THE LEGAL IMPLICATIONS OF RATIONING IN THE NHS

A. THE LEGAL FRAMEWORK

1. Sections 1 to 3 of the National Health Service Act 2006, formerly sections 1 to 3 of the National Health Service Act 1977, require the Secretary of State to continue to promote a comprehensive health service designed to secure improvement in the physical and mental health of people in England, and in preventing, diagnosing and treating illness. With some exceptions, the services so provided must be free of charge. See *R v North and East Devon Health Authority, ex parte Coughlan* [2001] QB 213. Lord Woolf MR, giving the judgment of the court in that case, who said at paragraph 20 that, as the original National Health Service Act 1946 makes clear, the 1977 Act, (now the 2006 Act) is the dominant Act for the purposes of the provision of healthcare.

2. By section 3(1)(e), the Secretary of State is required to provide to the extent that he considers necessary to meet all reasonable requirements, in addition to hospital accommodation and other services which are obviously health care,

   "such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after care of persons who have suffered from illness as he considers are appropriate as part of the health service."

   Thus expressed, there is in the Secretary of State a degree of judgment as to what he considers necessary, reasonable and appropriate. Frequently, the Secretary of State's duty is delegated to the relevant Primary Care Trust.

3. The primary duties of Primary Care Trusts are set out in section 15 of the National Health Service Act 1977, the 2006 Act's precursor, and are "to

administer the arrangements made in pursuance of this Act for the provision of primary medical services ..." The general duties of the Secretary of State initially set out under section 2 of the 1977 Act were delegated to Primary Care Trusts (and Strategic Health Authorities) as from 1 October 2002 by Regulation 3 of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002 SI No. 2375.

4. The general duties of the Secretary of State under s.3 of the 2006 Act remain delegated to Primary Care Trusts and Strategic Health Authorities, by virtue of s.7(1) of the 2006 Act read together with 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) (as amended).

5. However, with a finite limit on the financial resources available to the NHS, there remains a continuing, and sometimes almost irreconcilable, conflict between the duty imposed on those bodies charged with resource allocation to balance the interests of individuals as against the need to promote the health of the community as a whole.

6. From a legal perspective, therefore, those legal challenges which are brought against bodies charged with the allocation of NHS Resources are challenges against the extent to which the relevant body, or in the case of the Secretary of State for Health, individual, has incorrectly discharged the relevant duty within accepted legal principles. This talk seeks to examine, and hopefully elucidate, the way in which challenges to decisions on the allocation of resources have been brought in the courts, whether against decisions of Primary Health Care Trusts, or in the case of directions on resource allocation given by the Secretary of State for Health, the Secretary of State themselves.

7. The issue is perhaps best illustrated by the dual duties imposed on the Secretary of State for Health respectively contained in sections 1 to 3 of the National Health Service Act 2006 and section 229 of the 2006 Act. Sections 1 to 3 provide: -

1 Secretary of State's duty to promote health service

(1) The Secretary of State must continue 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.

(2) The Secretary of State must for that purpose provide or secure the provision of services in accordance with this Act.

(3) The services so provided must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed.

General power to provide services

2 Secretary of State's general power

(1) The Secretary of State may—

(a) provide such services as he considers appropriate for the purpose of discharging any duty imposed on him by this Act, and

(b) do anything else which is calculated to facilitate, or is conducive or incidental to, the discharge of such a duty.

(2) Subsection (1) does not affect—

(a) the Secretary of State's powers apart from this section,

(b) Chapter 1 of Part 7 (pharmaceutical services).

Provision of particular services

3 Secretary of State's duty as to provision of certain services

(1) The Secretary of State must provide throughout England, 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,

(c) medical, dental, ophthalmic, nursing and ambulance services,

(d) such other services or facilities for the care of pregnant women, women who are breastfeeding and young children as he considers are appropriate as part of the health service,

(e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service,

(f) such other services or facilities as are required for the diagnosis and treatment of illness.

8. That duty, however, must necessarily be balanced against the concurrent duty set out in section 229 of the 2006 Act, which provides conversely that:-

(1) Each Primary Care Trust must, in respect of each financial year, perform its functions so as to secure that its expenditure which is attributable to the performance by it of its functions in that year (not including its pharmaceutical services expenditure) does not exceed the aggregate of—

(a) the amount allotted to it for that year under section 228(1)(b),
(b) any sums received by it in that year under any provision of this Act (other than sums received by it under that section), and
(c) any sums received by it in that year otherwise than under this Act for the purpose of enabling it to defray any such expenditure.

(2) The Secretary of State may give such directions to a Primary Care Trust as appear to be requisite to secure that it complies with the duty under subsection (1).

9. The issue of rationing and the legal framework surrounding the provision of drugs and treatments by the National Health Service falls broadly into two categories: the obligation imposed on Primary Care Trusts to provide drugs in primary care and the obligation on Primary Care Trusts to provide drugs in secondary care. The precise regulations pertaining to each being slightly different.

10. However, as a general rule, such challenges as are brought against the decision of the Secretary of State or the relevant PCT to whom the duty has been delegated, will be advanced on the basis that the relevant body has in some way failed adequately to provide or consider correctly the need for "*such other services or facilities for the prevention of illness, the care of persons suffering*

from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service", when balanced against the constriction of the finite resources of the NHS, as articulated in section 229 of the 2006 Act.

(a) Generic Prescribing in Primary Care

11. At present, generic prescribing in primary care is specifically covered by the General Medical Services (Contracts) Regulations 2004. Amongst other things, the 2004 Regulations primarily impose a duty on GPs to "***order any medicines which are needed***" by their patients.

12. That duty and the problems of prescribing in primary care and the relevant statutory regulations which have been enacted pursuant to the 2006 Act, (currently the 2004 Regulations cited above), are discussed and analysed in some depth in the case of ***R v Secretary of Health, ex parte Pfizer*** [1999] Lloyds Rep Med 289. Though a case brought under the old 1992 Regulations, the principles and the way in which the court approaches such challenges to decisions made about resource allocation in primary care remain substantially the same. The case is a useful example of the way in which courts are likely to approach challenges to generic prescribing in primary care.

13. In **Pfizer**, the court was asked to rule on whether the Secretary of State for Health's advice to General Practitioners to the effect that the erectile dysfunction drug Sildenfil, marketed under the name Viagra, should not be prescribed except in exceptional circumstances was lawful. The court held, inter alia, that advice or guidance promulgated by a public authority could be the subject of judicial review if it contained an error of law, particularly if it was likely to be acted upon by those it addressed. In particular, the court found

that advice could be struck down if its purpose and effect was to achieve what could not lawfully be achieved had certain safeguards not been overridden.

14. The court found that the advice of the Secretary of State to G.Ps, was tantamount to prohibiting them from prescribing Viagra if the advice was followed correctly, and it therefore had the same effect as if Viagra had been placed on the list of prohibited drugs in Schedule 11 of the 1992 Regulations. Had it been expressly prohibited and put on the list of drugs in section 11, which de facto it was as a result of the Secretary of State's advice, various safe guards would have had to have been complied with in order for the drug to be on the prohibited list.

15. In fact, none of those safeguards were complied with and accordingly the court found that the advice, taking into account the effect it had of prohibiting the prescribing of Viagra, had been intended, consciously or not, to circumvent the safeguards, which was something that the Secretary of State had no discretion to do under either the 1977 Act (now the 2006 Act) or the subordinate Regulations.

16. The specific problem with the Secretary of State's circular, so the court found, was that it was given in such terms that many GPs would inevitably regard it as over riding their professional judgment. Whilst the court accepted that it was right that advice could be given in strong terms so as to discourage the prescribing of Viagra, the advice must make clear that it did not purport to exclude the GP's professional judgment.

17. Further, the court held in addition that to state in broad terms that Viagra should not be prescribed except in exceptional circumstances which were undefined within the advice that had been given, was again tantamount to telling recipients of the advice that they could not prescribe Viagra in general. This again had the effect of restricting the General Practitioner's professional

judgment as to the medical efficacy of a drug, which had not been explicitly put on the prohibited register.

(b) Generic Prescribing in Secondary Care & Exceptional Case Review

18. It goes without saying, that all Primary Care Trusts are required to have a reasonable and lawful policy to control their expenditure. The corollary of this, if the policy is to be fair and lawful, is that the policy should also include procedures to deal with 'exceptional cases'. A policy which cannot take into account cases where the facts are of an extreme or egregious nature, would usually be held to be too intransigent and therefore unlawful.

19. Accordingly, the majority of legal challenges that are brought against the decisions of PCTs concerning the allocation of resources in secondary care relate to challenges as to what should constitute an "exceptional case". The matter was recently addressed in the case of ***The Queen on the application of Colin Ross v West Sussex Primary Care Trust*** [2008] EWHC B15.

20. The case addressed the issue of the Primary Care Trust's attitude and response to what constituted an 'exceptional case' and whether the drug Lealonidomide should be made available, in the light of the particular clinical circumstances of the claimant, who was suffering from multiple myeloma. Of particular interest was the fact that the drug had yet to be assessed by the National Institute for Health and Clinical Excellence. As the court noted, in relation to policies in general and the need for 'exceptional case' provisions within the policy the at paragraphs 32 to 35: -

32. The Role of the Secretary of State is set out in HSC 1999/176[4]. Thus the PCT has a duty to commission medical services as it considers necessary to meet

the healthcare needs of the local population as a whole and within allocated resources, and to do any other thing which will facilitate, or is conducive or incidental to the discharge of such a duty.

33. *It is a matter for the PCT how it allocates its resources, so long as it does so reasonably, which will involve difficult and agonizing judgments as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients (R v Cambridge Health Authority ex parte B [1995] 1 WLR 898 at 906D).*

34. *In reaching these decisions, the PCT should consider the nature and seriousness of each type of illness, and the effectiveness of various forms of treatment (R v NW Lancashire HA ex parte A [2000] 1 WLR 977 at 991 E – G). However, it would be very difficult, if not impossible, to challenge a decision not to fund treatment that took into account financial restraints and the particular circumstances of the individual patient (R on the application of Rogers v Swindon NHS PCT [2006] EWCA Civ 392 at paragraph 58).*

35. *It is lawful for PCTS to have a policy not to fund a treatment save in exceptional circumstances, so long as it is possible to envisage, and the decision maker does envisage, what such exceptional circumstances might be, as the policy will otherwise in practice be a complete refusal of assistance, and unlawful because it is justified not as a complete refusal, but as a policy of exceptionality (Rogers at paragraph 62).*

36. *The court's role is not to be an arbiter of the merits of cases of this kind, nor is it to express opinions as to the likelihood or the effectiveness of medical treatment or on medical judgment, but is strictly limited to ruling upon the lawfulness of decisions (R v Cambridge limits the ability of the courts to review decisions of this kind). Nevertheless, where life and death decisions are involved, the courts must submit the decision making process to rigorous scrutiny.*

21. Applying those principles outlined above to the particular facts of the case, the Judge found that the PCT's decision not to fund the claimant's request for Leanolidomide was illegal, on the basis that it was not an adequate policy for exceptional cases, since under the policy a person was automatically disqualified if he could be likened to another: in order to qualify, a patient had in effect to show that he is unique, rather than merely exceptional in the ordinary sense of the word as being 'of the nature of or forming an exception; out of the ordinary course, unusual, special.'

22. In practical terms, in a case such as the claimant's, the court found that it would have been impossible to show uniqueness, so the policy was incapable of fulfilment. This was on the grounds that it would always be possible for another patient to emerge who was appropriately comparable and the comparison depended on how widely the label was drawn by the PCT, for example whether the Claimant should be compared to any cancer patient who suffers unpleasant side effects or to something more specific. The Judge therefore, held that it was impossible to envisage circumstances other than those where the applicant shows that his or her circumstances were unique, whereas in a simple policy of exceptionality as encountered by the expert witness in the case Professor Sikora and set out in his report, a reviewing panel would have no difficulty in applying the ordinary meaning of 'exceptional'.

23. Whilst each case necessarily turns on its own clinical facts, given the very nature of the definition of 'exceptional case', the case gives a clear and very recent indication of the way in which a court is likely to approach appeals against decisions by PCTs relating to exceptionality. In a similar vein in the Court of Appeal case of ***The Queen on the application of Ann Marie Rogers V Swindon NHS Primary Care Trust*** [2006] EWHC 171 (Admin), the Court of Appeal recently held that a Primary Care Trust's refusal to fund the breast cancer drug Herceptin to the claimant was irrational.

Comment [JHMBJ1]:

24. The court held that once the PCT decided (as it did) that it would fund Herceptin for some patients and that cost was irrelevant, the only reasonable approach was to focus on the patient's clinical needs and fund patients within the eligible group who were properly prescribed Herceptin by their physician. This would not open the floodgates to those suffering from breast cancer because only comparatively few satisfy the criteria so as to qualify for the eligible group.

25. Accordingly, the court held that that the policy of the PCT was irrational, since it could not properly be said that it was not imperative to identify individual characteristics which might justify distinguishing between one patient within the eligible group and another. The evidence did not establish the possibility of there being relevant clinical circumstances relating to one patient and not another and, in the case of personal characteristics, there was no rational basis for preferring one patient to another.

26. However, it is of note the Court of Appeal were of the view that they did not have the power specifically to order the PCT to fund the treatment. It was, following the court's ruling, then a matter for the PCT to reconsider their policy in the light of the court's findings and to formulate a lawful policy upon which to base decisions in particular cases which was compatible with the legal principles the court had outlined.

B. THE REMIT AND BOUNDS OF JUDICIAL REVIEW IN GENERAL

27. As a general principle, the courts will only be willing to overturn decisions made by the bodies charged with allocating NHS resources where the decision is in some way irrational, illogical or flawed, though it is debatable the extent

to which this principle has been consistently applied in practice. Legally, therefore a court can only interfere with the decision made by a body charged with allocating resources if it finds that that body has reached a conclusion which no reasonable authority could have made.

28. In the recent lead case on the provision of Herceptin to HER2 positive breast cancer sufferers the Court of Appeal, with the Master of the Rolls Sir Anthony Clarke giving the judgment of the court, took as the correct approach at common law in cases of this kind, which was accepted by either party, the position of Sir Thomas Bingham MR in the case of ***R v Ministry of Defence ex parte Smith*** [1996] QB 517 in which he stated at paragraph 554E

> *"The court may not interfere with the exercise of an administrative discretion on substantive grounds save where the court is satisfied that the decision is unreasonable in the sense that it is beyond the range of responses open to a reasonable decision-maker. But in judging whether the decision maker has exceeded this margin of appreciation the human rights context is important. The more substantial is the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable in the sense outlined above."*

29. The duties and considerations which should be taken into account by any body charged with the allocation of NHS resources will vary according to the precise direction or guideline from the Secretary of State in force at the relevant time, and the relevant statutory provision under which the relevant decision making body is charged with allocating resources. Thus in the case of ***R v Secretary of Health, ex p Pfizer*** [1999] Lloyds Rep Med 289, as discussed previously, a case concerning the specific issue of generic prescribing of Viagra in primary care, the criteria in force at the time under which the Secretary of State for Health had exercised her power in recommending to GPs not to prescribe Viagra were the National Health Service (General Medical Services Regulations) 1992 and in particular Schedules 10 and 11 thereto which provided for drugs for which the NHS would not pay. When

deciding whether the decision was one which was reasonable would now be judged against the General Medical Services (Contracts) Regulations 2004.

30. The courts have consistently emphasised and acknowledged the difficulties that exist for any decision maker as regards the allocation of NHS resources. In particular, the courts have stressed the difficulty of reconciling the ever present tension between the increasingly conflicting demands made of the NHS by individuals on the one hand and the need to preserve the finite resources for the wider community as a whole on the other. Once the money is spent in one sphere of healthcare or on one particularly costly treatment, it stands to reason that it is no longer there to be spent again should someone or some other area of the community emerge with a similarly meritorious claim to that money.

31. The principle, from which the majority of cases in the area of resource allocation take their lead is carefully articulated in well known observations of Sir Thomas Bingham MR, in the case of ***R v Cambridgeshire Health Authority Ex parte B*** [1995] 1 WLR 898 at paragraph 905 in which he stated:-

> *"the courts are not, contrary to what is sometimes believed, arbiters as to the merits of cases of this kind. Were we to express opinions as to the likelihood of the effectiveness of medical treatment, or as to the merits of medical judgment, then we should be straying far from the sphere which under our constitution is accorded to us. We have one function only, which is to rule upon the lawfulness of decisions. That is a function to which we should strictly confine ourselves"*

32. He went on to say at paragraph 906D:-

> *"I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if 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."

C. ATTEMPTS AT EUROPEAN CHALLENGES TO RESOURCE ALLOCATION

33. In conjunction with the normal use of the domestic Judicial Review process, certain attempts have also been made to challenge the Secretary of State's entitlement to restrict the use of certain drugs under European law, most notably challenges based on the use of Viagra in the Pfizer cases ***R v Secretary of Health, ex p Pfizer*** [1999] Lloyds Rep Med 289 and latterly ***R v Secretary of State for Health, ex parte Pfizer Ltd*** [2002] EWCA Civ 1566.

34. In the latter case before the Court of Appeal, the claimant argued that the Secretary of State's decision did not contain a statement of reasons based on objective and verifiable criteria and was thus in breach of Art.7 Council Directive 89/105/EEC (The Transparency Directive) and that the secretary of state ought to have conducted an analysis as to whether treatment for impotence ought properly to be regarded as constituting a lower priority than the treatment of other non life-threatening conditions. The Secretary of State submitted that the application of the criterion in any given case, i.e. the forming of the judgment as to competing priorities and thus the affordability

of the product was entirely a matter for the Secretary of State and did not require further explanation.

35. The Court of Appeal held that Art.7 of the Directive did not require the Secretary of State to conduct an in depth analysis of competing priorities within the NHS before he could restrict the prescription of any product. The Secretary of State's decision did not require any other form of analysis or explanation. The transparency required by the Directive was in the published criteria and they themselves were objective and verifiable.

36. Similarly, in the initial application for judicial review, discussed earlier in ***R v Secretary of State for Health, ex p Pfizer*** [1999] Lloyds Rep Med 289, a collateral challenge was brought under European law in addition to the successful application for judicial review. The claimant, the makers of Viagra, argued that the restriction on GPs prescribing Viagara, or the refusal to allow its being prescribed at all, as the court held it de facto amounted to, was in breach of Article 28 of the European Treaty and the freedom of inter state trade.

37. Since Viagra was imported from another Member State it was argued that there was prima facie discrimination against it which amounted to a quantitative restriction upon it. The court held that ECJ had given a very wide interpretation to Art.28 EC Treaty and it extended to prohibiting all trading rules which were capable of hindering intra-community trade, whether directly or indirectly, actually or potentially (see ***Procureur du Roi v Dassonville*** (1974) ECR 837).

38. However, the first question was whether the circular constituted a "measure" within the meaning of Art.28. Relying on Commission of the ***European Communities v Ireland*** (1982) ECR 4005 the court held that it was clear, in

view of the purpose of the circular and its effect upon the sales and imports from another Member State of the product, that the circular did constitute a measure within the meaning of Art.28. If the effect of the circular was to restrict, or be capable of restricting, community trade it was unlawful. The secretary of state had failed to demonstrate that the measure was incapable of contravening Art.28 and the authorities cited did not overrule ***Duphar v Netherlands*** (1984) ECR 523, which had concerned measures akin to Schedules 10 and 11 of the 1992 Regulations, now the 2004 Regulations.

39. Nevertheless, the court found that Art.28 was to be qualified by Art.30 (formerly Art.36) by reference to the protection of health and life of humans; and although it was clear that when the circular was introduced the secretary of state had been thinking in purely economic terms, that had been because of the potential effect on the availability of the Health Service to provide for others such that the health of the nation could be adversely affected. Therefore, although there was discrimination against Viagra, the measure was justified under Art.30.

40. It is submitted therefore, that European attacks are unlikely to form the basis of many future challenges to PCT decisions on the allocation of drugs given the comparatively unreceptive way in which the courts have entertained arguments based on European law in comparison to the often successful attempts at Judicial Review discussed earlier.

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