requiring the funding of Herceptin to all the eligible group, since only then would the treatment be one which the authorities had undertaken to make available to the population generally. Since on that hypothesis the Claimant would have succeeded anyway as a matter of domestic law, Mr Havers did not address oral argument to me on Article 2. Mr Wise's closing written submissions on ECHR issues indicate some second thoughts about the concession. But I consider that it was correctly made, and that it is clear from *Nitecki* and *Pentiacova* that the Claimant has no claim based on Article 2.

74. Turning to Article 3, Mr Wise relied on the recent decision of the House of Lords in *Limbuela and others v Secretary of State for the Home Department* [2005] 3 WLR 1014. The respondents, asylum seekers rendered destitute by Government policies which both denied them support and prohibited them from working, succeeded in their claims that they were being thereby subjected to inhuman and degrading treatment. Mr Havers, however, relied on the observations of Lord Scott of Foscote (at paragraph 66) that "treatment" requires something more than mere failure, and of Lord Bingham of Cornhill (at paragraph 7) that where the case does not involve the deliberate infliction of pain or suffering the threshold is a high one. The threat to Ms Rogers' life is potentially more serious than the destitution inflicted on Mr Limbuela, but it is less immediate. As Mr Havers submitted, it would be curious if Article 3 applied in this case when Article 2 does not. I find that there has been no breach of Article 3.

75. Under Article 8 Mr Wise submitted that the Defendant "failed to give due or any regard to the wishes and fears of the Claimant". But Ms Rogers' real complaint is about the outcome, namely that her application was rejected. The Trust's decision-makers were well aware, as I am, of her fear that without Herceptin her cancer will recur and may be fatal. But Mr Wise could not point to any case which demonstrated that the Claimant has an Article 8 right to the treatment which she seeks. Indeed, the fact that in *Nitecki* the Court held that no separate issue arose under Article 8 points strongly the other way.

Conclusion

76. To summarise:

i) Ms Rogers has not shown that Swindon PCT's refusal to fund her treatment with Herceptin is contrary to a direction or guidance from the Secretary of State for Health;

ii) Many Primary Care Trusts have a policy of funding Herceptin treatment for early stage breast cancer sufferers who are HER2-positive, but Swindon's is not to provide such funding unless the individual case is exceptional. The court's task is not to say which policy is better, but to decide whether Swindon's policy is arbitrary or irrational and thus unlawful;

iii) For the reasons given in this judgment I find that Swindon's policy is not unlawful, whether in English domestic law or under the jurisprudence of the European Court of Human Rights;

iv) Accordingly, despite my sympathy with Ms Rogers' plight, I must dismiss the claim for judicial review.