Resource allocation and rationing strategies in the NHS.

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1. Introduction

When a treatment funding decision is appealed by an individual patient, the lawfulness of that decision must be tested for its compliance with UK law, European law or Convention rights. The medical issues that flow from the implementation of the law, while not irrelevant, are often of secondary importance. Consequently, the law can only ensure the fair allocation of healthcare resources in so far as it enforces the fair and reasonable interpretation of the legal framework within which clinical decision makers operate.

Deontological reasoning dictates that the extent to which rationing decisions are fair is determined purely by their compliance with the established law, while the consequentialist position, in recognition of the wider ethical dilemmas that face funding authorities, is more pragmatic in the legal defence of those same rationing strategies. It will emerge in the discussion that follows, and from the examination of individual cases, that some rationing strategies are readily defensible because they adhere closely to the principles of distributive justice; such strategies and the funding decisions that they generate are protected by the law. Conversely, those strategies that appear inconsistent with these principles may be vulnerable in law. The success of a legal challenge to a treatment funding decision under such circumstances is a measure of the extent to which the law maintains equitable access to healthcare resources by individual patients.

Such legal challenges are often celebrated in the media for they strike a cord with the national psyche, sensitive as it is to protecting the rights of NHS patients to the best possible healthcare, free at the point of delivery and according to clinical need. The founding utilitarian principles of the NHS, providing the maximum benefit for the maximum number of patients, were well meant, but as the nation grew older, and healthcare more complex and expensive, the anticipated equilibrium in resources and demand failed to materialise. Sixty years on, and with the NHS consuming around 10% of GDP, rationing of healthcare is an inevitable daily reality.

The statutory law concerning resource allocation within the NHS will first be considered, as this will serve to contextualise the subsequent examination of the legal challenges to rationing decisions based in European law, Convention rights and administrative law.

2. Statutory regulation of healthcare spending

NHS Act 2006[1]

In the NHS Act 2006 s.1(1), the Secretary of State for Health has a duty to ensure the:

'*...promotion in England of a comprehensive health service designed to secure improvement-*
(a) in the physical and mental health of the people of England, and
(b) in the prevention, diagnosis and treatment of illness'.

Therefore, services which are not demonstrably in alignment with this, that is to say that they cannot be shown to secure an improvement in physical or mental health, fall outside of the scope of his duty, which is distributed to PCTs and SHAs under Part 1 Section 7 of the Act. Consequently the PCTs, to which around 85% of the NHS budget is allocated, inherit an obligation to consider which treatments promote health and which do not, effectively requiring them to develop rationing strategies to ensure allocation of resources to where there is evidence of clinical benefit to patients.

Without unduly detaining the discussion focused on *treatment*, consideration should be briefly given to the case of *Couglan* v *North and East Devon Health Authority*[2] which set important precedent relating to the entitlement to residential nursing care provided by local authorities. This case invoked statute contained in the National Assistance Act 1948[3] (amended by the National Health Service and Community Care Act 1990[4]) which allowed for the provision by the NHS of:

' *residential accommodation for persons who by reason of age, illness, disability or any other circumstances are in need of care and attention which is not otherwise available to them*'

The claimant appealed against the authority's decision to close a specialist NHS residential facility, Mardon House, to which she had been promised life-long access, the effect of which would be to transfer care provided by the NHS to social services in a new community home. It was held that this was contrary to the 1948 Act and that the authority had raised, and had been in breach of, the legitimate expectation of continued care at Mardon House. It was also accepted that the proposed closure amounted to a trespass upon her article 8(2) Convention right[5] (the right to a private and family life):

'*There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law.*'

The Coughlan case established that where an individual's main needs are healthcare-related, then NHS remains responsible for that person's care and accommodation,

[1] National Health Service Act 2006
[2] *R. Ex p. Coughlan* v *North and East Devon HA* [2001] Q.B. 213
[3] National Assistance Act 1948 (c.29) s.21(1a)
[4] National Health Service and Community Care Act 1990 (c.19) s.42(1a)
[5] European Convention on Human Rights 1950.

precedent that was followed in *Grogan* v *Bexley NHS Care Trust*[6] but distinguished in *Green* v *South West SHA*[7]. The balance between healthcare and social needs was similarly contested in *St Helens Borough Council* v *Manchester Primary Care Trust*[8] where the two public authorities were in dispute over which should provide care to a patient with significant mental problems. May LJ held that it was the Primary Care Trust, as the delegate of the Secretary of State, who was the primary decision maker, and better placed to determine matters related to healthcare.

The NHS constitution

The financial viability of the NHS as a whole is clearly in the overriding interests of all patients. This notion of sustainability is reflected as a key principle of the new NHS constitution, published in January 2009[9] in the wake of Lord Darzi's report 'High Quality Care for All'[10]. This key principle states that:

'*The NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources.*'

Under the terms of the constitution, patients are informed of the right *'...not to be refused access* (to NHS services) *on unreasonable grounds*' and to '*expect local decisions on funding of* (non NICE-approved) *drugs and treatments to be made rationally following a proper consideration of the evidence*.'

These rights, which are already established in administrative law, are transparent and unequivocal, and patients are also appraised of their right *'...to make a claim for judicial review if you think you have been directly affected by an unlawful act or decision of an NHS body.*'

All NHS bodies, pursuant of the Health Act 2009, which gained Royal assent on 12 November 2009, will have a statutory duty to have regard to the NHS constitution when making rationing decisions[11].

The National Institute for Health and Clinical Excellence (NICE)

The National Institute for Clinical excellence (NICE) was established in 1999[12] (becoming the National Institute for *Health and* Clinical Excellence in 2005[13]) with statutory powers to perform:

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[6] *R, (on the application of Grogan)* v *Bexley NHS Care Trust* [2006] EWHC 44 (Admin)
[7] *R, (on the application of Green)* v *South West SHA* [2008] EWHC 2576 (Admin)
[8] *R, (on the application of St Helens BC)* v *Manchester Primary Care Trust* [2008] EWCA Civ 931
[9] Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093419
[10] Available at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_085828.pdf
[11] The Health Act 2009 (c.21) s.2(1)
[12] National Institute for Clinical Excellence (Establishment and Constitution) Order 1999/220
[13] National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 2005/497

'*such functions in connection with the promotion of clinical excellence, and the effective use of available resources in the health service*'.

The scope of NICE guidance relates to areas of public health, clinical practice and 'medical technologies', including new drugs, treatments or procedures[14]. Guidance in areas of clinical practice makes recommendations for the care of specific groups of patients, not only *how* they should be treated but also *by whom*.

NICE adopts assessment tools such as quality-adjusted life years (QALYs) and incremental cost effectiveness ratio (ICER) when issuing guidance, especially in consideration of the introduction of new drugs to the NHS. Patients have a constitutional right for NICE-approved drugs to gain PCT funding where clinically indicated.

Difficulties have arisen where decisions taken by NICE are different from those of the Scottish Medicines Consortium, the equivalent regulatory body for Scotland. An anti-rheumatoid drug, tocilizumab (Roactemra®), approved for use in Scotland, is currently under review by NICE[15]. Early indications are that the appraisal committee are 'minded not to recommend' approval for its use in England and Wales. This has led to media accusations of 'medical apartheid'[16].

Inevitably, NICE decisions which effectively block the entry of new drugs to the NHS market have a significant adverse financial impact upon the pharmaceutical companies that manufacture them, and unsurprisingly legal challenges have arisen following such decisions.

3. Challenges to NICE decisions and European jurisprudence

Such was the case with sildenafil (Viagra®), licensed for use in erectile dysfunction. The manufacturers of the drug, Pfeizer, challenged the lawfulness of a Department of Health circular that restricted its prescription to patients in whom there was an exceptional clinical need in order to avoid crippling expense to the NHS.[17]

The criteria for exceptionality, however, were not specified and as such it was held that the circular amounted to a ban on treatment and a breach of Article 7 of Directive 89/105/EEC[18] (the 'transparency Directive') in European law. Article 1 of the transparency directive requires member states to:

'*...publish in an appropriate publication and communicate to the European Commission the criteria which are to be taken into account by the competent authorities to decide whether or not to include medicinal products on a positive list for use in their national health insurance systems or to exclude individual or categories or medicinal products from such system*.'

[14] See http://www.nice.org.uk/aboutnice/
[15] Rheumatoid arthritis - tocilizumab: appraisal consultation document 2. NICE. Available at: http://www.nice.org.uk/guidance/index.jsp?action=article&o=46642
[16] NICE blocks arthritis lifeline. The Daily Telegraph, January 19, 2010.
[17] Department of Health Circular No. 1998/158
[18] Directive 89/105/EEC

It was also contested that the circular, in effect, deterred GPs from their duty to prescribe a drug to those patients for whom they considered it to be clinically indicated. Although its overriding motives were clearly to safeguard NHS resources, at appeal[19] Collins J observed that:

'*…whether the reasons be good or bad cannot affect the lawfulness of the circular if its purpose and effect is to cause G.P.s to act contrary to their professional obligations and contrary to their duty*'

The appeal was upheld. In response, regulations were issued to permit the prescription of sildenafil to certain *categories* of patients, with no requirement for them to demonstrate *exceptionality*. Pfeizer's further challenge, with its basis once again in the transparency directive, was dismissed in the Court of Appeal[20].

Most recently, Bristol-Myers-Squibb contested NICE's decision to refuse approval of a new anti-rheumatoid drug abatacept (Orencia®) in the High Court[21,22], alleging a breach in the transparency directive, contrary to EU law.

In his judgment, Blake J returned to the ruling of Brown LJ in the Pfizer and the observation that *affordability* was a legitimate reason for exclusion within the terms of the directive. He also considered the fairness of the NICE decision by reference to precedent established in *Eisai Ltd* v *National Institute for Health and Clinical Excellence.* [23]

Eisai Ltd is the manufacturer of the drug donepezil hydrochloride (Aricept®) for which a licence was sought in the treatment of early Alzheimer's disease. Approval was initially withheld by NICE but was successfully challenged on the grounds of procedural unfairness since the cost-effectiveness model used by NICE in the appraisal process was a read-only version and was not, therefore, amenable to independent scrutiny and testing by the manufacturer.

Where Eisai Ltd succeeded, however, Bristol-Myers-Squibb failed. The Orencia case was distinguished on the basis that it was the manufacturer, rather than NICE, who supplied a cost-effectiveness model which, on the basis of a modification by the evidence review group (ERG), did not support the introduction of the drug. Also, Blake J held that the statistical modifications that were made by the ERG did not amount to procedural unfairness since the manufacturer was informed of them and had adequate opportunity to make representations.

In these three cases the law decided not upon the *clinical value* of the individual drugs but on the *lawfulness* of the approval process adopted by NICE as arbiter of cost-effectiveness within the wider context of resource allocation in the NHS. Here, the

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[19] *R, (on the application of Pfizer Ltd)* v *Secretary Of State For Health* [1999] EWHC Admin 504
[20] *R, (on the application of Pfizer Ltd)* v *Secretary of State for Health* [2002] EWCA Civ 1566
[21] *R, (on the application of Bristol-Myers Squibb Pharmaceuticals Ltd)* v *National Institute for Health and Clinical Excellence* [2009] EWHC 2722 (Admin)
[22] Dyer C. High Court upholds NICE decision in face of legal challenge. BMJ 2009;339:b4686.
[23] *R, (on the application of Eisai Ltd)* v *National Institute for Health and Clinical Excellence (NICE)* [2008] EWCA Civ 438

fairness of resource allocation is seen to focus upon the entire patient population rather than individuals.

For individuals, therefore, the choice remains either to abide by NICE recommendations, and to receive sanctioned treatments within the NHS only, or to privately fund some or all aspects of their healthcare, an issue which has been considered within the context of cancer treatment[24] and within the NHS as a whole[25].

The concept of NHS 'top-up' payments (whereby patients who can afford non NICE-approved drugs pay a fee to the NHS to receive them) may be unpalatable, but there appears to be a reluctant acceptance[26] that patients who wish to access additional privately-funded treatment can do without losing their entitlement to basic NHS care, providing that this is delivered at a separate facility, out of sight of other NHS patients[27]. There seems to be little difference between the two.

Ultimately, expedient NICE appraisals and effective rationing strategies should minimise the requirement for patients to seek such remedies, and greater weighting, perhaps, should be afforded to the views of clinicians when determining individual cases of exceptional clinical need[28].

4. Challenges to PCT treatment funding decisions and European jurisprudence

Under Article 49 of the Treaty establishing the European Union[29]:

'*…restrictions on 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*.'

Healthcare services are protected under Article 50 which cite '*activities of the professions*'[30] as a service for which remuneration is normally provided. In order to uphold this freedom to provide services, restrictions cannot be placed upon persons wishing to avail themselves of those services; NHS patients are, therefore, entitled to seek medical treatment in other European Union member states.

The question that arose in *Watts* v *Secretary of State for Health*[31] was whether or not the NHS had a statutory obligation to fund such treatment and if so under what circumstances?

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[24] Improving access to medicines for NHS Patients. November 2008. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_089927

[25] Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096428

[26] Kmietowicz, Z. Organisations reluctantly come out in support of top-up payments. BMJ 2008;337:a1685.

[27] Coombes, R. Rules on top-up payments risk creating two tier system in NHS, MPs warn. BMJ 2009;338:b1973.

[28] Waxman J. Must doctors fight the NHS to save lives in danger? The Times, December 4, 2009.

[29] Treaty establishing the European Community: Article 49

[30] Treaty establishing the European Community: Article 50 (d)

[31] *R, (on the application of Watts)* v *Secretary of State for Health* [2004] EWCA Civ 166

Central to the argument was the issue of NHS waiting lists and the appropriateness of any delay in providing treatment, in this case to a patient awaiting a hip replacement operation. Article 22 of Council Regulation 1408/71[32], as of 14 June 1971, was considered. This provided that authorisation for treatment may not be refused:

'*where* (the person) *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 current state of health and the probable course of the disease.*"

The court recognised the overriding interest that lay in the long term viability of the NHS and its ability to plan and apportion resources appropriately. It was accepted that this would be fatally undermined by patients seeking funding for treatment in other member states unless treatment was unavailable within agreed NHS waiting times and subject to prior authorisation. For future reference, the *obiter* of May LJ criticised the reliance placed upon Article 49, indicating that:

'*…submissions based on the literal meaning of Article 49 and related articles may not be regarded as persuasive. There has been much judicial policy-making, and the policy goes well beyond the words of the Article.*'

5. Challenges to rationing decisions based in Convention rights[33]

Most challenges to rationing decisions achieve a remedy within administrative or EU law, but occasionally Convention rights are engaged.

In the case of *North West Lancashire Health Authority* v *A, D, G*[34], (considered at greater length in the following section), articles 3 and 8 of the Convention were tested. The appellants claimed that denial of funding for gender reassignment surgery represented a contravention of their article 3 right not to be subjected to degrading or inhuman treatment (in forcing them to maintain the outward characteristics of an unwanted gender), along with a contravention of their right to a private life - article 8.

In Buxton LJ's view, while article 8 protects a person's right to a sexual *behaviour* of their choosing, it could not be held to extend to definitions of *sexuality*. Under article 3, the level of degradation or humiliation which would be required to qualify as a contravention of that right far exceeded that which could be expected by patients with gender identity dysphoria, and in any case there is no basis in article 3 for challenging decisions of resource allocation.

The view of the judiciary appears to be that Convention rights should be reluctantly engaged in cases of resource allocation, since their role is more importantly in protecting fundamental freedoms. The *obiter* of Buxton LJ is significant:

'In a case where neither Convention nor Community rights can be asserted, the case either succeeds or fails on domestic law grounds and on no other. And with the imminent coming into force of the Human Rights Act it will be even more important

[32] Regulation (EEC) No 1408/71 of the Council, 14 June 1971
[33] European Convention on Human Rights 1950.
[34] *North West Lancashire Health Authority* v *A, D, G* [2000] 1 W.L.R. 977

than it is at present to ensure that Convention rights are not asserted in inappropriate circumstances; so that they play their proper, and important, role, but only their proper role, in the protection of the citizen's interests.'

6. Challenges to rationing decisions based in administrative law: demonstration of exceptionality.

The commissioning bodies of the NHS, the Primary Care Trusts, are empowered to formulate funding policies that restrict funds for certain treatments while making available funds for others. These policies take in to account the scope of the relevant clinical evidence concerning a particular treatment, including guidance from NICE and from the Department of Health. Discrepancies in how guidance is implemented by PCTs invites the familiar 'postcode lottery' charge, recently levelled at funding arrangements for body contouring procedures following bariatric surgery[35]

Treatments that are regarded as low priority for funding are those for which the cost- and clinical-effectiveness of treatment cannot be proven, often following NICE review, or where that treatment has only limited healthcare value, such as cosmetic surgery. NICE-approved drugs or treatments, however, are automatically funded under the terms of the NHS constitution.

Individual patients wishing to challenge rationing policy decisions must demonstrate an exceptional clinical need, over and above other patients in the same treatment cohort, to receive that treatment. It follows that the successful applicant, who satisfies the exceptionality criteria, would derive significantly greater clinical benefit than would other patients with the same condition. The funding authority must be able to envisage circumstances under which conditions defining exceptionality can be met, otherwise its policy would amount to a blanket ban, unlawfully fettering its discretion to award funding for treatment to any patient.

The default position is that PCTs *are* permitted in law to make rationing decisions where the failure to do so would result in the irresponsible diversion of valuable resources away from the majority of patients in order to benefit individuals. This was established in *Regina* v *Cambridge Health Authority*.

Regina v *Cambridge Health Authority* concerned the refusal of the authority to fund treatment for acute lymphoblastic leukaemia in a minor (B). The authority's position was that the proposed treatment (a third course of chemotherapy, whole body irradiation and allogenic bone marrow transplantation) lacked clinical effectiveness and that approving funding would misdirect finite resources away from other patients. On appeal Laws J declined to order mandamus to compel funding; instead an order of centorari was made to force a rethink of that decision. The authority appealed against the order of centorari, while B appealed against the lack of mandamus.

At judicial review[36], Sir Thomas Bingham MR considered the issue of resource allocation and determined that:

[35] Hujazi I, Henderson J. Option of plastic surgery is a postcode lottery. BMJ 2009;339:b4961.
[36] *R.* v *Cambridge DHA Ex parte B* [1995] 1 W.L.R. 898

'*It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay the nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonising judgements have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients*.'

Having established in common law that PCTs are entitled to exercise rationing of healthcare resources to individual patients, a number of important challenges followed.

In *Fisher* v *North Derbyshire Health Authority*[37], there was argument over the interpretation of an executive letter - EL(95)97[38] - from the Secretary of State for Health regarding the prescription of beta interferon to patients with multiple sclerosis One issue was whether or not the circular provided *guidance* or *directions* to commissioning bodies to facilitate the introduction of interferon-beta as an NHS treatment. The authority interpreted the circular as guidance and, citing a lack of resources, chose to sanction funding for treatment within the context of a clinical trial only.

Given that no such trial existed (having been indefinitely postponed), the authority was judged to have fettered its discretion to allocate funds since it would have been impossible to meet the conditions required. In failing to account rationally for their departure from the guidance contained in the circular, the authority's policy was also deemed to have been unreasonable in the Wednesbury sense[39]; on these two points the policy was judged as unlawful and an order of mandamus was made to oblige the authority to bring its policy in to alignment with EL(95)97.

Judicial review was sought under similar circumstances where funding restrictions were imposed upon patients seeking gender reassignment surgery[40]. Here, Auld LJ considered the statutory duty of the Secretary of State to *promote*, rather than to *provide* a comprehensive health service, pursuant of the National Health Service Act 1977[41], citing *R.* v *Secretary of State for Social Services Ex p. Hincks* [42] as evidence that rationing decisions in healthcare can be lawfully made in accordance with government economic policy.

The policy of North West Lancashire Health Authority was to fund surgery for gender identity dysphoria only in cases of exceptional clinical need; this was confined to patients exhibiting serious mental illness such as psychosis or significant depression. However, any decision to fund treatment on this basis would require supporting evidence demonstrating a reversal of such illness following gender reassignment surgery, evidence which was notably thin at that time.

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[37] *R, (on the application of Fisher)* v *North Derbyshire Health Authority* [1997] EWHC Admin 675
[38] Executive Letter (95)97
[39] *Associated Provincial Picture Houses Ltd* v *Wednesbury Corporation* [1947] EWCA Civ 1
[40] *North West Lancashire Health Authority* v *A, D, G* [2000] 1 W.L.R. 977
[41] National Health Service Act 1977 (c.49) s.1(1)
[42] *R.* v *Secretary of State for Social Services Ex p. Hincks* [1980] 1 BMLR 93

This qualification to the policy was regarded as unlawful fettering of the authority's discretion to approve funding and was irrational in the sense that it did not adequately reflect an understanding trans-sexualism as an illness (Wednesbury unreasonableness). These factors equated to a blanket ban on funding and led to the observation by Auld LJ that:

'*...if a Regional Health Authority devises a policy not to provide treatment save in cases of overriding clinical need, it makes a nonsense of the policy if, as a matter of its medical judgment, there is no effective treatment for it for which there could be an overriding clinical need.*'

The judgement in the North West Lancashire HA case was followed in *Rogers* v *Swindon NHS Primary Care Trust*[43]. Once again, the PCT's policy was considered irrational because it did not envisage circumstances under which patients suffering from early stage breast cancer could claim an exceptional clinical need to receive the drug trastuzumab (Herceptin®). Herceptin was licensed for the treatment of patients with advanced breast cancer but was unlicensed for early disease.

The PCT's policy was to fund off-license treatment wherever it was prescribed by a clinician, irrespective of cost, providing that personal or clinical factors qualified individual patients as exceptional in their requirement of it. At the time of judicial review there had been no NICE appraisal of the use of Herceptin in the adjuvant setting, but the National Cancer Research Institute had identified clinical criteria for eligibility for treatment which were cited in guidance issued by the Secretary of State and which the appellant satisfied.

The difficulty facing the PCT, therefore, was how to determine which patients within the eligible group demonstrated exceptionality since there was no identifiable clinical factors which could separate them. This effectively rendered any policy of exceptionality irrational as no patient could be distinguished from any other within the eligible cohort; furthermore there was no rational basis for preferring to treat individual patients on account of non-healthcare, personal or social circumstances.

Consequently the PCT's policy, and hence its funding decision, was unlawful, but, as in *Fisher* v *North Derbyshire Health Authority*, the PCT was not ordered to fund treatment, merely to make amendments to its policy to bring it into alignment with the law.

In *Ross* v *West Sussex Primary Care Trust*[44] similar issues were encountered; firstly in that there had been no NICE review of the new myeloma drug lenalidomide (Revlimid®) and secondly in the PCTs interpretation of what defined exceptionality. The PCT called expert evidence to assess the efficacy of lenalidomide but failed to take in to account a range of professional opinion.

This resulted in an unbalanced appraisal and led to a material misunderstanding on the PCT's part of the potential usefulness of the drug and also its cost effectiveness, since the available evidence suggested a cost per QALY below the NICE threshold of

[43] *Rogers* v *Swindon NHS Primary Care Trust* [2006] EWCA Civ 392
[44] *R, (on the application of Ross)* v *West Sussex Primary Care Trust* [2008] EWHC 2252 (Admin)

£30,000. Furthermore the PCT struggled to understand the difference between unpleasant side effects of lenalidomide (peripheral neuropathy) from side effects so severe that they became intolerable and made further treatment impossible, rendering the case for treatment with the new drug as exceptional.

The PCT's policy was to refuse applications for funding based in exceptionality to *cohorts* of patients. Grenfell J held that this indicated that a patient had to demonstrate *uniqueness* rather than exceptionality; this he regarded as unreasonable and irrational in the Wednesbury sense. Although treatment with lenalidomide was ordered to commence, provision was made for the PCT to give effect to the ruling by a revision of its policy; thereafter the PCT would be in a position to lawfully withhold continued treatment.

Where a funding policy is considered lawful, however, the claimant must demonstrate that its *interpretation* has been unlawful, as was the case in *Otley* v *Barking and Dagenham NHS Primary Care Trust*[45]. In this case Dagenham PCT withheld funding for a second course of combined chemotherapy, to include the drug bevacizumab (Avastin®), to a patient with metastatic colorectal cancer who had responded clinically to an initial, privately funded, course of treatment. The PCT held that conditions of exceptionality were not satisfied and provided a list of those circumstances where exceptionality criteria would be met (contrast with *Fisher* v *North Derbyshire Health Authority* and *Rogers* v *Swindon NHS Primary Care Trust*).

Mitting J determined that when considering the funding application the appeals panel were irrationally distracted by consideration of the precise ratio of drugs in the chemotherapy regime and that they had overlooked the fact that the aim of treatment was to reduce liver metastases to such a size as made them operable (rather than to achieve more significant tumour shrinkage), which remained the only chance of survival for this patient. Consequently, the interpretation of a lawful policy was deemed irrational and the PCT was ordered to fund a further course of treatment.

Similar circumstances were encountered in *Murphy* v *Salford Primary Care Trust*[46] concerning another cancer drug sunitinib (Sutent®). Although the funding authority correctly considered, and dismissed, the individual factors that were claimed to confer exceptionality, they failed to consider the summative effect of these factors. Had they done so the decision to withhold funding for treatment might have been different. This establishes an important principle as expressed by Burnett J in directing the PCT to reconsider their decision such that:

'*…when a body such as the Commissioning Panel is faced with a panoply of arguments all directed towards a single outcome, that the time should come in the decision-making process for the constellation of factors to be looked at as a whole.*'

[45] *R, (on the application of Otley)* v *Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin)
[46] *R, (on the application of Murphy)* v *Salford Primary Care Trust* [2008] EWHC 1908 (Admin)

7. Conclusion

Lawful adherence to NICE guidance appears to be the most persuasive defence to current rationing strategies adopted by NHS funding authorities. In the absence of a clear procedural failing, the lawfulness of a NICE-based rationing decision is unlikely to be successfully challenged in European law, and it seems that the judiciary will be unsympathetic to the engagement of Convention rights under circumstances in which an infringement of a fundamental freedom cannot be readily appreciated.

It is not known what proportion of *all* challenges to rationing decisions, including those made without the assistance of the courts, are successful and what proportion are unsuccessful or remain uncontested, but after *Regina* v *Cambridge Health Authority*, few of the challenges to rationing decisions, although made successfully in law, resulted in the appellants actually receiving the treatment they sought.

With the exception of *Otley* v *Barking and Dagenham NHS Primary Care Trust* (where the funding policy was lawful already), rather than promoting the allocation of resources to individual patients, these cases are illustrative of the law providing an opportunity to funding authorities to improve upon the lawfulness of their rationing strategies. The *fairness* of this process is assumed to flow from the protection of the wider interests of all patients and the financial viability of the entirety of the NHS.

However, with no clear prospect that a successful appeal will actually secure the desired treatment, the likelihood of further challenges to rationing decisions by individuals may diminish, making it difficult to imagine how the *fairness* of resource allocation under the governance of the law, to *individual patients* deserving of that treatment, will continue to be called to account.

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