1 Introduction

Towards the end of 2005, a major news story broke in the British media. Under headlines such as 'NHS denies woman life-saving drug to treat breast cancer',[1] 'Why can't I have breast cancer drug now?'[2] and 'Bureaucracy threatens cancer sufferers' lives',[3] it was reported that a number of Primary Care Trusts (PCTs) and health boards, whose responsibility it is to commission provision of healthcare services for their local populations, had refused requests to provide funding for a new 'wonder drug', Herceptin, for the treatment of early stage breast cancer. Journalists and commentators cited evidence that there were geographical variations in access to the treatment (an example of the so-called 'postcode lottery' in the provision of care),[4] reported dissatisfaction with 'bureaucratic' regulatory processes which were perceived as delaying access to the treatment,[5] and noted that a number of disappointed patients were threatening to make use of the courts in an attempt to overturn decisions to deny access to the treatment.[6]

Across the globe, similar incidents are occurring as health systems of all types come under significant strain from the increasing demands placed upon them. Decisions on the allocation of resources for healthcare represent some of the most pressing and controversial choices faced by modern governments. Yet, this was not how it was supposed to be. For example, in the United Kingdom (UK), the belief was that the establishment of the National Health Service (NHS) would reduce the demand for healthcare services and thus offset the requirement to establish priorities

[1] *The Independent*, 9 November 2005.
[2] *BBC News Online*, 19 October 2005, available at http://news.bbc.co.uk/1/hi/health/4355950.stm (accessed 8 January 2007).
[3] *Daily Mail*, 14 November 2005.
[4] See e.g. 'Scots get Breast Cancer "Wonder Drug"', *The Scotsman*, 17 February 2006; 'Postcode Lottery for Cancer Wonder Drug', *Daily Mail*, 10 April 2006.
[5] See e.g. *Daily Mail*, above n. 3, 'Life or Bureaucracy?', *The Times*, 16 February 2006.
[6] See e.g. 'Nurse Sues for Right to Have Breast Cancer Drug', *Sunday Times*, 18 September 2005; 'Mother's legal fight for life', *Daily Express*, 9 November 2005.

for expenditure. Put simply, 'the assumption in 1948 was that there existed a finite amount of ill-health in the land, that this could be reduced by improved healthcare and that thereafter the maintenance of the good health of the population would be a relatively simple matter'.[7] Today, with the hindsight afforded by more than half a century of growing pressure on a publicly funded health service which has been described as existing in a state of 'almost perpetual crisis',[8] such a view seems almost astonishingly naïve.

Nevertheless, demanding as it is, the policy problem arising within health systems is not 'simply' the need to manage the mismatch between the demand for healthcare and the supply of available resources. Disappointed individuals who have been denied access to treatment seem increasingly unwilling to accept such decisions without question. The process of allocative decision-making in healthcare is thus strongly marked by volatility. As an eminent commentator notes: 'suspicion, distrust and even resistance [will] often greet efforts to set limits on access to medical services'.[9] Accordingly, there is a need to undertake steps to address the systemic instability which tends to be generated by the 'rationing' of healthcare resources.

The most straightforward reading of the increasing readiness to resort to litigation in cases of this type would suggest that this is a symptom of such instability. It follows that those policy-makers and academic commentators who are concerned to find means to resolve this problem will tend to regard the involvement of the law with disapproval. This book seeks to propose an alternative perspective, which provides the basis for a more positive evaluation of the role of law, and particularly of the courts, in this field. However, working from the premise that a proper appreciation of the function of law cannot be developed in isolation from the socio-political environment in which it operates, it is necessary also to attain an understanding of the character of allocative decision-making in healthcare and of the nature of the difficulties which arise. In this respect, the Herceptin episode affords an instructive illustration, and examination of it in more depth therefore offers a useful starting-point for analysis.

[7] B. Salter, *The Politics of Change in the Health Service* (Basingstoke: Macmillan, 1998) at 17.
[8] R. Klein, 'Self-Inventing Institutions: Institutional Design and the UK Welfare State' in R. Goodin (ed.), *The Theory of Institutional Design* (Cambridge: Cambridge University Press, 1996) at 243.
[9] N. Daniels, 'Accountability for Reasonableness in Private and Public Health Insurance' in A. Coulter and C. Ham (eds.), *The Global Challenge of Health Care Rationing* (Buckingham: Open University Press, 2000) at 89.

Herceptin and the NHS: a case study of the rationing of treatment

Herceptin (the brand name of the drug trastuzumab) is a targeted treatment for breast cancer. It takes the form of a monoclonal antibody which attaches itself to those cancer cells containing large amounts of the HER2 protein which functions as a growth factor receptor, stimulating cancer cells to grow and multiply. It has been used on its own and in combination with chemotherapy for advanced breast cancer for a number of years, and guidance issued by the National Institute for Clinical Excellence (NICE, an independent agency whose responsibilities include the appraisal of the clinical and cost-effectiveness of new medical technologies)[10] in May 2002, recommended that it be made available on the NHS in England and Wales for certain categories of patient suffering from the disease in its advanced state. Subsequently, three major international clinical trials on patients with early-stage breast cancer reported preliminary results which suggested that treatment with Herceptin significantly improved response rates, with the cancer returning in half as many cases as those in which treatment took the form of chemotherapy alone.[11] However, the drug is very expensive, with a standard 38-week course of therapy costing £15,500 per patient, as distinct from the cost of £2.39 per month for Tamoxifen,[12] currently regarded as the 'gold standard' anti-hormonal agent for breast cancer.

Unsurprisingly, once the results of the clinical trials started to emerge, pressure began to mount upon the British Government to make the drug available on the NHS for those suffering from early stage breast cancer. A campaign group, Women Fighting for Herceptin, was established in July 2005 and it subsequently organised a march on Downing Street, presenting a petition of more than 30,000 signatures demanding access to the treatment.[13] The media campaigned for the drug to be made available.[14]

[10] For further discussion of the Institute (now renamed the National Institute for Health and Clinical Excellence), see below Chapters 2 to 4.

[11] See M. Piccart-Gebhart, M. Proctor, B. Leyland-Jones *et al.*, 'Trastuzumab after Adjuvant Chemotherapy in HER2-positive Breast Cancer' (2005) 353 *New England Journal of Medicine*, 1659; E. Romond, E. Perez, J. Bryant *et al.*, 'Trastuzumab Plus Adjuvant Chemotherapy for Operable HER2-Positive Breast Cancer' (2005) 353 *New England Journal of Medicine*, 1673; R. Dent and M. Clemons, 'Adjuvant Trastuzumab for Breast Cancer: We Need to Ensure that Equity Exists for Access to Effective and Expensive Treatments' (2005) 331 *British Medical Journal*. 1035.

[12] See 'Live or Die? Your Postcode Decides', *The Guardian*, 6 October 2005.

[13] See 'Breast Drug Campaign Frustration', *BBC News Online*, 22 September 2005, available at http://news.bbc.co.uk/1/hi/health/4270548.stm (accessed 8 January 2007); also 'Herceptin Group Takes to Streets', *BBC News Online*, 13 November 2005, available at http://news.bbc.co.uk/1/hi/england/staffordshire/4430036.stm (accessed 8 January 2007).

[14] 'Breast Cancer Campaign', *The Sun*, 30 September 2005.

The issue was also regularly raised in both Houses of Parliament,[15] was discussed in Select Committee[16] and was the subject of both a private members' debate in Westminster Hall[17] and an Early Day Motion sponsored by the shadow Health Secretary.[18]

Such pressure prompted a political response. The Government announced that all women with early stage breast cancer were to be tested to ascertain whether they could benefit from the drug,[19] indicated that PCTs and health authorities should not refuse access to the treatment on cost grounds alone,[20] and promised that the drug would be 'fast-tracked' for appraisal of its clinical and cost-effectiveness by NICE as soon as a marketing licence had been issued by the European Medicines Agency (EMA).[21] More broadly, concern over delay in accessing this and other treatments, given the usual length of a NICE technology appraisal, prompted the Institute to review its decision-making processes, leading to the introduction of a Single Technology Appraisal which would issue recommendations within eight weeks, in contrast to the 54-week average length of the existing process. Herceptin was identified as one of the first treatments scheduled for appraisal via the new process, once implemented.[22]

In certain parts of the UK, the response to these developments was to make Herceptin immediately available for early stage breast cancer patients for whom it had been recommended.[23] However, elsewhere, a number of other PCTs became embroiled in controversy over decisions to deny access to the treatment. Such refusal was justified primarily on the basis that regulatory processes should not be circumvented by permitting access to the treatment prior to its evaluation by EMA and NICE. This enabled the argument to be made that the safety and effectiveness of the

[15] See e.g. *House of Commons Debates*, vol. 439, col. 2268W (24 November 2005); vol. 440, cols. 398W and 403W (29 November 2005); *House of Lords Debates*, vol. 674, col. WA33 (10 October 2005).
[16] Health Committee, *Public Expenditure on Health and Social Services*, HC 736-ii (2005–06) qs. 271–281.
[17] *House of Commons Debates*, vol. 438, col. 185WH (1 November 2005).
[18] EDM 1020, 14 November 2005 (A. Lansley).
[19] See 'Breast Cancer Drug Test for All', *BBC News Online*, 5 October 2005, available at http://news.bbc.co.uk/1/hi/health/4311140.stm (accessed 8 January 2007).
[20] Department of Health, Chief Executive Bulletin No. 294, 4–10 November 2005.
[21] Department of Health Press Release 2005/0263 (20 July 2005).
[22] NICE Press Release 2005/027 (3 November 2005).
[23] See e.g. 'Herceptin Decision "Breakthrough"', *BBC News Online*, 18 October 2005, available at http://news.bbc.co.uk/1/hi/england/cornwall/4354448.stm (accessed 8 January 2007) (Devon and Cornwall); 'Minister in N.I. Cancer Drug Move', *BBC News Online*, 11 November 2005, available at http://news.bbc.co.uk/1/hi/northern_ireland/4426816.stm (accessed 8 January 2007) (Northern Ireland).

drug was as yet unproven. However, it was apparent that cost also played an important part in the thinking of PCTs, notwithstanding the injunction of the Secretary of State for Health that financial factors should not be the sole considerations underpinning decisions to deny access. Thus, one PCT argued that 'the evidence of [Herceptin] as a cost-effective use of the finite health resources available for [the PCT's] patients is not confirmed. It would therefore be premature to agree to introduce it as a routine treatment. To do so could seriously affect the availability of care to other patients, including those with other cancers.'[24] Financial concerns were exacerbated by the need for PCTs to allocate funding for any provision of Herceptin from their existing budgets, as the Government refused to provide any additional resources to pay for the treatment.[25]

For those patients who were refused access to Herceptin, two avenues of challenge were available. Initially, challenges were mounted through the PCT's *internal appeal process*. Here, the patient would appeal against the decision which had been reached under the PCT's 'Commissioning Exceptions Policy' (which covered cases in which treatment was not normally funded – for example, because there was insufficient evidence of effectiveness – but where individual clinical circumstances warranted an exception being made) to a Commissioning Appeals Panel. In some instances, this proved successful, as PCTs reversed the original decision.[26] However, in other cases, patients sought, or threatened, *judicial review* of the refusal to make the drug available. In two such cases, the threat of legal proceedings (coupled, in the second instance, with significant political pressure) prompted the PCT concerned to reverse its initial decision and to make the drug available, citing the patient's 'exceptional circumstances' as justification.[27] In a third case, the Court of Appeal (reversing the decision of the court at first instance) found that Swindon PCT had acted unlawfully in operating a policy which purported to allow for the provision of Herceptin upon proof of exceptionality but under which it was, in practice, impossible to envisage any

[24] North Stoke Primary Care Trust, Press Release, 8 November 2005.
[25] See *House of Commons Debates*, vol. 439, col. 1361 (22 November 2005) (J. Kennedy).
[26] For an example, see 'Cancer Woman Can Appeal Drug Ban', *BBC News Online*, 3 November 2005, available at http://news.bbc.co.uk/1/hi/england/manchester/4403614.stm (accessed 8 January 2007) and 'Cancer Patients Win Herceptin Bid', *BBC News Online*, 18 November 2005, available at http://news.bbc.co.uk/1/hi/england/manchester/4449966.stm (accessed 8 January 2007).
[27] See 'Breast Cancer Sufferer Wins Fight for Wonder Drug', *The Times*, 3 October 2005; 'Health Chiefs Avert Court Clash over Cancer Drug', *The Times*, 10 November 2005. In the latter case, the Secretary of State had sought an urgent meeting with the PCT to discuss the refusal: see 'Hewitt Steps in to "Wonder Drug" Cancer Row', *The Times*, 8 November 2005.

exceptional circumstances which would justify provision of funding for one patient and denial for another.[28]

Finally, in August 2006, NICE issued guidance recommending that Herceptin be made available on the NHS for women with early stage HER2-positive breast cancer, except where concerns existed as to cardiac function.[29] However, controversy continued to surround the treatment, with cancer specialists pointing out that cuts in other services would be required to fund provision of the drug.[30]

What conclusions may be drawn from the Herceptin episode? First, it is apparent that any decision to 'ration' the provision of healthcare will only emerge after engagement with a complex interplay of various factors, including those of a clinical, financial and political nature. This is significant because, while the development of more explicit methodologies and mechanisms for the allocation of resources in healthcare has served to render more publicly visible the necessity of making 'hard choices' in this field of public policy, the inherent 'messiness' of this form of decision-making can readily generate incomplete or confusing – and possibly, deliberately misleading – explanations for rationing decisions. For example, North Stoke PCT, as cited previously, purported to justify its initial refusal to provide Herceptin to a patient on the grounds of the insufficiency of evidence of the safety and *relative* cost-effectiveness of the drug.[31] Upon reversing the decision, it sought to refute media suggestions that the *absolute* cost of the treatment had been a factor (albeit that this claim was perhaps somewhat undermined by the PCT's simultaneous observation that it had no budget to provide for Herceptin in the current financial year and that it would cost £700,000 to provide in the following year).[32] The apparent confusion between these two arguments suggests that the PCT's reasoning was not fully understood by the public or by the patient, who were likely to perceive the decision indiscriminately as being 'about money'.[33] It might therefore be argued that decision-making in

[28] See *R (on the application of Rogers)* v. *Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] 1 WLR 2649, discussed in Chapter 6 below.
[29] NICE Press Release 2006/038 (23 August 2006).
[30] A. Barrett, T. Roques, M. Small *et al.*, 'How Much Will Herceptin Cost?' (2006) 333 *British Medical Journal*, 1118.
[31] See above n. 24 and accompanying text.
[32] North Stoke Primary Care Trust, Press Release, 9 November 2005.
[33] See e.g. A. d'Argue, quoted in 'Woman Waits for Herceptin Ruling', *BBC News Online*, 2 November 2005, available at http://news.bbc.co.uk/1/hi/england/manchester/4398588.stm (accessed 8 January 2005): 'It is an NHS lottery and it always will be and however they dress it up the bottom line is it's about money'; A. M. Rogers, quoted in 'Doctors "Prescribing Herceptin"', *BBC News Online*, 3 February 2006, available at http://news.bbc.co.uk/1/hi/health/4677538.stm (accessed 8 January 2007): 'I think it's down to money and I think they put money before life'.

this field continues to be somewhat opaque and that mechanisms should be devised through which those responsible for allocative decisions can be called to provide reasoned explanations and evidence for the choices which have been made, in a manner which is comprehensible both to those directly affected and the broader public. As will be argued subsequently in this book, such a development can benefit decision-makers as well as those subject to the decision, in that the process of justification should enhance public understanding both of the need for, and the criteria relevant to, limit-setting choices in healthcare. In turn, this can stimulate a process of democratic debate upon healthcare rationing.

The tendency for explicit rationing decisions to be socially and politically unstable is also amply demonstrated by the Herceptin case. Notwithstanding attempts to 'depoliticise' the process of resource allocation in healthcare through the establishment of technocratic modes of decision-making which draw upon scientific and social-scientific evidence to reach 'rational' conclusions upon priorities for expenditure (as reflected in this instance by the roles fulfilled by the EMA and NICE regulatory agencies),[34] this field of public policy remains strongly characterised by 'classic' pluralist politics. This takes the form of extensive interest group lobbying, direct government intervention and activation of internal and external mechanisms for appeal and review. Indeed, perhaps paradoxically, the techniques of 'evidence-based medicine' actually served to fuel the controversy in this instance, in that the campaign to make Herceptin available on the NHS for those suffering from early-stage breast cancer was largely stimulated by the results of the three major international clinical trials. This appears to reinforce the view that, while 'sometimes defining issues as questions of technique or evidence masks the underlying political disputes ... the political issues are still there, even when they are addressed indirectly using the language of technique and evidence. Battles over income, turf, and the goals of medicine and policy lie just below the surface. Under these circumstances, evidence becomes an instrument of politics rather than a substitute for it.'[35]

As well as being prone to political instability, it is readily apparent that decisions on the rationing of healthcare resources provoke a significant clash of ethical perspectives. Once again, this is clearly evident from the

[34] For discussion, see K. Syrett, 'A Technocratic Fix to the "Legitimacy Problem"? The Blair Government and Health Care Rationing in the United Kingdom' (2003) 28 *Journal of Health Politics, Policy and Law*, 715.

[35] M. Rodwin, 'The Politics of Evidence-Based Medicine' (2001) 26 *Journal of Health Politics, Policy and Law*, 439. See also Barrett, Roques, Small *et al.*, 'How Much Will Herceptin Cost?' at 1119.

events surrounding the availability of Herceptin. PCTs, such as that serving North Stoke, were apt to supplement explanations as to the need to avoid circumvention of the regulatory process by reference to utilitarian arguments:

> Primary Care Trusts strive to make good use of the resources entrusted to them in order to meet the requirements of their population in accordance with their statutory duties and to maintain and improve the health of their population to the greatest possible extent. North Stoke PCT is required to fund treatments (or preventative measures) of proven effectiveness for many groups of patients with well-recognised healthcare needs. In doing so it is necessary to make difficult choices about which services represent the best use of a finite resource.[36]

On the other hand, for their part, affected patients (and their supporters and advisors) would typically posit powerful individualistic claims based upon clinical need and human rights. Thus, Elaine Barber, the woman involved in the North Stoke case, argued that 'I need this drug to help me survive – without it I will die',[37] and remarked that 'I can't believe that I have been put through all this just so the health authority can balance the books. Human life cannot and should not be measured in pounds',[38] while her solicitor indicated that the threatened legal challenge would be based upon an alleged violation of the right to life under the Human Rights Act 1998. Statements such as these suggest that individualistic and community-based ethical perspectives on the fair distribution of scarce healthcare resources may ultimately be incommensurable. This presents a very significant political problem for a government which seeks to set priorities for expenditure in a manner which is publicly regarded as legitimate.

The final – and for the purposes of this book's central theme most significant – issue raised by the Herceptin episode relates to the proper place of law in the rationing of healthcare resources. It is interesting to note that those patients who chose to invoke the threat of legal proceedings in their efforts to obtain treatment claimed to be doing so with considerable reluctance, arguing that they had been forced to act in such a way out of 'sheer desperation',[39] and that 'the last thing that

[36] Above n. 24.
[37] See 'Mother Refused Breast Cancer Drug', *BBC News Online*, 8 November 2005, available at http://news.bbc.co.uk/1/hi/england/staffordshire/4417076.stm (accessed 8 January 2007).
[38] See 'Woman Gets Cancer Drug in U-Turn', *BBC News Online*, 9 November 2005, available at http://news.bbc.co.uk/1/hi/england/staffordshire/4421570.stm (accessed 8 January 2007).
[39] B. Clark, quoted in 'Dying Nurse Sues NHS for Denying Her Cancer Drug', *The Observer*, 18 September 2005.

[the patient] wants to do is to go to court'.[40] This suggests both that the legal process (or, to be more precise, public law adjudication) is regarded as being somewhat marginal to decision-making on the allocation of healthcare, and further, that it is perceived in largely negative terms. It is seen as an obtrusion into the work of those responsible for setting priorities, which should only be employed as a means of last resort. Nonetheless, it is clear from the statements cited in the preceding paragraph that both the allocative choices made by PCTs and the challenges which were raised to these by individual patients were conceived, at least in part, in terms of the relevant legal framework: hence the reference to the 'statutory duties' of the PCT,[41] in addition to the more self-evident deployment of the Human Rights Act 1998 by frustrated patients. It appears extremely likely, therefore, that law will become involved to some degree in rationing choices such as that which was at issue in the case of Herceptin. Indeed, the probability of such engagement has increased significantly in recent years. This is in part because trends such as a more litigious citizenry and the rise of a 'rights culture', coupled with declining deference to the judgment of professionals and the greater availability of information, have made it more likely that individuals will look to the law when seeking to obtain treatment which has been denied to them. However, it is also submitted that the evolution by governments of strategies and institutions through which priorities for healthcare expenditure can be *explicitly* established has brought this field of public policy firmly within the ambit of *public law*, which may broadly be defined as law relating to the exercise and control of governmental power and relationships between the individual and the state.[42]

Objectives, structure and scope of this book

It is this interface between public law and the rationing of healthcare resources which forms the subject-matter of this book. In keeping with its subtitle, the analysis which is offered reflects both a contextual and comparative approach, albeit one which is, in places, particularly informed by the author's British perspective.

[40] Y. Amin (solicitor), quoted in 'My Fight for Life', *ThisisWiltshire.co.uk*, 19 December 2005, available at www.thisiswiltshire.co.uk/display.var.663185.0.my_fight_for_life.php (accessed 8 January 2007).
[41] See above n. 36 and accompanying text.
[42] See e.g. A. Bradley and K. Ewing, *Constitutional and Administrative Law* (London: Longman, 14th edn, 2006) at 9–10.

Chapters 2 and 3 seek to provide the reader with an understanding of the *policy context* against the backdrop of which public law adjudication on healthcare rationing has evolved. As such, they may primarily be of interest to those with relatively little knowledge of recent policy developments within health systems who wish to comprehend the nature of the issues confronted by the courts in this area. The discussion will consider what it means to speak of the 'rationing' of healthcare, why rationing takes place, the extent to which it is both inevitable and of growing significance, which individuals or institutions should have responsibility for undertaking rationing choices, and the varying strategies (both implicit and explicit) which have been deployed in an attempt to manage the mismatch between demand and supply in this area.

By contrast, Chapters 4 and 5 focus primarily upon the *theoretical context*. Drawing upon recent academic analyses of health policy and, more broadly, upon theories of democracy, Chapter 4 will seek to explain why rationing (in particular, the explicit variant) has generated a problem of legitimacy for those who must make decisions on the allocation of scarce healthcare resources. It will also consider the proposals which have been put forward to address this problem. In Chapter 5, the emphasis will switch to law. Perceptions of the appropriate role for law (and, especially, for public law litigation) in this field will be examined in light of concerns as to the competence of the judiciary to adjudicate upon disputes centred upon the rationing of healthcare. It will be noted that, while objections to judicial engagement remain highly pertinent, those working within the fields of health policy and public law share a common interest in the legitimation of public power and advance similar prescriptions for alleviating any deficiencies in institutional legitimacy which might serve to impair the pursuit of collective state goals.

It is the central contention of this book that, given these significant points of confluence, those concerned with resolving the 'legitimacy problem' to which the rationing of healthcare gives rise should reassess the contribution which may be made by the courts in this area of public policy. The nature of that contribution will be examined in Chapters 6 to 8, by means of a *comparative analysis* of the public law jurisprudence on questions of the allocation of scarce healthcare resources and the financing of healthcare in three jurisdictions: England, Canada and South Africa. In view of the growing involvement of the legal process in this arena of public policy, a characteristic which is readily apparent from the Herceptin example, such an analysis appears crucial to the development of a full understanding and critique of this form of allocative decision-making. However, Chapters 6 to 8 do not set out to offer an exhaustive account of the statute and case law relating to the allocation of scarce