

# **Regulatory Governance in the National Health Service 1985-2004:**

## **Analysing Selected Reform Initiatives**

by

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# **Declaration**

Parts of this thesis have been presented as work in progress on various occasions:

- A version of Chapter 7 was presented at the annual conference of the Socio-Legal Studies Association, Aberystwyth, Wales in April 2002.
- A version of Chapter 4 was presented at the Annual Conference of the Irish Medical Organisation, Killarney, Ireland in April 2003.
- A version of chapter 5 was presented at the Annual Conference of the Political Studies Association, University of Lincoln, April 2004

# List of Abbreviations

ABPI	Association of British Pharmaceutical Industries
ACBS	Advisory Committee on Borderline Substances
ACD	Advisory Committee on NHS Drugs
BMA	British Medical Association
CHI	Commission for Health Improvement
CHAI	Commission for Health Audit and Inspection
CSAG	Clinical Standards Advisory Group
DHA	District Health Authority
DMU	Directly Managed Units
DoH	Department of Health
EBM	Evidence-Based Medicine
ED	Erectile Dysfunction
ESRC	Economic and Social Research Council
FHSA	Family Health Service Authority
HA	Health Authority
HAS	NHS Hospital Advisory Service, Health Advisory Service
HImP	Health Improvement Programme
HIMP	Health Improvement and Modernisation Programme
MoH	Ministry of Health
NAO	National Audit Office
NGO	Non-Governmental Organisation
NHS	National Health Service
NHSME	NHS Management Executive
NRT	Nicotine Replacement Therapy
NSFs	National Service Frameworks
PCT	Primary Care Trust
PIs	Performance indicators
PPRS	Pharmaceutical Price Regulation Scheme
PSB	Public service bargain
RHA	Regional Health Authority
SHA	Strategic Health Authority
SMAC	Standing Medical Advisory Committee
WHO	World Health Organisation

# Abstract

This thesis analyses the growth of regulation in the National Health Service (NHS) between 1985 and 2004. It argues that the development of the NHS over this period conforms to the pattern, asserted more generally in existing scholarship, of a rise of the regulatory state in Western European countries. One conventional explanation for the pattern of development—the increasing importance placed on establishing credible policy commitments—is shown to be compatible with observed patterns of development in the NHS. Building on earlier work, which argued that the organisation of the NHS was underpinned by an implicit concordat between politicians and the medical profession, it is argued that regulatory state type institutions potentially reconcile the imperative of credible commitment to the concordat with demands for greater governmental intervention in the provision of health services. Adapting an analytical framework developed by Brian Levy and Pablo Spiller, this thesis argues that regulatory reforms in the NHS are unlikely to achieve their publicly pronounced objectives if the legal and administrative framework for regulation does not demonstrate credible commitment to the implicit concordat. This is labelled the ‘regulatory commitment hypothesis’. In order to assess the plausibility of this hypothesis, three episodes of regulatory reform are examined which, on the basis of the modified Levy and Spiller framework, can be said to engender varying degrees of commitment. The three episodes are: (1) the Limited List of NHS Drugs; (2) The National Institute for Clinical Excellence; and (3) the Commission for Health Improvement. Overall, an examination of these three episodes of regulatory reform provides grounds for cautious support for the regulatory commitment hypothesis.

# Chapter 1

## Introduction

### 1.1 Motivation and Context

In the UK and elsewhere, the last two decades have witnessed an unprecedented growth of regulation of health services. Whereas regulation of health care professions, mainly in the form of self-regulation by professional bodies, has been a longstanding feature of the organisation of health care, regulation of health *services* has not until recently been particularly prominent. Since the 1980s, however—and particularly in the years since 1997—there has been a marked extension of regulatory intervention in the UK into aspects of health care provision not previously subject to formal state regulation. Ostensibly, this has been motivated by a number of concerns, including cost-saving, eliminating poor clinical performance and assuring patient safety, and a desire to ensure that ‘best practice’ is quickly and effectively extended to all parts of the health service. Moreover, other countries in the OECD and elsewhere, facing similar concerns, have looked to the UK as a source of lessons in how to introduce regulatory reforms into their own national systems.

This thesis examines the changes that have taken place in the way the NHS was governed between 1985 and 2004. It argues that lessons from the UK experience are likely to prove elusive if they do not explicitly take

into account the broader institutional context in which regulatory reforms have been implemented. In particular, it claims that the rise of the regulatory state inside the NHS may lead to disappointing outcomes if the legal and regulatory framework of health care regulation may undermine existing understandings on which the provision of health services is founded. On the positive side, one implication of the findings of this thesis is that increased regulatory intervention in the provision of health care may be both feasible and desirable, provided that reforms engender credible commitment to these understandings.

The following section of this introductory chapter briefly sets out more explicitly the hypotheses advanced in this thesis, and attempts to justify the particular research question and choice of hypotheses. A third section deals with the organisation of this thesis.

## 1.2 The Argument of this Thesis

### 1.2.1 Two Related Hypotheses

There have been a number of empirical studies of change in the NHS, and a range of theses have been put forward to explain these changes, within a variety of analytical frames. Drawing on the work of Hood *et al.*,<sup>1</sup> one perspective, from which many of the more prominent changes in the NHS can be understood, is as a domain of 'regulation inside government'. As the previous section noted, the last twenty years have witnessed an unprecedented growth of regulation in the NHS. Notwithstanding this

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<sup>1</sup> Hood, Scott, James, Jones and Travers (1999). *Regulation Inside Government: Waste-Watchers, Quality Police, and Sleaze-Busters*. Oxford, Clarendon Press, p. 19.

growth, relatively few studies, however, have sought to understand health care in the UK specifically as a regulated domain.<sup>2</sup>

Adopting the 'lens' of regulation, specifically the 'regulatory design' frame,<sup>3</sup> is not to deny the value of alternative approaches, such as those which characterise changes over the last twenty years or so in terms of the rise of the 'new public management'.<sup>4</sup> Applying this frame does however offer an advantage over existing approaches in that it focuses its attention on an aspect the governance of health care that has been relatively under-emphasised by the existing literature, and can therefore be said to complement more conventional approaches.

Two key hypotheses are set out in this research. The first is that the development of the NHS over the twenty-year time-span covered in this thesis corresponds to the pattern, asserted more generally, of a 'rise of the regulatory state' in Western European countries, and in the EU itself.<sup>5</sup> It is argued here that one conventional explanation for this pattern of development, namely that it is a response to an increase in the importance attached by governments to the establishment of credible policy commitments, is also capable of explaining developments in the UK health sector.

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<sup>2</sup> For a prominent exception, see Walshe (2003). *Regulating Healthcare: A Prescription for Improvement?* Buckingham, Open University Press. Walshe applies a framework for the evaluation of health care regulation based on seven areas of evaluation. The approach is not primarily evaluative, but rather aims to explain regulatory change, and to relate institutions to regulatory outcomes.

<sup>3</sup> For a review of the leading approaches in the analysis of regulation, see Lodge (1999). "Competing Approaches to Regulation", in Eliassen and Sjovaag (ed.) *European Telecommunications Liberalisation*. London, Routledge.

<sup>4</sup> For example, Ferlie, Ashburner, Fitzgerald and Pettigrew (1996). *The New Public Management in Action*. Oxford, Oxford University Press.

<sup>5</sup> This claim is, above all, associated with the work of Giandomenico Majone. See for example Majone (1994). "The Rise of the Regulatory State in Europe." *West European Politics* 17 (1): 77-101.

The second, and related, hypothesis concerns the design of regulatory institutions. Adapting a framework developed by Brian Levy and Pablo Spiller and their collaborators,<sup>6</sup> this thesis puts forward the following argument: regulatory reforms in the NHS are unlikely to achieve their intended, publicly pronounced objectives unless the legal and administrative framework of regulation is capable of securing credible commitment to implicit understandings between the medical profession and government concerning the scope of regulatory intervention, its effects, and other key variables of regulatory policy. Furthermore, the capacity of a regulatory regime to achieve credible commitment depends not only on the detailed regulatory enactments setting out the powers, duties and procedures of regulatory authorities—that shall later be termed ‘operational rules’—but on the interaction between these operational rules and the broader institutional setting.

The idea of institutional commitment closely links these two hypotheses. Institutional commitment is understood here as the capacity of legal and political institutions to enforce inter-temporal political bargains, specifically an ‘implicit concordat’ which, according to existing scholarship,<sup>7</sup> existed between the medical profession and the Department of Health, and which has underpinned the organisational structure of the NHS since its inception. On the one hand, an emphasis on administrative regulation over alternative policy instruments is, according to the first hypothesis, one strategy for reconciling (to the extent to which this is

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<sup>6</sup> See Levy and Spiller (1994). "The Institutional Foundations of Regulatory Commitment: A Comparative Analysis of Telecommunications Regulation." *Journal of Law, Economics and Organization* 10 (2): 201-246; Levy and Spiller, eds. (1996). *Regulations Institutions and Commitment: Comparative Studies of Telecommunications*. Cambridge, Cambridge University Press.

<sup>7</sup> Notably Klein (1983). *The Politics of the National Health Service*. London, Longman. The most recent edition is Klein (2001). *The New Politics of the NHS*. 4th Edition, Harlow, Prentice Hall.

possible), public and political demand for greater intervention by governments in the health care sector with the continued extension to the medical profession of privileges and entitlements as part of a public service bargain or implicit concordat. On the other hand, this thesis attempts to show that, as a strategy reconciling these potentially contradictory demands, this particular approach to instrument choice is only likely to be successful where a number of complementary institutional mechanisms are present. In particular, this thesis analyses the features of the legal and administrative framework for health care regulation that are conducive to credible commitment and consequently, to successful outcomes within 'Westminster-Whitehall' style constitutional arrangements.

In order to assess the plausibility of these arguments, the thesis analyses regulation in the NHS on two levels. Firstly, it looks at the broad pattern of NHS reforms over the last twenty years, taken as a whole. Second, it examines in detail three episodes of regulatory reform. These three episodes are: (1) The Limited List of NHS Drugs (later known as the Selected List scheme); (2) The National Institute for Clinical Excellence (NICE); and (3) the Commission for Health Improvement (CHI). The basis for the selection of these three episodes for detailed analysis is discussed in Section 1.2.3, *infra*. An observation about the jurisdictional scope of this study is in order: this thesis restricts its focus to the NHS in England and Wales. At the same time, since the first detailed episode of regulatory reform examined in this thesis—the Limited List—was common throughout Britain, Chapter 5 looks also at developments in Scotland.

### 1.2.2 Justification of Research Topic and Hypotheses

It has been argued that, in general, academic research in law and political science ought to fulfil two criteria: first, it should address matters of real-world importance; second, it should make a contribution to (at least one) existing scholarly literature.<sup>8</sup> In terms of real-world importance, the sheer size of the NHS, in terms of expenditure and activity ought to be sufficient to justify the present inquiry. Revenue expenditure for the NHS in England was £57.129 billion in 2002-03 (with an estimated outturn of £64.305 billion in 2003-04).<sup>9</sup> In terms of activity, in 2002-03, there were some 241 million GP consultations,<sup>10</sup> while in secondary care there were 9.13 million 'finished consultant episodes' in general and acute care alone.<sup>11</sup> Not surprisingly, given the sheer size of the NHS in terms of resources and activity, health care is one of the most salient electoral issues, repeatedly ranking among the top one or two issues in terms of importance to voters.<sup>12</sup> Moran has identified three aspects (or 'faces') of health politics, namely, 'consumption politics', 'production politics' and 'professional politics'.<sup>13</sup> It is, he argues, the intersection of these three aspects that gives health care its peculiar political significance.

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<sup>8</sup> King, Keohane and Verba (1994). *Designing Social Inquiry: Scientific Inference in Qualitative Research*. Princeton, Princeton University Press, pp. 15-18; Epstein and King (2002). "The Rules of Inference." *University of Chicago Law Review* 69 (1): 1-133, pp. 55-61.

<sup>9</sup> Department of Health (2004) *Departmental Report 2004*, Cm 6204, London, The Stationery Office, p. 38.

<sup>10</sup> Ibid. p. 100.

<sup>11</sup> Ibid. p. 96.

<sup>12</sup> Worcester and Mortimore (2001). *Explaining Labour's Second Landslide*. London, Politicos, 29-31.

<sup>13</sup> Moran (1999). *Governing the Health Care State: A Comparative Study of the United Kingdom, the United States and Germany*. Manchester, Manchester University Press.

Understanding the particular significance of regulation inside the NHS, is more problematic, raising important definitional and methodological difficulties. There is no doubt that regulation of NHS organizations consumes a significant amount of financial resources—even on the narrowest definition, well over £100 million was spent by government on independent regulation of NHS organizations in 2002-2003.<sup>14</sup> This figure does not take into account the undoubtedly large but difficult to measure costs to regulatory organisations of regulatory compliance. The contribution that health care regulation makes to the performance of health care providers is even more difficult to assess. According to Walshe, existing research into the regulation of health services suggests that it:

... has both positive (desirable) and negative (or undesirable) effects; and that those effects are not highly predictable or deterministic, in that they vary not only from regulatory programme to programme, but also within any one programme between organisations and over time.<sup>15</sup>

Given the significant resources devoted to health care regulation, as well as the uncertain outcomes associated with this investment of resources, the present effort to understand the regulation of the NHS is eminently justifiable in terms of real-world importance. Furthermore, because issues of regulatory governance, and in particular the problems associated with securing credible commitment, have been neglected in existing studies of health care regulation in the UK, a focus on these issues affords the potential for improving on existing understandings, derived from alternative approaches, of the relationship between regulatory activities and outcomes.

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<sup>14</sup> See Section 3.3.3 *infra*.

<sup>15</sup> Walshe, op. cit., p. 162.

In terms of contribution to the existing scholarly literatures, this thesis adds to existing scholarship in a number of distinct ways. The first literature to which the present study adds is the literature on the so-called regulatory state. This literature has mainly focussed on privatised sectors, notably the public utilities, with relatively little attention to health services. The case of health care may be regarded as something of a 'crucial case' for the literature asserting the rise of the regulatory state, due to the political and social significance of health care noted in Section 1.2.1, above. Furthermore, as Chapter 3 argues, the case study of the NHS offers clues as to the resolution of one particular difficulty in the literature, namely that explanations for the rise of the regulatory state in Western Europe emphasise restrictions on the scope of state intervention, while in Britain at least, the regulatory state has been associated with expanded rather than diminished ambitions.<sup>16</sup> The present account argues that in the case of health, the imperative of credible commitment to the implicit concordat meant that an expansion of intervention was likely to produce positive outcomes only in the presence of effective restraints on the use of regulatory authority.

Second, and conversely to this first contribution, this thesis contributes to the extensive existing literature on health policy change, by positing a new interpretation of existing knowledge about the changes that have occurred in the NHS over the last two decades. Specifically, it is argued that the 'regulatory state hypothesis' can explain trends towards the separation of policy-making and service delivery functions, the proliferation of regulatory agencies as well as the shift towards increasingly formalised modes of decision-making, all of which have been noted in existing

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<sup>16</sup> This problem was first identified in Moran (2003). *The British Regulatory State*. Oxford, Oxford University Press. See further Section 2.2 and Section 3.4 *infra*.

literature, without much recognition of any underlying connection such as is suggested by the regulatory state hypothesis.

Third, this thesis extends existing scholarship in the law and economics concerned with the design of regulatory institutions by extending the analytical approach of Levy and Spiller and their collaborators into the context of health care regulation. The framework developed by Levy and Spiller was originally used to examine the willingness of private investors to undertake financial investment in a regulated sector, telecommunications, particularly in developing countries. Although publicly financed through taxation, the NHS nonetheless requires investments and commitments of other sorts, notably from staff and professional groups. This thesis argues that a modified version of the Levy and Spiller framework set out in detail in Chapter 4 can be used to analyse these other sorts of commitments. At the same time, this thesis suggests that, viewed through the 'microscope' (as opposed to Levy and Spiller's 'telescope' approach), certain departures from Levy and Spiller's assessment of the UK's 'institutional endowment' are warranted.

### **1.2.3 Relationship Between Hypotheses and Case Study Evidence**

The influential 'Popperian' tradition in the philosophy of science emphasises the cycle of 'bold conjecture' and refutation of hypotheses in the process of scientific advancement. According to this view, theoretical hypotheses about the real world can never be 'proved' right; however, as hypotheses are subject to more and more rigorous testing, without refutation, then we have increasingly firm grounds for confidence in a hypothesis. Conversely, if empirical investigation reveals observations that

are inconsistent with those ‘predicted’ by the hypothesis, especially under ‘most favourable’ conditions, then the hypothesis is likely to be false.

In legal and policy research, the issues that matter to the real world usually involve considerable complexity. Case study research in these areas frequently confronts the ‘many variables/few cases’ problem, because the complexity of the problem under analysis is not matched by the complexity of the research design, so that hypotheses can never be falsified—it is always possible to ‘explain away’ inconvenient cases by arguing that *ceteris paribus* assumptions do not hold up in a particular case by appealing to the inevitable peculiarities that arise in all cases. This limits the level of confidence that we can have in a ‘positive’ result, i.e. one in which the evidence is consistent with the observable implications of the theory. Some, such as King Keohane and Verba place great emphasis on improving empirical methods and a rigorous approach to the principles of scientific inference—in particular, they point to the risk that researchers will mislead themselves if they add restrictive conditions where more general hypotheses do not hold up, and then proceeding as if the modified hypothesis were shown to be correct.<sup>17</sup>

An alternative approach, advocated by Fritz Scharpf involves a shift away from ‘brute empiricism’, towards a greater emphasis on the careful deduction of new hypotheses from existing knowledge:

[S]ince our methods for subjecting hypotheses to quantitative empirical tests are inherently weak, this requires a shift of emphasis in the methodological discussion—away from the dominant focus on the quality of testing procedures and towards a greater concern for

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<sup>17</sup> King, Keohane and Verba, p. 21.

the quality of the hypotheses that we bring to our empirical material.<sup>18</sup>

On this view, *ex post facto* restrictions on hypotheses are not regarded as illegitimate in themselves—indeed, because much policy research is interested in explaining outcomes in particular cases, this is likely to be unavoidable. What matters is that distinctions invoked to explain such outcomes are themselves indicated by the theoretical considerations. Scharpf puts the point elegantly:

In exactly the same manner in which common-law courts must deal with divergent precedents, our “distinctions” must also “make a difference,” which is to say that they themselves must be based on the identification of a causal mechanism that could *generally* produce the different outcome.<sup>19</sup>

Thus, although it may always be possible to explain away the failure of general hypotheses to explain the features of specific cases by pointing to specific features of ‘problematic’ cases, not all such attempts to explain away inconvenient outcomes would be regarded as convincing.

Scharpf’s approach is in many ways similar to the approach put forwards some fifty years ago by Friedrich von Hayek.<sup>20</sup> According to Hayek, while generating and testing a hypotheses is a central part of scientific activity, a substantial part of the enterprise of science is concerned with extending our knowledge into new areas, both to advance our understanding of these areas, as well as to help identify the scope of application of a hypothesis:

The question of what is the range of application or the capacity of a theory, whether it can or cannot account for a certain group of observed phenomena, or whether observed events are within the

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<sup>18</sup> Scharpf (1997). *Games Real Actors Play: Actor-Centered Institutionalism in Policy Research*. Boulder CO, Westview, p. 28.

<sup>19</sup> Scharpf, *op. cit.* p. 33.

<sup>20</sup> Hayek (1967). “Degrees of Explanation”, in Hayek (ed.) *Studies in Philosophy, Politics and Economics*. London, Routledge and Kegan Paul.

range of what might have been predicted from it if all the relevant factual data had been known and if we were capable of manipulating them adequately, is often as interesting a problem as that whether the particular conclusion derived from the theory can be confirmed; and it is clearly independent of that question.<sup>21</sup>

Hayek adds that although it is desirable in applying theories into new areas it is desirable to check ones conclusions against observations, to the extent that this is possible: “The conclusions which we can draw from a combination of well-established hypotheses will therefore be valuable though we may not be in a position to test them.”<sup>22</sup>

The approach of the present thesis is much closer to the approach of Scharpf and of Hayek than with that advocated by King, Keohane and Verba, both in the relative emphasis it places on theory-building and the selection of hypotheses in order to generate confidence in conclusions, as well as in the interpretation of case-study data. As the discussion in Section 1.2.2 has indicated, the two hypotheses investigated in this thesis have proved fruitful in other areas—the regulatory state hypothesis has, as noted, been put forward by Majone as a high-level explanation for the changes in the mode of economic governance in Western Europe. Similarly, the regulatory commitment hypothesis has had some success in explaining the impact of regulatory design on the willingness of firms to make financial investments. The objective of the research is less to establish whether these hypotheses are true, but rather to establish whether these “sometimes true theories” hold up within the specific institutional conditions of the NHS, and can explain observed phenomena in that domain.<sup>23</sup>

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<sup>21</sup> Ibid. pp. 5-6.

<sup>22</sup> Ibid. p. 6. See also Hayek, F. (1964) “The Theory of Complex Phenomena”, also reproduced in *Studies in Philosophy, Politics and Economics* at pp. 22-42.

<sup>23</sup> Scharpf, op. cit., attributes the phrase “sometimes true theories” to sociologist James Coleman.

Another, closely related, reason for choosing hypotheses that have proved fruitful in other areas is that this fits better with the presumption (not ‘assumption’) of simplicity than the alterative approach, which would have been to develop health-sector specific hypotheses. This can be seen as an application of Occam’s razor, or its modern interpretation in the form of the Jeffreys-Wrinch simplicity postulate, namely that: “Simple theories have higher prior probabilities.”<sup>24</sup> In other words, by presuming that health is not ‘different’ from other sectors (with respect to those features identified by the hypotheses as significant), this thesis brings to the empirical material hypotheses that have a higher *ex ante* likelihood of being correct. It goes without saying that empirical investigation may reveal evidence that rebuts this presumption.

The advantages of case study research over alternative methodologies include the ability to control for relatively few but explicitly specified rival hypotheses, and the ability to illuminate ‘how?’ and ‘why?’ questions concerning decisions, or sets of decisions; hence, case study research has flourished in the areas of political science, public policy and public administration.<sup>25</sup> Case study research is particularly appropriate to this thesis, which as noted seeks to assess the capacity of the two hypotheses outlined in Section 1.2.1 can account for patterns of change in the NHS. The particular case study research design used here corresponds to what Yin calls ‘embedded single-case’ design; that is to say, a single case—regulation inside the NHS—is analysed at a relatively general level. Within this case, several sub-units are analysed in depth. Such designs are said to have a

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<sup>24</sup> Jeffreys, quoted in King, Keohane and Verba, *op. cit.* p. 20.

<sup>25</sup> Yin (2003). *Case Study Research: Design and Methods*. Thousand Oaks, CA, Sage, pp. xiii-xiv.

number of advantages over more common ‘holistic’ designs, notably that they are less abstract, more flexible and more focussed.<sup>26</sup>

As noted in Section 1.2.1, the three episodes of regulatory reform that make up the sub-units of analysis are: (1) the Limited List of NHS Drugs; (2) the National Institute for Clinical Excellence; and (3) the Commission for Health Improvement. These three sub-units were chosen, first, because they capture differences in policy over time as well as differences of approach between the two main political parties in the UK. Perhaps more importantly, on the basis of the framework of analysis set out in detail in Chapter 4, the three cases can be said to embody different degrees of institutional regulatory commitment.

A final reason for this particular choice of sub-units relates to the theoretical goal of assessing the applicability of the commitment frame to different issues in health care regulation. The first two episodes, the Limited List and NICE are more obvious cases for analysis along the lines of the particular approach advanced in this thesis, involving in different ways issues of ‘cutting waste’ and ‘rationing’ central to the implicit concordat.<sup>27</sup> The third episode, CHI, is rather intended to assess whether the approach works in a less obvious setting, where the ultimate regulatory goal is the more general one of improving the quality of health care. As Chapter 7 shows, the approach claims a partial success in this respect.<sup>28</sup> These episodes are not therefore intended to be representative, and for good

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<sup>26</sup> *Ibid.*, pp. 39-46.

<sup>27</sup> The terms ‘waste’ and ‘rationing’ are used here as terms of art, and are explained in detail in Chapter 4.

<sup>28</sup> The approach adopted here, of assessing the limits of a theory by beginning under more favourable conditions and then extending empirical analysis in small steps from more to less favourable conditions has been common—though not without criticism—in the social sciences. For a colourful defence of this approach against one critic see Dowding and John (1997). “Fairy Tale Critiques and Political Science: A Reply to Kenneth Newton.” *British Journal of Political Science* 27 (1): 152-155, p. 153.

reasons. As Yin puts it: "...cases are not 'sampling units' and should not be chosen for this reason. Rather, individual case studies are to be selected as a laboratory experimenter selects the topic of a new experiment."<sup>29</sup> They provide, according to Yin, the basis for *analytic* rather than *statistical* generalisation analogous to the way in which researchers in laboratory sciences generalise from experiments to theory.

Stephen Vogel's *Freer Markets, More Rules* illustrate the strength of this general approach to the context of the analysis of regulatory reform.<sup>30</sup> *Freer Markets, More Rules* first undertakes a broad analysis of regulatory politics in Britain and Japan, before proceeding to more specific analyses of a range of sectors in these countries. Analyses of further countries are then used to bolster his conclusions finding, namely that differing degrees of liberalisation in different countries can be explained in terms of the differing national 'state traditions'. The present approach cannot claim all of the sophistication of Vogel's approach—it does not attempt a comparative analysis of the claims put forward. Nevertheless, within the context of a single-country study, it attempts to assimilate the strengths of Vogel's analysis, particularly his approach of proceeding at both the broad and detailed levels, and selecting examples for analysis that incorporate sufficient variation.

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<sup>29</sup> Yin, op. cit., p. 32.

<sup>30</sup> Vogel (1996). *Freer Markets, More Rules: Regulatory Reform in Advanced Industrial Countries*. Ithaca NY, Cornell University Press. For an analysis of Vogel's methodological approach, see Levi-Faur (2004). "Comparative Research Designs in the Study of Regulation: How to Increase the Number of Cases Without Compromising the Strengths of Case-Oriented Analysis", in Jordana and Levi-Faur (ed.) *The Politics of Regulation: Institutions and Regulatory Reform in the Age of Governance*. Cheltenham, Edward Elgar.

### 1.2.4 Sources of Data

This thesis draws on a variety of data-sources. The main source of information were official sources: these included official policy pronouncements, notably White Papers and legislation, comprising a small number of Acts of Parliament and a rather larger number of statutory instruments, and various forms of 'tertiary legislation' emanating from the Department of Health. Information on the performance of policy was gleaned primarily from official evaluations of policy, especially Select Committee reports, studies of the National Audit Office (NAO) and, to a limited extent, judicial reviews of policy decisions. The professional response to government policies was gleaned primarily from an examination of the responses of professional organisations, notably the British Medical Association (BMA) to official policy pronouncements. Reference was made to *Hansard* for accounts of debates over the implementation of regulatory reforms, but also for politicians' commentary on the performance of NHS regulation.

In addition, and mainly to assist in the interpretation of these sources, 24 interviews were conducted in relation to each of the three policy episodes investigated in detail in this thesis. Interviewees included current and former holders of ministerial office, civil servants, consultants, health service managers, doctors and allied professionals. These were mostly conducted on a one-to-one basis, lasted around an hour in length and were mostly recorded and transcribed for analysis. Some interviewees preferred not to be recorded. Others preferred to be interviewed in the presence of others. This usually occurred where politicians and senior civil servants requested to be interviewed in the presence of colleagues or advisors. On occasion, one-to-one interviews turned effectively into small focus groups when interviewees 'pulled in' colleagues whose perspectives were regarded

as particularly relevant by the primary interviewee. A coded list of interviews is provided in an Appendix. For examination purposes, interviewee names are linked to these codes in a separate statement.

Secondary sources from published academic journals, books and book chapters supplemented this primary data. Extensive reference was made to newspaper sources and the news and op. ed. sections of the professional medical journals, especially the *BMJ* and (to a lesser extent) *The Lancet*. Newspapers consulted included all the UK national daily broadsheets, *Financial Times*, *The Times*, *The Guardian*, *The Independent*, *The Daily Telegraph* (and their Sunday versions), as well as specialist professional publications, principally the *Health Service Journal*.

### **1.3 The Organisation of this Thesis**

The remainder of this thesis is organised in seven chapters. Chapter 2 reviews those existing themes in the literature on health policy and on regulation, which the thesis draws upon in later chapters. First, it points to the growth of academic interest in regulation, and to the increasing recognition in the literature of the 'maturation' of regulation both as an area of practice and of scholarly interest. Health care regulation, it is argued, is a partial exception to this trend. The chapter locates this growing scholarly interest in the context of assertions of the rise of the regulatory state in Western European countries over the last quarter of a century or so. It suggests that the more recent identification of a 'regulatory state inside the state' and the attendant development of scholarly interest in regulation inside government lends greater visibility to the phenomenon of health care regulation. It is further argued that one particular tradition in the regulation literature, the 'regulatory bargains' approach leads naturally to a focus on regulatory commitment issues and also shares important similarities in

approach and concerns with existing analyses in health care and in public administration more generally. For this reason, the regulatory bargains approach is well suited to a 'reading over' into the context of regulation inside the NHS. Finally, Chapter 2 points to existing analyses of health policy which have, to a greater or lesser extent, used the commitment frame as a basis of analysis, and suggests how a commitment-based analysis of regulation adds to these approaches.

Chapter 3 takes up the theme of the rise of the regulatory state, and assesses the extent to which changes in the NHS over the last twenty years or so conform to the pattern, asserted more generally, of a rise of the regulatory state in Western European countries. The chapter follows the approach of public lawyers Martin Loughlin and Colin Scott, who identify the rise of the regulatory state with three specific institutional trends, namely separation of policy-making from service provision, the proliferation of independent regulatory agencies and the increasing formalisation of regulatory relationships. Assessed against these criteria the analysis in Chapter 3 shows that the case of the NHS fits these claims very well. The chapter further argues that developments in the NHS are consistent with explanations for the rise of the regulatory state, such as those put forward by Majone, in which the renewed emphasis on regulation over other policy instruments is seen as a functional response to changing demands in public policy.

Chapter 4 sets out a framework for analysing regulatory commitment in the NHS, drawing heavily on Levy and Spiller's framework for analysing regulatory commitment in telecommunications. This chapter first sets out an account of the implicit concordat that is said to have underpinned the initial organisational structure of the NHS. Adopting a taxonomy of waste proposed by Blunstein and Marmor, it shows how regulatory reforms, can

under some circumstances vitiate the medical profession's historic privileges under the implicit concordat, particularly where the objective is eliminating 'waste'. Even 'well-intentioned' reforms can lead to professional opposition unless adequate institutional safeguards against bureaucratic and coalitional drift are built into the legal and administrative framework. Such professional opposition is likely to undermine the effectiveness of regulation in achieving its publicly espoused policy goals. Following Levy and Spiller, it is argued that the legal and administrative framework for regulation can provide the necessary reassurance, provided certain complementary institutional mechanisms are in place. Chapter 4 then sets out the observable implications of the theory, as a prelude for the detailed sub-case analysis in the following three chapters.

Chapter 5 investigates the Limited List of NHS Drugs, introduced in 1985. In line with the framework of Chapter 4, the thesis sets out the initial legal and administrative framework of the Limited List, and its subsequent development, including the extension of the prescribing categories covered by the Limited List scheme in 1992, and the sidelining of the Advisory Committee on NHS Drugs (ACD) after 1997. Following Blunstein and Marmor's taxonomy of waste, Chapter 5 argues that over a period of twenty years or so, the Limited List evolved from an initiative primarily intended to eliminate harmful or ineffective treatment into a mechanism for regulating the prescription of drugs that were not allocatively efficient (not cost-effective). After the side-lining of the ACD, the scheme further developed into a mechanism of pure rationing, i.e. it was used to restrict the prescribing of one treatment, sildenafil (Viagra) that was arguably not wasteful within any of Blunstein and Marmor's senses. This, it is argued, provides strong evidence that the legal and administrative framework of the Limited List scheme did not engender credible commitment. In line with the

observable implications of the theory Chapter 5 finds evidence that the Limited List scheme performed poorly.

Chapter 6 is a study of NICE, between 1999 and 2004. In contrast with the other two sub-case analyses in this thesis, NICE has been examined in detail in existing research, notably by Keith Syrett. The commitment frame, it is argued, provides an alternative explanation to the 'legitimacy problems' analysis of Syrett, although the two approaches yield relatively similar conclusions. Compared with the Limited List, it is argued that the legal and administrative framework of the Institute was relatively more credible. Although there was some evidence of slippage, and criticisms of NICE focussed on the need for reforms to make the Institute more credible, bureaucratic and coalitional drift were less pronounced than in the Limited List case study. Such drift that was observed occurred partly in terms of a legislative expansion in terms of Blunstein and Marmor's categories of waste, but perhaps more importantly in terms of the effect of NICE guidance on NHS organisations. In line with the observable implications of Chapter 4, the thesis argues that NICE was relatively more successful in achieving what were more ambitious objectives by any measure. Although these conclusions are similar to those of Syrett's analysis, it is argued that the commitment frame is preferable to Syrett's on the grounds that the present approach is purely positive, while Syrett's attempts to explain positive outcomes in terms of a normative assessment of the legitimacy of NICE.

Chapter 7 examines the establishment, operation and replacement of the Commission for Health Improvement. This chapter is more exploratory in nature, and its conclusions more tentative. The aim is to assess the applicability of the framework set out in Chapter 4 to an NHS inspection regime, where regulatory goals were relatively more amorphous, and which

raised commitment issues in rather different ways compared with the preceding two chapters. With respect to CHI, moreover, evidence of performance was both limited and ambiguous. The chapter puts forward reasons for this outcome, including the short lifespan of the Commission and the fact that, during CHI's brief life, it was subject to major legislative reform. Nonetheless, although the evidence of Chapter 7 does not provide strong support for the theory set out in Chapter 4, neither does it undermine it. Moreover, the analysis of Chapter 7 shows how the framework can yield interesting insights and questions for further investigation beyond the narrower context of the other two case studies.

Chapter 8 draws together the different analytical and empirical strands of the thesis. First, it draws together the findings of this thesis in terms of the two hypotheses outlined in Section 1.2.1 and developed further in Chapters 3 and 4. Second, returning to the starting point that good research in law and political science should both be important in the real world and contribute to scholarly literature it concludes on two levels. It reviews the contribution that this thesis has made to the scholarly literatures on the regulatory state, on health policy change, and on the law and economics of regulatory design. It then draws out some of the implications for policy of the findings of this thesis, reiterating the importance of credible commitment as a factor in the design of regulatory reform initiatives in the NHS. Finally, it suggests avenues for further research to build upon these findings, and to increase the confidence in those findings.

## Chapter 2

# A Selective Review of the Literature on Health Policy and Regulation

In every displacement of an old theory to a new situation there is a feeling of transition from helplessness to power. Before, we were aware only of what was puzzling and disturbing; now, suddenly, there is something like clarity and a basis for action.<sup>1</sup>

### 2.1 Introduction

The existing literature on health policy is vast; the literature on regulation, while relatively more modest, has experienced unprecedented growth in the last two decades or so. It would be impossible, within the space available, to provide anything approaching a comprehensive review of all the relevant literature. This chapter attempts to undertake the more limited task of setting out the central ideas and arguments in the existing literature which form the basis and intellectual context for what follows in the remainder of this thesis. First, it examines the increasing visibility of the phenomenon of regulation in the literature generally, and points, in addition to the increasing volume of literature on regulation, to the 'maturation' of this literature. It is argued, however, that at least until relatively recently, the literature on

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<sup>1</sup> Schon (1963). *Displacement of Concepts*. London, Tavistock Publications, p. 60.

health care regulation has been a partial exception to these developments. Section 2.3 then examines one strand of the growing literature on regulation literature, according to which, the last quarter of a century has seen the rise of a 'regulatory state'. One distinctive facet of this has been the claimed emergence of a 'regulatory state inside the state', identified by the regulation inside government scholarship of Christopher Hood and his collaborators. Drawing on this literature, it is suggested that transposing analyses of private sector regulation to the health care sector can be a fruitful source of insights into the evolution of the NHS, and of specific hypotheses for further investigation. Section 2.4 focuses on one particular approach in regulation and in public administration more generally—labelled the 'exchange paradigm' in this study—and argues that the literature on regulation of the private sector which follows this approach is well-suited to adaptation to the context of health care regulation, despite substantial criticism of this paradigm from scholars working within the disciplinary perspective of public law. Section 2.5 points further to the resonance between the exchange paradigm in regulation, and its attendant emphasis on establishing credible commitment to negotiated understandings between regulator and regulated, identifying a number of studies within the broader health policy literature that have, implicitly or explicitly, adopted the commitment frame. By way of conclusion, this chapter points to a number of questions which, it is argued have been under-emphasised in the literature on the reform of the NHS, which are taken up in the remainder of this thesis.

## 2.2 Regulation as an Academic Growth Industry

The study of regulation has become an ‘academic growth industry’ in recent years. As a review of Baldwin and McCrudden’s landmark *Regulation and Public Law*<sup>2</sup> points out, the word ‘regulation’ was not prominent in the UK literature surveyed by these authors until the very late 1970s, with a proliferation of articles and books containing the word ‘regulation’ in their titles occurring since the late 1980s.<sup>3</sup> The search hits for regulation and related terms in the *International Bibliography of Social Sciences* database are presented in Table 2.1 which shows that between 1990 and 2004, this proliferation continued apace.<sup>4</sup> Table 2.1 also shows the growth of interest in regulation of health and (by way of comparison) of telecommunications regulation. Interest in the regulation of health has exhibited a level of growth broadly consistent with the overall growth in the regulation literature, although this has in general been less pronounced than in the case of utilities, as demonstrated by the comparison with telecommunications.

What explains this earlier apparent neglect of regulation, and the more recent proliferation of interest? Arguably, what appears as neglect in fact reflects only changing linguistic usage. Daintith himself notes a number

<sup>2</sup> Baldwin and McCrudden (1987). *Regulation and Public Law*. London, Weidnefeld and Nicolson.

<sup>3</sup> Daintith (1989). "A Regulatory Space Agency?" *Oxford Journal of Legal Studies* 9 (4): 534-545, p. 534.

<sup>4</sup> Available at <http://www.ibss.bids.ac.uk>. This is admittedly a crude measure because it contains false positives and false negatives. False positives include articles containing the term ‘regulation’ used in senses not relevant here (the ‘regualtionist’ school of French political economy, uses in psychology). False negatives here include relevant articles not included in the *International Bibliography of the Social Sciences*, as well as articles about regulation that do not use the term (or any variant of it) in the title. The wildcard (\*) operator captures all endings, such as regulating, regulated, regulatory, etc.

of earlier studies, such as the work of Gabrielle Ganz, that address similar issues to Baldwin and McCrudden, without apparently feeling the need to resort to the term 'regulation'.<sup>5</sup> Similarly, Michael Moran has asked more recently whether talk of the 'regulatory state' (discussed more fully in Section 2.3, below) is merely, "a linguistic 'tic': 'part of the mania for pinning an adjective on the traditional focus of inquiry in political science, the state?'"<sup>6</sup> Along the same lines, it could be argued that concern with the governance of health care has been a longstanding focus of academic research, without distinguishing regulation from other modes of governance.<sup>7</sup>

**Table 2.1: Growth of Research into Regulation Over A Fifteen-Year Period. Source: Compiled from *International Bibliography of the Social Sciences*.**

Year	<i>Hits from the search string:</i>		
	regulat*	regulat* + health - safety	regulat* + tele-communications
1990	438	2	0
1991	536	1	5
1992	485	9	6
1993	403	4	3
1994	416	10	6
1995	404	7	2
1996	573	7	14
1997	466	11	11
1998	606	3	14
1999	624	5	11
2000	668	5	13
2001	650	10	22
2002	698	13	18
2003	652	8	14
2004	682	8	18
<b>Total</b>	<b>8301</b>	<b>103</b>	<b>157</b>

<sup>5</sup> Daintith, op. cit, p. 534

<sup>6</sup> Moran (2002). "Understanding the Regulatory State." *British Journal of Political Science* 32 (2): 391-413, p. 391.

<sup>7</sup> For a relatively recent example of a study which focuses on the regulation of health care, without use of the term in the title (and with little mention in the text) see Harrison and Pollitt (1994). *Controlling Health Professionals: The Future of Work and Organization in the NHS*. Buckingham, Open University Press.

Alternatively, it is possible that this growth of academic interest merely reflects changing priorities among the major sponsors of research in the social sciences. For example, from 1997, 'Regulation and Governance' became one of the thematic priorities of the Economic and Social Research Council (ESRC) for the funding of research postgraduate students. Part of the volume of literature on regulation after this time could be attributed to this.

At the same time, the development of regulation scholarship is reflected not only in its increasing volume. As Baldwin, Scott and Hood argue, there has been a 'maturation' of regulation in two separate but related senses.<sup>8</sup> First, they identify an intellectual maturation, by which they mean the development over time of "distinct analytic approaches and generic understandings that are capable of being applied over different regulatory sectors."<sup>9</sup> Second, Baldwin Scott and Hood point to a maturation of practice whereby "...administrative processes which were once seen as sector specific, and peculiar to individual domains... are coming to be seen as part of a generic set of instruments and strategies deployed by the state."<sup>10</sup>

This double maturation—of analysis and of practice—did not fully penetrate the health care arena until relatively recently.<sup>11</sup> While the professional (self-) regulation of doctors and other allied professions has

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<sup>8</sup> Baldwin, Scott and Hood (1998). "Introduction", in Baldwin, Scott and Hood (ed.) *A Reader on Regulation*. Oxford, Oxford University Press.

<sup>9</sup> *Ibid.*, p. 1.

<sup>10</sup> *Ibid.*, pp. 1-2.

<sup>11</sup> While this section is concerned primarily with Baldwin, Scott and Hood's second sense, of intellectual maturation, it is worth noting briefly that health has been a laggard in terms of practice. Interviews at the Department of Health, NICE and the Commission for Health Improvement all pointed to a reluctance to recognise the 1999 NHS reforms as introducing administrative processes analogous to governmental regulation of the business sector into the NHS (I16, I19, I22).

been an established field of academic inquiry by lawyers and public administration scholars, as well as being a matter of interest within the professional journals, there has been a relative paucity of academic literature which applied to analysis of health care the distinct analytic approaches and generic understandings to which Baldwin, Scott and Hood refer.<sup>12</sup> Only relatively recently have a number of studies begun to share a common understanding of regulation with those examining comparable developments in other sectors, suggesting that, as an area of intellectual inquiry, health care regulation has been a 'late developer'.<sup>13</sup>

The self-conscious nature of the attempt of some of these contributions seek to draw lessons from other sectors, such as the public utilities, to the health care sector points arguably to an intellectual 'adolescence'.<sup>14</sup> Extending the metaphor still further, the emergence of a number of recent studies, such as Kieran Walshe's *Regulating Healthcare*<sup>15</sup> and Allsop and Mulcahy's *Regulating Medical Work*<sup>16</sup> which incorporate the insights of political scientists and socio-legal scholars interested in regulation in a variety of settings arguably therefore marks the eventual 'coming of age' of health care regulation. Other studies applying a generic

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<sup>12</sup> Studies of professional regulation include Stacey (1992). *Regulating British Medicine: The General Medical Council*. Chichester, Wiley.

<sup>13</sup> For example, see Maynard (1995). "Reforming the National Health Service", in Bishop, Kay and Mayer (ed.) *The Regulatory Challenge*. Oxford, Oxford University Press; Propper (1998). "The effects of regulation and competition in the NHS internal market: the case of general practice fundholder prices." *Journal of Health Economics* 17 (6): 307-336; Rico and Puig-Junoy (2002).

"What Can We Learn From the Regulation of Utilities?" in Saltman, Busse and Mossialos (ed.) *Regulating Entrepreneurial Behaviour in European Health Care Systems*.

<sup>14</sup> See for example Rico and Puig-Junoy, op. cit.

<sup>15</sup> Walshe (2003). *Regulating Healthcare: A Prescription for Improvement?* Buckingham, Open University Press.

<sup>16</sup> Allsop and Mulcahy (1996). *Regulating Medical Work: Formal and Informal Controls*. Buckingham, Open University Press.

understanding of regulation to aspects of health care include article length contributions from Keith Syrett (applying Robert Baldwin's framework for evaluating regulation)<sup>17</sup> and Anne Davies (noting the replacement of a 'light touch, self-regulatory paradigm' to an 'interventionist, managerial paradigm').<sup>18</sup>

Notwithstanding these notable contributions, 'generic' approaches to health care regulation are relatively under-emphasised in the literature as a whole. As an indication of its 'late developer' status, it is worth noting that while generic textbooks on regulation have appeared in the UK with a focus on industrial regulation<sup>19</sup> and on public utilities,<sup>20</sup> no UK textbook has so far focussed on regulation in the health sector, or even on the regulation of welfare services more generally. The recent emergence of postgraduate programmes in this area, such as Anglia Polytechnic University's M.Sc. and Diplomas in Health and Social Care Regulation, suggests that this may be a niche in the market that remains to be filled.

In order to explore more fully the reasons for the growth in volume and maturity of the regulation scholarship, as well as the late development of health care regulation scholarship, the next section looks to one strand in this literature which asserts that the last quarter of a century has witnessed the rise of the regulatory state in Western European countries, and—as one facet of this—of the emergence of a 'regulatory state inside the state'.

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<sup>17</sup> Syrett (2002). "NICE Work? Rationing, Review and the 'Legitimacy Problem' in the New NHS." *Medical Law Review* 10 (1): 1-27.

<sup>18</sup> Davies (2000). "Don't Trust Me, I'm a Doctor: Medical Regulation and the 1999 NHS Reforms." *Oxford Journal of Legal Studies* 20 (3): 437-456.

<sup>19</sup> Ogus (1994). *Regulation: Legal Form and Economic Theory*. Oxford, Clarendon Press.

<sup>20</sup> Baldwin and Cave (1999). *Understanding Regulation: Theory, Strategy and Practice*. Oxford, Oxford University Press.

## 2.3 The Regulatory State

### 2.3.1 The Rise of the Regulatory State<sup>21</sup>

Alternatively to the two possible ways of 'explaining away' the growth of the regulation scholarship raised in the previous section (reflecting changing linguistic usage or research funding priorities), it has been argued that growth of academic interest in regulation in European countries reflects profound changes in the way societies are governed: "The relative neglect of regulatory analysis in the past corresponded to the low visibility of regulatory activities."<sup>22</sup> Majone argues that policies of privatisation and deregulation in the 1980s and 1990s created the conditions for the rise of the regulatory state in the countries of Western Europe, and in the European Union itself.<sup>23</sup> Following the introduction of these policies, according to Majone, a renewed emphasis on economic and social regulation, administered by specialised agencies operating outside hierarchical ministerial control and oversight has replaced patterns of public ownership, national planning and centralised administration characteristic of the 'positive state'. This, in turn, has directed the focus of public policy away from macro-economic stabilisation and redistributive welfare policies towards a greater concern with competitiveness and economic efficiency.

Martin Loughlin and Colin Scott further develop this idea by contributing an analysis of the precise nature of the regulatory state,

<sup>21</sup> A comprehensive review of the literature on the regulatory state can be found in Moran (2002). "Understanding the Regulatory State." *British Journal of Political Science* 32 (2): 391-413.

<sup>22</sup> Majone (1994). "The Rise of the Regulatory State in Europe." *West European Politics* 17 (1): 77-101, p. 78.

<sup>23</sup> Ibid. See also Majone (1996). "Public Policy and Administration: Ideas, Interests and Institutions", in Goodin and Klingemann (ed.) *A New Handbook of Political Science*. Oxford, Oxford University Press; Majone (1997). "From the Positive to the Regulatory State." *Journal of Public Policy* 17 (2): 139-167.

identifying three specific institutional changes associated with the rise of the regulatory state, namely: (1) the separation of policy-making from service delivery ('provision' and 'production' in their terminology); (2) the creation of free standing regulators; and (3) increasing formality of rules, roles and relations within the 'regulatory space'.<sup>24</sup> As Chapter 3 discusses at length, although each of these trends has been identified within the NHS in existing scholarship, these have not previously been analysed as related aspects of underlying changes in governance. The regulatory state literature potentially therefore provides for a new interpretation of existing understandings of organisational change in the NHS.

For Majone, a set of complex historical, institutional and motivational factors explain the rise of the regulatory state, including the exhaustion of earlier modes of governance, constraints on budget-raising powers, and (at the EU level) tendencies towards bureaucratic expansionism in the Commission. Underlying these proximate causes, however, is a form-and-function type argument, based on a particular view of the changing nature of policy-making. According to Majone's functional analysis, traditional positive state institutions are seen as ill-equipped to meet the demands caused by the complexity of policy issues, which is itself in part due to such factors as the emergence of efficiency as an over-riding policy goal, the strategic value of credibility in policy-making and the need for co-ordination of a large number of activities: "The growth of administrative regulation in Europe owes much to these newly articulated perceptions of a mismatch between existing institutional capacities and the growing complexity of policy problems."<sup>25</sup> Policy-making by expert, non-

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<sup>24</sup> Loughlin and Scott (1997). "The Regulatory State", in Dunleavy, Gamble, Holliday and Peele (ed.) *Developments in British Politics 5*. Basingstoke, Macmillan, pp. 205-207.

<sup>25</sup> Majone, op. cit., note 18, p. 85.

majoritarian institutions and through formal rules is seen as a more appropriate way of governing, better suited to these particular kinds of challenges where efficiency is a primary policy goal, and especially where the credibility (understood in the sense of 'time-consistency') of policies is a significant constraint.

This interpretation has been challenged, at least with respect to its applicability in the British context, by Michael Moran, who argues that: "...the fundamental forces that seem to be driving change within the British system appear to contradict the most important theoretical insights claimed by the theory of the European regulatory state."<sup>26</sup> Three aspects of the British regulatory state in particular seem, for Moran, to be at odds with Majone's explanation. First, although the regulatory state in Britain has abandoned the encompassing (and to a significant extent, redistributivist) ambitions of the Keynesian welfare state, it has at the same time been associated with expanded ambitions, in particular in the area of social regulation. Second, the shift of emphasis away from informal self-regulatory processes towards formal state regulation appears to have, in contradiction to Majone, to have led to increased hierarchical oversight. Finally, regulation has, perhaps contrary to expectations, been the focus of majoritarian politics while the decline of informality has expanded the majoritarian arena.<sup>27</sup> In short, in Britain, the regulatory state is associated with expanded *reach* as much as with diminished *scope*, while remaining overtly 'political' in character. This apparent revolt of the facts against the theory raises important questions about the extent to which functional arguments, such as those put forward by Majone, can explain the particular

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<sup>26</sup> Moran (2003). *The British Regulatory State*. Oxford, Oxford University Press, p. 20.

<sup>27</sup> Ibid., pp. 20-21.

historical changes that are captured by the idea of the regulatory state. This issue is taken up in more detail in Chapter 3.

### 2.3.2 Regulation Inside Government

Even more so than the regulatory state in general, the regulation of government has only lately been explicitly recognised as an object of scholarly interest, in the UK context, most notably by Christopher Hood and his colleagues.<sup>28</sup> Hood *et al.* identify a range of processes by which government regulates itself, analogous to the state regulation of the private sector. Arguably, this belated recognition can help to explain why health care has been a partial exception, or at least a laggard, in terms of Baldwin, Scott and Hood's diagnosed 'maturation' of regulation scholarship and practice. Hood *et al.* coin the phrase 'regulation inside government' to denote this phenomenon, which they distinguish from other forms of control, for example by the legislature or the courts, when three specific criteria are satisfied:

- one bureaucracy aims to shape the activities of another;
- there is some degree of organizational separation between the 'regulating' bureaucracy and the 'regulatee';
- the 'regulator' has some kind of official mandate to scrutinize the behaviour of the 'regulatee' and to seek to change it.<sup>29</sup>

On the basis of this stipulated definition, Hood *et al.* find a marked growth in regulation inside government in the two decades up to 1997 and continued planned expansion under the post-1997 Labour government. These trends, they argue, indicate the emergence of a 'regulatory state inside the state'. Following the more general example of the regulation inside

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<sup>28</sup> Hood, Scott, James, Jones and Travers (1999). *Regulation Inside Government: Waste-Watchers, Quality Police, and Sleaze-Busters*. Oxford, Clarendon Press; Hood, James and Scott (2000). "Regulation of Government: Has it Increased, is it Increasing, Should it be Diminished?" *Public Administration* 78 (2): 283-304.

<sup>29</sup> *Regulation Inside Government*, p. 8.

government literature, the scholarly literature has begun to recognise a similar rise of regulation inside the NHS.<sup>30</sup>

One potentially productive dimension of the regulation inside government research agenda has been the strategy, implicit in the regulation inside government literature generally, but exemplified in an article by Oliver James,<sup>31</sup> of transposing to the public sector concepts drawn from the literature on business regulation, as a source of insights and hypotheses for further investigation. James re-examines in the context of regulation inside government the now well-worn debate (in the business regulation literature) on public-interest justifications for regulation versus private-interest explanations for regulatory failure. Although official discourse on regulation of the public sector has focussed on the public interest justifications, James identifies three forms of government-regulatory failure, analogous to regulatory failure more generally, that offer reasons to question the post-1997 Labour Government's apparent faith in increased regulation inside government.

James's approach—indeed the approach of the regulation inside government literature more generally—can be seen as an almost paradigmatic instance of Donald Schon's notion of 'displacement of concepts'.<sup>32</sup> Schon uses this formulation to capture the idea that the development of new theories is cognate with the process of analogy and metaphor in language and with the development of new products in industry. For Schon, in the application of concepts to new kinds of situation outside their normal use, concepts themselves are transformed: "Through

<sup>30</sup> Walshe (2002). "The Rise of Regulation in the NHS." *BMJ* 324: 967-970, 20 April 2002.

<sup>31</sup> See James (2000). "Regulation Inside Government: Public Interest Justifications and Regulatory Failures." *Public Administration* 78 (2): 327-343.

<sup>32</sup> Schon, *op. cit.*

their displacement they have been transformed. They have been made into a new kind of instance.”<sup>33</sup> Similarly, it could be argued that only with the extension<sup>34</sup> of the concept of regulation to include regulation inside government does the phenomenon of regulation of NHS organisations and activities become ‘visible’. The next section suggests reasons why one particular tradition in the literature on regulation of the private sector, the ‘regulatory bargains’ approach (part of an exchange paradigm in public policy and administration more generally), may be particularly appropriate as a source of inspiration for an analysis of health care regulation.

## 2.4 The Exchange Paradigm

An ‘exchange paradigm’ (if that is not too grand a term) underlies many existing analyses of regulation, most notably informing what can be termed the ‘regulatory bargains’ approach. The fundamental assumption of the exchange paradigm is that political and administrative arrangements are the outcome of bargaining between contending interests, and that, by understanding the conditions under which bargaining took place, one can explain the resulting arrangements. At the same time, as discussed below, this paradigm also informs much work in health policy, as well as in public administration more generally. Because of this, a transposition of this particular approach into the context of regulation of the NHS, similar to James’s strategy discussed above, can ‘punch into’ existing debates in health policy and public administration, and address questions of regulation in the NHS in a way that engages with these debates.

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<sup>33</sup> Ibid. p. 31.

<sup>34</sup> For Schon, it is possible only after the fact to speak of an extension of a concept in this way.

The exchange paradigm has in recent times been most closely associated with the public choice school, whose influence has been fiercely criticised—and perhaps more often ignored—in the UK public law literature because of what some would see as its overtly ideological ‘new right’ bias as well as because of its alleged North American assumptions.<sup>35</sup> At the same time, the idea that political and administrative arrangements are based on exchange has a long and distinguished history, and is not associated only with the public choice approach.<sup>36</sup> The studies of Bernard Schaffer and, more recently, Christopher Hood into politician-bureaucrat relations, and the work of Rudolf Klein in health policy and politics testify to the fact that an exchange perspective can contribute interesting insights in the UK context, as well as demonstrating that the acceptance of the exchange paradigm goes beyond adherents of the public choice school.

The remainder of this section is organised as follows. First, the regulatory bargains approach is discussed. Second, the cognate public service bargains (PSB) approach in the public administration literature, associated with Bernard Schaffer and, more recently, Christopher Hood is reviewed. Finally, this section reviews the pioneering work of Rudolf Klein which argues that an implicit concordat between the government and the medical profession underpins the organisation of the NHS. It is argued here,

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<sup>35</sup> For a critique of public choice ‘ideology’ as well as an outline attempt to understand public choice from a UK legal policy perspective, see McAuslan (1988). “Public Law and Public Choice.” *Modern Law Review* 51 (6): 681-705, pp. 63, 163-165. See also Prosser (1999). “Theorising Utility Regulation.” *Modern Law Review* 62 (2): 196-217, pp. 203-206. In the US context, see Kelman (1988). “On Democracy Bashing: A Skeptical Look at the Theoretical and ‘Empirical’ Practice of the Public Choice Movement.” *Virginia Law Review* 74 (1): 199-273.

<sup>36</sup> Terry Moe traces the origins of this approach through the work of Herbert Simon to Chester Barnard. See Moe (1984). “The New Economics of Organisation.” *American Journal of Political Science* 28: 739-777.

that Klein's conception of the implicit concordat can be seen as a kind of a health-specific PSB.

### 2.4.1 The Regulatory Bargains Approach

The distinguishing feature of the regulatory bargains approach is a focus on the exchange which this approach identifies as occurring between regulators and regulated. This approach has been most fully developed with respect to regulation of the privatised utilities where it is argued that relations between regulators and the privatised utilities can best be understood as a loosely specified contract, according to which, in return for undertaking certain obligations—for example, to supply a basic level of service at an affordable and non-discriminatory price—the firm is rewarded with secure revenue streams, specified (in the case of UK regulated utilities) in the form of price caps.<sup>37</sup> The terminology of the 'regulatory contract' is unfortunate as it potentially leads to avoidable confusion, both with the juristic notion of contract, and discussion within the economic literature of incentive contracts as instruments of regulation. The term 'regulatory bargain', which is often used interchangeably with 'regulatory contract' in the economics literature on regulation will be used exclusively hereafter, to avoid this potential confusion.

Cento Veljanovski's analysis of the utilities privatisations of the 1980s typifies the regulatory bargains approach.<sup>38</sup> The sale of the utilities, he argues, was based on an implicit understanding between the government

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<sup>37</sup> Bishop, Kay and Mayer (1995). "Introduction", in Bishop, Kay and Mayer (ed.) *The Regulatory Challenge*. Oxford, Oxford University Press, pp. 2, 6.

<sup>38</sup> Veljanovski (1987). *Selling the State: Privatization in Britain*. London, Weidenfeld & Nicolson; Veljanovski (1991). "The Regulation Game", in Veljanovski (ed.) *Regulators and the Market*. London, Institute of Economic Affairs; Veljanovski (1993). *The Future of Industry Regulation*. London, European Policy Forum.

and shareholders that the initial rules of the game, notably light-touch regulation in terms of both price and quality would not be radically changed. Veljanovski sees the behaviour of regulatory agencies as going against the spirit of this bargain, as they have sought to introduce competition into the utilities sectors, and having resort to increasingly heavy-handed intervention to achieve this goal:

As a result many of the regulators have found themselves railing against the implicit understanding—the ‘regulatory bargain’—struck between the utilities (read shareholders) and the Government at the time of floatation. The regulators appear to have come to the conclusion: if the structure of industry and much of the regulation work against competition, then the ‘regulatory bargain’ must be broken by edging the controls against the utilities.<sup>39</sup>

The result of the breakdown of the regulatory bargain has been, according to Veljanovski, has been the emergence of a ‘regulation game’ between industry chiefs and regulators, characterised by informal power struggles and grandstanding by industry chiefs and regulators alike, as part of a struggle for control.

The adoption of a regulatory bargains approach naturally leads to a focus on the mechanisms by which the regulatory bargain is enforced. Veljanovski’s analysis points to an absence of effective safeguards in the UK and to the renegeing, on the part of Government on what he sees as an expectation that “...the prospectus [on privatization] would provide a binding commitment or bargain between the Government and shareholders...”<sup>40</sup> This is odd. While it is not contentious that a prospectus for the sale of shares must present a fair and true account of the company under offer, it could hardly, on any orthodox legal analysis, be argued to

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<sup>39</sup> Veljanovski, op. cit. (1991), p. 22.

<sup>40</sup> Veljanovski (1993). *The Future of Industry Regulation*. London, European Policy Forum, p. 59.

create binding (substantive) undertakings as to the future direction of government policy.

The work of Levy and Spiller on telecommunications regulation, which focuses on the particularly acute problem faced by many developing countries in attracting private sector investment, provides an interesting application of the regulatory bargains approach which is far more sophisticated than that of Velanovski, especially in terms of its analysis of how the regulatory bargain is maintained.<sup>41</sup> Drawing on the institutional economics approach developed by Coase, North, Williamson and others, Levy and Spiller look at the way in which, in the absence of formally binding policy commitments, the governance framework for regulation in different constitutional settings can enhance (or diminish) the credibility of the government's commitment to the regulatory bargain. Reform-minded policymakers, they argue, must select from a range of instruments that can potentially enhance the credibility of regulation, including precisely specified legislative provisions, delegation across tiers of government to independent regulatory agencies, legally binding licenses and reliance upon 'informal' constraints. Different instruments are appropriate to different national regimes, and they construct a decision-tree relating the appropriate choice of instruments to the 'institutional endowment' of a country, that is to say, its background pattern of legislative, judicial and executive institutions.<sup>42</sup> Elsewhere, with Martin Lodge, I have suggested that there are certain problems with the key (Jamaican) case study in Levy and Spiller's analysis, especially in

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<sup>41</sup> Levy and Spiller (1994). "The Institutional Foundations of Regulatory Commitment: A Comparative Analysis of Telecommunications Regulation." *Journal of Law, Economics and Organization* 10 (2): 201-246; Levy and Spiller, eds. (1996). *Regulations Institutions and Commitment: Comparative Studies of Telecommunications*. Cambridge, Cambridge University Press.

<sup>42</sup> Social norms and patterns of interest group organisation are also included by Levy and Spiller as contributing to a country's institutional endowment, and an analysis of these factors is included in their co-author's country studies in *Ibid.*, though they are not modelled within the decision-tree framework upon which their analysis is based.

the light of subsequent developments that, at first sight, seem to fly in the face of their predictions.<sup>43</sup> Nevertheless, their approach provides a rich theoretical analysis of the way in which institutional arrangements can help to mitigate commitment problem in regulation. For the moment, it is sufficient to note the difficulty facing governments of Westminster-style constitutional systems, such as Britain—in which the executive dominates the legislature, and where different parties compete for exclusive control of executive power—in establishing credible commitment to the regulatory bargain. To the extent that credible policy commitments are possible, these are likely, on Levy and Spiller's account, to rely on judicial enforcement of property (or analogous) rights and on traditions of civil service neutrality to protect against 'politicisation' in the exercise of administrative discretion.

In the context of utilities regulation, the regulatory bargains approach, and Levy and Spiller's approach in particular, has much to commend it; as Tony Prosser argues, something like the regulatory bargains approach underpinned much of the institutional design for utilities regulation adopted on privatisation in the UK.<sup>44</sup> As the work of Levy and Spiller in particular emphasises, the problem of establishing commitment to the initial regulatory arrangements is an acute one, with important real-world consequences in the case of utilities, where large sunk costs and asset specificity make these industries particularly vulnerable to 'administrative expropriation'. At the same time, Prosser has been a fierce critic of the approach for a number of reasons. First, the effect of the ascendancy of this view among the original architects of the UK's system of utilities regulation, he argues, was to privilege of dominant firms over other

<sup>43</sup> Stirton and Lodge (2003). "Re-Thinking Institutional Endowment in Jamaica: Misguided Theory, Prophecy of Doom or Explanation for Regulatory Change?" CARR/CRC/ABS Workshop on Risk Regulation, Accountability and Development, Hulme Hall, University of Manchester.

<sup>44</sup> Prosser (1999). "Theorising Utility Regulation." *Modern Law Review* 62 (2): 196-217, pp. 200-3. See also {Prosser, 2005 #186}

interests, such as new entrants and consumers. Second, whatever its earlier empirical content, the regulatory bargains approach made less sense of actual regulatory practice over time, especially in the context of more competitive markets in which a broader set of stakeholders compete for regulatory influence. Put simply, the regulatory bargains approach understates the essential (and increasing) pluralism of regulation.

While Prosser's criticisms hold some force, and cautions against inappropriate transposition of this approach into other sectors, his criticisms are arguably over-stated for a number of reasons. First, the association of the approach with (what for independent reasons may be regarded as) undesirable implications for policy, specifically, with the privileging of incumbents within the regulatory process, needs to be clearly separated with the value of the approach as a way of understanding regulatory reform; domination of the regulatory process by incumbents *was* a feature of early post-privatisation utility regulation and any theory that did not account for this would itself be problematic. Furthermore, the alleged privileging of incumbent firms may reflect underlying power relations and resource dependencies, as much as the application by policymakers of a particular, (and arguably flawed) theory of regulation. Second, as the commitment perspective of Levy and Spiller suggests, the observation that initial regulatory bargains in the utilities sectors have broken down over time does not invalidate the approach *per se*. Arguably, once one focuses on the issue of commitment to the regulatory bargain, the UK utilities sectors demonstrate precisely the pattern of development that the regulatory bargains approach would lead us to expect, namely an initial bilateral bargain coming under sustained pressure in the face of an opening up of the regulatory arena to wider set of interests, leading to a new and broader (and perhaps less stable) coalition of 'stakeholders'. Third, although Veljanovski's work in particular does not demonstrate this subtlety, there is

no fundamental reason why the regulatory bargains approach applies only where regulatory policy is based on bi-lateral relations between governments and incumbent providers. Indeed, Hood's PSB analysis, discussed later in this section, explicitly accommodates situations involving a *ménage à trois* (or more) suggesting that a regulatory bargains analysis might proceed along similar lines if such an approach was suggested by the facts on the ground.<sup>45</sup> Overall, it could be argued that, by focussing his criticisms on Veljanovski's account in particular, Prosser fails to see the best in the regulatory bargains approach.

## 2.4.2 The Public Service Bargains (PSB) Approach and the Implicit Concordat

As noted above, the regulatory bargains approach is highly cognate with prominent themes in the public administration literature more generally, namely, the public service bargains (PSB) analyses of relations between politicians and civil servants. The concept of the 'public service bargain' was put forward by Bernard Schaffer, who argued that the distinctive features of the British civil service, as it emerged in the Victorian era—including the politician-official distinction itself—were the result of a "highly complicated" and "peculiar" bargain between politicians and bureaucrats.<sup>46</sup> The essence of this bargain was that in return for granting permanent tenure (thus abrogating, in practice at least, the traditional

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<sup>45</sup> Given the strong similarities between the PSB approach within political science and the regulatory bargains literature, it is curious that Prosser does not refer to or make use of the work of Hood, Schaffer or Klein, especially given also his view that, "... though many of us [i.e. legal scholars] find it easy to work within the sort of theoretical approaches adopted by political scientists, many of us find it far harder to work with economists." See {Prosser, 2005 #186}

<sup>46</sup> Schaffer (1973). "Public Employment, Political Rights and Political Development", in Schaffer (ed.) *The Administrative Factor*. London, Frank Cass, p. 252.

doctrine that Crown servants were dismissible at pleasure), civil servants gave up certain political rights, including the right to challenge government policy publicly. Schaffer argued that many of the salient and enduring features of the British civil service, above all its neutrality and permanence and generalist competence, owed their origins to this implicit bargain.<sup>47</sup> More recently, Christopher Hood has extended the concept of PSBs as a tool for comparative analysis of politician-bureaucrat relations, defining the term more broadly as:

any explicit or implicit understanding between (senior) public servants and other actors in a political system over their duties and entitlements relating to bureaucratic responsibility, autonomy and political identity, and expressed in convention or formal law or a mixture of both.<sup>48</sup>

A central insight of Hood (and indeed of Schaffer) is that PSBs emerge, and can endure, only under certain historically specific conditions.<sup>49</sup> Like the regulatory bargains literature, an analysis of the exchange draws attention to the issue of commitment to the bargain, the mechanisms through which commitment is maintained and the extent to which reforms enhance (or undermine) credible commitment. Understanding how contemporary public management reforms challenge certain existing bargains, as well as analysing the conditions under which bargains underpinning new modes of control in the public sector can be sustained emerges as a central part of Hood's research agenda. Used by Hood as a tool of comparative analysis, the PSB concept has contributed important insights into various 'paradoxes'

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<sup>47</sup> Ibid.

<sup>48</sup> Hood (2000). "Paradoxes of Public-Sector Managerialism, Old Public Management and Public Service Bargains." *International Public Management Journal* 3 (1): 1-22. See also Hood (2002). "Control, Bargains and Cheating: The Politics of Public Service Reform." *Journal of Public Administration Research and Theory* 12 (3): 309-332.

<sup>49</sup> Schaffer, op. cit., pp. 252-3, puts it elegantly: "What we know is that ministers shuffle out of their part of the bargain, the demands of proficiency increase, and even British civil servants no longer get their old guaranteed ration of honours."

of public-sector managerialism, including paradoxes of globalisation or internationalisation, successful ‘failures’ and, most significantly for present purposes, paradoxes of half-hearted managerialism.

A health sector-specific variant of the PSB idea is put forward by Rudolf Klein in his seminal *The Politics of the NHS*.<sup>50</sup> Although Klein did not explicitly rely on Schaffer’s formulation of the idea (and the first edition of *The Politics of the NHS* pre-dates Hood’s work on PSBs by nearly two decades), his analysis is nonetheless highly congruent with the analyses of Schaffer and Hood and can be considered as part of the same broad approach. Klein argued that the structure of the NHS reflected an implicit bargain (or ‘concordat’ as he terms it) between the state and the medical profession. His analysis of the politics of the NHS thus shares with their approaches a focus on an initial exchange giving rise to administrative structures, as well as a concern with the conditions under which the bargain was maintained, and eventually broke down, only to re-assert itself in modified form. In a frequently quoted passage, Klein captures the essence of this professional PSB:

Implicit in the structure of the NHS was a bargain between the State and the medical profession. While central government controlled the budget, doctors controlled what happened within that budget. Financial power was concentrated at the centre; clinical power was concentrated at the periphery. Politicians in Cabinet made the decisions about how much to spend; doctors made the decisions about which patient should get what kind of treatment.<sup>51</sup>

The core of the bargain was thus that the profession agreed to support the NHS, and within a framework of policy set by the Government, including budgetary constraints set by the Government. In return for this, doctors

<sup>50</sup> Klein (1983). *The Politics of the National Health Service*. London, Longman. For the most recent edition, see Klein (2001). *The New Politics of the NHS*. 4th Edition, Harlow, Prentice Hall.

<sup>51</sup> Klein (2001). *The New Politics of the NHS*. 4th Edition, Harlow, Prentice Hall, p. 64.

practicing within the NHS continued to enjoy their historic autonomy, including the power over resource allocation and prioritisation within those budget constraints. As a result, professionals enjoyed a relative absence of hierarchical oversight and direction. However, as Klein notes, this was an evolving bargain, "... not so much a fixed settlement as a truce: an accommodation to what was, for both parties, a necessary rather than a desirable compromise."<sup>52</sup> This accommodation endured for a considerable period of time, but was increasingly challenged, beginning in the 1980s, with the managerial reforms recommended to the Secretary of State by Roy Griffiths (who subsequently became Sir Roy). Finally, the *Working for Patients* White Paper,<sup>53</sup> which re-organised the NHS along the lines of an internal market model, represented the imposition of a "new constitutional settlement" which the medical profession "proved powerless to prevent".<sup>54</sup> But although this was something of a unilateral modification of the pre-existing bargain, it was not an abrogation of it: following the introduction of the implementing legislation (which became the National Health Service and Community Care Act 1990), the implicit concordat, including a commitment to clinical freedom continued, albeit in modified form. This was symbolised for Klein by the creation of a multi-professional Clinical Standards Advisory Group, which reflected the reality, in his view, of continuing professional dominance in matters of clinical standards.<sup>55</sup> Klein interprets the Labour Government's NHS reforms of 1999 in similar terms, as a kind of 'forced renegotiation' (my term, not Klein's) of the terms of the concordat, and a reinterpretation of the idea of clinical autonomy. As a result of these reforms:

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<sup>52</sup> Ibid.

<sup>53</sup> Secretaries of States for Health Wales Northern Ireland and Scotland (1989) *Working for Patients*, CM555, London, HMSO.

<sup>54</sup> Klein, op. cit., p. 172.

<sup>55</sup> Ibid.

Self-regulation had survived, but it had been made accountable; collegial control over the performance of doctors had largely been maintained but at the cost of sacrificing the autonomy of individual doctors. Once again, it was apparent that there had been a shift in the balance of power between the state and the profession.<sup>56</sup>

What explains this pattern of development, of an enduring bargain that showed increasing signs of strain in the 1980s, leading to the imposition of a new settlement first by the government of Margaret Thatcher, and later by the post-1997 Labour government? For Klein, a large part of the answer clearly lies in the institutions of health policy, including the structures of the NHS, within which the profession effectively enjoyed a veto on any matters of significance. But the protection afforded to the initial bargain was limited by the fact that these institutions and structures were themselves nested within a wider context, which had the potential to upset the stability of the bargain. Moreover, to the Government, broadening out health policy-making into its wider context was a strategy to overcome the power that the profession enjoyed in private. Speaking of the profession's inability to resist the *Working for Patients* reforms (although the point is arguably more general), he says:

Its power, it turned out, was contingent on the arena in which it was exercised and the issues involved. When the health care policy arena was widened out—when reforms of the NHS were put in the wider context of modernising Britain's institutions—the medical profession lost its central place on the stage: it simply became an actor, and not necessarily the most influential, among many.<sup>57</sup>

There are obvious parallels here with Michael Moran's thesis that much of the 'hyper-innovation' in British Government over the last quarter of a century has been due, not only to a crisis of policy, but also to a crisis of 'club government', a system of rule he characterises as "oligarchic,

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<sup>56</sup> Ibid. p. 211.

<sup>57</sup> Ibid.

informal, secret... and highly pervasive.”<sup>58</sup> At the same time, even if these periodic episodes have been due to a crisis of club government, the implicit concordat has re-asserted itself, albeit with a shift in power relations between the Government and the profession. Drawing the comparison with the work of Hood still further, one could interpret Klein’s analysis as providing a resolution to a paradox of half-hearted managerialism: despite bold policy initiatives, successive attempts to transform the dynamics of the NHS have had limited effect.

Klein’s contribution to social policy in general, and to the analysis of health policy in particular has been enormously influential, and a substantial body of literature has developed the idea of the implicit concordat, and its implications. One strand of this body of literature goes further than Klein’s own analysis in charting the demise of the concordat over time. Another, closely related strand points to the positive practical contribution that the concordat has made to health policy in the UK, and look to the restoration of the concordat or a new variant of it. The work of Ham and Alberti and Brian Salter respectively, exemplifies each of these closely related strands. In Ham and Alberti’s account, the “implicit compact” (as they term it) is analysed as a *ménage à trois*—the third party in the relationship was the public—and which served to establish expectations as to the rights and responsibilities of the different parties.<sup>59</sup> Confronted with the breakdown of the implicit compact, they seek to identify the basis of a new, explicit compact emphasising the rights and responsibilities of each of the three parties—the profession, the government and the public—and setting out more realistic expectations about what the NHS can deliver. Salter’s

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<sup>58</sup> Moran (2003). *The British Regulatory State*. Oxford, Oxford University Press, p. 4.

<sup>59</sup> Ham and Alberti (2002). "The Medical Profession, The Public, and the Government." *BMJ* 324: 838-842, 6 April 2002.

account, on the other hand, places primary emphasis on the purpose served by the implicit concordat as a means of resolving certain contradictions in the UK health care system, as a consequence of which competing political parties promise citizens ever-increasing access to better health care, and which exceeds the capacity of the state to deliver.<sup>60</sup> Rather than involving the public, for Salter, the implicit concordat was a form (albeit, he argues, a necessary one) of collusion against it, in which the profession acted as 'gatekeeper', moderating impossibly high demands for care engendered by electoral competition and by the principles of the welfare state. But, as Salter argues, the concordat has been undermined first, by social changes, making it more difficult to maintain the pretence that access to health care is unlimited and second because of the Griffiths managerial reforms and the *Working for Patients* reforms. These reforms violated the implicit concordat by imposing a degree of managerial control on clinical standards in (what Salter sees as) a misplaced attempt to resolve the tension between finite supply and potentially unlimited demand through greater operational efficiency. They were therefore self-defeating because they only served to reinforce expectations about the level of performance of the NHS, and to increase the visibility of rationing decisions. The solution, as he sees it, is for a concerted effort to revise the concordat: "Unchanged for 50 years, the concordat is in need of serious revision if its considerable political utility to both sides is to be retained."<sup>61</sup> Building on these ideas, Salter has in subsequent work attempted to identify criteria for a politically sustainable way of regulating health services.<sup>62</sup>

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<sup>60</sup> Salter (1998). *The Politics of Change in the Health Service*. Basingstoke, Macmillan, pp. 11-15.

<sup>61</sup> Ibid., p. 125.

<sup>62</sup> Salter (2002). "Medical Regulation: New Politics and Old Power Structures." *Politics* 22 (2): 59-67.

As the discussion of the previous section has demonstrated, the issue of commitment figured within Klein's formulation of the implicit concordat. Specifically, he highlighted the importance of the capacity of the organisational structure of the NHS to support the concordat by allocating decision-making authority over different issues to different groups—though this capacity was limited to the extent that it was open to the Government to alter the structure of the NHS and, furthermore, to move the debate over the organisation of the Health Service into the wider political arena in which professional interests were not dominant. By contrast, the issue of credible commitment does not figure prominently either in the account of Salter or Ham and Alberti. By neglecting the commitment issue, Salter's exhortation for a renewal of the concordat is unrealistic; and while Ham and Alberti attempt to write an explicit concordat, the regulatory bargains literature suggests that identifying more clearly and transparently the respective duties and entitlements of different groups is not sufficient for their maintenance (though it may arguably be necessary outside the earlier context of a bilateral bargain). The issue of credible commitment relates, implicitly or explicitly, to prominent themes in the health policy literature more generally. The following section reviews briefly existing work in the area of health policy which, while not explicitly following Klein's implicit concordat analysis, contributes related ideas in the politics of health care reform.

### **2.4.3 Commitment and the Politics of Health Care Reform**

Analyses of the politics of health care reform which contribute important insights into the nature of credible commitment in the health care arena

include Carolyn Hughes Tuohy's *Accidental Logics*,<sup>63</sup> Theodore Marmor's *The Politics of Medicare*<sup>64</sup> and the work of Andrew Hindmoor, extended by Adrian Kay, on policy networks in the health care sector.<sup>65</sup> Only in the latter case is the commitment frame explicit (though this is developed in a manner that is substantially different from the present account). This section discusses each of these three contributions in turn.

In *Accidental Logics*, Carolyn Hughes Tuohy presents a comparative analysis of the introduction of market-based reforms into the health care systems of the United States, Canada and Britain.<sup>66</sup> The general claim made by Tuohy is that the development of health policy is shaped by a series of discrete and decisive policy episodes which may occur only during relatively rare 'windows of opportunity' at which point external events (a decisive election victory, perhaps or some kind of 'crisis' in the provision of health care) make it possible to overcome the institutionalised interests within the health care arena. The specific mix of three dominant institutional forms—hierarchy, market and collegium—chosen during these relatively rare moments determines the general direction of incremental reform that occurs during long periods of 'normal' policymaking. Applying this analytical frame to the UK case, Tuohy interprets the establishment of the NHS in 1948 as embedding within the UK health sector a system of

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<sup>63</sup> Tuohy (1999). *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada*. New York, Oxford University Press.

<sup>64</sup> Marmor (2000). *The Politics of Medicare*. Second edition, New York, Aldine de Gruyter.

<sup>65</sup> Hindmoor (1998). "The Importance of Being Trusted: Transaction Costs and Policy Network Theory." *Public Administration* 76 (1): 25-43; Kay (2001). "Beyond Policy Community: The case of the GP Fundholding scheme." *Public Administration* 79 (3): 561-577.

<sup>66</sup> Tuohy (1999). *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada*. New York, Oxford University Press.

“hierarchical corporatism”. This is the term she uses to denote a peculiar institutional mix in which collegial institution of social control by (primarily medical) professional interests tempered political and bureaucratic leadership in health policy. Although professional interests were antagonistic towards the introduction of market elements into the institutional mix of the NHS, the internal market reforms were possible, for Tuohy, due to the opening of a rare window of opportunity in the late 1980s. Reform, she argues, was possible due to a momentary concentration of political will generated by a third Conservative electoral victory, combined with the perception of ‘crisis’ in the NHS which persuaded Mrs Thatcher and her senior colleagues that the costs of inaction exceeded the costs of conflict with the medical profession and other producer interests. Although the Conservative government was able, in this exceptional moment, to enact these reforms, their implementation required a return to normal policymaking, the effect of which was to minimise the intrusion of market mechanisms into the institutional mix of the UK health care system. Although Tuohy does not explicitly adopt Klein’s formulation of the implicit concordat, she develops a similar understanding of the role of the organisational structure of the NHS in constraining the development of policy. The initial institutional form of the NHS is seen to have afforded the medical profession a voice, in normal circumstances amounting to an effective veto over non-incremental policy change. Tuohy’s analysis contributes an understanding of how health policy change becomes path-dependent (as well as demonstrating how similar issues arise in different national contexts). This approach may have the potential to inform PSB-type analysis by contributing an improved understanding of how political bargains can be maintained. At the same time, her focus on the market-based reforms of the early 1990s comes at the cost of a neglect of the rise of regulation in the NHS, and how new forms of policy-making might change this essential path-dependency.

The role of commitment in a legislative context emerges as a major theme in Theodore Marmor's seminal work, *The Politics of Medicare*. Marmor shows how, following the defeat of President Truman's plans for a universal health insurance scheme, a more modest hospital insurance programme for the elderly—Medicare—eventually became a 'policy success' (in the sense of making it 'off the drawing board' and into actual policy) in 1965, despite sustained and committed opposition that had prevented the adoption of the Medicare proposal in the preceding decade and half. Following the unusual Democratic control of House, Senate and Presidency that resulted from the landslide election of 1964, the enactment of Medicare became, according to Marmor a "legislative certainty". Faced with the infeasibility of cutting back on the administration's programme, opponents of Medicare Bill instead proposed an expanded "three-layer pie" comprising Medicare Part A (hospital insurance from the elderly), Medicare part B (physician coverage for the elderly) and Medicaid (medical assistance for the poor, not restricted to the elderly), and this was what was enacted. This apparently paradoxical conclusion to a long struggle is explained, for Marmor, by the combination of a coalition of supporters of universal health care willing to take what they could get, and opponents of 'socialised medicine' anxious to restrict the scope for future, incremental expansion of health care provision. Marmor's first edition thus posits the explanation for one of the major puzzles in the expanded second edition, namely why Medicare did not expand into a system of universal health care coverage, as its supporters had hoped. As Bruce Vladeck puts it, in a contribution to the symposium on *The Politics of Medicare* cited above, "You can't get from the three-layer cake... to the whole pie."<sup>67</sup> One of Marmor's central insights was to show how bargaining between fiercely opposed interests, led to a stable compromise that has survived the

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<sup>67</sup> Vladeck (2001). "Medicare and the Politics of Incrementalism." *Journal of Health Policy, Politics and Law* 26 (1): 153-160, p. 157.

ideological climate of the Reagan and elder Bush administration, the ‘New Republicans’ led by Newt Gingrich in the mid-1990s and the first term of the younger Bush presidency.<sup>68</sup> Marmor’s account therefore shows (without explicitly using the analytical frame of commitment) how the shape of Medicare was determined by the importance, to opponents as well as supporters of a federal health care system, of making the deal stick. At the same time, Marmor’s specific focus does not easily translate into the UK’s majoritarian unitary political system and majority party and electoral system, where (as Levy and Spiller’s argue, discussed in Section 2.4.1) legislation may not be as well-suited to generating credible commitment. His analysis does, however, demonstrate the value of institutional process analysis to understanding policy outcomes, including the extent of policy stability; this, more than Marmor’s substantial conclusions, does profitably translate across national contexts.

One of the few conscious attempts explicitly to place the commitment issue in the foreground of health policy analysis is provided by Andrew Hindmoor who looks at negotiations between the Ministry of Health and the British Medical Association (BMA) over the implementation of the National Health service legislation prior to 1948.<sup>69</sup> Hindmoor notes how the BMA and the MoH eventually overcame the commitment problem and reached an agreement, “... without the use of either legally binding contracts or the exercise of authority.”<sup>70</sup> Hindmoor models relations between the BMA and MoH as a prisoners’ dilemma. Rather than the usual

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<sup>68</sup> Compare Marmor’s account with Michael Moran’s assertion that in the US, “The reforms of the 1960s were not to produce a stable settlement in health care.” Moran (1999). *Governing the Health Care State: A Comparative Study of the United Kingdom, the United States and Germany*. Manchester, Manchester University Press, p. 80.

<sup>69</sup> Hindmoor (1998). “The Importance of Being Trusted: Transaction Costs and Policy Network Theory.” *Public Administration* 76 (1): 25-43.

<sup>70</sup> *Ibid.*, p. 26.

prediction that in a one-shot game it is not rational for either party to co-operate, Hindmoor argues that relations between the parties were embedded within a network of ongoing relations (a 'policy community') that effectively transformed a one-shot into a repeated game, in which co-operation and trust can develop. Building on this approach, Adrian Kay has examined the breakdown of co-operation between the medical profession and the DoH following the introduction of the Limited List in 1985, and the effect of this breakdown on the implementation of the GP fundholding scheme.<sup>71</sup>

The approach of Hindmoor, and the additional contribution made by Kay are both interesting, but can be criticised on two counts. First, although they focus attention onto the impediments to mutually beneficial co-operation between the medical profession and to the government, and to the possibility that trust can be established over time as a result of repeated interaction between actors within the policy community, these accounts do not explain when co-operation will occur and (in Kay's case, in particular) why the collapse of the health policy community occurred when it did. Secondly, in these analyses the 'game' in question occurs between organisational actors, the BMA, on the one hand and MoH/DoH on the other. But if elected politicians are included as actors in the analysis distinct from the organisational interests of the MoH/DoH, the assumptions of a repeated game analysis may not represent the true situation, because politicians face the perpetual possibility of replacement as a result of an election or cabinet re-shuffle.

For present purposes, the importance of these three strands in the literature—Tuohy, Marmor and Hindmoor/Kay is that they point to the

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<sup>71</sup> Kay (2001). "Beyond Policy Community: The case of the GP Fundholding scheme." *Ibid.* 79 (3): 561-577.

more general importance of the commitment within the wider health policy literature (although, with the exception of Hindmoor and Kay, this has not generally been explicit). The brief review of these works undertaken in this section suggest that a regulatory bargains analysis of regulation in the NHS, in particular, one which focuses on the *institutional* basis of regulatory commitment, can contribute to existing debates, by showing how commitment (and its absence) can contribute to the development of health policy.

## 2.5 Conclusions

This brief review points to a number of emergent themes and questions for further investigation, upon which the present thesis will attempt to shed light. First, why was health a 'late developer' in terms of the maturation of regulation identified by Baldwin, Hood and Scott? The regulatory state literature, discussed in Section 2.3.1 points to the, until recently, low visibility of regulatory activities in Western European countries. Could it be argued that the health care sector has seen a rise of the regulatory state, similar to patterns asserted more generally in the regulatory state literature? Secondly how far can the existing literature on the regulatory state describe and explain patterns of development in the NHS, especially given the potential difficulties of the literature on the European regulatory state in accounting for UK developments? Third, how far can transposing analyses of business regulation—in the manner suggested by the regulation inside government literature—contribute to an understanding of regulation of the NHS? In particular, how can a regulatory bargains analysis illuminate the relationship between the design of regulatory institutions and the performance under regulation of NHS organisations? Finally, how, if at all does the shift towards the regulatory state impact on existing NHS

institutions, and the maintenance of the implicit concordat, which is understood here as a kind of health-specific PSB? These themes are taken up in what follows in the next five chapters.

# Chapter 3

## The Health Care State Meets the Regulatory State?

To what extent should, or can, the welfare state be replaced by the regulatory state?<sup>1</sup>

### 3.1 Introduction

The previous chapter identified a puzzle in the development of the literature on regulation: despite the increasing volume, as well as the 'maturation' of the regulation scholarship in general, and the emergence of a focus on what Hood *et al.* term 'regulation inside government' as an area of scholarly interest, these developments have largely by-passed the field of health, at least until very recently. As evidence of this, Chapter 2 pointed to the relative dearth of literature on health services sharing a common analytical approach with studies of other regulatory sectors, and which regarded the setting, monitoring and achieving compliance with standards of performance within the NHS as instances of a generic activity of regulation. This is all the more surprising because there is an established tradition of scholarly interest in professional regulation in the health sector, not to mention in the licensing of pharmaceutical products, etc. A number of

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<sup>1</sup> Day and Klein (1987). "The Business of Welfare." *New Society*: 11-13, 19 June 1987, p. 12.

potential explanations for this late developments were put forward, including the possibility that talk of regulation and of the regulatory state was, as Daintith and Moran have suggested, merely an academic fad, from which (it might be added), academics working in the field of health policy have been (mostly) spared.<sup>2</sup> Alternatively, if the usage accurately captures a genuine shift in the patterns of governance in Britain over the last quarter of a century or so, have the changes been absent, or at least not particularly prominent, in health services? The purpose of this chapter is to interrogate the second possibility, by outlining, in the abstract, the features that are said to be associated with the regulatory state, and by investigating the extent to which these features have become present in the NHS. A second aim of this chapter is to assess the functional explanation for the rise of the regulatory state put forward by Majone, which argues that the increasing perception of the necessity of making credible policy commitments led to a search for more appropriate modes of policy-making.

This line of inquiry is of general interest, as well as providing an essential preliminary to the more detailed analysis of specific regulatory reform initiatives that follows in Chapters 5-7 of this thesis. As well as advancing a relatively broad understanding of the development of health care regulation over two decades, within which these specific regulatory reforms are later understood, it also provides an important challenge to the more general scholarship on the regulatory state. As Section 1.2.2 noted, the provision of health care is central to the politics of modern industrial societies, not only in terms of welfare provision, but also as a locus of professional power, and of productive economic activity. Recognising this, Michael Moran speaks of a “co-penetration” of state and health care institutions, and has coined the term “health care state” in an attempt to

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<sup>2</sup> See Section 2.2, above.

capture this interconnectedness.<sup>3</sup> Given these considerations, it matters to an understanding of the regulatory state whether health care fits the pattern asserted more generally. If not, then claims of a rise of the regulatory state, even if true, might be regarded as at best capturing what amounts to a peripheral development—a valid description of developments within some (arguably more marginal) sectors, but inapplicable to one of the largest, most central and most salient areas of state activity. Furthermore, the health care sector in the UK exemplifies some of the potential inconsistencies between theory and facts identified by Moran with respect to the literature on the European regulatory state and the UK experience, discussed in Section 2.3.1. If the theory of the European regulatory state can account for patterns of change under these less-than-favourable conditions, then this says something important about the value of the theory.

This chapter addresses these questions in three steps. Following closely the work of Loughlin and Scott, Section 3.2 outlines in more detail the features that are said to be associated with the regulatory state, and identifies the functional imperatives that are said to underlie the shift towards the regulatory state. In line with the overall focus of this inquiry, emphasis is placed on the explanation posited by Majone that the perceived need for greater policy credibility explains much of the changes associated with the regulatory state. Section 3.3 then examines the changes in the NHS over a twenty-year period, and attempts to identify trends in relation to the features associated with the regulatory state in Loughlin and Scott's analysis. Accordingly, Sections 3.4.1 through 3.4.3 assess the extent of separation of policy-making from service delivery, creation of free-standing

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<sup>3</sup> Moran (1995). "Three Faces of the Health Care State." *Journal of Health Policy, Politics and Law* 20 (3): 767-781; Moran (1999). *Governing the Health Care State: A Comparative Study of the United Kingdom, the United States and Germany*. Manchester, Manchester University Press.

agencies and increasing formalisation of standards within the NHS. Section 3.4 then assesses these trends against the theory, assessing first the extent to which there has been a rise of the regulatory state inside the NHS, and secondly the extent to which the theory of the European regulatory state can account for identified trends.

### 3.2 Criteria for Identifying the Regulatory State

As discussed in Section 2.3.1, at its most general, the rise of the regulatory state describes a change in policy emphasis from macro-economic stabilisation and redistributive welfare policies towards a greater concern with competitiveness and economic efficiency. As discussed in that section, Majone explains the rise of the regulatory state in functional terms. The growth of administrative regulation, in his analysis, is in part a response to "...newly articulated perceptions of a mismatch between existing institutional capacities and the growing complexity of policy problems."<sup>4</sup> A key reason for this mismatch is the lack of credibility of 'positive state' institutions, which he regards as essential where the object of policy is the co-ordination of different (state and non-state) actors in the pursuit of efficiency, rather than the (zero-sum) distribution between different groups: "In this new context, credibility becomes an essential condition of policy effectiveness."<sup>5</sup> It is the imperative of credibility which, for Majone, explains both the emphasis on rules, and the use of agencies operating outside central administration oversight for their promulgation. Within the health sector, this form of explanation has to contend with the objections

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<sup>4</sup> Majone, op. cit., p. 85.

<sup>5</sup> Majone (1996). "Public Policy and Administration: Ideas, Interests and Institutions", in Goodin and Klingemann (ed.) *A New Handbook of Political Science*. Oxford, Oxford University Press, p. 616.

levelled by Moran. There has been no significant 'rolling back' of state *provision* of public services (though, as Section 3.3.1 discusses, there has been an, albeit limited, shift towards private *production* of these services). Moreover, as Moran discusses, since the 1980s, medical practice within the NHS has been increasingly incorporated within managerial hierarchies, leading in turn to greater politicisation of a previously 'non-political' arena.<sup>6</sup> At first sight, therefore, the theory of the European regulatory state is potentially not applicable, either as a description or as an explanation for the changes that have occurred in the NHS over the last twenty years, despite the increased significance of regulation in the NHS recognised by existing scholarship.<sup>7</sup>

In contrast with the *grandes systèmes* perspective on the regulatory state of Majone and Moran, public lawyers Loughlin and Scott's more detailed, fine-grained approach, attempts to identify the specific institutional features that distinguish the regulatory state from other forms of governance.<sup>8</sup> Following closely the lead of Loughlin and Scott, the following three general trends can be said to be associated with the rise of the regulatory state:

1. The separation of 'provision' from 'production', that is, the separation of policy-setting and operational, service delivery activities. The transfer of state-owned enterprises to the private sector might be regarded as the 'classic' form of separation, but the

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<sup>6</sup> Moran (2003). *The British Regulatory State*. Oxford, Oxford University Press, pp. 139-141.

<sup>7</sup> Davies (2000). "Don't Trust Me, I'm a Doctor: Medical Regulation and the 1999 NHS Reforms." *Oxford Journal of Legal Studies* 20 (3): 437-456; Walshe (2002). "The Rise of Regulation in the NHS." *BMJ* 324: 967-970, 20 April 2002.

<sup>8</sup> Loughlin and Scott (1997). "The Regulatory State", in Dunleavy, Gamble, Holliday and Peele (ed.) *Developments in British Politics 5*. Basingstoke, Macmillan, pp. 205-7.

restructuring of public services through the creation of ‘corporatised’ service providers would fall within this heading;

2. The creation of free standing (semi-) independent agencies which perform such activities as setting standards of provision, monitoring compliance with standards and handling complaints from service users; and
3. The formalisation of relationships within the policy domain, including a shift from an implicit understanding of norms of adequate service, towards greater reliance on explicit formal rules, service standards and performance measures.

This ‘meso-level’ approach has a number of advantages. First, Loughlin and Scott’s formulation is neutral between Moran and Majone’s competing views, and therefore allows for a separate consideration of the descriptive and explanatory claims in the regulatory state literature. Second, the specific identifiable institutional features of the regulatory state, identified in Loughlin and Scott’s formulation, provide a useful basis for an empirical assessment of the extent to which the regulatory state has penetrated the health care state. Third, it avoids the flaws, inherent in some studies, of identifying the regulatory state with vague and overly broad phenomena, and in which the concept of the regulatory state consequently loses some of its analytical bite.

### **3.3 The Regulatory State Inside the NHS**

This section examines the development of the NHS, in order to assess whether assertions concerning the rise of the regulatory state apply in the health care context. It takes each of the three ‘dimensions’ of the regulatory

state identified by Loughlin and Scott in turn, namely separation of policy-making from service delivery, use of semi-independent agencies and increasing formalisation of relationship within the regulatory domain, in order to arrive systematically at an assessment of whether the health care state has become a regulatory state. Although this chapter adopts a twenty-year perspective, it is necessary, from time to time, to situate the discussion in an even broader historical perspective. This is done by reference to the now substantial secondary literature on the history of the NHS.

### **3.3.1 Separation of Policy-Making From Service Delivery**

In a sense, an institutionalised separation of policy-making and service delivery has been a long-standing feature of health services in the UK, reflecting in part the legacy of the pre-NHS era in which local authorities were the main providers of health services, with the Ministry of Health acting as the main agent of policy-making. Based on this earlier experience, the Ministry's image of itself was, according to Klein, "a department with a tradition of regulatory rather than executive functions, reluctant to take on direct administrative responsibilities for a complex service."<sup>9</sup> The original structure of the NHS preserved this pattern: policy—in the form of (mostly delegated) legislation and health service circulars—emanated from the Department of Health, while responsibility for implementation lay with NHS organisations at various levels. At the same time, these arrangements sat uncomfortably with Aneurin Bevan's oft-quoted assertion of ministerial responsibility for even the most trivial details of NHS performance.<sup>10</sup> Thus

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<sup>9</sup> Klein (2001). *The New Politics of the NHS*. 4th Edition, Harlow, Prentice Hall, p. 7.

<sup>10</sup> Bevan famously argued that, "when a bedpan is dropped on a hospital floor, its noise should resound in the Palace of Westminster." See for example Day

what in structural terms was a fairly clear separation between policy-making and service delivery functions, was in practice much more amorphous.

The perception that there was a confusion of roles (and following from this, insufficient attention given to service delivery) was central to the findings of the Griffiths Report into the management of the NHS.<sup>11</sup> In order to institutionalise a more robust separation between the national setting of policy and its implementation, the Report of the Inquiry recommended the establishment of a Health Supervisory Board, chaired by the Secretary of State, as well as a full-time multi-professional Management Board, whose chairman was effectively to fulfil the role of chief executive of the NHS. These two bodies were to be responsible respectively for policy-making and management within the NHS, with the latter to be accountable to the former for the implementation of policies established by the former. Significantly, the Inquiry recommended that the Health Services Supervisory Board and the NHS Management Board should be established informally, effectively, as Day and Klein note, as agencies within the DHSS, rather than as statutory authorities.<sup>12</sup> This was ostensibly a pragmatic decision, reflecting a desire to avoid the need for legislation, which would have delayed, and arguably watered down the implementation of the proposed reforms. The recommendations of the Griffiths Inquiry were accepted in full by the then Secretary of State for Social Services, Sir Norman Fowler, and were formally implemented in 1985.

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and Klein (1997). *Steering But Not Rowing? The Transformation of the Department of Health*. Bristol, The Policy Press, p. 2.

<sup>11</sup> Griffiths (1983) *NHS Management Inquiry: Report to the Secretary of State for Social Services*, London, DHSS. See also Wistow and Harrison (1998).

"Rationality and Rhetoric: The Contribution to Social Care Policy Making of Sir Roy Griffiths 1986-1991." *Public Administration* 76 (4): 649-668, especially pp. 650-652.

<sup>12</sup> Day and Klein, op. cit., note 4, p. 7.

If the objective of the proposed structures was to remove ministers and civil servants from the day-to-day running of the NHS, this was to prove illusory. From the outset, there was some cross-membership of the two boards. Furthermore, following the resignation of the first Chief Executive of the NHS, Mr Victor Paige, the Minister of State for Health, Mr Tony Newton, assumed the chairmanship of the Management Board. This ran directly counter to the intended separation of policy-making and service delivery functions. Whether or not as a direct result, the Supervisory Board failed to establish a role for itself and, despite repeated attempts at revival, first in 1991 (at which point it was re-christened the NHS Policy Board) and again in 1994, eventually fell into abeyance. For its part, the NHS Management Board increased in stature, though this was at the cost of giving the Management Board an increasing emphasis on matters of policy. The *Working for Patients* White Paper<sup>13</sup> (while, as discussed below, institutionalising a 'purchaser-provider split') established the principle of a clear chain of hierarchical command within the NHS, with the NHS Management Executive (as the Management Board was re-named) at the apex. At the same time, the original intention that it should have responsibility for management, with policy-making responsibilities remaining with the Department of Health lost favour. Following a review of the organisation of the Department by a team led by retired civil servant Teri Banks,<sup>14</sup> it was accepted that the NHS Executive ('Management' was dropped from the name at this time) ought to have responsibility over all 'stages' of the formulation and implementation of policy.<sup>15</sup> "The post-Banks settlement", according to Day and Klein, "...appears (fairly unequivocally)

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<sup>13</sup> Secretaries of States for Health Wales Northern Ireland and Scotland (1989) *Working for Patients*, CMS55, London, HMSO.

<sup>14</sup> Banks (1994) *Review of the Wider Department of Health*, London, Department of Health.

<sup>15</sup> Department of Health (1995) *Statement of Responsibilities and Accountabilities*, London, Department of Health.

to mark an acceptance that policy and management cannot be separated.”<sup>16</sup> This acceptance arguably became complete in October 2000 when Nigel Crisp assumed the combined role of Permanent Secretary at the Department of Health as well as Chief Executive of the NHS.

If the institutionalisation of a separation between policy-making and service delivery proved unsustainable at the level of the Department of Health and the NHS, the development of policies of contracting out, and later the internal market arguably provided for a more robust separation. Initially, contracting out was limited to ‘support’ services such as laundry, cleaning and catering, but soon extended to porter services, transport and computing and even clinical services in areas such as diagnosis and pathology. More important than the financial savings from contracting out (the ostensible justification), arguably, was its symbolic importance. As Butler puts it:

The real importance of these developments... lay less in the financial gains that were achieved, though these were by no means negligible, than in the principle they established; the core responsibility of health authorities is not to provide and manage services directly themselves, but rather to ensure that they are available where and when required at least cost to the authority and at least cost to patients using them.<sup>17</sup>

To this extent, contracting out was a direct antecedent to the NHS internal market, established by the *Working for Patients* White Paper.<sup>18</sup> Although the term ‘internal market’ never, in fact, appeared in the White Paper, the reforms were closely based on the ideas put forward in a pamphlet written by a US Health Economist, Alain Enthoven, in which he proposed the restructuring of the NHS along the lines of an ‘internal market model’ in

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<sup>16</sup> Day and Klein, op. cit., note 4, p. 16.

<sup>17</sup> Butler (1994). “Origins and Early Development”, in Robinson and LeGrand (ed.) *Evaluating the NHS Reforms*. London, King’s Fund Institute, p. 15.

<sup>18</sup> Op. cit., note 13.

order to increase performance and efficiency through the pressure of competition.<sup>19</sup> The reforms were subsequently enacted in the National Health Service and Community Care Act 1990.

The basis of the internal market was the separation of the roles of purchasing and provision of services in the NHS. On the purchasing side, the reforms first and foremost involved a re-focussing of the role of District Health Authorities (DHAs) on assessing local health needs, and on placing contracts with NHS providers and, if appropriate, from the private or voluntary sectors. Second, the reforms contained provisions—not originating in Enthoven's proposal, but from a proposal of UK health economist Alan Maynard<sup>20</sup>—for the establishment of 'fund-holding' GP practices who managed a budget from which they purchased certain hospital and community services on behalf of their patients.

On the provider side, hospitals were given greater autonomy from DHAs, and were expected to fund themselves by negotiating contracts with the Districts for the provision of care.<sup>21</sup> An additional, and subsequently significant innovation was that under certain conditions, hospitals had the option of opting out of direct DHA control.<sup>22</sup> These 'self governing' NHS Trusts were given certain freedoms over and above those enjoyed by

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<sup>19</sup> Enthoven (1985). *Reflections on the Management of the National Health Service, Occasional Paper 5*. London, Nuffield Provincial Hospitals Trust.

<sup>20</sup> Ibid., Sections 14-17. On the origins of the fund-holding idea, see Glennerster, Matsaganis, Owens and Hancock (1994). *Implementing GP Fundholding: Wild Card or Winning Hand?* Buckingham, Open University Press, pp. 7-11.

<sup>21</sup> On the nature and type of contracts used between NHS purchasers and providers, see Hughes (1991). "The Reorganisation of the National Health Service: The rhetoric and reality of the internal market." *Modern Law Review* 54 (1): 88-103; Allen (1995). "Contracts in the National Health Service Internal Market." *Modern Law Review* 51 (3): 321-342.

<sup>22</sup> NHS and Community Care Act 1990, Sections 5-11.

'directly managed units' (DMUs)—i.e. those hospitals that chose to remain under DHA control. These included increased autonomy in relation to personnel policies, capital expenditure and management structures, as well as the fact that NHS Trusts were excluded from much central regulation.<sup>23</sup>

In terms of introducing competition to the NHS, the establishment of the internal market may be regarded as having somewhat disappointed the expectations of its proponents (as well as perhaps the fears of its most vocal critics).<sup>24</sup> In other respects, including what is, for present purposes, more important, the separation of policy-making from service delivery in the NHS, the reforms were perhaps even more far-reaching than the government at the time could have foreseen. Despite initial hostility within the service, by 1994 some 400 provider organisations, accounting for 95 per cent of NHS activity had been given Trust status. Likewise, it was initially assumed that fund-holding practices would be somewhat marginal to the reforms, but by 1994 a third of the population were served by fund-holding GP practices (eventually, over half the population were covered by the scheme). At the same time, GP fund-holding evolved not as a single, uniform scheme, but became differentiated into a number of distinct variants. In order to expand the reach of the scheme different 'models' were introduced. For example smaller practices could elect to hold funds over a more limited range of hospital services. Community fund-holding emerged as an option for practices that wished to purchase community but not hospital services. In 1996 the scheme was extended with the establishment of a number of 'Total

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<sup>23</sup> Smee (1995). "Self-Governing Trusts and GP Fundholders: The British Experience", in Saltman and Von Otter (ed.) *Implementing Planned Markets in Health Care*. Buckingham, Open University Press, p. 180.

<sup>24</sup> LeGrand, Mays and Mulgan, eds. (1998). *Learning From the NHS Internal Market*. London, King's Fund; Tuohy (1999). *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada*. New York, Oxford University Press, Chapter 6.

Purchasing Pilots', as a means of experimenting with allowing GPs to purchase a far wider range of services. This reflected the Conservative government's view that, "...GP fund holders were the more effective purchasers of services and should become the purchasers of choice."<sup>25</sup>

The development of the internal market had in turn prompted further reforms of the structure of the NHS hierarchy. In 1993, Secretary of State for Health, Mrs. Virginia Bottomley put forward proposals for further organisational reforms, designed to simplify the structure of the NHS.<sup>26</sup> Legislation was introduced to Parliament and enacted in the Health Authorities Act 1995. The main thrust of the reform was to create unitary Health Authorities, merging the existing functions of Family Health Service Authorities (FHSAs)—responsible for oversight of the provision of services required of GPs under their Terms of Service—with DHAs. At the same time, the Act also provided for the abolition of the 14 existing Regional Health Authorities (RHAs). Some of their functions were devolved to the new Health Authorities, while at the same time 8 Regional Offices, 'outposts' of the NHS Executive, took over the remaining functions. The reforms were presented as the consolidation of the devolution initiated by the internal market reforms. Others, saw the reforms as "...the apotheosis of a process of centralisation that had gradually, almost stealthily been creeping up... Instead of the loose conglomeration of different services... there was to be one unified managerial structure."<sup>27</sup>

The reforms to the NHS introduced by the New Labour government following its election in May 1997 are arguably best interpreted as building

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<sup>25</sup> Smee (2000). "United Kingdom." *Journal of Health Policy, Politics and Law* 25 (5): 945-951, p. 948.

<sup>26</sup> Department of Health (1993) *Managing the New NHS*, London, Department of Health.

<sup>27</sup> Klein, op. cit., p. 182.

on the earlier Conservative reforms, despite the rhetoric of “replacing] the internal market with integrated care.”<sup>28</sup> The division introduced by the NHS and Community Care Act 1990, between purchasers and providers of care remained—although the language of “purchasing” (of hospital and community health services) gave way to that of “commissioning” or “planning”, and the structure of the provider side remained unchanged, initially. On the purchaser side, two significant reforms were introduced. First, Health Authorities were abolished, and in their place 28 Strategic Health Authorities were established.<sup>29</sup> At the same time the NHS Executive Regional Offices were abolished. Second, the reforms abolished the GP fundholding scheme. In its place, some 500 Primary Care Groups (PCGs), were established to commission services for local patients.<sup>30</sup> Reflecting the proliferation of different ‘models’ of fundholding, described above, different options of PCGs were created, appropriate to different local circumstances, ranging from supporting Health Authority commissioning, to establishment as “freestanding bodies accountable to the Health Authority for commissioning care”, and potentially “with added responsibility for the provision of community services for their population.”<sup>31</sup> For these options, the Health Act 1999, Section 2 provided for the establishment of Primary Care Trusts (PCTs) by order of the Secretary of State. Each PCGs and PCTs was expected to consult with its respective Health Authority, over the development of Health Improvement Programmes (HimPs), three-year plans covering the assessment of local needs and requirements and service

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<sup>28</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office, p. 2.

<sup>29</sup> National Health Service Reform and Health Care Professions Act 2002, Section 1.

<sup>30</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office, Chapter 5.

<sup>31</sup> *Ibid.* para. 5.12.

provision. These were subsequently re-badged Health Improvement and Modernisation Programmes (HIMPs).

In one important respect, the reforms of the post-1997 Labour Government extended the approach of the previous Conservative government, in terms of the separation between policy-making and service delivery at the level of purchaser-provider split. Whereas (as noted) the *Working for Patients* reforms allowed purchasers to place contracts with the private and voluntary health care provider sectors, *The NHS Plan*, introduced in 2000, provided for the expansion of the role of those sectors, proposing a new 'concordat' between the NHS and private providers, setting out a more systematic framework within which Health Authorities could make use of independent capacity.<sup>32</sup> A concordat was agreed in October 2000, focussing initially on three areas of joint working: elective care, critical care, intermediate care facilities.<sup>33</sup> In 2002, The Health Select Committee gave an ambivalent assessment about the effects of the concordat, pointing to the threat to public sector resources and wide regional variations in the costs of work undertaken under the concordat<sup>34</sup>

A final development was the provision in the Health and Social Care (Community Health and Standards) Act 2003, for the establishment of a

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<sup>32</sup> Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office, paras. 11.5-11.10.

<sup>33</sup> Department of Health/ Independent Healthcare Associateion (2000) *For the Benefit of Patients: A Concordat with the Private and Voluntary Health Care Provider Sector*, London, Department of Health, 30 October 2000. ; O'Neale Roache (2000). "Alan Milburn Signs Concordat with the Private Sector." *BMJ* 321: 1101, 4 November 2000.

<sup>34</sup> House of Commons Health Committee (2002) *The Role of the Private Sector in the NHS*, HC 308-1, London, The Stationery Office, 15 May 2002, paras. 10-46.

new type of provider organisation, NHS Foundation Trusts.<sup>35</sup> Certain NHS Trusts will be able to apply for Foundation Trust status, which will give them the status of public benefit corporation—a new legal form, analogous to a mutual organisation—created by Schedule 1 of the Act. Foundation Trusts were to be freed from the Secretary of State's power over NHS Trusts to issue binding directions, but operated under license from the Independent Regulator of NHS Foundation Trusts (discussed below).<sup>36</sup> Davies notes the Government's original intention that all NHS Trusts will have attained Foundation status in four to five years.<sup>37</sup> Although this target might seem ambitious, the unexpectedly rapid take-up of NHS Trust suggests that, whatever scepticism may be appropriate, commentators would be wrong to be incredulous.

In summary, separation of policy-making and service delivery can be seen, in the case of the NHS, to derive from a number of overlapping, somewhat mutually reinforcing divisions—between the NHS and the Department of Health, between commissioners and providers of services, between primary and secondary care, and between the NHS and the independent sector—none of which by itself could arguably be said to establish a robust separation. Seen in this way, the partial reversal of the trend, in terms of the abandonment of the attempt to separate policy-making and management, between the NHSME and the Policy Board, is less fatal to the interpretation of an overall trend. And despite the problems inherent in

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<sup>35</sup> Health and Social Care (Community Health and Standards) Act 2003, Section 1. For an analysis, see Davies (2004). "Foundation Hospitals: A New Approach to Accountability and Autonomy in the Public Services." *Public Law* (Winter): 808-828.

<sup>36</sup> Health and Social Care (Community Health and Standards) Act 2003, Section 2.

<sup>37</sup> Davies, *op. cit.*, p. 810.

the approach, the Department of Health has remained attached to the principle of separation, renewing its commitment in the NHS Plan.<sup>38</sup>

### 3.3.2 Creation of free-standing agencies

As discussed in the Section 3.2, a second change associated with the rise of the regulatory state is the increasing use of free-standing regulatory agencies. In assessing the extent to which changes have occurred, definitional issues, of course arise. As discussed in Section 2.3.2 Hood *et al.* speak of ‘regulation inside government’ where the following exist together: (1) one bureaucracy shapes the activities of another; (2) there is an organisational separation between the regulator and the regulatee; and (3) the regulator has some mandate to scrutinise the behaviour of the regulatee and some authoritative basis to change it.<sup>39</sup> For the purposes of the present analysis, these conditions are neither wholly necessary nor sufficient. The National Institute for Clinical Excellence had no direct mandate to scrutinise compliance with the clinical standards it sets. Another free-standing regulator, the Commission for Health Improvement, and later the Commission for Health Audit and Inspection (also known as the Healthcare Commission), undertook that function. Furthermore, the analytical interest in *free-standing* agencies, that is, those operating to some extent outside of hierarchical oversight by ministers questions raises definitional difficulties. Would the NHS Modernisation Agency—an agency wholly within the DoH, but considered by the Department to be an arm’s length body, albeit one that

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<sup>38</sup> Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office, para. 6.6.

<sup>39</sup> Hood, Scott, James, Jones and Travers (1999). *Regulation Inside Government: Waste-Watchers, Quality Police, and Sleaze-Busters*. Oxford, Clarendon Press, p. 8.

is “close to the Department of Health”<sup>40</sup> — fall within this definition? For present purposes it is excluded so as not to inflate the rise of free-standing agencies. Even taking a restrictive approach, since the election of the Labour Government in 1997, there has been a proliferation of agencies regulating various aspects of the NHS.<sup>41</sup> At the same time, there are important antecedents to these more recent developments, and these need to be mentioned briefly.

The first free-standing regulator of the NHS was the NHS Hospital Advisory Service (HAS), established following revelations of patient abuse and neglect at the Ely Hospital, Cardiff.<sup>42</sup> Secretary of State Richard Crossman initially favoured the establishment of “some system of inspection” of hospitals, but was apparently persuaded by officials that an “advisory system” would be more acceptable to the profession.<sup>43</sup> HAS was formally established in November 1969, to advise and report into conditions in long-stay hospitals. In 1975, HAS was amalgamated with the Social Work Service, and was re-christened the Health Advisory Service, with an extended remit covering hospital, community and local authority care services relating to psychiatric and geriatric patients.<sup>44</sup> HAS was formally abolished in 1997, but continued, albeit in somewhat emasculated form, as an NGO, later amalgamated with the Centre for Mental Health Services Development to form the Health and Social Care Advisory Service.

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<sup>40</sup> See Department of Health (2004) *Reconfiguring the Department of Health's Arm's Length Bodies*, London, Department of Health, p. 22.

<sup>41</sup> Walshe (2002). "The Rise of Regulation in the NHS." *BMJ* 324: 967-970, 20 April 2002.

<sup>42</sup> For details of the circumstances surrounding the establishment of HAS, see Webster (1996). *The Health Services Since the War Volume II*. London, The Stationery Office, pp. 231-239.

<sup>43</sup> Ibid., p. 235.

<sup>44</sup> Ibid., pp. 635-637.

A second set of free-standing agency, which also owed its origins to the concern about patient neglect and abuse in the 1960s at Ely and elsewhere, was the Health Service Commissioners offices, whose function was to investigate on behalf of Parliament complaints into maladministration in NHS bodies. Originally established under the National Health Service Reorganization Act 1973, the powers and responsibilities of the Health Ombudsman are set out in the National Health Service Commissioners Act 1993. The National Health Service Commissioners (Amendment) Act 1996 extended the role of the Commissioner in various ways.<sup>45</sup> There were separate offices of Health Service Commissioner for Wales, Scotland and England, though for a time these were held by the same individual.

Under the Conservative governments of 1979-1997, there was some expansion of the number of free-standing agencies (in addition to the extension of powers of the Health Service Commissioners, just discussed). Most notably, this period saw the establishment of the National Audit Office (NAO) as a free-standing (from executive government) agency in 1983, as well as the extension of the powers of the Audit Commission in relation to the NHS as part of the *Working for Patients* reforms.<sup>46</sup> Neither of these organisations have a sectoral focus. They are concerned, in different ways with the scrutiny of the use of public funds, generally, but their work with respect to the NHS falls within the concept of 'regulation inside government' as understood by Hood *et al.* (and as elaborated upon, above),

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<sup>45</sup> Separate legislation covers Northern Ireland. For a recent analysis, focussing on the extension of responsibilities, see Harpwood (1996). "The Health Service Commissioner: The Extended Role in the New NHS." *European Journal of Health* 3 (2): 207.

<sup>46</sup> For a detailed discussion and comparison of the role of these bodies with respect to the NHS, see Walshe (2003). *Regulating Healthcare: A Prescription for Improvement?* Buckingham, Open University Press, pp. 116-122.

and ought to be considered in this context. The NAO was established by the National Audit Act 1983. It is essentially the secretariat of the Comptroller and Auditor General, who is an officer of the House of Commons, and who reports to the Public Accounts Committee. The Audit Commission was created by the Local Government Finance Act 1982, and was originally responsible for auditing the financial accounts of local authorities in England and Wales, as well as undertaking more general 'value-for-money' studies. The *Working for Patients* White Paper proposed to extend the functions of the Audit Commission to cover the NHS. Section 20 of the National Health Service and Community Care Act 1990, brought about this proposed change. More recently, as discussed in detail in Chapter 6, the Audit Commission's value-for money work has been transferred to the new Commission for Health Audit and Inspection, leaving the former body with a much reduced role, relating mainly to the appointment of auditors of NHS organisations.

A second free-standing regulator created under the National Health Service and Community Care Act 1990 was the Clinical Standards Advisory Group (CSAG). Originally introduced as an accommodation between the government and those sceptical of the introduction of the NHS internal market, CSAG's legislative mandate was:

to provide advice on the standards of clinical care for, and the access to and availability of services to, national health service patients and, in this connection, to carry out investigations into such matters (if any) and make such reports in relation thereto as the Health Ministers may require.<sup>47</sup>

CSAG eventually found a role for itself in spreading 'best practice' throughout the NHS (I23). Section 25 of the Health Act 1999 abolished CSAG, its function replaced by the Commission for Health Improvement.

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<sup>47</sup> National Health Service and Community Care Act 1990, Section 62 (1) (a).

The most pronounced growth of free standing agencies followed the election of the Labour Government in 1997. This period has seen the establishment of the National Institute for Clinical Excellence (NICE), the Commission for Health Improvement (CHI), subsequently replaced by the Commission for Health Audit and Inspection (CHAI), the National Patient Safety Agency, the National Clinical Assessment Authority, and the Independent Regulator of NHS Foundation Trusts. This chapter does not discuss the work of these free-standing agencies in detail, but simply confirms Kieran Walshe's assertions of a proliferation of regulatory agencies with responsibility over the NHS since 1997, even when taking a different definition (emphasising the 'free standing' criterion), and in the light of two additional years of data. Table 3.1 (adapted and updated from Walshe) shows the free-standing government-sponsored regulatory agencies with an NHS-wide focus, as they existed at the end of 2004. The table demonstrates a substantial proliferation of free-standing agencies since 1997. All of the free-standing regulators created by the Labour government which existed prior to 2003 (i.e. excluding CHAI and 'Monitor') have been described in detail by Walshe.<sup>48</sup> CHAI is described briefly in Chapter 7. A.C.L. Davies describes the role of the Independent Regulator of NHS Foundation Trusts, established by Section 2 of the Health And Social Care (Community Health and Standards) Act 2003.<sup>49</sup> It is worth stressing that although in 2004 there was a degree of retrenchment, with replacement of three health care regulators by the single CHAI, this did not signal a change in the government's commitment to inspection by free-standing agencies.

<sup>48</sup> Walshe (2002). "The Rise of Regulation in the NHS." *BMJ* 324: 967-970, 20 April 2002; Walshe (2003). *Regulating Healthcare: A Prescription for Improvement?* Buckingham, Open University Press, pp. 126-144.

<sup>49</sup> See Davies (2004). "Foundation Hospitals: A New Approach to Accountability and Autonomy in the Public Services." *Public Law* (Winter): 808-828, pp. 815-818.

**Table 3.1: An overview of post-1997 regulatory agencies in the NHS<sup>50</sup>**

Regulator	Who it regulates	Date established	Budget 2003-04	Mission/purpose	Legal basis
National Institute for Clinical Excellence (NICE)	NHS in England and Wales	April 1999	£17.7 million	To provide national guidance to the NHS on clinical and cost effectiveness and on the effective use of available resources	A Special Health Authority, set up by Statutory Instrument (SI 1999/220 and SI 1999/2219)
National Patient Safety Agency (NPSA)	NHS in England and Wales (initially only England)	April 2001	£16 million	To collect and analyse information on adverse events in the NHS, assimilate safety information from elsewhere, learn lessons and feed back into the NHS, produce solutions, set national goals and establish mechanisms to track progress	A Special Health Authority, set up by Statutory Instrument (SI 2001/1743)
National Clinical Assessment Authority (NCAA)	NHS in England and Wales (initially only England)	April 2001	£5.9 million	To provide a support service to NHS organisations who are faced with concerns over the performance of an individual doctor	A Special Health Authority, set up by Statutory Instrument (SI 2001/2961)
Commission for Health Audit and Inspection (CHAI, Healthcare Commission)	NHS and privately provided health care in England and Wales	April 2004 (replaced CHI, NCSC and some Audit Commission functions)	Expected total income of £75 million (2004-05)	To review and improve the quality of patient care; to conduct value for money studies of health care; to publish performance data on the provision of health care; to investigate serious service failures	A statutory authority established by Health and Social Care (Community Health and Standards) Act 2003, S. 41.
Independent Regulator of NHS Foundation Trusts (Monitor)	NHS Trusts in England and Wales granted Foundation Trust status by Secretary of State	January 2004	£3.4 million (period January-April only)	To authorise NHS Foundation Trusts, and to monitor and enforce compliance with authorisations	A statutory authority established by Health and Social Care (Community Health and Standards) Act 2003, S. 2.

<sup>50</sup> Expanded and updated from Walsh (2003). *Regulating Healthcare: A Prescription for Improvement?* Buckingham, Open University Press, pp. 128-9.

### 3.3.3 Formalisation of Standards of Performance

Loughlin and Scott's third characteristic of the regulatory state is an increased emphasis on formal rules and explicit standards of performance over informal, discretionary or implicit standards. As with the other two dimensions, developments in the direction of greater formality conform, overall, with the trends predicted by claims of a rise of the regulatory state. As with the growth of free-standing regulatory agencies, developments have been most pronounced since the change of Government in 1997, though trends towards greater formalisation are also evident earlier.

Perhaps the most salient example of formalisation of standards of performance in the NHS has been in terms of the development of formal performance indicators (PIs). First introduced across the NHS as a whole in 1983 (previously they had existed in the area of mental health service), they were, as Klein has put it, essentially "an extremely crude set of instruments using the statistics routinely generated by the NHS", repackaged and made more accessible by advances in information technology.<sup>51</sup> PIs took on added significance in 1991 with the introduction of the *Patient's Charter*<sup>52</sup> which enshrined a number of 'rights' as well as further secondary (non-enforceable) standards of performance. Beginning in 1993-94, the NHSME began publishing comparative performance guides on the compliance with Patient's Charter standard and with performance standards established by NHSME.

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<sup>51</sup> Klein (2001). *The New Politics of the NHS*. 4th Edition, Harlow, Prentice Hall, p. 122. On the origins and development of PIs in the NHS more generally, see Harrison and Pollitt (1994). *Controlling Health Professionals: The Future of Work and Organization in the NHS*. Buckingham, Open University Press, pp. 51-60.

<sup>52</sup> Secretary of State for Health (1991) *The Patient's Charter*, London, Department of Health.

The Post-1997 Labour Government's health policy, as set out in *The New NHS White Paper*, and *A First Class Service*, criticised the earlier emphasis on measuring what was readily measurable and proposed a radical overhaul of the approach to PIs in the NHS.<sup>53</sup> In 1999, the new Performance Assessment Framework was introduced, covering key areas of NHS performance at Health Authority level.<sup>54</sup> From 2001, this was extended to all NHS Trusts, and to PCTs providing community services. In the first year, assessment was undertaken by the Department of Health, but in subsequent years was transferred to the Commission for Health Improvement's Office for Information on Healthcare Performance. Complementing this was the declared intention to revise *The Patient's Charter*. Following a review by Greg Dyke,<sup>55</sup> the DoH published its new NHS Charter under the title, *Your Guide to the NHS*.<sup>56</sup> In line with 'New Labour' thinking, *Your Guide to the NHS* stressed responsibilities as well as rights, but also reflected an overall philosophy of basing standards on what (it was claimed) 'mattered'.

A second instance of increasing formality in the NHS can be seen in changes to GPs' terms of service, first in 1990, and again in 2004. Traditionally, the terms under which GPs supplied services to the NHS did not specify in any detail the standards of performance. The duties of a general practitioner were circularly defined in terms of the services "usually provided by general practitioners", and consequently became known

<sup>53</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office, Chapter 8. ; Department of Health (1998) *A First Class Service: Quality in the New NHS*, HSC 1998/113, London, Department of Health, 4.46-4.56.

<sup>54</sup> NHS Executive (1999) *The NHS Performance Assessment Framework*, Leeds, NHS Executive.

<sup>55</sup> Dyke (1998) *The New NHS Charter: A Different Approach*, London, Department of Health.

<sup>56</sup> Department of Health (2001) *Your Guide to the NHS*, London, Department of Health.

colloquially as the ‘John Wayne contract’—a GP’s gotta do what a GP’s gotta do! A significant step towards formalisation occurred in 1985 with the introduction of the Limited List in 1985 (discussed in detail in Chapter 5) into the pre-1992 Terms of Service. Longstanding concern at the inexorable rise of the NHS drug budget had been addressed primarily through exhortation, and through the provision of information on prescribing to GPs. With the Limited List, specific treatments within certain therapeutic categories were excluded from use within the NHS (‘black-listed’) or restricted to certain specific types of condition, or patient (‘grey-listed’). The ‘GP contract’ (in fact a statutory instrument, the National Health Service (General Medical Services) Regulations 1992<sup>57</sup>) introduced explicit targets for certain activities, combined with financial incentives for meeting those targets, covering such areas as screening cervical cytology, immunisation, and check-ups for the elderly and patient education. A new GMS contract (now between Health Authorities and GP *practices*), implemented in April 2004, extended this approach, introducing a further level of detailed specification of services, including a new quality and outcomes framework.<sup>58</sup>

A third area of increased formalisation has been the growth of formal clinical and service standards in the NHS. In terms of clinical standards, the work of the National Institute for Clinical Excellence (NICE) has, as chapter 6 discusses in detail, assumed prominence as the body responsible for the development of clinical guidelines, and on the formal assessment of health technologies in the UK. An increasing emphasis on clinical guidelines pre-dates NICE, with various bodies in the NHS, and

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<sup>57</sup> National Health Service (General Medical Services) Regulations 1992, S.I. no. 635 of 1992.

<sup>58</sup> National Health Services (General Medical Services Contracts) Regulations 2004, S.I. No. 291 of 2004.

beyond (the medical Royal Colleges, for example) developing clinical guidelines since the 1990s.<sup>59</sup> In part, the tendency towards formalisation in this area may have been the result of the practice of some purchasers, of specifying specific guidelines in NHS internal market contracts.

Another significant development towards greater formalisation, occurring in the area of service standards, was the development of the Labour Government's programme of National Service Frameworks (NSFs), which was based on the model of the Calman-Hine report into commissioning Cancer services.<sup>60</sup> NSFs were published by the Department of Health with the assistance of an "external reference group" comprised of experts in the field, and were intended as a "way of being clear with patients about what they can expect from the health service."<sup>61</sup> Each NSF contained measures, against which progress towards meeting standards could be monitored, within an agreed timescale. Monitoring took place through the NHS performance monitoring framework, through systematic reviews by the Commission for Health Improvement (CHI), as well as through the framework of the NHS Charter.<sup>62</sup>

To summarise this section, the last twenty years has witnessed an unrelenting trend towards increased formalisation, exemplified in the increasing use of performance indicators, 'charterism', increasingly prescriptive terms of service for GPs, and in the increasing emphasis on

<sup>59</sup> Day, Klein and Miller (1998). "Introduction", in Day, Klein and Miller (ed.) *Hurdles and Levers: A comparative US-UK study of guidelines*. London, The Nuffield Trust: 6-10.

<sup>60</sup> Expert Advisory Group on Cancer To the Chief Medical Officers of England and Wales (1995) *A Policy Framework for Commissioning Cancer Services*, London, Department of Health.

<sup>61</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office, para. 7.8.

<sup>62</sup> Department of Health (1998) *National Service Frameworks*, HSC 1998/074, London, Department of Health.

quality standards, both at the clinical level (in the case of clinical guidelines) and at the level of service standards (as in the case of National Service Frameworks). The next section analyses these observations, in order to reach an assessment of how far, and why, there has been a rise of the regulatory state inside the NHS.

## 3.4 Analysing Institutional Change in the NHS

Section 3.2 suggested one important advantage of the approach adopted here, of assessing trends in the development of the Health Service against the criteria associated, in Loughlin and Scott's analysis, with the rise of the regulatory state. This advantage was that it allows for the separation, for analytical purposes, of an assessment of the descriptive and explanatory claims of the regulatory state literature. Section 3.4.1 answers in the affirmative the descriptive question of whether there has been a rise of the regulatory state inside the NHS; Section 3.4.2 argues further that, notwithstanding the problems identified by Moran, once the analysis is refined to take account of policymakers' need to contend with the implicit concordat, the theory of the European regulatory state can yield a persuasive explanation for the rise of the regulatory state inside the NHS.

### 3.4.1 The Rise of the Regulatory State in the NHS

Assessed against Loughlin and Scott's three criteria, the changes in the organisation of the NHS between 1985 and 2004 point clearly towards a rise of the regulatory state inside the NHS, analogous to the growth of regulation inside government more generally. This is itself an important conclusion, demonstrating that health is not, in any significant respect a special case. This interpretation is not diminished by some particular instances of

retrenchment—for example, the failure to embed the policy-making/service delivery split proposed by the Griffiths review, or the amalgamation of the functions of some free standing health care regulators. Neither of these called into question the commitment of the Department of Health towards a separation of policy-making and service delivery, or to the use of free-standing regulatory agencies.

This raises the question, alluded to in Section 3.2 as to what kind of regulatory state exists in the NHS. The question evokes Moran's discussion of various contrasting 'images' of the regulatory state.<sup>63</sup> Arguably, the discussion in Section 3.3 also reveals a qualitative shift in the nature of regulation in the NHS, reflecting an increased emphasis on regulation of clinical issues. For example, whereas the broad value-for-money remit of the National Audit Office and the Audit Commission allowed these bodies to look at clinical matters, as part of this broader remit, the free-standing health care regulators established by the post-1997 Labour Government have a sustained focus on clinical issues. Similarly, while Section 3.3.3 indicated a general increase in formality, the discussion of this section also reveals, over time, a shift in emphasis towards greater focus on clinical outcomes. This can be seen for example in the shift towards greater emphasis on clinical quality reflected in the performance indicators, including the targets contained within the GMS regulations. Furthermore, these changes have been driven from the centre, apparently reflecting differences of approach between the Labour and the earlier Conservative governments.

This picture in many ways confirms Moran's description of the British regulatory state, in terms of increasing penetration of hierarchical

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<sup>63</sup> Moran (2003). *The British Regulatory State*. Oxford, Oxford University Press, Chapter 2.

state control into areas not previously subject to formal state regulation. The extent to which the functional explanation for the rise of the regulatory state propounded by Majone can explain changes of this nature will be considered in the next section.

### **3.4.2 Explaining the Rise of Regulation in the NHS**

Majone's explanation for the rise of the regulatory state focuses on a perceived mismatch between the capacities of positive state institutions and the increasing complexity of policy problems.<sup>64</sup> Policy-making by expert, non-majoritarian institutions governing through formal rules is, on this account, better suited to these challenges, where efficiency is a primary goal and where credibility, understood in the sense of time-consistency, is a significant constraint. How does this square with the description of the rise of the regulatory state inside the NHS, where the effect of the changes described in Section 3.3 has been to increase central control over clinical decision-making?

Anticipating somewhat the argument of Chapter 4, this paradox can arguably be explained, once the analysis takes into account the way in which health policy in the UK was underpinned by a peculiar kind of PSB, identified by Klein under the rubric of the implicit concordat.<sup>65</sup> Part of the duties and entitlements originally established by the concordat included, according to Klein, an understanding on the part of the Government that it would not become involved in setting clinical priorities, in return for which the medical profession accepted the DoH's responsibility for setting the broad framework of policy, including the power to set overall budget limits. This was the starting point of an evolving bargain, with subsequent reforms

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<sup>64</sup> See Section 2.3.1, above.

<sup>65</sup> See Section 2.4.2, above.

moving in the direction of facilitating greater intervention by the DoH in clinical decision-making.

Even so, it could be argued that increased intervention in the form of explicit standards established by free-standing agencies—whether motivated by a desire for cost-saving, to eliminate poor performance or assure patient safety, or to spread ‘best practice’—is less disruptive of the implicit concordat, compared with other modes of intervention. If this is correct, then regulatory state-type governance may be more compatible with the continued functioning of the NHS along existing lines, compared with approaches which place a greater amount of decision-making directly under the control of the Department of Health, or which confer a greater degree of administrative discretion on decision-makers. On these assumptions, the rise of the regulatory state inside the NHS can be seen, on the one hand, as a trend towards greater state intervention and, at the same time, as a search for more credible policy instruments necessary to make a more-interventionist approach ‘work’ within the existing NHS. Admittedly, this reconciliation of facts and theory, comes at the cost of some of the parsimony that is one of the strengths of Majone’s approach.

### 3.5 Conclusions

The main aim of this chapter has been to analyse the extent to which the public health care sector in the UK has seen a shift towards the regulatory state over the last two decades or so, comparable to changes asserted more generally in the countries of Western Europe and at the level of the EU. Each of the trends identified by Loughlin and Scott as associated with the regulatory state has been the subject of existing scholarship. What this chapter has added, using the lens of Loughlin and Scott’s criteria of the

regulatory state, is an understanding of the broader picture—the interconnections between (changes in the) the different features of governance that together define the regulatory state. A second contribution has been its attempt to assess the plausibility of Majone's argument that the rise of the regulatory state can be understood (in part, at least) to select modes of intervention that are better suited to the demands of contemporary policy-making, including the perceived need for more credible policies. It was argued that this general explanation is plausible once this type of explanation is extended to take into account the idea of a PSB—in this case the implicit concordat—underpins the provision of public services. These observations are not, of themselves, sufficient to demonstrate that Majone's general explanation accounts for these developments, only (with some additional assumptions associated with PSB-type analysis) that it *could*.<sup>66</sup>

One way of advancing the argument further is to investigate the extent to which the institutions of healthcare regulation *are* credible. To the extent that they are not, this may be regarded as calling Majone's explanation into question. The case study chapters of this dissertation (Chapters 5-7) address this question at the more detailed level. As a preliminary to this, Chapter 4 sets out an understanding of why commitment is important to the effectiveness of NHS regulation, and develops a more detailed understanding of the features of regulatory governance that make regulation in the NHS credible.

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<sup>66</sup> Thanks perhaps to the efforts of Hood, Mueller's analysis of the adoption of civil service exams in Britain and Prussia is taken as the paradigmatic example of how the same reform measures can be adopted for opposite, contradictory reasons. See Mueller (1984). *Education and Monopoly*. Berkeley, University of California Press.

# Chapter 4

## Regulation, Institutions and Commitment in the NHS

An implicit contract isn't worth the paper it is written on.<sup>1</sup>

### 4.1 Introduction

The previous chapter examined the proposition that in the UK, the evolution of health services corresponded to an overall pattern of development encapsulated in claims of a shift from the 'positive' to the 'regulatory' state. Following the features identified with the regulatory state proposed by Loughlin and Scott, trends towards a 'regulatory health care state' were identified, namely: (1) the separation of responsibility for health policy and for the delivery of health services; (2) the creation of (semi-) independent regulatory bodies in the NHS; and (3) the formalisation of standards of performance. Furthermore, the previous chapter examined in some detail the proposition, associated primarily with the work of Giandomenico Majone, that these changes have been a functional response to a perceived mismatch between the capacities of positive state institutions and the nature of contemporary policy challenges, including the need for credible, time-consistent policies.

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<sup>1</sup> Seen in the window of a high street solicitor in Troon, Ayrshire in 1996.

This chapter revisits these themes from a different perspective, one that will lay out more clearly the analytical framework for an examination of specific episodes of regulatory reform which follow in the next three chapters. The purpose is to sketch out an account of the institutional basis of commitment to implicit understandings between the medical profession and elected politicians (and their civil service 'agents') which underpinned the NHS and to show how increased regulatory intervention can challenge these understandings. For the most part, the existing scholarship advancing the foundational ideas put forward by Rudolf Klein regarding the implicit concordat simply documents the progressive erosion of the concordat, and urges the establishment of a new (perhaps, as in the case of Ham and Alberti, 'explicit') concordat.<sup>2</sup> The present account therefore seeks to advance the existing scholarship in one important respect: by focussing on the issue of credible commitment to the concordat, and to the role of institutions in generating credible commitment, the present account can potentially contribute our understanding of the institutional requirements for effective regulatory reforms in the NHS, and (what is the other side of the same coin) to our understanding of why such reforms often fail to achieve fully their intended, publicly-espoused objectives.<sup>3</sup> Furthermore, in its focus on the contribution of legal and administrative arrangements that comprise the 'governance structure' of NHS regulation to the establishment of

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<sup>2</sup> Salter (1998). *The Politics of Change in the Health Service*. Basingstoke, Macmillan, p. 440; Ham and Alberti (2002). "The Medical Profession, The Public, and the Government." *BMJ* 324: 838-842, 6 April 2002. The original contribution of Rudolf Klein is to be found in Klein (1983). *The Politics of the National Health Service*. London, Longman. See further Section 2.4.2, above.

<sup>3</sup> Arguably, this emphasis on institutional mechanisms for 'enforcing' the concordat is more faithful to Klein's original analysis—which emphasised how the concordat was built-in to the structure of the NHS—than other existing attempts to extend the idea of the implicit concordat. Brian Salter's more recent emphasis on the criteria for a 'politically sustainable' model of medical regulation is perhaps also shares this same spirit. See Salter (2002). "Medical Regulation: New Politics and Old Power Structures." *Politics* 22 (2): 59-67.

credible commitments in the NHS, this analysis builds on existing work in administrative law as well as in public administration. The framework developed here draws inspiration from the work of Pablo Spiller and his co-authors on the institutional foundations of regulatory commitment in the utilities sectors, especially the work of Levy and Spiller.<sup>4</sup> The present contribution goes beyond these existing accounts insofar as it adapts them to the context of health policy and regulation, where the relevant bargain is an implicit concordat between the profession and the government, rather than (as in Levy and Spiller's original account) between the government and private investors.

The organisation of this chapter is as follows: first, it reiterates the idea that the NHS was based on an 'implicit concordat' between the government and the medical profession, and that this has shaped the subsequent development of health policy; second, it is argued that the rise of regulation in the NHS has the potential to further undermine the implicit concordat, and that—to the extent that successful reforms depend on the support and co-operation of the medical profession—that this presents a central challenge that proposed reforms must meet, the problem of securing commitment to the implicit concordat, if they are to achieve their intended outcomes; third, it shows specifically the ways in which effective regulation depends on professional support, focussing in particular on the contribution of the profession to effective compliance; fourth, it considers commitment strategies available to reformers, emphasising those that rely on the design

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<sup>4</sup> Levy and Spiller (1994). "The Institutional Foundations of Regulatory Commitment: A Comparative Analysis of Telecommunications Regulation." *Journal of Law, Economics and Organization* 10 (2): 201-246; Levy and Spiller, eds. (1996). *Regulations Institutions and Commitment: Comparative Studies of Telecommunications*. Cambridge, Cambridge University Press. See also Spiller (1995). "A Positive Theory of Regulatory Instruments: Contracts, administrative law or regulatory specificity?" *Southern California Law Review* 69 (3): 477-515.

of the legal and administrative framework for; finally, it sets out some of the observable implications of the theory put forward in this chapter. In doing so, it prepares the ground for the case study analyses undertaken in the following three chapters.

## 4.2 The Implicit Concordat

As discussed in Section 2.4.2 Rudolf Klein first put forward the idea that the UK health care system is based on an implicit concordat between the state and the medical profession in the first edition of his seminal *The Politics of the NHS*.<sup>5</sup> It was argued that the concept can be seen as a specific application of the more general idea of the public service bargain, first proposed by Bernard Schaffer, and developed more recently by Christopher Hood. In the context of this study, the implicit concordat refers not specifically to the outcome of the negotiations between the BMA and the Ministry of Health over the legal and administrative structure of the NHS between 1946 and 1948; rather it refers also to the broader principles which that legal and administrative structure were intended to enshrine. Indeed, it is possible to regard the specific points on which agreement was reached—the independent contractor system for GPs, consultants' contracts, professional medical involvement in decision-making at all levels of the NHS—as a means of *institutionalising* the implicit concordat into the structure of the NHS. In this sense, like Hood's implementation of the PSB idea, the implicit concordat is an analytic construct, though one which is grounded in actual historical agreements, and which is arguably necessary to make sense of them.

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<sup>5</sup> Klein (1983). *The Politics of the National Health Service*. London, Longman.

The implicit nature of the concordat, together with the fact that it was to be an evolving bargain means that it is not necessarily possible to state with any precision the respective duties and entitlements of the profession and Government under the concordat. Drawing on the transaction costs economics, we could say that the implicit concordat was a classic 'incomplete contract' in the sense that its meaning, even if transparent to the original parties to it, was ambiguous to third parties, including to successor generations of politicians and officials and to the leaders of the organised interests of the medical profession. If this were the case, then we would expect to see relations between the Government and the medical profession to be characterised by disagreement over whether certain proposed interventions were 'legitimate' (although it is perhaps not necessary that such disagreements should be couched specifically in the language of 'fidelity' to the implicit concordat). Nevertheless, some generalities are hopefully not contentious. For the medical profession, the implicit concordat meant acceptance of the principle that decisions regarding the broad policy framework, including the overall level of funding for health services were political decisions to be taken by Ministers, in return for which the profession was to enjoy economic security and the enhanced ability of the profession to regulate its own affairs, including the privilege of enjoying a large measure of control over the nature of medical work.<sup>6</sup> A central principle—though one that has subsequently been fiercely contested—was that of 'clinical autonomy' or 'clinical freedom'. This refers to the idea that the profession's unique access to, and control over, the body of relevant clinical knowledge, made it inappropriate for the Government (or others

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<sup>6</sup> Salter (1998). *The Politics of Change in the Health Service*. Basingstoke, Macmillan, p. 125.

outside the profession) to intervene directly in decisions over what treatment was appropriate for different patients.<sup>7</sup>

As noted in Section 2.4.2, a limited degree of protection to the terms of the concordat was afforded by the structure of the NHS, and by the relatively stable power relations within it. Nevertheless, a number of scholars have pointed to the progressive unravelling of the concordat over time, and to the detrimental consequences that this raises.<sup>8</sup> In other words, it was recognised that it is possible for the respective parties to the concordat—the government and the medical profession—to ‘defect’ from their respective undertakings. For the purposes of the present account, the incursion of the regulatory state into the health care arena constitutes an important challenge to the implicit concordat. As the next section attempts to demonstrate, the key features of the regulatory state described in the previous chapter, creates an environment in which the implicit concordat is no longer enforced by the structure of the NHS as it arguably was in an earlier era, especially where, as Moran correctly identifies, the rise of the regulatory state in Britain has had the effect of extending the reach of state control.<sup>9</sup> Thus, without denying the relevance of the arguments put forward by Majone, and which were discussed in the previous chapter, the association between the rise of the regulatory state and the imperative of credibility is by no means ‘automatic’; rather it depends on the institutional

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<sup>7</sup> Hampton (1983). "The End of Clinical Freedom." *BMJ* 287: 1237-8; Calnan and Williams (1995). "Challenges to Professional Autonomy in the United Kingdom? The perceptions of general practitioners." *International Journal of Health Services* 25 (2): 219-241.

<sup>8</sup> Ham and Alberti (2002). "The Medical Profession, The Public, and the Government." *BMJ* 324: 838-842, 6 April 2002; Salter (2002). "Medical Regulation: New Politics and Old Power Structures." *Politics* 22 (2): 59-67.

<sup>9</sup> The point that compliance with regulation still relies heavily on existing structures of hierarchical corporatism is explored below in section 5.

details of regulatory governance—a theme to which section five, below, returns in more detail.

### 4.3 Regulation, Waste and the Concordat

In terms of the implicit concordat, a central problem in implementing regulatory reforms into the NHS is the potential for slippage.<sup>10</sup> Once in place, mechanisms intended to facilitate intervention for non-controversial purposes may be adapted to purposes which are semi-llicit or even downright violations of existing understandings of duties and entitlements. In the absence of credible commitment, this may lead the profession to oppose interventions which, on the face of them, do not necessarily offend against the concordat. In other words, like the original establishment of the NHS, the profession may regard the introduction of regulatory reforms into the health care sector as "...objectionable far less for what it is than for what it might become."<sup>11</sup>

The goal of eliminating waste in the NHS provides a good example of how regulatory initiatives that are not necessarily inconsistent with the concordat may nonetheless give rise to the hostility of the medical profession. To a large extent, this problem arises because, as Blunstein and Marmor argue, 'waste' is not a simple, clearly defined phenomenon; rather the term covers a "conceptual hodgepodge" of situations, incorporating a number of different senses in which health care can be said to be

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<sup>10</sup> The term 'slippage' is used here in an expansive sense to denote both intentional and unintentional expansion of regulatory initiatives. The terminology of 'bureaucratic drift' and 'coalitional' drift is introduced below to denote different types of intentional slippage.

<sup>11</sup> Editorial (1948). "Safeguards." *The Lancet*: 561, 10 April. Quoted in Hindmoor (1998). "The Importance of Being Trusted: Transaction Costs and Policy Network Theory." *Public Administration* 76 (1): 25-43, p. 37.

'wasteful'.<sup>12</sup> In order to make sense of these different senses, Blunstein and Marmor propose the following taxonomy of waste, summarised in Figure 4.1, below:<sup>13</sup>

1. *Ineffective or harmful treatment.*<sup>14</sup> A well-known example of a treatment that is both ineffective and harmful is the prescription of antibiotics for viral infections, which in addition to having no impact on the condition, contribute to anti-microbial resistance, now a major public health threat (although it is difficult to diagnose, for example, whether a sore throat is caused by a virus or by the bacterium *Streptococcus pyogenes*).<sup>15</sup> For present purposes, ineffective treatment can be taken to include treatments providing no *net* clinical benefit, that is, those which provide no additional clinical benefit over other, less expensive, therapies. The paradigmatic example of treatments of no *net* clinical benefit is proprietary drugs where exact generic equivalents are available. Although arguments have sometimes been made to the contrary, restrictions on such treatments cannot be considered to be 'rationing' in the sense that they deny of beneficial care to patients.

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<sup>12</sup> Blunstein and Marmor (1992). "Cutting Waste By Making Rules: Promises, Pitfalls and Realistic Prospects." *University of Pennsylvania Law Review* 140: 1543-1572, p. 1545.

<sup>13</sup> Figure taken from *Ibid.*, p. 1572.

<sup>14</sup> *Ibid.*, pp. 1548-1555.

<sup>15</sup> In 1998, a report of the Science and Technology Committee found evidence of widespread misuse, of which "...the greatest bulk of imprudent use of antimicrobials in human medicine in the United Kingdom is the prescription of antibacterials by GPs for self-limiting or viral infections and in other inappropriate situations." See House of Lords Science and Technology Committee (1998) *Resistance to Antibiotics*, HC 81-5, London, The Stationery Office, 23 April 1998, para. 11.12. See also the Standing Medical Advisory Committee Sub-Group on Antimicrobial Resistance (1997) *The Path of Least Resistance*, London, Department of Health.

2. *Treatment of uncertain effectiveness.*<sup>16</sup> In addition to treatment falling into the first category which covers treatment that is (known to be) harmful or ineffective, there exists a broad range of treatments for which there is very little data on effectiveness, or concerning which there is genuine disagreement over how to interpret the data. There is thus ample room for disagreement about the effectiveness of much medical treatment, and even the best efforts of the evidence-based medicine movement often seem unable to provide specific guidance, leading to suggestions of a “stainless steel” law of evaluation, according to which the best designed outcome evaluations often seem to produce the least evidence that an intervention is effective.<sup>17</sup>
3. *Treatment that is ethically troubling.*<sup>18</sup> While many of the most controversial ethical questions in medicine concern the decision to *withhold* life-prolonging treatment, many therapies also give rise to considerations about whether it is ethical to provide a certain kinds of treatment. Although discussion often focuses on controversial new (and even not-yet-existing) treatments, there are many real-world examples in relation to population control and reproduction, and in the field of mental health.
4. *Treatment that is not allocational efficient (not ‘cost-effective’).*<sup>19</sup> Perhaps the most controversial category of ‘waste’ is the provision of treatment that is expensive, but which is nonetheless clinically effective (as defined here, confers a *net* benefit). As Blunstein and Marmor argue, within this category, there is an inevitable nexus

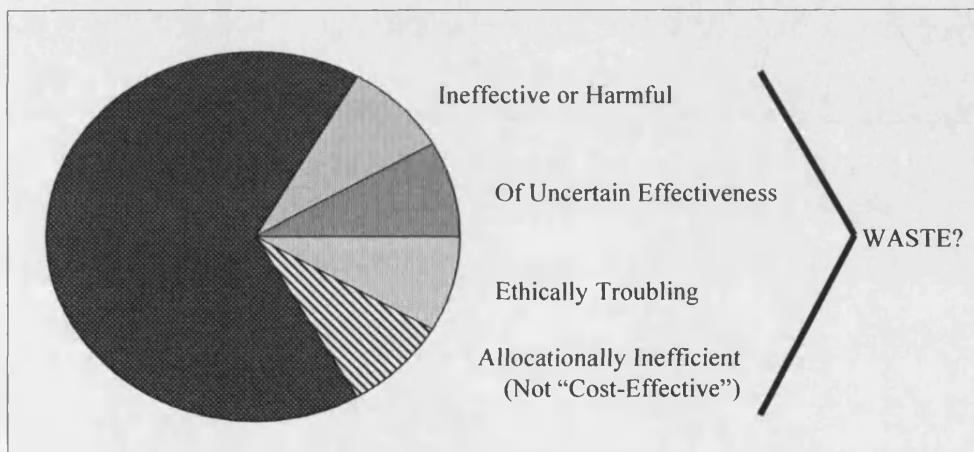
<sup>16</sup> Blunstein and Marmor, *op. cit.* pp. 1555-1556.

<sup>17</sup> Petticrew (2003). "Why certain systematic reviews reach uncertain conclusions." *BMJ* 326: 756-758.

<sup>18</sup> Blunstein and Marmor, *op. cit.* pp. 1556-1558.

<sup>19</sup> *Ibid.* pp. 1558-1563.

between eliminating 'waste' and 'rationing': "If 'waste cutting' means 'trimming the fat' and 'rationing' means 'making rules to limit the use of beneficial services,' it will necessarily be the case that in trimming the fat we deny some people beneficial services.<sup>20</sup> A controversial example, discussed further in Chapter 6 is the treatment of multiple sclerosis by prescribing beta interferon and glatiramer acetate, which has been estimated to have a cost per QALY of upwards of £42,000.<sup>21</sup> Again, as Blunstein and Marmor have emphasised, judgements about whether costly treatments are 'wasteful' simply do not make sense independently of an assessment of overall resources.<sup>22</sup>



**Figure 4.1: Blunstein and Marmor's Taxonomy of Waste**

The value of this particular taxonomy is that it illustrates how different regulatory interventions raise different kinds of issues—initiatives intended to eliminate waste falling within the first category require only a purely 'technical' assessment of outcomes, avoiding the 'hard choice' of

<sup>20</sup> *Ibid.*, p. 1561.

<sup>21</sup> Chilcott, McCabe, Tappenden, O'Hagan, Cooper and Abrams (2003).

"Modelling The Cost Effectiveness of Interferon Beta and Glatiramer Acetate in the Management of Multiple Sclerosis." *BMJ* 326: 522-527, 8 March 2003.

<sup>22</sup> Blunstein and Marmor, *Op. Cit.*, p. 1543.

denying potentially beneficial treatment to patients, for example. Restrictions on the availability of treatment in the third and fourth categories inevitably involve (albeit on different grounds) denying effective treatments to patients.

A major difficulty that follows from this for the design of regulatory policies is that many potential interventions cut across the different categories of waste, as well as the distinction between wasteful and non-wasteful care, making it problematic to translate these conceptual distinctions into what Hood calls “robust rule categories.”<sup>23</sup> Put simply, it may be difficult or impossible to design a legal and administrative framework that confers on regulators adequate powers to deal with any particular category that is not also over-inclusive, incorporating other categories of waste, or in extreme cases potentially restricting the availability of treatments that are not ‘wasteful’ within any of Blunstein and Marmor’s four senses. An example (albeit a debatable one) is the prescription of sildenafil (Viagra) for the treatment of broad-spectrum erectile dysfunction which has been argued to perform well on conventional assessments of cost-effectiveness.<sup>24</sup>

From a purely ‘technical’ standpoint, the problems of distinguishing reliably between different categories of waste, and between wasteful and non-wasteful care in framing the scope of regulatory authority may lead to undesirable outcomes to the extent that a regime designed to address waste within one particular category may do a poor job of eliminating waste—and of preserving non-wasteful treatment—within other categories, or else may

<sup>23</sup> Hood (1986). *Administrative Analysis: An Introduction to Rules, Enforcement and Organisation*. Brighton, Wheatsheaf Press, pp. 35-43.

<sup>24</sup> Smith and Roberts (2000). "The Cost-Effectiveness of Sildenafil." *Annals of Internal Medicine* 132 (12): 933-937.

lack the authority to deal as effectively as possible with waste arising within a single category. In other words, Blunstein and Marmor's analysis points to the importance of paying attention to the legal and administrative framework of regulation, if for no other reason than that failure to do so might be expected to lead to a high degree of administrative error.

Seen through the lens of the implicit concordat, and the problem of commitment, the difficulties inherent in attempting to reduce different kinds of 'waste' to robust rule categories give rise to an additional and altogether different set of issues, arising from the observation that, while some forms of intervention may be compatible with the implicit concordat—after all, the Government is responsible for setting the broad policy framework for the Health Service—others potentially constitute 'illegitimate' intrusions into the medical sphere that are outside the medical profession's 'zone of acceptance' of the decision-making authority of the Department of Health.<sup>25</sup> Even well-intentioned reforms, if they confer over-broad regulatory authority beyond that which would be regarded as within this 'zone of acceptance', may over time lead to an erosion of the concordat, as the scope of intervention expands as a result of the regulatory policy. The problem of *bureaucratic drift* thus arises where the legal and administrative framework of regulation does not adequately constrain regulatory decision-makers.

There is, however, a further threat arising from the fact that, after a reform has been implemented, the Department of Health may even have an incentive to encourage the extension of regulatory policy, and can do so by

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<sup>25</sup> The idea that authority is characterised as a two-way relationship, in which the subordinate has a 'zone of acceptance' within which she submits to the direction of the superior is widely recognised to originate with Herbert Simon, though precedents are to be found in the work of Chester Barnard. See Moe (1984). "The New Economics of Organisation." *American Journal of Political Science* 28: 739-777, p. 745.

declining to police the limits on bureaucratic discretion, or even modify the legal and administrative framework to allow the extension into other categories. In other words, if it is to secure the support of the medical profession for its regulatory reforms, the Department of Health must also contend with the problem of *coalitional drift*.<sup>26</sup> An important consideration is that relations between the profession and government are nested within a broader set of relationships within the 'regulatory space'.<sup>27</sup> Other interests with a 'stake' in the regulation of the NHS include the organised interests of the allied professions, pharmaceutical companies, patients' groups, medical charities, all of which potentially have a destabilising effect on any bilateral understandings. Any of these groups may have objectives that are, on occasion, antagonistic to the implicit concordat, and the Department of Health may have to choose between retaining the support of the profession, and the support of some other affected interest. For example, it has been argued that the implicit concordat has been weakened by the increasing assertiveness of consumer interests in health policy.<sup>28</sup> Similarly, on occasion, professional interests have supported restrictions on prescribing that have been opposed by the Association of British Pharmaceutical Interests and *vice versa*.

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<sup>26</sup> Horn and Shepsle (1989). "Commentary on 'Administrative Arrangements and the Political Control of Agencies': Administrative process and organisational form as legislative responses to agency costs." *Virginia Law Review* 75 (2): 499-508. For present purposes, the 'enacting coalition' includes the relevant legislative coalition but all those interests whose support is necessary for the success of a reform—including, crucially, organised medical interests.

<sup>27</sup> Hancher and Moran (1989). "Organizing Regulatory Space", in Hancher and Moran (ed.) *Capitalism, Culture and Economic Regulation*. Oxford, Clarendon Press.

<sup>28</sup> Ham and Alberti (2002). "The Medical Profession, The Public, and the Government." *BMJ* 324: 838-842, 6 April 2002.

The *scope* of a permitted intervention, however, represents only one dimension along which bureaucratic and coalitional drift can occur. Rules possess different dimensions, and slippage along any one of them can potentially affect whether an intervention is regarded as compatible with the implicit concordat.<sup>29</sup> For example, taking Baldwin's rule-dimension of *legal force or effect*, it is plausible that regulatory intervention to tackle waste within Blunstein and Marmor's second category, treatment of uncertain effectiveness, may be regarded as compatible with the respective rights and obligations of the government and the medical profession so long as compliance with rules is voluntary, but may be regarded as an intrusion into clinical freedom if the professional prerogative to disregard standards based on their clinical judgement is not preserved. As Chapter 6 will show, the effect of NICE guidance within the NHS provides an example. Following the decision of a Devon PCT, contrary to the recommendation of NICE, not to fund zanamivir (Relenza) the Department of Health introduced guidance requiring NHS bodies to fund NICE-approved treatments prescribed by individual GPs. Alternatively, the *prescription or sanction* (in Baldwin's terms) may affect the status of an intervention vis-à-vis the implicit concordat. The profession may tolerate sanctioning powers by the Department of Health provided that enforcement strategies are primarily based on supporting professional self-regulation, with more punitive measures 'held in reserve' in the manner suggested by Ayres & Braithwaite's 'responsive regulation' model, for example.<sup>30</sup> Of course, these are empirical issues for investigation, and such assessments of what is and is not consistent with the concordat may be complex, a problem that will be encountered repeatedly in the next three chapters.

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<sup>29</sup> For an account of the different dimensions of rules, see Baldwin (1995). *Rules and Government*. Oxford, Clarendon Press, pp. 7-11.

<sup>30</sup> Ayres and Braithwaite (1992). *Responsive Regulation: Transcending the Deregulation Debate*. New York, Oxford University Press, Chapters 2 & 4.

Given these factors, a major objective of any regulatory initiative, where professional support is likely to have a significant impact on the success of the initiative, must therefore be to signal credible commitment to the implicit concordat. In the absence of credibility, the outcome of regulatory reforms may well be unsatisfactory, leading to further changes, quite possibly further eroding the implicit concordat. As Spiller puts it, “Without credibility, the expectation of a future policy reversal may become a self-fulfilling prophecy, defeating the purpose of the reform.”<sup>31</sup> The next two sections take up different parts of this argument. Section 4 addresses in more detail how the absence of professional support can undermine the effectiveness of reforms, while Section 5 argues that the design of the legal and administrative framework for regulation can help to secure credible commitment to the implicit concordat.

#### **4.4 Professional Politics and the Effectiveness of Regulation**

It was suggested above that the incursion of the regulatory state into the health care arena challenges the implicit concordat because regulation raises the possibility for policy-making outside of the framework of hierarchical corporatism that characterised the original structure of the NHS. Why, then, does fidelity to the implicit concordat matter? One answer draws inspiration from Carolyn Hughes Tuohy’s argument concerning the limited impact of the market-based reforms of the 1990s in Britain.<sup>32</sup> Tuohy suggests that while

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<sup>31</sup> Spiller (1995). "A Positive Theory of Regulatory Instruments: Contracts, administrative law or regulatory specificity?" *Southern California Law Review* **69** (3): 477-515, p. 477.

<sup>32</sup> Tuohy (1999). *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada*. New York, Oxford University Press, Chapter 6.

the Conservatives were able to reconfigure the NHS along the lines of the internal market in 1990 even in the face of professional opposition, the underlying balance of professional and state power within Britain's 'hierarchical corporatist' health care regime was largely unaffected:

The introduction of this mechanism [i.e. the internal market] changed the formal mode whereby participants in the system related to each other and to some extent the sanctions that they could bring to bear in seeking to achieve their objectives. But the informal networks and modes of relationship that characterised the system prior to the reforms continued to exist within the form of the market. The prevalence of block contracts, the limited degree of competition, the preservation of the clinical arena as a zone of collegial decision-making, and the continued regulation of managerial behavior through central directives and "guidances" all represent the survival of an institutional mix in which hierarchy and collegiality had a heavy weight.<sup>33</sup>

Thus, the impact of these reforms was lessened by the continued reliance on collegial networks and state authority for decision-making.

In the same way, it can be argued that even if regulatory policies can be framed without professional (or indeed Department of Health) support, collegial networks as well as state authority is still essential to the task of securing compliance with regulation. There is a strong tradition within the broader literature on regulation which argues that regulation is most effective when there is co-operation between regulators and regulated, and which analyses different kinds of problems encountered in engendering co-operation.<sup>34</sup> Building on the work of Ayres and Braithwaite and McBarnet and Wheelan, Christine Parker argues that the success of compliance-

<sup>33</sup> Ibid., p. 197.

<sup>34</sup> Scholz (1991). "Cooperative Regulatory Enforcement and the Politics of Administrative Effectiveness." *American Political Science Review* 81 (1): 115-136; Ayres and Braithwaite (1992). *Responsive Regulation: Transcending the Deregulation Debate*. New York, Oxford University Press, Chapter 2; McBarnet and Wheelan (1999). "Challenging the Regulators: Strategies for resisting control", in (ed.) *Regulation and Deregulation: Policy in practice in the utilities and financial services industries*. Oxford, Clarendon Press.

oriented regulatory strategies requires, among other things, that “...regulators and regulatees must share some common commitments to the goals and purposes of regulation...” in order to avoid the risk of ‘creative compliance’, that is, where regulatees comply with the technical requirements of regulation (the ‘letter of the law’) in such a way as to frustrate the overall objectives of regulation.<sup>35</sup>

Extending this argument, it is reasonable to suppose that regulation will not effectively achieve desired outcomes if it is perceived as a form of ‘cheating’ on (or ‘defection’ from) the implicit concordat on the part of the Department of Health. Indeed, building on some of the above-mentioned sources, Anne Davies drew attention to a number of “risks of subversion” which she claims are inherent in the 1999 NHS reforms.<sup>36</sup> To back up her argument (which is prospective), she cites examples of subversion found in existing studies of regulation in the NHS, including ignoring regulatory requirements, cheating to evade detection in the case of non-compliance, and ‘absorbing’ or ‘neutralising’ the impact of standards and monitoring requirements through their translation into professional organisation and clinical practice.<sup>37</sup> This, then, is why commitment to the concordat is so important to policymakers: without sufficient reassurance, such subversive strategies may defeat the purpose of intervention.

While it is not suggested here that perceived defection on the implicit concordat is the only cause of resistance to regulation on the part of the medical profession, it can plausibly be argued to be one major source of

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<sup>35</sup> Parker (1999). "Compliance Professionalism and Regulatory Community: The Australian trade practices regime." *Journal of Law and Society* 26 (2): 213-39.

<sup>36</sup> Davies (2000). "Don't Trust Me, I'm a Doctor: Medical Regulation and the 1999 NHS Reforms." *Oxford Journal of Legal Studies* 20 (3): 437-456, p. 454.

<sup>37</sup> Ibid., pp. 448-454.

opposition. It follows that if some way is found of designing regulatory institutions so as to minimise the potential for bureaucratic and coalitional drift, then this ought to contribute positively to the effectiveness of regulatory reforms. How this might be done is considered in the following section.

## 4.5 Designing Credible Regulatory Regimes

### 4.5.1 Multi-Level Commitment Strategies

Regulation, then, offers substantial opportunities for eliminating waste, but also raises problems, including the possibility that even well-intentioned reforms may not achieve their publicly espoused goals if the enacting coalition does not take steps to protect its reforms against subsequent bureaucratic drift, or from challenge by subsequent coalitions. This section considers strategies available to the Department of Health in order to reassure the medical profession that regulatory reforms will be faithful to the implicit concordat and (consequently) to enable it to retain the confidence of the profession.

It should be noted at the outset that, as Breton and Fraschini have remarked, two commonly discussed strategies widely discussed in the more general analytical literature may be of limited value to democratic governments.<sup>38</sup> Firstly, as discussed in Section 2.4.2 establishing a reputation for trustworthiness may only be regarded as an effective strategy so long as one assumes 'bureaucratic dominance' over elected officials. Second, by itself, the design of substantive written rules is likely to be of limited value, not only because of the relative absence of robust rule

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<sup>38</sup> Breton and Fraschini (2003). "Vertical Competition in Unitary States: The Case of Italy." *Public Choice* 114 (1): 55-77, pp. 62-65.

categories in the area of health policy, but also because the government itself is responsible for enforcing these rules, and it may be difficult or impossible to compel it to do so.<sup>39</sup>

Following the lead of Douglass North, who has demonstrated the role played by a country's broader formal and informal institutions in relation to the capacity of governments to establish credible policy commitments,<sup>40</sup> Levy and Spiller have focussed on the role of the governance structure of a regulatory system, which they define as "...the mechanisms that societies use to constrain regulatory discretion and to resolve conflicts that arise in relation to these constraints."<sup>41</sup> In order to analyse regulatory governance in the telecommunications sector, they apply a three-level analysis of the institutional arrangements restraining arbitrary behaviour. Their approach thus explicitly contends with the problem of coalitional as well as bureaucratic drift by focussing not only on the substantive rules confining regulatory discretion, but also on the question of match and mismatch between these rules and the broader 'institutional endowment' of a country. Their analysis suggests that the governance structure of regulation must address three different levels if reforms are to be credible, namely:

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<sup>39</sup> Stiglitz (1998). "The Private Uses of Public Interests: Incentives and Institutions." *Journal of Economic Perspectives* 12 (2): 3-22.

<sup>40</sup> See for example North (1993). "Institutions and Credible Commitment." *Journal of Institutional and Theoretical Economics* 149 (1): 11-23.

<sup>41</sup> Levy and Spiller (1994). "The Institutional Foundations of Regulatory Commitment: A Comparative Analysis of Telecommunications Regulation." *Journal of Law, Economics and Organization* 10 (2): 201-246, p. 205. See also the more recent attempt to 'broaden' and 'deepen' Levy and Spiller's original approach in Spiller and Tommasi (2003). "The Institutional Foundations of Public Policy: A Transactions Approach with Applications to Argentina." *Journal of Law, Economics and Organization* 19 (2): 281-306.

- (a) substantive restraints on the discretion of the regulator that are written into the regulatory system,
- (b) restraints on changing the regulatory system, and
- (c) institutions for enforcing both the substantive restraints and restraints on system changes.<sup>42</sup>

Although Levy and Spiller's three-level analysis is developed independently of it, there is an obvious correspondence with Elinor Ostrom's multi-level approach to institutional analysis, and the two approaches share common strengths.<sup>43</sup> Ostrom distinguishes between *operational rules* which directly affect decision-making situations, and which are themselves made within a set of *collective choice rules* governing policy-making and *constitutional choice rules* which determine how collective choice rules are made. As both of these approaches demonstrate, introducing multiple levels of analysis has an additional analytical payoff (beyond a single-level focus) because there are inter-linkages between the different levels, and because an understanding of institutional change therefore depends on an understanding of these inter-linkages. As Ostrom puts it:

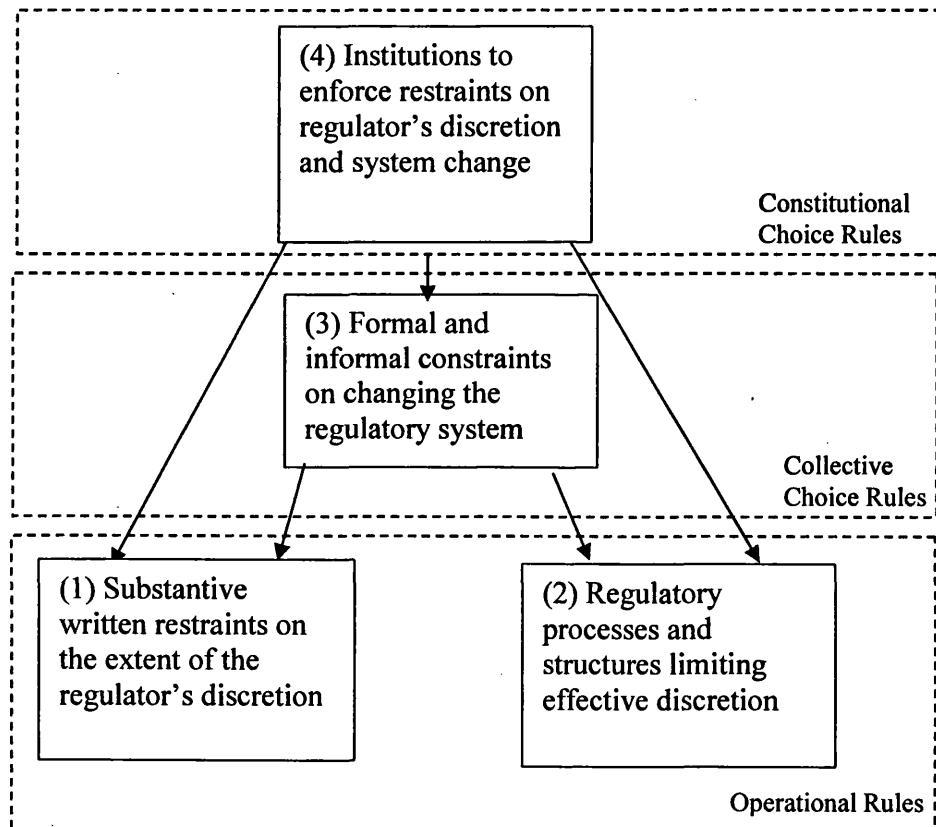
1. Changes in the rules used to order action at one level occur within a currently "fixed" set of rules at a deeper level
2. Changes in deeper-level rules usually are more difficult and more costly to accomplish, thus increasing the stability of mutual expectations among individuals interacting according to a set of rules.<sup>44</sup>

<sup>42</sup> Levy and Spiller, Op. Cit., pp. 202, 211, 220.

<sup>43</sup> Ostrom (1990). *Governing the Commons: The evolution of institutions for collective action*. Cambridge, Cambridge University Press, pp. 50-55. See also Kiser and Ostrom (1982). "The Three Worlds of Action: A Metatheoretical Synthesis of Institutional Approaches", in Ostrom (ed.) *Strategies of Political Inquiry*. Beverly Hills, Sage.

<sup>44</sup> Ostrom, Op. Cit., p. 52.

One further distinction is in order. While Levy and Spiller make it clear that what they term “substantive restraints” encompasses procedural restraints, in addition to specific substantive rules,<sup>45</sup> in practice their analysis of substantive and procedural rules is sometimes conflated. To clarify matters, in what follows, it is useful to distinguish more sharply between substantive and procedural restraints on regulatory discretion. The relationship between these complementary commitment mechanisms is illustrated in Figure 4.2. Each of these complementary mechanisms is discussed in turn below.



**Figure 4.2: Complementary Mechanisms for Restraining Bureaucratic and Coalitional Drift**

<sup>45</sup> Levy and Spiller, *op. cit.*, p, 211.

#### 4.5.2 Substantive Written Restraints

Together with regulatory structures and processes (discussed immediately below), substantive written rules make the operational rules governing the day-to-day decisions made by regulators concerning, for example, which drugs are excluded from use within the NHS, and which treatments are approved.<sup>46</sup> As the discussion in Section 3, above, has indicated, because of the 'robust rule categories' problem of distinguishing different categories of waste, and of distinguishing wasteful from non-wasteful treatment, there may be limits to the extent that substantive rules can eliminate the potential for slippage, without also eliminating necessary discretion to achieve intended policy objectives. Nevertheless, attention to substantive written rules is vitally important because, while even the best-drafted substantive rules may not solve the problem, poorly drafted rules can certainly make it worse. Drafting provisions conferring the scope of regulatory discretion will in practice be a fine judgement between providing the necessary authority to act effectively, and conferring over-broad authority that may threaten the ability of a reform to command the support of the profession. This can be seen as an application within the domain of health policy of Colin Diver's argument that, while compromises and trade-offs between different 'dimensions' of rule precision are inevitable, failure to achieve a socially optimal trade-off between three dimensions (*transparency, accessibility* and

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<sup>46</sup> Of course, because we are concerned with regulatory-decision making, these decisions will themselves usually be expressed in rules or other standards. Distinguishing between different levels of analysis requires further assumptions about the 'standpoint' and 'role' of different actors. From the standpoint of a regulator, the decision to exclude a particular treatment from the NHS is an operational decision, but from the standpoint of a physician, this same decision be seen an exercise of collective choice, pertaining to her decision, e.g. how to treat a particular condition. On the importance of 'standpoint' and 'role' in understanding rules, see Twining and Miers (1999). *How to Do Things With Rules: A Primer of Interpretation*. Fourth edition, London, Butterworths, pp. 67-77, 168-175.

*congruence* in his terminology) may lead to the failure of many reasonable policies to achieve their intended objectives.<sup>47</sup>

#### 4.5.3 Restraints Based on Structure and Process

Because of the inherent limitations in relying on substantive rules to solve the commitment problem, the use of regulatory structures and processes to further constrain the exercise of substantive discretion has an important role to play in ensuring that operational regulatory choices are faithful to the implicit concordat.<sup>48</sup> As McCubbins, Noll and Weingast put it, an alternative to specific substantive rules, "...is to constrain an agency's policies through its structure and process by enfranchising the constituents of each political actor... that is party to the agreement to enact policy..."<sup>49</sup> In terms of process, the power to set the regulatory agenda, the power to reject decisions and the outcome in the absence of a policy decision will all have an effect on the ability of the respective parties to 'enforce' compliance with the implicit concordat.<sup>50</sup> For example, with respect to the National Institute for Clinical Excellence (NICE), the Department of Health decided (albeit latterly in accordance with written guidelines) which treatments were to be evaluated (agenda-setting power) and, in addition, had the authority to

<sup>47</sup> Diver (1983). "The Optimal Precision of Administrative Rules." *Yale Law Journal* 93 (1): 65-110.

<sup>48</sup> On the role of processes and structures, see McCubbins, Noll and Weingast (1987). "Administrative Procedures as Instruments of Political Control." *Journal of Law, Economics and Organization* 3 (2): 243-277; McCubbins, Noll and Weingast (1989). "Structure and Process, Politics and Policy: Administrative arrangements and the political control of agencies." *Virginia Law Review* 75 (2): 431-481; Macey (1992). "Organizational design and Political Control of Administrative Agencies." *Journal of Law, Economics and Organization* 8 (1): 93-110.

<sup>49</sup> McCubbins, Noll and Weingast (1989). "Structure and Process, Politics and Policy: Administrative arrangements and the political control of agencies." *Virginia Law Review* 75 (2): 431-481, p. 440.

<sup>50</sup> Romer and Rosenthal (1978). "Political Resource Allocation, Controlled Agendas and the Status Quo." *Public Choice* 33 (1): 27-43.

decide whether NICE's recommendations were to be disseminated as guidance to the NHS (veto power). In the absence of guidance, decisions concerning which treatments were to be considered clinical and cost-effective lay at the local level (the reversion). Such an arrangement (it shall be argued in Chapter 6) gave substantial degree of influence to the Department of Health, despite NICE's status as an 'arm's length' Special Health Authority. The ability to design a regulatory agency in different ways according to different needs has been described by Macey as "the ultimate structural solution" potentially, providing a solution to problem of coalitional as well as bureaucratic drift.<sup>51</sup> Key design variables identified by Macey include the extent to which different interest groups are 'enfranchised' within the agency's decision-making process, the expertise which populates an agency and the extent of competition among agencies. An example of the latter variable (discussed in Section 3, above and more fully in Chapter 6) was NICE's technology appraisal guidance which 'competed' with the alternative guidance provided by the Consumer Association's *Drug and Therapeutics Bulletin*, until guidance from the Secretary of State required NHS organisations to fund treatment provided by the Secretary of State.

An interesting discussion of the regulatory processes to generate credible policy commitments in the health policy arena is to be found in Moshe Maor's comparative analysis of drug reimbursement policies in New Zealand, Australia and British Columbia.<sup>52</sup> Maor argues that the use of evidence-based medicine in the decision to fund particular drugs amounts to a 'gold standard', that is, to "...a world-wide shared scientific standard

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<sup>51</sup> Macey, op. cit., p. 99.

<sup>52</sup> Maor (2004). "Competing Commitments? Independence versus "gold standard" for policy choice in the reimbursement of pharmaceutical drugs". 20th Anniversary SOG Research Committee of the International Political Science Association, Vancouver.

applied when assembling, evaluating, and interpreting evidence in a particular policy area.”<sup>53</sup> The requirements of evidence-based medicine, in terms of what counts as acceptable justification for decisions injects a degree of predictability into the regulatory decision-making process. Furthermore, any departures from the standards of evidence-based medicine is likely to be transparent to scrutiny. For these reasons, Maor argues that embedding an evidence-based medicine standard into the process of deciding to fund particular drugs is likely to be more resilient in the face of aggressive supply-side policies.

#### 4.5.4 Constraints on System Changes

In Ostrom’s terms, restraints on changing the regulatory system operate at the level of collective choice, and comprise both the formal procedural rules and the informal institutions through which changes both to the substantive rules and the regulatory structures and processes discussed in (1) and (2) must be made. These include, most obviously, the procedures for amendment of the regulations conferring regulatory authority, including the laying of ministerial regulations, or the enactment of primary legislation (as the case may be). Following Helmke and Levitsky, informal institutions are understood here as “*socially shared rules, usually unwritten, that are created, communicated and enforced outside of officially sanctioned channels.*”<sup>54</sup> An example of informal constraints on system changes in the United Kingdom context offered by Spiller and Vogelsang is the convention that significant changes in policy will be preceded by a Government White Paper:

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<sup>53</sup> Ibid. p. 3.

<sup>54</sup> Helmke and Levitsky (2004). “Informal Institutions and Comparative Politics: A Research Agenda.” *Perspectives on Politics* 2 (4): 725-740, p. 727.

The commissioning of a report serves to announce the government's intention, providing an opportunity for interest groups to make their positions known. The process prevents hasty changes in policy, made without public and political consultation<sup>55</sup>

In this way, the informal institution of White Papers serves to prevent changes to regulatory regimes to be presented as a *fait accompli*.

Because of the varieties of forms by which substantive and procedural rules at the operational level can be enacted, different constraints can be invoked by policymakers wishing to design more or less credible policies. Most obviously, where regulatory authority is conferred by statutory instrument, in the absence of objection from either House of Parliament, the Secretary of State can make changes by the 'laying' the regulation before Parliament, usually for forty days.<sup>56</sup> On the other hand, primary legislation is required to pass through various stages in each House. Again, in this case, it is difficult (certainly compared to delegated legislation) for policy changes to be presented as a *fait accompli*.

#### **4.5.5 Institutions for Enforcing Lower-Level Commitment Mechanisms**

At the level of rules of constitutional choice, are the legislative, judicial, and executive institutions through which the lower-level rules are enforced. A key insight from Levy and Spiller's analysis is that, due to the different

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<sup>55</sup> Spiller and Vogelsang (1996). "The United Kingdom: A Regulatory Pace-Setter", in Levy and Spiller (ed.) *Regulations, Institutions and Commitment: Comparative studies of telecommunications*. Cambridge, Cambridge University Press, p. 82.

<sup>56</sup> The Statutory Instruments Act 1946 standardised the procedures for making and scrutinising delegated legislation. For commentary, see Craig (2003). *Administrative Law*. Fifth edition, London, Sweet & Maxwell, 371-378; Wade and Forsyth (2004). *Administrative Law*. 9th Edition, Oxford, Oxford University Press, 891-896.

background pattern of legislative, and executive institutions in different countries, the approach to regulatory governance that is appropriate to one country may perform poorly in other settings. At the same time, it is possible to take issue with a number of their specific assertions about the British constitution in particular.<sup>57</sup>

Taking legislative institutions first, they assume that, compared with countries such as the United States in which legislative power is shared between two Houses of Congress and the President, legislation is a poor means of engendering institutional commitment in Britain's parliamentary system in which the executive controls Parliament, and in which alternate parties take turns at forming the executive. As discussed in Section 2.4.3, if this were wholly true, studies such as Marmor's seminal *Politics of Medicare*,<sup>58</sup> would have limited relevance for the British experience. However, it is possible to take issue with Levy and Spiller's position on two grounds.

First, parliamentary time is sufficiently limited that there is a significant opportunity cost associated with introducing primary legislation, namely that other parts of a party's programmatic commitments must be given lower priority, perhaps dropping off the legislative agenda altogether. Much of the legislative business of Parliament (which usually amounts to less than fifty pieces of legislation in any parliamentary session) is 'routine', including finance and appropriations legislation, or is otherwise 'non-

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<sup>57</sup> For a critique of their assumptions about the institutional endowment of Jamiaca, one of their other country studies, see Stirton and Lodge (2003). "Re-Thinking Institutional Endowment in Jamaica: Misguided Theory, Prophecy of Doom or Explanation for Regulatory Change?" CARR/CRC/ABS Workshop on Risk Regulation, Accountability and Development, Hulme Hall, University of Manchester.

<sup>58</sup> Marmor (2000). *The Politics of Medicare*. Second edition, New York, Aldine de Grutyer.

programmatic', in that it has to be fitted into the legislative programme in response to unexpected occurrences, such as an adverse judicial decision. It is not surprising, therefore, that the Health Act 1999 was the only major health enactment passed during New Labour's first term of office. While these constraints are far from absolute, they do suggest a level of enforcement of restraints on system change that could never be attained by delegated legislation. A second argument, is that the UK Parliament is bicameral, with the House of Lords acting mainly as a revising chamber, but with the power to reject legislation, subject to the provisions of the Parliament Acts of 1911 and 1949.<sup>59</sup> Though the commitment value of legislation may therefore be lower in the UK setting compared with constitutions based on divided institutions sharing power, the contrast is arguably less stark than Levy and Spiller suggest.

In terms of executive institutions, UK civil servants are permanent career civil servants who serve whichever political party is in office (compared with the US in which senior civil servants are appointed by the President of the day). This gives a degree of neutrality, though at the same time civil servants are regarded as the agent of the minister to whom they are responsible to the minister (unlike, Germany, which regards civil servants as servants of the Constitution). While Levy and Spiller's characterisation of Britain as enjoying a strong respect for bureaucratic process is not in itself controversial, the loyalty of civil servants to the Government of the day tends to suggest that procedural restraints will have a greater effect on outcomes, and thus be more effective in protecting the implicit concordat, if decision-making power is vested outside the ministerial hierarchy. This may be one reason why the Department of

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<sup>59</sup> Wade and Forsyth (2004). *Administrative Law*. 9th Edition, Oxford, Oxford University Press., p. 26.

Health has a strong tradition of arm's length bodies operating outside ministerial control.<sup>60</sup>

Finally, in terms of judicial institutions, Britain benefits from an independent and competent judiciary, capable of enforcing the substantive limits on regulatory authority and procedural restraints, and preventing changes that do not follow prescribed procedures. Michael Harker has emphasised to good effect that Levy and Spiller's analysis of the UK is predicated on the assumption of a 'weak' model of judicial review, meaning that the Courts will give broad leeway to regulators to interpret their powers, especially given the broad delegation of authority that the UK utilities legislation has conferred.<sup>61</sup> Even so, given the 'weak' model of judicial review as described by Harker, the courts are most likely to be an effective mechanism where their role is explicitly invoked, in terms of precisely specified substantive limits to regulatory authority and well-defined procedural requirements, on which the courts can adjudicate. Nonetheless, even on this 'weak' model of judicial review, the courts provide an important institutional constraint, policing the boundaries between priority-setting in the allocation of resources and clinical decision-making.

A brief review of a number of recent cases involving challenges to decisions by Health Authorities to deny certain treatment to patients illustrates this latter point. In *R v Cambridge Health Authority, ex p B*<sup>62</sup> the applicant, who suffered from acute myeloid leukaemia, sought to challenge a decision of Cambridge HA not to fund a third course of chemotherapy and a second bone marrow transplant, after earlier treatments failed. The doctors

<sup>60</sup> For a recent account see Department of Health (2004) *Reconfiguring the Department of Health's Arm's Length Bodies*, London, Department of Health.

<sup>61</sup> Harker (2005). "UK Utility Regulation: Licences, Commitment and Judicial Review." *Annals of Public and Cooperative Economics* 76 (1): 5-33.

<sup>62</sup> (1995) 23 BMLR 1 (CA)

responsible for her earlier treatment took the view that B would not benefit from further treatment, other than palliative care, although B's father sought and obtained a medical opinion that estimated the probability of success of a course of chemotherapy to be between 10 and 20%, with a similar probability of success of a second bone marrow transplant. The Court of Appeal overturned a decision in her favour, holding that this was a decision which the Authority, on a proper review of all the relevant considerations, could reasonably have reached.

A second case, *R v North Derbyshire HA, ex p Fisher*<sup>63</sup> concerned the decision by the Health Authority to deny additional resources to Central Sheffield University Hospitals NHS Trust, to fund the prescription of beta interferon to the applicant, who had been diagnosed as suffering from relapsing and remitting multiple sclerosis. Guidance contained in a Circular (EL (95) 97) issued by the NHS Executive covered the introduction of this new treatment, under which HAs and providers were required to develop and implement arrangements to manage the introduction of the drug. Two consultant neurologists at the Royal Hallamshire Hospital had assessed the applicant as suitable for beta interferon therapy, but the Trust took the view that it could not afford to fund beta interferon treatment within its existing block contract with North Derbyshire. The Health Authority maintained a policy of funding beta interferon only as part of a clinical trial. Dyson J took the view that, as there was no imminent prospect of a trial, and because there was no realistic prospect that the Trust could fund the treatment out of its block contract with North Derbyshire, its policy effectively amounted to a blanket ban on beta interferon, contrary to the guidance set out in EL (95) 97. The Authority had thus failed properly to take into account the guidance of the NHS Executive in adopting and maintaining their policy.

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<sup>63</sup> [1997] 8 Med LR 327.

Finally, the case of *North West Lancashire HA v A, D & G*<sup>64</sup> concerned a challenge by three transsexuals against the refusal by North West Lancashire to fund gender reassignment treatment, including surgery for 'gender identity dysphoria'. A & G had been diagnosed by a specialist consultant as having a clinical need for gender reassignment surgery, while D was awaiting an assessment of suitability for the treatment. The Authority maintained a policy under which no treatment, other than general psychiatry and psychology was provided, "save in the event of overriding clinical need or exceptional circumstances." Furthermore, expert clinical judgement that a patient needed this treatment was not, under the Health Authority's policy, sufficient to fall under this exception. The Court of Appeal upheld a decision at first instance in favour of A, D & G. While the setting of clinical priorities, and the application of its finite resources to those priorities was a matter for the Authority, in reaching its decision it had not treated transsexualism as an illness, and had consequently failed to consider properly the circumstances of the applicants' cases, including the existence of clinical need.

Taken together, these three cases support the proposition that, in allocating resources to different priorities, Health Authorities can not altogether exclude from consideration clinical judgement in individual cases. Furthermore, the more that policies of priority-setting discount the importance of clinical judgements, the higher the standards of accountability to which resource allocation decisions will be held by the courts. In the 'Child B' case, where original team were sceptical about the benefits of further treatment, and even the more favourable opinion obtained by B's father held out only a small hope of success, Sir Thomas Bingham MR forcefully rejected the suggestion of Laws J at first instance that the

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<sup>64</sup> [1999] Lloyd's Rep Med 399.

Authority must explain the priorities on which the decision not to fund B's treatment was based. By contrast, in the case of *A, D and G*, the court made it clear that the decision not to provide treatment, for which medical diagnosis revealed a clinical need, must be justified. In requiring the Authority to reconsider its decision not to find gender reassignment therapy, Buxton LJ took the view that, "...to the extent that such procedures continue to be subordinated to other claims on the Authority's resources [it should] indicate, at least in broad terms, the reasons for the Authority's choice."<sup>65</sup> *Fisher* focussed on the Authority's failure properly to take into account NHS Executive guidance, but also supports the principle that a denial of funding for treatment may have to be justified by clear reasons where clinical judgement supports the provision of the treatment to a particular patient. This is emphasised in Dyson J's comment that: "As for clinical decisions, they were not for the respondents [i.e. the Health Authority] to take."<sup>66</sup>

## 4.6 Observable Implications

In order for the case studies set out in the next three chapters to demonstrate support (or the lack of it) for the theory set out in this chapter, it is necessary first to identify the observable implications of the theory, and to delineate how they can be observed.<sup>67</sup> In terms of identifying observable implications, the theory laid out in this chapter would suggest, first and foremost, that regulatory reform initiatives in health policy are more likely to achieve their publicly-espoused goals when the legal and institutional framework for

<sup>65</sup> [1999] Lloyd's Rep Med 399 at p. 413.

<sup>66</sup> [1997] 8 Med LR 327, at p. 337.

<sup>67</sup> King, Keohane and Verba (1994). *Designing Social Inquiry: Scientific Inference in Qualitative Research*. Princeton, Princeton University Press, Chapter 1; Epstein and King (2002). "The Rules of Inference." *University of Chicago Law Review* 69 (1): 1-133, 65-76.

regulation is credible according to the three-level analysis suggested by Levy and Spiller, and re-specified in the context of the NHS in this chapter. Although instances of unexpected failure (or success) may not, of themselves, be regarded as falsifying the theory, they do represent a 'puzzle' for which specific answers, supported by evidence needs to be given, if the theory is to be 'saved'. Were the publicly espoused goals of a particular initiative unrealistic, making their achievement unlikely? Did other factors intervene to lead to unexpected policy failure (or success)? A second observable implication derives from the fact that, according to the theory developed here, the phenomenon of 'slippage' plays a causal role in relating institutional arrangements to regulatory outcomes. Consequently, the case study narrative ought to identify examples of such slippage following less successful reform initiatives (and, correspondingly, ought not to find such extensive evidence of slippage in more successful cases) if the relationship between institutions outcomes is not to be regarded as spurious. Furthermore, to the extent that a reform is judged to have failed, this should be associated with some identifiable subversive behaviour on the part of the medical profession.

In terms of observing these implications, evidence from official sources is the primary evidence on which the case study is based. This includes published reports on matters relating to the case studies, as well as interviews with officials and representatives of the medical profession. In addition, the views published in medical journals such as the *BMJ*, particularly its editorial pages, can be taken to give an indication of the views of the medical profession. Evidence of this nature may be regarded as mostly 'reputational', i.e. it provides evidence of different actors' perceptions of effectiveness, rather than direct observation e.g. of health outcomes. Such evidence may nonetheless provide a useful indication of policy success and failure, in an area in which it is notoriously difficult to

gather direct evidence. To mitigate the problem of bias, efforts are made whenever possible to draw on evidence from different sources and from different institutional viewpoints.

## 4.7 Conclusions

The key claims of the analytical framework developed in this chapter are (a) an implicit concordat between the Department of Health and the medical profession established the 'rules of the game' for the subsequent development of policy in the health care arena; (b) the rise of regulation in the NHS constitutes a potential threat to the implicit concordat because regulatory authority can be used to develop policies that violate the concordat, or which may come to do so at a later point in time; (c) the effectiveness of regulatory reforms in the NHS will depend on the ability of the Department of Health to credibly commit to the implicit concordat, because effective compliance with regulatory goals depends on the cooperation of the profession, and there are number of strategies by which the profession can subvert regulation if they fear that the regime is susceptible to deliberate or unintentional slippage; and (d) the governance structure of regulation, understood in terms of a modified version of the three-level analysis suggested by Levy and Spiller, can generate credible institutional commitment to the implicit concordat, by limiting the opportunities for coalitional drift. The following three chapters each apply the analysis developed here to a different case study of regulatory reform in the NHS. The three cases are each chosen because they represent a range of governance structures, providing different degrees of credibility as predicted by the modified version of the Levy and Spiller framework presented in Section 5. The fact that this analytical approach was developed from existing analyses with a proven track record ought to give some confidence

in its validity. Following the case studies of the next three chapters, the overall issue of how well the approach stands up to the evidence is considered in the conclusions.

# Chapter 5

## The Limited List of NHS Drugs

In Britain, in contrast with many other countries, which have gone down different routes, we have resisted any system of limiting the freedom of the doctor to prescribe whatever he thinks his patient needs. Not for us are such devices as limited lists, black lists, the compulsory substitution of generics, or the financial pressures involved in reimbursement regimes or the like.<sup>1</sup>

### 5.1 Introduction

In 1985, the Conservative Government introduced a national Limited List of NHS Drugs, whereby some 1800 or so products within eight therapeutic categories were excluded from the NHS, or else restricted to use for certain conditions suffered by certain categories of patients. Several European countries operated national 'selected lists' of approved drugs, and such measures had been considered for introduction in the UK in the 1950s. These had been rejected, among other reasons because they were thought to be likely to arouse the hostility of the profession. In the UK, efforts to limit the range of drugs used by clinicians had therefore been restricted to local

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<sup>1</sup> Patrick Jenkin, Secretary of State for Social Services, 1981, quoted in GMSC (1984). "Limited List of Drugs Opposed." *British Medical Journal* 289: 1468-9, 24 November 1984.

initiatives, mainly in the hospital care sector, to create local formularies.<sup>2</sup> This chapter examines in detail the introduction of the Limited List, and its subsequent development, applying the framework of analysis developed in the previous chapter.

There are a number of reasons why the Limited List episode makes a compelling study in the context of this thesis. First, the Limited List was the first sustained effort by the Government to regulate clinical behaviour in order to limit aspects of NHS expenditure. It therefore provides an early example of a regulatory reform initiative within the NHS, and of its effects on relations between the Government and the medical profession. Second, anticipating the argument that follows, the legal and administrative framework of the Limited List performed poorly in terms of the three-level analysis of regulatory commitment developed in the previous chapter. The episode therefore provides a demonstration of the performance of regulation under conditions of inadequate commitment. Furthermore, Adrian Kay, whose work was discussed briefly in Section 2.4.3, has claimed that the introduction of the Limited List was one of the key events that provoked a breakdown of a 'health policy community', which had previously sustained trust between the profession and the government.<sup>3</sup> If this is correct, then from this point onwards, *institutional* commitment might have been expected to become more important. The Limited List therefore provides an episode of regulatory reform in which the effects of institutional commitment can be studied in relative isolation.

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<sup>2</sup> Collier and Forster (1985). "Management of a Restricted Drugs Policy in Hospital: The First Five Years' Experience." *The Lancet*: 331-333, 9 February 1985.

<sup>3</sup> Kay (2001). "Beyond Policy Community: The case of the GP Fundholding scheme." *Public Administration* 79 (3): 561-577, pp. 567-8.

This chapter proceeds as follows. Section 5.2 narrates the history of the Limited List scheme from its origins in 1985, and traces its development over time. Applying the taxonomy of waste proposed by Blunstein and Marmor, introduced in Section 4.2, the original purpose of the Limited List could be said to have been to eliminate certain ineffective or harmful treatments. Over time, it expanded into other categories of ‘waste’ and latterly even included at least one drug, sildenafil (Viagra) that was arguably not wasteful within any of Blunstein and Marmor’s senses. Section 5.3 assesses the effectiveness of the Limited List scheme, concluding that, judged against publicly proclaimed intentions the scheme performed poorly. Section 5.4 provides an analysis of the regulatory governance of the Limited List, relating diagnosed poor performance to the legal and regulatory framework of the scheme. By way of conclusion, Section 5.5 considers the extent to which the evidence presented in this chapter supports the argument of this thesis.

## **5.2 The Limited List of NHS Drugs: Origins, Implementation and Development**

The purpose of this section is to give an account of the background to the Limited List scheme, its introduction and subsequent evolution. In line with the theoretical aims, attention is focussed on the publicly pronounced policy objectives and the legal and administrative framework through which these were pursued. Section 5.2.1 considers the background to the Limited List; Section 5.2.2 looks at the government’s proposals; Section 5.2.3 examines the introduction of the scheme, including the legal provisions through which the scheme was implemented. Following the introduction of the Limited List, the government agreed to the establishment of an Advisory Committee on NHS drugs, considered in Section 5.2.4. Despite earlier assurances to the contrary, in 1992, the government extended the scope of the Limited List scheme, adding ten further categories. This is considered in Section 5.2.5.

Finally, Section 5.2.6 considers the decision, in 1998, to have the ACD 'stood down', and the operation of the Limited List scheme without the advice of the Committee.

### 5.2.1 Background to the Limited List

An initial expectation regarding the NHS was that expenditure would be self-limiting. As the major problems of ill health were conquered, so the argument went, a healthier population would demand fewer services. This expectation was, to say the least, over-optimistic and in the decades since 1948 all aspects of the service have witnessed relentless increases in cost. One factor that placed additional pressure on the drugs budget in particular is that while most services are subject to overall spending limits, prescribing costs were essentially 'demand-led'; if GPs prescribed more, or more expensive drugs, the drug budget would increase. Furthermore, there were few existing instruments through which this could be countered. The Conservative government of the 1980s was by no means the first administration to contemplate regulatory measures to control the relentless rise of the NHS drugs budget. The idea of restricting the range of drugs available for use in the NHS had been broached in the 1950s, but was rejected by successive expert committees.<sup>4</sup> More recently, the idea of a limited list was rejected by the Greenfield Report, which favoured a system of voluntary generic substitution.<sup>5</sup> Ironically, in its evidence to the Greenfield Committee a little more than a year before the announcement of

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<sup>4</sup> On the Guillebaud Report, see Webster (1988). *The Health Services Since the War Volume I*. London, HMSO, pp. 204-211. On the Hinchliffe and Douglas reports, see Webster (1996). *The Health Services Since the War Volume II*. London, The Stationery Office, 140-8.

<sup>5</sup> Department of Health and Social Security (1983) *Report of the Informal Working Group on Effective Prescribing*, London, DHSS.

the Limited List scheme, the Department of Health and Social Security (DHSS) had argued forcefully against a limited list of drugs, claiming:

It is almost impossible to establish whether the introduction of a limited list of drugs will in itself produce any financial saving for the NHS. What does seem apparent is that any attempt so to do is likely to arouse hostility, result in higher administrative costs, affect the pricing of drugs and the industry, generate unwelcome pressures for general practitioners and pharmacists, and possibly cast some doubt on the government's intentions towards the standard of provision of medical services in the NHS.<sup>6</sup>

Too much should not be made of this apparent U-turn, since the label 'limited list' has been applied to what were in fact substantially different schemes. In the conventional understanding of the term, a limited list was a list of approved products giving what the Douglas Report<sup>7</sup> called the "full therapeutic armamentarium" of drugs. This was distinguished from a "black lists" approach in which drugs included in the list were excluded from use. It was arguably in this sense of the term, that the DHSS had rejected the introduction of a Limited List just a year earlier.

Despite the successive rejections of proposals for restrictions on GP prescribing, the idea for a more interventionist approach was not without its advocates. In an influential book, *The Wrong Kind of Medicine?*, Charles Medawar made the case for a new Medicines Act providing for the elimination of many drugs, and control of many others, within the NHS, arguing that: "In Britain, we have far more drugs than we need, and too many to use effectively."<sup>8</sup> Listing some 800 drugs which he claimed were either ineffective, or inappropriately or extravagantly prescribed, he argued

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<sup>6</sup> GMSC (1984). "Limited List of Drugs Opposed." *British Medical Journal* 289: 1468-9, 24 November 1984.

<sup>7</sup> Department of Health for Scotland (1959) *Report of the Scottish Committee on Prescribing Costs*, Edinburgh, HMSO.

<sup>8</sup> Medawar (1984). *The Wrong Kind of Medicine?* London, Consumers' Association/Hodder & Stoughton, p. 15.

that "...little effort would be needed to save at least £100 million a year on the national drugs bill...; and with real commitment the NHS could save several times that amount."<sup>9</sup> For Medawar, financial savings was only one advantage of a restricted drug list. Other benefits included a reduction in the number of patients prescribed ineffective or unsafe drugs. Nevertheless, as Medawar recognised, the prevailing view at the time was that such a move would restrict clinical freedom, and would be countered by the pharmaceutical industry.

### **5.2.2 The Government's Proposals and the Response of the Profession**

On 8 November 1984, the Secretary of State for Social Services, Mr Norman Fowler announced that he intended to introduce prescribing restrictions. This came as a surprise to the medical profession, which had not been consulted on the measure. Rejecting the recommendations of the Greenfield Report, the Secretary of State argued against a policy of "...indiscriminate generic substitution, which would limit the freedom of the medical profession and have a serious effect on the research-based pharmaceutical industry in Britain."<sup>10</sup> Nonetheless, the Secretary of State drew the Commons' attention to the costs of prescribing in two areas, namely branded medicines for minor conditions (such as coughs and colds), and sedative and tranquilliser drugs. While rejecting generic substitution across the board, the Secretary of State saw "...no reason... why in the two groups that I have set out the NHS should not limit itself to providing only the cheaper generic alternatives which are available."<sup>11</sup> This, it was reckoned, would generate savings for the NHS in the order of £100 million per year (against a total national drugs bill approaching £2,000 million in

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<sup>9</sup> *Ibid.*, p. 19.

<sup>10</sup> *Parliamentary Debates, Sixth Series*, H.C. Vol. 67 col. 226.

<sup>11</sup> *Ibid.*

1984) and was even predicted to "...rise in the near future as generic alternatives become available for some of the branded products on our selected list."<sup>12</sup>

There followed a three-month period for consultation, and as a basis for this, the government published a 'white list', the *Provisional List of Medicines Remaining Available for Prescription on the National Health Service*.<sup>13</sup> The *Provisional List* covered eight therapeutic categories: antacids, laxatives, inhalations, antiussives, analgesics for mild to moderate pain, vitamins, tonics and bitters, benzodiazepine sedatives and tranquillisers. Although many doctors and some of the Royal Colleges supported the measure, the General Medical Services Committee (GMSC) of the BMA, under the chairmanship of Dr Michael Wilson, voted in favour of opposing the Limited List scheme.<sup>14</sup> The GMSC consequently refused the government's offer of discussions over the content of the *Provisional List*. The pharmaceutical industry strongly attacked the proposals, although they arguably had little to lose on the face of the proposals, because the loss of sales to the NHS of many branded drugs for minor ailments would be offset by increased over-the-counter demand. The Association of British Pharmaceutical Industries (ABPI) mounted a £1 million advertising campaign, the content of which might best be described as 'scare tactics'. There was, in addition, sustained opposition from individual pharmaceutical companies. Roche Products Ltd, for example, produced a pre-printed letter, which it sent to every GP practice in the country with the request that it be

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<sup>12</sup> H.C. Vol. 74 col. 275w.

<sup>13</sup> Department of Health and Social Security (1984) *Provisional List of Medicines Remaining Available for Prescription on the National Health Service*, London, DHSS.

<sup>14</sup> GMSC (1984). "Limited List of Drugs Opposed." *British Medical Journal* 289: 1468-9, 24 November 1984.

endorsed with their surgery stamp and forwarded (in the pre-paid envelope provided) to their local MP.

The outcome of this titanic struggle was that the number of drugs retained on the 'selected list' of drugs to be retained for use on the NHS was increased from 30 to around 100. In line with this increase, the estimated savings from the introduction of the Limited List were revised downwards to £75 million in the year 1985-1986. Furthermore, in response to parliamentary and more general pressure, the government agreed that the scheme should incorporate an appeal mechanism by which decisions to restrict particular drugs could be challenged.

### **5.2.3 The Introduction of the Limited List**

Following the conclusion of the three-month consultation period, the Secretary of State for Health laid regulations before Parliament, amending the National Health Service (General Medical Services Regulations) Regulations 1974, which set out GPs' Terms of Service. The power to make Regulations derived from S. 29 (2) of the National Health Service Act 1977, which empowered the Secretary of State to make regulations governing "...the definition of the personal medical services to be provided..." by general practitioners. Regulation 2 (4) of S.I. No. 290 of 1985 introduced into the Terms of Service a new Paragraph 36A which stated:

- (1) In the course of treating a patient to whom he is providing treatment under these terms of service, a doctor shall not order on a prescription form a drug or other substance specified in Schedule 3A to these regulations but may otherwise prescribe such a drug or other substance for that patient in the course of that treatment.
- (2) In the course of treating such a patient a doctor shall not order on a prescription a drug specified in an entry in column 1 of Schedule 3B unless—
  - (a) that patient is a person mentioned in column 2 of that entry; and

- (b) that drug is prescribed for that patient only for the treatment of the condition specified in column 3 of that entry; and
- (c) the doctor endorses the face of that form with the reference "S3B".

but may otherwise prescribe such a drug for that patient in the course of that treatment.

These provisions gave effect respectively to the establishment of 'black' and 'grey' lists. Schedule 3A, the 'black list' consisted of "Drugs and Other Substances Not to be Prescribed for Supply Under Pharmaceutical Services". The grey list set out in Schedule 3B initially contained only one product, Clobazam. The use of this drug was restricted to the treatment of patients with epilepsy.<sup>15</sup> Corresponding amendments were made to chemists' terms of service preventing them for supplying drugs listed under schedule 3A or under schedule 3B without the appropriate endorsement from the doctor. The black list contained around 1800 products, described in the explanatory notes which accompanied S.I No. 290 of 1985 as "drugs which are more expensive than others which have the same clinical or therapeutic effect, and substances which are not regarded as drugs forming part of pharmaceutical services."

The laying of the Regulations, and equivalent provisions for Scotland, gave rise to a fierce debate on the floor of the House of Commons, during which the government was heavily criticised for the slovenly way

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<sup>15</sup> An examination of the form of Schedule 3B helps to make sense of the drafting of S. 36A (2):

**DRUGS TO BE PRESCRIBED FOR SUPPLY UNDER PHARMACEUTICAL SERVICES  
ONLY IN CERTAIN CIRCUMSTANCES**

Drug 1	Patient 2	Condition 3
Clobazam	Any Patient	Epilepsy

Schedule 3A, and its Scottish equivalent had been put together.<sup>16</sup> Although it had been intended that the two lists were to be identical, there were some differences due to drafting anomalies. For example, Vicks Cold Care capsules were included in the English Schedule 3A, but were not black-listed under the Scottish Regulation. Conversely, Vicks inhaler was restricted in Scotland but remained unrestricted in England. Furthermore the printed Regulations laid before Parliament contained a number of (allegedly barely legible) hand-written additions to the printed text. Despite these anomalies, and the consequent suspicion that the Regulations had been prepared with excessive haste, the Regulations were passed by the Commons, and entered into effect without further amendment.

An initial challenge to the compatibility of the Limited List with European Law was mounted in the case of *R v Secretary of State for Social Services, ex parte Schering Chemicals Ltd.*<sup>17</sup> Schering, a German pharmaceutical company, manufactured a drug marketed under the brand name Noctamid, whose generic name was lormetazepam. Initially, the DHSS proposed that the product should be black-listed on the ground that it served no clinical need that was not satisfied by temazepam, which was cheaper. Following the publication of the draft list, Schering sought to have its product reinstated, at the same time, lowering the price so that it was no more expensive than temazepam. The DHSS acceded to the request to retain lormetazepam on the selected list, but scheduled the brand-name 'Noctamid'. The effect of this was that the product could be prescribed by its generic name only, and when Schering's patent on the product expired, it would have been open to pharmacists to choose between Noctamid and a generic version. Schering challenged this move under Article 30 (as it was prior to

<sup>16</sup> See for example, *Parliamentary Debates, Sixth Series*, HC Vol. 75, col. 681, 18<sup>th</sup> March 1985 (Mr. Donald Dewar).

<sup>17</sup> [1987] 1 C.M.L.R. 277.

the Treaty of Amsterdam renumbering exercise, now Article 28) as a measure having equivalent effect to a quantitative restriction on imports, claiming also that the measure deprived them of their intellectual property rights to the brand name 'Noctamid'. The claim was rejected by the High Court, arguing that although Schering was likely to have lost sales as a result of the decision, there was nothing in the Limited List scheme that was inherently discriminatory against the imported product. The main strand of the DHSS strategy, effectively introducing compulsory generic substitution, albeit within a relatively narrow range of clinical activity, thus survived the only legal challenge until the *Viagra* cases, discussed *infra*.

#### **5.2.4 The Advisory Committee on NHS Drugs**

As noted in Section 5.2.2, one of the points conceded by the DHSS was for the creation of an 'appeal mechanism', through which black-listed drugs could be reconsidered. This proposal was fleshed out, into the establishment of an Advisory Committee on NHS Drugs (ACD), which was to play a role in keeping current the content of the black and grey lists. The ACD comprised fifteen persons drawn from the professions (doctors, dentists, pharmacists) with expertise within one or more of the therapeutic categories covered by the scheme, and was chaired by the Deputy Chief Medical Officer. Under its initial terms of reference, the ACD was charged with advising UK health Ministers on an ongoing basis as to the composition of Schedule 3A and "in order that drugs to meet all real clinical needs at the lowest possible cost to the NHS" across the nine categories covered by the Limited List scheme were available.<sup>18</sup>

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<sup>18</sup> The content of Schedule 3A also subject to recommendations of a separate committee, the Advisory Committee on Borderline Substances (ACBS). The function of the ACBS was to advise whether particular substances, preparations

The working methods of the ACD, and the relationship between the ACD and the DHSS more generally can be described briefly.<sup>19</sup> The Committee would meet roughly once per year, at which time it would typically consider a single therapeutic category. Prior to the meeting, the secretariat to the ACD would gather data on the prices of drugs within that category, and would rank them in order of price, from the cheapest to the most expensive. The Committee would meet and consider the price-ranked list of drugs. Proceeding from the cheapest to the most expensive, it would set a 'guide-price' corresponding to the price at which it was agreed that all clinical needs could be met, i.e. the price of the most expensive drug in the list considered to be clinically necessary. The ACD would then formulate a recommendation that all drugs more expensive than the guide-price should be black-listed. The manufacturers were then notified by the Committee, and were invited to appeal. Where the manufacturers could show that the product in question fulfilled a clinical need which could not be met by the other products, or where the manufacturer agreed to lower the price to the level of other, equally effective products (as in the case of lormetazepam in the *Schering* case, discussed in Section 5.2.3 above), then it would be 'reprieved'. If the manufacturer did not appeal, or if its submissions were not considered to be persuasive, then the Committee would advise that the product should be 'black-listed'.

Once the ACD had formulated its advice to Ministers, there would follow a one month period for broader consultation, during which patient groups or other interested parties could make representations to the DHSS. On the basis of the advice of the Committee, and on the public consultation,

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or items should not be treated as drugs under the relevant General Medical Services Regulations.

<sup>19</sup> This description draws heavily on interview I21.

officials would compile advice to the Minister (known as a 'solution') regarding whether to accept or reject the recommendations of the Committee. Typically, official advice would follow the expert opinion of the committee, but might differ if it was feared that a particular decision might be susceptible to possible legal challenge. For example, the Committee may have had based its decision on the judgement that two products were equivalent, while the manufacturer of a more expensive product had asserted that some extra benefit—perhaps it came with an applicator, for example—justified a higher price. This cautious approach stemmed from the fact that the ACD secretariat felt that it did not have the resources, either in terms of funding or manpower, to become involved in litigation.

Not all black-listing decisions followed the recommendation from the ACD. In 1993, Ministers took the decision that the NHS should not fund nicotine replacement therapy (NRT), despite evidence that this was effective in helping smokers to quit. The various brands of nicotine patches and chewing gum that were then available were black-listed.<sup>20</sup> A subsequent memorandum between civil servants explained the reasoning behind this decision:

Nicotine patches do have a role in helping some people to stop smoking, but there is no reason why their cost should be met by the NHS. People who can afford to smoke can also afford to buy the products, which may help them to stop smoking. It is also worth emphasising that there are around 11 million ex-smokers in this country—and the vast majority have given up without pharmacological help.<sup>21</sup>

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<sup>20</sup> More recently, following the advice of NICE, all but two of the six products initially 'black-listed' were de-Scheduled.

<sup>21</sup> Extract from a document obtained from the Department of Health following a Freedom of Information Act request. Ref. DE6008103.

This reveals a fundamentally different decision-making process to that of the ACD. Whereas the ACD's procedures were designed so that effective treatments would remain available, in the case of NRT, a conscious decision seems to have been taken to exclude a product, which was assumed to be effective, on the grounds that those who could benefit from NRT could afford to pay for it privately.

### 5.2.5 The Extension of the Limited List

The Limited List scheme had originally been added onto the 1974 Terms of Service. When the new GP contract was introduced in 1992, the relevant provisions were carried forward into the new regulations, the National Health Services (General Medical Services) Regulations 1992.<sup>22</sup> S. 44 of the Regulations re-enacted S36A, while the new Schedules 10 and 11 replaced Schedules 3A and 3B respectively. This continuity gave no indication of the Government's intention to introduce more fundamental changes to the scheme. In November 1992, the Department of Health announced the extension of the Selected List into ten categories: appetite suppressants; antidiarrhoeal drugs; drugs acting on the skin; drugs acting on the ear and nose; drugs for vaginal and vulval conditions; contraceptives; drugs for allergic disorders; topical antirheumatics; hypnotics and anxiolytics; drugs used in amnesia. These categories were, according to the government, "chosen on the basis that they contained a wide range of medicines of apparently similar therapeutic effects at significantly different prices, that they were categories that incurred substantial prescribing costs, and they did not relate to life-threatening conditions."<sup>23</sup> In order to accommodate the

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<sup>22</sup> S.I No 635 of 1992

<sup>23</sup> Secretary of State for Health (1994) *Government Response to the Second Report from the Health Committee, Session 1993-94*, Cm 2683, London, HMSO, p. 10.

necessary expertise to deal with the additional categories within the ACD, membership of the Committee was increased from fifteen to twenty persons.

Although the expansion of categories was dismissed by some within the medical community as a "diversion rather than threat",<sup>24</sup> in principle, this represented a major expansion of the Limited List scheme. Apart from benzodiazepines and tranquillisers, the original seven categories covered mainly the 'symptomatic' treatment of mainly self-limiting conditions; overall prescribing within the original categories covered perhaps 5-10% of prescribing within general practice. The new categories, by contrast, covered major areas of essential drug therapy, and would have extended the coverage of the Limited List scheme to around a third of all prescribing by GPs. An entire medical specialty—dermatology—was restricted by the single new category of drugs acting on the skin.

This extension was perhaps more apparent than real, not least because of the delays by the ACD in developing recommendations within any of the new categories. It took almost two years following the announcement of the two categories for the ACD to develop recommendations in any of the new categories. Patient advocacy groups, some funded by the pharmaceutical interests, intensively opposed black-listing decisions, taking advantage of the procedure outlined in Section 5.2.4. For its part, the Department of Health found consultation with patient groups to be a convenient excuse for limited action within the new categories.

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<sup>24</sup> Bateman (1993). "The Selected List." *BMJ* 306: 1441-2.

## 5.2.6 The Limited List *Sans ACD*

A more significant reason for the absence of progress within these new categories was that the Committee stopped meeting after 1998. A number of reasons have been put forward for this. A Ministerial Submission of 3<sup>rd</sup> February 2003 recommended the dissolution of ACD suggesting that: “The key reason [for dissolving the ACD] is the development of the National Institute for Clinical Excellence (NICE) which amongst other things looks at the clinical and cost-effectiveness of drugs.”<sup>25</sup> It was also suggested (I21), however, that a key circumstance surrounding the abeyance of the Committee in 1998 was the expiry (in April 1998) of the Pharmaceutical Price Regulation Scheme (PPRS), the voluntary agreement between the Department of Health and the pharmaceutical industry which regulated the price paid for drugs by the NHS. On this account, the renegotiation of the PPRS occurred at the same time as the ACD was preparing to develop recommendations in some of the post-1992 categories. The Department of Health did not wish to allow this to prejudice negotiations with the ABPI, and took the decision to have the ACD ‘stood down’. This, it was claimed, was at not originally intended to be more than a temporary hiatus, until negotiations with the ABPI could be concluded.

Despite the dissolving of the ACD, the power to place drugs on Schedule 11 was used to limit the use of sildenafil (Viagra), a revolutionary drug in the treatment of erectile dysfunction (ED). On conventional assessments of cost-effectiveness Sildenafil (Viagra) performs favourably compared to alternative treatments.<sup>26</sup> At the same time, erectile dysfunction

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<sup>25</sup> Freedom of Information Act request, ref. DE6008103

<sup>26</sup> Stolk, Brower and Bussbach (2002). "Rationalising Rationing: Economic and Other Considerations in the Debate About Funding Viagra." *Health Policy* 59

has often been regarded as a natural part of the aging process, and treatment of the elderly for ED has been seen as a 'lifestyle choice'.<sup>27</sup> At the same time, the licensing of sildenafil had serious resource implications. It has been reckoned that some 1.8 million men in the UK suffer from ED, and up to a further 8 million from partial ED. At £4.84 per 50mg tablet, the cost to the NHS if Viagra were to be made available to all who could benefit from it has been estimated to be as high as £1 billion per annum, though a more conservative estimate (put forward by Pfizer, the drug's manufacturer) was a much more modest £50 million after five years.<sup>28</sup>

As an interim measure, the government took action to exclude Viagra from the NHS. On 16 September 1998, one day before sildenafil was due to be approved by the European Medicines Evaluation Agency, the NHS Executive issued a Health Service Circular<sup>29</sup> advising that doctors should not prescribe sildenafil, and that Health Authorities should not support its use "other than in exceptional circumstances which they should require be cleared in advance with them." This followed advice from the Standing Medical Advisory Committee (SMAC) that pending a more considered evaluation, Viagra should be excluded from prescription on the NHS, to avoid a situation where patients who might not meet future eligibility criteria received Viagra, only to have it later withdrawn. HSC 1998/158 declared itself to be "...for guidance only and aims to share good practice on a particular issue." Nonetheless there was a high degree of compliance, perhaps because of competing demands on resources, and

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(1): 53-63, p. 54. See also Smith and Roberts (2000). "The Cost-Effectiveness of Sildenafil." *Annals of Internal Medicine* 132 (12): 933-937.

<sup>27</sup> Stolk, Brower and Bussback, op. cit., p 55.

<sup>28</sup> Brooks (1998). "Viagra is Licensed in Europe But Rationed in Britain." *BMJ* 317: 765, 19 September 1998.

<sup>29</sup> HSC 1998/158, 16 September 1998.

because a final position was expected within a few weeks.<sup>30</sup> Many GPs reportedly deferred treatment of patients with ED in anticipation of final guidance, which was issued (some four months later) only after the General Practitioner Committee threatened to develop its own guidance, if a final position were not reached by the time it met on 21 January 1999.<sup>31</sup>

On BBC Radio 4's *Today* programme on the morning of 21 January, the Secretary of State announced the promulgation of draft Regulations, based on advice received from the SMAC some 10 weeks earlier, that sildenafil should be restricted to certain categories of patients and forms of ED, by placing it in Schedule 11 (the grey list). Viagra was to be restricted to patients with ED arising from restrictively specified underlying causes (in total amounting to around 15% of ED to sufferers who might benefit from Viagra).<sup>32</sup> The restriction took initial effect on June 10 1999, and (after a review and consultation) became 'permanent' on October 10 2000. The result of the review was that Viagra was made available to a slightly more expansive range of 'acceptable' conditions, covering up to 20% of those who might potentially benefit. Patients receiving drug treatment for impotence on or prior to 14 September 1998 were to be eligible. In addition, men who suffered "severe distress" as a result of ED, but who were not otherwise eligible, could receive Viagra on the NHS, but only after specialist assessment.<sup>33</sup> This use of the Secretary of State's power to restrict the availability of drugs through Schedule 11, based on the aetiology

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<sup>30</sup> Between September and December 1998 an average of only 108 NHS prescriptions for Viagra were issued each week.

<sup>31</sup> Chisolm (1999). "Viagra: A Botched Test Case for Rationing." *BMJ* 318: 273-4.

<sup>32</sup> National Health Service (General Medical Services) Regulations Amendment (No. 2) Regulations 1999, S.I. No. 1627 of 1999. See also Beecham (1999).

"UK Issues Guidance on Prescribing Viagra." *BMJ* 318: 279, 30 January 1999.

<sup>33</sup> Ferriman (1999). "UK Government Finalises Restrictions on Viagra Prescribing." *BMJ* 318: 1305, 15 May 1999.

(underlying cause) of a disease was unprecedented, and in two separate cases, Pfizer, the drug's manufacturers, challenged the interim Health Service Circular guidance and the inclusion of sildenafil on the grey list.

In the case of *R v Secretary of State for Health, ex p. Pfizer*<sup>34</sup> the interim guidance was declared unlawful under both domestic and European law. The manufactures argued that the guidance interfered with the duty of GPs under their Terms of Service to provide all "necessary and appropriate" services to their patients. This was accepted by Collins J, who reasoned that:

To state in bald terms that Viagra should not be prescribed save in (undefined) exceptional circumstances is tantamount to telling the recipients of advice to follow it. They cannot know how their professional judgement should be influenced by the advice.<sup>35</sup>

The court also found that the Circular guidance breached Article 7 of Directive 89/105 EEC on transparency of pricing in medicinal products, which required that any decision to exclude a medicinal product from national health care coverage must be based on objective and verifiable criteria, published in advance and communicated to the persons responsible for the product. At the time, the UK had not notified to the Commission the criteria under which products could be excluded. The Court held that Article 7 of Directive 89/105 EEC applied not only to complete exclusion, but also to restrictions on coverage by the NHS falling short of complete exclusion.

In the second Viagra case, *R (on the Application of Pfizer Ltd) v Secretary of State for Health*<sup>36</sup> the decision of the Secretary of State, to place sildenafil/Viagra on the Schedule 11 'grey' list was challenged, in terms of its compliance with Article 7 of the 'Transparency' Directive

<sup>34</sup> [1999] 3 C.M.L.R. 875.

<sup>35</sup> [1999] 3 C.M.L.R. 875, at p. 887.

<sup>36</sup> [2003] 1 C.M.L.R. 19. This case is discussed at length in Syrett (2004).

"Impotence or Importance? Judicial review in an era of explicit NHS rationing." *Modern Law Review* 67 (1): 5-33.

89/105. The applicants argued that the Directive required the Secretary of State, in advance of restricting the availability of a drug, conduct a full analysis of the reasons for Scheduling. The Court rejected this interpretation, pointing out that the Directive required only that the criteria under which medicinal products are excluded, not the application of those criteria in particular circumstances, were required to be objective and verifiable and published in advance. The UK had, by this time, finally notified to the Commission, pursuant to Art. 7.2 the following criterion:

A medicinal product or a category of medicinal products may be excluded entirely from supply on NHS prescription. It may alternatively be excluded except in specified circumstances, or except in relation to specified conditions or categories of condition, or specified categories of patient. A medicinal product or category of them may be so excluded where the forecast aggregate cost to the NHS of allowing the product (or category of products) to be supplied on NHS prescription, or to be supplied more widely than the permitted exceptions, could not be justified having regard to all the relevant circumstances including in particular: the Secretary of State's duties pursuant to the NHS Act 1977 and the priorities for expenditures of NHS resources.

The Court found that these criteria met the requirements of the directive. Further, since decisions of affordability were essentially political decisions, any more explicit ranking of NHS priorities would have been artificial. Compliance with the requirements of the Transparency Directive was the only grounds of challenge in this case. Thus, the Court found the restrictions on sildenafil (Viagra) to be lawful, the established procedures having been followed.

### 5.3 The Effectiveness of the Limited List

It has been argued that success and failure in public management is often a question of ones' perspective.<sup>37</sup> The approach taken in this chapter, and in the following two chapters, is to assess the effectiveness of regulatory reforms against their intended, publicly pronounced policy goals. As discussed in Section 4.6, evidence of effectiveness was gained primarily from 'official' assessments of performance, and from assessments in the

<sup>37</sup> Hood (1998). *The Art of the State: Culture, Rhetoric and Public Management*. Oxford, Clarendon Press, p. 24.

medical literature. This is supplemented by evidence from the secondary literature.

Although the introduction of prescribing restrictions could potentially have served a number of objectives, controlling the rate of increase in the NHS drugs budget was the overriding policy goal of the Limited List scheme, at least in the original categories (I1, I5, I17, I21), though benzodiazepine sedatives and tranquillisers represented a partial exception. As discussed in Section 5.2.2, after the initial 'downgrading' of expectations, the Limited List scheme was intended to save £75 million per year on the NHS drugs bill in the year 1985-6; further, it was expected that this sum would increase over time, as generic versions of an increasing number of proprietary drugs became available. In addition to these direct savings, it was claimed that the initiative had led to a more general awareness among the profession of the system-wide effects of individual prescribing practices. As the Secretary of State for Health and Social Security, Mr Norman Fowler, put it: "An advantage of the debate that we had is that there is now much more concern about prescribing habits, and I hope to be able to follow that with further advice from the Department."<sup>38</sup>

Against these claims, evidence of success of the Limited List scheme is patchy, to say the least. In evidence to the Health Select Committee, the Department of Health claimed that the anticipated savings had been realised in the first year, but that monitoring of the impact of the Limited List scheme had been discontinued thereafter.<sup>39</sup> The Audit Commission examined the impact of the Limited List as part of a broader investigation of

<sup>38</sup> *Parliamentary Debates, Sixth Series*, H.C. Vol. 75, col. 137 (1985) 12 March 1985 (Mr. Norman Fowler).

<sup>39</sup> House of Commons Health Committee (1994) *Priority Setting in the NHS: The NHS Drugs Budget*, HC 80-I, London, HMSO, p. xxv.

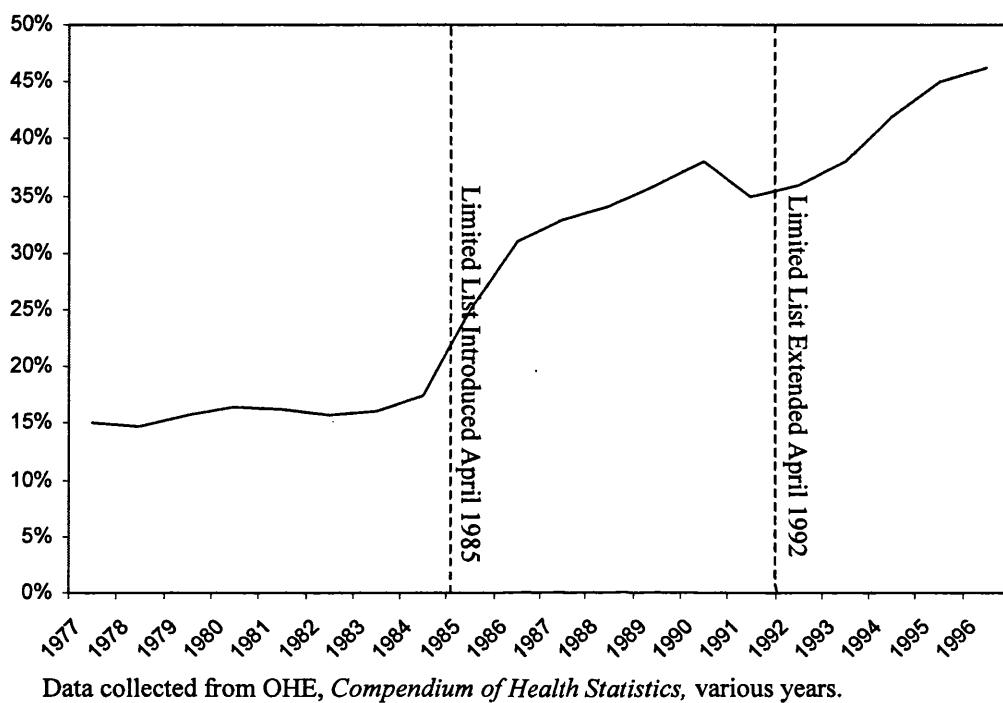
prescribing in general practice, and concluded that the introduction of the Selected List led to a “one-off reduction in prescribing costs”, but found “no evidence that it stemmed the rate of increase in drug expenditure.”<sup>40</sup>

At the same time, as Figure 5.1 below shows, Fowler’s claim that the initiative had indirect as well as direct benefits, in terms of increased awareness about prescribing habits may not be without foundation. Following the introduction of the Limited List, there was a sharp, and constant increase in the proportion of generic drugs prescribed on the NHS. This contrasts sharply with a roughly constant proportion of generic prescribing in the years leading up to the introduction of the Limited List.

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<sup>40</sup> Audit Commission (1994) *A Prescription for Improvement: Towards More Rational Prescribing in General Practice*, London, HMSO, p. 9.

**Figure 5.1: Level of Generic Dispensing as a Percentage of Prescriptions Dispensed (1977-1996)**



The House of Commons Health Committee undertook a detailed official assessment of the Limited List in 1993-4, as part of a broader investigation of the NHS drugs budget, which also looked at the PPRS.<sup>41</sup> The Committee endorsed the “principle” of the Limited List and the “right of the NHS, as the major purchaser of medicines in the UK, to decide which drugs can be bought on the NHS.”<sup>42</sup> Nonetheless, it was highly critical of the operation of the scheme, especially regarding the openness and

<sup>41</sup> House of Commons Health Committee (1994) *Priority Setting in the NHS: The NHS Drugs Budget*, HC 80-I, London, HMSO.

<sup>42</sup> *Ibid.* para. 119.

transparency of the decision over which categories should be included within the scheme.<sup>43</sup>

Against this mixed evidence of the initial success of the Limited List, the development of the scheme following its extension after 1992 counts more clearly as a failure. As with the initial introduction of the Limited List, the Department of Health had intended to monitor the impact of the scheme on the NHS drug budget for one year. Due to delay on the part of the ACD in developing recommendations within the new categories, as well as the eventual falling of the Limited List scheme into abeyance, this in fact never happened. Moreover, it has been suggested that pharmaceutical companies had, by this time, begun to challenge the ACD through strategies of creative compliance (I21). Specifically, because the policy of the ACD had been to promote the prescribing of generics as far as possible, many preparations were 'black-listed' by brand name. In response, some manufacturers would re-brand their product under a different proprietary name, thus circumventing the black-listing, forcing the Department of Health either to allow the prescription under the new proprietary name, or to start over. Moreover, the lengthy procedure of notification, appeal, the preparation of a 'solution' by officials, the 'laying' of regulations before Parliament, prior to a product becoming officially Scheduled, as well as the potential for legal challenge by the manufacturers, made it difficult for the Department of Health to respond effectively to such strategic behaviour.

More recently, use of the 'grey list' to restrict the prescribing of sildenafil may be judged to have generated more significant savings, though as Section 5.2.6 noted, estimates of the resource implications of permitting

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<sup>43</sup> Ibid. para. 123-6.

unrestricted prescribing of the drug varied enormously. Prior to the licensing of sildenafil, the NHS had spent around £12 million per year in treating impotence. In evidence presented on behalf of the Secretary of State for Health in the second Viagra case, it was suggested that this had risen to £25 million, whereas the cost of making Viagra available to all those who could benefit from it was around £125 million. At the same time, such savings were not made by restricting ineffective and harmful treatments, the original objective of the initiative, but by restricting the availability of a cost-effective treatment. It is arguable whether this figure can therefore be described as a 'saving', since the 'cost' was passed onto patients, either through self-funding or through 'going without'. The same can be said for NRT.

Summarising this section, the Limited List can be said to have been, for the most part, a failure. The Limited List scheme was not seen to have resulted in any significant reduction in the NHS drug budget and where significant savings to the NHS were achieved, for example in restricting sildenafil (Viagra) to patients whose ED stemmed from specific underlying causes, this was not achieved through eliminating ineffective or harmful treatment. The next section relates this failure to poor regulatory design.

## **5.4 Commitment, Governance and the Limited List**

This section attempts to assess the extent to which the governance structure of the Limited List scheme provided for credible commitment, applying the modified version of Levy and Spiller's three-level framework of analysis set out in Section 4.5. Accordingly, the following four sub-sections deal respectively with substantive written restraints, restraints based on structure

and process, constraints on system changes, and the broader institutional endowment for enforcing lower-level commitment mechanisms. On the basis of this analysis, it is argued that the Limited List scheme failed to engender credible commitment, and that this contributed to the failure of the Limited List scheme.

### **5.4.1 Substantive Written Restraints**

The Limited List scheme vested regulatory authority in the DHSS (and later, the Department of Health), through the power of the Secretary of State, under Section 19 (2) to make regulations providing for the definition of “personal medical services” to be provided by general practitioners. This Act did not impose any specific, substantive restraints on the exercise of this power, although it was qualified, in a vague sense, by the duty imposed on the Secretary of State under Section 1 of the Act, to “...continue the promotion in England and Wales of a comprehensive health service.” The one potentially significant substantive restraint on the exercise of ministerial regulatory authority derived from the Transparency Directive 89/105 EEC. As a result of this measure, the Department of Health could only restrict products through their inclusion in Schedule 10 and 11 in accordance with objective and verifiable criteria published in advance. In practice, this did not provide an effective restraint on the Secretary of State’s authority, firstly because the UK was extremely slow in notifying its criterion to the Commission, submitting criteria nearly 10 years after the time limit, and secondly because the terms eventually communicated to the Commission were extremely broad. As demonstrated by the second *Viagra* case, the broad criteria set by the UK government were incapable of preventing significant drift from the original purposes of the Limited List Scheme. Overall, therefore, the legal framework of the scheme provided for few substantive written restraints on regulatory discretion.

### 5.4.2 Restraints Based on Structure and Process

Although the Limited List scheme provided few substantive restraints on the discretion of the Secretary of State, the procedures under which the Limited List was maintained were arguably a little more significant. As discussed in Section 5.2.4, after the creation of the initial lists, decisions as to the composition of the black and grey lists, for the most part originated in recommendations from the ACD. By placing substantial agenda-setting power in the hands of an expert committee, with a professional membership, this arguably made the resulting decisions more in line with implicit understandings about the scope of prescribing freedom. As the House of Commons Health Committee put it: “The very existence of this technical committee, working at arm’s length from Ministers and departmental management, represents a significant improvement over the way the initial decisions on the scheme were taken in 1986 [sic].”<sup>44</sup>

But although this may have made routine decision-making more respectful of the medical profession’s zone of acceptance of ministerial regulatory authority, it can be said to have been relatively ineffective as a commitment strategy. First, unlike the approach adopted by NICE (and discussed in the next chapter), the ACD did not adopt a transparent ‘gold-standard’ evidence-based evaluation: “There was very little in the way of clinical judgement, apart from the fact that particular products were equivalent.” (I21). Second, Ministers could (and did) take black-listing decisions without reference to the Committee. This was evident in the case of NRT, where the decision was taken by the Department of Health that it should not provide funding for this treatment. Furthermore, the ACD did not meet after 1998, and was dissolved in 2003. In dealing with the resource

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<sup>44</sup> Op. cit., para. 122.

implications of the introduction of sildenafil (Viagra) the Secretary of State did consult medical opinion through the SMAC.

### **5.4.3 Constraints on System Changes**

Moving from the level of operational rules to collective choice rules, it can be argued that restraints on changing the regulatory system were relatively slight. It was noted in Section 5.4.1, that the Limited List scheme was given legal effect by statutory instrument, using the Secretary of State's power under Section 29 (2) of the National Health Service Act 1977 to make regulations providing for the definition of personal medical services to be provided by GPs. As set out in Section 126 of that Act, this power was "...exercisable by statutory instrument..." and was "...subject to annulment in pursuance of a regulation of either House of Parliament", thus bringing the Secretary of State's regulatory power within ambit of the Statutory Instruments Act 1946, which provides for established procedures for Parliamentary oversight and challenge.<sup>45</sup> Briefly, in accordance with the standard procedure provided by the Statutory Instruments Act 1946 there was a forty-day period for the 'laying' of regulations, during which time a Member of Parliament can move a 'prayer' for annulment by Order in Council; if, after the forty day period no successful challenge has been made, the regulations take effect. No such provisions governed the establishment or dissolution of the ACD, which had no basis in statute. Furthermore, although ministerial approval for the dissolution of the Committee was not given until 2003, it had not met for some time beforehand, surviving 'on paper' only, with no appointees and no chairman at the time it was dissolved.

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<sup>45</sup> Statutory Instruments Act 1946, S. 1.

In terms of the analytical framework presented in Section 4.5, informal institutions also play a role in restraining arbitrary changes to the regulatory system. An example offered in Section 4.5.4, was Spiller and Vogelsang's suggestion that the convention whereby major policy changes are preceded by the publication of White Papers prevents hasty changes without consultation. This, it was argued, prevented major changes of regulatory policy being presented as a *fait accompli*, allowing for the mobilisation of opposition. At the same time, experience of the Limited List scheme calls into question the effectiveness of this particular convention. Not only was there no White Paper in advance of the scheme, the DHSS limited consultation to the content of the Limited List, making it clear that the major decision on principle had been taken. Furthermore, as discussed in Section 5.2.3, the draft regulations laid before parliament (quite literally) bore the mark of being hastily put together, with the detailed institutional arrangements for revision of the scheme, including the ACD left to be worked out later. Similarly, there was no consultation prior to the extension of the scheme in 1992. This drew criticism from the Health Select Committee, which was critical of the fact that:

...neither the industry, nor the NHS, nor representatives of patients, nor even the Advisory Committee itself, is consulted before decisions are taken by Ministers on the inclusion of new therapeutic categories within the Scheme.<sup>46</sup>

Overall, therefore, it can be said that although structural and procedural arrangements allowed for some sensitivity to respective duties and entitlements under the concordat over routine issues. At the same time, the possibility of disregarding these arrangements limited the extent to which they could provide the basis for commitment to the implicit concordat.

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<sup>46</sup> House of Commons Health Committee, op. cit., para. 123.

### 5.4.4 Enforcement of Lower-Level Commitment Mechanisms

Turning to the level of constitutional choice rules, this section considers the role of legislative, executive and judicial institutions in enforcing lower-level commitment mechanisms.

Taking first the legislative institutions of the United Kingdom Parliament, the procedures for parliamentary scrutiny of delegated legislation seem to have been little used, although the initial changes to the National Health Service (General Medical Services Regulations) 1974 introducing the black and grey lists were considered both by the Standing Committee on Delegated Legislation and on the floor of the House of Commons. Furthermore, there was a debate on an early day motion over the 1992 extension of the categories covered by the Limited List.<sup>47</sup>

In terms of executive institutions, regulatory authority was vested in the Secretary of State, and although the ACD enjoyed some agenda-setting power, the Committee had no executive authority. As a consequence of this absence of genuine regulatory independence, executive institutions may be regarded as providing a poor mechanism for establishing neutrality between political and professional interests. Furthermore, it was possible to 'stand down' the committee, and later to dissolve it, purely through the exercise of ministerial authority.

Judicial institutions provided for relatively most effective enforcement of restraints on the arbitrary exercise of discretion. On three occasions, decisions to exclude or restrict drugs were challenged: the

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<sup>47</sup> *Parliamentary Debates, Sixth Series*, H.C. Vol. 229 cols. 948-966, 26 July 1993.

*Schering* case, and the first and second *Viagra* cases. Although there has been no successful challenge to the substance of a decision, in the first *Viagra* case the courts enforced procedural restraints on regulatory discretion. In that case it was held that HSC 1998/158, advising GPs not to prescribe Viagra except in undefined “exceptional circumstances” interfered with the ability of a GPs to perform their duties under their Terms of Service. In that case, the Court emphasised the availability of Schedules 10 and 11 as established means of excluding or restricting particular drugs, and overturned the guidance, which it saw as an attempt to circumvent these procedures. This did at least prevent the government from evading procedures for the scrutiny of delegated legislation, although this section has argued that these were not particularly effective, after the detailed scrutiny of the initial establishment of the Limited List scheme.

The role of the judiciary has consequently been restricted to the enforcement of proper procedures, as in the second *Viagra* case, discussed above. Even here, however, this has been limited to preventing attempts to circumvent the statutory Scheduling procedures where this interfered with GPs’ statutory duties. No argument was raised that black- or grey-listing a product without a recommendation to that effect by the ACD was a breach of proper procedures. Nor was the issue raised of the lawfulness of using the Schedule 11 procedure, not to ensure that clinical need was met as cost-effectively as possible, but in order to ration access to treatment.

Concluding this section, it can be said that the governance structure of the Limited List scheme was poor, in terms of substantive restraints, structural and procedural restraints, and constraints on changing the regulatory structure of the scheme. In the absence of an effective governance structure, even the willingness of the judiciary to enforce procedural requirements was not particularly effective. At all three levels of

analysis, therefore, the legal and administrative framework of the Limited List did not provide for effective regulatory commitment.

## 5.5 Conclusions

It can be seen from Section 5.3 and 5.4 that the Limited List was relatively ineffective, and that, in line with the regulatory commitment hypothesis, this corresponded to a governance structure that did not engender effective regulatory commitment. Furthermore, as the narrative of Section 5.2 showed, there was significant slippage of the Limited List scheme over time. Initially intended as a means of cutting out ineffective and harmful treatment, the Limited List was extended in 1992 into more controversial categories in which it could no longer strictly be claimed that patients were not being denied effective treatment. The NRT and Viagra episodes, moreover, demonstrate that both Labour and Conservative governments were prepared to use the scheme to restrict access to treatments that were not thought to be wasteful in any of Blunstein and Marmor's senses. Moreover, this was predicted from the outset. For example, in the debate over the introduction of the scheme, several MPs expressed concern that the scheme would later be extended into other areas and declined to accept reassurances from the Secretary of State. For example, Mr Willie Hamilton quoted a letter from one of his constituents, Dr G. Lindsay Smith who feared that "Once this list has been introduced there is nothing to prevent the Government extending it to cover other groups of drugs." Hamilton added, "Despite the Minister's assurance this afternoon, we do not believe him. Despite what he says, this is the thin end of a sinister wedge."<sup>48</sup>

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<sup>48</sup> *Parliamentary Debates, Sixth Series*, H.C. Vol. 75. col. 732, 18 March 1985 (Mr Willie Hamilton). See also For example, *Parliamentary Debates, Sixth Series*, H.C. Vol. 75. col. 692, 18 March 1985 (Mr Colin Shepard).

In spite of these predictions, it is difficult to assert with confidence that the disappointing results of the introduction of the Limited List were caused by the absence of a credible governance structure. For one thing, unlike the example of NICE discussed in the next section, from the point of view of the GPs whose prescribing practices were regulated by it, enforcement was automatic, in the manner of the 'enforcement machines' discussed by Hood.<sup>49</sup> There was therefore little scope for the sort of subversive strategies outlined by Davies and discussed in Section 4.4, above. At the same time, it can plausibly be argued that the limited initial ambition of the scheme, including the downgrading of the expected savings from £100 million to £75 million was in part due to professional opposition.

Although the evidence is consistent with the regulatory commitment hypothesis, it could be counter-argued that the failure of the Limited List scheme resulted from causes other than inadequate institutional commitment. Plausible alternative reasons include the opposition of the pharmaceutical industry, as well as the intrinsic difficulty of the regulatory task itself, which may have been underestimated by the architects of the scheme. Although a study such as this could not hope to disentangle the relative effects of each of these, some further comments on the plausibility of the regulatory commitment hypothesis are appropriate.

Firstly, in the case of alternative possible explanations, such as the sustained opposition of the pharmaceutical industry, or the intrinsic difficulty of the regulatory task, it can be argued that the effects of these factors were exacerbated by the lack of credible commitment to the implicit concordat. For example the success of creative compliance on the part of the pharmaceutical companies through the strategy of re-branding products

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<sup>49</sup> Hood (1986). *Administrative Analysis: An Introduction to Rules, Enforcement and Organisation*. Brighton, Wheatsheaf Press, Chapter 3.

discussed in Section 5.3 arguably depended on the connivance of general practitioners prepared to prescribe proprietary products under new brand names. Similarly, it can be argued that the intrinsic difficulty of the regulatory task was heightened by the lack of support from the medical profession—the boycotting of the BMA of consultation on the content of the Limited List is perhaps the clearest example. Finally, the existence of other factors contributing to the failure of the Limited List scheme does not take away from the fact that the lack of credible commitment was one factor contributing to this failure independently of other factors.

The more significant point is that although the evidence presented in this chapter may be, for the most part, equally consistent with alternative accounts of regulatory failure, it is nonetheless highly consistent with the hypothesis put forward in this thesis. In particular, as Section 5.2 demonstrated, the expansion of the scheme occurred more or less exactly in the manner that might have been expected, given the framework put forward in Chapter 4. Furthermore, had the analysis shown the Limited List scheme to be a great success, in spite of an inadequate governance structure, or had poor performance occurred in spite of more effective commitment mechanisms, this would have counted as evidence against the commitment hypothesis. That this was not observed must count as a success.

At the same time, a major puzzle remains: why did the DHSS in 1985 choose an institutional design that, as suggested here, clearly lacked credibility? It could be argued that this was simple miscalculation on the part of the government. As the Minister of State for Health, Mr Kenneth Clarke is reported to have said, “I knew the [pharmaceutical] industry would be upset, but I didn’t count on such a vehement response from the

doctors.”<sup>50</sup> At the same time, as the discussion has shown, it was widely (and correctly) feared that the introduction of the Limited List scheme in 1985 was to be “the thin end of the wedge.” If opposition MPs could predict this, why couldn’t the Government? After all, if the argument of this thesis is correct, it is in the interest of the Government as well as of the profession that the former should be able to commit credibly to the implicit concordat. Chapter 8 returns to this puzzle.

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<sup>50</sup> “Take Only as Directed: UK Health Costs.” *Financial Times*, 29 January 1985.

## Chapter 6

# The National Institute for Clinical Excellence

Some commentators have argued that the Government should prescribe at national level what treatments the NHS should provide. The Government does not believe that this is right. No such list of treatments could ever hope to accommodate the range and complexity of the different cases which individual clinicians face all the time. There would be a real risk of taking decisions out of the hands of the clinicians treating patients and into the province of others who possess neither the experience of caring for patients nor the expertise to make such decisions.<sup>1</sup>

### 6.1 Introduction

Geographical differences in the availability and quality of clinical care have always been a feature of the NHS. The Health Service was created out of a pre-existing array of local authority services and voluntary hospitals as well as the great teaching hospitals. Beginning in the 1970s, successive attempts were made to address this problem through targeting funding towards under-resourced areas, through the Resource Allocation Working Party (RAWP). With the introduction of the purchaser-provider split in the 1990s, the RAWP formula, which had determined the allocation to the regions and districts was replaced, though the basic underlying approach remained.

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<sup>1</sup> Secretary of State for Health (1996) *The National Health Service: A Service With Ambitions*, cm 3425, London, The Stationery Office, p. 39.

From the early 1990s, there was a renewed interest, initially led by the medical royal colleges, in the use of clinical standards as instruments to address questions of appropriate treatments for particular conditions, and for promoting 'best practice'. Despite this proliferation of interest, official interest in formal clinical standards developed only slowly. This changed dramatically following election of the Labour Government in 1997. The new administration's plans for the reform of the NHS included the establishment of a new National Institute for Clinical Excellence (NICE) "to provide new coherence and prominence to information about clinical and cost effectiveness."<sup>2</sup> Since its establishment in 1999 the Institute has played a prominent role, producing and disseminating various forms of guidance for use in the NHS.

The establishment and subsequent development of NICE makes an appropriate episode of regulatory reform for examination for at least three reasons. First, the establishment of the Institute brought into sharp relief themes related to the issue of commitment to the implicit concordat that is central to this thesis. Second, the emergence of a centralised standard-setting body for the NHS raised questions relating to the boundaries between cutting waste and rationing similar to, but arguably more acute than in the case of the Limited List scheme, discussed in the previous chapter. While there was broad support for the role of NICE in promoting clinical and cost-effective treatment, there was also widespread suspicion that the Institute was (or would become) an instrument for deciding on the affordability of expensive treatments. An assessment of the ability of NICE's governance structure to allow it to perform the former functions effectively while restraining drift towards the latter provides for a further evaluation of the theoretical framework set out in Chapter 4, relating the

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<sup>2</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office, para. 7.11.

effectiveness of regulation inside the NHS to the credibility of the governance arrangements. Third, in contrast to the other episodes of regulatory reform discussed in this thesis, NICE has been subject to detailed institutional analysis by other scholars, notably Keith Syrett, who deploys an alternative theoretical perspective, based on the legitimacy claims of the Institute. An analysis of NICE using the framework of analysis set out in Chapter 4 therefore allows for an examination of the advantages of that framework *vis-à-vis* competing approaches.

The organisation of this chapter is as follows. Section 6.2 outlines the approach of the work of Syrett, which can be seen as a competitor to the approach of this thesis, though the approaches are not necessarily fundamentally incompatible. Section 6.3 relates the background to NICE, its establishment, and subsequent evolution. Two particular controversial decisions of NICE, relating to zanamivir (Relenza) for influenza and beta intereron for multiple sclerosis are examined in detail in 6.4. Moving from description to analysis, Section 6.5 considers the effectiveness of NICE, while Section 6.6 applies the three-level framework for assessing regulatory governance set out in Section 4.5. By way of conclusion Section 6.7 considers the extent to which the evidence of this chapter supports the argument of this thesis, and returns to the contrast between the present approach and rival theoretical perspectives.

## 6.2 Existing Institutional Analyses of NICE

Across a series of articles, Keith Syrett has developed a compelling thesis about the performance of NICE.<sup>3</sup> The fundamental problem, as he sees it, is

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<sup>3</sup> Syrett (2002). "NICE Work? Rationing, Review and the 'Legitimacy Problem' in the New NHS." *Medical Law Review* 10 (1): 1-27; Syrett (2003). "A

that as responsibility for deciding on the appropriateness of different treatments in different situations has passed from individual doctors to organisations such as NICE, it brings into focus within the political realm decisions involving the denial of effective treatment to patients. For Syrett, this gives rise to a legitimacy problem: "why should patients or clinicians accept the authority of such organisations to make 'moral decisions' which limit the access to healthcare and therefore affect individual well-being?"<sup>4</sup> The response of the Blair government, through the establishment of NICE, has been to base rationing decisions on scientific evaluation and economic analysis of health outcomes. Syrett regards this as a "technocratic fix", meaning that it aims to present what are essentially political judgements as the result of a purely technical processes involving the application of neutral criteria of the clinical and social sciences. Such a strategy is unlikely to produce socially acceptable outcomes, he argues, because claims towards legitimacy on this basis cannot withstand critical scrutiny. Syrett argues for a turn towards the public law values of participation and accountability, as a means of providing the basis for an ongoing dialogue. Such a 'responsive' approach, he argues, is more likely to be capable of establishing the acceptability of 'rationing' decisions, compared with attempts to establish a once-and-for-all solution, based on an appeal to technocratic expertise.

This view of the use of economic and clinical evaluation makes an interesting contrast with the contending approach of Moshe Maor, discussed in Section 4.5.3. It will be recalled that, for Maor, one advantage of the use

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Technocratic Fix to the "Legitimacy Problem"? The Blair Government and Health Care Rationing in the United Kingdom." *Journal of Health Politics, Policy and Law* 28 (4): 715-746, 2003; Syrett (2003). "Legitimizing 'Fourth Hurdle' Pharmaceutical Regulation in Europe: Learning the NICE Way?" *European Public Law* 9 (4): 509-532.

<sup>4</sup> Syrett (2002). "NICE Work? Rationing, Review and the 'Legitimacy Problem' in the New NHS." *Medical Law Review* 10 (1): 1-27, p. 6.

of evidence-based evaluation within drug reimbursement decisions is that this injects a greater degree of certainty into decision-making processes, which he likens to a 'gold standard'.<sup>5</sup> Such an approach, it can be argued, allows governments to make credible commitments. His analysis of drug reimbursement policies in New Zealand, Australia and British Columbia suggests that where a shared scientific standards exists for assembling, evaluating and interpreting evidence, this provides an alternative commitment strategy to delegation to independent authorities. Unlike Syrett's analysis, the significance of evidence-based approaches to decision-making for Maor is not so much that they allow moral and political decisions to be presented as neutral technocratic decisions but rather because they make departures from pre-established criteria highly visible, thereby preventing veiled changes to the criteria used in decision-making.

### **6.3 NICE: Origins, Implementation and Development**

This section provides an account of the background to NICE, its introduction and subsequent evolution, focussing on the stated aims of the Institute and the legal and administrative framework through which these were pursued. Section 6.3.1 outlines the proposals of the post-1997 Labour government, setting them in the context of the earlier approach of the preceding Conservative Government and looking also at the reaction to the proposals. The establishment of NICE is considered in Section 6.3.2, while Section 6.3.3 looks at the subsequent reforms of NICE.

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<sup>5</sup> Maor (2004). "Competing Commitments? Independence versus "gold standard" for policy choice in the reimbursement of pharmaceutical drugs". 20th Anniversary SOG Research Committee of the International Political Science Association, Vancouver.

### 6.3.1 The Government's Proposals For NICE

As the introduction to this chapter noted, tentative steps towards national standards relating to clinical and cost-effectiveness were made during the early 1990s, mainly under the auspices of the medical royal colleges.<sup>6</sup> By and large, however, the Conservative Government of the 1990s foreswore more prescriptive, centralized clinical standards, as shown by the epigram to this chapter taken from the White Paper *A Service With Ambitions*. NHS Executive involvement was limited to the encouragement (including the funding) of standard-setting initiatives by different professional groups. This avowed self-restraint was arguably due to an absence of credibility on the part of the Conservatives. Consistent with this interpretation, the *Service With Ambitions* White Paper has been described as "...an exercise in political persuasion and reassurance" at a time when the Conservative Government was seen as antagonistic towards the NHS.<sup>7</sup>

By contrast, the Labour government elected in May 1997 followed a more interventionist approach, reflecting scepticism within government at approaches based on exhortation (I18). In December 1997, the government issued a White Paper *The New NHS*, setting out its proposals for reform of the Health Service. Included in the White Paper were proposals for a number of new measures for the setting and monitoring of national clinical standards within the NHS. These were developed further in a subsequent Department of Health consultation document on quality in the NHS, *A First*

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<sup>6</sup> For an account of clinical guidelines in the UK during the 1990s, see Day and Klein (1998). "The UK Experience: Control Over, or By, The Medical Profession?" in Day, Klein and Miller (ed.) *Hurdles and Levers: A Comparative US-UK Study of Guidelines*. London, The Nuffield Trust.

<sup>7</sup> Klein (2001). *The New Politics of the NHS*. 4th Edition, Harlow, Prentice Hall.

*Class Service.*<sup>8</sup> In addition to the establishment of NICE, the government's proposals included a programme of National Service Frameworks and a new national Performance Assessment Framework, while the Commission for Health Improvement was intended to monitor compliance of NHS organisations with quality standards.<sup>9</sup>

Two central, inter-related preoccupations emerged from the White Paper and *A First Class Service*. First, that the NHS was beset by "unjustifiable variations" in the quality of care across Health Authorities.<sup>10</sup> Second, that there was a need for a more consistent approach within the NHS to setting clinical standards based on "best evidence" of clinical and cost-effectiveness.<sup>11</sup> NICE was to ensure that "... interventions with good evidence of clinical and cost-effectiveness will be actively promoted, in order that patients would have faster access to treatments known to work. Equally, it will help protect patients from new interventions with inadequate evidence of clinical and cost effectiveness..."<sup>12</sup>

Against these publicly pronounced policy objectives, some detected a hidden agenda, namely that the Government were attempting to implement 'rationing' within the NHS. Ministers denied this charge, as did the Chairman-elect of NICE, Professor Sir Michael Rawlins, in evidence to the House of Commons Health Committee.<sup>13</sup> However, the opposition remained

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<sup>8</sup> Department of Health (1998) *A First Class Service: Quality in the New NHS*, HSC 1998/113, London, Department of Health.

<sup>9</sup> NSFs were discussed briefly in Section 3.3.3, above. CHI is discussed in detail in the following chapter.

<sup>10</sup> For an extreme example of what has been called the 'postcode lottery', see the case of *R v. North West Lancashire Health Authority, ex parte A, D. & G.* discussed in Section 4.5.5.

<sup>11</sup> *The New NHS*, para. 7.5

<sup>12</sup> *A First Class Service*, para. 2.17.

<sup>13</sup> House of Commons Health Committee (1999) *Minutes of Evidence for Thursday 4 February 1999—National Institute for Clinical Excellence*:

unconvinced, drawing attention to the government's intention that NICE was to be established by statutory instrument as a Special Health Authority. This, it was alleged, was an attempt to avoid the Parliamentary scrutiny accorded to those aspects of the reforms contained in the 1999 Health Bill.<sup>14</sup> Liberal Democrat health spokesman Dr Evan Harris did not explicitly assert a hidden agenda, but he observed that by not including NICE in the Health Bill, the door had been left open to the possibility that "...a future Government might use NICE to make rationing decisions instead of doing so themselves."<sup>15</sup>

The overall response of the BMA was positive. In its response to *A First Class Service*, it welcomed the introduction of NICE, describing the "principles" on which it was based as "long overdue".<sup>16</sup> Nonetheless, specific issues raised by the BMA indicated concern to ensure greater medical control, insisting that NICE "...must include medical representatives from all sectors (including primary care, secondary care and public health)."<sup>17</sup> In order to ensure the "...confidence of the profession... any guidelines should be fully referenced and scientifically robust."<sup>18</sup> Moreover, it was important to the BMA that the work of NICE should not

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*Professor Sir Michael Rawlins, Dr Gina Radford and Dr Timothy Riley, HC 222-i, London, The Stationery Office.*

<sup>14</sup> House of Commons Session 1998-1999, Third Standing Committee on Delegated Legislation, National Institute for Clinical Excellence (Establishment and Constitution Order 1999, Wednesday 10 March 1999. Mr Phillip Hammond: "Many people... will have assumed that, as NICE is a key part of the Government's health programme, the provisions to establish it would be found in the Government's keynote Health Bill. Not so. By creating NICE as a special health authority, the Government are sneaking it into being through the back door without proper scrutiny of its real function..."

<sup>15</sup> House of Commons Health Bill [Lords] in Standing Committee A, 11<sup>th</sup> sitting, 11 May 1999 (afternoon) Part II.

<sup>16</sup> BMA (1998) *Response to 'A First Class Service: Quality in The New NHS'*, London, BMA, August 1998, p. 1.

<sup>17</sup> Ibid. p. 3.

<sup>18</sup> Ibid. p. 5.

“...lead to ‘managed care’ which would interfere with doctors’ clinical freedom to treat each and every patient in his/her best interests.”<sup>19</sup>

### 6.3.2 The Establishment of NICE

NICE was established as a Special Health Authority on 1 April 1999.<sup>20</sup> The original remit of the Institute was to “perform such functions in connection with the promotion of clinical excellence as the Secretary of State may direct.”<sup>21</sup> In practice, this was to amount to the promulgation of three main forms of guidance. Clinical guidelines covered the treatment of specific diseases and conditions. Clinical audit methodologies were procedures through which clinicians could evaluate their practice against the standards set out in clinical guidelines. More importantly and controversially, NICE was to be responsible for technology appraisals of new and existing medicines and treatments for use within the NHS. Although most of the guidance products of NICE (at least in the period under study) were to take the form of technology appraisals, no specific mention was made of this function in the White Paper, although there was a fairly detailed discussion in *A First Class Service* and in a subsequent consultation document *Faster Access to Modern Treatment*.<sup>22</sup>

The Institute originally consisted of a Chairman, seven non-executive members and four executive officers.<sup>23</sup> The National Institute for

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<sup>19</sup> Ibid.

<sup>20</sup> National Institute of Clinical Excellence (Establishment and Constitution Order) S.I. No. 220 of 1999.

<sup>21</sup> S.I. No. 220 of 1999, Regulation 3.

<sup>22</sup> *A First Class Service*, para. 2.13. A further discussion paper set out in detail the proposed technology appraisal function of NICE. See Department of Health (1999) *Faster Access to Modern Treatment: How NICE appraisal will work*, Leeds, NHS Executive.

<sup>23</sup> S.I. No. 220 of 1999, Regulation 4.

Clinical Excellence Regulations 1999 gave further shape to the structure of the Institute.<sup>24</sup> These provided for the establishment of two NICE advisory Committees.<sup>25</sup> A Partners' Council, comprising members drawn from patient groups, health professions, NHS managers, the pharmaceutical industry, trade unions and other organisations responsible for the quality of health care, was required to review the Institute's annual report, but in fact met regularly as a 'sounding board' to the Institute. The Appraisal Committee had mainly 'expert' composition (though it also reflected a more 'political' balance of interests, including patient groups, industry representatives, and NHS interests) and was responsible for NICE technology appraisals. In addition to these two committees, whose existence was required by the regulations, NICE was empowered to establish additional committees.<sup>26</sup> A Guidelines Advisory Committee was established in May 2000 under this power, which had again mainly 'expert' composition, but with some representation from industry, consumers and the NHS. The work of the Institute was supported by a staff initially of around 10 people, originally seconded from the Department of Health, with operating costs of around £9.5 millions in its first year of operation, funded mainly by the Department of Health.<sup>27</sup>

### 6.3.3 The Evolution of NICE

From the very outset, the role of NICE was intended to be an evolving one. As the White Paper had stated, "The Government will consider developing the role and function of the National Institute as it gathers momentum and

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<sup>24</sup> S.I. No. 260 of 1999.

<sup>25</sup> S.I. No. 260 of 1999, Regulation 9.

<sup>26</sup> S. 9 (4).

<sup>27</sup> National Institute for Clinical Excellence (2000) *Annual Accounts 1999-2000*, London, NICE. , p. 16, 18.

experience.”<sup>28</sup> This evolution had, as discussed, in a sense, begun even before the Institute came into existence, as its intended responsibilities were developed from the skeletal account in the White Paper, including the incorporation of a technology appraisal function.

A more substantial change occurred within months of the establishment of NICE, which seemed to confirm fears expressed by the opposition that the Institute would, over time, be transformed into an instrument of cost-reduction. Whereas the Government had from the outset spoken of NICE’s role in relation to both clinical and cost-effectiveness, the functions conferred on the Institute by S.I. No. 220 of 1999 referred only to “such functions in the promotion of clinical excellence in the health service as the Secretary of State may direct.”<sup>29</sup> An amendment laid in August 1999 conferred on NICE the additional responsibilities with respect to promoting “...the effective use of available resources.”<sup>30</sup> This choice of wording apparently went beyond the original intention that the Institute should have regard to issues of cost-effectiveness, to include considerations of affordability. The move was seen by some as a betrayal of assurances given by ministers in debates on the Health Bill and on S.I. No. 220 of 1999 that NICE would not undertake ‘rationing’ decisions that were properly the responsibility of the Secretary of State. As the pugnacious Conservative shadow health secretary, Dr Liam Fox later alleged: “The Government changed the criteria for NICE because that was merely another spin trick for Ministers who wanted an arms-length rationing mechanism as they were too cowardly to take decisions directly.”<sup>31</sup> The controversy was further

<sup>28</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office. , para. 7.12.

<sup>29</sup> S.I. No 220 of 1999, Regulation 3

<sup>30</sup> S.I. No 2219 of 1999, Regulation 2 (2).

<sup>31</sup> *Parliamentary Debates Sixth Series*, H.C. Vol 353, col. 146, 4<sup>th</sup> July 2000 (Mr Liam Fox).

compounded because the Order had been laid during the summer recess, leading to accusations that this had been an attempt to introduce the amendment without proper scrutiny.<sup>32</sup> The change, and the specific choice of wording, was ostensibly a response to legal advice received in the light of the *Viagra* cases.<sup>33</sup> In the episode surrounding those cases the Secretary of State had been advised that it was not appropriate to refer sildenafil (Viagra) to NICE, because the issue at hand was not the clinical effectiveness but the overall affordability of sildenafil (Viagra) and political priorities over the use of funds.

A second significant change concerned the status of NICE guidance. From 1 January 2002, Directions to Health Authorities, Primary Care Trusts and NHS Trusts in England<sup>34</sup> required Health Authorities to fund interventions recommended by NICE Technology Appraisal Guidance, and prescribed by a doctor or otherwise recommended in the course of treatment, within three months of the Guidance being issued. Primary Care Trusts, and NHS Trusts, for their part, were required to apply funds received from Health Authorities in accordance with this obligation. This followed concern that certain NHS organisations had decided not to follow NICE guidance on various matters. For example, the largest PCT, Hillingdon, rejected NICE guidance on cardiac care, while in a widely publicised move,

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<sup>32</sup> See for example H.C. Session 1998-1999, Third Standing Committee on Delegated Legislation, Wednesday 10 March 1999 (Mr Philip Hammond): “Like a sneak thief, the Government—having given Opposition Members all the reassurances that they reasonably could in Committee on the Health Bill and in the debates on the NICE regulations—went away over the summer saying nothing about their intentions. They waited until everyone had gone on holiday... to lay a regulation on 6 August that fundamentally changed the nature of the National Institute for Clinical Excellence.”

<sup>33</sup> Discussed at Section 5.2.3, above.

<sup>34</sup> Directions to Health Authorities, Primary Care Trusts and NHS Trusts in England, 11 December 2001. See also Kmietowicz (2001). “Government Insists NHS Pays For Drugs Approved By NICE.” *BMJ* 323: 1386, 15 December 2001.

a mid-Devon PCT rejected NICE's technology appraisal of zanamivir (Relenza).<sup>35</sup>

Further changes followed *Learning from Bristol*, the Report of the Kennedy Inquiry into paediatric cardiac surgery at Bristol Royal Infirmary (although the government did not accept the recommendations of the Kennedy Inquiry in full) as well as the Health Committee report into the National Institute for Clinical Excellence<sup>36</sup> Most importantly, from the end of 2002, changes were made to the process by which topics were selected for NICE appraisal, intended to make the process more open and transparent.<sup>37</sup> A second set of amendments changed the membership of NICE Board, removing the requirement of the Secretary of State to appoint the Chief Officer.<sup>38</sup>

Other significant changes included the assumption of responsibility for appraising whether 'interventional procedures', that is, procedures undertaken by surgeons and other specialists for the diagnosis and treatment of patients were safe enough for routine use within the NHS.<sup>39</sup> An

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<sup>35</sup> See further Section 6.4, *infra*.

<sup>36</sup> Kennedy (Chairman) (2001) *Learning From Bristol: The Report of the Public Inquiry into Childrens Heart Surgery at the Bristol Royal Infirmary 1984-1995*, London, The Stationery Office. ; House of Commons Health Committee (2002) *National Institute for Clinical Excellence: Second Report of 2001-02*, HC 515-I, London, The Stationery Office. The government's response to the Kennedy Report can be found in Secretary of State for Health (2002) *Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*, Cm 5363, London, The Stationery Office.

<sup>37</sup> Department of Health (2002) *National Institute for Clinical Excellence: Arrangements for Topic Selection*, London, Department of Health.

<sup>38</sup> The National Institute for Clinical Excellence (Amendment) Regulations 2002. S.I. No. 1759 of 2002, Regulation 2.

<sup>39</sup> The Interventional Procedures Programme: Working with the National Institute for Clinical Excellence to promote safe clinical intervention, HSC

Interventional Procedures Advisory Committee of NICE was established within NICE (chaired by Professor Bruce Campbell) to replace the existing Safety and Efficacy Register for New Interventional Procedures (SERNIP), an initiative of the Royal Colleges. A further committee of NICE, the Citizens' Council was established in 2004, based on the model of the citizens' juries polled by the King's Fund, to advise NICE on social value judgements.<sup>40</sup>

## 6.4 Technology Appraisals of Zanamivir and Beta Interferon

An examination of two controversial NICE technology appraisals, of zanamivir (Relenza), an anti-viral inhaler for the treatment of influenza, and beta interferon for multiple sclerosis provides further insight into the ability of NICE to sustain credible commitment. It is important to note that these are not intended as 'representative' examples; rather, by selecting episodes in which the credibility of the Institute was questioned, these examples help to illustrate the limits of institutional commitment engendered by NICE's governance structure.

### 6.4.1 Zanamivir (Relenza)

Zanamivir (Relenza) was included in the first NICE work programme. While a full technology appraisal, lasting around eight months was underway, a 'fast-track' assessment was conducted, in order that interim NICE guidance was available in advance of the 1999-2000 'flu season. The

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2003/011; see also Campbell and Maddern (2003). "Safety And Efficacy of Interventional Procedures." *BMJ* 326: 347-8.

<sup>40</sup> Rawlins and Culyer (2004). "National Institute for Clinical Excellence and its Value Judgements." *Ibid.* 329: 224-7.

specially created Rapid Assessment Committee, chaired by NICE Chief Executive Andrew Dillon, made the recommendation (which was leaked to the press) that for 1999-2000, zanamivir (Relenza) should not be prescribed. After an internal appeal to NICE Board by the manufacturer failed,<sup>41</sup> NICE made a final recommendation against use of the drug in the treatment of influenza. This recommendation received the endorsement of the Secretary of State, allowing NICE to issue its guidance to the NHS. NICE's decision was based on findings that for the population at large, the use of zanamivir (Relenza) within 48 hours of the onset of influenza symptoms, reduced the median duration of symptoms from six to five days, while the Institute was unable to conclude "... that the product reduces the frequency of serious secondary complications..." for 'at risk' patients (including the elderly, those with cardiovascular disease, asthma, chronic obstructive pulmonary disease or immunosuppression).<sup>42</sup> No explicit cost-effectiveness analysis was undertaken. However, the Rapid Appraisal Committee did undertake an analysis of the resource implications, tentatively estimating a cost of between £9.9 million in a 'normal' year, rising to £15 million in an epidemic if zanamivir was to be freely available, while finding insufficient support for the manufacturer's claim that there was a corresponding benefit that patients taking zanamivir could return to work sooner.<sup>43</sup>

NICE's decision was supported by the Royal College of General Practitioners, who argued in favour of increased immunisation against influenza for at risk groups. However, the profession and the pharmaceutical

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<sup>41</sup> Anonymous (1999). "NICE Rejects Glaxo Wellcome Appeal Against Relenza NHS Ban." *The Pharmaceutical Journal* 263 (7066): 561, 9 October 1999.

<sup>42</sup> National Institute for Clinical Excellence (1999) *Rapid Assessment - Zanamivir (Relenza)*, London, National Institute for Clinical Excellence, 12 October 1999. , para. 6.2.

<sup>43</sup> *Ibid.* , para. 6.4.

industry challenged it on different fronts. The BMA General Practitioners Committee criticised the failure to give the NICE ruling legislative force, by placing zanamivir (Relenza) on the Schedule 10 black list, lamenting that this would make it difficult for GPs to adhere to the recommendation in the face of pressure from patients.<sup>44</sup> The manufacturer warned that pharmaceutical companies would go elsewhere if the UK environment became "antagonistic" to the industry, while rumours of a drawn-out legal challenge to the Institute circulated in the press.<sup>45</sup>

Following a full appraisal, the interim guidance was revised in November 2000. While zanamivir was still not recommended for general use, under the revised guidance it was recommended for at risk adults presenting within 36 hours of developing symptoms, when influenza is circulating in the community (i.e. when there are more than 50 cases per 100,000 GP consultations as determined by a reporting system operated by the Royal College of General Practitioners). This change was ostensibly based on new research by the manufacturers which showed an average reduction in the duration of flu symptoms in at risk patients by 1.2 days, from six to five days, with a 6% reduction in complications requiring the use of antibiotics.<sup>46</sup> This new evidence was controversial, because it was not made public until some time after the new guidance was issued, ostensibly on the grounds of commercial confidentiality. The Appraisal Committee relied on an economic model which suggested an incremental cost per

<sup>44</sup>Yamey (1999). "Dobson Backed NICE Ruling on Flu Drug." *BMJ* 319: 1024, 16 October 1999.

<sup>45</sup> See for Example, *The Guardian*, "Anti-Flu Drug Relenza Rejected for NHS, *The Guardian*, 2 October, 1999; *The Guardian*, "Dobson Rejects Flu Drug Despite Threats" 8 October 1999.

<sup>46</sup> National Institute for Clinical Excellence (2000) *Guidance on the Use of Zanamivir (Relenza) in the Treatment of Influenza*, London, National Institute for Clinical Excellence, November 2000. ; O'Neale Roache (2000). "NICE Recommends Flu Drug For "At Risk" Patients." *BMJ* 321: 1305, 25 November 2000.

QALY of £38,000 for adults when influenza is circulating, while for at risk adults, it estimated an incremental cost per QALY of between £9,300 and £31,000 when influenza is circulating.<sup>47</sup>

As noted in passing in Section 6.3.3 NICE's final guidance was rejected by a mid-Devon PCG representing some 70 GPs in twenty practices. In support of this decision they cited the poor evidence base of the NICE recommendation, the erosion of their clinical responsibility, the high cost of the drug as well concern at the recommendation that Relenza was to be prescribed by nurses and GPs based on generalised GP supervision, given also particular difficulties in the diagnosis of influenza.<sup>48</sup> Though warned of the likelihood of adverse consequences by Sir Michael Rawlins, and by the Department of Health, their position was given credibility by the *Drug and Therapeutics Bulletin*. The *Bulletin*, a highly regarded independent publication of the Consumers' Association, edited by Professor George Collier of St George's Hospital Medical School, advised that there was still insufficient proof that zanamivir was effective in the treatment of at risk patients and that claims that the product prevented serious complications were unfounded.<sup>49</sup> Furthermore, it was warned that the drug may have adverse effects in patients suffering from asthma or lung disease.<sup>50</sup> This latter point was reinforced by a product warning issued by Glaxo Wellcome that zanamivir (Relenza) could cause bronchospasm and

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<sup>47</sup> National Institute for Clinical Excellence (2000) *Guidance on the Use of Zanamivir (Relenza) in the Treatment of Influenza*, London, National Institute for Clinical Excellence, November 2000. , para. 4.2.

<sup>48</sup> *The Observer*, "GPs Warned as They Snub Advice on Anti-Flu Drug", December 10, 2000; *The Guardian*, "GPs Rebel Against Flu Drug Advice", 11 December 2000.

<sup>49</sup> Anonymous (2001). "Why Not Zanamivir?" *Drug & Therapeutics Bulletin* 39: 9-10.

<sup>50</sup> *Ibid.*

serious respiratory deterioration, and advising special caution when treating patients with asthma or chronic obstructive pulmonary disease.<sup>51</sup>

#### 6.4.2 Beta Interferon

The treatment of beta interferon by NICE and the Department of Health has already attracted attention within the regulatory state literature.<sup>52</sup> Beta interferon drugs had been introduced in the mid-1990s, amid fears that, at a cost of £10,000 per patient per year, the treatment could absorb as much as 10 per cent of the NHS drugs budget, were it made available to all patients with the relapsing and remitting form of multiple sclerosis.<sup>53</sup> Guidance was issued at the time by the NHS Executive, under which only consultant neurologists were able to prescribe interferon drugs to patients, when referred by their GP according to a referral protocol. Health Authorities were required to make provision to fund treatment in accordance with the guidance. Following the decision by a number of Health Authorities not to fund beta interferons in defiance of the NHS Management Executive, a legal challenge was successfully brought against one such authority, in the case of *R. v. North Derbyshire HA, ex p. Fisher*.<sup>54</sup>

It was in the context of this controversy that the appraisal of beta interferon drugs was included in NICE's first work programme in August 1999. After lengthy consultations with manufacturers, patient groups and professional bodies, and having commissioned a review of the published

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<sup>51</sup> Yamey (2000). "Drug Company Issues Warning About Flu Drugs." *BMJ* 320: 334, 5 February 2000.

<sup>52</sup> Crinson (2004). "The Politics of Regulation Within the 'Modernised NHS: The Case of Beta Interferon and The 'Cost-Effective' Treatment of Multiple Sclerosis." *Critical Social Policy* 24 (1): 30-49.

<sup>53</sup> New (1996). "The Rationing Agenda in the NHS." *British Medical Journal* 312: 1593-601, 22 June 1996.

<sup>54</sup> [1997] 8 Medical Law Reports 327. This case was discussed in Section 4.5.5.

evidence on clinical and cost effectiveness, the Appraisal Committee arrived at a Provisional Appraisal Determination (PAD), recommending that, based on the high cost of the drug and evidence of modest clinical effectiveness, the treatment should not be extended to patients not already receiving beta interferon drugs. The PAD was leaked to the BBC and details were broadcast on the evening News on June 20. The broadcast led to an outcry from the Multiple Sclerosis (MS) Society, which accused NICE of being "...uncooperative, uncommunicative and biased towards health economic data..." and for treating "...patients, support groups and pharmaceutical companies with disdain".<sup>55</sup> The Appraisal Committee was apparently unmoved at this criticism, and arrived at a Final Appraisal Determination (FAD) on 27 July 2000, and draft guidance was circulated.

Eight internal appeals were lodged, from manufacturers, patient groups including the MS Society and professional bodies including the Association of British Neurologists and the Royal College of Nursing. The appeals were upheld in part on the grounds of failure to give sufficient notice of consultation to the MS Society, failure to explain the basis on which the drugs were found not to be cost-effective, and failure to give adequate weight to long-term benefits of beta interferon.<sup>56</sup> NICE then asked the Appraisal Committee to reconsider the evidence, and also to consider new economic evidence submitted by Schering, one of the manufacturers, during the appeal hearing. On 13 December the Appraisal Committee reiterated their original view that beta interferon (and now glatiramer acetate) was not cost-effective. However, the Committee expressed serious

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<sup>55</sup> Kmietowicz (2000). "NICE's appraisal procedures attacked." *BMJ* 321: 980, 21 October 2000.

<sup>56</sup> National Institute for Clinical Excellence (2000) *Appraisal of the Use of Beta Interferons in the Treatment of Multiple Sclerosis - Decision of the Appeal Panel*, London, NICE, 8 November 2000. ; Dobson (2000). "NICE to Reconsider Evidence on Interferon Beta." *BMJ* 321: 1244, 18 November 2000.

reservations about the economic models which they had considered. On the basis of these reservations, NICE agreed to an extension of the timetable for appraisal, in order to commission new economic modelling (which was expected to take around five months). After further consultation, the Appraisal Committee met again on 26 July 2001 and a new PAD was issued on 4 August, and a FAD was issued on 30<sup>th</sup> October. The new economic model, which used additional clinical data supplied by Schering and Biogen, estimated a cost per QALY gained of upwards of £35,000 and on this basis recommended against the use of beta interferon and glatiramer acetate.

Seven appeals were again lodged, this time unsuccessfully, against the FAD.<sup>57</sup> NICE guidance recommending that neither beta interferon nor glatiramer acetate should be made available to new patients was finally published in January 2002.<sup>58</sup> However, parallel developments had by this time overtaken NICE's decision. Since November 2001, the Department of Health had been in negotiations with manufacturers of beta interferon drugs and with patient groups to make the treatment available.<sup>59</sup> Negotiations centred around the idea of a risk-sharing scheme, under which the drugs would be funded for patients with relapsing and remitting multiple sclerosis on the basis of a 'sliding scale'. Under an agreement arrived at by these various parties, the NHS would fund for treatment to be prescribed by a consultant neurologist, while an ongoing study of patients prescribed the drugs would provide additional data against which cost-effectiveness could

<sup>57</sup> National Institute for Clinical Excellence (2002) *Appeal of the Use of Beta Interferons in the Treatment of Multiple Sclerosis*, London, NICE, 25 January 2002. .

<sup>58</sup> National Institute for Clinical Excellence (2002) *Beta Interferon and Glatiramer Acetate for the Treatment of Multiple Sclerosis*, Technology Appraisal No. 42, London, NICE, January 2002. .

<sup>59</sup> Mayor (2001). "Health Department to Fund Interferon Beta Despite Institute's Ruling." *BMJ* 323: 1087, 10 November 2001.

be assessed. If treatment proved to be less effective than expected, the cost of drugs would be adjusted, and sums refunded to the NHS.<sup>60</sup> Around 10,000 patients were expected to receive treatment under the scheme, at a cost of £6000-£9000 per patient per year.<sup>61</sup> The scheme was nonetheless criticised for undermining the authority of the Institute.<sup>62</sup> As a result of the risk-sharing agreement, NICE's guidance on beta interferon and glatiramer acetate was not approved by the Secretary of State.

## 6.5 Effectiveness of NICE

In assessing the effectiveness of NICE, it must first be noted that those involved with the establishment of the Institute had high expectations for it (I7, I8, I14, I15, I19). Moreover, NICE was the focus of the hopes of many within the NHS who may also have had competing expectations of the Institute. For example, some saw it as a champion of evidence based medicine,<sup>63</sup> while others, accepting rationing as inevitable, were disappointed in their assessment of the extent to which they thought the Institute was leading to a more rational approach.<sup>64</sup>

There were three main 'official' assessments of NICE during the period under examination. First, *Learning from Bristol*, the Report of the Kennedy Inquiry looked into the work of NICE, as part of an assessment of

<sup>60</sup> For a critical account, see Sudlow and Counsell (2003). "Problems With UK Government's Risk Sharing Scheme For Assessing Drugs For Multiple Sclerosis." *Ibid.* 326: 388-392.

<sup>61</sup> Little (2002). "NHS to Fund Treatment for 10,000 Patients With MS." *Ibid.* 324: 316, 9 February 2002.

<sup>62</sup> Mayor (2001). "Health Department to Fund Interferon Beta Despite Institute's Ruling." *Ibid.* 323: 1087, 10 November 2001.

<sup>63</sup> Sculpher, Drummond and O'Brien *Ibid.* "Effectiveness, Efficiency and NICE." 322: 943-944, 21 April 2001.

<sup>64</sup> Smith (1999). "NICE: A Panacea for the NHS?" *Ibid.* 318: 823-4, 27 March 1999.

leadership and of appropriate standards of care in the NHS.<sup>65</sup> Second, the Health Committee of the House of Commons undertook a detailed investigation into NICE during the 2001-2002 parliamentary session.<sup>66</sup> Finally, following the Health Committee's criticisms of NICE, the institute invited the World Health Organisation (WHO) to undertake an evaluation of the scientific validity of NICE's technology appraisal process.<sup>67</sup> All of these sources were broadly favourable to NICE, to a greater or lesser extent finding criticism of particular aspects of the work of the Institute. These 'official' views are supplemented here by a consideration of the conclusions of the relevant professional medical literature.

The Report of the Kennedy Inquiry focussed mainly on the institutions of regulation inside the NHS, and their relation to patient confidence. *Learning from Bristol* argued for a clear separation between the Department of Health, as the headquarters of the NHS, and bodies, including NICE, whose role was in relation to the regulation of health care. With respect to the latter, regulatory function, the proper role of the Department of was restricted to establishing the framework for regulation.<sup>68</sup> Accordingly, the report emphasised the need to strengthen the independence of NICE, noting the close involvement of the Department of Health in developing guidance for the NHS.<sup>69</sup> The Inquiry criticised the insufficient co-ordination of standards produced by a variety of bodies, which it claimed

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<sup>65</sup> Kennedy (Chairman), op. cit., note 36, chapters 24 and 27.

<sup>66</sup> House of Commons Health Committee, op. cit., note 36.

<sup>67</sup> WHO (2003) *Technology Appraisal Programme of the National Institute of Clinical Excellence: A Review by WHO*, Ref. no. 5045738, Copenhagen, WHO Regional Office for Europe.

<sup>68</sup> *Learning from Bristol*, Chapter 24, paras. 34-46.

<sup>69</sup> *Ibid.* Chapter 24, para. 39.

created the potential for confusion.<sup>70</sup> Furthermore, there were inadequate mechanisms to enforce the observation of NICE guidance.<sup>71</sup>

The report of the Health Select Committee welcomed the introduction of NICE, as did the majority of those submitting evidence to it. Nonetheless, it found evidence both of under- and over- implementation of NICE guidance.<sup>72</sup> It was claimed on the one hand that NICE had struggled to establish pre-eminence over other, more established sources, such as the Consumer Association's Drug and Therapeutics Bulletin, and that there was insufficient collaboration between different authorities on clinical effectiveness.<sup>73</sup> It was also argued that implementation of NICE guidance was given a low priority by some, given other targets, such as those relating to emergency care. In this context, it was suggested that guidance from the Secretary of State requiring Health Authorities fund treatments within three months of approval by NICE had the reverse effect of diverting resources away from other treatments, thus making treatment more inconsistent.<sup>74</sup> Furthermore, evidence to the Health Committee raised concerns highly pertinent to the approach of this thesis. In evidence to the House of Commons Health Committee Dr Deirdre Cunningham expressed succinctly the problem of bureaucratic drift: "NICE was set up to give robust guidance on the basis of evidence, and it appears now to be almost being asked to do

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<sup>70</sup> *Ibid.*, Chapter 27, paras. 14-16,

<sup>71</sup> *Ibid.*, Chapter 24, para. 42; Chapter 27, para. 29-30.

<sup>72</sup> House of Commons Health Committee (2002) *National Institute for Clinical Excellence*, HC 515-I Session 2001-02, London, The Stationery Office, paras. 70-76.

<sup>73</sup> *Ibid.*

<sup>74</sup> {House of Commons Health Committee, 2002 #19@paras. 60-67}; see also Burke (2002). "NICE May Fail to Stop "Postcode Prescribing," MPs Told." *BMJ* 324: 191, 26 January 2002; Burke (2002). "No Cash to Implement NICE, Health Authorities Tell MPs." *BMJ* 324: 258, 2 February 2002.

resource allocation by the Department of Health.”<sup>75</sup> Similarly, the North Liverpool Primary Care Trust submitted that in comparison to rival sources of information, “NICE is widely viewed as pursuing a political agenda at the expense of clinical credibility.”<sup>76</sup>

By contrast, WHO was upbeat about NICE’s technology appraisal process, delivering what has been described as a “ringing endorsement”, despite numerous recommendations suggestions for its strengthening.<sup>77</sup> The Institute was praised for its “commitment to the use of rigorous methodology throughout the [technology appraisal] process”.<sup>78</sup> The review concluded that, “in only four years, NICE has developed a well-deserved reputation for innovation and methodological development that represents an important model for technology appraisals internationally.”<sup>79</sup>

At the same time, there was evidence that NICE guidance had not always been systematically implemented. A study by Sheldon *et al.* suggested that the Institute had led to faster uptake of some technologies, such as taxanes for cancer and orlistat for obesity, but that implementation had been variable overall.<sup>80</sup> Similarly, a study by Wathen and Dean examined the impact of NICE guidance on GP prescribing and found that

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<sup>75</sup> House of Commons Health Committee (2002) *National Institute for Clinical Excellence*, HC 515-II Session 2001-02, London, The Stationery Office.

<sup>76</sup> *Ibid.*, Ev. 68.

<sup>77</sup> Devlin, Parkin and Gold (2003). “WHO Evaluates NICE.” *BMJ* 327: 1061-2, 8 November 2003.

<sup>78</sup> WHO (2003) *Technology Appraisal Programme of the National Institute of Clinical Excellence: A Review by WHO*, Ref. no. 5045738, Copenhagen, WHO Regional Office for Europe.

<sup>79</sup> *Ibid.*

<sup>80</sup> Sheldon, Cullum, Dawson, Lankshear, Lowson, Watt, West, Wright and Wright (2004). “What’s The Evidence That NICE Guidance Has Been Implemented? Results From a National Evaluation Using Time Series Analysis, Audit of Patients’ Notes, and Interviews.” *BMJ* 329: 999-1004, 30 October 2004.

NICE guidance, in isolation, had negligible impact on prescribing patterns, although where recommendations coincided with other sources or practical experience it led to increased prescribing.<sup>81</sup> Furthermore, they reported that NICE guidance on zanamivir (Relenza) had been almost universally rejected, and that this had undermined overall confidence in NICE.<sup>82</sup> Implementation tracking of NICE guidance commissioned by the Institute itself supports this overall conclusion.<sup>83</sup> Although take up of NICE-approved treatments had increased, out of 28 individual pieces of NICE guidance, only 12 were judged by the study to have good compliance. A further 12 sets of guidance were insufficiently acted upon, while the remaining four were 'over-implemented'.<sup>84</sup>

In interpreting the findings of this section, it should be pointed out that, compared with the Limited List scheme discussed in the previous chapter, as well as with the drug reimbursement policies operated by some other countries such as Australia and New Zealand, the effectiveness of NICE depended much more on active (and from the clinician perspective, largely voluntary) compliance with guidance. The impact of NICE guidance on clinical practice has, according to official evaluation, been somewhat diminished by confusion and lack of co-ordination between NICE and other sources of guidance. Consistent with this, academic studies have pointed to variable rates of implementation with NICE guidance. At the same time,

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<sup>81</sup> Wathen and Dean (2004). "An Evaluation of the Impact of NICE Guidance on GP Prescribing." *British Journal of General Practice* 54: 103-107.

<sup>82</sup> *Ibid.*

<sup>83</sup> Abacus International (2004) *NICE Guidance Implementation Tracking Data Sources, Methodology and Results*, London, NICE, 29 June 2004.

<sup>84</sup> *Ibid.*; White (2004). "NICE Guidance Has Failed To End 'Postcode Prescribing'." *BMJ* 328 29 May 2004.

notwithstanding some sources of dissent,<sup>85</sup> the overall assessment has been, in a broad sense, favourable towards NICE.

## 6.6 Governance, Commitment and NICE

Following the approach of the previous chapter, this section attempts to assess the extent to which the governance structure of NICE provided for credible commitment, applying the modified version of Levy and Spiller's three-level framework of analysis set out in Section 4.5. Section 6.6.1 deals with substantive written restraints on the discretion of NICE. Section 6.6.2 looks at the effectiveness of restraints based on structure and process. Section 6.6.3 looks at the constraints on changing the regulatory system, while Section 6.6.4 deals with the institutions for enforcing these lower-level commitment mechanisms. On the basis of this analysis, it is argued that the governance structure of NICE was relatively credible, based primarily on structural and procedural restraints, though the analysis also identifies some institutional weaknesses.

### 6.6.1 Substantive Written Restraints

As discussed in Section 6.3.2, NICE was established as a Special Health Authority, that is, in exercise of the Secretary of State's power under S. 11 of the National Health Service Act 1977 to establish special bodies "...for the purpose of performing any functions which he may direct the body to perform on his behalf..."<sup>86</sup> Although formally separate from the Department of Health, the Institute was nonetheless subject to the direction of the Secretary of State, and (in Wales) the Welsh Assembly. The original

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<sup>85</sup> For example Smith (2000). "The Failings of NICE." *BMJ* 321: 1363-4, 2 December 2000.

<sup>86</sup> National Health Service Act 1977 Section 11 (1).

delegation of functions to the institute was extremely broad, and was broadened still further by S.I No 2219 of 1999. This extension of power rectified the anomaly that while from its inception in the White Paper, NICE had been intended to have a role in promoting cost- as well as clinical effectiveness. However the precise choice of the words, "effective use of available resources" was, as discussed, apparently broader than necessary to correct this anomaly, and can therefore be interpreted as an initial instance of coalitional drift, opening up the possibility that NICE might rule on the affordability, as distinct from the cost-effectiveness of expensive treatment.

The substantive breadth discretionary authority can be gauged by the technology appraisals of zanamir and beta interferon, discussed in Section 6.4. In the former case, the fast track appraisal recommendation, that zanamivir should not be used in the treatment of influenza, was based not on an explicit cost-effectiveness analysis, but on an assessment of the overall resource implications of making the treatment generally available. In the case of beta interferons and glatiramer, NICE's recommendation against the use of the treatment was in effect (without implying that this was part of a 'master plan') the opening gambit in negotiations between the Department of Health and the manufacturers to make the drug available at a lower (and risk-adjusted) price. These two appraisals, and surrounding events led to suggestions (denied by NICE) that the Government and the Institute were applying an upper limit of £30,000 per QALY on NHS-funded treatments.<sup>87</sup> The point here is that the legal framework within which NICE was operating was sufficiently flexible to accommodate these developments. It therefore seems highly plausible to suppose that the absence of significant

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<sup>87</sup> Mayor (2001). "Health Department to Fund Interferon Beta Despite Institute's Ruling." *BMJ* 323: 1087, 10 November 2001; House of Commons Health Committee (2002) *National Institute for Clinical Excellence*, HC 515-I Session 2001-02, London, The Stationery Office, para. 103.

substantive written restraints, and especially the broad scope of the amendment of S.I. No. 2219 of 1999 contributed substantially to the belief (especially among Members of Parliament) that NICE had been established with cost-containment as a primary objective.

### **6.6.2 Restraints Based on Structure and Process**

By contrast, structure- and process-based restraints played a relatively important role in restraining the arbitrary exercise of discretionary powers on the part of NICE and the Department of Health. As a Special Health Authority, NICE was intended to operate at “arm’s length” from the Department of Health, although it remained “accountable to the Secretary of State.”<sup>88</sup> This organisational separation between NICE and the Department of Health focuses attention on the allocation of agenda-setting and veto power between them. The extent of competition between NICE guidance and that of other organisations, the kind of expertise possessed by the agency and the extent to which different interests were enfranchised within the decision-making process are in addition relevant to an assessment of the restraints on arbitrary action.

In Directions to the National Institute for Clinical Excellence, the Secretary of State gave himself substantial agenda-setting as well as veto power over decisions of NICE. Direction 2 (1) (a)-(c) provided for the Institute to produce guidance on such topics “as may be notified by the Secretary of State or the National Assembly for Wales.” By Direction 2 (1) (d) the Institute is directed to disseminate guidance, “subject to the approval of the Secretary of State and the National Assembly for Wales”. By Direction 2 (2) the Institute could exercise its own initiative to endorse

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<sup>88</sup> Department of Health (1998) *A First Class Service: Quality in the New NHS*, HSC 1998/113, London, Department of Health, para. 2.29.

guidance produced by bodies other than NICE itself, and to develop clinical audit methodologies, but again this was “subject to the approval of the Secretary of State and the National Assembly for Wales.” The Government accepted the recommendation of the Kennedy Report in favour of removing the requirement of approval from the Secretary of State and the Welsh Assembly for disseminating NICE guidance.<sup>89</sup> No revisions to the Directions had been made during the period under examination. Furthermore, there was initially a perception that the process of topic selection was not transparent, leading some to advocate that NICE should be empowered to determine its own work programme.<sup>90</sup> The government rejected this proposal, but published a consultation document suggesting ways in which the process could be opened out to wider consultation.<sup>91</sup>

In terms of inter-agency competition, there was (formally, at least) initially no requirement that Health Service Organisations should adhere to NICE guidance. To this extent, NICE was effectively in competition with other organisation producing clinical guidance. This, it can be argued, was a significant restraint on the discretion of NICE to the extent that it required NICE to develop guidance that would serve the needs of the users, if it was to be accepted. An example of competition between rival guidance was given in Section 6.4.1. As discussed in that section, a Devon PCG prominently rejected NICE’s final guidance on zanamivir, relying instead

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<sup>89</sup> Secretary of State for Health (2002) *Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*, Cm 5363, London, The Stationery Office.

<sup>90</sup> House of Commons Health Committee (2002) *National Institute for Clinical Excellence*, HC 515-I Session 2001-02, London, The Stationery Office. , paras. 117-118.

<sup>91</sup> Department of Health/ National Assembly for Wales (2002) *Clinical Guidance from the National Institute for Clinical Excellence - Timing and Selection of Topics for Appraisal*, London, Department of Health/National Assembly for Wales.

on the recommendations of the *Drug and Therapeutics Bulletin*. In the light of this analysis, the Secretary of State's Directions to Health Authorities, Primary Care Trusts and NHS Trusts, requiring Health Authorities to fund NICE-approved treatments, and requiring NHS Trusts and PCTs to apply funds received from Health Authorities in accordance with this obligation, takes on special significance. By this measure, NICE in effect acquired greater latitude to develop guidance at variance from that sought by clinicians.

As the discussion has observed, NICE incorporated considerable clinical and latterly economic expertise. Quite apart from the legitimating function of this "technocratic fix" discussed by Syrett,<sup>92</sup> this emphasis on technocratic expertise may have contributed to the effectiveness of NICE's governance structure, committing the Institute to reaching its decisions in accordance with technocratic procedures and values. Following the arguments of Moshe Maor<sup>93</sup> (whose contribution is discussed in Section 6.2) it could be argued that embedding the 'gold standard' of evidence-based medicine, with its accepted modes of argument and its acknowledged hierarchy of evidence, into the decision-making framework of NICE, time-inconsistencies were more transparent, and therefore subject to criticism and rebuke. As discussed in Section 6.5, following initial doubts raised by the House of Commons Health Committee, NICE was praised by WHO for its methodological rigour, which was impressive by any standard, despite alleged lapses. The decision of the Department of Health to reject NICE's appraisal of beta interferon and glatiramer acetate and instead to agree a lower (and risk-adjusted) price with the manufacturers was interpreted by

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<sup>92</sup> See Section 6.2, above.

<sup>93</sup> Maor (2004). "Competing Commitments? Independence versus "gold standard" for policy choice in the reimbursement of pharmaceutical drugs". 20th Anniversary SOG Research Committee of the International Political Science Association, Vancouver.

some as a change of policy forced by patient pressure, in spite of weak clinical evidence.<sup>94</sup> But given the procedures of NICE, including its evidence-based standards of evaluation, it was at least transparent, and could be judged on its merits.

As discussed in Section 4.5.3, a key claim of Macey, and of McCubbins, Noll and Weingast is that by selectively enfranchising certain interest groups, agency decision-making procedures can replicate the political environment existing at the time of the creation of a regulatory agency, ensuring that issues arising subsequent to the creation of the agency are decided in the interests of the enacting coalition. Similarly, according to this literature consultation and evidential requirements shape the kind of information on which bureaucrats base their decisions. In addition to the general requirement to "endeavour to conduct its business in an open and transparent manner", the governance structure of NICE incorporated a number of such procedural devices.<sup>95</sup> Foremost among these was NICE's committee structure. This included NICE Partners Council, made up of representatives of different key interest groups, including patient groups and health professionals, which had a formal function of receiving the annual report of the Institute, but operated as a general 'sounding board' for NICE. Furthermore, the processes through which technology appraisals (and other forms of guidance) were produced were designed to facilitate input from interested groups, and this commitment has been strengthened over time. And while patients groups, such as the MS society criticised the process, if the arguments discussed in Section 4.5.3 about administrative structure and

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<sup>94</sup> Mayor (2001). "Health Department to Fund Interferon Beta Despite Institute's Ruling." *BMJ* 323: 1087, 10 November 2001; House of Commons Health Committee (2002) *National Institute for Clinical Excellence*, HC 515-I Session 2001-02, London, The Stationery Office.

<sup>95</sup> Secretary of State's Directions to the National Institute of Clinical Excellence, S. 2.

process are correct, this could arguably be interpreted less of a democratic deficit than means of establishing credible commitment in the face of high uncertainty.

### **6.6.3 Constraints on System Changes**

Moving to the level of collective choice rules, as discussed in Section 6.3.2, NICE was a special health authority established by statutory instrument. It is not necessary to repeat here the discussion of Section 5.4.3 concerning the procedures for parliamentary scrutiny of delegated legislation under the Statutory Instruments Act 1946. At any rate, following the extension of NICE's functions under S.I. No 2219 of 1999, conferring upon the institute responsibility "for the effective use of available resources", it is difficult to see that the statutory instrument provisions provided any substantive restraints on NICE's regulatory discretion.

In terms of procedural requirements, these were derived partially from statutory instrument, but largely from directions issued by the Secretary of State. By contrast with the provisions for scrutiny of statutory instruments, ministerial directions, which as we have seen were concerned mainly with process-based restraints, could have been introduced without any 'laying' requirement or any other formal process for notifying changes to Parliament; nor was there any well-established Westminster-based scrutiny procedure, equivalent to the work of the Standing Committee on Delegated Legislation with respect to statutory instruments. The National Institute for Clinical Excellence (Establishment and Constitution) Order, S.I. No. 220 of 1999 was described as:

...an empty piece of secondary legislation, with the meat to be put on it by directions from the Secretary of State that will not be subject to any form of parliamentary scrutiny.<sup>96</sup>

While these criticisms have some force, it is also worth noting that under devolution arrangements, directions were agreed jointly by the Secretary of State for Wales and by the National Assembly for Wales. To some extent, what was absent in Westminster, in terms of restraints on changing the regulatory system through directions issued by the Secretary of State, may have been provided in Cardiff. Furthermore, the necessity of obtaining the consent of both bodies (the Department of Health and the Welsh Assembly) may therefore have provided a degree of restraint against arbitrary system-changes.

Moving to a discussion of informal institutions, in Section 4.5.4 it was suggested, following Spiller and Vogelsang, that the British convention that major policy changes are preceded by the publication of a government White Paper served to discourage rapid policy changes without prior consultation with affected parties. At the same time, it was noted in Section 5.4.3 that in the case of the Limited List, the scheme was implemented, extended, and the ACD 'stood down' and later dissolved, all without recourse to a White Paper. In the present case, the establishment of NICE was preceded with the publication both of a White Paper as well as the consultation document on quality, *A First Class Service*, and a further consultation paper *Faster Access to Modern Treatment*, which specifically dealt with NICE's technology appraisal function. At the same time, the

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<sup>96</sup> Third Standing Committee on Delegated Legislation 1998-99, 10 March 1999 (Mr Phillip Hammond).

White Paper outlined a role for NICE only in terms of clinical guidelines and clinical audit methodologies; the more controversial technology appraisal role was gradually revealed in *A First Class Service*, and concretised in *Faster Access to Modern Treatment*, albeit still providing opportunity for affected parties to make their views known. Adherence with such norms of publicity did not however prevent a number of drafting anomalies in the relevant statutory instruments. These included not only the lack of authority to consider cost-effectiveness discussed in Section 6.3.2, but also included failures to correctly cite the authority under which the delegated power was exercised.<sup>97</sup> Similarly, although the initial Directions to the National Institute for Clinical Excellence were not made the basis of a broad consultation, proposals to amend the Directions were announced in the relatively high-profile Government's response to the Report of the Kennedy Inquiry.

#### **6.6.4 Enforcement of Lower Level Commitment Mechanisms**

The constitutional level of analysis looks at the broader legislative, judicial and executive institutions within which regulatory reforms are embedded. Taking first the legislative institutions, the role of Parliament in enforcing restraints was further limited by the fact that the Government declined to enshrine the functions of NICE in legislation. As discussed in Section 6.3.1, this led to accusations that the Government was trying to avoid the scrutiny accorded to the legislation, as well as to suggestions that NICE was being set up in such a way as to allow it, further down the line, to divert responsibility for decisions on the affordability of treatments away from the government. The decision to avoid the use of primary legislation certainly

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<sup>97</sup> Corrected by the National Institute for Clinical Excellence (Amendment) Regulations, S.I. No. 2218 of 1999.

made it easier for the Government to expand the Institute's responsibility to include "the effective use of available resources", notwithstanding scrutiny of the relevant delegated legislation. This amendment, it will be recalled, had been introduced during the 1999 summer recess, amid accusations that the Government was attempting to evade accountability for reneging on undertakings that NICE would not be involved in resource allocation decisions. It is worth stressing, however, that if evading Parliamentary scrutiny had been the intention for the timing of the amendment, it failed spectacularly, since the Standing Committee on Delegated Legislation took time to debate the provisions in detail.

An examination of the relevant instruments seems to indicate that they did not provide a substantial role for the judiciary in ensuring that NICE remained true to its original purposes, other than through the enforcement of proper procedures. The role of the judiciary was however not tested during the period under investigation, though pharmaceutical companies did on occasion threaten legal action against the Institute. Legal challenge from pharmaceutical companies is most foreseeable as part of an attempt to overturn a decision by NICE not to recommend a treatment. This may not always have been in what the medical profession perceived to be its best interests. The zanamivir (Relenza) episode provided an illustration of this, in that the 'fast-track' appraisal was attacked by the manufacturers for being too restrictive, and by the BMA general practitioner committee for being not strict enough—they wanted zanamivir black-listed under Schedule 10 in order to alleviate pressure on GPs from patients to provide the product.

The role of executive institutions in enforcing restraints on system changes is particularly important in the present case, given the emphasis on regulatory processes and structures to provide the necessary credibility. This

effectiveness of executive institutions depends, in turn, on the existence of a strong bureaucracy. Wade and Forsyth note the UK Civil Service's "combination of executive ability with political neutrality."<sup>98</sup> While with regard to departments of central government, it was long held that Crown servants are not the delegate but the *alter ego* of the Secretary of State,<sup>99</sup> this of course does not apply to statutory authorities such as NICE, which is *independent* as well as neutral. This follows a longstanding use of stand-alone national organisations sponsored by the Department of Health undertaking a variety of executive functions.<sup>100</sup>

Again, because of the substantial powers of the Secretary of State and Welsh Assembly with respect to determining NICE's programme of work, and approving its guidance for dissemination, full use was not made of this mechanism. The extensive powers the Secretary of State enjoyed over the personnel of NICE is relevant in this regard. These included the power to appoint the Chairman as well as non-officer members of NICE Board.<sup>101</sup> The chief officer was appointed by the Institute, but subject to the approval of the Secretary of State.<sup>102</sup> As an opposition member of the Standing Committee on Delegated Legislation put it, in effect, "the Government [was to] have an in-built majority of five out of eight places on NICE, so that the Secretary of State can, in effect control it."<sup>103</sup> The power to veto appointment initially extended to members of the NICE Partners' Council and NICE Appraisal Committee, although this control

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<sup>98</sup> Wade and Forsyth (2004). *Administrative Law*. 9th Edition, Oxford, Oxford University Press, p. 53.

<sup>99</sup> *R v. Home Secretary ex p. Oladenhinde* [1991] 1 AC 254, at 284.

<sup>100</sup> See for example, Department of Health (2004) *Reconfiguring the Department of Health's Arm's Length Bodies*, London, Department of Health.

<sup>101</sup> S.I. No. 260 of 1999, S. 2 (1).

<sup>102</sup> S.I. No. 260 of 1999, S. 4 (2).

<sup>103</sup> H.C. Session 1998-1999, Third Standing Committee on Delegated Legislation, Wednesday 10 March 1999 (Mr Geoffrey Clifton-Brown).

was subsequently removed in 2002, in response to the recommendations of the Kennedy Report.<sup>104</sup> The level of the Secretary of State's control was diminished somewhat in 2002, with the increase in the size of the Institute<sup>105</sup>, and with the removal of the requirement for the Secretary of State to approve the chief officer of the institute, and to approve the appointment of members of the Partners' Council.<sup>106</sup> Overall, a gradual increase in emphasis on executive institutions to generate credibility can therefore be seen.

## 6.7 Conclusions

The evidence from NICE is broadly in line with the observable implications of the theory put forward in Chapter 4. At the level of operational rules, while NICE was relatively unencumbered by substantive restraints on its regulatory discretion, it benefited from a number of substantive and procedural restraints, which included, most importantly, an embedded 'gold standard' of evidence-based medicine and initially at least, competition between NICE and other sources of guidance.

Procedural arrangements were not in every respect supportive of the credibility of NICE. For example, as discussed in Section 6.6.2, the Department of Health enjoyed substantial agenda-setting and veto power, in terms of control over the work programme of NICE, as well as control over the final decision to disseminate NICE guidance to the NHS. In terms of NICE's work programme, although moves were made in 2002 to make the

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<sup>104</sup> S.I. No. 260 of 1999, S. 9 (3), repealed by the National Institute for Clinical Excellence (Amendment) Regulations, S.I. No. 1759 of 2002, S. 3 (3).

<sup>105</sup> National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 2002. S.I. No. 1759 of 2002.

<sup>106</sup> National Institute for Clinical Excellence (Amendment) Regulations 2002. S.I. No 1760 of 2002.

selection of topics more transparent, and to consult a wider range of interests over the selection of topics, this did not significantly shift control away from the Department of Health comparable with making the Institute responsible for determining its own programme of guideline development and technology appraisals. Similarly, although the Department of Health accepted the recommendations of the Kennedy Inquiry to remove the requirement of the Secretary of State for the dissemination of NICE guidance, the necessary changes in the Directions to the National Institute for Clinical Excellence had not been made by the end of 2004.

At the level of collective choice rules, there were few formal restraints on changes to the regulatory system. Not only was NICE established under delegated legislation rather than by Act of Parliament, but many of the most important constraints were imposed by means of Directions issued by the Secretary of State, which did not require the notification of Parliament. Interestingly, institutional credibility did not seem to be an issue in choosing for NICE the form of a special health authority. In a summary answer obtained under the Freedom of Information Act it was explained that:

There is no prescribed way of assessing the appropriate status for bodies such as NICE... If the body will provide a service to the NHS as a whole, then Special Health Authority status is appropriate... [NICE was established] ...specifically to provide a national resource on behalf of and as part of the NHS.<sup>107</sup>

Furthermore, the Department of Health rejected calls to enshrine NICE in primary legislation. Most prominently, The Kennedy Report recommended that NICE should be reconstituted along the lines of the Food Standards agency (which would have included reconstituting the body under primary

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<sup>107</sup> Freedom of Information Act request for information to the Department of Health, Ref. DE6008103.

legislation).<sup>108</sup> This suggestion was, however, rejected by the Department of Health, which cited its "...wish to minimise the disruption caused by the establishment of new bodies or changes in the existing bodies."<sup>109</sup>

Informal constraints appear to have been relatively more effective. The establishment of NICE was announced in a White Paper, albeit only in the most skeletal terms, and a more substantial discussion paper followed. Other changes, such as those concerning the procedures for selecting topics for appraisal were also subject to consultation in advance. At the same time, incremental changes, such as the Directions under which Health Authorities were required to fund NICE-approved treatments, were not pre-announced in any form of consultation paper.

Finally, at the level of enforcement of these lower level commitment mechanisms, the main instrument was through delegation across tier of executive government. Whatever powers of direction, of agenda setting and of veto power were enjoyed by the Department of Health, NICE was an independent legal entity with its own Board. The significance of this may however have been diminished by significant power of control over appointments on the part of the Secretary of State.

Given this description of the overall institutional arrangements within which NICE undertook its functions, it is consistent with the theory set out in detail in Chapter 4 that evidence of implementation of NICE guidance was varied. As with the discussion of the Limited List scheme discussed in the previous chapter, it is worthwhile to consider how far the

<sup>108</sup> *Learning from Bristol*, Chapter 24, para. 43.

<sup>109</sup> Secretary of State for Health (2002) *Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*, Cm 5363, London, The Stationery Office, para. 4.5.

evidence suggests that the (in the case of NICE, partial) failure to achieve publicly pronounced policy goals can be attributed to a lack of credibility on the part of NICE. There is some evidence, discussed in Section 6.5 suggesting that the perception that NICE was perceived within the NHS as having drifted into a resource allocation role or was pursuing a political agenda. Furthermore, in contrast with the Limited List scheme, the effectiveness of NICE was highly dependent on the willingness of clinicians to implement NICE guidance, and credibility was therefore more clearly connected with effectiveness.

Finally, it is worthwhile to contrast the interpretation put forward in this chapter with the arguments of Syrett, discussed in Section 6.2. Clearly there are many similarities between the two accounts. Both suggest that the institutional arrangements through which clinical guidance is developed is likely to impact on the extent to which guidance is accepted and implemented. But while Syrett presents a sophisticated normative analysis of NICE, it can be argued that the present account provides a superior explanation for the degree of regulatory effectiveness of NICE, on both theoretical and empirical grounds.

First, regulatory legitimacy is a normative assessment and cannot be directly observed. As Baldwin and Cave (on whose framework Syrett relies in the original statement of his views<sup>110</sup>) acknowledge: "Judging the extent to which regulation is legitimate is not to offer a sociological assessment of the actual support that a regulator enjoys...; it is, rather to make an assessment of the legitimacy that a regulatory *deserves*."<sup>111</sup> Second, even

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<sup>110</sup> Syrett (2002). "NICE Work? Rationing, Review and the 'Legitimacy Problem' in the New NHS." *Medical Law Review* 10 (1): 1-27, pp. 7-14.

<sup>111</sup> Baldwin and Cave (1999). *Understanding Regulation: Theory, Strategy and Practice*. Oxford, Oxford University Press, p. 82.

measuring empirical criteria against the normative framework of Baldwin and Cave and others, it may be impossible to assess reliably whether legitimacy has increased, especially where complex trade-offs between different bases of legitimacy are involved. While the present approach is by no means free from this problem (certain reforms may equally enhance some aspects of the governance framework while weakening others), at least in principle, the framework applied here is empirically testable. Thirdly, the present approach is more general than that of Syrett, who develops his account only in the context of NICE. Finally, one of the observable implications of the present approach, not present in Syrett's account, is the mechanisms of bureaucratic and coalitional drift are likely to play a role in relating institutions to any lack of acceptance on the part of clinicians, and this seems to be supported by the evidence.

In conclusion, without claiming that the account offered in this chapter is superior to the work of Syrett as a normative assessment of NICE, taking Syrett's analysis as the leading contending scholarly account, it can be argued that this chapter contributes to the literature by developing a more testable explanatory theory. Insofar as an assessment is possible, it appears that the evidence supports the theory. The performance of NICE fell short of expectations, while the governance structure also was weak in several respects. Furthermore, there is some empirical support for a widespread perception that an absence of credibility was a cause of mixed evidence of compliance.

# Chapter 7

## The Commission for Health Improvement

It must be asked whether CHI is a genuine experiment in quality control which will be sensitive to local operating conditions, or whether it is a tool of central government ideologically committed to central control of professional groups. The answer will not be known for many years, but it is likely to be a mixture of both.<sup>1</sup>

### 7.1 Introduction

This chapter looks in detail at the Commission for Health Improvement (CHI), the independent body which acted as an inspectorate of the NHS from 1999 until 2004, when its functions were transferred to a new Commission for Healthcare Audit and Inspection (CHAI, or 'Healthcare Commission'). The Commission was established ostensibly in response to a perceived crisis in the quality of care in the NHS, following a number of high-profile service failures, most prominently, in paediatric cardiac surgery at the Bristol Royal Infirmary over a decade or so between the mid-1980s and the mid-1990s.

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<sup>1</sup> Power (2000). "The Evolution of the Audit Society, its Politics of Control and the Advent of CHI", in Miles, Hampton and Hurwitz (ed.) *NICE, CHI and the NHS Reforms: Enabling Excellence or Imposing Control?* London, Aesculapius Medical Press., p. 132.

Although hailed by the government as the first independent inspectorate of the NHS,<sup>2</sup> CHI had a number of antecedents. As discussed in Section 3.3.1, the NHS Hospital Advisory Service (HAS), later the Health Advisory Service, was responsible for the inspection of long-stay institutions, until 1997. Further, the Clinical Standards Advisory Group (CSAG), established under Section 62 of the National Health Service and Community Care Act 1990 performed a broadly similar investigative and advisory function, until it was abolished by Section 25 of the Health Act 1999. CHI nonetheless was a more high profile and far-reaching institution than these two bodies.

There are important differences between CHI and the other two episodes of regulatory reform discussed in Chapter 5 and Chapter 6. Unlike the Limited List scheme and NICE, CHI was not involved in assessing which treatments should be provided by the NHS, although CHI did play a role in monitoring compliance with NICE guidance. The establishment of the Commission did not therefore raise issues of bureaucratic and coalitional drift across the boundaries between waste-cutting and rationing, in the way that these other two regulatory reform initiatives did. At the same time, the Commission raised questions of commitment to the implicit concordat in other ways. The quotation by a leading academic accountant at the head of this chapter suggests that there was an initial uncertainty about the role that CHI would play in the NHS, and whether it would lead to increased central control over the profession. As discussed in Section 2.4.2, for Klein, it was the combination of centralised financial power and decentralised clinical power that allowed the implicit concordat to endure. Based on the theory put forward in Chapter 4, the extent to which the governance structure of CHI

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<sup>2</sup> See, for example, Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office. para. 2.29.

restrained the possibility that the Commission might serve as an instrument for centralising clinical power might therefore be thought to be crucial to its effectiveness as a mechanism for quality control. If the theory is correct, then one might additionally expect to observe careful attention paid to the institutional arrangements for CHI. Furthermore, shortcomings of regulatory design would be expected to result in the failure of CHI to achieve its policy objectives.

This chapter is organised as follows. Section 7.2 narrates the history of CHI, recounting its background, establishment, reform and eventual abolition. Section 7.3 examines evidence of CHI's effectiveness, while Section 7.4 applies the framework for analysis set out in Section 4.5 in order to assess the degree of credibility engendered by CHI's governance structure. Section 7.5 then considers the plausibility of the regulatory commitment hypothesis in the light of evidence from CHI, concluding that there is insufficient evidence to provide substantial support for the hypothesis. Despite this absence of support, it is argued that the application of the framework of Chapter 4 to CHI is instructive, raising a number of interesting insights and questions about the development over time of CHI, and also pointing to the limitations of the framework. Furthermore, although the evidence does not support the hypothesis, it is important to stress that nor does it contradict it.

## **7.2 CHI: Origins, Implementation and Reform**

This section sets out the background to CHI, its introduction, reform and eventual replacement by CHAI in the Health and Social Care (Community Health and Standards) Act 2003. Section 7.2.1 looks at the initial proposals for the Commission and the response by the profession and in Parliament. Section 7.2.2 looks at the establishment of CHI by the Health Act 1999 and the related subordinate legislation while Section 7.2.3 describes the reforms of CHI made

by the National Health Service Reform and Health Care Professions Act 2002. Finally Section 7.2.4 looks briefly at the abolition of CHI under the Health and Social Care (Community Health and Standards) Act 2003.

### **7.2.1 The Government's Proposals and the Response of the Profession**

The government's plans for the Commission for Health Improvement were first set out in *The New NHS* White Paper.<sup>3</sup> The purpose of this new body, according to the White Paper, was to "...ensure that the drive for excellence is instilled throughout the NHS..." and to "...offer an independent guarantee that local systems to monitor, assure and improve clinical quality are in place."<sup>4</sup> The proposals were fleshed out in the quality consultation paper, *A First Class Service*.<sup>5</sup> As set out in the consultation paper, the role of the Commission was to be closely related to the government's proposals to establish a system of clinical governance, under which NHS provider organisations were required to put in place and maintain arrangements for improving the quality of the care they provide.<sup>6</sup> CHI was to provide advice and guidance on clinical governance arrangements<sup>7</sup> and to review local arrangements, through a rolling programme of 'clinical governance reviews' of NHS Trusts and PCTs,<sup>8</sup> and to conduct national service reviews on the implementation of NSFs and NICE guidance.<sup>9</sup> In addition, the Commission

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<sup>3</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office.

<sup>4</sup> *Ibid.* para. 7.13.

<sup>5</sup> Department of Health (1998) *A First Class Service: Quality in the New NHS*, HSC 1998/113, London, Department of Health, paras. 4.3-4.45.

<sup>6</sup> *The New NHS* paras 6.12-6.15; *A First Class Service*, paras. 3.2-3.27; Scally and Donaldson (1998). "Clinical Governance and the Drive for Quality Improvement in the New NHS in England." *BMJ* 317: 61-65, 4 July 1998.

<sup>7</sup> *A First Class Service*, paras. 4.8-4.9.

<sup>8</sup> *Ibid.*, paras. 4.10-4.16.

<sup>9</sup> *Ibid.*, paras. 4.17-4.21.

was to have a role in investigating serious or persistent problems.<sup>10</sup> CHI was thus to serve a number of different policy goals:

The Commission for Health Improvement will provide an independent reassurance to patients that effective systems are in place to deliver high quality services throughout the NHS. It will also be able to offer rapid support where there is a need to help local NHS organisations resolve particularly difficult problems. The Commission has an important role in working to reduce variations in services across the NHS through its systematic reviews of services, providing feedback into the National Service Frameworks and its monitoring of the uptake of NICE guidance.<sup>11</sup>

The BMA gave the government's proposals a cautious welcome, "...provided that the Commission adopts a supportive, and not a critical approach."<sup>12</sup> In its comments on the details of the government proposals, the Association was keen to ensure that CHI worked closely with the BMA, and to ensure adequate medical representation among the members of the Commission.

As with NICE, some asserted a hidden agenda on the part of the government. Fears that the establishment of CHI was part of a ploy to shift responsibility for poor performance in the NHS away from the Secretary of State were apparently exacerbated by the fact that CHI's remit focussed on providers and not commissioners of care. As Liberal Democrat health spokesman, Dr Evan Harris put it:

If I were suspicious—which I am—I would say that the Government deliberately do not want their quality inspectorate to look at the types of decisions that are being made about commissioning because the inspectorate may find that the guidance being given to

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<sup>10</sup> Ibid., paras. 4.22-4.31.

<sup>11</sup> Ibid., para. 4.45.

<sup>12</sup> British Medical Association (1998) *Response to 'A First Class Service: Quality in the new NHS'*, London, BMA, August 1998, p. 13.

commissioners, or the policy being taken by commissioners because of financial stringencies leads to poor quality services.<sup>13</sup>

Conservative Members, for their part, claimed to detect a different agenda, namely that the purpose of CHI was to "...impose a centralised command and control structure on the health service." Thus, although clinical autonomy was formally to be preserved, "...the potential threat of being named and shamed by [CHI] will provide them with an in-built incentive to act in the one prescribed manner approved by Government"<sup>14</sup> Equally, it was feared that the Commission could become a loose cannon, spending "...too much time chasing high profile media-driven imperatives rather than concentrating on its core function of a rolling programme of improving clinical standards."<sup>15</sup>

### 7.2.2 The Health Act 1999

Unlike NICE, CHI was established under primary legislation.<sup>16</sup> Section 20 of the Health Act 1999 set out the functions of the Committee in line with the tasks of the Commission elaborated in *A First Class Service* (discussed above in Section 7.2.1). First, the Commission was to provide advice or information with respect to the arrangements by PCTs and NHS Trusts for the purpose of monitoring and improving the quality of care for which they have responsibility.<sup>17</sup> Secondly, CHI was given the function of conducting reviews of, and making reports into the clinical governance arrangements

<sup>13</sup> H.C. Standing Committee A, Thursday 13 May 1999 (Morning), *Health Bill [Lords]*, Dr. Evan Harris.

<sup>14</sup> H.C. Standing Committee A, Thursday 13 May 1999 (Morning), *Health Bill [Lords]*, Miss Ann Widdecombe.

<sup>15</sup> H.C. Standing Committee A, Thursday 13 May 1999 (Afternoon), *Health Bill [Lords]*, Mr David Amess.

<sup>16</sup> Health Act 1999, Section 19 and Schedule 2. For a critical analysis of the Health Act more generally, see Davies (2000). "Don't Trust Me, I'm a Doctor: Medical Regulation and the 1999 NHS Reforms." *Oxford Journal of Legal Studies* 20 (3): 437-456.

<sup>17</sup> Health Act 1999 Section 20 (1) (a).

put in place by NHS Trusts' and PCTs.<sup>18</sup> Third, it was empowered to undertake investigations into the "management provision or quality of health care" for which NHS bodies have responsibility.<sup>19</sup> Fourth, CHI was to conduct reviews of the "management, provision or quality of, or access to or availability of, particular kinds of health care" for which NHS bodies or service providers were responsible.<sup>20</sup> This latter function related to the intended role of NICE with respect to national service reviews.

In addition to these enumerated powers, the Secretary of State was given substantial delegated authority over the Commission's exercise of its functions, including the power to make regulations conferring further functions relating to the "...management, provision or quality of, or access to or availability of, health care for which prescribed NHS bodies or prescribed service providers have responsibility",<sup>21</sup> and to make regulations and to give directions to CHI governing the discharge of its functions.<sup>22</sup> These powers over the Commission were exercised initially in The Commission for Health Improvement (Functions) Regulations 2000 S. I. No. 662 of 2000, and the Commission for Health Improvement (Functions) Amendment Regulations 2000, S. I. No. 797 of 2000 (though the latter merely corrected referencing errors in the former). Regulation 2 of S.I. No. 662 of 2000 addressed, albeit by subordinate instrument, the criticism articulated by Dr Harris that CHI did not have oversight over the activities of Commissioning bodies (including the commissioning functions of PCTs), also extending its remit to Special Health Authorities.

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<sup>18</sup> Section 20 (1) (b).

<sup>19</sup> Section 20 (1) (c).

<sup>20</sup> Section 20 (1) (d).

<sup>21</sup> Section 20 (1) (e).

<sup>22</sup> Section 20 (2) and (3);

### 7.2.3 NHS Reform and Health Care Professions Act 2002

CHI had been in operation for little more than a year when the Government introduced reforms intended to enhance the independence of the Commission, as well as expanding its role.<sup>23</sup> Two policy developments set the context for the legislative changes introduced by The NHS Reform Bill. The first was *The NHS Plan*,<sup>24</sup> the Department of Health's ten-year strategy to increase funding of the NHS combined with reforms designed to improve 'delivery' in the NHS. The second was the *Learning from Bristol* report, and the response to it by the Department of Health. These two separate influences on the Act covered some similar ground, although they differed in their emphasis. Between them, they set out a number of themes that form the background to the NHS Reform Act.

A first theme was the institutionalisation of a more complete separation of the roles of CHI and the Department of Health than existed under the 1999 Act. As noted in Section 6.5, the Kennedy Report had argued for a clear separation between the roles of regulation and management of health care.<sup>25</sup> Section 14 (2) of the NHS Reform Act addressed a key limitation on the independence of CHI, namely the powers of the Secretary of State and the Welsh Assembly to appoint the chairman and other members of the Commission, and to determine the conditions of appointment and tenure of Commissioners. It did so by empowering the Secretary of State to delegate this function to "...a Special Health

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<sup>23</sup> Dobson (2001). "Standards Watchdog to Get a Bigger Role in NHS." *BMJ* 323: 1145, 17 November 2001.

<sup>24</sup> Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office. for comment, see Dixon and Dewar (2000). "The NHS Plan." *BMJ* 321: 315-316, 5 August 2000.

<sup>25</sup> *Learning from Bristol*, Chapter 24, paras. 34-46.

Authority.” This enabled these functions to be passed to the NHS Appointments Commission, which had been established in fulfilment of undertakings in *The NHS Plan* to depoliticise appointments to NHS Trusts and Health Authorities.<sup>26</sup> The Act did not, however, repeal Section 20 (2) and 20 (3) of the Health Act 1999, so the Secretary of State retained his powers to make regulations and give directions governing the work of the Commission (how far these powers represented a significant limitation on the formal independence of CHI is discussed in Section 7.4 below). Nor did the 2002 Act implement the Kennedy Report’s proposal, accepted by the Department of Health,<sup>27</sup> for the establishment of a Council for the Quality of Healthcare to co-ordinate the activities of NICE, CHI and other bodies responsible for the safety and quality of healthcare. Accordingly, this function remained within the responsibilities of the Department.

A second theme related to performance standards, and the assessment against such standards by CHI. Unlike the Clinical Standards Board for Scotland, the Commission did not conduct clinical governance reviews against explicit standards. This was addressed, in different ways, by *The NHS Plan* and by the Kennedy Report. *The NHS Plan* had proposed an extension of the existing NHS Performance Assessment Framework, which was initially focussed on Health Authorities, to cover NHS Trusts and PCTs providing community services.<sup>28</sup> Publication of the results of the expanded Performance Assessment Framework was to be transferred to CHI. The

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<sup>26</sup> Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office. para. 6.54-6.55.

<sup>27</sup> *Learning from Bristol*, Chapter 24, para. 36; Recommendations, para. 39; Secretary of State for Health (2002) *Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*, Cm 5363, London, The Stationery Office. para. 4.3.

<sup>28</sup> Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office. para. 6.19.

Kennedy Report similarly proposed that CHI investigations should take place against a framework of 'generic standards' (that is, standards operating at the level of the healthcare organisation as a whole). To bring together and to co-ordinate national-level monitoring, the Kennedy Report proposed the establishment of an independent Office for Information on Healthcare Performance.<sup>29</sup> The Act addressed these proposals in two principal ways. First, CHI was charged with reviewing and reporting on the quality of data and the methodology of data collection and analysis by NHS bodies or service providers.<sup>30</sup> As part of its responsibilities for reviews and investigations, CHI was authorised to collect and analyse data, and to assess performance against criteria.<sup>31</sup> Relatedly, the Commission was given the responsibility of preparing an annual report on its findings with respect to NHS bodies and service providers.<sup>32</sup> In keeping with the emphasis of *The NHS Plan* on the 'patient experience', the duty of quality, introduced by Section 18 of the Health Act 1999 was extended to include responsibility for

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<sup>29</sup> Recommendations, Para. 146-147; See also Chapter 27, para. 54 proposing an "Office for Monitoring Healthcare Performance."

<sup>30</sup> NHS Reform and Health Care Professions Act Section 12 (2).

<sup>31</sup> National Health Service Reform and Health Care Professions Act 2002, Section 12 (3). This amendment equally reflected the Kennedy Report's emphasis on 'generic standards for healthcare organisations'; see , Chapter 37, paras. 31-45. The Commission's constitution was amended, allowing for the subcommittee(s) of the Commission exercising this latter function to be designated The Office for Information on Healthcare Performance. Section 14 (4). The publication of NHS performance ratings, as proposed in *The NHS Plan* was envisaged to be a key function of the Office for Information on Health Care Performance, thus bringing together the two 'streams' of influence.

<sup>32</sup> Section 14 (5). The first report, a highly glossy affair, was published in May 2003. See Commission for Health Improvement (2003) *Getting Better? A Report on the NHS*, London, Commission for Health Improvement, 9 May 2003. ; Coombes (2003). "Improvements in the NHS Are Patchy, Report Says." *BMJ* 326: 1052, 17 May 2003..

the environment in which health services were provided, thus enabling the Commission to deal directly with those aspects of NHS performance.<sup>33</sup>

Closely related to the theme of assessing performance against standards, was the insistence, particularly in the Kennedy Report, that standards should apply uniformly regardless of where NHS Patients were treated, including in the private and voluntary sectors: “It is plainly not acceptable for a patient to receive care paid for by the NHS in a private sector hospital if the standards of care are below those which apply to NHS hospitals.”<sup>34</sup> Consequently, the Health Act 1999 was re-worded to provide for this. For example, the new function of carrying out inspections extended not only to “NHS bodies and service providers” but also to “persons who provide or are to provide health care for which NHS bodies or services providers have responsibility.”<sup>35</sup>

A third theme, on which *The NHS Plan* and the Kennedy Report took somewhat different approaches, related to compliance strategy. *Learning from Bristol* proposed a shift of philosophy, from an approach based on ‘inspection’ to one of ‘validation’, that is, from discrete and infrequent episodes of oversight with “punitive overtones”, towards a “constructive and continuous process... to help in the improvement of the quality of health care.”<sup>36</sup> If anything, the 2002 Act represented a shift in the opposite direction. Section 13 (1) conferred on CHI the function of carrying out “inspections” which had not been part of the Health Act 1999. The

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<sup>33</sup> National Health Service Reform and Health Care Professions Act 2002, Section 11; see Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office. para. 3.15.

<sup>34</sup> *Learning from Bristol* Chapter 27, para. 41.

<sup>35</sup> National Health Service Reform and Health Care Professions Act, Section 13 (1).

<sup>36</sup> *Learning from Bristol*, Chapter 27, para. 34.

legislation also reflected the Department of Health's rather than Kennedy's views on the consequences of non-compliance. The Kennedy Report had proposed that CHI should have the power to place an NHS organisation on 'validation watch' and in more serious cases of non-compliance, to withhold, suspend or even withdraw validation.<sup>37</sup>

The Department of Health rejected this proposal on the grounds of the potentially "...detrimental impact on the delivery of services to sectors of the population..." that could arise if CHI were effectively able to shut down a Trust, citing also the Secretary of State's statutory duty for the provision of health services.<sup>38</sup> Instead, the Act gave CHI an advisory role in relation to the powers of intervention by the Secretary of State that had been outlined in *The NHS Plan*.<sup>39</sup> The Health And Social Care Act 2001, Section 13 had given the Secretary of State the power to issue 'intervention orders' to Health Authorities and Special Health Authorities, NHS Trusts and PCTs which were failing adequately to perform any of their functions, or where there were significant failings in the way the body was being run.<sup>40</sup> Under Section 13 (1) (b) of that Act, the Commission was required to report to the Secretary of State where it had formed the view that care was "of unacceptably poor quality" or where there were "serious failings" in the running of services, and was empowered to recommend to the Secretary of State that he take "...special measures in relation to the body or service provider." No definition of 'special measures' was given (nor was any

<sup>37</sup> *Learning from Bristol*, Chapter 27, para. 37.

<sup>38</sup> Secretary of State for Health (2002) *Learning from Bristol: The Department of Health's Response to the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*, Cm 5363, London, The Stationery Office. para. 4.21.

<sup>39</sup> Secretary of State for Health (1997) *The New NHS: Modern, Dependable*, Cm 3807, London, The Stationery Office. , paras. 6.39-6.45.

<sup>40</sup> Under an intervention order, the Secretary of State could require the suspension or replacement of some or all of the board members of an NHS body, and to give directions to the body to which the order related.

explicit mention made the 'intervention orders' of Section 13 of 2001 Act). The power to recommend special measures did not extend to services provided in the private or voluntary sectors.

The reaction to the reforms of the Commissions functions and powers was largely positive. The BMA had expressed its support for the objective of CHI's increased independence from the Department of Health.<sup>41</sup> Likewise, Liberal Democrat Health Spokesman, Dr Evan Harris praised this change, but noted that the Government's commitment to enhancing the Commission's independence did not extend to abolishing the Secretary of State's power under Section 20 (2) and 20 (3) to make regulations and give directions relating to the way in which CHI undertook its work.<sup>42</sup> The broadening of CHI's oversight received broad support. A major concern remained the multitude of inspecting bodies, and the lack of co-ordination between them. The BMA likened the resultant disruption to the 'hole in the road' scenario, in which different utility providers repeatedly dug up the same patch of tarmac, and called on the Government to initiate a review of the various inspection and monitoring procedures aimed at reducing what it saw as the existing level of overlap, duplication and disruption.<sup>43</sup>

#### **7.2.4 Health and Social Care (Community Health and Standards) Act 2003**

These changes had yet to take effect when the Government announced a further set of reforms. On 17 January 2002, the Secretary of State for

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<sup>41</sup> BMA (2001) *Commission for Health Improvement: Review of the various inspection mechanisms*, December 2001..

<sup>42</sup> H. C. Session 2001-02, Standing Committee Debates, NHS Reform and Health Care Professions Act, Column 202, Tuesday 4 December 2001.

<sup>43</sup> BMA (2001) *Commission for Health Improvement: Review of the various inspection mechanisms*, December 2001..

Health, Alan Milburn announced: "Steps will be taken at the earliest opportunity to rationalise the number of bodies inspecting and regulating health and social care."<sup>44</sup> These were eventually enacted by the Health and Social Care (Community Health Standards) Act 2003. Section 44 (1) abolished the Commission for Health Improvement, replacing it with a new Commission for Health Audit and Inspection (CHAI). A detailed analysis of the new legal and administrative arrangements for CHAI introduced by that Act is beyond the scope of this thesis, but a brief discussion is warranted insofar as this can shed light on the 'official' verdict about CHI, analogous to economists' use of 'revealed preferences'.

As noted above, the BMA had expressed concern at the multitude of organisations inspecting health care. During the passage of the 2002 Act, the BMA had called for a merger of CHI with the National Care Standards Commission (NCSC) "to achieve uniform, high quality patient care across both these [public and private] health sectors, avoiding unnecessary duplication."<sup>45</sup> Similarly, the Kennedy Report had highlighting what the inquiry saw as "the need for reappraising" the value-for-money role of the Audit Commission, now that CHI had been established.<sup>46</sup> In *Delivering the NHS Plan*, setting out the Department of Health's progress to date and proposed next steps in implementing *The NHS Plan*, the government accepted the force of these criticisms.<sup>47</sup> In place of the existing arrangements, the Department of Health proposed a Commission for Health Audit and Inspection (CHAI), incorporating the previous work of CHI,

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<sup>44</sup> Freedom of Information Act request, Department of Health, ref. DE6008103.

<sup>45</sup> BMA (2002) *NHS Reform and Health Care Professions Bill: Committee stage, House of Lords*, March 2002.

<sup>46</sup> *Learning from Bristol*, Chapter 27, para. 50.

<sup>47</sup> Secretary of State for Health (2002) *Delivering the NHS Plan: Next steps on investment, next steps on reform*, Cm 5503, London, The Stationery Office, April 2002. , paras. 10.6-10.8.

NCSC and the Audit Commission (although the latter was to continue to perform its work as financial auditor to the NHS). The move from CHI to CHAI in many ways represented a continuation of the theme of separation from the Department of Health. As *Delivering the NHS Plan* put it:

The new Commission will be more independent of Government than the Audit Commission, CHI, or the NCSC. Commissioners will be appointed by the independent Appointments Commission, rather than by Ministers, and in accordance with the Nolan rules. The Commissioners, rather than Ministers, will appoint a Chief Inspector of Healthcare.<sup>48</sup>

In other ways, too, the changes represented a development of earlier themes. As one might have expected, given that the BMA had advocated this move, the reforms received broad support from the profession, although a comment in the *BMJ* expressed concern that the new proposals for CHAI, "...mix[ed] up independence and developmental intent with a limited and tightly controlled political mandate."<sup>49</sup>

### 7.3 The Effectiveness of CHI

An assessment of the success of CHI is even more problematic for a number of reasons. CHI had a shorter lifespan than either NICE or the Limited List, also getting off to what was arguably a slow start. There is therefore less evidence on which to base an assessment compared to these other two reform initiatives. Second, CHI does not appear to have attracted the same degree of official attention compared with NICE, limiting the potential for an assessment based on reputational evidence. Third, while it is possible to assess the activity of CHI, say in promoting clinical governance, the relationship between the implementation of clinical governance

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<sup>48</sup> *Ibid.* , para. 10.8

<sup>49</sup> Dewar and Finlayson (2002). "The I in the new CHAI." *BMJ* 325 (19 October 2002): 325-6.

arrangements and the broader goal of improving the quality of care experienced by patients remained obscure, including to CHI itself.<sup>50</sup>

The most prominent official assessment of the effectiveness of CHI was a VFM study by the National Audit Office into the progress made by NHS Trusts in implementing clinical governance arrangements.<sup>51</sup> The report found that structural and organisational arrangements for clinical governance had been put in place in nearly all Trusts, though it suggested that there was further work to be done in getting beyond the organisational and structural aspects of clinical governance. Nonetheless, the report found evidence that clinical governance had contributed to improved organisational culture, and even to improved patient care.<sup>52</sup> Significantly, of the various stimuli for change, the report found that CHI clinical governance reviews were perceived to have had the greatest impact:

...even though most trusts considered that the reviews rarely identified wholly new information and that the review process had largely confirmed their own perceptions of the areas for development or need of change or their own assessment of the position.<sup>53</sup>

In addition to this official assessment, two major academic studies into the effectiveness of CHI clinical governance reviews.<sup>54</sup> Of these two

<sup>50</sup> Bawden and Lugon (2002). "The Role of the Commission for Health Improvement." *Clinical Risk* 8: 148-152; Degeling, Maxwell, Coyle and Macbeth (2003). "The Impact of CHI: Evidence from Wales." *Quality in Primary Care* 11: 147-154.

<sup>51</sup> National Audit Office (2003) *Achieving Improvements Through Clinical Governance: A Progress Report on Implementation by NHS Trusts*, HC 1055, Session 2002-2003, London, The Stationery Office, 17 September 2003.

<sup>52</sup> *Ibid.* paras. 4.3, 4.8.

<sup>53</sup> *Ibid.* para. 2.19.

<sup>54</sup> Benson, Boyd and Walshe (2004). *Learning from CHI: The Impact of Healthcare Regulation*. Manchester, The Manchester Centre for Healthcare Management; Day and Klein (2004). *The NHS Improvers: A Study of the Commission for Health Improvement*. London, King's Fund.

studies, that of Day and Klein is the more critical, as a result of which it attracted some attention.<sup>55</sup> But although they criticise the CHI's review methods for sacrificing reliability for greater validity, in terms of the effects of CHI's clinical governance review, Day and Klein do not take a position. Having reviewed their data, drawn primarily from detailed interviews, they remain "agnostic", commenting that: "As researchers, we can only sympathise with CHI's problem in obtaining 'evidence' about its effectiveness..."<sup>56</sup> Moreover, they acknowledge the achievements of the Commission in establishing itself in such a short period, and in completing their goal of inspecting every acute Trust within four years.

Benson *et al.* present a more positive impression, concluding that "...CHI's clinical governance reviews have had a significant effect on NHS trusts and their performance..."<sup>57</sup> Arguably, the difference between these two accounts lies less in the nature of the evidence they collected, but in their differing methodological assumptions with respect to the way they attribute causation. Day and Klein are reluctant to attribute to CHI all of the credit for changes recommended by the Commission: not all of these may in fact have been implemented; furthermore, because (as they found) in many cases NHS Trusts were already aware of areas identified by CHI as requiring action they did not attribute to the Commission credit for subsequent improvements. Benson *et al.*, for their part, were willing to give the Commission credit for the whole range of direct and indirect effects of inspection. While direct effects included only changes in inspectees'

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<sup>55</sup> Singh (2004). "CHI's Methods for Inspecting Trusts Are Flawed Says King's Fund." *BMJ* 328: 542-3, 6 March 2004.

<sup>56</sup> Day and Klein (2004). *The NHS Improvers: A Study of the Commission for Health Improvement*. London, King's Fund, p. 35.

<sup>57</sup> Benson, Boyd and Walshe (2004). *Learning from CHI: The Impact of Health Care Regulation*. Manchester, The Manchester Centre for Healthcare Management, p. 40.

behaviour that are directly initiated or recommended by the regulator, other effects of regulation range from the effects of a regulatory agency's mere existence, including voluntary compliance with its standards of 'good practice', improvements brought about in preparation for an inspection as well as the changes that follow from a regulatory intervention that are not directly recommended or explicitly sought. Benson *et al.* are well disposed to the possibility that these indirect effects are likely to be far more significant overall.<sup>58</sup> Commenting on the observation that clinical governance reviews tended to "...confirm local understanding and knowledge of problems and need for action...", they remark:

Of course, the fact that an issue had been raised in an NHS trust in the past, perhaps on many occasions, is no reason to conclude that action would have followed without CHI's intervention. Indeed, the converse could be argued: that longstanding problems that had been raised but not solved locally were eventually addressed (perhaps successfully) through CHI's external review.<sup>59</sup>

Seen in this light, an evaluation of CHI's effectiveness ought to take account of such 'catalytic' effects. That these two studies, by Day and Klein and by Benson *et al.*, could have reached substantially different conclusions, based less on access to different information but on methodological differences in attributing improvements to regulations only serves to underscore the difficulties in making confident evaluative assertions about the effectiveness of CHI in relation to this aspects of its work.

There was a general neglect of CHI in the professional journals. To provide a comparative illustration, an Ovid Medline search for "Commission for Health Improvement" at the end of 2004 yielded 14 results, compared with 152 for "National Institute for Clinical Excellence. One of the few opinion pieces to have offered judgement was contained in

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<sup>58</sup> *Ibid.*, p. 5.

<sup>59</sup> *Ibid.*, p. 36.

*The Lancet* of October 6 2001. Noting the high ideals of the Commission, it suggested the reality was less impressive:

Results from CHI's first 18 months suggest that it might not be up to its task, nor is its role clear. At present it is a routine inspection agency, a special investigations force, a jury that assesses the evidence and pronounces the verdict, and the judge who can order sanctions against hospitals that it perceived to have failed in some way.<sup>60</sup>

## 7.4 Governance, Commitment and CHI

This section applies the framework set out in Section 4.5 in order to assess the credibility engendered by CHI's governance structure. Section 7.4.1 assesses the substantive written restraints on the discretion of CHI. Section 7.4.2 looks at restraints based on structure and process. Constraints on changing the regulatory system are considered in section 7.4.3, while Section 7.4.4 discusses enforcement of these lower-level commitment by judicial, legislative and executive institutions.

### 7.4.1 Substantive Written Restraints

Compared with the other regimes examined in this thesis, careful efforts were made to insert substantive restraints on the discretion of CHI. The four principal functions initially performed by the Commissions—clinical governance reviews, investigations, national service reviews and advice and guidance, were all explicitly set out in statutory rules, with further details set out in regulations. Significantly, CHI did not initially have the authority to inspect services provided by PCTs and NHS Trusts; rather, their remit was in respect of "...arrangements...for the purpose of monitoring and improving

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<sup>60</sup> Anonymous (2001). "How (Not) to Improve a Health Service." *The Lancet* 358: 1111, 6 October 2001.

the quality of care...”<sup>61</sup> According to one interviewee, this was part of a conscious strategy by officials to avoid CHI becoming “...the NHS version of OFSTED... We thought we had very cleverly, in the way in which the legislation was framed moved ministers away from this...” (I24). This was altered by the NHS Reform Act, which conferred the additional function of carrying out inspections. Due to the abolition of CHI, it was not possible to see how these changes played out.

#### **7.4.2 Restraints Based on Structure and Process**

A number of structure and process-based restraints were evident in the regulatory governance of CHI. The Commission was established, as discussed in Section 7.2.2, as an independent statutory authority accountable to the Secretary of State. A first set of issues relates to the agenda-setting and veto power of the Department of Health. A second set of issues, include such issues as inter-agency competition, agency expertise, and the ‘enfranchisement’ of different interest groups in decision-making.

Legislative provisions gave the Secretary of State substantial agenda-setting power. Under Regulation 3 the Commission for Health Improvement (Functions) Regulations 2000, the Commission was required to prepare an annual work programme, relating initially to advising on clinical governance arrangements, clinical governance reviews, and national service reviews.<sup>62</sup> Regulation 3 required the Secretary of State not only to approve the Commission’s annual work programme, but also to vary the plan, and to veto variations proposed by CHI.<sup>63</sup> This power was singled out in the Kennedy report as an example of the existing limitations upon the

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<sup>61</sup> Health Act 1999, Section 20 (1) (b).

<sup>62</sup> S. I. No. 662 of 2000, Regulation 3 (2).

<sup>63</sup> S. I. No. 662 of 2000, Regulation 3 (2) and (3).

credibility of healthcare regulators: "...CHI's independence cannot be manifested or enjoyed as long as it is the Department rather than CHI itself which sets the targets for the number of trusts which must be inspected each year."<sup>64</sup> Day and Klein similarly interpret the exercise of this authority as an attempts by the Department of Health to use this provision to "performance-manage" the Commission.<sup>65</sup>

Perhaps the most controversial power of the Secretary of State, at least as judged from Parliamentary debates, related to the power of the Secretary of State to order CHI investigations. Mr. David Amess expressed concern that this power might be used as a means by which the Government might be used as a blame-shifting strategy:

The calling in of Chimp... should not simply be an arbitrary decision for the Secretary of State to take in response to political or media pressures... It should be clearly set out in regulations when it will be necessary for the Chimp to intervene."<sup>66</sup>

Despite these concerns, the Regulation 11 of the 2000 Regulations (which were never debated by the Standing Committee on Delegated Legislation) sets out CHI's role vis-à-vis investigations in the most general terms. The Commission was required to undertake an investigation when requested to do so by the Secretary of State.<sup>67</sup> Additionally, it was empowered to carry out an investigation when empowered to do so by any person or body, or where it otherwise appeared to the Commission to be appropriate.<sup>68</sup>

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<sup>64</sup> *Learning from Bristol*, Chapter 27, para. 42.

<sup>65</sup> Day and Klein (2004). *The NHS Improvers: A Study of the Commission for Health Improvement*. London, King's Fund., p. 11.

<sup>66</sup> H. C. Standing Committee A, Thursday 13 May 1999 (afternoon) Health Bill [Lords] (Mr David Amess.)

<sup>67</sup> S. I. No. 662 of 2000, Regulation 11 (1).

<sup>68</sup> S. I. No. 662 of 2000, Regulation 11 (2).

It is worth emphasising that this broad power of the Secretary of State to order an investigation also included the decision *not* to require a decision. In other words, the ability of the Secretary of State to 'bypass' CHI constituted a potential limitation on the ability of CHI to act as an 'intermediary organisation'. For example, when photographs of deceased persons stored in the chapel of Bedford Hospital NHS Trust (which had been used as a makeshift, un-refrigerated mortuary) appeared in the press,<sup>69</sup> the Secretary of State ordered an investigation not by CHI but by the NHS Regional Office.<sup>70</sup> It was suggested (I23) that the resignation of the Trust Chief Executive had been driven by the media, and that had the Secretary of State ordered a CHI investigation, it may have acted more as an 'insulator' than as a 'political lightning rod'. To this extent, inter-agency competition, such that it existed, differed fundamentally from the case of NICE. The choice of agency, in this case, was made by the Secretary of State, rather than by the organisation under investigation.

In terms of agency expertise, Commissioners came from a variety of backgrounds, including academic and practicing medicine, and voluntary sector work. The Director of Health Improvement, Dr Peter Homa, on the other hand, had previously been the NHS waiting list 'czar' (his 'Dr' was a PhD in management, not a medical qualification). Review teams themselves were dominated by the clinical professions, and included an NHS doctor, nurse and allied professional, as well as an NHS manager and a lay member. Review team members remained in their existing positions (usually in the NHS), and were seconded to up to two clinical governance reviews per year. Similarly, investigation teams, comprised of an investigation manager (a

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<sup>69</sup> See *The Sunday Telegraph*, 14 January, 2001.

<sup>70</sup> For the outcome of the investigation, see NHS Executive Eastern Regional Office (2001) *Investigation into Mortuary Arrangements at Bedford Hospital NHS Trust*, NHS Executive, 31 January 2001.

full-time employee of CHI), a lay member and a number of members chosen according to the requirements of each investigation, but who were usually NHS employees. Following the arguments of Macey,<sup>71</sup> outlined in Section 4.5.3, the NHS domination of review and investigations might be regarded as an important factor in providing credibility.

In the case of NICE, discussed in the previous chapter, it was argued (drawing on the work of Moshe Maor), that reliance on the 'gold standard' of evidence-based medicine was an important factor in the credibility of the Institute. By contrast with NICE (and also, incidentally, with CHI's Scottish counterpart, the Clinical Standards Board for Scotland. CHI did not follow a strategy of reviewing NHS organisations against an explicit set of standards. Thus while the Commission may have asserted that it has been "evidence based",<sup>72</sup> this claim may not have had the force that NICE could assert, with studies questioning the consistency of CHI reviews.<sup>73</sup>

To summarise this part of the section, CHI enjoyed considerable independence. At the same time, the Secretary of State still enjoyed some influence, in terms of power over CHI's work programme, and in terms of the power (not enjoyed solely by the Secretary of State) to initiate a CHI investigation. The expertise of the Commission was primarily drawn from the constituency of the NHS and other medical interests, but unlike NICE, decision-making was not hardwired to the 'gold standard' of EBM.

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<sup>71</sup> Macey (1992). "Organizational design and Political Control of Administrative Agencies." *Journal of Law, Economics and Organization* 8 (1): 93-110.

<sup>72</sup> Hine, Homa and Patterson (2001). "Quality of Patients' Care in the UK National Health Service." *The Lancet* 358: 1454-5, 27 October 2001..

<sup>73</sup> Day and Klein, op. cit.

### 7.4.3 Constraints on System Changes

In contrast with the other two reform initiatives examined in this thesis, NICE and the Limited List, the initial legal basis for CHI was set out in primary legislation, The Health Act 1999. At the same time, under Section 20 (1) (e) and under Section 20 (2) and 20 (3), the Secretary of State was given the authority to prescribe further functions of the Commission and to govern the details of the manner in which CHI exercised its functions. Given the divergent expectations of Ministers on the one hand, and civil servants and the Commission on the other, noted above, it might have been expected that these powers would have been used to confer greater discretionary power on CHI. This was the concern of Conservative MP for Southend West, Mr David Amess, who drew attention to the potential loophole, arguing that:

... Chimp's powers are not clearly set out in the bill... Chimp's potential powers are currently set out in regulations, with the Secretary of State given wide-ranging powers to extend the scope and range of Chimp's activities...<sup>74</sup>

Against this, it has to be noted that such extensions of the Commission's functions that did occur under regulations were arguably used to make the Commission *more* credible. As discussed in Section 7.2.1, some suspected that the decision to exclude reviewing commissioning bodies from CHI's functions under the Health Act 1999 reflected a strategy to divorce responsibility for the quality of care from funding decisions. The Commission for Health Improvement (Functions) Regulations 2000 resolved this state of affairs. The Regulations extended the existing powers of CHI to review and to provide guidance to PCTs on the implementation of arrangements for clinical governance to cover not just "health care for which they have responsibility" but also over "health care provided by their

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<sup>74</sup> H.C. Session 1998-1999, Health Bill [Lords] in Standing Committee A, 13 May 1999.

relevant service providers".<sup>75</sup> CHI's responsibility to provide information and advice was extended over Health authorities and Special Health Authorities and their service providers.<sup>76</sup> Clinical governance reviews were introduced over Health Authorities and certain Special Health Authorities (to which the Section 18 duty of quality had been applied).<sup>77</sup> CHI was empowered to investigate Special Health Authorities,<sup>78</sup> while the Commission was given an advisory role with respect to the establishment of health service inquiries.<sup>79</sup> The 2003 regulations, which replaced the 2000 regulations made provision for the replacement of Health Authorities with the new Strategic Health Authorities.<sup>80</sup> On the whole, then, the evidence does not suggest that the Secretary of State used his powers to circumvent the restraints of primary legislation. *Contra* any blame-shifting interpretation, it could be argued that this measure served to remedy a credibility problem, namely the suspicion that CHI was intended to shift blame away from funding decisions. It is noted, however, that by addressing this anomaly by delegated legislation, the Act gave the Secretary of State the power to reinstate it, if 'necessary'.

Turning attention to informal constraints on system change, the establishment, reform and abolition were set out in White Papers signalling in advance these policy changes.<sup>81</sup> The original proposal for CHI was set out in *The New NHS* White Paper and explained in detail in *A First Class*

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<sup>75</sup> S. I. No. 662 of 2000, Regulation 2 (b) and (d).

<sup>76</sup> Ibid., Regulation 2 (a)

<sup>77</sup> Ibid., Regulation 2 (c); Those Special Health Authorities included the National Blood Authority, the Ashworth Hospital Authority, the Broadmoor Hospital Authority and the Rampton Hospital Authority. See The Special Health Authorities (Duty of Quality) Regulations 2000, S. I. No 660 of 2000.

<sup>78</sup> S. I. No. 662 of 2000, Regulation 2 (e)

<sup>79</sup> Ibid., Regulation 2 (e).

<sup>80</sup> S. I. No. 1587 of 2003, Regulation

<sup>81</sup> On the role of White Papers in restraining arbitrary policy change, see Section 4.5.4

Service. The decision to extend the Commission's remit was put forward in *The NHS Plan*, and the decision to amalgamate CHI, NCSC and the health-related VFM functions of the Audit Commission were publicised in the White Paper, *Delivering on the NHS Plan*. Furthermore, the original proposal, together with the subsequent changes, enjoyed the broad support of the BMA, and to an extent later changes, especially the amalgamation of the established inspectorates into CHAI responded to concerns from the medical profession at the excessive burden of inspection. The main organised representatives of the medical profession, and other allied professions subscribed to *The NHS Plan*, which was presented as a new settlement between the professions and government.<sup>82</sup> Overall, therefore, the informal institution of publicising policy changes in advance was effective in this case.

#### **7.4.4 Enforcement of Lower-Level Commitment Mechanisms**

Turning to the constitutional level of analysis, it can be argued that CHI made use of legislative and executive enforcement mechanisms, with the potential use of judicial mechanisms following the NHS Reform Act.

Taking first legislative institutions, it was argued in Section 4.5.5, *contra* Levy and Spiller that legislative institutions can play a useful role in enforcing restraints on system changes. In contrast to the other regulatory reform initiatives examined in this thesis, CHI was established under primary legislation. Relatively speaking therefore, regulatory system change was more difficult than was the case with respect to NICE or the Limited

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<sup>82</sup> Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, a Plan for Reform*, Cm 4818-I, London, The Stationery Office. Foreword by the Prime Minister.

List. This argument is not defeated by the fact that Parliament was twice able to alter the provisions relating to the CHI, extending its functions in 2002, and abolishing the Commission in 2003. These changes had broad cross-party support, as well as the support of the organised interests of the medical and allied professions, and of private providers of health care.

In terms of executive institutions, the provisions of the Health Act 1999 made some significant use of the Commissions arm's length independence, although, as Day and Klein point out, there existed "...a certain ambiguity about just how independent it would be in practice..."<sup>83</sup> In terms of institutional arrangements, this ambiguity was expressed in a number of ways.

First, the Secretary of State initially enjoyed substantial discretionary power over the appointment of Commissioners, and over the terms of their appointment. This was seen to have diminished, at least symbolically, the independence of CHI (I24). Similarly, the decision of the Commission to appoint the Director of Health Improvement, CHI's chief executive officer, was subject to the approval of the Secretary of State. Although the NHS Reform Act made provision to transfer this power to the NHS Appointments Commission, this did not have any practical effect on CHI until its demise in 2004.

The role of the judiciary was never tested, though some limited speculation may be ventured, based on an analysis of the legislative provisions. As noted above, notwithstanding the Secretary of State's powers to lay regulations and to give directions to CHI, Section 20 (1) of the Health Act 1999 did place important statutory limits on the Commission. The legality and rationality, and procedural propriety of acts of the Commission itself, or the exercise of those delegated functions by the Secretary of State,

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<sup>83</sup> {Day, 2004 #96@p. 7}

were clearly matters falling within the competence of the courts. At the same time, it is difficult to see who might have had both the standing as well as the motivation to bring such an action—certainly not NHS organisations, although following the 2002 Act, private providers treating NHS patients may have had the motive and interest, in the event of a negative inspection. In contrast with the previous two case studies, ACD and NICE, pharmaceutical companies had at best an indirect interest in the work of the Commission.

## 7.5 Conclusions

In conclusion, applying Chapter 4 framework to CHI adds to existing understandings of regulatory governance in the NHS. First, it suggests that the commitment issue was central to the establishment of inspection in the NHS, though in a different way to the other episodes of regulatory reform discussed in the previous two chapters. The Commission was born out of a tension between officials who emphasised the developmental role of CHI, and ministers who saw it as the ‘NHS version of OFSTED’ (I24, discussed in Section 7.4.1). According to Day and Klein, this tension continued even after the establishment of the Commission:

Ministers see the commission as a quality police—identifying and reporting laggards—whereas the commission sees itself as a developmental agency, promoting “the ethos and practice of continuous improvement” rather than apportioning blame.<sup>84</sup>

Despite this tension, the government was able to attract the continued support of organised medical interests for the reform and then replacement of the Commission. Second, officials appear to have paid close attention to the institutional arrangements, in an attempt to ‘hardwire’ the more developmental role. Judged in terms of the framework of Section 4.5, the

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<sup>84</sup> Day and Klein (2001). "Commission for Health Improvement Invents Itself." *BMJ* 322: 1502-3, 23 June 2001..

governance structure of CHI appeared overall to be relatively credible, based on a combination of substantive rules and structural and procedural arrangements at the level of operational rules, and with a requirement of explicit Parliamentary approval constraining changes to the regulatory regime.

This chapter does not claim that the evidence presented in this chapter provides direct support for the hypothesis advanced in Chapter 4, which related the effectiveness of regulation in the NHS to the governance structure of regulation, but nor does it refute that theory. Furthermore, using the framework as a mapping device, it sheds light in an area that is not well understood in existing law and political science research.

# **Chapter 8**

## **Conclusions**

### **8.1 Overall Conclusions and Observations**

The preceding chapters have sought to set out a framework for the analysis of health care regulation, and to use this framework to help to understand regulatory change in the NHS at the general level as well as to analyse and explain a number of specific episodes of regulatory reform. This concluding chapter attempts to draw together the various strands of this thesis, and to set the findings in context.

A first task of this concluding chapter, undertaken in Section 8.2, is to assess how far the evidence presented, taken as a whole, supports the theoretical claims. A second task of this concluding chapter is to evaluate the overall contribution of this thesis. As discussed in Section 1.2.2, King Keohane and Verba suggest two criteria for choosing a research topic: contribution to scholarly literature and importance to the real world. These criteria can be used to provide benchmarks against which the present contribution can be assessed. Section 8.3 considers the contribution of this thesis in terms of three distinct literatures: the literature on the regulatory state; the literature on health policy and regulation; and finally, the literature on the law and economics of regulatory design. Section 8.4 considers the implications for policy of the findings of this thesis, especially as it relates

to the design of regulatory institutions. Section 8.5 addresses some of the limitations of the present research, while Section 8.6 offers some concluding thoughts relating including a brief indication of how future research can build on this contribution.

## **8.2 Findings**

At the outset, this thesis identified two key hypotheses concerning regulation in the NHS. First, it was argued that the institutional development of the NHS over the past twenty years shows a transformation similar to that asserted by Majone and others more generally in Western European countries and in the EU, of a shift towards the regulatory state. Furthermore, it was hypothesised that the explanation put forward more generally for this shift could also explain comparable developments in the provision of health care in the UK. Second, it was argued that the effectiveness of regulation in the NHS depended (among other factors) on the capacity of the legal and administrative framework of regulation to engender credible commitment to the implicit concordat, understood as a set of 'rules of the game' governing relations between the medical profession and the Department of Health. This section first considers the extent to which the evidence supports each of these propositions.

### **8.2.1 The Regulatory State**

As discussed in Section 3.2, it is useful to separate the descriptive and explanatory claims made associated with the regulatory state. The evidence presented in this thesis provides strong support for the descriptive claim that overall patterns of change in the provision of health care fits the claim that there has been a rise of the regulatory state inside the NHS. All three of the trends identified by Loughlin and Scott as associated with the regulatory

state—separation of policy-making from service delivery, the creation of semi-independent agencies and increased formality—were evident in the evolution of the governance of the NHS between 1985 and 2004. Much of the overall institutional change in the NHS over the last twenty years is captured by this descriptive claim, despite the fact that Loughlin and Scott's formulation is arguably more specific than other attempts to capture what is entailed by the regulatory state. Although Section 3.3 pointed to some isolated examples of retrenchment of the regulatory state inside the NHS, Chapter 3 did not identify any significant counter-trends to this overall pattern. This is all the more remarkable because one of the reasons for choosing Loughlin and Scott's formulation is that it is precise, and therefore helps to avoid the pitfall of identifying the regulatory state with overly-broad phenomena.

In terms of the explanatory claims of the regulatory state hypothesis, it was argued in Section 3.4.2, that the case of the NHS is consistent with Majone's argument that the rise of the regulatory state has been a functional response to a perceived 'mismatch' between positive state institutions and contemporary policy challenges. In particular, Majone has stressed a renewed emphasis on efficiency as a primary policy goal as well as an increasing awareness of the importance of credibility to the success of public policies. Once the implicit concordat is taken into account in the analysis, Moran's objection that in Britain the regulatory state is associated with expanded reach as much as with the diminished scope, and with continued politicisation, is not fatal to the regulatory state hypothesis. Intervention through regulatory-state type institutions can be understood to have been less disruptive to the existing organisation of the NHS, compared with alternative institutional arrangements for intervention. The penetration of the clinical realm by state institutions was, on this view, dependent on the

increased level of credibility provided by regulatory state-type governance arrangements.

The detailed analyses presented in Chapters 5-7 provide some additional support for this view. The first episode of regulatory reform discussed in this thesis, the Limited List scheme, was opposed much more vociferously by the profession compared NICE and CHI. These latter reforms in fact commanded the cautious support of the BMA. Various suggestions have been put forward to explain why, in response to the Labour Government's *New NHS* White Paper, "...the dog did not bark—let alone bite."<sup>1</sup> These included overall satisfaction on the part of the profession that the *Working for Patients* reforms had been disavowed; that the profession's aspirations had changed; and that they simply did not grasp the implications of the Government's reforms. The explanation suggested by this thesis is that these later reforms, while going much further than the Limited List in terms of the extent of their reach into clinical practice, at the same time benefited from a legal and administrative framework that provided greater credibility. This explanation is at least as convincing as the alternatives suggested by Klein, and could be said to complement them. Furthermore, following the views put forward by Scharpf and Hayek, discussed in Section 1.2.3, it can be argued that this explanation is preferable as it proceeds directly from well-established hypotheses with some overall support within the health care sector and beyond. How far this explanation is empirically sustainable is taken up in the following section.

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<sup>1</sup> Klein (2001). *The New Politics of the NHS*. 4th Edition, Harlow, Prentice Hall, p. 206.

### **8.2.2 Credible Commitment and Regulatory Design**

Chapter 4 set out in detail a hypothesis relating the effectiveness of regulatory reform initiatives to the legal and administrative framework of regulation. Drawing on the work of Levy and Spiller, it was suggested that reforms are unlikely to achieve their publicly pronounced policy objectives unless the legal and regulatory framework for regulation embodied, at three levels, certain complementary mechanisms to secure credible commitment to the implicit concordat.

To what extent do the three episodes discussed in Chapters 5-7 bear out this prediction? Comparing the Limited List with NICE seems to show relative outcomes consistent with the theory developed in Chapter 4. The Limited List represented a reform initiative which, evaluated against the three-level analysis put forward in Section 4.5, did not benefit from a credible governance structure. Consistent with the theory, the scheme was generally regarded as not being particularly effective in achieving its intended objectives. Furthermore, the narrative of Chapter 5 suggested that the processes by which poor regulatory design translated into poor performance conformed to the expectations of the theory. The sustained initial opposition of the profession was seen to have contributed to the initial downwards revision of expected financial savings. This is significant because compliance with the requirements of the Limited List scheme was almost 'automatic', and so, unlike the other two episodes examined in Chapters 6 and 7, *ex ante* opposition was the main means by which the profession could subvert the scheme. Furthermore, there was ample evidence of slippage over the years, including the extension of categories in 1992, the black-listing of nicotine replacement therapy and the grey-listing of Viagra in 1999. Applying Blunstein and Marmor's taxonomy, this was

shown to represent an expansion from its initial purpose of eliminating ineffective and harmful treatment.

By contrast, on the basis of the framework set out in Chapter 4, the legal and administrative framework of NICE provided relatively more credibility, notwithstanding a number of institutional shortcomings. NICE embodied a number of (mainly structural and procedural) restraints, including a commitment to transparent evidence-based evaluation. Nonetheless, procedures for topic selection, as well as the fact that dissemination of NICE guidance to the NHS required the authority of the Secretary of State, limited the extent to which NICE's independence from the Department of Health provided an institutional basis for credible commitment. Significantly, unlike CHI, NICE's status and independence was not enshrined in primary legislation, although successive legislative measures were scrutinised by the Standing Committee on Delegated Legislation, suggesting that enforcement of the constraints on arbitrary policy changes introduced by ministerial order were taken seriously, to the extent that this was possible.

Against this, there was some evidence of coalitional drift from NICE's original remit. The added responsibility for "the effective use of available resources" was arguably broader than the changes minimally required to correct drafting anomalies, while the Secretary of State's Directions to NHS organisations of December 2001 fundamentally changed the force of NICE guidance, imposing an obligation on Health Authorities to fund NICE-approved treatment. Criticism of the Institute, for example by the House of Commons Health Committee and by the Report of the Kennedy Inquiry, focussed on the credibility issue, thereby suggesting that there was a general awareness of the problem of bureaucratic and coalitional drift, and its potential impact on the effectiveness of policy. Furthermore,

there appeared to be a degree of willingness on the part of the government to address the problems identified by these bodies.

It is worth noting that, compared with the Limited List, NICE was intended to be more far-reaching, from the outset avowedly covering (again, in Blunstein and Marmor's terminology) treatment of uncertain effectiveness as well as treatment that was not cost-effective. Moreover, unlike the Limited List, NICE was not restricted, at the operational level, to prescribed therapeutic categories. Potentially, therefore, this episode represented a greater threat to the implicit concordat, consequently placing greater demands on institutional restraints. In spite of this, NICE commanded the cautious support of the BMA and (initially at least) the editorial pages of the *BMJ*. The study of NICE in Chapter 6, especially when contrasted with the examination Limited List, can therefore said to support the regulatory commitment hypothesis, demonstrating both strengths and flaws in terms of its legal and administrative framework, as well as achievements and shortcomings in terms of its effectiveness. There was some evidence of slippage, but also of conditional support from the profession.

The study of CHI in Chapter 7 shows how the analytical framework developed in Chapter 4 can contribute insights into the process of regulatory reform in the NHS beyond issues of waste-cutting and rationing that were, in different ways, the focus of Chapters 5 and 6. The introduction of inspection by the CHI, it was argued, raised similar issues of commitment to the implicit concordat. As Chapter 7 demonstrated, the BMA were prepared to support the establishment of CHI provided that it adopted a supportive, rather than a critical approach. Assessments of the Commission suggested that the Department of Health was frustrated at CHI's emphasis on its supportive role. The issue of (the avoidance) of coalitional drift was thus

central. Furthermore, prior to the introduction of the Commission, there was general concern that it would function as an instrument for shifting the blame for poor performance away from funding decisions of government and onto the quality of care provided by NHS organisations, or that the commission would become a 'loose cannon', pursuing a high profile media agenda to the detriment of its overall mission. Although some criticisms of CHI were offered, including by the Kennedy Inquiry, there was no suggestion that these fears had significantly materialised.

Second, there was some evidence that faced with these challenges, officials consciously attempted to contend with these commitment issues, and to restrain impulses to make the Commission into the NHS version of OFSTED. The powers of the Commission were enshrined in primary legislation, although the Secretary of State enjoyed delegated authority to extend these powers by statutory instrument. These powers were more strictly defined compared with the Limited List and NICE, although the Department of Health retained important powers in terms of agenda-setting and veto power. In the case of the Commission, these were evident in terms of the power of the Secretary of State to require a Commission investigation and to sanction poor performance identified in an inspection or investigation. Given the fears discussed above, the fact that the BMA supported (albeit reservedly) the establishment of the Commission, as well as lending its support to successive reforms—including the replacement of the Commission by CHAI—aimed at strengthening inspection in the NHS—provides some support for the proposition that CHI, and its successor, CHAI, were credible institutions.

At the same time, caution should be exercised in interpreting the findings of Chapter 7, which also demonstrates some of the difficulties in applying the analytical framework developed in Chapter 4. It is possible to

compare CHI with the other two episodes of regulatory reform only in the most general terms. For one thing, as an inspectorate body, the functions of the Commission were of a different nature than NICE and the Limited List, even if the commitment issues were broadly similar. Furthermore, Chapter 7 contended with a number of problems in the assessment of the effectiveness of CHI: the policy objectives behind CHI were broader and less precise; attributing outcomes to the initial reform initiative was difficult; and it was not possible, within the short life-span of CHI, to assess with confidence whether the observed absence of coalitional drift was due to effective restraining mechanisms, or to the fact that they were never seriously tested.

Most importantly, although Chapter 7 arguably adds little in the way of hard support for the regulatory commitment hypothesis, it is important to note that the evidence from this chapter does not contradict the hypothesis. Counterfactually, had the evidence from this chapter suggested that CHI was an ineffective institution, or had the profession strongly opposed the establishment of the Commission, this may well have given grounds for thinking that the theory put forward in Chapter 4 was false, or at any rate had limited value as a tool for analysing regulatory reform in the NHS. To this limited extent at least, the evidence from this episode supports an overall favourable assessment of the regulatory commitment hypothesis.

### **8.3 Contribution to Scholarly Literatures**

Applying King, Keohane and Verba's criteria<sup>2</sup> as benchmarks for assessing the overall contribution of this thesis, a first issue is the contribution that it makes to the existing literature. The thesis contributes in different ways to three distinct scholarly literatures, namely: (1) the literature on the regulatory state; (2) the literature on health policy and regulation; and finally (3) the law and economics of regulatory design. Each of these three contributions is discussed in turn.

### **8.3.1 The Regulatory State**

Taking first the contribution to the literature on the regulatory state, this thesis suggests that, by explicitly incorporating an exchange perspective, the regulatory state literature can generate additional analytical power. As discussed in Section 2.3.1, one prominent explanation explains the rise of the regulatory state in terms of a perceived mismatch between the capabilities of positive state institutions and the emerging challenges of public policy, especially given the complexity of many policy problems. The present analysis has attempted to show that, among the challenges with which health policy must contend is the difficulty of reconciling demands for more far-reaching intervention with existing understandings of the respective duties and entitlements of the government and the medical profession. The inability of positive state institutions to solve this problem (other than by the 'solutions' of simple non-intervention or abrogating the concordat) can be seen as a further limitation, to which the emergence regulatory state was a response. Such an explanation might potentially hold wherever the organisation of public services is based on a PSB or similar implicit understandings.

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<sup>2</sup> See Section 1.2.2, above.

'With this additional refinement, the regulatory state hypothesis can potentially explain patterns of regulatory reform beyond its original application, which was in the context of privatisation and deregulation in the 1980s and 1990s. In many areas of public service provision, the changes of the last two decades or more can be seen not as a replacement of the positive state by the regulatory state; rather, regulation has supplemented existing modes of governance and, with the overall effect being an extension rather than a diminution of state control. While this may sacrifice the parsimony of Majone's thesis, this is more than off-set by the additional analytical power that comes with introducing a PSB analysis into the approach.

### **8.3.2 Health Policy and Regulation**

As set out in Sections 2.4.2 and 2.4.3, there is a lively existing literature which analyses UK health policy in terms of an evolving PSB or implicit concordat. Insofar as these accounts analyse the expansion of state regulatory control over the provision of health services, these accounts have tended to diagnose an erosion of the concordat. While the present approach does not deny that this may be the case, it also suggests that the fact that much intervention has occurred through the particular institutional forms associated with the regulatory state, rather than say through direct command by the Department of Health, may have been a way of preserving the concordat in some shape or form. That later reforms, including the introduction of NICE and CHI, commanded the cautious respect of organised medical interests supports this conclusion. More generally, the findings of this thesis support the view that, far from rendering obsolete analyses of the NHS based on the implicit concordat, this general approach can contribute to debates about regulation of health services. At the same time, this thesis suggests that in order to shed light on the regulation of

health service, greater sensitivity has to be shown to the problem of commitment to the concordat in a changing institutional setting.

A second contribution to this literature follows from the fact that the determinants of the effectiveness of health care regulation are not currently well understood.<sup>3</sup> While the effects of regulatory governance is only one part of the story, and the present, and an exclusively commitment-focussed analysis does not even attempt an overall assessment of that part, the findings of this thesis suggest that the credibility of regulatory reforms may be one factor involved. Until now, this has been neglected in the literature on health policy and health care regulation.

### 8.3.3 Law and Economics of Regulatory Design

Chapter 4 developed in the context of the regulation of health care a modified version of the framework of analysis originally proposed by Levy and Spiller. The main purpose of these authors was to understand the capacity of developing countries to develop approaches to regulation under which firms are willing to make financial investments in an industry in which there is a risk of administrative expropriation of investors' sunk costs. By developing and applying a modified version of their framework, this thesis contributes to existing work in the law and economics of regulatory design in two related ways. First, it transposes the framework into the context of regulation inside government, and shows that the approach can generate additional insights and interesting new hypotheses in this new setting. This is as an advance on existing understandings because although Levy and Spiller indicate the possibility that expropriation could occur

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<sup>3</sup> See for example the discussion of Kieran Walshe in Section 1.2.2, *supra*.

within the state-owned enterprises,<sup>4</sup> they do not develop this insight into a theory of regulation of the public sector. Secondly, by focussing on the ways in which regulation of health care can undermine the implicit concordat, and the way that regulatory design can alleviate (or exacerbate) the problem, the present account extends Levy and Spiller's beyond the original problem of the willingness of private investors to make financial commitments. The present study shows that a similar framework can shed light on how other the governance structure of regulation affects the decisions of other kinds of actors to make other kinds of commitments.

This thesis contributes to the literature on the law and economics of regulatory design in another, more critical respect. Levy and Spiller's (and their co-authors') comparative analysis views the institutional endowment of the UK through a telescope, as it were, observing the limits of administrative law approaches, as well as the strengths of private law rights enforced by an independent judiciary. In particular, they emphasise the limits of legislation within Britain's Westminster-style democracy, with its executive dominance of the legislature. By contrast, the magnifying glass approach of the present analysis calls into question some of these assumptions. Firstly, while this thesis broadly confirms their scepticism towards administrative law this has to be qualified in a number of respects. Firstly, the ineffectiveness of judicial review in enforcing lower-level commitment mechanisms, seen especially in Chapter 5, was arguably as much a failure of regulatory governance structures to make effective use of this potentially useful commitment mechanism. For example, it is plausible to argue that had the UK been more creative in drafting the criteria notified to the Commission under the Transparency Directive (discussed in Section

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<sup>4</sup> Levy and Spiller (1994). "The Institutional Foundations of Regulatory Commitment: A Comparative Analysis of Telecommunications Regulation." *Journal of Law, Economics and Organization* 10 (2): 201-246, fn. 10.

5.2.6) then this could have been a more effective device for restraining subsequent coalitional drift, while still leaving sufficient discretion for eliminating wasteful treatment. Secondly, this study seems to question Levy and Spiller's dismissive view of the effectiveness of legislation in establishing regulatory commitment. If their view was wholly correct, then it should not have mattered in the present studies whether operational rules governing regulatory discretion were set out in primary or secondary legislation or even in Directions from the Secretary of State. The evidence of this thesis does not support that view. At the very least, experienced legislators thought the form of legislation mattered.

Overall, then, this thesis contributes to the literature on the law and economics of regulatory design by extending Levy and Spiller's analysis to regulation within the public sector, and to the non-financial commitments on which effective policy depends. At the same time, it offers some refinement of their view of the UK constitutional setting.

## 8.4 Importance to the Real World

A second benchmark against which the contribution a piece of research ought to be assessed, is the importance of the research to the real world. The point is not that certain recommendations are justified by the findings of this thesis but, more modestly, that the findings point in the direction of certain implications for policy.

The framework developed in Chapter 4 offers suggestions to policymakers interested in introducing reforms in order to improve the effectiveness of regulation in the NHS. Moreover, such advice seems likely to be durable. On the one hand, only on the most extreme assumptions about the future development of health policy could it be thought that the principal

institutional features of the NHS—that it is overwhelmingly tax funded, predominantly free at the point of use, and dominated by the medical profession with respect to clinical decisions—will change radically, however much they may be eroded at the margin. In short, it may reasonably be assumed the future development of health policy will have to contend with the problem of credible commitment to the concordat. Similarly, there are no good reasons to suppose that the rise of the regulatory state inside the NHS is likely to be reversed any time soon, though again, reform at the margins is perfectly conceivable. Together, these two considerations point to the continued importance of credible commitment to the concordat, as a precondition for successful regulatory reforms in the NHS. The evidence of Chapters 5-7 suggest that credibility has only sometimes been a key consideration of policymakers, and that where it has been neglected, most obviously in the case of the Limited List, outcomes have been disappointing.

As well as pointing the importance of credible commitment, this thesis also suggests ways in which the design of regulatory regimes can contribute to the credibility of regulatory reforms. In particular, the analysis suggested that collective choice rules are often neglected by policymakers and advocates, and that greater attention at this level could improve outcomes. By way of illustration, Ham and Alberti's suggestion for a new explicit concordat, discussed in Section 2.4.2 may not lead to the outcomes they desire, unless additional attention is given to the mechanisms for its enforcement. While codification may well be desirable, it may not by itself be sufficient.

## 8.5 Limitations

In order to reach an assessment of the degree of confidence appropriate to these findings, it is essential also to understand the limitations of the approach of this thesis. This section focuses on two particular limitations: first, the exclusive theoretical focus on the commitment problem; and second, the single-country focus of the research.

In terms of the exclusive focus on the commitment problem, this contrasts most starkly with the type of analysis undertaken by Murray Horn in *The Political Economy of Public Administration*. Horn develops a model in which commitment costs are just one of four categories of transaction costs faced by legislatures; the others are agency costs, decision costs and uncertainty costs.<sup>5</sup> On this account, institutional design choices, for example the decision to delegate some administrative function, depend on the 'cost profiles' associated with different policy areas. Even Levy and Spiller profess to undertake an examination of the trade-off between flexibility and commitment in the design of regulatory regimes, though their practice, and that of their collaborators, has been criticised as differing from their own description of their approach.<sup>6</sup>

A study along these lines, especially following Horn's approach, would have developed insights substantially different to those that emerge from the present study. For example, given an exclusive focus on the commitment problem, it is tempting to see the failure to create more credible regimes in the case of NICE, and especially in the case of the

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<sup>5</sup> Horn (1995). *The Political Economy of Public Administration: Institutional Choice in the Public Sector*. Cambridge, Cambridge University Press. See especially Chapter 2, "Basic Theory and Method".

<sup>6</sup> Stirton and Lodge (2003). "Re-Thinking Institutional Endowment in Jamaica: Misguided Theory, Prophecy of Doom or Explanation for Regulatory Change?" CARR/CRC/ABS Workshop on Risk Regulation, Accountability and Development, Hulme Hall, University of Manchester.

Limited List, as an example of 'irrational' design. It may well be, however, that once the full range of transactions problems are understood, the adopted approaches reflected a difficult compromise between competing demands. If nothing else, this observation cautions against a hasty assessment of the policy implications of this thesis.

Notwithstanding this limitation, the present approach can be defended on a number of grounds. Most obviously, an understanding of commitment issues in isolation, while incomplete, may be a necessary preliminary step towards a fuller understanding incorporating an analysis of the compromises and trade-offs between different transaction costs faced by policymakers. Second, even if it is acknowledged that the commitment problem may not always be the paramount consideration in designing health care regulation, commitment issues are likely to have some importance in the health care sector, at least where reform initiatives seek to intervene within the clinical arena. For most practical purposes, the extent to which the design of institutions for regulation in the NHS address commitment issues is therefore likely to have a significant impact on the effectiveness of the regulatory regime.

These remarks together point to one further advantage of the present, commitment-based approach over an approach based on a consideration of the totality of transaction problems in the manner of Murray Horn: the present approach does at least yield clear hypotheses for investigation and analysis. By contrast, once multiple transacting problems are incorporated into the theory, many different observations are consistent with the theory. This does not diminish the usefulness of Horn's approach as a 'mapping tool', i.e. as a means of exploring the choice variables of institutional design in the public sector, and the range of factors affecting such choices. It does

suggest, however, that in order to develop meaningful hypotheses, it may be necessary to make simplifying assumptions.

The second limitation, identified above, relates to the single country focus of this thesis. The confidence that one can place on conclusions drawn from a single case study—even one which adopts an embedded research design as this thesis does—is naturally less than would be appropriate if the same hypotheses were supported by evidence from a number of countries. This raises the question as to how far it is possible to extend implicit concordat issues beyond a purely UK context.

It could perhaps be argued that the issue of cross-country comparison does not apply, unless it could first be established that health services in other countries were based on a similar bargain between the profession and the government. A more sophisticated approach would be to ask this question: if an implicit concordat (or some cognate institution) does not underpin health care regulation in other countries, what alternative arrangements exist? This question provokes us to look for 'functional equivalents' to the implicit concordat in other national settings. Functional equivalents might include 'explicit concordats'—including formal legal or constitutional protection of the autonomy of the medical profession. Alternatively, in the event that no such equivalents exist in any given country, one might speculate that the autonomy and professional identity of doctors might be difficult to sustain within a systems of public provision or regulation of health care. Heightened professional opposition to 'socialised medicine', whether through ownership or regulation, would be expected to arise in such cases. This hypothesis can easily be refined to develop observable implications concerning government-profession relations across different countries, and concerning the effects of a shift towards regulatory state-type institutions within health care sectors in different countries. While

such speculation may be interesting, the main point here is that good comparative analysis often proceeds from detailed knowledge of a single country. While acknowledging that a comparative focus could add to the confidence appropriate to the present findings, the single country focus of this study is can be said to be justifiable as a first step, on which future research may well profitably build in different ways.

## **8.6 Concluding Thoughts**

The commitment frame has proved extremely productive for analysing regulatory reforms in the NHS. The approach developed in this thesis has provided both a broad interpretation of institutional change in the health service, as well as providing more specific insights into particular reform initiatives. At the same time, this thesis has no more than pointed to the potential of this general approach, and there is much further work to do. As suggested by Section 8.5, potential avenues for further research include further testing of the framework in cross-country comparison as well as investigating the trade-offs in regulatory design between credible commitment and other transactions problems. The contribution of this thesis is sufficient to suggest that further research along these lines would be highly fruitful.

# Appendix

## Interview Codes

Code	Date	Position
I1	27 November 1997	Former senior politician, Scottish Office
I2	27 February 1998	Former consultant geriatrician
I3	5 March 1998	Senior politician, formerly DHSS
I4	19 March 1998	Former office holder, BMA
I5	23 March 1998	Consultant clinical pharmacologist
I6	28 July 1998	Two general practitioners
I7	20 August 1998	Official, Department of Health
I8	27 August 1998	Official, Department of Health
I9	3 September 1998	Official, NHS Executive
I10	11 September 1998	Management consultant
I11	22 September 1998	Former senior official, DHSS
I12	11 December 1998	Manager, National Centre for Clinical Audit
I13	9 July 1999	Former NHS Trust Chief Executive
I14	8 July 1999	Official, NHS Executive
I15	14 July 1999	Official, NICE
I16	16 July 1999	Senior Official, Department of Health
I17	21 July 1999	Former senior politician, Department of Health
I18	12 August 1999	Senior politician, Department of Health
I19	18 August 2000	Senior official, NICE
I20	20 August 2000	Former NHS Trust Chief Executive
I21	14 December 2001	Official, Department of Health
I22	5 March 2002	Senior official, CHI
I23	June 11 2002	Senior official, CHI
I24	19 August 2002	Former senior official NHS Executive

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