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ORIGINAL ARTICLE

Law, Patient's Rights and NHS Resource Allocation: Is Eurostar the Answer?

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Abstract Historically attempts to use the courts as a means of challenging decisions to refuse NHS resources have met with little success. However two recent developments, that of the Human Rights Act 1998 and the development of European Union law through the application of Article 49 of the EC Treaty have provided the prospect for a challenge to this position. This article examines the impact of a recent case that of *Watts v Bedford PCT* in which a woman sought to by-pass NHS waiting lists by seeking treatment in France and then claimed reimbursement of the cost of the operation and the possible impact of this case in the context of patients's rights and resource allocation.

Keywords Medical treatment · European Union law · Resource allocation · Human rights

Introduction

Mrs Watts a 72 year old woman had osteoarthritis in both her hips.[1] She sought a hip-replacement operation. There was a standard NHS waiting time of 12 months. Her case was not classed as urgent and she was placed upon the waiting list. Mrs Watts was in severe pain. She therefore asked Bedford PCT to authorise her treatment overseas under the E112 scheme.[2] The Trust refused taking the approach that her case was not specifically supported by the consultant orthopaedic surgeon, was one which was routine in nature and that the standard 12 month waiting time for such an operation did not amount to "undue delay." Judicial review proceedings were launched and in the meantime in January 2003 Mrs Watts travelled to France. She was seen by a surgeon and an anaethetist. The latter was concerned by the fact that she was suffering continuing weight loss and that as a result there could come a point where she was not suitable for surgery. The orthopaedic surgeon recommended as a result that the operation should be undertaken by March 2003. In preliminary judicial review

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[1] *Watts v Bedford Primary Care Trust* (2003). EWHC 2228.

[2] Discussed below under section EU Law and Resource Allocation.

proceedings later in January 2003 it was recommended that she should be re-examined. As a consequence she was seen again by a consultant in the UK. Her condition was consequently reclassified as "soon" which meant that she should be seen within three to four months. The NHS operation date was therefore April or May 2003. Mrs Watts did not wish to delay her operation further. She returned to France where the operation was performed on 7th March 2003. She then claimed the cost of the operation from Bedford PCT some £3900.[3] The Trust rejected her claim.

Historically challenging NHS resource allocation decisions in the courts has been exceedingly difficult. The courts have generally accorded considerable discretion to the health care professions and the National Health Service. What made Mrs Watts case so different was that she was attempting to challenge the decision of the PCT not simply through the route of judicial review which would be generally used in such cases but also using the Human Rights Act 1998 and in addition and perhaps most importantly using EU law. In recent years the EU has had an increasing impact upon health care provision in the UK in areas ranging from clinical trials on medicinal products,[4] through blood safety[5] to the EU Tissue Directive.[6] Does the use of EU law in the *Watts* case as a means of challenging NHS resource allocation present yet another example of the encroaching impact of the EU upon health care delivery in the UK? Indeed is it the case that a trip on Eurostar will in the future be a means of patients obtaining resources which they cannot get quickly at home and just what will be the consequent impact of this upon resource allocation decisions in the NHS?.

This paper examines the impact of the *Watts* case, which is at the time of writing still on-going before the European Court of Justice. First, the paper considers the background to the *Watts* litigation through judicial review cases attempting to challenge resource allocation decisions in the courtroom. The impact of the Human Rights Act 1998 is discussed. Finally the role of EU law is examined. The paper concludes by asking whether the impact of *Watts* and the prospect of the use of EU law in this context will have a revolutionary impact upon patient's rights to access health care services and resource allocation within the NHS or whether the practical difficulties in obtaining access to health services in another jurisdiction may mean that its consequent impact is much more circumscribed.

The Watts Litigation

Judicial Review

In the High Court Mumby J considered her claim in three parts- domestic law, the Human Rights Act and EU law. Here we likewise begin by examining the problems facing litigants

[3] Interestingly in evidence given during the litigation it was suggested that the equivalent operation if undertaken on the NHS would cost some £4000 and if undertaken privately in England would have cost some £6000.

[4] Through the Clinical Trials Directive, Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use OJ 2001 L 121/34.

[5] Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components OJ 2002 l 33/30.

[6] See generally Hervey and McHale (2005) "Law, Health and the European Union" 25(2) *Legal Studies* 228.

such as Mrs Watts using judicial review as a means of challenging resource allocation. Historically the English courts have been unwilling to intervene where case law concerned NHS resource allocation issues. Section 1 of the National Health Service Act 1977 provides that the Secretary of State for Health is under a duty

> "to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement (a) in the physical and mental health of the people in 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."
>
> Section 3(1) further provides that the Minister is obliged
>
> "to provide throughout England and Wales, to such extent as he considers necessary to meet all reasonable requirements:
>
> (a) hospital accommodation,
> (b) other accommodation for the purpose of any service provided under this Act; medical dental nursing and ambulance services;
> (c) such other facilities for the care of expectant mothers and young children as he considers are appropriate as part of the health service;
> (d) such facilities for the prevention of illness and aftercare of persons who have suffered illness as he considers are appropriate as part of the health service."

NHS resource allocation decisions have been challenged over several decades by means of judicial review.[7] Actions in judicial review may be brought against a public body challenging the decision on the basis of illegality, irrationality and procedural impropriety.[8] An action can be challenged on the basis of illegality where a public body acts outside its statutory powers. A decision can be held to be irrational in two situations "one is the barely known decision which simply defies comprehension; the other is a decision which can be seen to have proceeded by flawed logic."[9] The decision will not be found to be substantively irrational unless it is beyond the range of responses which is available to the decision maker.[10] Procedural impropriety applies in a situation in which a public body has acted contrary to the rules of natural justice through the decision maker being biased or through failing to give a proper hearing. There is also the prospect for a challenge where resources have been allocated on a basis which is manifestly discriminatory.[11] This is a *review* and not an *appeal* and thus while a court may review the decision, declare it unlawful and at times strike it down it cannot substitute its judgment for that of the original body- instead the decision may be referred back to the original decision making body to redetermine.

Attempts to use judicial review as a means of challenging NHS resource allocations have been notably unsuccessful. In *R* v. *Secretary of State for Social Service ex parte Hincks* a judicial review action was brought to challenge the refusal of a health authority to provide

[7] Brazier (1993) "Rights and Health Care" in R. Blackburn *Rights of Citizenship* Mansell: C. Newdick "The Organisation of Health Care" in A. Grubb (ed) *Principles of Medical Law* Oxford: OUP (2004). McHale "Enforcing Health Care Rights in English Courts" in Burchill, Harris, Owers (eds) *Economic, Social and Cultural Rights: Their Implementation in English Law* University of Nottingham, Human Rights Centre in association with Justice (1999).

[8] *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374.

[9] Per Lord Woolf in *R v North and East Devon HA ex parte Coughlan* [1999] Lloyds Rep Med 306.

[10] *R v Lord Sackville ex parte A* [1999] 4 All ER 860.

[11] *R* v *St Mary's Hospital NHS Trust ex parte Harriot* [1988] 1 FLR 512.

an orthopaedic unit.[12] The application failed. In the Court of Appeal, Lord Denning held that the Secretary of State's duty under the NHS Act 1977 needed to be read in the light of the financial resources which he had available. In *R v Secretary of State ex parte Walker* a premature baby required an operation to repair a hole in his heart but the resources were not available to stock the necessary intensive care beds.[13] The claim was again rejected. In the Court of Appeal Sir John Donaldson stated that

> "It is not for this court or indeed any court to substitute its own judgment for the judgment of those who are responsible for the allocation of resources."

Subsequent challenges were equally unsuccessful.[14] One of the most well known cases in the 1990's was that of *R* v. *Cambridge District Health Authority ex parte B*.[15] Jaymee Bowen ('Child B'), aged 10, developed acute myeloid leukaemia and had treatment which included a bone marrow transplant. After a period of remission the cancer recurred and it was decided by clinicians that no further treatment was appropriate as the chances of a successful outcome were slim. It was also felt that further treatment would be painful and distressing. Her father sought advice from the United States which suggested that further treatment and a second transplant offered 'a significant chance of success.' He challenged Cambridge and Huntington Health Authority in the courts when they refused to authorise further treatment. Medical evidence was to the effect that the treatment was unlikely to succeed and would also cause considerable pain and distress.'

At first instance in the High Court, Laws J. said that in determining whether to give treatment, the Health Authority must act reasonably and in making the decision, the Health Authority should have regard to all relevant considerations. In this case he said the Health Authority had not taken into consideration the views of B's family. He commented that in a situation where, as here, a patient was at risk of death, the Health Authority had to explain why it had decided not to fund the treatment. However, his judgment was overturned in the Court of Appeal. Sir Thomas Bingham, the Master of the Rolls held that, although the Finance Director of the Health Authority had not spoken directly to the family he had noted the family's interests.

He stated that:

> 'difficult and agonising judgements had to be made as to how a limited budget could best be allocated for the maximum advantage of the maximum number of patients. That was not a judgment for the court.'

Furthermore he commented that

> "it would be totally unrealistic to require the authority to come to court with its accounts and seek to demonstrate that if this treatment were to be provided for B then there would be a patient, C who would have to go without treatment. No major authority could run its financial affairs in a way which would permit such a demonstration."

Sir Thomas Bingham held that in reaching their decision the Health Authority had weighed up the various factors and had not acted unreasonably. Relevant factors were that the treatment was untested and that it could almost be regarded as being experimental in its nature.

[12] (1980) (1979) 123 Sol J 436.

[13] (1987) but not reported until (1992) 3 BMLR 32.

[14] See for example, *R v Central Birmingham HA ex parte Collier* (1988) LEXIS 6 January.

[15] [1995] 2 All ER 129.

There was only around a 1–4% success rate. In addition, the court noted the fact that there were potentially debilitating side effects. Overall, it was decided, the decision of the health authority was not unreasonable.

Subsequent challenges in relation to allocation of NHS resources have been rare and have usually only succeeded where the case concerns a challenge to a particular blanket policy for example, excluding a particular type of therapy. So for example, in *R v North Derbyshire HA exparte Fisher* a blanket refusal of the HA to buy beta inferon for patients with multiple sclerosis was challenged successfully.[16] Similarly in *R v North West Lancashire HA ex parte A,D, and G*[17] a blanket ban on gender reassignment surgery was successfully challenged.

In *R v North and East Devon HA ex parte Coughlan* the decision of a Health Authority to close a residential home for the disabled was overturned in the Court of Appeal.[18] They followed the approach taken in the earlier case of *R v Ministry of Defence ex parte Smith* where Sir Thomas Bingham LJ stated that

> "The more substantial the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable."[19]

However while the prospect of challenges of resource allocation through judicial review does exist nonetheless judicial activism remains limited. Furthermore in cases concerning disputes involving whether medical treatment should be compelled in the face of clinical opposition the courts had also indicated that they were unwilling to compel clinicians to treat. So for example in *Re J*, J was a 16 month old severely handicapped infant.[20] He had cerebral palsy, severe epilepsy and was largely fed through a naso-gastric tube. An order was sought from the court as to whether if he suffered a life-threatening event he should be given life sustaining measures. Here Balcombe L.J. emphasised that the courts would not compel medical treatment.

> "I would stress the absolute undesirability of the court making an order which may have the effect of compelling a doctor or health authority to make available scarce resources(both human and material) to a particular child without knowing whethere there are not patients to whom the resources might more advantageously be devoted . . .{it might} require the health authority to put J on a ventilator in an intensive care unit and thereby possibly to deny the benefit of those limited financial resources to a child who was much more likely than J to benefit from them."

Similarly Lord Donaldson noted that "no doctor could be required to treat a child whether by the court in exercise of its wardship jurisdiction, the parents or anyone."

However there were indications in *R v Portsmouth NHS Trust ex parte Glass* of a different approach.[21] In the Court of Appeal in this case Lord Woolf indicated that while a court would abstain from interference in the exercise of clinical judgment when it could be avoided nonetheless he reserved the power of the court to intervene to require treatment in the patient's best interests. This statement can be seen alongside other judicial statements at that time suggesting an enhanced willingness to scrutinise clinical decision making.

[16] [1977] 8 Med LR 327.

[17] [2000] 1 WLR 977.

[18] [2000] 2 WLR 622.

[19] [1996] QB 517 at p554.

[20] [1992] 4 All ER 614.

[21] [1999] Lloyd's Rep Med 367.

Three perceptible policy issues underpin these decisions. The first was that the courts can be seen as an inappropriate forum for determining policy matters which are of such a "polycentric" nature involving multiple complex issues. Secondly, particularly in those cases involving individual treatment, judicial unwillingness to intervene was reflective of a general judicial unwillingness to become involved in issues concerning clinical judgement. So for example, until recently overt deference to clinical decision making has been a characteristic of judicial responses in clinical negligence actions[22] or in relation to end of life treatment decisions.[23] Thirdly, the individual litigant's ability to challenge NHS resource allocation decisions has been circumscribed by the nature of the judicial review action. The courts have traditionally allowed a degree of room for manoeuvre by the public body. As noted above judicial review is crucially *review* not an appeal against the decision of a public body.

Given this backdrop it was unsurprising that judicial review was not an effective means for Mrs Watts to challenge Bedford PCT in this case and Mumby J recognised this. He overviewed the existing case law and he quoted in particular from the Court of Appeal in *R v North West Lancashire ex parte A* where the judgments had emphasised the need for respect to be given to discretionary decisions of health authorities.

Human Rights

At first instance in Watts the High Court considered the application of the Human Rights Act 1998. While the prospect of a successful challenge to NHS resource allocation through judicial review was remote the passage of the Human Rights Act 1998 introduced a new dimension and the prospect of new challenges.[24] This legislation allows English courts to interpret existing law in the light of the European Convention of Human Rights and ECHR provisions and directly applies to public bodies.[25] It enables the court to issue a "declaration of incompatibility" where existing statute is found to be incompatible with the ECHR.[26] In addition it enables the court to interpret existing law in line with ECHR jurisprudence.[27] The prospect of failure to provide certain NHS resources may thus potentially be challenged using human rights principles. A number of provisions of the ECHR were relevant in this context. First, Article 2 which provides that:

> 'Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.

In *LCB v UK* it was stated that

> "The first sentence of Art 2(1) enjoins the state not only to refrain from the intentional and unlawful taking of life but also to take appropriate steps to safeguard the lives of those within its jurisdiction."[28]

[22] Brazier and Miola (2000) "Bye Bye Bolam" *Medical Law Review* 85.

[23] Though c/f *Bolitho* v *Hackney Health Authority* [1997] 3 WLR 1151.

[24] J. V. McHale and A. Gallagher (2004) *Nursing and Human Rights* Elsevier.

[25] Section 6.

[26] Section 4.

[27] Section 3.

[28] (1998) 27 EHRR 212.

In *Scialacqua v Italy* the Commission took the view that Article 2 did impose an obligation to meet costs of life-saving therapy.[29] On the facts of the case itself a claim that the Italian authorities had breached Article 2 by refusing to fund the cost of allegedly life-saving herbal medicines because these were not included on a list of officially recognised medicines was declared inadmissible. Subsequently in *Osman v UK* the European Court of Human Rights held that Article 2

> "must be interpreted in a way which does not impose an impossible or disproportionate burden on the authorities. Accordingly not every claimed risk to life can entail for the authorities a Convention requirement to take operational measures to prevent that risk from materialising."[30]

Article 3 which prohibits torture, inhuman and degrading treatment may also be applicable. So for example, in *Tanko v Finland* it was held that to failure to provide "proper medical treatment" can contravene Article 3.[31]

Article 8 may also be the basis of a claim. This Article safeguards the interests of the individual in home and family life nonetheless the extent to which it can be effectively utilised to support a claim to health care resources was questioned in R v *North West Lancashire HA ex parte A, D, G*.[32] Here Auld L.J commented that the notion of "respect" for private and family life under Article 8 was not clear-cut. He stated that

> "In determining whether or not a positive obligation exists, regard must be had to the fair balance that has to be struck between the general interests of the community and the interests of the individual, the search for which balance is inherent in the whole Convention."

As this statement illustrates one of the most fundamental problems in attempting to use human rights analysis the problem of conflicting human rights. Indeed this case suggested that little had fundamentally changed with the advent of the Human Rights Act and in such cases concerning conflicting human rights considerations the issues concerned were rarely amenable to effective judicial resolution. The prospect still remains that in some situations there may have been for example, a binding policy which should not have been used or in some cases the decision may have been so irrational as to warrant it being struck down but this would only operate at the margins. However generally speaking the effective utility of the application of ECHR jurisprudence is questionable. So for example, Buxton LJ in *North West Lancashire ex parte A* stated that

> "it is plain that in this case there has occurred no interference with either the applicants private life or with their sexuality. The ECHR jurisprudence demonstrates that a state can be guilty of such interference simply by inaction, though the cases in which that has been found do not seem to go beyond an obligation to adopt measures to prevent serious infractions of private or family life by subjects of the state. Such an interference could hardly be founded on a refusal to fund medical treatment."

In *Watts v Bedford PCT,* the court considered whether her rights under Article 3–the prohibition upon torture and inhuman and degrading treatment had been infringed and under

[29] (1998) 26 EHRR 164.

[30] (2000) 29 EHRR 245.

[31] Case 23634/94 (1994) unreported.

[32] [1999] Lloyd Rep Med 399.

Article 8 the protection of privacy of home and family life. Mumby J initially recognised the prospect for human rights scrutiny here and that such rights may impose positive obligations. However he then went on to quickly dismiss these claims. He found that application of Article 8 was precluded by the decision of the Court of Appeal in *R v North West Lancashire HA ex parte A* in which the Court of Appeal had held that Article 8 did not impose a positive obligation to fund medical treatment.

Mumby J was also of the view that Article 3 was not engaged in Mrs Watts case. Again relying on *NW Lancashire ex parte A* he took the view that Article 3 did not apply to questions which simply involved policy decisions concerning resource allocation. He also relied upon the judgment of Lord Hoffman in the House of Lords in *Matthews v Ministry of Defence*

> "I think it is well arguable that human rights include the right to a minimum standard of living without which many of the other rights would be a mockery. But they certainly do not include the right to a fair distribution of resources or fair treatment in economic terms- in other words, distributive justice. Of course distributive justice is a good thing but it is not a fundamental human right . . ."[33]

Furthermore he was of the view that Article 3 concerned positive conduct which reached a minimum level of severity and involves actual bodily injury or intense physical or mental suffering.

EU Law and Resource Allocation

Nonetheless while the use of human rights jurisprudence in the context of resource utilisation cases seems no more effective than the judicial review on is own there is now the prospect of the courts impacting on NHS resource allocation through the application of European Union law. The third pillar of the judgement of Mumby J in *Watts v Bedford PCT* rested on Mrs Watts claim based upon EU law. Mrs Watts first relied upon the E112 scheme which was in turn based upon Article 22 of Council Regulation 1408/71. This is a regulation which relates to social security. EU law provides that member states have competence to organise their own social security systems.[34] However at the same time this is subject to respect for fundamental principles of free movement recognised under EU law. Article 22(1) of Regulation 1408/71 enables those who may be entitled to social security benefits in one member state to receive services in another member state and then claim reimbursement from another member state. Different provisions exist for different groups. One group which comprises pensioners, those looking for employment in another member state, persons working in another member states and students can claim reimbursement automatically.[35] In other cases Article 22.1.a EEC Regulation 1408/71 provides that in the case of non-urgent treatment prior authorisation is needed and the states have considerable discretion in determining whether authorisation is

[33] [2003] 1 AC 1163.

[34] Article 137(4).

[35] See further T. K. Hervey and J. V. McHale (2004) *Health Law and the European Union* Cambridge: OUP chapter 4; P. Cabral (2004) "The Internal Market and the Right to Cross- Border Medical Care" 29(5) *European Law Review* 673.

given.[36] While prior authorisation can be required before a service is obtained reimbursement cannot be refused where

> "the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his state of health and the probable course of the disease."[37]

The NHS E112 scheme flows from Article 22 of Regulation 1478/01 and provides a framework for the processing of claims made for the cost of treatment given abroad. In order to enable the cost of treatment abroad to be funded by the NHS first it is necessary for a consultant to give an opinion supporting the treatment being given abroad. Secondly, the PCT must also agree to pay the cost of the treatment. Thirdly, the Department of Health must give ultimate approval of the scheme. It was argued by the Department of Health that the threshold test for standard treatment was that of the NHS waiting list time. This was challenged in *Watts*. One argument advanced in the court was that this was inadequate given that the Government itself had stated that existing waiting list times were unduly lengthy.

The operation of Regulation 1408/71 needs also to be seen alongside the operation of the EC Treaty. Article 49 of the EC Treaty provides that

> "Restrictions on the freedom to provide services within the Community shall be prohibited in respect of nationals of Member States who are established in a State of the Community other than that of the person for whom the services are intended."

Mrs Watts relied on Article 49 in addition, and in alternative, to the Article 22 of Regulation 1408/7 claim. It was argued that this Article had the effect that Mrs Watts had a right to the re-imbursement of the cost of her operation in France.

In a whole series of cases the European Court of Justice (ECJ) has held that individuals who obtained medical services in other member states can obtain reimbursement of the cost of those services from their home member state. These decisions are based upon the application of the free movement principles contained in Article 49. Treatment has long been regarded by the ECJ as a "service."[38] So for example, in *Kohll*,[39] Kohll was insured in Luxembourg but sought orthodontic treatment in German. The health insurance fund refused prior authorisation of the treatment and then refused to pay on the grounds that this was not urgent treatment which could have been provided in Luxembourg. The ECJ upheld his claim. In *Vanbraekel* the ECJ held that these principles equally applied in the context of hospital care.[40]

These issues were further explored in *Geraet Smits and Peerbooms*.[41] The ECJ held that medical services fell within the EC Treaty and this applied to hospital services which had been paid for. Furthermore although it was the case that member states could impose limitations on the ability of individuals to access services in another member state these must

[36] E. Mossialos and W. Palm (2003) "The European Court of Justice and the Free Movement of Patients in the EU" 56 *International Social Security Review* 3.

[37] Article 22(2) as amended.

[38] Luisi and Carbone.

[39] Case C-158/96 *Kohll* [1998] ECR-I-1935.

[40] Case C-368/86 *Vanbraekel*.

[41] Case C-157/99 Judgement of 21 July 2001, *Smits and Peerbooms*.

be proportionate and supported by reference to the overriding public interest. In *Muller-Faure* the ECJ went further and drew a distinction between extra-mural and hospital care.[42] In the former it was suggested that there was no requirement for a prior-authorisation rule whereas in the situation of hospital services it was suggested that without such authorisation there was the danger that this would fundamentally undermine the planning of hospital services. However the ECJ indicated that it would be prepared to scrutinise what amounted to "undue delay" and this must relate to the condition of the individual patient rather than to the fact that there were waiting lists. This line of cases was confirmed by the ECJ in *Inizan*.[43] The ECJ has subsequently confirmed that member states can impose some restrictions in situations in which without those restrictions there may be consequent instability to the operation of national health systems. Without this there is otherwise a risk that resource allocation decisions regarding health care made by individual member states are undermined. Such restrictions such as waiting lists may be justifiable as long as these restrictions were necessary and proportionate.[44]

But did these cases apply in the English courts? In *Watts* Counsel for the Secretary of State argued that only Article 22 of Regulation 1408/71 applied but not the free movement right contained in Article 49 of the EC treaty. Article 49 applied to the provision of services however the NHS was not an institution which provides services in the manner encompassed by Article 49. It was argued that "services" within the meaning of the Treaty are those "normally provided for remuneration" and this did not apply to the NHS.[45] However at first instance in *Watts* Mumby J following the earlier ECJ cases held that the free movement principles did indeed apply to the UK in this context. These cases of course concerned health care provision in states where this is provided through social insurance. In contrast in the UK there is the principle that there is state provision of free access to health care through the National Health Service which is funded through taxation. In *Watts* Mumby J relied upon the decision in *Gerats-Smits and Peerbooms* and *Muller-Faure* discussed above. Here the ECJ responding to government submissions, including those of the UK, rejected the argument that these principles would not be applicable in the context of the NHS.

If EU law was applicable however could limitations be imposed? Mumby J agreed that the ECJ cases notably *Muller-Faure* did suggest that limitations such as requiring prior authorisation before treatment was sought abroad could be "justified" but these requirements must be justified by reference to "relevant overriding considerations."

> "provided that the condition is construed to the effect that authorisation to receive treatment in another member state may be refused on that ground only if the same or equally effective treatment can be obtained without *undue delay* from an establishment with which the insured person's sickness insurance fund has contractual arrangements."[46]

Mumby J suggested that "considerations of a purely economic nature" do not justify restrictions being imposed upon a patient from receiving treatment in a different member state earlier than the time stated in the NHS waiting lists. Thus in the case of Mrs

[42] Case C-385/99 *Muller-Faure and van Riet* [2003] ECR I–6447.

[43] Case C-56/01 *Inizan v Caisse primarie d'assurance maladie des Hauts de seine* [2003] ECR I-.

[44] *Muller Faure* and *Van Riet* Case C 385/99 [2003] ECR I-4509.

[45] Article 50 EC.

[46] Note 1 *supra* at para 130.

Watts 12 months would be an undue delay. However on the facts of the case because Mrs Watts had been re-classified due to the deterioration of her condition and the operation was now to be undertaken within 3 to 4 months, Mumby J held that she herself had not suffered undue delay and thus her claim failed. This is something which may be criticised given that Mrs Watts had suffered delay between October 2002 and February 2003-but this was not taken into account in ascertaining whether she had suffered undue delay.

However Mumby J also held that the existing E112 scheme was not a lawful prior-authorisation scheme under EC law. In order to come within EC law it should be based upon objective, non-discriminatory criteria known in advance with a procedural system which was easily accessible.

As far as Article 22 of Regulation 1478/01 was concerned the judge held that the threshold test for the patient was higher than under Article 40. He relied upon the statement of the Advocate General Tesauro in *Kohll*[47] that

> "Member States are bound to grant authorisation . . . only where the treatment cannot be provided within such time as to ensure its effectiveness, thereby leaving all other eventualities to the Member States' discretion."

Mumby J. went on to hold that

> "The national authority's otherwise unfettered discretion is limited only in this one respect. And the test the patient has to surmount before bringing herself within Article 22 is, in my judgment, a significantly higher test in the present type of case than that required to bring herself within Article 49. Waiting lists and waiting times, although relevant under Article 49 will typically, as we have seen, have little if any significance in that context. In contrast, they are plainly of central significance in the context of Article 22 which, although it requires one to take account of the patient's current state of health and the probable course of the disease, primarily directs attention to "the time normally necessary for obtaining the treatment in question in the Member State of residence."

Here the existing 12 months waiting list time was a normal waiting time within Article 22.

The case was then subject to an appeal to the Court of Appeal.[48] May LJ delivering the opinion of the Court of Appeal in this case held that it was clear that in *Muller-Faure* the ECJ had rejected the argument that Article 49 did not apply to a national health service such as the UK NHS. When interpreting Art 22 of Regulation 1408/71 and ascertaining what time would be normally necessary for this treatment this was something to be ascertainable by reference to clinical judgement and the impact of the delay upon this patient. It was not something which would require consideration of what otherwise were normal waiting times. Nonetheless the Court of Appeal were also of the view that given the wide-ranging policy implications of this issue there was need for a preliminary ruling from the ECJ to clarify the application of both Article 49 and of Art 22 of Regulation 1408/71 in this case. The case was referred in 2004. In late 2005 the Advocate General delivered his opinion in the case.[49] The Advocate General Leendert Adrie Geelhoed has found that the NHS does come within Article 49. He stated that

[47] *Kohll v Union des caisses de maladie (Case C-158/96)* [1998] ECR I-1931.

[48] *Secretary of State for Health v R (on the application of Watts)* [2004] 2 CMLR 55.

[49] *The Queen on the application of Yvonne Watts* Case C-372-04.

> "The absence of a clearly defined procedure within the NHS for considering applications for treatment abroad restricts the possibilities for patients to seek treatment outside the system. It therefore constitutes a restriction of their freedom to receive services and is contrary to the EC treaty.

Here to be compatible with Community law, there needs to be flexibility in waiting lists management in order to ensure that waiting times set so as to balance patient needs with those of resource allocation. A simple rejection that treatment can be given within the waiting list time is not enough. Factors to take into account are the particular illness, pain, nature of the disability and the patient's medical history. Furthermore considerations of budgetary allocation are only applicable where there are larger scale demands for resources which may impact on the system.

Similarly when determining what amounts to "undue delay" must be determined with regard to the specific circumstances of each case. Again what is relevant is the patient's medical condition but also his medical history. The main issue is whether the condition of the patient render the postponement of treatment unacceptable. Although it is the case that waiting times and other clinical priorities can be taken into account if determined on the basis of individual needs this does not apply to targets which are too abstract. This opinion operates as a preliminary stage but it is not binding upon the ECJ. However the Advocate General's opinion sent out a powerful indicator of the approach ultimately followed in the ECJ.

Subsequently this approach has been confirmed in the European Court of Justice.[50] The ECJ held that Article 49 EC applies in a situation in which a patient such as Mrs Watts receives medical services in which a person's state of health necessitates medical treatment travels to another member state and then receives treatment falls within the Treaty provisions on the freedom to provide services. They also held that

> "it is not in dispute that the corollary of the Secretary of State's duty under sections 1 and 3 of the NHS Act.. is the right to obtain treatment available under the NHS free of charge in NHS hospitals without having to seek prior authorisation"[51]

They went on to hold that the current system of prior-authorisation "deters or even prevents patients seeking treatment abroad and thus constitutes an obstacle to the freedom to provide services. The ECJ confirmed that restrictions on the provision of hospital treatment abroad could be imposed by member states as these were consistent with resource allocation decisions. However the ECJ noted that prior-authorisation would need to be subject to certain requirements. So for example, NHS bodies will need to establish a system of prior authorisation which is non-discriminatory, easily accessible, capable of being dealt with impartially and in a reasonable time, capable of being challenged by judicial review. In addition it will be necessary to provide a clear reasoned explanation to the patient and furthermore there will need to be a mechanism for the reimbursement of costs.

Furthermore following the ECJ judgement in the future authorisation for going abroad can only be refused if the waiting list time is medically acceptable and the PCT will need to consider the medical condition, the history/probable course of their illness, degree of pain they are in and the nature of the disability at the time authorization has been sought.

[50] *Secretary of State for Health v R on the application of Yvonne Watts*, Case No C1/2003/239; [2004] EWCA Civ 166.

[51] Para 98.

The matter has now been referred back to the domestic courts and we await the next phase in the saga.

Conclusions

The *Watts* case presents a fascinating insight into the potential for enhanced judicial activism in the area of resource allocation. As was noted above historically the English courts have steered away from involvement in resource allocation decisions save in very limited situations. Will *Watts* have a huge impact on NHS resource allocation in practice?[52]

One possible impact of the decision in the ECJ may be that greatly increased numbers of patients will seek treatment abroad with the aim of bypassing waiting lists and then seek to have the cost of that treatment re-imbursed. In the Court of Appeal in *Watts* May LJ expressed his concerns regarding this prospect stating that

> "We consider that the court should proceed on the assumption that, if the NHS were required to pay the cost of some of its patients having treatment abroad earlier than they would receive it in the United Kingdom, this would require additional resources. In theory this could only be avoided if those who did not have treatment abroad received their treatment at a later time than they otherwise would or if the NHS ceased to provide some treatment that it currently does."[53]

As Newdick argues that this comment is welcome because he suggests neither in the ECJ nor in the High Court in *Watts* has there been full appreciation of the "opportunity costs" of diverting finite resources from one patient to another."[54] Moreover he notes that there is a political dimension. He argues that

> "Should EU law seek to undermine national policy by encouraging "low priority" patients to obtain treatment abroad. Given the need to make difficult choices, surely national governments are best placed to determine national health priorities?"[55]

But is there a risk of panicking unduly here? Is there really the prospect for a Eurostar revolution with patients rushing to seek treatment abroad? One possibility if that even if it is the case that EU law is applicable it may prove to be of limited utility in many cases. Sick patients may simply not want to travel too far. This was a problem in the 1990s when there was an attempt to introduce an internal market in health care in the UK-the utility of the market was limited by issues such as nature of treatment sought and geographical considerations. How much more magnified will the issue be if travel is envisaged across the member states of the EU? It is likely that in the vast majority of cases in practice emergency care and treatment persons in intensive care units are likely to be excluded. In addition it is also likely that the impact of the "Eurostar" factor may be more limited in many aspects of care concerning children and of the mentally ill.

[52] As to the impact of the ECJ judgements on member states see generally Hervey and McHale *op cit* at pages 138–144.

[53] *Op cit* at para 112.

[54] Newdick (2005) op cit at page 244.

[55] *Ibid*.

However even if its impact is not felt through the NHS as a whole one further concern is that there is the prospect that the long-term impact of *Watts* may perpetuate or even widen inequalities in access to health care. As Newdick notes

> "Ad hoc responses to individual claims as they arise willk benefit the articulate and powerful. For the rest however they are more likely to produce an unpredictable, uncoordinated and chaotic health service."[56]

The "Eurostar" factor may be seen as discriminatory. It may come to be regarded as a "middle class" solution.[57] Those with more limited disposable income will not have the funds to pay up front and then reclaim the costs from the NHS. The very wealthy in contrast will be able to easily access private care within their member state.

What seems certain however is that whatever the final decision in *Watts* in the ECJ these cases can be seen as having a broader impact upon health policy issues in the EU and upon the law. Patients are increasingly being seen as "consumers" of health care rather than passive or semi-passive recipients.[58] Interestingly these cases are also likely to impact on the issue of standards of health care provision across member states. Some of this stems from concerns over the consequences of cross-border health care provision should something ultimately go wrong in the surgical procedure undertaken abroad. This was an concern raised in the UK when in 2001 the Government indicated that it was sending some patients to France and Belgium for some routine surgical procedure as a means of working around the waiting lists.[59] This has led to suggestions that there is need for review of standards of health care provision across the EU with some provision being made for a minimal standards threshold. This is yet another indication of the impact which even de-regulatory measures are having upon health policy across the EU.[60]

The involvement of EU law here may also impact upon patient expectations of what services are provided in other ways. The EU Charter of Fundamental Rights and Freedoms which is now incorporated in the new EU Constitution contains a number of rights which are reflective of those contained in the ECHR such as Article 2-the right to life, Article 4-the prohibition on inhuman and degrading treatment.[61] In addition Article 35 provides that

> "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

At present the Charter of Fundamental Rights and Freedoms is currently non-binding "soft-law" although it is influential. Its status would change considerably if the new EU

[56] *Ibid* at page 245.

[57] See further J. McHale in "The EU and Reproductive Services: Enhancing Choices or Entrenching Attitudes" in Millns, S, and Mateo-Diaz, M, *The furture of gender equality in the European Union* Palsgrave (forthcoming 2006).

[58] See generally P. Koutrakos "Healthcare as an economic service under EC law" in M. Dougan and E. Spaventa (eds) (2005) *Social Welfare and EU law* Hart Publishing; Oxford.

[59] J. McHale and M. Bell (2002) "Traveller's checks" *Health Service Journal* 39.

[60] See further Hervey and McHale (2004) *op cit* above pages 397–398.

[61] See further T. Hervey (2003) "The right to health in EU law" in T. K. Hervey and J. Kenner (eds.) *Economic and Social Rights Under the EU Charter of Fundamental Rights* Hart Publishing: Oxford.

constitution is adopted by member states though at present the fate of that document very much hangs in the balance.

Further evidence of the impact of the free movement cases was shown when in November 2005 the High Level Group on health service and medical care published a document regarding their work in 2005.[62] These include suggested guidelines for commissioners of health care involved in cross-border purchasing and provision of health care. They include suggestions such as malpractice liability in relation to the patient and provider should be determined by reference to private international law or any public law. In addition health care commissioners should ensure that liability insurance is in place for all health services provided under the contract. Further provisions relate to pricing and sharing of information. It is expected that EU proposals regarding patient mobility will be published in September 2006. It is believed that this may include information for patients, reimbursement and also the transparency of regulation.

Following the judgement of the ECJ in *Watts* there is indeed a real prospect that the Eurostar factor may help to further reshape the relationship between patients and the NHS in relation to resource allocation decisions in the future.

[62] "Work of the High Level Group on health services and medical care" in 2005, HLG/2005/16.