The London School of Economics and Political Science

The Political Consequences of Regulatory Reforms:

Drug Rationing Policies in England and France

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Declaration

I certify that the thesis I have presented for examination for the MPhil/PhD degree of the London School of Economics and Political Science is solely my own work other than where I have clearly indicated that it is the work of others (in which case the extent of any work carried out jointly by me and any other person is clearly identified in it).

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Abstract

The past few decades have seen the proliferation of regulatory agencies, expert committees, and other "non-majoritarian" institutions in Europe. Scholars tend to assume that once created, policies corresponding to these institutions persist, disrupting the existing governance structure. This thesis instead argues that policy continuity following the creation of agencies depends on the locus of regulatory decisions. Specifically, it proposes that the extent to which elected politicians are excluded from the decision-making, i.e. their level of "political insulation", affects policy continuity. Where elected politicians are excluded from the decision-making, this enables unpopular policy choices. But such choices, once made, generate a greater counter-mobilisation, undermining policy continuity over time. By contrast, where elected politicians have the final say on decisions, they can prevent unpopular policy choices from being taken, which contributes to policy continuity.

To illustrate these mechanisms, this thesis takes restricting the funding of pharmaceutical products by the healthcare system as a case of an unpopular regulatory policy and compares its development in England and France. Both countries established regulatory agencies tasked to assess the benefits of drugs for funding decisions, but the nations subsequently followed divergent trajectories. In England, high political insulation enabled policy choices that otherwise would have been too politically costly. Yet these choices, over time, led to a greater counter-mobilisation through public and electoral arenas, resulting in a partial policy reversal. By contrast, in France, low political insulation allowed ministers to choose not to follow the agency's outputs when they considered them too politically costly; ministers also prevented rule changes that might have made more politically-costly outputs possible. The findings highlight the endogenous drivers of post-regulatory reform policy development. Contrary to the linear trajectory, where "depoliticised" agencies reinforce themselves, the thesis suggests that under certain conditions, the policies that accompany regulatory agencies can undermine themselves by becoming a source of greater politicisation.

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List of Abbreviations

AAI	Autorité administrative indépendante
ABPI	Association of the British Pharmaceutical Industry
Afssaps	Agence française de sécurité sanitaire des produits de santé
ALD	Affections de longue durée
ANAES	Agence nationale d'accréditation et d'évaluation
ANDEM	Agence Nationale pour le Développement de l'Évaluation Médicale
ANSM	Agence Nationale de sécurité du Médicament et des produits de santé
ASMR	Amélioration de service médical rendu
ATU	Autorisations Temporaires d'Utilisation
BBC	British Broadcasting Corporation
BIGT	Bioscience Innovation & Growth Team
BMA	British Medical Association
BMJ	British Medical Journal
CDF	Cancer Drugs Fund
CEESP	Commission Evaluation Economique et de Santé Publique
CEM	Comité économique du medicament
CEPS	Comité économique des produits de santé
CSMF	Confédération des syndicats médicaux français
CHI	Commission for Health Improvement
CNAM	Caisse nationale de l'assurance maladie
CNAMTS	Caisse nationale de l'assurance maladie des travailleurs salariés
CSIS	Conseil stratégique des industries de santé
CSS	Code de la Sécurité Sociale
CT	Commission de la transparence
DEC	Development and Evaluation Committee
DH	Department of Health (UK)
DRG	Diagnosis-Related Groups
DSS	Direction de la sécurité sociale
EBM	Evidence-Based Medicine
EMA	European Medicines Agency (2004-)
EMEA	European Agency for the Evaluation of Medicinal Products (1995-2004)
EoL	End of Life
EC	European Community
EU	European Union
EUROCARE	European Cancer Registry based study on survival and care of cancer patients
FDA	Food and Drug Administration
GP	General Practitioner
HAS	Haute Autorité de Santé
HCAAM	Haut Conseil pour l'avenir de l'assurance maladie
HIV	Human immunodeficiency virus
HoCHC	House of Commons Health Committee
HSJ	Health Service Journal

HTA	Health Technology Assessment
ICER	Incremental cost-effectiveness ratio
IGAS	Inspection générale des affaires sociales
ITR	Index Thérapeutique Relatif
LEEM	Les Entreprises du médicament
LFSS	Loi de financement de la Sécurité sociale
LIR	Laboratoires internationaux de recherche
MECSS	Missions d'évaluation et de contrôle de la Sécurité sociale
MISG	Ministerial Industry Strategy Group
MTA	Multiple Technology Appraisal
MP	Member of Parliament
MS	Multiple Sclerosis
NCCHTA	National Coordinating Centre for Health Technology Assessment
NICE	National Institute for Clinical Excellence (1999-2005); National Institute for Health and Clinical Excellence (2005-2013); National Institute for Health and Care Excellence (2013-)
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
OFT	Office of Fair Trading
ONDAM	Objectif national des dépenses d'assurance maladie
PCT	Primary Care Trust
PICTF	Pharmaceutical Industry Competitiveness Task Force
PMSI	Projet de médicalisation des systèmes d'information
PPRS	Pharmaceutical Price Regulation Scheme
PS	Parti socialiste (Socialist Party, France)
QALY	Quality-Adjusted Life Year
QOF	Quality and Outcomes Framework
R&D	Research and Development
RMO	Références médicales opposables
RPR	Rassemblement pour la République (Gaullist Party 1976-2002, France)
SMR	Service médical rendu
SNIP	Syndicat national de l'industrie pharmaceutique
STA	Single Technology Appraisal
T2A	Tarification à l'activité
UDF	Union pour la démocratie française
UMP	Union pour un mouvement populaire (Gaullist Party 2002-2015, France)
UNCAM	Union Nationale des Caisses d'Assurance Maladie
VBA	Value-based Assessment
VBP	Value-based pricing
WHO	World Health Organisation

Introduction

With technological advances and demographic change, governments across the industrialised world have been under often contradictory pressures regarding funding medical technologies through public health care systems. On the one hand, they have introduced various measures in an attempt at controlling costs, concerned with the fiscal sustainability of the welfare state. On the other, they have committed to enabling citizens' access to sophisticated technologies by making them available via public health care systems. To add further complexity, the latter imperative of securing access to technologies has often gone hand in hand with the goal of rewarding the industries producing them, such as the pharmaceutical and medical device industries, which have often been seen as strategically important in the knowledge-based economy.

The focus of the present study is on a particular set of policy responses to these conflicting pressures. Most European countries underwent major procedural and institutional reforms in the 1990s and 2000s, which involved the establishment or reorganisation of regulatory agencies tasked to assess the clinical and cost-effectiveness of medical technologies and healthcare interventions. Partly stemming from intellectual movements called Health Technology Assessment (HTA) and Evidence-Based Medicines (EBM), the underlying idea of such reforms was to base decisions on funding or excluding technologies from health care systems – or "rationing" in the popular idiom – more on technical expertise. Rationing is, by its nature, a political act: policy decisions to ration technologies inevitably mean some have their wellbeing more socially protected than others, and hence have profound implications for both individual lives and the allocation of health care resources. With the establishment of agencies, experts within them have been seen to play a prominent role in such decisions, in an attempt at providing legitimacy based on their technical expertise – and hence providing a type of solution to political conflicts arising from the countervailing pressures.

Yet the establishment of regulatory agencies by no means resolved the conflicting imperatives concerning funding technologies. Nor have the agencies yielded uniform effects on subsequent developments across nations. Countries have followed divergent policy trajectories both in terms of their policy orientation on funding drugs and the patterns of institutional modification. Why have countries confronting similar challenges and introducing a similar type of institution followed different trajectories? Why did regulatory institutions created by the reforms remain stable in some countries but alter over time in others? Focusing

on decision-making over funding drugs through public health care systems, the present study investigates how, and under what conditions, policies accompanying newly-created regulatory institutions are maintained or changed over time.

By examining the process through which the development of regulatory institutions takes place in the subsequent period, the study situates battles over drug rationing in broader political struggles over the transformation of the roles and organisational structures of the state in Europe, in particular of what is often called the "regulatory state" (Majone 1994, 1996). In the past few decades, regulatory agencies, expert committees, and other delegated policymaking bodies have spread across Europe and across different policy areas. Broadly labelled as so-called "non-majoritarian" institutions – a government entity separate from other institutions and neither directly elected by citizens or managed by elected officials[1] - the creation of these organisations was widely seen as a significant institutional innovation, leading to disruption of the existing mode of governance structures and its replacement with a new one (e.g. Majone 1997; Moran 2003; Thatcher and Stone Sweet 2002). In his seminal article, Majone (1997), for instance, has argued that the proliferation of non-majoritarian institutions indicates the transformation of the mode of governance, namely, the transformation that is in the process of the transition from the "positive state" to the "regulatory state". He claimed that instead of the direct intervention through redistribution that states in post-war Europe once enjoyed, the role that states play today has increasingly been becoming one of rulemaking and regulation to correct market failure. For him, this shift in the role of the state not only means changes in its organisations and instruments, but also leads to corresponding shifts in governance structures linking the state with society. The latter shift takes place by replacing corporatist policymaking between the state and dominant societal actors with more pluralistic rulemaking by regulatory agencies serving diffuse interests. On this account, the spread of regulatory agencies is seen as a sign of broader transformation of state-society relations.

The regulatory state thesis has gained much currency among scholars of European politics and public policy (cf. Lodge 2008; Holzinger and Schmidt 2015). Inspired by the delegation theory in American politics, a vast research programme has emerged, which examines underlying sources and determinants of delegating power(s) to non-majoritarian institutions, issues in their institutional design including political control and accountability, and formal and actual independence of regulatory agencies; it has also covered a wide range of policy

[1] This definition is modified from Thatcher and Stone Sweet 2002, p.2.

domains at both national and supranational levels. Scholars have argued that delegation to non-majoritarian institutions is driven by the need for technical expertise,[2] the necessity for credible commitment,[3] the problem of political uncertainty,[4] and the desire to shift the blame for unpopular policy outcomes.[5]

While much has been studied about the creation and design of delegated bodies, less attention has, however, been paid to political dynamics after delegation. A particular lacuna is whether and how the creation of regulatory institutions affects a broader landscape of policymaking and political struggles where the state and society interact. This is despite Majone's original thesis that the proliferation of independent agencies does not end in itself, but transforms the governance structures of state-society relations. The predominant scholarly account in this regard tends to see the establishment of regulatory agencies as an ongoing march towards "depoliticisation" (Hay 2007; Mair 2013). For instance, in a recent book Mair (2013) laments that the spread of non-majoritarian institutions has contributed to the erosion of party democracy in Western countries. Policymaking by parties is replaced by non-majoritarian institutions, whose officials are less often recruited from parties and more accountable to judicial and regulatory controls. And with the formation of a network of regulators at supranational and national levels with ever more dispersed authorities, "… the very notion of accountability being exercised through parties, or of the executive being answerable to *voters* (as distinct from citizens or stakeholders) becomes problematic. Party, in this sense, loses much of its representative and purposive identity, and in this way citizens forfeit much of their capacity to control policy-making through conventional electoral channels." (69, italics original). The result of loss of parties' role in democracy is that "… we are left with a stripped-down version of constitutional or Madisonian democracy … or other post-popular version of democracy … or those systems of modern governance that seek to combine 'stakeholder participation' with 'problem-solving efficiency'" (15).

A problem common to both Majone's original formulation of the regulatory state and the depoliticisation thesis is that they tend to conflate institutional creation with its subsequent maintenance. But the former is crucially distinct from the latter. Based on analyses of major policy reforms intended to serve diffuse interests in the United States, Patashnik (2008) argues

[2] Bawn 1995; Epstein and O'Halloran 1999.
[3] Majone 2001; Levy and Spiller 1994.
[4] Moe 1990.
[5] Fiorina 1982; Hood 2002

that the successful enactment of a policy reform by no means guarantees its durability over time. This is because, to make such a "general interest" reform durable, it must disrupt the existing coalitions of vested interests while creating new ones. This insight is readily applicable to the context of reforms establishing regulatory institutions in Europe, especially because at the time of their creation these institutions were often intended to serve diffuse interests as opposed to concentrated, particular ones. Hence the creation of non-majoritarian institutions may not necessarily lead to their maintenance; the reproduction of these newly created institutions remains an open question.

To be sure, delegation to bureaucrats and non-majoritarian institutions, as Patashnik claims (2008, 151-152), may increase the chances of reforms sustaining in the post-enactment phase. After all, a delegated institutional design is intended to make it more difficult for future politicians to remove it (cf. Moe 1990). But this safeguard by institutional design is not without limits. On the contrary, the very conditions that are said to be behind the delegation to non-majoritarian institutions might also generate greater forces to hinder the reproduction of the institutions. For this is, after all, an area characterised by technical complexity that requires sustained investment in analytical and regulatory capacity, vested interests that politicians tomorrow might be tempted to be drawn to, and unpopular policies that attract blame on the incumbent government – all should pose significant challenges to the durability of the regulatory state institutions. In short, there is little theoretical reason to believe that delegated institutions created by reforms are automatically reproduced in the subsequent periods; the conditions under which that takes place must be empirically investigated rather than theoretically assumed.

By examining the trajectories of drug funding policies in England and France since the late 1980s, the present study contends that policy trajectories following institutional reforms reflect to a great extent past institutional and policy choices. To understand policy and institutional development after delegating reforms, it argues, we need to look at ways in which existing institutions produce forces that reinforce and undermine themselves.

Drug rationing policies as a site of inquiry

Drug funding policy provides an excellent opportunity to develop insights about the post-reform politics of the regulatory state in Europe for two main reasons. First, it is an area where procedural reforms involving the establishment of regulatory institutions took place across

European countries in response to common policy challenges. Moreover, in line with the regulatory state thesis, in this area the establishment of regulatory institutions constituted a potential departure from existing governance structures – an institutional choice that some scholars have considered as a transition towards the "regulatory health care state" (Hassenteufel and Palier 2007; cf. Moran 2003). At least until the mid-1980s, doctors had sole discretion over treatment choices. Rationing typically took a "hidden" form, such as "bedside rationing" by individual clinicians (cf. Klein 1993; Mechanic 1995). The delegation of clinical governance to the medical professions was underlined by their political power as a vested interest, which, according to some scholars, reflected historical bargains struck between the state and medical profession over the latter's clinical autonomy in exchange for expanding the popular coverage of health care (Tuohy 1999). Another feature of traditional governance structures, especially in Europe, is a relatively lenient drug approval regime - a characteristic related to another vested interest: drug companies. In European countries, post-war drug approval regulation was favourable to manufacturers, especially compared to the United States, due to a less stringent approval process and regulatory bodies lacking expertise and independence from the pharmaceutical industry (Hauray 2006; Carpenter 2010, chapter 9). It was only after the late 1980s that this feature began changing, with the creation of the European Medicines Evaluation Agency (EMEA, later renamed the European Medicines Agency, or EMA) and concomitant developments of independent approval agencies at the national level. Even after these developments, however, drug approval has its own limitations. It is typically based on randomised-controlled trials compared with placebo to demonstrate its safety, efficacy, and quality; once a drug obtains approval few rules and little information have existed to evaluate whether it is effective in real-world settings, let alone whether it is more clinically or cost-effective compared to other interventions.[6] With the absence of guidance and information, doctors have often relied on drug companies as the bases of their clinical judgements.[7]

Reforms to establish regulatory agencies that assess the clinical and cost-effectiveness of drugs, and explicit decisions for drug reimbursement based on such assessments thus represented a potentially significant break with the traditional governance structure dominated

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[6] Scholars and practitioners alike distinguish the term *efficacy*, understood as "the extent to which an intervention does more good than harm under ideal circumstances" from *effectiveness*, which means "the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice". The European Commission, 2008, 58.

[7] This is connected with the issue of clinicians' conflicts of interest. Cf. Rodwin 2011.

by clinicians and the pharmaceutical industry. Since the 1990s, agencies in charge of assessments of drugs' benefits spread rapidly across European countries.[8] While these agencies vary in their missions, structures, processes, and methods, they are active at both national and European levels. At national level, they play a role in drug reimbursement decisions, informing decision-makers or making decisions. At EU level, through a network of the regulatory agencies, they engage in collaborative projects by identifying "best practices" and sharing information about methods and assessment tools.[9]

The move towards agencies in drug benefit assessment was closely linked with the growing currency of HTA as an intellectual movement among policymakers in Europe. HTA involves a systematic evaluation of impacts of the use of health care technologies within health care systems, from medical, economic, and social perspectives.[10] The agencies use various methods of HTA to assess a drug's benefit, with varying analytical frameworks and criteria across countries. A cost-effectiveness analysis compares costs and benefits of drugs to derive a "cost-effectiveness ratio" -- the incremental cost of an intervention with the corresponding incremental improvements. It thus uses economic models to evaluate the drug's benefit. In addition to drug reimbursement and pricing, the agencies use HTA for other policy programmes, including clinical practice guidelines and public health programmes.

Policymakers and academics alike have given several rationales behind the use of HTA for reimbursement decisions, all against the backdrop of rising health care costs. Indeed, while those advocating HTA for policy-making often attribute its origins to the US Congress's Office of Technology Assessment in the early 1970s, domestic health policy debates also stimulated the growth of institutions dedicated to HTA in Europe .[11] First, the use of HTA was justified on the ground of concerns about impacts of high-tech medical technologies on health care expenditure and about the medical practices that lacked evidence of clinical effectiveness. HTA was also considered to inform rationing decisions to achieve efficient resource allocation. Assessing "value for money" of a technology, hence, aids priority-setting to maximise

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[8] 16 out of the 28 (12 out of the 15 pre-2004) EU member states had established HTA agencies by 2011. Löblová 2016, 257.
[9] Garrido et al. 2008, 38ff.
[10] For an overview of HTA, Sorenson et al. 2008, 3-8; Garrido et al. 2008, 31-51. A related but distinct intellectual movement is Evidence-based Medicines (EBM). Whereas HTA is to support decision-making at policy level, EBM aims to support decision-making at the individual clinical level. Garrido 2005, 3; Luce et al. 2010, 269.
[11] Garrido et al. 2008, 33-34; Sorenson and Chalkidou 2012, 25-26.

healthcare outcomes from the available resources.[12] Finally, the use of HTA for rationing decisions was linked with the rationales for evidence-based policy-making and transparency in the policy-making process.[13] In short, it has been widely recognised that the creation of regulatory agencies that use HTA for drug funding would potentially yield impacts on clinical practices, rationing decisions, and resource allocation.[14] These potential impacts, in turn, have *political* implications – by disrupting the traditional governance structure and altering the power balance between the state, drug companies and clinicians. Examining policy development will thus shed light on conditions under which policies corresponding to the transition to the regulatory state reproduced or changed over time.

Another, no less important, reason for studying battles over drug rationing is that policy choice in this area highlights a tension, perhaps in its starkest form, between democratic governments and non-majoritarian institutions, due to its core attribute: a policy choice to explicitly exclude drugs from reimbursement is highly unpopular. The policy choice can impose significant, visible losses on both powerful organised interests *and* the public with only diffuse policy benefits and beneficiaries. It is somewhat counterintuitive that a risk-averse democratic government chooses to make such a decision, which is not only morally controversial but also predictably results in real-world contestation. Moreover, while this unpopular nature of the policy choice should generate a stronger incentive for politicians to shift the blame to a regulatory agency, the same attribute may also imply that there is a potential for greater societal forces that put politicians under pressure to undermine the functioning of the regulatory institutions. Exploring the role of these countervailing forces in the maintenance of the regulatory institutions in this policy area will thus have wider implications for changes in the state-society relations after the rise of the regulatory state.

Through the study of drug funding policies in England and France, the thesis adds to the nascent but emerging political science research on drug pricing and reimbursement policy – a subject that has been studied largely by health economists and legal scholars.[15] Inspired by the

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[12] Oliver et al. 2004, 3; Sorenson et al. 2008, 6. Sorenson and Chalkidou 2012, 26.
[13] Sorenson and Chalkidou 2012, 26; Sorenson et al. 2008, 6.
[14] It should be noted that the use of HTA for efficient healthcare resource allocation is different from healthcare *cost-containment*. Deciding to include a treatment that proves cost-effective to the health care system may in fact lead to *increase* in the health care expenditure. Cf. Sorenson and Chalkidou 2012, 39.
[15] For health economist works that give overviews of drug pricing and reimbursement policies as well as HTA in Europe, e.g. Jacobzone 2000; Mossialos, et al. 2004; Sorenson et al. 2008; Kanavos 2011. For legal analyses on drug rationing, Syrett 2007. For a notable exception of earlier political science works, Hancher 1990.

proliferation of agencies in charge of HTA, in recent years political scientists are beginning to study HTA agencies, which have thus far largely revolved around two issues. A first concern is the creation and design of HTA agencies (Landwehr and Böhm 2011). Löblová (2016, 2018) highlights the role (and limits) of local epistemic communities in the creation of HTA agencies in Central and East European countries. Another is HTA's knowledge dimension, such as the approach and methods used by the agencies. Benoit (2016) shows how the English and French states incorporated regulatory concepts originated from outside the state, affecting private actors' practices. By and large, scholars have found continued cross-national diversity in both institutions and approach of HTA despite the common pressures that facilitated policy diffusion and learning (cf. Klinger et al. 2013; Wright et al. 2017; Hassenteufel et al. 2017).[16]

This study seeks to contribute to the literature by focusing on a different aspect. It brings distributive struggles over rationing decisions after the creation of agencies to the forefront of the analysis. In the end, what makes HTA controversial is less about the knowledge per se than how it is used. From the vantage point of the loss-imposing nature of rationing decisions, the present study emphasises political contestations over the use of HTA for these decisions. Rooted in the very institutional arrangements around HTA agencies, the thesis will show, these political contestations have driven drug funding policy development.

The argument in brief

This study proposes that policy trajectories after regulatory reforms depend on the locus of decision-making over drug funding. I argue that the degree to which elected officials are excluded from the decision-making – which I shall call political insulation – has major implications for the trajectories. Political insulation matters for subsequent policy development because it affects policymakers' ability to make policy choices that impose losses on societal actors. These different policy choices, in turn, structure forms of political conflicts, including actors' strategies for mobilisation and the arenas in which conflicts are mediated. The varying forms of conflicts, then, affect the persistence of existing policies. By creating its own political dynamics, political insulation thus shapes post-reform policy development.

[16] On the continuing divergence of drug pricing and reimbursement as well as HTA despite Europeanised drug approval regulation, Permanand 2006; Smith 2016, Ch4; see also Hauray 2006 for drug approval regulation. On the EU-level HTA regulatory network, Böhm and Landwehr 2014; Greer and Löblová 2017.

The process that links political insulation with later policy development operates in different settings. A high politically-insulated setting enables policymakers to produce policy outputs that would otherwise have been too unpopular to enact. But the policy choices create a greater magnitude of counter-mobilisation in the public arena, creating an impetus for policy change. By contrast, a low politically-insulated setting allows elected officials to avoid making costly policy choices. By blocking the opportunity for expanding political conflicts, the policy choices contribute to policy continuity.

The study develops these arguments based on the study of drug funding policies in England and France. In England, the establishment in the late 1990s of a regulatory agency assessing clinical and cost-effectiveness of drugs created a locus of decision-making highly insulated from politicians, with the agency's recommendation directly becoming a final policy decision for the National Health Service (NHS). This institutional arrangement enabled English policymakers to produce more decisions to not fund drugs that the regulator judged not cost-effective. During the 2000s, however, while the agency adhered to the existing policy orientation, there was a gradual expansion of policy that allowed for greater flexibility in funding that applied to particular types of drugs. The partial policy change occurred through various instruments, including a greater use of faster regulatory assessment processes, specific regulatory criteria and pricing mechanisms to allow for greater flexibility in assessment of drugs for end-of-life care, and perhaps most notably, a specialised fund applied to the cancer drugs rejected by the regulator.

In France, whereas an expert committee, later reorganised into an independent regulatory agency in the early 2000s, assessed clinical effectiveness of drugs, it remained the health minister who made the final decision on whether a drug should be reimbursed by the national health insurance body. This institutional arrangement with low political insulation enabled ministers to selectively refuse to follow the regulator's negative advice, still reimbursing the drugs that experts judged not effective. The government used various tactics to avoid total exclusion of these drugs from reimbursement, including price reduction, incremental or partial reduction of the reimbursement rate and the creation of a new reimbursement rate. It also extensively used pricing control to rationalise resource allocation, where traditionally the government has held a strong power over the pharmaceutical industry. Policy continuity over drug funding largely persisted despite repeated unsuccessful attempts to change the reimbursement criteria and despite a major drug scandal which was itself a partial by-product of the existing policy choices.

These developments had significant (re-)distributional implications. In England, while regulatory decisions were driven by rational resource allocation, by allowing flexibility for a particular type of drugs the state partially redistributed resources between different groups of patients, prioritising some over others based on political considerations. In France, by adjusting the reimbursement rate of, or totally de-reimbursing, some drugs while still funding others based on political decisions, and by extensively using pricing control as a tool for resource allocation, the state has managed to partially shift the costs of policy adjustment to both the pharmaceutical industry and the supplementary insurers as well as patients themselves.

In both cases, distinct political dynamics produced by different institutional arrangements have been highly consequential to policy development. For England, this study shows how negative policy choices in a highly-insulated locus of decision triggered a broader counter-mobilisation involving the public and legislative arenas, leading to a partial policy change; how and why the partial policy change applied to a particular area, such as cancer drugs, but not others; and how the counter-mobilisation ultimately ended up with a "bounded" policy change rather than a full-scale reversal, due to the resistance of actors whose positions are also shaped by existing institutions. For France, this study shows how in a less-insulated institutional setting, ministers who worried about costly consequences of their policy choices avoided de-reimbursing the drugs that experts judged clinically ineffective; and how elected officials and civil servants prevented repeated attempts at policy changes that would have enabled more rationing decisions. These policymakers' attempts to minimise the possibility for rationing decisions facilitated policy continuity, while they tackled fiscal challenges by using pricing control as a tool for resource allocation.

In examining the driving forces of post-reform drug funding politics, the study draws on the historical institutionalist literature on endogenous change (Streeck and Thelen 2005; Mahoney and Thelen 2010) – a literature that has been separated from studies on the regulatory politics. While this study is broadly resonant with the historical institutionalist idea that emphasises ways in which institutional reproduction and change take place through its distributive consequences, the current literature does not necessarily provide fully-developed hypotheses that are specific enough to be systematically tested against the post-regulatory reform politics. The study therefore inductively develops propositions that are testable in other country settings and policy domains. In fact, one of the contributions that the study seeks to make is to examine an underexplored role of political insulation in endogenous development, by fruitfully combining it with insights about regulatory politics.

Why England and France?

This study uses comparative case studies and process tracing to develop arguments about the role of political insulation in post-reform policy development. It takes up England and France as country cases to examine in detail.[17] I have chosen to study these countries based on their similarities in a number of respects, on the one hand, and differences in institutional structures around drug funding policy, on the other. First, the two countries share several background conditions that have put them under pressure regarding drug funding. Both are developed democracies with similar demographic trends.[18] Moreover, with the establishment in 1995 of the EMEA, the drug approval regulator at EU level, the approval process of "innovative" medicines was partially centralised, giving the same drugs approval across member states. These common characteristics allow me to hold both demographic changes and new medical technologies – two major sources of challenges for the health care state – largely constant. Second, despite the different public health care financing models (health service in England and health insurance in France), in both countries the state has determined whether a drug should be covered by public health care systems. Policymakers in both countries thus have held the responsibility – or else the blame – for making a drug available through the public health care systems. Third, in response to the drug funding challenge, in the 1990s and early 2000s both countries reformed their drug pricing and reimbursement decision-making process, including setting up or reorganising a regulatory agency or expert committees that assess the clinical or cost-effectiveness of drugs. The UK is generally seen both as a frontrunner and as a paradigmatic case for the regulatory state thesis (cf. Moran 2003). In France, the establishment of the independent regulatory agency in this policy area was considered as a convergence towards the regulatory state model in Britain, reflecting a wider trend in countries with Bismarckian health care regimes (Hassenteufel and Palier 2007). Policymakers in France have, in fact, often made an explicit reference to the English experience, both as a model and for lessons to draw from.

Despite these similarities, the two countries followed divergent trajectories in terms of both policy choices over drug funding and subsequent policy continuity. Using variations in sector-

[17] Due to the jurisdiction of the National Health Service the thesis focuses on England instead of UK.
[18] The share of persons >65yo in the total population (2016): 17.9% (UK), 18.8 % (FR), EU-28 average= 19.2%; Life expectancy at birth for total population (2015): 81.0 (UK), 82.4 (FR), EU-28 average= 80.9. Source: Eurostat (online data code: demo_pjanind, demo_gind)

level institutional arrangements around drug funding policy, the study develops arguments about how the different institutional structures affect the divergent trajectories.

An additional methodological merit of studying England and France is based on the fact that both countries are located at a stronger end of the spectrum among advanced democracies in terms of the degree of executive dominance (cf. Lijphardt 2012). This macro-institutional characteristic provides a useful opportunity to develop hypotheses on political dynamics involving loss imposition on organised interests and the public, because it is a less favourable environment for them to effectively mobilise against state actions. The constitutional structure of the French Fifth Republic was famously designed to grant strong powers to the executive while deliberately making the powers of the legislative branch weak (cf. Knapp and Wright 2006, 53f). The French executive branch is known to hold strong powers not only in relation to its legislative counterpart but also to societal actors. It is often seen as a paradigmatic case of the "strong state" with unilateral state intervention and weak societal inputs (e.g. Levy 1999). For its part, the UK is widely regarded as the birthplace of the "Westminster model", with strong executive and weak legislative powers – a feature reinforced by strong party discipline and majoritarian electoral rules (e.g. Finer 1975; Dunleavy 2006 cf. Flinders 2005).[19] The concentration of executive powers in the two countries implies that these are cases where the state is more likely to be able to impose its preferences upon societal actors. If we see political accommodation of societal interests even in such institutional settings, then we should observe similar dynamics in other settings as well.

Some readers may feel that these two countries are so different from each other at the starting point, in terms of rationing as a policy problem inherent in the respective health care system, that a meaningful comparison is impossible. They might think, for instance, that with a traditionally smaller pharmaceutical spending per capita,[20] drug rationing could be a policy problem in England but not in France. In this view, the observed variation in political dynamics in the post-reform period would simply reflect the prior nature and the intensity of the policy problem and be unrelated to institutional structures created by the reforms. To consider this potential objection, in Chapters 2 and 3 I briefly look at the history of health care funding

[19] Note that this description is about *formal*, constitutional structures at macro level. There has been a long debate over *actual* characteristics of the pattern of policymaking and governance structures especially at meso-level in both Britain and France.

[20] The 2015 retail pharmaceutical expenditure capita (including both prescription and over-the-counter medicines): $497(UK), $637(FR) (Organisation for Economic Co-operation and Development (OECD)-31 average=$553 PPP). Source: OECD Health Statistics 2017 http://dx.doi.org/10.1787/888933605388

policy of the two countries prior to the procedural reforms in the 1990s. As these chapters will show, both countries had a history of policy measures that explicitly excluded drugs from health care coverage, and in both countries such measures were widely seen as an unpopular policy that could threaten incumbent governments. Rather than confronting qualitatively different policy problems, the two countries have been faced with a similar challenge but responded in different ways.

The analysis for each country begins with the late 1980s and ends with the mid-2010s (around 2016). The starting point of the analysis is when, in both countries, the policy debates that would result in major institutional reforms of their drug funding processes in the 1990s began in earnest, together with some background analysis of earlier post-war decades. The study explores the emergence of reforms to establish regulatory institutions in the 1990s and in the 2000s, followed by examination of the post-reform period, with the analyses ending in the mid-2010s. The length of the time period covered in this study is designed to enable me to examine mid-term political dynamics and policy and institutional development, which tended to be missed out in analyses focusing solely on individual regulatory choices or policymaking processes over a shorter period.

A roadmap of the thesis

The next chapter sets out an analytical framework to examine political struggles following the establishment of the regulatory state institutions. It describes how different levels of political insulation affect forms of political conflicts, such as political actors' strategies for mobilisations and the different arenas in which political conflicts are mediated; and how the conflicts in turn shape policy trajectories. Chapters 2 and 3 examine the emergence of institutional structures with different levels of political insulation. They give a brief description of each country's post-war institutional structure and actor constellation as well as their coalitions. In doing so, they situate the policy debates and political struggles that gave rise to the regulatory state institutions in their deeper institutional contexts. By describing policy development around the emergence of different degrees of political insulation, they establish varied institutional and policy strategies for tackling an unpopular policy such as rationing.

The following four chapters then examine the consequences of the different institutional structures. Through comparative analysis and process tracing, they show how different levels of political insulation endogenously created forces to reinforce or undermine existing drug

funding policies over time. Chapters 4 and 5 examine the post-reform trajectory in England. Chapter 4 shows how the institutional structure with a high level of political insulation, while enabling politically costly decisions, later led to a partial policy reversal by provoking a greater counter-mobilisation channelled through public and electoral arenas. Chapter 5 then demonstrates how policymakers nevertheless did not achieve a fuller policy reversal. Chapters 6 and 7 look at the French trajectory after institutional reforms with low political insulation. Chapter 6 zooms in onto ministers' policy choices about whether to follow expert opinions about a drug's clinical benefit, showing that how the anticipated political costs associated with exclusion of drugs informed ministers' choices to avoid politically costly decisions. Chapter 7 then looks at the broader political struggles over changing rules governing the expert opinions. Here again, the potential of politically costly choices discouraged elected officials from enacting reforms; instead of changing rules that might enable more politically costly choices, the government kept tackling the drug provision dilemma largely through existing instruments, such as pricing control, containing conflicts within the existing organised channels. Together, these two chapters show the role of low political insulation in policy continuity.

Chapter 8 puts together empirical findings and discusses theoretical implications for the scholarship of both the regulatory politics and endogenous development. The thesis ends with wider implications of the study's findings for debates about regulatory reforms, depoliticisation and democratic politics.

Chapter 1 Studying political dynamics in the post-reform period: An analytical framework

The proliferation of regulatory agencies in Europe over the past few decades is considered significant as it indicates larger changes in state-society relations. As set out in the Introduction, however, whereas regulatory agencies occupy a central place in this "regulatory state" thesis, scholars to date have not paid enough attention to the processes through which policies accompanying the creation of agencies evolve over time. The present thesis addresses this gap through the study of drug funding policy in England and France – a policy that, as the regulatory state thesis argues, might lead to disruption of the existing governance structure and that, due to rationing decisions' highly unpopular nature, highlights tensions between non-majoritarian institutions and democratic politics. The thesis examines how institutional structures created by regulatory reforms can reinforce or undermine their accompanying policies. It thus studies endogenous drivers of post-reform policy development.

This chapter presents an analytical framework for understanding the post-reform trajectories of drug funding policy. It looks at how institutional arrangements around this policy shape political dynamics; and how these, in turn, affect policy development. The argument is that policy durability after a regulatory reform depends greatly on the locus of decision-making over drug funding. Specifically, this study suggests that political insulation, namely, the extent to which elected officials are excluded from decision-making, has major implications for subsequent trajectories by creating its own political dynamics. The chapter considers how different levels of political insulation affect policy choices; and how the different policy choices generate subsequent mobilisation over policy change.

The analytical framework builds on the literatures on regulatory politics and on the historical institutionalist analysis of endogenous change –two scholarships that have been largely separate from each other. Regarding the scholarship on regulatory politics, through its inquiry into the post-reform political dynamics this study engages with a key argument of the regulatory state thesis in Europe, that is, the proliferation of regulatory agencies is part of a larger transformation in state-society relations. It advances the notion of political insulation – a notion that departs from the literature's conventional focus on a regulator's independence -- and explores its implications for post-reform policy development. Regarding the endogenous change literature, I build on its emphasis on the role of underlying coalitions to address the gaps in the functional premises of the regulatory state thesis. I also draw on the historical

institutionalist ideas about the role of past policy choices and of arenas in political conflict to explore post-reform political dynamics.

The chapter proceeds in five steps. First, it presents the main interest of the study: development of drug funding policy after regulatory reforms. I provide a conceptual definition of an explicit drug rationing strategy, and set out how I empirically assess its occurrence. Second, the chapter discusses the locus of decision-making over drug funding. I provide the notion of political insulation, and how it is different from the delegation literature's conventional focus on the regulator's independence. Third, I present an analytical framework for the study of endogenous policy development after regulatory reforms. The focus is on how political insulation generates forces for both policy durability and change, by structuring the power balance between political actors' coalitions. The fourth section discusses methods and sources used for the empirical research, followed by conclusions in the fifth section.

1. The outcomes of interest: The post-reform trajectories of drug rationing policies

In this thesis drug funding policy refers to government policies for covering (parts of) the cost of pharmaceutical products by public health care systems, regardless of whether they are a general tax-funded health service, which directly delivers reimbursable treatments, or a contribution-based health insurance, which reimburses their costs.[21] By policies, I mean written rules (i.e. formal rules and informal guidelines) as well as decisions on individual drugs based on these rules.

The thesis's analytical focus is on *explicit drug rationing strategy*– a policy strategy that can be understood here as an explicit decision or non-decision by a public policy-making body to limit the usage of a particular drug via the public healthcare system compared to the scope of approved usage. This is a somewhat peculiar definition of drug rationing, based on the present study's focus on the consequences of setting up regulatory agencies, and several clarifications are in order. First, rationing takes various forms and methods, and analyses in this thesis are centred on one particular form: an "explicit" form of rationing, that is, a rationing decision made by public authorities. It does not look in detail at an "implicit" form of rationing, where decisions to restrict treatments are not publicly discussed and are typically made by

[21] Throughout the thesis I use the terms of "reimbursement", "coverage", and "funding" of drugs interchangeably.

medical professionals. Examples of such rationing may include "bedside rationing" where individual clinicians choose either not to use specific treatments or to substitute them with cheaper or less intense treatments, and rationing by delay through waiting lists for specialist appointments (cf. Klein 1993; Mechanic 1995). The focus on explicit rationing does not mean that I do not consider implicit rationing important – far from it; as set out in the Introduction, setting up regulatory agencies assessing a drug's benefit meant a potential departure from the traditional governance structure precisely because they replaced a clinician-centred implicit rationing with an explicit one. Rather, the focus on explicit rationing reflects this study's central concern with the *consequences* of the creation of regulatory agencies -- and the concomitant shift in institutional structure that enables explicit rationing strategies. To further narrow down the focus, this thesis examines rationing of on-patent medicines; generic medicines are not examined, as the institutional arrangements for these drugs involve a different set of regulatory processes and actors.

Second, this study looks at a regulatory decision over funding a drug that comes *after* its approval. It uses the scope granted at drug approval as the "baseline" of drug usage and considers explicit rationing strategy as restriction compared to that scope. Before a new drug or a new indication of an existing drug enters a jurisdiction, a drug approval agency within the jurisdiction must grant an approval ("marketing authorisation") based on the drug's safety, efficacy, and quality.[22] When an explicit rationing strategy is available to policymakers, however, the approval of the drug does not automatically mean that the healthcare system will cover the cost of the drug for all the publicly insured population in the jurisdiction. Based on the assessment of a regulatory agency or expert committee – usually a different body to the drug approval regulator -- about the drug's clinical or cost-effectiveness, policymakers might decide to limit its usage. Such a restriction can take place through either the breadth of population covered by funding – the drug will then be reimbursable for a certain patient subpopulation but not others -- or the proportion of costs covered by the public health system – i.e. refusal to cover the cost of the drug altogether or a change in the healthcare system's reimbursement rate.[23] Another form of explicit rationing strategy is the time lag caused by

[22] In the UK, the term "licensing" is often used to describe marketing authorisation. The narrative of the thesis (especially the chapters on the English case) uses approval, "marketing authorisation, and licensing of a drug interchangeably.

[23] In addition to denying funding of a technology or changing its reimbursement rate, policymakers can also use non-reimbursable user charges of the public healthcare system to restrict access to technologies.

non-decision of a regulator – the delay that is to do with the agency's role as a gatekeeper of a product's market entry.[24] The reimbursement regulator may put the drug into the assessment process but not make a timely decision. In such a case, even after the drug approval agency has licensed a drug, patients are not able to access it through the public healthcare system until the reimbursement regulator concludes its judgement.

Third, it is worth noting that although explicit rationing decisions affect the availability of drugs, they are hardly equal. Crucially, the absence of an explicit rationing decision for a drug does not mean that the drug will be available via the given public healthcare system. Even if policymakers decide to include a drug on the reimbursement list, the actual availability of the drug is determined by several other factors, including delays in implementation, local-level funding decisions, and implicit rationing mentioned above. The thesis focuses on the explicit decision by policymakers and does not examine the problem of drugs' availability.

The outcomes that the present study examines are the development – both continuity and change – of drug funding policy after regulatory reforms, in terms of the occurrence of explicit rationing strategies. Temporal variation in the occurrence is assessed in two main ways. First, it looks at the introduction and use of rules about drug funding – criteria that define what kinds of drug should be funded or excluded by public healthcare systems. This study looks at not only the adoption of rules but how policymakers apply them in practice. The latter is necessary, because given the unpopular nature of an explicit rationing strategy using rules for decision in practice can be a major site of political struggles. Second, this study examines the adoption and use of policy instruments that are designed to change the application of drug funding rules to an explicit rationing strategy. The multiple policy instruments and processes involved in drug funding means that policymakers can use instruments other than those directly related to drug funding to manipulate the occurrence of explicit rationing strategies. For example, even if the application of funding criteria would have otherwise led to an explicit rationing decision, policymakers might change the terms of drug pricing to avoid its occurrence. In this case, as the intervention takes place in a way that is interlinked with but outside of the process of drug funding decisions, the application of drug funding rules alone cannot correctly assess the occurrence of explicit rationing strategies. In either case, the analytical aim to examine the

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As such a user charge is not within the remit of the regulatory agencies both in England and France, it is outside the scope of analysis.

[24] This issue is well-documented in approval regulation. For a theory of regulator as a gatekeeper and its application to drug approval, Carpenter 2004.

occurrence of explicit rationing strategies reflect this study's interests in the final policy products that are to be imposed on society; after all, the hallmark of political struggles over rationing is whether policymakers can decide to impose it or not.

2. The locus of decision over drug funding: The concept of political insulation

An inquiry into the post-reform policy trajectories involves a rethinking of the premises behind regulatory reforms. As the Introduction noted, the regulatory state thesis argues that the growth of regulatory agencies is a key part of larger transformations in the governance structure that link the state with society. (Majone 1997). Yet, although the proliferation of regulatory agencies constitutes a core indicator of the regulatory state thesis, it does not specify much about the processes that link the creation of agencies to the wider shifts in state-society relations. Instead, such a transformation is functionally assumed, following the perceived failure of the existing "positive" state and the creation of agencies that are supposed to replace functions of the state apparatus. The agencies are also assumed to have possessed the qualities that constitute the state-society relations in the regulatory state from the beginning, such as expertise and rule enforcement—an assumption that warrants a fuller empirical scrutiny. Moreover, as I shall argue in this section, the principal-agent framework of delegation – a dominant approach to the creation of an agency and hence closely intertwined with the regulatory state thesis – fails to fully capture the process of the post-reform dynamics either. To address these gaps, this thesis will clarify the process through which the institutional features created by regulatory reforms endogenously affect the subsequent policy development. As a first step towards such an inquiry, this section argues that, instead of taking a somewhat narrow focus on the independence-control dilemma that characterises much of the principal-agent framework of delegation, there is merit in looking at the wider institutional structures that allocate powers among political actors.

In understanding the regulatory state thesis in Europe and delegating reforms to agencies, the principal-agent framework of delegation offers a good starting point. Rooted in its core concern of the democratic control of unelected officials, both the US-based and the more recent European literatures typically consider the creation of regulatory agencies through the lens of principal-agent relations, where the principal – an elected politicians – delegates tasks to the agent – a regulatory agency (For the US-based literature, e.g. McCubbins et al. 1987; Epstein and O'Halloran 1999; Huber and Shipan 2000; for the European literature, e.g. Thatcher and

Stone Sweet 2002; Gilardi 2009). The formal independence of the agency from elected officials, understood as the amount of discretion granted to the agency by the elected politicians, constitutes a crucial component of delegation.[25] When delegating tasks to a regulatory agency, elected politicians are concerned about the loss of political control, as the agency may develop its own preferences that differ from those of the politicians – a problem known as "bureaucratic drift". To tackle this loss, politicians can design the agency's legal structures that define the level of discretion given to the agency; they can also devise various mechanisms to monitor and control the agency's behaviour so that the agency fulfils the original mandate behind its creation (McCubbins et al. 1987, 1989).

The principal-agent framework of delegation has also proposed determinants of the level of formal independence given to regulatory agencies, which is linked to the rationales behind delegation. A major account emphasises the technical complexity of the issue. Bawn (1995), for instance, argues that in designing an agency's independence, politicians trade political control of the agency for its expertise. While the higher independence of the agency leads to a better application of its expertise, it is also more likely to result in bureaucratic drift. In a technically complex issue, politicians give more independence to the agency, because they are more willing to benefit from the agency's expertise at the expense of control over the agency's behaviours.[26] Another prominent reasoning behind delegation is to enhance credible commitment. The credibility problem arises when politicians promise a long-term policy goal that is beneficial to society. Because politicians tomorrow may have different preferences from the present ones, their intention to commit to the goal is not credible. Delegating powers to an independent agency separate from the government, according to this view, alleviates the credibility problem – a motivation that often takes the metaphor of the principal "tying their own hands".[27] Credible commitment is considered important in regulatory policy not only because of the benefit for constituencies but also because of the necessity to attract private investment (Levy and Spiller 1994). Third, scholars have argued that the government delegates

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[25] This understanding of formal independence as referring to discretion follows that of Epstein and O'Halloran 1994; Thatcher and Stone Sweet 2002; Hanretty and Koop 2012. It should be noted that scholars commonly distinguish formal independence from actual independence (Cukierman et al. 1992; Maggetti 2012). The latter can be conceived of as an agency's ability to "carry on their regulatory action without constraints within the limits of their mandate" (Maggetti 2012, 39). To avoid confusion, in this thesis I use the term "autonomy" to refer to actual independence.

[26] For a similar argument emphasising benefits from the agency's expertise, Epstein and O'Halloran 1994.

[27] The credibility-based theory of delegation is first developed in the literature of central banking. See Rogoff 1985 for an early theorisation. For a recent review, Fernández-Albertos 2015.

powers to a regulatory agency to shift the blame for negative policy outcomes (Fiorina 1982; Weaver 1986; Hood 2002). Weaver (1986), for instance, claims that politicians care more about blame resulting from negative policy outcomes than credit from positive ones. Rooted in the "negativity bias" of voters, he argues, the motivation of politicians to avoid blame leads them to delegate more responsibility. Empirical works on both US and European regulation have investigated the validity of these different theories.[28]

The impact of the delegation theories on studies of regulatory politics cannot be exaggerated. They offer powerful propositions about why formal features of regulation exist as they do. This thesis, by examining the trajectories after creation -- rather than creation and design – of delegated bodies, has a different focus from the delegation literature; at a more fundamental level, as later discussions shall show, by emphasising power-distributional implications of institutions, my analytical framework rests on a different foundation from much of the delegation literature's functional, equilibrium-based ones. Notwithstanding these major differences, the analysis to follow is still consistent with some of the insight of the delegation theories. It draws on the idea that elected politicians consider the (perceived) cost and benefit of regulation in making policy choices. Specifically, this study looks at how politicians' blame-avoidance motivation can shape their strategic behaviours.

Nevertheless, the principal-agent framework's focus on formal independence of the agency – and its underlying concern about the independence-control trade-off -- is perhaps less helpful in understanding trajectories after regulatory reforms than to interpret the statutory features of regulation. Part of the problem is conceptual. In measuring regulatory agencies' formal independence, scholars typically equate the level of delegation to the amount of the agency's discretion -- i.e. the formal ability of the agency to act without political interference -- and use the latter to capture the degree of formal independence. The problem is that, as Hanretty and Koop (2012, 202-203) have pointed out, scholars tend to conflate the amount of discretion with the range of competence or powers of a regulatory agency.[29] But the two are conceptually distinct. A highly independent agency which produces its outputs without political interference

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[28] For Europe-based empirical works, e.g. Gilardi 2002, 2005; Elgie and McMenamin 2005; Elgie 2006; Wonka and Rittberger 2010.

[29] This conceptual conflation of discretion with competence results in a measurement issue. For instance, Cukierman et al.1992 's influential index of central bank independence uses indicators describing both the central bank's discretion (appointment rules, budgeting etc.) and its regulatory competence. Building on this index, indices on the regulatory agency's independence used by Gilardi 2002, Wonka and Rittberger 2010 and others also includes indicators on both discretion and competence to measure an agency's independence.

can have few powers, where its outputs may have little impact on the final product of public policy. Conversely, it is also possible that an agency has little formal discretion, but the outputs it produces will have legally-binding powers.

The distinction of discretion with powers is also theoretically important. Indeed, some of the rationales behind delegation that scholars have proposed seem to be applicable only in a setting where regulatory agencies have substantial competence or powers. For instance, an agency cannot be a device of credible commitment if the agency's outputs can easily be overridden. Likewise, shifting the blame of policy outcomes to a regulatory agency can be a meaningful strategy only when that decision is attributable to the agency -- a condition that is unlikely to be met, again, if the agency does not have the powers to decide. To be sure, theorists of delegation are hardly unaware of this distinction. Majone (2001) hence stressed that delegation as a commitment device follows a logic that is quite different from delegation based on expertise. For him, the principal-agent logic of delegation and control is not relevant to the commitment-based delegation. For, in the former the principal designs control mechanisms to align the agent's preferences with his/her own. An agent who follows the principal's preferences, however, does not make the principal's commitment credible. A credibility-based delegation, he argued, involves an irrevocable transfer of the principal's "political property rights" (cf. Moe 1990) in a given policy issue to the delegate. In contrast with aligning the agent's preferences with the principals through control mechanisms, in the case of credibility-based delegation, the delegate – or what he terms "trustee" – has different preferences from the principal and the powers to decide and implement her preferred policy.[30] Yet, the subsequent empirical application of delegation theories to regulatory policy does not clearly differentiate the situations involving the trustee from the ones involving the agent.[31]

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[30] Scholars of monetary policy have long recognised this problem of revocability of a central bank's decisions. Keefer and Stasavage 2003, for instance, argued that the presence of an independent central bank can enhance credibility (i.e. reduce inflation) only in a political system with multiple veto points and polarised veto players that can limit policy reversal. See also Lohmann 1998.

[31] For instance, in an agenda-setting article on delegation to non-majoritarian institutions in Europe, Thatcher and Stone Sweet (2002) acknowledge distinction between trustee and agent, by citing the Majone argument mentioned above, but fail to differentiate discretion from powers or competence. As a result, while they point out, following Majone, that the same actor (such as the European Commission) can act more as a trustee in some situations while acting more as an agent in others, they conclude, "the problem of knowing how to identify the exact point, along any given spectrum that arrays various forms of delegation, the agent is more properly theorised as a trustee has not been resolved" (7). Yet, if we distinguish powers with discretion, the trustee situations seem to be more related to the delegate's powers than to its discretion. Indeed, many of the examples they cite as a trustee situation (e.g. some constitutional courts and independent central banks) seems to be related to the competence of the delegate and the irrevocability of its outputs.

Considering powers allocated to the agency as a matter distinct from that of discretion (or formal independence) has major implications for the present inquiry into the trajectories after regulatory reforms. After all, it is the former that defines the final product of policy decision that imposes a loss on society. As a later part of this chapter shall discuss, the loss imposition by policy decisions inspires subsequent mobilisation for and against the decisions. The political actions triggered by regulatory decisions hence affect the political dynamics to follow, shaping policy trajectories over time. Examining endogenous roles of institutional arrangements in later policy development thus calls our attention to the structural features that differ from the independence of a regulator. At the same time, paying attention to the powers given to the agency in a given policy task also means that we no longer have to follow the principal-agent framework's underlying assumption of hierarchy between the principal and the agent, where the former allows discretion of, and exercises control over, the latter. What matters instead are how the powers are allocated among political actors, be they agencies or politicians, and where the decision takes place in a given policy issue. In short, an inquiry into the post-reform trajectories involves reframing the underlying questions that have shaped studies of delegation to regulatory agencies.

Building on this discussion, this study explores how the allocation of powers among actors over decision-making affects policy development after the creation of regulatory agencies. Specifically, based on the study of drug funding policy in England and France, the thesis proposes that the post-reform policy continuity hinges on the extent to which elected politicians are excluded from decision-making over a given issue – a variation that is here called *political insulation.* The question of where decision-making takes place is of fundamental importance in defining political conflicts after regulatory reforms. The degree of political insulation deserves special attention because of the core feature of explicit drug rationing strategies that imposes losses on different societal actors. As the discussions to follow shall detail, political insulation not only defines the ability of policymakers to enact an unpopular policy but also has significant implications for subsequent political dynamics and policy development.

The level of political insulation varies across institutional settings. As a parameter of the decision-making locus, it defines the roles of different political actors who share the public decision-making process for a given issue. Of particular importance in distinguishing different levels of political insulation is the role of the elected official in the decision-making process. On the one hand, in a setting with high political insulation, elected officials have no say on decisions over drug funding. With the creation of a regulatory agency assessing a drug's

benefit, it is the agency that decides on drug funding. The agency's outputs, once concluded, become decisions and are non-revocable by elected officials. On the other hand, where political insulation is low, elected officials hold the decision-making powers over drug funding. In such a setting, even after the creation of a regulatory agency, the agency's outputs do not mean policy decisions; instead, elected officials have decision-making powers in their hands. Low political insulation may in practice involve different procedural arrangements, such as where an agency's outputs have an "advisory" or "informal" status, or the formal legally-binding powers rest with the minister. In either case, however, the agency's outputs can be overridden by elected politicians. The varied levels of political insulation thus make major differences to the powers left in the hands of elected politicians in a given decision-making after the creation of a regulatory agency.

By exploring the role of the political *insulation* of a decision-making locus in shaping the post-reform trajectories, this study thus departs from the principal-agent framework's focus on the political *independence* of the regulator. In doing so, it makes a concomitant shift in the analytical interest from political control of the independent agency to the locus of the authority in a broader institutional landscape that defines a given policy issue. The central question is *not* whether a regulator can act independently from politicians, or whether politicians can control the regulator's actions. Rather, paying attention to the locus of decision brings us to different questions -- where the decision takes place, who has the powers to decide, to what extent elected politicians are excluded from the decision-making. This study looks at institutional arrangements that structure the process of regulatory policy-making – the constellation of actors involved in the chain of the regulatory policy-making process, and the institutionalised allocation of powers among them.

To some extent, this emphasis on the locus of authorities is consistent with some of the earlier works of European regulatory politics and political economy before the delegation theory became dominant. In particular, the metaphor of "space" draws attention to the allocation of authority among actors who are its partial occupants, and interdependence and bargaining among them. Crouch (1986) uses the term "political space" to describe how political struggles over authority – such as the destruction of guilds and the monopoly of legitimate authority by the parliamentary state -- affected the subsequent allocation of public authorities between the state and organised interests. Crouch's metaphor of space was converted by some regulatory politics scholars, such as Hancher and Moran (1989), to portray the interdependence of political actors who fill up the "regulatory space" – "the range of regulatory issues subject to public decision" (153). The space metaphor helps further contrast

my approach from the principal-agent framework. Unlike that framework, where actors' relations are pre-determined and hierarchical, paying attention to the allocation of powers points to dynamic elements that emerge from power struggles at a particular point in history. Just like the modern state replaced guilds' authority, the hallmark of the regulatory state thesis is its possibility for non-majoritarian institutions to replace the authority previously held by organised interests -- such as doctors in healthcare rationing.

The preceding discussions on the discretion and powers of a regulatory agency also point to a broader issue that is relevant to this study of the post-reform political dynamics -- that is, the possibility of changing political coalitions in the post-reform phase. The delegation theories, again, offer a useful starting point. As described above, scholars of credible commitment begin with the idea that the principals tomorrow will have different preferences from the ones today. This temporal variation is partly due to the uncertainty inherent in politics, where the "enacting coalition" who set up the agency will be replaced by their successors (cf. Moe 1990). Even without the turnover, however, tomorrow's politicians may be inclined to short-term interests despite their own commitment to the long-term policy goal today – a problem known as time-inconsistent preferences. In either case, scholars argued, there can be a shift away from the preferences of the enacting coalition behind institutional creation -- or what is called "coalitional drift" (Shepsle 1992; Horn and Shepsle 1989). These scholars pointed out that mechanisms of political control in the standard principal-agent model actually exacerbate coalitional drift. In this sense, as Shepsle (1992) suggested, there is a trade-off between bureaucratic drift and coalitional drift.

These claims about coalitional drift highlight a potential source of the post-enactment political dynamics and policy development. To be sure, reflecting its functional understanding of institutions – an institution exists because it is beneficial for those involved -- in the delegation theory of regulation, the problem of coalitional drift is largely tackled through formal institutional design (cf. Horn 1995). Majone (2001)'s claim about the functional imperative of delegation to a trustee described above can hence be read as one such solution to tackle this problem of coalitional drift. If the problem can be resolved by institutional engineering, it would be no surprise, then, that the implications of shifting coalitions for later policy development are largely unexplored.

Notwithstanding these formal safeguards, however, there are still reasons to believe that the implications of coalitional drift for post-reform development deserve serious consideration. Of particular importance for the present study is that politicians' shifting positions may arise

from the very functioning of regulatory institutions. First, through its implementation regulatory policy inevitably creates winners and losers;[32] and in politics, as scholarship of endogenous institutional change argued, "the losers do not necessarily disappear" (Thelen 1999, 385). Rather than adapting to existing institutions, those who are negatively affected by the policy may mobilise themselves and seek to change the rules. As a policy with significant visible loss-imposition on both organised interests and the public, an explicit drug rationing strategy may especially be subject to intense counter-mobilisation. Moreover, as we shall see later in this chapter, the loss-imposition on different societal actors also implies that once the institutions begin to operate, there is a greater possibility of coalitional drift. This could, for example, occur via the politicians adjusting their position in response to mobilisation of organised and/or popular interests – a point that I will come back to in the next section to discuss mechanisms more carefully, but for now there are reasons for elected politicians to drift away from their initial position. The drift can be particularly serious for the persistence of regulatory policy, which -- unlike some central banks and constitutional courts – does not typically require constitutional amendments to modify its rules and hence only has relatively lower hurdles to policy modification.[33] In short, the operational phase of a regulatory reform possesses the significant possibility of coalitional drift that is shaped by the ongoing functioning of the regulatory policies accompanying the reform. The coalitional drift, in turn, has potential impacts on policy continuity and change. To understand the development in the post-reform phase of regulation, we need to consider how the existing policies generate political contestation and shift actors' positions over time through their operation.

Empirically, coalitional drift is widely observed across different areas of regulation. As Schillemans and Busioc (2014) summarise, contrary to the principal-agent model's expectation about bureaucratic drift, "[n]ational and European agencies are found to be guardians of specific policies and contents and they are, in line with their formal mandates,

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[32] As Moe 2005, 220 argued in his critique of an efficiency-based understanding of political institutions, even if a regulatory agency is created because it is mutually beneficial for all the actors involved in the institutional design, such as bureaucrats, elected politicians in the enacting coalition and societal interests they represent, once it starts operation it exercises power over society as a whole – including the rest of the population that is not included in the institutional design. There can therefore be significant gaps between those who agreed on rules and those on whom the rules are imposed. Inspired by the very operation of the rules, the gaps may give rise to political conflicts over policy continuity and change. For a similar point based on the same argument by Moe, see Héritier 2007, 9.

[33] For a similar point, see Jacobs 2010, 102 on constraining effects of public policy programmes. The ability to set institutional barriers against policy reversal in such a situation is also why, as noted above, studies of central bank independence (e.g. Keefer and Stasavage 2003) argue for polarised veto players and many veto points as a precondition for credible monetary policy.

strongly protective of the independence of their expertise against political intervention" (201). Instead of the bureaucrats running away from the mandate to do what they want, they report, what studies have repeatedly suggested is coalitional drift, or what they call "forum drift" -- "the accountability forum drifting away from agreed upon goals and measures" (Ibid.) These observations further underline the necessity of developing a framework for understanding the policy development that takes into account coalitional change.

In sum, to understand the roles of the locus of decision in post-reform trajectories requires an analytical framework that is different from the dominant theories of regulation. Discussions in this section have already given some clues about components that such an analysis should contain. First, such an analysis should look not just at a regulator's relations to politicians but also broader institutional arrangements for drug funding. Its second component should be endogenous changes in political coalitions during the operational phase and their implications for policy development. The possibility of endogenous coalitional change also underscores the need for a temporal analysis that traces the processes unfolding over time. Having laid down its necessity, the next section presents an analytical framework for endogenous policy development in the post-reform period.

3. How political insulation shapes the post-reform trajectories: An analytical framework for endogenous development

A coalition-based perspective on endogenous development

In analysing policy development in the post-reform period, the study builds on the basic assumptions of the recent literature on endogenous change that emphasise the distributional effects of institutions (Mahoney and Thelen 2010; Streeck and Thelen 2005).[34] As discussed in the previous section, the regulatory state thesis does not tell us much about the processes through which the creation of regulatory agencies affects state-society relations. The endogenous change literature offers a promising avenue to complement this lacuna because of its emphasis on power struggles inherent in institutions and its focus on temporal dynamics.

[34] Following the literature, policies are here conceived as part of institutions. As the later discussions show, scholars of endogenous change often talk of institutional change that alters functioning of institutions without changing formal rules. Like institutions, policies also constrain subsequent political dynamics – an effect that constitutes a major component of this study. It is therefore appropriate to consider policies as institutions in discussions of endogenous policy development.

This literature rests on the premise "that conceives institutions above all else as *distributional instruments* laden with power implications" (Mahoney and Thelen 2010, 8, italics original). A fundamental insight here is that institutional stability is inherently a political process (Mahoney and Thelen 2010, 7f; Hall and Thelen 2009). If institutions have distributional consequences, they hold frictions and tensions within them. The maintenance of institutions or policies, then, requires ongoing mobilisation of support from their underlying political coalition. From this perspective, one of the sources of endogenous change is shifts in the power balance between the coalition supporting the existing institutions and the coalition opposing them. The understanding that institutional evolution comes out of power struggles is based on an assertion associated with historical institutionalism in comparative politics (Thelen and Steinmo 1992; cf. Hall and Taylor 1996) but is also consistent with the power-based rational choice theories mentioned above (Knight 1992; Moe 2005). The focus of an inquiry into endogenous change should be, then, to identify when and how relative strengths of underlying coalitions change over time, and how existing institutions affect subsequent policy development by structuring the coalitional balance.

This latter point – the role of institutions in shaping coalition politics and policy development -- poses a significant analytical challenge, as the literature of endogenous change has invited criticism for conceiving institutions as overly "plastic" (Capoccia 2016, 1100; Hall 2016, 39; Pierson 2006, 116; Blyth 2016; cf. Pontusson 1995). If institutions can easily be deployed and modified by political actors, critiques note, the notion of institutions that constrain actors' preferences and strategies loses much of its analytical leverage, making institutions epiphenomenal. This is legitimate criticism; a framework for endogenous change must show that institutions or policies are not a mere vehicle used by political coalitions to achieve their goals; they also structure the coalitions.

This study tackles this question about the role of institutions in structuring politics based on two interrelated building blocks, both of which are related to the intellectual traditions of historical institutionalism. The first concerns the role of different arenas in politics. Specifically, this study looks at how political dynamics channelled through different arenas can affect endogenous policy development by expanding or containing conflicts between actors' political coalitions.

By examining the mediating roles of different arenas, this study seeks to elucidate mechanisms of policy development that are not fully explored in the current scholarship of endogenous change. Scholars have devoted much attention to developing modes of

incremental change that is driven by a "hidden" subterranean form of politics (Hacker et al. 2015; Streeck and Thelen 2005). While suggesting its different variants, a common image of the change that scholars have invoked is the one where elite political actors who work around well-entrenched formal rules take small actions that, over time, lead to transformative change. Such a hidden change includes what scholars call "drift", that is, the failure to update rules despite changes in the external environment; "conversion", namely, redeploying established rules for a new purpose without changing them; and "layering", that is, adding new rules on top of established ones to change their functioning (Hacker et al. 2015; Streeck and Thelen 2005). The common analytical thread here is to identify elite actors' reinterpretation of, and defection from, established rules – or lack thereof – that bring about de facto changes without passing a large-scale reform through the legislature. The literature hence calls our attention to courts, bureaucracies and other agents charging implementation of rules and influences of powerful societal actors through these organised political arenas.

Yet, as Capoccia (2016, 1101) recently points out, organised interaction within elite-level politics may not be the sole avenue where political struggles over endogenous change take place (see also Weir 2006, 174 for a similar point). If the battles that are consequential to endogenous change can occur in the absence of successful reforms channelled by public and electoral arenas, the opposite is also possible. Actors who contest established institutions should avoid difficult paths where institutions are well-entrenched and instead find "weak spots" to initiate change. Efforts by political actors to circumscribe the blockages created by the existing rules should, then, in large part depend on the existing institutional landscape in a given policy domain – a landscape that is shaped by not only the structures of macro-level political institutions but also domain-specific institutional arrangements and policy programmes.

Indeed, for sectoral regulation in Europe, it may not be the organised interaction of elite actors where the entrenchment of post-war institutions was weakest and most susceptible to change. As the regulatory state thesis reminds us, in Western Europe the dominant status quo founded after the post-war years was sectoral corporatist bargaining between bureaucratic departments and organised interests.[35] What made the creation of regulatory agencies in the past few decades potentially important for the governance structure was, in fact, that it could lead to opening up the political space to other political actors who had previously been

[35] See works related to sectoral (or "meso-") corporatism in the 1980s. E.g. Cawson 1985; Schmitter and Streeck 1985.

excluded from the organised bargaining, including single-issue interest groups and the courts in charge of judicial reviews (Majone 1997). The entry of these newly empowered actors to political conflict over regulation, then, may have important implications for coalition formation and management, tipping the power balance in favour of or against supporters of the maintenance of existing institutions – a coalitional politics that is not solely mediated by traditional bargaining channels.

Through the analysis of how different arenas channel political mobilisation, this study thus pays attention to the ability of different arenas to affect coalitional balance by expanding or containing conflicts. To be sure, this emphasis on coalitional balancing through different arenas is hardly new: as Schattschneider (1960) argued, politics can be conceived as control over the scope of conflict; what constitutes politics is countervailing forces between what he calls "privatisation" and "socialisation" of conflicts, that is, those who try to reduce the number of individuals involved in a conflict and those who try to expand it (p.7ff). Conflict expansion occurs when the losing side brings others who were previously not involved into the conflict. Arenas have a mediating role in this process of conflict expansion as they define whether a conflict gets expression. By shaping the scope of conflict, arenas can thus have impacts on coalitional balance. While Schattschneider's idea about conflict inspired many intellectual traditions of institutionalism, the insights have yet left room for a fuller incorporation to the study of endogenous change. This study seeks to contribute to the literature through a framework that considers the roles of arenas in regulator politics.[36]

The second building block of the analysis to follow is how past policies structure the present politics. The growing literature on "policy feedback" offers a useful analytical tool to link policy choices to subsequent political struggles (Pierson 1993; for reviews, Béland 2010; Moynihan and Soss 2014). The idea is that once enacted, past policies create their own political dynamics, generating sources of both durability and change over time. The effects of policies on subsequent political dynamics take place through their impacts on the capacity, coalitions, and information processing of different political actors. These political dynamics, in turn, affect subsequent policy development. The feedback effects can be labelled as self-reinforcing or self-undermining. On the one hand, policies can create positive, self-reinforcing, feedback

[36] Some of the recent theoretical works on endogenous change has suggested a similar direction to the present study. Capoccia (2016) proposes that an institutional defender's ability to delay the timing of reforms affects institutional persistence. While he does not link his discussions to the concept of arenas, his claim can be read as a variant of conflict containment in existing arenas to suppress the reform coalition.

by creating supporting coalitions among societal and government actors; such a coalition may resist policy changes in the later period. On the other hand, policies can also generate negative, self-undermining, feedback by triggering a backlash and counter-mobilisation among the political actors who seek to change them.

For the present inquiry into explicit drug rationing, it is important to examine both positive and negative feedbacks. Due to its loss-imposing nature, an explicit rationing strategy could make itself especially susceptible to political backlash. For the durability of explicit rationing policy, it is important to minimise self-undermining feedback that expands coalitions for policy change while, through self-reinforcing feedback, crafting and maintaining coalitions for policy continuity.

When combined with the above-mentioned logic about the role of different arenas, the notion of policy feedback is especially useful for the study of post-reform policy development. For instance, self-undermining feedback may generate a greater magnitude of counter-mobilisation when the counter-mobilisers expand the political conflicts to outside the existing arena. The broadened coalitions for policy change should then put policymakers under greater pressure. Conversely, the containment of self-undermining feedback within an existing arena can limit counter-mobilisers' attempts to broaden their coalitions. The blockage of expanding self-undermining forces hence should contribute to policy continuity. Discussions below will further consider how a particular feature of an institutional arrangement -- such as political insulation – expands or limits self-undermining feedback.

In sum, coalition-based perspectives on endogenous change can provide a promising avenue for research into post-reform policy development when fruitfully combined with the insights about the roles of arenas and policy feedback. Such an analysis pays attention to how existing policy choices can craft political coalitions over policy change; and how the coalitional dynamics are mediated by different arenas.

Based on these analytical building blocks, Figure 1.1 sketches this study's analytical framework for understanding how political insulation affects policy development after regulatory reforms. Having first set out this study's perspective on drug funding policy as coalitional politics, the analytical framework will describe a causally-connected chain of events that links political insulation to post-reform policy development: (i) how the different levels of political insulation of the locus of decision affect policy choices on drug funding, in particular whether elected politicians can prevent a politically costly policy choice for explicit rationing when experts recommend one; (ii) how different policy choices structure

downstream political dynamics, including both counter-mobilisation and mobilisation of different actors through different arenas; and (iii) how the downstream political dynamics, in turn, affect policy development. Let me now discuss each of them in turn.

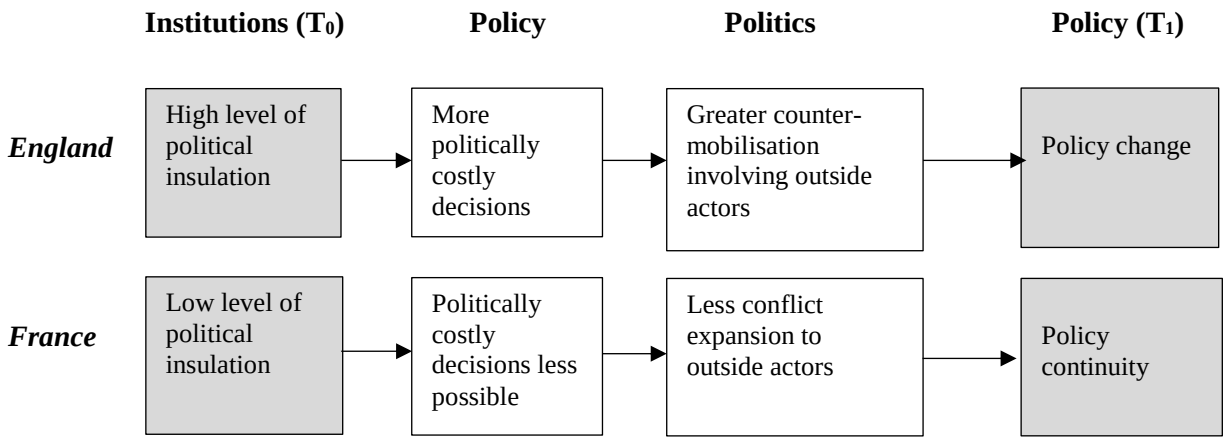

Figure 1.1 The political dynamics and endogenous development in the post-reform period

Drug funding policy as coalitional battles

This study conceptualises drug funding policy as political struggles between coalitions among public and private actors formed around what can be called *producers* and *payers*. On the one hand, producers are political actors who benefit from policies to cover the cost of a drug via the public healthcare system. The actor that lies at the heart of such a "pro-access" coalition is the pharmaceutical manufacturer of a given drug, whose income heavily depends on whether the government chooses to pay the cost of the drug through the public healthcare system. Given the fact that in European countries on average about three-quarters of healthcare provision is financed by the public healthcare system, be it a general-tax-funded health service or contribution-based obligatory social insurance, a decision not to fund the drug through the public healthcare system can result in significant loss in the company's income. Patient groups specialising in particular disease areas are also often involved in the pro-access coalition. Representing the "constituency" of a given medical technology or disease area, such groups mediate collective action to advocate for better access to drugs in the disease area. On the other

hand, the payers' coalition is formed around the entities who pay the cost of a technology available via the public healthcare system, either the national health service or the national insurance bod(ies), and the parent government department supervising the entities. They do not deny access to technologies, but payers tend to try to avoid wasteful spending on clinically ineffective or less cost-effective drugs; they also tend to be interested in incorporating assessments measuring drugs' clinical or cost effectiveness to aid their choice.

In analysing public and private actors' coalitions, it is useful not to conceive the state as a unitary entity and instead to disaggregate it into multiple organisational units and branches (cf. Morgan and Orloff 2016). This is especially the case for pharmaceutical policy, where several conflicting policy goals and instruments are involved. In such an issue area, several actors within the state act as carriers of different policy goals and instruments, generating rivalries and turf wars between each other. In some cases, the alignment of coalitional battles among supporters for different policy goals within the state may be along organisational boundaries. For instance, a ministry in charge of industry might be more inclined to industrial policy goals and therefore more sympathetic to the producer's coalition, whereas a ministry in charge of health and the treasury might be more aligned with the payers' coalition, and we might observe turf wars among these different government departments. In others, however, the same organisation may be tasked with different policy goals. For example, the formal mandate of drug pricing often explicitly speaks of both an industrial policy goal, such as incentivising innovation, and a health policy goal, including controlling healthcare costs. In that case, the public organisation in charge of pricing may have to deal with these conflicting demands. Discussions on political dynamics below and in the empirical chapters will further suggest how government actors located within different parts of the state link up with different coalitions, and how existing policy can shape such coalitions.

Low vs high political insulation affects policy choices

At the heart of the policy choice on drug funding lie elected officials, typically ministers in charge of health and pharmaceutical policy. Another corollary of the multiple goals that pharmaceutical policy serves means that the policy preference of ministers regarding drug funding is ambiguous and not readily apparent. How ministers weigh costs and benefits of funding or excluding drugs shall depend on multiple factors. Yet ministers are blame-avoiding in that they worry about the real or potential loss that a decision to explicitly ration drugs can impose on different actors, including the pharmaceutical industry and electorate. As we shall

see, however, the policy strategies that ministers can take to avoid the blame for an explicit rationing strategy depend greatly on the allocation of powers in a given policy issue, which constrains ministers' room for manoeuvre.

With the creation of non-majoritarian institutions, experts are said to play a more prominent role in the decision-making process. In practice, however, it is rare that experts are granted complete powers and responsibility. To recap the discussion in the previous section, it is more useful to consider post-reform decision-making over drug funding as a "regulatory space" shared by experts in the regulator and elected officials. And this shared space is not created equally; the processes as well as the location of decision-making differ from one another across institutional settings. For the present discussion a crucial variation lies in the allocation of decision-making powers between experts and elected politicians, and, in particular, whether and to what extent elected politicians are excluded from the locus of decision-making -- a variation that is labelled low versus high political insulation. In a decision-making process that is less insulated from elected officials, ministers have the final say on whether to fund a drug following expert bodies' assessment. By contrast, in a decision-making process with high political insulation an assessment by the expert body becomes the final ruling, and ministers do not have powers to overturn it.

The differences in the allocation of powers have profound implications for policy choices, especially when experts in the regulator make a negative judgement—that is, they recommend an explicit rationing strategy, concluding that the public healthcare system should not cover the cost of a drug. The literature on blame-avoidance has argued that in an unpopular policy choice, such as explicit rationing, politicians will try to shift the blame of negative policy outcomes to the regulator (Weaver 1986; Hood 2002). As I noted in the previous section, however, such a blame-shifting strategy commonly discussed in the literature is meaningful only where the regulatory agency has substantial powers in the given policy decision. High political insulation is such a situation -- ministers have no final say on the regulator's policy outputs; only once the regulator has imposed a loss on society, can the minister then attempt to shift the blame for the loss onto the regulator.

The situation is quite different if the locus of decision is less politically insulated, whereby the minister is involved in the decision over drug funding. In such a setting, ministers do not have to wait until the negative policy outcomes arise. If the regulator makes a negative judgement, ministers can still make a final decision, considering the perceived "political costs" – anticipated losses imposed on societal actors by the negative decision -- compared to the

benefit of choosing to follow experts' outputs and excluding the drug. If the elected official believes that excluding a drug from reimbursement is too politically costly, they can then refuse to follow experts' outputs and choose to make the drug available. The question is then: when do ministers find the political cost of excluding a drug that experts have concluded a negative judgement about "too much", compared to the benefit of keeping it on the reimbursement list? To answer that question, we need to know which societal actors are expected to have a loss imposed on them by the decision, and how ministers weigh the anticipated loss on them. An explicit rationing strategy imposes loss on different societal actors, including the manufacturer and the consumer of the drug. Knowing that experts have made a negative judgement (or that a negative judgement is likely), those actors who foresee a loss to themselves may try to persuade the minister, through lobbying, public campaigning or other means, to choose not to follow the experts' outputs. We can then further ask: when are ministers convinced by such mobilisations? What are the tactics that ministers can use to deal with negative expert outputs? Chapter 6 will explore these questions. Using the variation of drugs with different types of manufacturers and consumers involved, it inductively develops arguments about when, in an institutional setting with low political insulation, ministers follow experts' policy outputs and when they refuse to do so. Regardless of the precise content of political cost, however, the overall picture is that ministers can take an anticipated action, using their decision-making powers, to prevent an unpopular decision from taking place.

The differences in institutional structure and locus of authority may thus yield ministers' different blame-avoidance strategies, leading to different policy choices. Depending on the level of political insulation, ministers may use either "anticipatory" or "reactive" blame-avoidance strategies – a distinction that scholars are only beginning to recognise (cf. Sulitzeanu-Kenan and Hood 2005; Hinterleitner and Sager 2017). On the one hand, in a setting with low political insulation, ministers can use an *anticipatory* form of blame-avoidance strategy to prevent an unpopular policy choice, by refusing to follow an expert's outputs. As a result of ministers' pre-empting action, there should be less explicit rationing of the drugs that ministers otherwise find too politically costly to impose. On the other hand, in an institutional setting with high political insulation such an option is not available to elected politicians. They will engage in a *reactive* form of blame-avoidance strategy, by shifting the blame for an already existing unpopular policy outcome to the regulator. As a result, the highly-insulated decision-making process should enable more policy decisions that are otherwise too costly to make.

Policy choices structure downstream political dynamics

The different policy choices, linked with varying levels of political insulation, have distinct downstream effects on subsequent political dynamics. By structuring the *forms* of political conflicts, including which arenas political conflicts are mediated in and which political actors are involved, the downstream effects, in turn, shape different policy trajectories over time. The endogenous political dynamics involve both counter-mobilisation and mobilisation. We will, first, examine how policy choices generate counter-mobilisation by political actors, creating a *self-undermining* dynamic. While high political insulation enables policy decisions that is otherwise too politically costly, the decisions should trigger a greater magnitude of counter-mobilisation channelled by public and electoral arenas. By expanding their societal coalitional base, counter-mobilisers seek to reverse existing policies from outside the existing locus of decision-making. By contrast, since ministers in low political insulation settings prevent policy decisions they deem too politically costly, there should be less opportunities for such counter-mobilisation mediated in the public arena. Second, we will discuss the *self-reinforcing* dynamic by looking at how policy choices give rise to political forces that contribute to policy continuity. Such feedback effects from existing policy should be observed in relation to different organised actors, including regulatory agencies, drug companies, and clinicians.

(a) Counter-mobilisation against loss-imposition

Let us first consider how policy choices affect subsequent political dynamics by generating political contestation against them. Recall Schattschneider's (1960) idea of politics as control over the scope of conflict. From this perspective, the preceding discussions on policy choices over drug rationing can be seen as a part of the government's attempt to contain conflicts over drug funding to the existing locus of decision-making. In a less-insulated setting, elected politicians can try to contain potential or real conflicts that an explicit rationing decision might trigger by considering the political costs involved. By making a decision not to exclude the drug, ministers can attempt to accommodate societal interests that would otherwise have had losses imposed on them and, as a consequence, try to contain political conflicts within the existing locus of decision-making. By contrast, in a highly insulated locus of decision-making, such strategies for conflict containment are not possible. Unlike a less politically insulated setting, where societal actors avoid loss-imposition during the decision-making process, in a highly-insulated setting the producer coalition experiences clear visible losses imposed by the policy choice.

A key mechanism that links a policy choice to subsequent contestation over policy is policy feedback. This may have an influence on subsequent policy development through a number of pathways, but the most relevant to the present discussion is "interpretive" feedback (Pierson 1993, 611–624; 1994; Campbell 2012). Pierson (1993) has argued that the design of specific policy and government programmes affects subsequent politics by shaping ways in which societal actors, especially the mass of the public, process information. Specifically, he points out two aspects of policy design that may condition this effect. The first is visibility, which refers to whether the public may be aware of policy outcomes. The second is traceability, or whether the public can attribute the blame for a negative policy outcome to specific political actors. The varying degrees of a policy's visibility and traceability, therefore, and the efforts of political actors to manipulate these factors, affects whether mobilisation over existing policies is likely to follow.

This feedback effect plays an important role in political contestation over regulatory policies because of the nature of their policy decisions. First, negative outcomes of regulatory decisions can be highly visible as they impose a loss on clearly identifiable specific individuals and organised interests who bear the burden of the decisions, with diffuse benefits and beneficiaries (Wilson 1980, 357–394). Moreover, decisions by a regulatory agency – especially in a high- politically insulated setting -- can also be highly traceable compared to other forms of governance where decision-making authorities are shared by multiple actors. In fact, an independent regulatory agency can be a useful device for politicians to shift the blame for policy outcomes precisely because of this high level of traceability.

These attributes of policy decision, in turn, translate themselves into a political strategy for counter-mobilisation. Actors seeking to challenge the existing orientation of a policy exploit the high level of visibility. They may illuminate the negative consequences of policy choices while obscuring their benefits, framing them as a "policy failure" caused by the regulator's decisions.[37] Political campaigns to "raise awareness" enable actors to build a broader base of mobilisation that is not limited to narrow "stakeholders". Judicial reviews to challenge policy decisions are not only sought for their own purpose but also served to help actors broaden their coalition through raising public attention to the issue. The heightened level of salience may

[37] Both the literature on blame-avoidance (Hood 2002, 2011) and problem definition (Baumgartner and Jones 2010; Stone 1989) highlight the importance of how political actors frame the attribution of blame – namely, who causes the negative policy consequences.

draw the attention of vote-seeking politicians who are otherwise not interested in the issue.[38] These politicians may then join the coalition of actors advocating for policy reversal. As the pressure rises, incumbent elected officials may also adjust their policy positions, for fear of being punished by the voters. In sum, the institutional arrangement of regulatory decisions is prone to generate negative self-undermining feedback that fuels the pressure on policy-makers to change policies. The pressure may therefore limit the government's ability to keep on imposing the existing orientation of the policy choice.

Under what conditions is this feedback effect more likely to be amplified? A number of factors condition this interaction of elite actors with mass politics, but the capacity of elite counter-mobilisers to attract broader coalition hinges, in important ways, on political costs that a policy decision triggers, and in particular, how the cost of a policy is distributed within society (Jacobs and Weaver 2014; cf. Pierson 1994, 45–46). If a policy choice imposes a loss on tightly-linked groups, the policy may generate a greater counter-mobilisation; and if the negative impact of a policy is felt through a dramatic event that captures intense public attention over a short period of time, known as a "focusing event" (cf. Kingdon 1994), it triggers a greater magnitude of feedback effects.

This pathway to counter-mobilisation does not deny other strategies that a pro-access coalition can use. On the contrary, we expect that actors seeking to get better access to a drug and challenge existing policy orientation should combine different strategies to achieve their goal. One such strategy is to seek to forge an alliance with government actors. This may include informal lobbying of, and formal consultation by, regulatory agencies and the parent ministries in charge of health; representation channelled by ministries in charge of the industry, which are likely to be their natural ally; and informal linkages and lobbying to parliamentarians and party politicians who are sympathetic to business interests.

Actors from producers' coalition should also attempt at expanding their coalitions by allying with other societal organised interests, such as clinicians. For example, some of the specialist doctors who are particularly keen on novel treatments in their specialised area might be particularly receptive to a coalitional appeal by drug companies. These clinicians may not only help the pro-access coalition's mobilisation through elite-level debates but also help broaden the producers' coalitional base by joining their public campaign, and, through their

[38] For the role of public attention in drawing politicians' responses, Baumgartner and Jones 2010; Murillo 2009; Culpepper 2010.

public legitimacy as the professional authority, advocating for better access in the public sphere.

Yet, a key difference between actors' strategies in a highly insulated setting and those in a less insulated one is that, in addition to those strategies operating at the elite-level of interaction, the former can expand the conflict to mass politics by exploiting the visibility and traceability of the loss-imposition. Such a strategy to win the "noisy politics" in order to influence the policy process may, in fact, be more costly than "quiet politics" taking place within a closed circle of elite actors (cf. Culpepper 2010). In this sense, as Schattschneider (1960: 16) has pointed out, expanding conflicts to mass politics is a strategy deployed by the losing side of a conflict.[39]

In short, by endogenously structuring political strategies for counter-mobilisation challenging the status quo through expanding the coalitional base, a policy choice for rationing in a highly insulated environment tends to produce a greater magnitude of *self-undermining* feedback. Moreover, with the expansion of conflicts, counter-mobilisation and the resulting political battles are channelled through the legislative arena. By contrast, in a less insulated environment the magnitude of this dynamic should be relatively limited. The regulator's negative recommendations may still arouse a counter-mobilisation due to the potential loss it is likely to trigger. But since the minister, who has final decision-making powers, is receptive to such a counter-mobilisation when they find the cost of proceeding to exclude the drug too high, the regulatory outputs should result in less accumulation of actual losses that counter-mobilisers can exploit to broaden their coalitional base in mass politics. As a result, political conflicts are channelled less through the public and legislative arenas, and operate more in the existing decision-making arenas for drug funding.

(b) Endogenous development of institutional defence against counter-mobilisation

For its part, the capacity and strategies of the pro-payer coalition to defend the status quo against counter-mobilisation hinges greatly on its ability to harness *self-reinforcing* feedback flowing from existing institutions. We shall here discuss feedback effects emerging from two distinct sources. First, the institutional defence against counter-mobilisation is shaped by the regulatory agency's own actions. A regulatory agency does not stand still after its creation; once operating, its activities to achieve its policy mandate generates feedback effects on

[39] Developed also from Schattschneider's conflict expansion model, a vast literature on venue-shifting and agenda-setting (Baumgartner and Jones 2010) and on "outside" lobbying (Kollman 1998) has advanced a similar idea.

different actors, including itself, the regulatee (drug companies), and actors in the chain of service delivery (clinicians). Second, feedback effects can also emerge from outside the political struggles over drug rationing. In particular, the multiple interlocking institutions in the pharmaceutical policy mean that political actors' strategies against counter-mobilisation depend not only on drug funding but also on neighbouring institutions interlinked with the issue. Let us explore each of them in turn.

The first element of self-reinforcing feedback concerns regulatory agencies' use of experts and expertise. A regulator's experts and expertise deserve special attention, given their key roles as assumed in the regulatory state thesis. All else being equal, impacts of the use of expertise on policy should be self-reinforcing in nature because of what scholarship of policy feedback has called its "resource" effects (as opposed to interpretive effects discussed above), that is, effects on capacities or incentives for mobilisation, on both interest groups and the state (Pierson 1993). The operation of regulatory agencies and the mobilisation of a particular set of experts and expertise should generate "sunk costs" by encouraging different actors to invest their resources and energy in the specific set of regulatory requirements. The "asset specificity" of these investments means that actors who have invested in these particular skills and requirements will be reluctant to switch to other sets of requirements (Pierson 2000).

A regulator's mobilisation of expertise creates a self-reinforcing dynamic for the agency itself in two major ways. First, establishment of a regulatory agency is followed by the creation of its own stakeholder network comprised of experts who support its work. Unlike agencies in the United States, which tend to develop in-house expertise, a distinct characteristic of regulatory agencies in European countries and the EU is that they tend to draw on existing resources and the expertise of outside experts for their regulatory process. This is true for pharmaceutical policy, where agencies both in England and France, with their historical lack of in-house experts and resources, have built on networks of existing domestic academic experts. The operation of agencies and the particular set of experts and expertise that they rely on, in turn, should create their own vested interests of academic industries by forging "epistemic communities". Depending on the specific set of regulatory requirements, such communities include different combinations and power balances among various types of experts related to pharmaceutical policy, including clinicians, economists, epistemologists, and pharmacologists, among others.

Second, the regulator's active mobilisation of expertise both to produce policy outputs and justify them further contributes to policy continuity. The creation of an agency has, in this

regard, downstream consequences for its policy continuity through its outputs for at least two reasons. First, continuity in the agency's outputs is closely linked with its desire to fulfil its core missions and do so with autonomy (Wilson 1989, 182; Carpenter 2001). Since Max Weber highlighted predictability as a major principal of bureaucracy, scholars have grappled with bureaucratic organisations' risk-averse tendency (cf. Olsen 2008). Contemporary public administration scholars have argued that public bureaucracy tends to be risk-averse in its policy decisions, due to its fear of "reputational damage" (Carpenter 2010, 67) or of getting criticised or blamed (Hood 2011, 5; Wilson 1989, 191-192). In either perspective, bureaucracy prefers a familiar and predictable course of actions because the lack thereof runs the risk of policy errors and these will lead to the reduction of autonomy. Once the mobilisation of a particular expertise shapes an agency's mission-fulfilling activities, it should therefore become self-reinforcing in nature.

Moreover, the agency's active mobilisation of expertise to justify its decisions also facilitates policy continuity. In mobilising expertise for their mission fulfilment, regulators tend to develop several mechanisms to ensure that their use of expertise contributes to policy continuity. For instance, regulators may develop explicit codified regulatory criteria and reasoning behind their outputs. Such rules help create consistency in the regulator's application of expertise to cases.[40] Regulators may also craft various internal procedural rules and external accountability mechanisms to fend off criticisms. Through the presentation of explicit rules that appeal to procedural fairness and accountability, regulators may try to tackle criticisms and reframe the "parameter of blame and accountability" (Black 2010 quoted in Lodge and Busioc 2016, 250; cf. Koop 2014). These effects of shaping the agency's justification as a "presentation strategy" (Hood 2011, 52-53) to manage blame should be stronger where the regulator faces criticisms and policy debates concerning its policy outputs. In such a situation, the regulator should try to justify its outputs and defend itself by using its expertise and elaborating on the reasoning behind its decisions. Through these mechanisms of organisational defence about its application of expertise, regulators may further strengthen its continuity and predictability in its policy even in the face of criticisms.

[40] Legal scholars have argued how courts (especially in common law countries) use precedents and judicial doctrines to develop "argumentation frameworks" that connect past decisions with future ones, creating self-reinforcing judicial decision-making (Stone Sweet 2002, 124ff; Hathaway 2000).While somewhat different in nature, regulatory doctrines and codified criteria might have an analogous effect.

The self-reinforcing nature of regulatory expertise is not only on the regulator's side. Drug companies, who wish to get market access, also have to invest their resources in a specific set of expertise, the evidence to support applications and other regulatory requirements to win the regulator's positive guidance. Given the dominance of public healthcare as payers in both England and France, even though drug companies may be lobbying for changes to regulations to lower the hurdles in the long-term, in the short-term they still have strong reasons to make these investments. And the considerable differences in regulatory criteria and procedural rules for drug pricing and reimbursement across one country to another means that these investments are highly specific to a jurisdiction. As a result, in a later lobbying effort to change rules drug companies are constrained by their own past investment; they must weigh the benefit of change against the cost resulting from investments they have already made.

Another self-reinforcing feedback of regulatory activities is in relation to intermediary actors between regulatory decisions and its delivery to citizens – in this case, clinicians. The above-mentioned resource effects of policy feedback may also operate in relation to clinicians, as they may have to update their skills and treatments, while having to make their familiarised treatments obsolete, to comply with the regulator's guidance. In addition to investment in skills, however, the loss-imposition nature of an explicit rationing strategy may generate a powerful interpretive effect for clinicians, which alters the terms of responsibility and blame-attribution for rationing. Scholars of healthcare politics have long claimed that physicians have always tried to protect their clinical autonomy; and any attempts to encroach on it by the state have met fierce resistance from the medical professions (cf. Starr 1982). However, when it comes to rationing, doctors' preferences are ambiguous at best. The idea that doctors defend clinical autonomy rests on assumptions from the era when clinical judgment, and any resultant rationing, was individual and hidden. Once rationing begins to take a collective form, either through local-level decision-making or via ministers and regulators at the national level, its practice becomes more visible to the public. For clinicians the shift to more collective and explicit forms of rationing is, on the one hand, a loss of the full autonomy that they used to enjoy. Instead, they now find themselves in the chain of service delivery, with authority being shared with the government and payers. On the other hand, the increase in visibility of unpopular practices such as rationing means that their perceived benefit of exercising autonomy and taking responsibility for clinical judgement and rationing may become significantly discounted. They might even *benefit* from the regulator's decisions to aid them to implement otherwise unpopular choices without receiving blame from the public. These actors may no longer wish to take back full control over the regulatory process by abolishing

the regulator, because this implies that they would become the subject of blame for policy outcomes. Clinicians may still want to "make their voice heard" and change the substance of regulation, but they may resist the wholesale breakdown of regulatory institutions.

Hence, by interacting with blame-avoidance, the transition to the regulatory state may impact on clinicians' preferences for maintaining existing regulatory institutions. Again, the level of visibility and traceability of policy design may play a role in how likely it is that this effect will take place. When the regulator's dominant position in the process of implementation is easily traceable -- which should be more likely the case in a high politically-insulated setting -- and societal actors are well-integrated in the process, such a policy design may allow societal actors at the implementation stage to attribute blame for losses resulting from the policy to the regulator instead of taking it up themselves. The actors may therefore oppose a policy agenda aimed at shifting the burden of decision-making back onto them.

In addition to these feedback effects coming directly from institutional reforms of regulatory institutions for drug funding, the multiple decision-making processes involved in pharmaceutical policy means that the inter-connected institutions provide an endogenous source of reproduction of pro-payer coalitions.[41] In particular, the drug pricing regime – a process profoundly linked with drug reimbursement decision -- has important implications. Again, the idea of the scope of conflict is useful to help understand the political dynamics. Unlike drug reimbursement, where explicit rationing decisions can trigger the involvement of multiple outside actors, the sole actors involved in the decision-making venue for drug pricing are the government department in charge and the pharmaceutical industry. The secrecy of the pricing process and terms of bargaining may also enhance this hidden insulated nature of policy process. Regardless of whether drug pricing takes the form of free pricing for individual drugs with profit control, as in Britain, or the statutory pricing led by bureaucrats, like in France, compared to the reimbursement process we would expect the pricing one to tend to preserve the existing power balance between the industry and the government better. Hence, if the existing distribution of power is favourable to the government and the payer vis-à-vis the industry, the government should reinforce pricing power as a weapon at its own disposal to contain conflicts. Conversely, if the existing pricing regime is favourable to the industry, the government and the payer should have a hard time reversing the power balance.

[41] This is related to the network externality of existing institutions. Pierson 1996, 2004; Hall 2016.

Policy and institutional change

Taken together, existing institutional arrangements with varying degrees of political insulation have significant implications for subsequent policy development. In an institutional setting where the locus of decision-making is highly insulated from elected politicians, the accumulation of politically costly decisions should lead to wider mobilisation involving high-profile public debates, with the regulatory agency being in the forefront of criticism. Drives for policy and institutional changes should come from *outside* the existing locus of decision-making, eventually destabilising existing policy and institutions. The capacity of the pro-payer coalition to counteract these counter-mobilisation and to defend the existing orientation of policy and institutions depends on its academic expertise, support from clinicians, and stabilising effects of the pricing regime. By contrast, in a less politically insulated decision-making process, we should observe fewer decisions that are otherwise politically too costly for the incumbent government. This containment of conflicts to existing policy-making arenas blocks negative feedback effects from being set in motion. The conflict containment hence contributes to policy persistence.

4. A note on methods and sources

From the next chapter onwards, the thesis turns to empirical exploration of the trajectories of drug funding policy in England and France. Through comparative case studies and process tracing, I develop arguments about endogenous development of drug funding policy after regulatory reforms. This section discusses the methodological considerations that guide this inquiry.

This study is largely a theory-building exercise. Since the claims developed in this chapter are partially generated from the empirical study to follow, the thesis cannot claim to provide an independent testing of the theoretical framework. Instead, the aim is to generate a theory of endogenous policy development. Through the study of drug funding policy in England and France, the thesis seeks to develop claims about how certain institutional features such as political insulation affect policy development.

This study combines comparative case studies with process tracing to study post-reform policy development. Comparisons are nested at several levels and are not only made cross-

nationally. It applies several longitudinal comparisons by using variation before and after changes in organisational structures and other variables of interest. Employing it with process tracing, such "before-after" comparison provides a powerful tool for clarifying the sequence of events while evaluating alternative explanations. The study also uses a series of "within-sector" comparisons by looking at variations across different disease areas and different types of drugs. As discussions in this chapter have suggested, political dynamics in the post-reform period may vary greatly depending on political attributes – costs and benefits – that a given drug or disease area carry to different political actors. The within-sector comparison enables me to develop hypotheses relevant to this claim; it also allows me to generate claims on when the mechanisms identified are more likely to be observed.

The study mainly uses inductive process tracing to identify mechanisms linking institutional structures with policy trajectories.[42] It clarifies a chain of events that constitutes the processes through which political insulation affects subsequent policy development. This methodological choice is appropriate because the study traces particular, complex processes that lead to policy development –processes that are either unknown or underspecified by the literature. In some of the narratives to follow, process tracing is also used in assessing alternative explanations for the observed events. The deductive process tracing is used here for a supplementary purpose; it is designed to help me propose the mechanisms and processes generated by inductive process tracing with more confidence.

The study uses a variety of materials to trace policy development. It draws on different types of primary source materials, including government documents and policy reports, parliamentary minutes and reports, statements made by various societal actors;[43] and newspapers, trade journals, and other secondary materials written by clinicians, economists, legal scholars, journalists, and other observers.[44] Different types of sources enable me to use process tracing with greater precision by providing a detailed narrative about the position of actors, policy-making, and the sequence of events. In citing materials, I corroborate the evidence with other independent sources wherever possible.

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[42] For an inductive use of process tracing, George and Benett 2005, Chapter 10; Falleti 2016.
[43] All the translations of quotes from French sources in this thesis, unless specified otherwise, are mine.
[44] Newspapers were used both as sources of events and, in some of the chapters, for an indicator to measure the level of issue salience in public debates. See Chapter 4 for methodological details.

In addition, the study supplements these written materials with open-ended or semi-structured interviews with different actors involved in the policy process. They were mainly former and current officials from the ministries and agencies in charge of pharmaceutical policy, as well as academics close either to the government or the pharmaceutical industry.[45] I identified and selected interview partners based on their roles in episodes of policy debate and policy-making, where I relied on both published information and so-called "snow-ball" sampling. The interviews were conducted either in person or over the phone, typically lasting for an hour. The interviews are not designed to provide the main source of evidence but to complement the analysis based on written materials.

As to regulatory practices for individual drugs, analyses in the thesis are mainly based on documents written by regulatory bodies, supplemented by other primary and secondary sources where necessary. The data on the prices and reimbursement status of drugs mainly draws on the official database of national formulary, again supplemented by other publicly available sources.[46]

5. Concluding remarks

This chapter proposed an analytical framework for the study of post-reform policy development. Drawing on the delegation theory and the endogenous change literatures, it discussed the role of political insulation in shaping policy development. The chapter suggested how political insulation affected policy choices, and how policy choices generated mobilisation over policy change. A high politically-insulated setting enables policymakers to produce explicit rationing strategies that would have been otherwise too political costly; but the policy choice generates a greater counter-mobilisation channelled by the public arena, thereby undermining policies over time. In a less politically-insulated setting, by contrast, elected politicians prevent such a choice; the absence of opportunities for expanding conflicts over policy choice, in turn, contributes to policy continuity.

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[45] For the anonymised list of interviewees, see Appendix.

[46] I mainly consulted the British National Formulary (https://www.bnf.org/products/bnf-online/) for the English case, and the national health insurance body for salaried workers' (CNAMTS: Caisse nationale de l'assurance maladie des travailleurs salariés) Base des médicaments et informations tarifaires (http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI) for the French one. In some cases, the official data was supplemented by publicly-accessible databases provided by commercial companies such as Vidal (https://www.vidal.fr/) for the French case.

The analytical framework developed here has its own limitations. Perhaps the most apparent is that the origins of the designs of the decision-making process are outside the scope of the framework. If differences in political insulation are so important, where do they come from? It should be noted that whether politicians prefer high or low insulation when creating delegated bodies cannot readily be deduced. The literature on blame-avoidance tends to assume that ministers have incentives for shifting blame to delegated bodies; it follows that in an unpopular policy area they should prefer to delegate more responsibilities to regulators (Weaver 1986; Hood 2002). But this premise is not as self-evident as it looks. It is equally possible – as indeed the discussions above have suggested and the chapters to follow shall demonstrate -- that ministers may want to keep powers to themselves so that they can avoid unpopular policy outputs from happening in the first place. Moreover, the origins of political insulation can be affected by a number of other factors, which requires a separate analytical framework. Preferences of elected officials regarding political insulation are thus outside the scope of this study; the empirical part will instead inductively identify politicians' strategies over rationing.

This study's analytical framework departs from the dominant theory of delegation based on the principal-agent framework in two respects. First, the principal-agent framework typically assumes preferences of elected officials are exogenously given and stable, and problematises bureaucratic drift that departs from the elected officials' preferences. By contrast, the present study does not assume fixed preferences of actors, especially those of elected officials. This enables me to capture the dynamic process of changes in the position of elected officials over time, responding to varying level of pressures and to perceived political costs of rationing drugs. Second, examining the locus of decision-making calls our attention to institutional variations and political struggles that differ from the scholarship on delegation. The approach adopted here enables me to examine a set of political struggles involving multiple actors and organisational processes that is wider than the principal-agent relations.

This study draws on the endogenous change literature's emphasis on underlying coalitions of institutions, but delineates the processes that are somewhat different from the image of gradual hidden change that the literature has advanced. In a regulatory policy that imposes losses on the organised interests and the public, the former's elite-level of interactions is not the only arena that drives change. In addition to such interactions through the organised channel of politics, broadening the coalitional base via the public arena can also shift the power balance of underlying coalitions that becomes a source for change. The analytical framework suggested that different degrees of political insulation structured the forms of political conflicts,

including the possibility of coalition expansion mediated by the public arena. It hence called attention to the roles of multiple arenas in the politics of endogenous change and feedback effects on actors' mobilisation and counter-mobilisation.

The thesis now turns to an empirical inquiry into the trajectories of drug funding policy in England and France. As later chapters shall uncover, the different institutional arrangements created by regulatory reform structured the subsequent political battles over drug rationing, shaping the post-reform trajectories of the two countries. Before examining the post-reform trajectories, however, the next two chapters first depict the policy debates over explicit drug rationing in the period leading up to the creation of regulatory agencies and different institutional arrangements.

Chapter 2 Experts rule: The emergence of high political insulation in England, 1989-1999

Between the 1990s and mid-2000s both England and France addressed the issue of drug rationing. They experienced procedural reforms that created regulatory agencies assessing a drug's clinical or cost-effectiveness for funding decisions. In both countries, these institutional reforms were considered significant for the existing structure that had governed drug provision within the health care system for decades. Yet, the shape of the regulatory state over drug rationing varied across the two nations, with a marked difference in the locus of decision-making.

The following two chapters describe institutional arrangements for drug funding to explore this variation. By tracing policy debates during the years leading up to the reforms that created regulatory agencies assessing a drug's benefit, each of the chapters identifies the constellation of actors involved, their interests and the patterns of their coalitions. They also discuss key attributes of the institutional arrangements, such as their political insulation. As later chapters shall show, political insulation structured conflicts and policy development in its subsequent years. The present chapter considers the England case, while the next chapter examines the French one.

It is also worth noting what the two chapters are *not* about. Each of the chapters describes the institutional structures around drug funding and the policy debates around their creation. As noted in the previous chapter, however, the origins of the institutions are outside the scope of this thesis's analysis. The chapters hence do not examine where actors' preferences for certain institutions come from.

The present chapter examines policy debates over drug funding leading up to the creation of a regulatory agency, the National Institute for Clinical Excellence (NICE).[47] It highlights that with its establishment, NICE was not only expected to make advice but also to play the decision-making role in drug rationing within the NHS. By the early 2000s, it was established that NICE's guidance signalled the final decision for the NHS; the health minister was not involved in decisions once NICE had issued guidance. The English case hence represents an

[47] With an expansion of remit, NICE was later renamed the National Institute for Health and Clinical Excellence, and then the National Institute for Health and Care Excellence.

institutional structure with high political insulation, where experts' decisions cannot be overturned by the minister. This chapter shows that incumbent governments' political strategies towards unpopular decisions such as rationing played a role in shaping both the terms of policy debates and the institutional structure. While the introduction of the internal market by the Conservative government ushered in collective explicit rationing by local level health authorities, despite the advocacy by societal actors the government was reluctant to address its own national responsibility for rationing. It instead aided the development of local expertise that helped local health authorities' funding decisions. The reluctance to take on the rationing responsibility remained unchanged after the election of the Labour government. While centralising the expert network through the creation of NICE, the government attempted to keep shielding itself from taking on the responsibility for explicit rationing decisions. In short, events that led to the institutional arrangements with high political insulation were shaped by strategies of the incumbent government, both Conservative and Labour, to avoid addressing its responsibility for an unpopular policy.

This chapter begins by briefly describing institutional structures and the actor constellation since the post-war period. It then examines policy debates and actors' strategies over drug rationing following the Conservative government's introduction of an internal market from the beginning of the 1990s, tracing the events leading up to the creation of NICE. The chapter next turns to the institutional arrangements for drug funding created in the late 1990s. It highlights the high level of political insulation, whereby NICE's guidance about a drug was the final decision for the NHS without ministerial involvement.

1. Institutional and policy legacies

In the post-war decades, the English institutional arrangements for drug pricing were characterised by informal governance.[48] Rather than being governed by direct state intervention, pricing took the form of industrial association-led self-control - a typical mode of governance in the era of British "club government" (Moran 2003). Every five years from 1957, the Association of the British Pharmaceutical Industry (ABPI) and the government made voluntary agreements for controlling the profit the industry earned from the NHS. Having rebranded itself as the Pharmaceutical Price Regulation Scheme (PPRS) in 1977, the

[48] For an overview of the history of PPRS, Hancher 1990, Chapter 2; Sargent 1985.

agreement's core features, such as its voluntary and informal mode of governance through profit control, remained largely unchanged. The PPRS benefited the industry, especially large, research-orientated firms located in the UK, in several respects. First, under the scheme companies freely set the price that the NHS paid for individual drugs. Second, setting the limits of firms' overall profits for the next five years allowed for both certainty and flexibility in company strategies. Third, PPRS's indirect control had the merit of a faster product launch. Unlike countries with pricing control, profit control through PPRS meant few additional layers of regulatory process existed once a drug got approval. Given these features, scholars have argued that, together with the existence of elite research universities for medicines and their close collaboration with the industry, the NHS, and the government's research funding bodies, PPRS helped develop the research-intensive pharmaceutical industry (e.g. Hancher 1990, Ch. 2; Thomas 1995; Howells and Nearly 1995). This status quo had profound impacts on the options and instruments that policymakers could deploy. Unlike countries with statutory pricing control, containing drug expenditure through setting the price of individual drugs was not possible. The government hence had to rely on instruments to control the volume of drugs, especially those related to drug reimbursement from the NHS.

The institutional arrangements around drug rationing since the post-war years were embedded in the health care system, which was also characterised by informal governance. Although the NHS had a hierarchical structure in fiscal terms, "implicit bargains" between physicians and government granted doctors extensive clinical autonomy (Tuohy 1999, 41, 240). This institutional balance at the founding moment locked the institutions into the path it followed in subsequent decades. At least until the mid-1980s there was little government control over clinicians' prescription behaviour. While the government set out a global budget to control health care expenditure, it was individual clinicians who decided on clinical priorities and treatment strategies. Rationing was thus "hidden": "bedside rationing", together with techniques such as waiting lists and General Practitioners (GPs) not referring their patients to specialists, was thus the dominant mode of decision-making.

The implicit and hidden form of rationing was further complicated by the budgetary rules specific to pharmaceuticals. In primary care, drug prescription was cash unlimited[49] – hence theoretically there was no drug rationing in primary care; GPs' demands for prescribed drugs should always be met, as any excess spending for prescription was taken from other services.

[49] In 1991 GP fundholders became cash limited.

This cash-unlimited budget was consistent with the doctrine that obliged GPs to prescribe according to medical needs.[50] By contrast, hospital drug expenditure was funded from the general budget, and therefore was cash limited. In either case, however, drug rationing remained hidden, under the sole discretion of doctors. Any attempts at encroaching on the authority of doctors to prescribe met fierce opposition from doctors themselves and the pharmaceutical industry. The Thatcher government's attempt to introduce the "Limited List" is a case in point. In November 1984, Health Secretary Kenneth Clarke announced its introduction, which would restrict the availability of a range of drugs that GPs could prescribe in seven therapeutic categories, such as cough medicines and tranquillisers.[51] The proposal unleashed counter-mobilisation by both the ABPI and the British Medical Association (BMA). The ABPI, as well as individual firms, challenged the measure through all possible means, from advertising campaigns, lobbying the government and Members of Parliament (MPs), to legal actions. The following spring the government introduced the List in a watered-down form, covering seven therapeutic groups (Medawar et al. 1992, 176-180; Hancher 1990, 199-204).

This governance structure underwent profound changes when the Thatcher government adopted a reform to introduce an "internal market" within the NHS. The reform separated the purchaser and provider of health care by transforming local health authorities (bodies that had previously delivered care to local districts) into purchasers. It also created GP fundholders, which were allocated budgets and purchased services. Apart from its official rhetoric of efficiency through market forces, the purchaser-provider split had its own political consequences: it strengthened the management body's decision-making power over clinicians (Giaimo and Manow 1999, 973f). In the new organisational arrangement, district health authorities were designed to set clinical priorities and purchase medical services. As the next section shows, the collective and explicit decision-making at the local level not only revealed rationing practices but also exposed the regional unevenness in the practices that had been hitherto concealed. By the mid-1990s, the variation in funding across regions began attracting considerable political attention (Klein 2013a, 176–179). The rise of the rationing debate over the course of the 1990s conditioned institutional reforms over drug funding.

[50] Cf. Newdick 1998.
[51] Cf. Baines 2014.

2. The NHS internal market and the rise of "rationing" debates

The introduction of the internal market prompted debates over explicit healthcare rationing among elite political actors. The BMA began advocating public debates on rationing once the introduction of the internal market took place. In 1992 its annual conference backed a motion claiming that rationing was "an unfortunate fact of life"; it called for the government to initiate a public debate to define how it should be conducted.[52] The BMA's advocacy also reflected, in part, the shift in its political strategies as the internal market, which doctors had been vocal in opposing, now became inevitable. It hence came to accommodate itself with the internal market as a new status quo and shifted its attention to operational problems. At the same time, the BMA continued highlighting the NHS's chronic underfunding, which it hoped that a rationing debate would draw renewed attention to.

The BMA was hardly alone in addressing rationing debates. Professional organisations in medicine, such as the Royal College of Physicians, also called for the involvement of the national government. A report by the Royal College in 1995 proposed to establish a National Council for Health Care Priorities, an independent body which would consist largely of experts; its role would be to review methods of rationing and monitor decisions taken at local level.[53] A subsequent meeting jointly led by the BMA and the Royal College of Physicians, together with the NHS Executive, reported that senior NHS officials had come to accept that there might be a case for national, as well as local, guidelines on rationing.[54] Likewise, expert communities, such as health policy think tank The King's Fund, among others, promoted public debates on rationing by bringing together academics and NHS practitioners.

Rationing debates were seen as significant among elites, not only in their own right but also for their implications for the core principles of the NHS, such as being a tax-funded, comprehensive service free at the point of delivery. By the mid-1990s, concomitant with discussions of rationing, a growing debate emerged over the sustainability of the NHS. For instance, in 1995, a pharmaceutical industry-funded report commissioned by Sir Duncan Nichol, a former chief executive of the NHS, claimed that with growing consumer demand and an ageing population the tax-funded NHS could no longer offer comprehensive treatments free for all. This would not only require rationing of treatments, the report argued, but also

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[52] *Financial Times* 7 July 1992; *The Guardian* 7 July 1992, 29 April 1992.
[53] Cf. *Financial Times*, 19 September 1995.
[54] *The Guardian* 27 October 1995.

expansion of private-sector financial contributions.[55] At around the same time, a report by Rodney Walker, a retiring chairman of the NHS Trust Foundation, advanced a similar proposal, calling on people to buy private health insurance to help leave the service to the old and the vulnerable, by introducing tax relief on insurance premiums.[56] Actors closer to the Labour Party, as well as NHS managers, were wary of these advocacies for private options, seeing them as attempts to undermine the founding principle of the NHS, ultimately leading to its residualisation. For instance, a report by the left-leaning Institute of Public Policy Research think tank warned that the growing use of the private care would prove "a development which threaten[ed] to create a two-tier system with poor service for the poor"[57]. The National Association of Health Authorities and Trusts' (an umbrella body of hospitals and regional health authorities) chief executive likewise publicly dismissed the claims put forward by the "ration and privatise brigade".[58]

The rise of elite-led policy debates mirrored public controversies over rationing individual treatments as instances of restriction of access to treatments by local health authorities began appearing in press headlines. To be sure, in practice most of the district health authorities tried to avoid blanket exclusion of treatments.[59] Yet, controversial decisions, even if small in number, were widely reported, especially when followed by lawsuits. In particular, the case of "Child B", where a local heath authority took a decision to deny a second course of treatment to a paediatric leukaemia patient on the ground that the chances of success were very slight, provoked both public attention and academic debates.[60]

The Parliament Committee provided a political arena to bring rationing debates to the national level. The House of Commons Health Committee (HoCHC) opened a series of inquiries related to health care priority setting in 1994, which covered a range of different pillars of the NHS. An inquiry was held specifically into NHS drugs expenditure. The Committee's resulting report proposed establishing a National Prescribing List, a "positive list" of drugs covering all therapeutic categories that could be prescribed within the NHS.[61] A separate inquiry in 1994 was devoted to purchasing decisions by local health authorities, and

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[55] *The Guardian* 19 September 1995; *Financial Times* 20 September 1995.
[56] *The Guardian* 16 September 1995.
[57] Lenaghan 1996, ii.
[58] *Financial Times* 3 November 1995.
[59] Ham 1993, 435
[60] On the case of Child B, see New 1996, 1596; Ham 1999.
[61] House of Commons Health Committee (hereafter HoCHC) 1994 (80-I), para. 132f (xxxl).

hence more directly took up rationing debates. The committee's Conservative chairperson called for "an honest and realistic set of explicit, well-understood ethical principles at national level"[62]: among other proposals demanding a stronger lead by the Department of Health, the committee advocated for a purchasing framework to define local packages of services and the criteria on which local purchasing decision should be based. In drawing up its recommendations the Committee considered experiences of explicit rationing decisions in other countries including Oregon State in the USA, New Zealand, and the Netherlands, among others, and together with societal actors' promotion of rationing debates, by mid 1990s policymakers as well as elite societal actors were aware of examples of other countries where explicit rationing took place through institutionalised settings.

In contrast to the rise of rationing debates among societal actors and MPs, however, the Conservative Major government refused to publicly acknowledge rationing, which it preferred instead to call 'priority-setting'. Ministers repeatedly rejected the idea of setting treatment priorities at the national level. Responding to the BMA's call for public debates on rationing in 1992, Health Secretary Virginia Bottomley noted that while priority setting must take place at every level the role of the government was to give service strategic decisions; it would not be appropriate for the national government to take decisions on clinical priority. Instead, she argued, such decisions should be taken locally. [63] Likewise, in its 1995 response to the House of Commons Health Committee's inquiry on priority setting in the NHS, the government explicitly rejected the idea of a national list of treatments. Referring to "some of the radical approaches to rationing health care used in other countries" such as the Oregon Health Plan, it claimed: "Such approaches are neither necessary nor appropriate for the NHS. No one list could ever hope to accommodate the range and complexity of the different cases which individual clinicians face all the time".[64] In the previous year the government had, on the grounds of its operational cost, also dismissed the idea of the National Prescribing List endorsed by the HoCHC.[65]

The avoidance of rationing debates was further reflected in ministers' political rhetoric. For instance, by not taking up their responsibility for rationing ministers tended to shift the blame on to managers on the ground. Hence in 1995, in refuting Labour's claim that one-third of

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[62] *The Guardian* 1 February 1995.
[63] *The Guardian* 12 March 1993.
[64] DH 1995 (Cm2826), 1.
[65] DH 1994 (Cm 2683), 11.

district health authorities restricted a range of surgical operations, Health Secretary Stephen Dorrell stated that if local authorities did not follow the obligation to use resources to meet priorities for care they "would be hauled before parliament for 'an abuse of public funds'".[66] Moreover, instead of seeing it as a policy problem to be tackled, the government took existing variations in health authorities' decisions and approaches to rationing as evidence justifying its hands-off approach to local decision-making. As Bottomley put it, "[t]he fact that different approaches are used suggests that there is no place for national setting of local priorities when the determination of local needs is elusive, even to people living in the district".[67]

Rather than addressing rationing debates, the government influenced local decisions in a subtler way. Two such alternative strategies are highlighted here. The first concerns the national framework of priorities. As noted, ministers set the strategic framework for the NHS, expecting 'local strategies to be developed within the national framework, but aimed at addressing particular challenges specific to the needs of the local population'[68]. Such national priorities were communicated through the Department of Health (DH)'s annual Priorities and Planning document, which contained the government's key policies with targets specific to each of them; in addition, the DH issued a large number of guidance notes to local authorities, some in response to specific inquiries while others addressed different matters in an ad-hoc manner. The resulted was what the HoCHC report called "priority overload": local health authorities received an overwhelming number of "national priorities" that were sometimes contradictory, without clear directions of which items were most crucial. The lack of meaningful prioritisation, driven by the national government's inaction, in turn, implied that it was the local authorities that adjudicated these different demands by the national government and made decisions.

The second strategy for rationing concerns strengthening the knowledge base for decisions. The reluctance of the government to engage with rationing debates, let alone making a policy choice, does not mean that the government shied away from allowing knowledge and expertise to guide local decisions. On the contrary, the government championed various research and development initiatives for approaches to measure and compare effectiveness of different treatments, such as Evidence-Based Medicine (EBM) and Health Technology Assessment

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[66] *Financial Times* 18 November 1995.
[67] Bottomley 1994, 338
[68] HoCHC 1994 p.xv

(HTA). Such efforts were pursued through enhancing the scientific capacities of the NHS in collaboration with academic communities of health economists

The government's enthusiasm for HTA had only begun to emerge in the past few years. In response to the House of Lords Select Committee's 1988 inquiry on priorities in medical research, the Department of Health appointed a cancer specialist, Michael Peckham, as the first NHS Director of Research and Development. In 1991, under his leadership, it launched the NHS R&D Programme, with a national target to spend 1.5% of the total NHS budget on R&D, to be achieved in five years. Health technology assessment sat at the centre of the R&D Programme. In 1993 the Department of Health set up the HTA Programme - a strategy planned to spend the majority of the NHS R&D budget, £317 million at the time, on research on health technology assessment. With the ambition of creating an "evaluation culture" in the NHS, the HTA Programme was "to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS".[69] As a part of the NHS R&D Programme, the DH established research centres dedicated to the development of evidence-based medicines and health technology assessment, such as the UK Cochrane Centre, opened in Oxford in 1992, and the NHS Centre for Review and Dissemination, based at York University and established in 1994. The former, in collaborating with the worldwide Cochrane Collaboration on evidence-based medicines, was dedicated to systematic reviews on randomised controlled trials; the latter centre, by focusing on research in the areas of comparative effectiveness and cost-effectiveness of health care interventions, was aimed to "disseminate the results of research to the NHS in order to enhance effective decision making".[70] A related government-funded initiative was the Effective Health Care bulletins started in 1992; jointly produced by the Universities of York and Leeds, and the Royal College of Physicians, the bulletins provided meta-analyses of clinical and cost effectiveness of a range of health interventions, which were made available to district purchasers. According to the HoCHC report, the bulletins received "widespread and enthusiastic support" from district purchasers.[71] In a later year, the Department of Health set up a national register of cost-effectiveness analysis to collate results of comparative effectiveness research.

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[69]NHS R&D Health Technology Assessment Programme description.
https://www.journalslibrary.nihr.ac.uk/hta/about-the-hta-journal.htm Cf. *Financial Times* 8 July 1993;
[70] HoCHC 1995 (134-I), xxxix.
[71] HoCHC 1995 (134-I), xl.

The Labour shadow health minister saw these government initiatives on HTA as "nothing but a smoke screen for rationing".[72] For his part, Health Secretary Stephen Dorrell emphasised that evidence-based medicines would not be "rationing by the backdoor"[73]; he argued that "[the] guidelines were to promote good value as opposed to least cost". The government's rhetoric to legitimise guidelines' development revolved around reducing wasteful, clinically ineffective treatments while making information on cost-effective care readily available to local managers and clinicians. In the 1996 white paper "The National Health Service: a service with ambition", it contended: "Managing the introduction of new technologies is a continuing challenge, but the NHS is becoming more effective in this, identifying and adopting those which will bring real benefit while discouraging those which are less cost-effective." It also explicitly ruled out rationing of clinically effective treatments.[74] These were not just rhetorical commitments; the emphasis on clinical and cost effectiveness also increasingly appeared in Priorities and Planning documents and other guidance to local authorities.[75]

In parallel with the development of national-level programmes, the early 1990s also saw the growth of region-level initiative for HTA. Controversies over rationing debates put local health authorities under pressure. With the absence of an established basis for making judgements, health authorities used different tools and methods to guide their decisions, some involving public opinion surveys to elicit views on priorities of different treatments, while others sought inputs from GPs in conducting "needs assessment". As health policy scholar Chris Ham reported in the early years of operation, the lack of information – and cost effectiveness of services in particular - to guide priority setting was perceived as a major problem among health authorities.[76] A related observation was made by the Royal College of Physicians, who highlighted the failure of local authorities to collect epidemiological information in making judgements.[77] In making choices in a technically complex and often controversial environment, some region-level authorities turned to an emerging academic community of health economists to provide evaluation of technologies based on their cost effectiveness. Perhaps the most notable case of such region-level initiatives was the Development and Evaluation Committee (DEC) of Wessex Regional Health Authorities (later

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[72] *Financial Times* 11 January 1996.
[73] *Financial Times* 11 January 1996.
[74] DH 1996 (Cm 3425), Ch.3.
[75] Cf. Hayward 1994; Thomson 1995.
[76] Ham 1993, 436.
[77] HoCHC 1995 (134-I), xvx.

extended to cover all the South and West Regions). Established in 1991, the Committee was mainly comprised of senior clinicians, with the help of Southampton University's public health research centre (Wessex Institute of Public Health Medicine). It assessed the cost-effectiveness of new and existing technologies using Quality-Adjusted Life Years (QALY), a measure of the effects of health intervention.[78] Based on this assessment, the Committee made recommendations on whether the authority should purchase a technology or not, and the results were disseminated throughout the region. Claiming itself as "the first and most systematic initiative" of its kind, the Committee hence provided an early example of use of cost-effectiveness analysis to inform local rationing decisions.[79] Similar initiatives were subsequently developed in some other regions, including the West Midlands Development and Evaluation Committee, the Trent Working Group on Acute Purchasing, and the Scottish Health Purchasing Information Centre.[80]

In fact, at district level the majority of health authorities did not appear to use cost-effectiveness analysis to inform their decisions, at least during the initial years of the internal market. Based on a study of the 116 district health authorities' 1992-1993 purchasing plan, health policy scholar Rudolf Klein stated that he did not find a single example of authorities who reported they used cost-utility analysis for their decisions.[81] Another study, conducted by The King's Fund, reported a rather different picture. Based on a survey of the 187 English district health authorities, in 1992 it found that 21 percent of authorities used QALYs to assist their decisions, and a further 17 percent planned to do so. It concluded that "for a significant minority, therefore, QALYs have now become part of the rationing process".[82] Regardless of which one was closer to the reality, however, the local-level practices in the use of clinical and cost-effectiveness information left some legacies. First, by the mid-1990s, both through these local practices and debates over them, elite actors in the policy sector were well aware that district health authorities not only varied significantly with each other in terms of their policy

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[78] QALY measures both the length of life and quality of life gained by a health intervention. See also Chapter 4 for later use for the English drug funding policy.
[79] Stevens et al. 1995, 38; HoCHC 1995 (134-I), xl-xli
[80] These regional committees later formed the "InterDEC", an inter-regional collaboration of assessment to avoid duplication.
[81] Quoted in HoCHC 1995 (134-I), xvi. A similar finding was presented by Ham's study based on interviews in six health districts, which claimed "there was very little evidence that the research on QALYs had exerted any influence on district health authorities. Indeed, there seems to be a considerable gap between the work of health economists in this area and the world in which purchasers operate". Ham 1993, 435.
[82] New and Le Grand 1996, 14.

decisions, but also in their decision criteria. Second, as we shall see later in this chapter, policy practices at local level, notably the use of cost-effectiveness analysis, would later provide an example and existing resources to draw on in establishing NICE.

The growth of regional-level initiatives for health technology assessment, such as DECs, cannot be fully understood without a broader context of national development. To be sure, key figures of the Committee tended to see national-level initiatives on cost-effectiveness often as slow, long-term and only covering limited topics; they argued that to meet demands from local commissioners it was necessary to complement national initiatives with rapid evaluations on more topics produced at local level.[83] Yet initiatives at regional level were boosted by their incorporation to the funding from the NHS Regional R&D Programme. Moreover, the health technology assessment programme for Wessex DEC took a pivotal role in HTA initiatives, as the National Coordinating Centre for Health Technology Assessment (NCCHTA), which oversaw the NHS HTA programme, was located in Southampton University's Wessex Institute for Health Research and Development. Bottom-up policy practices were thus at least partly facilitated by the government strategy on HTA.

The contrast between the government's reluctance to address the rationing debates and its emphatic support for guideline development underlines the importance of political incentives for the ministers to avoid blame for health care rationing. To be sure, the increased visibility and explicitness in rationing decisions was something that government policymakers should have been aware of when introducing the internal market. In a 1991 interview shortly before the operation of the internal market, when asked whether "politicians should be more upfront that not everything can be afforded", Health Secretary William Waldegrave affirmed that it would be "utterly necessary under the new system". As he put it: "[O]ne of the things that will be thrown up will be a much more explicit demonstration of what we are and are not buying. That will cause those decisions to have to be justified - not only by politicians but also by the clinicians. The system will become more open and explicit, and therefore more argumentative. I think that must be a good thing, although it will take a little getting used to."[84] Explicit rationing at local level was thus hardly an unintended consequence, if a by-product, of the new internal market organisational arrangements. However, once the internal market became the reality, successive ministers refused to address rationing debates, let alone define priorities based on their national government's initiative. Waldegrave himself, in November that year at

[83] E.g. Stevens et al. 1995, 42.
[84] Wadgrave 1991. For a similar statement, see *The Times* 30 March 1991.

a medical conference, took a more cautious attitude towards rationing; while commenting on the example of New Zealand, where "[they] have put their toes into the shark-infested waters of limiting the services available from the public health service", he declared that "These are waters in which we do not intend to swim."[85]

The shift in Waldegrave's political rhetoric might partly reflect a stronger electoral incentive for the latter phase, as the 1992 general election was then approaching. More important, however, the reluctance of Waldegrave and the successive ministers to engage with rationing debates may be driven by a greater level of controversy, and hence political incentive to avoid blame, that ministers were faced with in the post-enactment phase of the internal market. Instead of taking initiatives in rationing debates and some roles in setting priorities in public, ministers hence took a more overt approach, such as facilitating guideline development for clinical and cost-effectiveness while leaving unpopular decisions to local NHS managers and individual clinicians.

When it comes to the policies specifically targeting pharmaceuticals, the government strategy was somewhat nuanced. Policymakers were wary of drug expenditure, which grew faster than general health expenditure.[86] In 1992 the Health Secretary announced that the government would extend the Selected List to a further ten categories.[87] The expansion of the List may appear surprising, given the widespread grievance over rationing at the time, combined with the government's reluctance to take up the issue in public. The move could have been more controversial than the 1985 scheme, since unlike the latter, which covered symptomatic relief such as cough medicines and laxatives, the proposed schemes, as the BMA put it, included "significant treatment".[88]

Why did the government expand the scheme for blacklisting drugs on the NHS, while trying to avoid responding to the rise of rationing debates? Two interrelated factors may be relevant here. First, drug companies failed both to forge an alliance with doctors and to create a public backlash by connecting it with the rationing debate. Available evidence suggests that public debates regarding the expansion of the scheme were not framed around rationing. The government did not regard the Selected List Scheme as something that could be linked with

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[85] *The Guardian* 29 April 1992.
[86] *The Times* 24 January 1992.
[87] Cf. Bateman 1993.
[88] HoCHC 1994 (80-I), DB40A (Memorandum submitted by the British Medical Association), point 10. cf. HoCHC 1994 (80-I), xxv.

the rationing debates: instead it frequently labelled the List as a part of the rational prescribing agendas. Perhaps more importantly, neither did societal actors who addressed local rationing decisions manage to link the scheme with the rationing debates.[89] Actors critical of the 1985 scheme, such as doctors, did not attempt to frame the issue around rationing.

In fact, unlike the fierce counter-mobilisation and public campaigns against the 1985 scheme, this time doctors' opposition had somewhat waned. While the BMA wrote in its submission to the HoCHC's inquiry into NHS priority-setting that they were "concerned", in particular, with the proposed inclusion on the list of some specific areas which they perceived as cost-effective care, such as oral contraceptives, , little evidence indicates that this resulted in salient public campaigns. While the representatives of GPs voted for a resolution to condemn the expansion of the List, as the Chair for General Medical Services Committee's Prescribing Subcommittee put it, for doctors the Limited List was acceptable compared to other instruments for cost-containment, such as the imposition of cash-limited budgets.[90]

The pharmaceutical industry was hence the main loser of the expansion of the scheme. The ABPI saw it as implicit additional price-control, through the threat to include drugs on the list. Individual companies lobbied heavily, while the ABPI used advertising campaigns. However, unlike the 1985 scheme, the industry failed to mobilise doctors, who came to accept the proposed expansion. Moreover, what could have been framed as rationing - and a report published by the ABPI indeed criticised the scheme as an "unacceptably blunt instrument to ration health care"[91] - never caught sustained public attention; and in fact, the industry did not manage to exploit the frame of rationing well enough for it to galvanise public counter-mobilisation. In contrast to the ongoing highly salient debates over rationing by local health authorities, the expansion of the scheme rarely got publicised by general news media.

Second, again unlike the 1985 scheme, the government took a more accommodationist strategy in an attempt at silencing likely opponents. In translating its announcement into a concrete plan the government consulted the ABPI and the BMA. Institutionalised channels

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[89] Throughout the entire debates about the House of Commons report *Priority setting at the NHS: Drugs bill*, the only occasion that rationing was mentioned in describing the Limited List was within a memorandum submitted by a local health authority, who *welcomed* the change in government initiatives for explicit rationing, since "it is encouraging to see the guarded support of the medical profession". Memorandum Submitted by Derbyshire Family Health Services Authority (DB 26), HoCHC 1994 (80-vii), 370f.

[90] "Opposition to UK NHS Backlist Moves", *Pharma Marketletter* 5 July 1993.

[91] "ABPI slams NHS administration costs", *Pharmaceutical Business News* 18 October 1993.

such as the Advisory Committee on the NHS Drugs – a committee that gave advice to the minister on which drugs to be included to the List - played a role in such consultations. An access point to policymakers, which the BMA had won in the battle over the 1985 scheme,[92] the committee became a vehicle for doctors to exert their influence. Hence, as the BMA Chair for General Medical Services Committee Prescribing Subcommittee, who was also one of the members of the Advisory Committee on NHS Drugs, testified before the House of Commons Health Committee: "I am certainly, as a member of the Committee, quite prepared to put my neck out and say I disapprove thoroughly of contraceptives being on that list".[93] This government strategy for accommodating societal actors, in turn, explains why the process of deciding on the List in the subsequent years took place only slowly and partially: by 1996, only 63 drugs were included on the List; and of them, only one was a prescription-only medicine.[94]

Another indicator to gauge the government's strategy for drug rationing is what happens when ministers encounter exogenous shocks, such as the arrival of a costly new medicine. In 1995 the Department of Health took the unprecedented step of issuing a circular that restricted the prescription of beta interferon, a new drug approved for relapsing or remitting forms of multiple sclerosis. Apart from the Selected List Scheme and bans for safety reasons, this was considered the first time that the national government explicitly restricted the availability of a specific drug. In the circular the Department of Health advised that the drug should only be prescribed by neurologists in hospitals and not by GPs, and only in strict accordance with approved indications (Walley, et al. 1997, 345). There was some controversy before the launch of the drug, not only because its efficacy was disputed but also because it was expensive – the drug was likely to cost as much as £10,000 per patient per year, and one estimate projected that it could consume10% of the NHS budget (Walley and Barton 1995, 797; Dyer 1995). The circular was broadly supported by neurologists and GPs, many of whom were sceptical about the effectiveness of the drug (Walley et al. 1997, 346). The patient group the Multiple Sclerosis Society was critical of the decision, as the lengthy waiting list to see specialists would

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[92] As a part of a compromise between the government and BMA over the List in 1985, when the Advisory Committee was set up, three of the four GP members appointed to the Committee were senior BMA figures. *The Guardian*, 13 July 1985.
[93] HoCHC 1994 (80-I), Minutes of Evidence (British Medical Association) 22 para 113. By 1994 contraceptives were dropped from the list after the consultation.
[94] Earl-Slater and Bradley 1996, 401; cf. Walley et al. 1995, 328.

effectively mean that beta interferon was rationed, even if the government had not deliberately done so.[95]

Behind the scenes, Health Minister Gerry Malone was very reluctant to exclude the drug altogether. The guidance was prepared in consultation with the Multiple Sclerosis Society and the British Association of Neurologists.[96] According to his account years later, after the event the minister told the Department's officials to "go away and devise some schemes where ministers do not have to take these decisions."[97] While the minister hence tried to reduce the likely impacts of an unpopular decision by accommodating societal actors, in the future he wanted to avoid the blame for such decisions through institutionalised mechanisms that would protect him.

If the blame-avoidance strategy helped reduce the level of conflict that could have been otherwise generated by the minister's decision, it did not contain it. During the preceding year the Department had asked health authorities to develop "effective management of new drugs into the NHS", and beta interferon was the first nationally-coordinated attempt at such a "managed entry".[98] The circular on beta interferon was advisory, and the actual decision to fund it was left to local health authorities. This generated variation in funding beta interferon across local authorities, as some authorities refused to fund the drug. In one case, the refusal led to a judicial review, where the illegality of not complying with the minister's circular was contested.

The beta interferon episode provided a further catalyst for development of government HTA projects, especially with regard to early responses to expensive new or emerging technologies.[99] The Department of Health developed a horizon-scanning project within the NHS HTA Programme, an "early warning" system that identified new emerging technologies that were likely to affect the NHS resources and in need of evaluation. [100] In parallel, since 1996 the National Prescribing Centre identified emerging technologies based on systematic scanning of the literature and contact with drug companies and with the drug approval agency

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[95] *The Times* 5 Oct 1995.
[96] *The Independent*, 5 October 1995; Timmins 2016, 32.
[97] Timmins 2016, 32. In an interview by the same author, NICE's first chair, Michael Rawlins, attributed the origin of NICE to the beta interferon event. See Timmins 2009, 1360.
[98] "NHS's timely new product information" *Scrip*, 5 August 1998.
[99] Cf. Timmins 2016, 33.
[100] Stevens et al. 1999.

(Medicines Control Agency), and disseminated the summary of cost and clinical effectiveness information to local health authorities and clinicians.[101]

In sum, the introduction of the internal market gave rise to debates over the NHS rationing. Despite demands from clinicians and other elite societal actors for the government to publicly address the rationing debates, the incumbent policymakers tried to avoid them, leaving explicit decisions to the local health authorities. Instead, the government encouraged the development of local expertise to aid health authorities' decisions. As the remainder of the chapter shall show, these developments during the Conservative years left important legacies. On the one hand, the Conservatives' emphasis on local-level NHS rationing decisions left both controversies and fragmented local-level practices. When Labour took over power, it would inherit this institutional landscape and its perceived policy problems. On the other hand, the development of local experts and expertise on HTA as an alternative to national rationing debates left the resources that policymakers in the Labour government and NICE would later draw on. These policy and institutional legacies thus set the scene for institutional reform for the regulatory state in the Labour years.

3. The Blair Government and the establishment of NICE

The Blair government entered office with relatively vague agendas on the NHS reform. During the 1997 election campaign, the Labour party leader Tony Blair did not make commitments to increasing NHS spending. Labour's electoral manifestos pledged to increase spending in real terms, without any specification; its emphasis was on critiques of the internal market and the reduction of waiting lists, among others. The increase in spending compared to the preceding year was modest until early 2000, when Prime Minister Blair announced that he would raise NHS spending to the average level of the European Union countries.[102] In its first white paper, *The New NHS: modern, dependable*, published in December 1997, the government attacked the internal market as a source of fragmentation. Instead, it claimed that the internal market would be replaced by an emphasis on performance and partnership: it promised to abolish GP fundholders, creating Primary Care Groups, later Primary Care Trusts (PCTs), which had budgetary responsibility and set priorities.[103] Contrary to its political

[101] "NHS's timely new product information" *Scrip*, 5 August 1998.
[102] Klein 2013a, 191ff.
[103] DH 1997 (Cm 3807), paras. 2.12f

rhetoric of criticising the internal market, however, the purchaser-provider split was maintained.

The proposal for establishing the National Institute for Clinical Excellence (NICE) was bundled into its overall plans for a "new drive of quality" in the NHS. The agendas were framed around its call for a "national dimension"[104]. Criticising "unjustifiable variations in the application of evidence on clinical and cost effectiveness", it claimed to "spread best practice and drive clinical and cost-effectiveness". Along with an emphasis on the existing R&D Programme for disseminating evidence on cost-effectiveness and the "National Service Framework" that set out national standards of care, it promised to set up a National Institute for Clinical Excellence which would produce clinical guidelines, together with a Commission for Health Improvement (CHIMP/CHI), which would monitor quality of care. The emphasis on quality continued in its subsequent green paper, *A first class service: quality in the new NHS,* published in the following July, in which the DH set out detailed proposals for establishing NICE.

In the policy debate for setting up NICE the government stressed the national character of its guidance. The green paper noted that NICE would be committed to "promoting clinical and cost effectiveness through guidance and clinical audit". An underlying rationale was to tackle so-called "postcode prescribing": Health Secretary Frank Dobson argued that NICE would "help end unacceptable geographical variations in care that have grown up in recent years", by producing guidance used across the country.[105] Another rationale that the Health Secretary highlighted was that NICE would give a "single, authoritative advice" for clinicians to avoid duplication of guidelines. The White Paper also underlined that existing guidelines in some areas produced contradictory advice, while others lacked evidence to guide local staff.[106] The order establishing NICE was formally issued in February 1999, and the Institute opened in April. Michael Rawlins, a professor in clinical pharmacology and the chairman of the Committee on Safety of Medicines until 1998, was appointed as NICE's first chair.

The proposal to establish NICE did not meet visible oppositions from doctors. The BMA broadly supported NICE in principle, but expressed concerns about limiting doctors' clinical freedom.[107] Little evidence indicates, however, that doctors openly mobilised themselves

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[104] DH 1997 (Cm 3807), paras. 7.1ff.
[105] *The Guardian* 6 February 1999; cf. Warden 1998.
[106] DH 1998a, 2.5.
[107] Wright 1999, 21.

against the establishment of NICE. Rather, doctors welcomed NICE as it would address the rationing debates at national level, which the BMA had been advocating for years.

The pharmaceutical industry remained much more cautious about NICE's implications. It warned the government that NICE would become a "bottleneck" for innovative new therapies.[108] As part of its campaign, the ABPI published a booklet claiming variations in drug care existed across the country. Although it came to accept NICE as a measure to "drive up standards of care and iron out inconsistencies", nevertheless, the industry stressed that "there is a grave danger that such an activity could be used as a barrier to prevent patients getting prompt and ready access to innovative new medicines"[109]. In the wake of NICE's launch, the industry proposed several alternatives to the procedural design of NICE's guidance, warning that the Institute's approach could be "anti-innovative" and damage the UK research base.[110]

If the Labour government scaled up the explicit choice of rationing to the national level through uniform national guidance, its policy preference was far from taking the responsibility for it. In opposition, Labour had been highly critical about rationing within the NHS. Once in power, however, the Labour ministers were as reluctant as their Conservative predecessors to openly talk about rationing. Ministers as well as DH public officials – and indeed also key figures within NICE - used the term 'priority setting' instead of 'rationing' during parliamentary debates.[111] For its part, it was now the Conservatives' turn to criticise the government for not facing up to the rationing debates.

Labour ministers' policy strategy for explicit rationing were reinforced by another high-profile episode concerning a specific drug – an explicit decision to restrict the use of Viagra (sildenafil), a drug for the treatment of impotence (aka erectile dysfunction). Viagra was often seen as a landmark case of explicit rationing decisions, because in this case - unlike beta interferon – the efficacy of the drug was not questioned; it was considered to be the first time

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[108] *Financial Times* 21 January 1999.
[109] "72% generic Rxing target set for English GPs; UK industry warns over NICE", *Pharma Marketletter* 26 January 1999. Cf. BBC News 20 January 1999.
[110] "UK industry suggests "collaborative" alternative to proposed NICE process" *Pharma Marketletter* 7 April 1999; "PPRS "could be used to reduce attraction of parallel imports", *Pharma Marketletter* 9 April 1999.
[111] NICE's chair, Michael Rawlins, participated in lengthy definitional discussions on rationing before Parliament as well as in an article, noting that the dictionary definition of rationing defined (such as during World War II, as he argued) had never occurred in the NHS. Rawlins 1999, 1082.

a health secretary had imposed a restriction on the availability of a drug on the NHS purely based on its cost.[112]

Viagra received extensive media coverage as a "breakthrough drug" for impotence before approval in Europe – an expectation which led the minister to worry that the drug would prove a "serious drain" on the NHS. The BMA estimated that the drug bill would exceed £1 billion if all the men who might benefit from the drug were prescribed it, while the manufacturer Pfizer argued that it would cost £50 million after five years.[113] Viagra was licensed in Europe in September 1998. On the preceding day, the NHS executive issued guidance stating that the minister was drawing up policy proposals and in the interim doctors should not prescribe Viagra. The Standing Medical Advisory Committee drew up advice for the Minister on the drug, pointing out that there were no medical reasons why it should not be available on the NHS, nor why GPs should not prescribe the drug. Subsequently in January 1999, however, the minister announced that he would be restricting the availability of Viagra: he intended to use his statutory powers to issue Regulations, putting Viagra on the Selected List. This restriction implied that the drug was to be made available by GPs only for patients with erectile dysfunction who had had prostatectomy, radical pelvic surgery, spinal injuries, diabetes, multiple sclerosis, or single gene neurological disease. An additional guidance stated that for certain patients the drug would only be available after specialist consultation. Just 15% of impotent patients were said to be eligible for the drug.[114] Dobson emphasised a resource-allocation imperative in making the decision: "We have to find a sensible balance between treating men with a distressing condition, and protecting the resources of the NHS to deal with other patients, for example with cancer, heart disease and mental health problems."[115] His justified the decision by claiming that impotence is "neither life-threatening nor causes physical pain".[116]

Doctors, who had already been frustrated with the interim banning of Viagra, contested the announcement. The BMA had seen the temporary restriction as a failure to protect GPs from a surge in the demand for the drug.[117] It had pressed the government to issue guidance by threatening that otherwise it would advise doctors to routinely prescribe the drug. When the

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[112] Dewar 1999; Klein 2013a, 202.
[113] Brooks 1998.
[114] Beecham 1999.
[115] Quoted in Beecham 1999; cf. Klein 2013a, 202.
[116] Quoted in *Financial Times* 22 and 23 January 1999; Beecham 1999.
[117] "Dobson failed to protect GPs from the surge of requests for Viagra" *Pulse* 26 September 1998.

decision was announced, the BMA immediately condemned it, noting that the proposal made "cruel, unethical, and inequitable distinction between "acceptable" and "unacceptable" forms of impotence". [118] Doctors contested the criteria for distinguishing those who were eligible from those who were not, which were not based on clinical reasons but on causes of impotence. As the General Practitioner Committee chair noted, the drug proved clinically effective and was cost-effective in QALY terms.[119] The BMA advised its members to defy the guidance and to prescribe Viagra according to clinical needs, although, to the surprise of the BMA leadership, the majority of the GPs appeared to abide by the government's policy for rationing.[120] For its part, the chief executive of the NHS Confederation (the representative of the NHS trusts) backed the announcement.[121] After public consultation, in April the government expanded the eligibility to include some other conditions; and the protest by the BMA leadership somewhat toned down. The guidance went into effect in July.

The manufacturer Pfizer brought the case to the court. The High Court ruled that May that the guidance announcing the interim ban was unlawful, because it constrained GPs clinical judgement under their statutory Terms of Service. It also ruled that the government had breached the EU Transparency Directive, which required it to give public notification of its reasons based on "objective and verifiable criteria".[122] While this did not stop the Regulations from limiting the availability of Viagra, the process amplified the salience of rationing in public debates.

Viagra arrived shortly before the launch of NICE. If Viagra's "focusing event" did not affect the design of NICE, it reinforced the terms of the debates surrounding it in two respects. On the one hand, it reinforced perceived rationales of NICE in the eyes of different actors. In the wake of Viagra being licensed in Europe the minister Alan Milburn, when asked about the government's position on it in a House of Commons debate, noted, "[f]or a drug such as Viagra, the national institute would need also to advise on how such treatments should best be targeted to ensure that the most appropriate patients are selected for treatment, and that NHS resources overall are used in the most effective possible way."[123] After Dobson's guidance and the eventual High Court ruling, major news media interpreted his handling of the issue as a

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[118] Chisholm 1999, 273.
[119] Ibid., 274.
[120] "GPs back NHS rationing of Viagra" *Pulse* 6 February 1999.
[121] *Financial Times* 22 January 1999; Beecham 1999.
[122] On this ruling, Syrett 2004. Cf. *The Guardian* 27 May 1999.
[123] HoC Hansard debates for 14 July 1998, Column 322.

demonstration of "the flaws of the current system" (BBC News, 6 August 1999).[124] This interpretation of the guidance was also shared by the BMA, which wanted the minister to refer the Viagra case to NICE when it came into being.[125] In either case, it was widely assumed that once NICE started work it would no longer be the minister but NICE who would make rationing choices. On the other hand, the Viagra case provided the precedent of a high-profile judicial review by a manufacturer successfully challenging a government's decisions about health care rationing. In short, NICE was launched into an already controversial environment vis-a-vis the rationing debate.

4. The structure and the processes of reimbursement decisions

NICE was established as a special health authority covering England and Wales. In formal terms the independence of NICE from the Department of Health was relatively fragile. Its creation was based on secondary legislation, or a Statutory Instrument, ordered by the Health Secretary under the 1977 National Health Service Act, rather than enacted by primary legislation; and like other bodies under the umbrella of the NHS, NICE was sponsored by the Department of Health and ultimately accountable to the Health Secretary. Its establishing order's wording exemplifies the formally predominant position of the Department of Health to NICE:

> "Subject to and in accordance with such directions as the Secretary of State may give, the Institute shall perform such functions in connection with the promotion of clinical excellence and of the effective use of available resources in the health service as the Secretary of State may direct."[126]

Management rules also followed this formal predominance of the Department of Health. Hence NICE's Chair, seven non-executive members of the NICE Board, and its chief

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[124] This was especially true of the way in which the news media all reported the news on the front page, and framed the issue with relations to NICE following the High Court ruling in May regardless of their ideological leanings. "Mr Dobson believed he had found a way to distance politicians from the difficult decisions over what the NHS can and should afford by setting up the National Institute for Clinical Excellence" wrote *The Guardian* 27 May 1999.

[125] "GPs face longer wait over Viagra" *Pulse* 27 February 1999. In practice the minister did not refer the case to NICE. "Government rules out NICE review of Viagra" *Pulse* 17 February 2001.

[126] SI 1999/220 article 3 as amended by SI 1999/2219. SI 1999/219 inserted the words "and of effective use of available resources". This amendment raised some debate as some critics, as well as the shadow health ministers, suspected that NICE would take into account affordability in making decisions, and thereby more directly engage in rationing. The minister and NICE's chief both denied that NICE would consider affordability.

executive were appointed by the Health Secretary. NICE also discussed its work with its Partners' Council, comprised of representatives of different stakeholders, including the medical professions, pharmaceutical and health industries and patient groups, appointed by the Health Secretary. The Council reviewed NICE's annual reports and the development of its work programme, which would be commissioned by the Department of Health.

Yet, the picture is different when we look at the procedural rules of NICE's work. NICE carried out "technology appraisals" – recommendations about whether new technologies and health care interventions should be available on the NHS. Apart from the above-mentioned functions, few legal provisions existed in NICE's establishing order. Informal rules to guide the procedure were instead envisaged in a DH discussion paper circulated shortly before NICE's launch; and then NICE set out its procedure in its official documents.[127]

NICE's technology appraisal process involved (i) topic selection, (ii) assessment, and (iii) appraisal. First, topics that NICE appraised were selected and were formally referred to it by the health ministers. The pool of potential topics came from the emerging technologies identified by Birmingham University's Horizon Scanning Centre, funded by the NHS HTA programme; suggestions by stakeholders, such as the medical professions and patient groups; and proposals from the Department of Health. An advisory group within the Department of Health then screened and make recommendations to the health minister, who made final decisions on the topics for appraisal.

In the next stage, independent academic groups, organisationally separated from NICE, carried out assessment. After NICE set out the scope of the appraisal, identifying relevant issues and questions in consultation with different stakeholders ("consultees", which not only included societal actors but also the Department of Health), the NCCHTA commissioned an "assessment report", produced by an independent academic group called the Assessment Group, which was normally one of the academic centres of NHS HTA Programme. In writing an assessment report, the Assessment Group reviewed the literature and evidences submitted by the manufacturer including data on cost-effectiveness. NICE then compiled the "evaluation report", which consisted of the assessment report and other evidences, including comments on the assessment report.

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[127] DH 1999; HoCHC 2002a, 55-58.

The third stage involved appraisal by NICE's Technology Appraisal Committee. The Committee, appointed by NICE, considered the evaluation report. The Committee was usually chaired by clinicians and its members were drawn from the NHS, academia, patient groups and the pharmaceutical and medical device industries. Once the Technology Appraisal Committee agreed a recommendation, called the Final Appraisal Determination, it was circulated and stakeholders were given a certain period to submit appeals to a panel comprised of five members appointed by NICE. Following the appeal period, NICE guidance was published to the NHS.

As this description highlights, in making appraisals NICE drew on existing resources and the expertise of academic communities developed by both the NHS HTA Programme and region-level HTA initiatives. After all, it was the Assessment Groups of academic institutions, contracted out by NICE, rather than NICE itself, that produced the assessment report based on clinical and cost-effectiveness analysis, which would be crucial for final decisions. As Rawlins explained, this organisational choice – NICE as a "virtual" Institute which harnessed a network of existing academic centres, rather than developing in-house expertise – was mainly due to its small budget; the academic centres forming Assessment Groups, as well as their assessment reports, were funded by the NHS HTA Programme, not by NICE.[128]

Yet, this organisational adaptation created an unintended consequence for the political insulation of NICE's appraisal process. As Wood (2014) has pointed out, the organisational structure whereby the Appraisal Committee appointed by NICE, rather than NICE itself, considered and made decisions on technology appraisal guidance, provided a high level of de facto insulation of the Committee from both the DH and NICE senior officials. The double delegation, from ministers to NICE, and then from NICE management to the Appraisal Committees, further shielded the appraisal process from outside pressures including elected officials. Yet, the chain of delegation might go even further; the main bulk of evidence, especially data on cost per QALY of the technologies under consideration, were produced by independent academic centres with their funding organisations, and operation, separated from NICE. The independent production of cost per QALY had important implications in the subsequent years. As we shall see in Chapter 4, as NICE operated it developed its "case laws" of a certain threshold of recommendation, mainly based on cost per QALY of the given drug - data given externally by the assessment report - and the room for manoeuvre was greatly

[128] Rawlins 1999, 1081. Cf. Timmins 2016, 59.

narrowed down once its cost per QALY gained were established. The informal practices of NICE hence would further reinforce its operational independence from any political interference.

Moreover, during the technology appraisal process the hands of elected officials were heavily constrained. Few provisions gave specific explicit roles to the minister during NICE's appraisal of individual drugs. To be sure, it was the DH who was formally responsible for referring a selected technology to NICE[129]; the dissemination of the NICE appraisal's recommendation was, at least initially, subject to the minister's approval[130]; and more generally, as noted, ministers had a formally predominant position to NICE, since NICE must act "subject to and in accordance with such directions as the Secretary of State may give".[131] Yet, once a topic was referred, throughout the procedure the Department of Health remained one of the stakeholders. The procedural rules were highly formalised, explicitly codified, and transparent; such an "unambiguous" rule would circumscribe the room for manoeuvre of outside actors including elected politicians.[132] A high level of judicialisation may also reinforce the enforcement of the explicit codified rules, since, as we have seen, any deviations from the standard procedure might trigger a credible threat of legal action. There remained an apparent contrast to an arrangement where the minister assumed the final responsibility for a decision to fund a drug, and the agency's guidance was merely advisory.

Two further points should be noted about the minister-NICE relations in technology appraisal. First, it was explicitly debated whether NICE would review a drug's affordability to the NHS. The government and NICE alike repeatedly stressed that the issue of affordability rested with the health minister and was a separate issue from a drug's cost-effectiveness.[133] The government, they argued, would decide on affordability of treatments by setting budgets.

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[129] The modification of the minister's role in the topic selection process in the subsequent years also went towards the direction of reducing its scope of control, and increasing NICE's involvement. In response to criticisms, since 2006 NICE could also propose topics for appraisals; it could also conduct horizon-scanning.

[130] In the discussion paper "Faster access to modern treatment," NICE's appraisal was envisioned to be directly issued to the NHS by NICE.

[131] In 2005, the government used Directions to give more precise guidance on the factors that NICE should take into account when conducting appraisals, including (a) the broad balance of clinical benefits and costs; (b) the degree of clinical need of patients with the condition or disease under consideration; (c) any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of the Institute by the Secretary of State and any guidance issued by the Secretary of State; (d) the potential for long-term benefits to the NHS of innovation.

[132] For "ambiguous" rules see Mahoney and Thelen 2010.

[133] E.g. HoCHC, Minutes of Evidence for 8 November 2000, Q.336.

The health minister also set out overall priorities in the NHS, and through the National Service Framework, set standards in specific priority areas. Second, and as a corollary, NICE was not intended as an instrument for cost containment. In fact, a uniform recommendation to make a treatment that it judged cost-effective available across the nation may lead to an increase, rather than decrease, in expenditure. As Michael Rawlins put it before the HoCHC, if NICE considered a drug cost-effective, it would, if necessary, "bully the Department [of Health] into seeing things our way"[134].

Two procedural changes during the early years of NICE further reduced the scope for government involvement in decision-making. First, in 2001, the government announced that NICE's guidance would no longer require a minister's approval before dissemination to the NHS. It is worth noting that this announcement took place in the context of the government's response to the HoCHC's inquiry into the Bristol Royal Infirmary scandal,[135] which generated high-profile debates on the quality of care within the NHS. The report called for a fuller independence of NICE and the CHI from the government and making them accountable to Parliament. While the government rejected the recommendation, keeping NICE accountable to the health secretary, it laid out, among other measures to increase NICE's independence, such as letting it appoints its own committees and structures, and the direct dissemination of NICE appraisals without ministerial approval – a change welcomed in the subsequent years by a HoCHC inquiry into NICE.

Second, in December 2001, the government announced that from January 2002 onwards PCTs and Health Authorities would have a statutory obligation to fund the technologies recommended by NICE within three months. The change can be understood in the context of governmental concern about the implementation of NICE guidance. As the government wanted NICE to end the 'post-code lottery', it was keen on strengthening the capacity to monitor PCTs' implementation. For instance in 2000, Health Minister Alan Milburn stated that the government would monitor the progress of implementation of NICE's appraisals across PCTs, first shortly after the publication of NICE's guidance and then six months later, and subsequently followed by clinical governance monitoring by CHI.[136]

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[134] HoCHC, Minutes of Evidence for 4 February 1999, Q.36.
[135] The scandal involved an unusually high rate of babies' deaths after cardiac surgeries at the Bristol Royal Infirmary.
[136] Ferriman 2000.

The funding obligation was supported by NICE, drug companies and patient groups. The ABPI welcomed the government's direction. As we have seen, it had been calling for an end to the postcode lottery. Likewise, patient groups had been advocating for strengthened implementation, highlighting persisting unevenness in the availability of drugs. Although implementation of guidance was not within NICE's remit, it also expected PCTs and clinicians to follow its advice. Hence NICE's chair Michael Rawlins stated that doctors should keep a note when they deviated from NICE guidance in case of medical negligence claims.[137] Now that implementing NICE appraisal was mandatory, Rawlins encouraged patients to bring the PCTs that would not follow NICE guidance to judicial reviews.[138] The threat of legal action was not only a rhetorical pose but also increasingly credible in the NHS; partly due to the cost of lawsuits shifting through conditional fee arrangements, negligence claims increased dramatically, with the rate of new claims per thousand consultant episodes jumping by 72 percent between 1990 and 1998, and reaching 23,000 outstanding claims as of March 2000.[139]

By contrast, the funding obligation put NHS managers under pressure. They were worried about the decision, since without an increase in expenditure they had to fund the recommended drug out of existing resources. As the policy director of the NHS Confederation put it, unless all the possible treatments were examined by NICE, it would be "a big gain for a small group of drug companies whose product is being recommended".[140] Health Secretary Philip Hunt, in turn, offered reassurance to health authorities that the Treasury's three-year spending reviews would ensure sufficient funding to cover NICE implementation, along with baseline requirements, was allocated to them.[141] The funding obligation of the NICE-recommended technologies thus tied both local health authorities and clinicians further into the chain of service delivery. The pressure on local authorities to implement NICE's guidance was not only exercised through the fear of legal action; the reinforced external monitoring and performance targets also aimed at ensuring the enforcement of NICE's recommendations. For instance, the Healthcare Commission, which took over the CHI, included whether local trusts followed NICE's recommendations in its performance ratings.[142] Policy efforts were hence geared

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[137] The Medical Defence Union, who insured doctors against medical negligence cases, also advised them to keep records when they diverged from NICE guidance. *The Guardian*, 10 August 2007.
[138] "NICE demands patient action" *HSJ*, 7 October 2004; "Michael Rawlins: playing fair on treatments", *HSJ* 26 July 2012. *Financial Times* 8 January 2012.
[139] NAO 2001, 3, quoted in Klein 2013a, 202.
[140] "NHS told to implement NICE guidance with no extra cash"; *HSJ* 18 October 2001.
[141] "UK govt pledges on funding for NICE treatments queried by industry", *Pharma Marketletter*, 7 December 2001.
[142] "Trusts must take guidelines 'very seriously' or face penalties", *HSJ* 9 December, 2004.

towards a system that did not allow "second-guessing" NICE recommendations once they were made.

These institutional modifications, in turn, had major implications for the political insulation of decision-making. NICE recommendations were directly published throughout the PCTs, and if they gave positive guidance PCTs would be legally obliged to make a drug available. The revised institutional arrangement thus meant that once NICE guidance was published, there were few powers granted to the ministers to overturn it. These institutional features hence indicate that policy decisions over drug funding were highly insulated from elected officials.

5. Conclusion

Until the mid-1980s, the governance structure for drug rationing was informal, whereby clinicians had the authority over hidden, individual rationing. This structure was transformed throughout the 1990s. By the early 2000s, drug rationing became collective and explicit; for a significant proportion of the new drugs, it became the national regulator who issued guidance on whether they should be funded by the NHS; the guidance was national and authoritative, in that politicians and other actors had no say once the regulator had issued it. For the remaining drugs, since the early 1990s the local health authorities had made explicit funding decisions. This chapter charted the transformation of regulatory institutions, describing key policy debates and actors' positions and strategies. In doing so it stressed the locus of decisions for drug rationing was taken away from elected politicians.

The English regulatory state over drug funding was a cumulative product of events under both the Conservative and Labour governments. The chapter found that incumbent politicians' reluctance to address rationing debates played an important role in the development. Following the introduction of the internal market, the Major government consequently faced a surge of policy advocacy that demanded a national response to local-level rationing decisions. While repeatedly refusing to address rationing debates, the Conservative government supported the development of local-level expertise that aided health authorities' rationing decisions. If the Blair government created NICE to tackle the regional variation in rationing decisions, it was also reluctant to address rationing by the national government. Hence, despite the difference between the Conservatives, who would leave rationing decision to local health authorities, and Labour, who would delegate it to a regulatory agency, neither of them would openly take on the rationing responsibility. The advocacy of societal groups such as doctors, who demanded

national rationing debates, together with "focusing events" involving high-profile drugs, such as beta interferon and Viagra, further alarmed ministers, by highlighting the downsides of directly engaging in unpopular decisions. Furthermore, during the early years of NICE, the attempt to reduce the implementation gaps via an obligation to fund NICE-recommended technologies reinforced NICE's authoritative statues over drug funding.

As a result of these developments, the English institutional structure for drug rationing exhibits a high level of political insulation. In terms of formal independence, the Health Secretary was predominant to NICE in its managerial rules and legal basis. However, when it comes to the powers to overturn NICE's guidance, the minister's hands were extremely constrained by both the funding obligation and detailed procedural rules. Once NICE issued guidance, it was expected to be implemented across the nation. As Chapter 4 shall show, when NICE began operation, the highly-insulated arrangements would bring about major consequences for both subsequent policy choices and political dynamics.

Chapter 3 Ministers decide: The emergence of low political insulation in France, 1990-2004

The French institutional landscape around drug funding evolved considerably between the beginning of the 1990s and the mid-2000s. In the mid-1980s, there was no drug approval agency that assessed risk and efficacy of a drug, and assessment for drug approval was carried out by an expert committee within the health ministry; the relevant ministries collectively negotiated the prices of individual drugs; and the assessment for reimbursement was conducted by another health ministry committee. In the mid-2000s, an independent agency assessed drug approval; the price of individual drugs was negotiated by a civil-servant-led inter-ministerial committee that was organisationally separate from individual ministries; and another independent agency assessed effectiveness of drugs for pricing and reimbursement decisions. The process of this evolution was hardly linear; multiple institutions within the policy sector were proposed, established and then reorganised over time, adding institutional complexities.

The purpose of this chapter is not to assess every step of these institutional developments. Rather, it is to describe the constellation of actors and recurrent policy debates throughout the process, exploring how they are related to institutional arrangements established by the mid-2000s. It demonstrates that, despite repeated impetuses for the creation of regulatory agencies, politicians and bureaucrats' preference for maintaining ministers' powers to decide on drug rationing was built into new institutional arrangements. As later chapters shall show, the institutional arrangements with low political insulation established during this period, in turn, shaped the subsequent interaction of political actors.

The chapter shows that the locus of decision-making over drug funding, whereby health ministers have the final responsibility for reimbursement decisions, largely reflected the government's policy preferences. Indeed, at several junctures a recurrent theme of policy debates was whether an independent agency could take what is called an "economic", as opposed to "scientific" technical, role. The ministers, both left and right, as well as high-level civil servants, explicitly rejected the idea of an autonomous agency making decisions in the "economic" realm, such as pricing and reimbursement. Instead, they preferred decision-making powers to rest with ministers. While this demarcation of responsibility kept the decision-making process of funding drugs less insulated from elected politicians throughout the period (and thereafter), this low political insulation did not mean that ministers did not take explicit rationing decisions; nor were these decisions implemented without opposition. On the

contrary, the successive French governments repeatedly used de-reimbursement of treatments -- total exclusion from the reimbursement list -- or changes in the reimbursement rate as a technique for cost containment, and these initiatives sometimes triggered major counter-mobilisation. The difference between the French and the English institutional and policy settings is, hence, not that these two country cases fundamentally vary in the policy history of explicit rationing prior to the procedural reform that established the regulatory agencies; in both cases, explicit rationing existed and it was unpopular. Rather, the feature distinguishing the French institutional setting from its English counterpart is that even after setting up an independent agency that assessed drugs' clinical benefit, the minister firmly held final decision-making powers for drug funding.

With regard to the overall arguments of the thesis, the present chapter thus describes low political insulation of the locus of decision as a matter distinct from the independence of a regulator. The cumulative changes in institutional arrangements provided the committee assessing a drug's benefit with a greater formal independence from the health minister. Despite the changes, however, the health minister maintained the decision-making powers over inclusion of a drug on the reimbursement list. The French institutional setting for drug funding policy thus represents the low level of political insulation, where elected officials hold the final decision-making powers over drug funding.

The chapter proceeds as follows. It begins with a brief sketch of the French health care system and the structure of the pharmaceutical industry in the post-war decades. The legacies of these structures shaped policy options, debates, and coalitions of actors since the 1990s. Second, the chapter examines key organisational changes in drug pricing and reimbursement which took place between the 1990s and mid-2000s, describing government actors' preferences and strategies during the reforms. It shows how the state imposed its preferences, leading to a locus of decision-making less insulated from elected politicians. Third, it discusses the structure and the process of drug reimbursement decisions. It shows that while the creation of an independent agency, Haute autorité de sante (HAS), led to the expert committee assessing a drug's clinical benefit having greater formal independence from the health minister, both before and after its inception this minister had the final decision-making powers on drug funding.

1. Institutional and policy legacies

The French government has exercised strong statutory control over drug prices. The state intervention dates back to 1939, when the government imposed a price freeze to tackle inflation. In the immediate post-war years drug prices remained frozen against the backdrop of the general discretion granted to the Ministry of Finance on the price of products. The Ministry's powers remained unchanged after price controls over other products were lifted. From 1948, the price of drugs was governed by the formula of production cost plus margins of profit.[143] This system of the *cadre de prix* was replaced with the *grille de prix* (price schedule) in 1967, whereby the new government committee (the Coudrier commission) recommended the list of drugs covered by the national health insurance. The modality of setting prices was also partially replaced by a comparison of benefits within the same therapeutic class.[144] In 1980, in an attempt to differentiate innovative drugs, the system was reformed: a quasi-competitive logic was introduced, with drug prices depending on a comparison of benefits with existing products. To evaluate improvement in therapeutic benefits, the Coudrier commission was terminated and replaced by the newly established Transparency Committee (*commission de la transparence*), which gave advice on the reimbursement list to health ministers.[145] As a result of strict pricing control, for decades drug prices were kept lower than in comparable European countries. [146]

The stringent pricing control was often considered, in turn, as a source of firms' volume-oriented strategy (Jeunemaitre 1990; Hancher 1990, esp. 90, 254; Thomas 1994; Chauveau 1999, esp. 297, 667-669; Jacobzone 1998, 47). French drug companies sought to develop "me-too" products based on their old products, instead of innovative ones. Policymakers repeatedly highlighted the domestic industry's lack of innovative capacities, its relatively low R&D spending and its high promotion expenditure. The rationales behind the evolution of pricing methods mentioned above partly reflected policymakers' attempts to address the adversarial impact of pricing control. Yet, such attempts were often overridden by the imperative to control costs, with repeated impositions of price reductions and price freezes. In the end, the

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[143] Hancher 1990, 75-77. For an overview of postwar development of pricing regulation, see Jeunemaitre 1985, esp. 139-140; Buisson and Giorgi 1997, 122-123. For a historical overview of pharmaceutical policy, see Dafon and Suhard 2018.
[144] Hancher 1990, 88-97.
[145] Hancher 1990, 229-233;
[146] For example, according to the European Consumer Organisation (BEUC; an umbrella consumer group at European level)'s 1989 price index, against the European average (100), France (68), Germany (146), UK (110), Italy (78), Netherlands (131). Cited in Le Pen 1995, 124.

core characteristic of pricing control and low prices largely remained unchanged until the late 1980s.

Another characteristic was the persistence of a fragmented industrial structure. The domestic industry largely consisted of two categories. The first comprised of large firms originating from subsidiaries of the chemical industry, such as Rhône-Poulenc and Sanofi.[147] The second were numerous small and medium-sized firms. Being typically family-owned, these so-called "independent" firms often relied on a small number of products and were considered lacking in international competitiveness (e.g. Jeunemaitre 1985, 140; Cheauveau 1999, 665-666). As Chapter 6 will show, these legacies would have implications for firms' reactions and their interactions with the government when the latter attempted to impose de-reimbursement plans as a form of explicit drug rationing strategies in the 2000s.

France has a national health insurance system. The freedom of access to both ambulatory and specialist doctors remained granted until the mid-2000s.[148] Clinicians, protected by the principle of freedom of prescription enshrined in the Social Security Code, had little constraint on their treatment choice.[149] The fee-for-service payment for outpatient care, the high expenditure on drug promotion and doctors' reliance on such promotion for information, and the firms' volume-oriented strategy -- all contributed to high expenditure on health care, including drugs. As the rising health care cost drew policymakers' attention, they considered *surconsommation* (overconsumption) of drugs a major policy problem in the French health care system.

Explicit decisions about drug rationing also have a long history. Indeed, if clinicians had freedom in choosing treatments, the government was still able to control the range of available options. Under the 1967 decree, ministerial orders defined the list of drugs reimbursable by the Social Security. From the 1970s, successive governments used changes in the reimbursement status of drugs in an attempt at cost control. In 1976, the Barre government reduced the reimbursement rate of certain drugs to 70%, and in the following year it set out rules classifying products into different reimbursement rates: drugs for chronic conditions and particularly expensive drugs were reimbursed at 100%, those used for minor pains and so-

[147] As a result of mega-mergers since the 1990s, both are now part of Sanofi: once the largest domestic firm Rhône-Poulenc merged with Hoechst to become Aventis in 1999, then Aventis merged with Sanofi to become Sanofi-Aventis.
[148] The 2004 reform introduced a gate-keeping system. Cf. Palier 2015, 106.
[149] Lebas and Certain 1992, 457; Buisson and Giorgi 1997, 39-40.

called "comfort drugs" at 40%; and the remainder at 70%. Since then, policymakers have repeatedly reduced the reimbursement rate, and sometimes implemented *déremboursement* (de-reimbursement), which means the total exclusion of treatments from the reimbursement list. The increase of the co-payment was often intended to tackle overconsumption of medicines, based on the assumption that this was caused by the moral hazard of patients; it was hence intended to make them responsible for medical costs they incurred.[150] At the same time, however, the increase in co-payment was compensated by another feature of France's health care system: complementary insurance. Provided by non-profit mutual insurance bodies or for-profit private insurers, this covered patient co-payment. By the mid-1980s, more than 85% of the population purchased complementary insurance. For this reason, politicians tended to see the reduction of the reimbursement rate as less politically painful than total de-reimbursement or other measures that directly impose costs on patients. At the same time, this coverage by complementary insurance might diminish the intended policy effect by making the costs on the patients less visible.

Attempts to shift visible costs on to patients, either through reducing existing entitlement or imposing direct costs on them, have faced significant political contestation. For instance, in 1979 the Barre government, led by the coalition of the Gaullist RPR (Rassemblement pour la République) and the centre-right UDF (Union pour la démocratie française), attempted to introduce the *ticket modérateur d'ordre public*, a type of co-payment that prohibited complementary insurance from full coverage. But after protests mobilised by insurers and blockage at the national assembly it dropped the measure.[151] Another example of such cost-shifting measures was the Séguin plan in 1986-1987, whereby the RPR Chirac government adopted measures to reform the *affections de longue durée* (ALD), which exempted patients with certain serious and chronic diseases from co-payment for treatments. For patients admitted to the ALD regime treatment costs were thus reimbursed at 100%. While the plan extended the disease areas subject to ALD to 30 diseases, it also limited its entitlement: only prescriptions directly linked to the ALD diseases would now be exempted from co-payment; and even the patients admitted to ALD were no longer exempted from co-payment for drugs reimbursed at 40%. The ALD reform was so unpopular that one observer noted it "undoubtedly contributed to the defeat of the Conservative government [i.e. the incumbent

[150] Cf. Palier 2015, 33-34.
[151] The subsequent Mitterand government formally annulled the decree.

RPR]" in the following 1988 election.[152] When the Socialists returned to office after the election, they annulled the measure. Politicians, especially those from the RPR, seemed to learn from this event. In 1993, when the health minister Simone Veil of the Balladur government (the RPR-UDF coalition) proposed a non-reimbursable charge both per treatment form (5 francs) and package of medicine (3 francs), she confronted deputies from the ruling RPR-UDF coalition, who saw the measure as a "copy of the Séguin plan"[153] and protested. They preferred a reduction of the reimbursement rate for fees and prescriptions to the non-reimbursable user charge.[154] As a result, the Veil plan abandoned the proposal, and instead introduced a general reduction of the reimbursement rate by 5% and an increase in hospital fees. The "education effect" of such a measure, to make patients conscious about their consumption, was questionable, as the Fédération nationale de la Mutualité (the federation of mutual insurance bodies, also known as the Mutualité) decided to increase its contribution rate to compensate for the reimbursement rate reduction.[155]

Health technology assessment in France, or "medical evaluation" (*évaluation médicale*), was gradually developed throughout the 1980s and 1990s. Its emergence was closely related to growing pressures about health care costs and the quality of care.[156] As early as 1982, public university hospitals in Paris (Assistance publique–Hôpitaux de Paris, or AP-HP) established the Committee for Evaluation and Dissemination of Innovative Technologies (Comité d´Evaluation et de Diffusion des Innovations Technologiques), a group of experts who advised the director of the hospitals on purchasing new expensive medical technologies (especially medical equipment). In the mid-1980s, the Socialist government began addressing the lack of means to evaluate medical practices and technologies. Commissioned by the Ministry of Health, a report by a prominent physician recommended creating a foundation, independent from the Ministry of Health, dedicated to the dissemination of medical evaluation.[157] The agenda emerged again in 1989 when the Socialists returned to power. The Ministry of Health commissioned a report led by the chair of the Union Nationale des Associations de Formation Médicale Continue (a generalist association for continued medical education), involving

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[152] Lancry and Sandier 1999, 27.
[153] *Les Echos* 1 July 1993
[154] *Les Echos* 24 June 1993
[155] *Les Echos* 1 July 1993
[156] Concern about the quality of care was also linked with safety concerns, triggered by salient events such as the human immunodeficiency virus (HIV)-contaminated blood transfusion scandal. De Pouvourville 1997, 163.
[157] Robelet 1999, 88; Weill and Banta 2009, 109.

leading figures in health technology assessment in France.[158] The initiative led to the creation of the Agence Nationale pour le Développement de l'Évaluation Médicale (ANDEM) in 1990, an independent agency that was in charge of assessment of health technology and procedures except pharmaceuticals. Based on a systematic literature review, it produced health technology assessments examining their safety, efficacy and cost-effectiveness and provided this knowledge to its institutional clients, including the Ministry of Health and CNAMTS (Caisse nationale de l'assurance maladie des travailleurs salariés).[159]

Policymakers used various instruments linked with the rise of medical evaluation in an attempt at tackling health care costs. One such strategy targeted doctors' prescription behaviours. Often referred to as "medicalised" control of health care expenditures, as opposed to "accounting" control, such a measure included medical practice guidelines. Private clinicians came to accept the measures as they considered guidelines a lesser evil than alternative options, including capping medical expenditure, which would result in income loss.[160] An agreement was signed by CNAMTS and medical associations in 1993 on the introduction of mandatory medical practice guidelines, Références médicales opposables (RMO), which applied to the ambulatory care sector. Since 1995, the ANDEM (replaced in 1996 by the Agence nationale d'accréditation et d'évaluation en santé, or ANAES, which, in addition to clinical guidelines, carried out hospital accreditation) produced an RMO based on its assessment of scientific evidence and professional consensus regarding guidelines. The RMO was legally-binding in that doctors who did not comply could face fines.[161]

Another strategy involved attempts at controlling expenditure and management in the hospital sector. In 1983 the Socialist government introduced a new payment system for public and private non-profit hospitals, which replaced per-diem payment with global budgeting. In the new system, each hospital was set an annual prospective budget based on a national rate of increase. At around the same time, based on the Diagnosis-Related Groups (DRG) developed in hospital management in the United States, the Ministry of Health began pilot projects of a "medicalised" information system, the PMSI (projet de médicalisation des systèmes d'information), which measured hospitals' medical outputs based on the

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[158] Weill 1995, 114; Robelet 1999, 89
[159] De Pouvouville 1997, 168 ; Weill and Banta 2009, 109 ; Robelet 1999, 90-91.
[160] De Pouvouville 1997, 168
[161] Durand-Zaleski et al. 1997. In practice, RMO faced considerable difficulties in enforcement, with the lack of means to monitor clinicians. Durieux et al.2000.

classification of pathologies and treatments.[162] The initial idea behind the pilots was to reallocate resources according to clinical activities. To surmount resistance from physicians, the majority of whom remained hostile to sharing epidemiological data for managerial controls, however, reformers expanded the project gradually, presenting it as a tool for computerisation and physicians' self-evaluation.[163] It was only after the Juppé reform in 1995 that PMSI was introduced as a resource allocation tool through modulation of the global budget at inter- and intra-regional levels;[164] and it was after the 2004 reform, which replaced global budgeting with a new payment system, that the DRG-based information about clinical activities was used for hospital budgeting. The implications of the latter for the politics of drug rationing are discussed in Chapter 7.

These attempts at French health technology assessment left important legacies. During the process of the early institutional development, with physicians dominating bureaucratic organisations, economic expertise became subordinate to medical knowledge. Thus, although the nascent health economist community contributed to formulations of the proposals for medical evaluation, clinicians dominated the operation of ANDEM (Benamouzig 2005, 331-333; Robelet 1999, 90f). Likewise, as already mentioned, the initial introduction of PMSI was converted by physicians into a non-budgetary tool until the Juppé plan reconverted it. The organisational balance would remain the status quo until medico-economic evaluation by health economists drew policymakers' attention again in the 2000s (see Chapter 7).

2. Institutional reforms and government policy preferences

A series of institutional reforms in the 1990s and early 2000s changed the institutional arrangements of drug pricing and reimbursement. In the area of pricing, the government instituted an interministerial committee, the Comité économique du medicament (CEM) in 1994-1996, which became the Comité économique des produits de santé (CEPS) from 2000. Comprised of the relevant administrative directorates from the Ministry of Health, the Ministry of Economy and Finance and others, and chaired by a civil servant, the CEM was responsible for negotiating and concluding drug prices with companies; from 1994 it was also tasked to

[162] For the history of PMSI and hospital budgeting reform, Banamouzig 2005, 302-310; De Pouvourville 1989, 344-348; Michelot and Rodrigues 2008.
[163] De Pouvouville 1997, 168-169.
[164] Michelot and Rodrigues 2008, 126.

sign price-volume agreements with individual firms based on framework agreements with the pharmaceutical industry association SNIP (le Syndicat national de l'industrie pharmaceutique). As the section will show, the establishment of the CEM was related to organisational changes in a neighbouring area of drug approvals, namely the establishment in 1993 of an independent agency, the Agence du Médicament (the Medicine Agency, renamed the Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps) in 1999). The area of reimbursement also saw organisational changes. The Transparency Committee (la Commission de la transparence), which was originally established in the 1980 decree, assesses a drug's comparative clinical benefit - the information that was used for pricing and reimbursement decisions. During this period the organisational location of the committee changed over time. Launched as a committee within the Ministry of Health, it was transferred to the Medicine Agency on its creation. In 2004, the Transparency Committee moved again to a new independent agency, the Haute Authorité de Santé (HAS).

This section describes policy debates around the establishment of the CEM in the 1990s and the creation of the HAS in the early 2000s. In both cases, government policymakers demanded a clear distinction between the "scientific" technical role of an agency and decision-making in matters such as pricing and reimbursement. The latter, they considered, must be strictly the responsibility of the government. The section discusses each of the episodes in turn.

The CEM (1991-1994)

The impetus for change came in the late 1980s, when the European Community (EC) moved to establish a common standard on drug approval regimes. At around the same time policymakers were wary of French industry's competitiveness, especially in the context of the Single European Market expected in 1992. The 1989 government report pointed out the weak innovative capacity and the low level of R&D in the French pharmaceutical industry.[165] When the Socialist Rocard government appointed the rapporteur Jean Weber, a former Director of the Pharmacy and Medicine (the head of the directorate in charge of drug approval) to report on the new drug approval system, to be in line with the EC directive, in early 1991, it also gave a mandate on recommending pricing system changes. While the Weber report recommended

[165] *Le Monde* 8, 13 and 15 April 1989.

the "Haut comité du medicament" (High Medicine Committee), an independent agency in charge of pricing and reimbursement, ministers and high-level civil servants alike rejected the proposal; they claimed that 'while determination of "quality, harmlessness, and therapeutic effect" of drugs might be a scientific matter, putting drugs on the market has "social, political, and economic implications that should be decided by the state, not by scientists"' (Nathanson and Bergeron 2017, 652).

Instead of creating an agency, the government, who were hostile to the idea of giving away ministerial powers in economic matters, preferred an interministerial committee. In August 1991, when the government proposed a law to establish the Medicine Agency, the second part of the proposed law was dedicated to provisions on a new pricing regime. It set out the price-volume agreement and the role of the new interministerial committee, the CEM. The government had initially considered a profit-based contract, modelled after the British PPRS and in line with the Weber report's recommendation, whereby each firm would contractually agree an overall package of price increases for their products based on an annual growth of expenditure target.[166] The final proposal departed considerably from the British system, but its principle of contractual agreement remained. In the proposal, the CEM would negotiate contracts with each firm on their products' price, volume (expenditure of reimbursable medicines), and their promotional expenditure. The government explained that with the new system the prices of innovative medicines would align with European ones.[167] The price-volume agreement hence aimed at controlling expenditure while stimulating the development of the pharmaceutical industry. Although some firms, and the SNIP, welcomed the proposal, several others voiced concerns that the new measure would penalise small companies and old products.[168]

However, once the bill was sent to the parliaments it entailed executive-legislative conflicts. Deputies at the National Assembly did not oppose the Medicine Agency, and their criticism was focused on pricing regimes. Delegates from the opposition RPR had welcomed the government's initial emphasis that "contractual logic" would replace the "administrative logic" of pricing control, but far from seeing such a "liberal" principle, they criticised the eventual text as *dirigiste*.[169] Prime Minister Édith Cresson invoked Article 49-3 of the French

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[166] *Les Echos* 18 July 1991; *Les Echos* 23 April 1991.
[167] *Les Echos* 29 August 1991, 26 August 1991 ; *Le Monde* 29 August 1991
[168] *Les Echos* 30 August 1991, 5 September 1991
[169] *Les Echos* 4 October 1991 ; Le Monde 5 October 1991, 7 October 1991

Constitution, which allowed the government to halt parliamentary discussions and adopt the bill.[170] At the opposition-controlled Senate the RPR rapporteur repeated similar criticisms against an "inadequate dirigisme".[171] She called for "an independent body, comprised of eminent members and with full decision-making power".[172] The Senate made amendments which brought back the "Haut comité du médicament" and its strong independent agency model. Next, the Senate-National Assembly joint committee adopted a text based on the Senate amendments. In the agreed text the High committee would conclude an agreement with firms, set the list and prices of reimbursable medicines, and establish the amount of repayment the industry would make when exceeding the volume or the promotion expenditure defined by the Committee. It also proposed that, within the overall budget, the industry would freely set the price, hence introducing partial price liberalisation.[173] This structure adopted by the legislative branch clearly deprived the minister of powers; the only prerogative left to the minister was setting the target reimbursable medicine expenditure. With the hostility of the government, especially from both Pierre Bérégovoy (minister of the economy and finance) and Jean-Louis Bianco (minister of social affairs and integration), Édith Cresson opted to withdraw the bill.[174]

The proposals for the Medicine Agency and the new pricing system were, hence, once shelved, but they resurfaced in the subsequent years. First, the plans for the Medicine Agency re-emerged during debates triggered by the blood contamination scandal.[175] In debates leading up to the adoption of a bill to reform the blood transfusion system in December 1992, the Senate rapporteur (UDF) proposed an amendment that incorporated the establishment of the Medicine Agency. Behind the scenes, according to Nathanson and Bergeron (2017, 665-666), in order to surmount the hurdle within the government, the ministers as well as cabinet officials agreed to "excise all "industrial" and price-control consideration from the AM [Medicine

[170] Under Article 49-3, the government can make a bill a matter of confidence and immediately adopt it without vote. As a minority government the Socialist Rocard government resorted to the Article more frequently than other governments in the fifth republic. Elgie and Maor 1992, 70-71. Knapp and Wright 2006, 146.
[171] *Le Monde* 30 October 1991 ; *Les Echos* 29 October 1991
[172] Les Echos 29 October 1991.
[173] Cf. Bégué et al. 1993, Annex 2.
[174] *Les Echos* 18 December 1991.
[175] It was revealed in 1991 that in 1985 the national blood bank knowingly distributed HIV-contaminated blood products to haemophiliacs. For details of the scandal and its impact on the Medicines Agency bill, Nathanson and Bergeron 2017.

Agency] bill". The amendment passed the Senate and the agency was established the following year.

The demarcation between the agency's technical role and any economic competences was important both to government policymakers and the pharmaceutical industry. For instance, the following spring, when the government proposed a decree giving detailed rules of the structure and the function of the agency, the industry joined UDF and RPR politicians in opposing a provision that required drug companies wanting to license a new drug to indicate whether, and at what price, they would seek to obtain reimbursement. Threating to boycott meetings, the SNIP criticised the provision as it "mix[ed] up the technical analysis of new molecules, which should constitute the role of an independent agency, with negotiations on their price that should remain the prerogative of the Transparency Committee and the government". The minister, in turn, reassured that "the agency does not have any economic competence".[176] The provision was abandoned when the government later proposed a price-volume agreement.[177]

For its part, the other half of the 1991 proposal – the pricing system – was brought back to the agenda in May 1993, this time by the Gaullist government formed after the 1993 election. Health Minister Philippe Douste-Blazy proposed a price-volume agreement with the industry, which set an overall target for the annual price and volume increases; the government also proposed an agreement with individual companies within this industry-wide agreement. As the minister explained, the aim of such a price-volume agreement remained the same as in the 1991 proposal: to reconcile the objectives of controlling expenditure with industrial growth. The concomitant idea of the Comité économique du medicament -- an interministerial committee rather than an independent agency -- as the unique interlocutor with the industry was also brought back.[178] Following negotiation, the government and the SNIP signed an industry-wide framework agreement in January 1994. This was followed by negotiations with individual firms. Between 1994 and 1996, approximately 130 agreements were signed between individual companies and the CEM, covering 95% of the reimbursable medicines (Buisson and Giorgi 1997, 136).

In short, throughout the debate leading up to the institutionalisation of the pricing system, government policymakers preferred to keep matters related to pricing and reimbursement issues – as opposed to drug approval, which they conceived as a technical or scientific matter

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[176] *Les Echos* 10 March 1993. cf. *Les Echos* 18 March 1993; *Le Monde* 27 May 1993.
[177] *Les Echos* 26 May 1993 ; *Le Monde* 27 May 1993.
[178] *Les Echos* 26 May 1993 ; *Le Monde* 27 May 1993

-- under the exclusive powers of the government. Indeed, both ministers and civil servants were against the idea of creating an independent agency in charge of pricing and reimbursement as it would deprive ministers of the decision-making powers. Instead, they preferred an interministerial committee. When the Socialist minority government failed to pass the bill and the agency model was adopted, the government withdrew the bill. And when the successive Gaullist government brought back virtually the same agenda and finally realised it, it also preferred an interministerial committee.

HAS (2004)

We can see a similar pattern in debates over the role of the government in the reimbursement system during the formation of HAS, the independent agency assessing a drug's clinical benefit. Government policymakers wanted to draw a strict demarcation line between the "scientific" role of the agency and the reimbursement decision, the latter of which they considered must be the exclusive power of the minister.

A proximate event that set off policy debates about the creation of an independent agency was a proposal forwarded by the Mutualité, the federated body of mutual insurance companies (Fédération nationale de la mutualité française). In June 2003, at its conference, the Mutualité proposed an independent body (*Haute autorité*, or a high authority) in the area of health, which would be in charge of determining the benefits of different health care interventions. This was part of its broader proposals for reforming the health care system's governance structure. The underlying idea was to limit the state's role to "a guardian of functioning", moving towards a system based on negotiations among obligatory and complementary sickness funds and medical professions.[179] The Mutualité hence envisioned a process with strong independence from the state, whereby after the high authority's recommendation the state would withdraw from the process and let the obligatory and complementary insurance providers set their respective benefits within the framework of the high authority's recommendation.[180] In the same vein, it also proposed a national union of sickness funds, a management body that would bring together obligatory and complementary insurance firms, to collectively manage ambulatory care through negotiation with medical professions.[181]

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[179] See an interview with the chair of the Mutualité in *Libération* 12 June 2003.
[180] *Les Echos* 16 June 2003; *Le Monde* 16 June 2003
[181] *Le Monde* 16 June 2003; *Libération* 12 June 2003.

The Mutualité's proposal for an independent agency appeared to be related to ongoing controversies over the government agendas for de-reimbursement. As we shall see further in Chapter 6, in the preceding few years waves of de-reimbursement plans had been heavily debated. Started as the Socialist government's plan in 1998 and carried on by the successive both left and right-wing governments, the plans, based on the Transparency Committee's re-evaluation of all the drugs reimbursed by the national insurance funds, attempted to de-reimburse the drugs that the Committee judged as of insufficient clinical benefit, amounting to 835 drugs (of the 4,490 reimbursable drugs). In September 2002, Health Minister Jean-François Mattei of the Raffarin government (UMP) announced a three-wave plan to de-reimburse 650 such drugs, starting from the following year.[182] In April 2003, he further announced reducing the reimbursement rate of 617 drugs with low or moderate clinical benefit, according to the Transparency Committee's evaluation, from 65% to 35%. As a cost-bearer of the partial de-reimbursement, the Mutualité heavily criticised the measure.[183] The Mutualité's proposal for an independent agency hence meant to limit the state's unilateral action on reimbursement issues, while enabling a greater role for insurance bodies through participation in policy-making.

Health Minister Mattei responded with an agenda for an "Haut conseil du remboursement" in charge of the reimbursement of medical and paramedical acts. Covering an area larger than the Transparency Committee in charge of drugs, the minister envisioned that such a body would provide a fuller justification of health care provisions.[184] To be sure, Mattei did not give much specification about the body at the time. Perhaps more importantly, while he promised that the complementary insurance bodies would be closely involved in specific tasks through the new independent body, the state, he noted, would be responsible for reimbursement decisions.[185] The government thus from the outset did not intend to give away its prerogative over the decision-making powers for reimbursement. The proposal was nevertheless welcomed both by the complementary insurance and doctors. The largest generalist unions CSMF (Confédération des Syndicats Médicaux Français) demanded an independent body that

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[182] *Le Monde* 25 September 2002 ; Le Figaro 25 September 2002 ; *Les Echos* 24 September 2002.
[183] *La Croix* 24 April 2003 ; *Les Echos* 24 April 2003 ; *Libération* 24 April 2003 ; *Le Monde* 29 April 2003.
[184] *Le Figaro* 16 June 2003 ; *Le Monde* 16 June 2003.
[185] Déclaration de M. Jean-François Mattéi, ministre de la santé,de la famille et des personnes handicapées, Toulouse le 14 juin 2003. http://discours.vie-publique.fr/notices/033002140.html Cf. *Le Monde* 16 June 2003 ; *La Croix* 17 June 2003.

would not only bring together obligatory and complementary insurance bodies but also include the medical professions.[186]

The government considered the proposal for the body as a first step towards long-term reform agendas in the health care system.[187] In seeking broad consensus among actors over policy problems, the government created the Haut conseil pour l'avenir de l'assurance maladie (HCAAM), a consultative body comprised of the government and societal actors such as employers, trade unions, obligatory and complementary insurance bodies, medical professions and patient groups.[188] Highlighting the the sickness funds' massive budgetary deficit, expected to reach 11 billion euros in 2004, the resulting report addressed an imperative of reforms in functioning of the health care system. Among matters related to reimbursement, it introduced the notion of "reimbursable scope" (*périmètre remboursable*) of sickness funds and highlighted the lack of its active management. It emphasised the importance of clinical effectiveness (e*fficacité*) and cost-effectiveness (*efficience*) in defining such a scope.[189] And, in line with Mutualité and Mattei's claims, it affirmed, without specifying agendas, the necessity to reform the governance structure. In particular, it argued for reallocating powers, and where necessary delegation of them, in order to re-clarify competence and responsibility.[190]

The following spring, Health Minister Douste-Blazy, who replaced Mattei, laid out a concrete agenda for HAS as part of his major healthcare reform package. HAS, which took the form of an "independent public authority of a scientific character",[191] was tasked to evaluate the benefit of medical acts, provisions, and products, to elaborate recommendations for the admission of reimbursement.[192] Taking up the Mutualité's proposal for governance reform, the government also noted that it would introduce greater delegation of managerial powers to the sickness funds by creating a management body for them, the Union Nationale des Caisses d'Assurance Maladie (UNCAM).

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[186] *Libération* 16 June 2003.
[187] Cf. *Libération* 16 June 2003 ; *Le Monde* 16 June 2003.
[188] The council was modelled after a similar government-private consultative body in pension policy (the Conseil d'orientation retraites created by the Socialist government in 2000).
[189] Hcaam 2004, 16-17, 65-76.
[190] Hcaam 2004, 26-29.
[191] Assemblée Nationale, Projet de loi relatif à l'assurance maladie, le 16 juin 2004, Exposé de motif, 15.
[192] *Le Monde* 28 May 2004.

In terms of the allocation of decision-making powers between the government and the agency, however, the government's policy preference remained a firm demarcation between an assessment, "scientific" technical advice offered by the agency's experts, and decisions of reimbursement made only by the health minister. Responding to a National Assembly deputy's question about whether the HAS would only play a role of providing scientific expertise or if it would also have decision-making powers, the health minister stated:

> "We do not entrust the High Authority with decision-making powers, that is clear … We consider that the High Authority must give its opinion on the medical benefit of the products and the acts that apply for admission to reimbursement. After that, the State remains the guardian of the final decision regarding the definition of the reimbursable scope." [193]

Such a clear definition of responsibility for reimbursement decisions was considered important for both incumbent policymakers and societal actors, especially in the context of controversies over de-reimbursement plans. Not surprisingly, National Assembly deputies were quite sensitive about the proposed agency's relations to de-reimbursement plans. The left-wing opposition criticised the agency as an instrument for de-reimbursement. The minister defended it by pointing out that it was the Socialist government who had started the de-reimbursement plan.[194]

The concern over the locus of reimbursement decisions can also been seen in an amendment made by the National Assembly. The original proposal provided that in conducting its tasks HAS would take into account the multiannual framework of expenditure in sickness funds, in addition to multiannual objectives of public health interest.[195] Both the Gaullist rapporteur and Socialist deputies in the legislative committee found this provision problematic, since they considered that the HAS must be a "scientific body" and that "the decisions concerning the level of reimbursement must remain strictly in the prerogative of the State".[196] To make sure of this point they collectively put forward an amendment that proposed deleting the mention of the multiannual framework of health care expenditure. With the government's backing, the

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[193] Assemblée Nationale, Compte rendu intégral 26e séance – 2e SÉANCE DU 11 JUILLET 2004, 6533.
[194] E.g. Ibid., 6527, 6533.
[195] Art 19 2, 2°
[196] Assemblée Nationale, Compte rendu intégral 26e séance – 2e SÉANCE DU 11 JUILLET 2004, 6550 ; See also RAPPORT FAIT AU NOM DE LA COMMISSION SPÉCIALE CHARGÉE D'EXAMINER LE PROJET DE LOI (n° 1675) relatif à l'assurance maladie, Président, M. YVES BUR, 212-213.

National Assembly adopted the amendment.[197] Thus, throughout the legislative process incumbent and opposition politicians alike had a shared policy position in that both wanted ministers to exclusively keep the reimbursement decision-making powers.

The bill was adopted at the end of July.[198] The Senate agreed an amendment that the HAS would absorb the ANAES, which was justified by the overlapping tasks of the two agencies, such as elaboration and diffusions of clinical guidelines and good use of drugs. The HAS was launched in January 2005. Laurent Degos, a professor of haematology and a former chair of Afssaps, became the first Chair of the HAS Board. The eight Board members, based on nominations by the President, the Senate, the National Assembly, and the Economic and Social Council, included the current chair of ANAES and the Transparency Committee, reflecting the character of the agency that took over these organisations; other Board members also seemed to reflect the bill's enacting coalition - they included a former Director of Social Security, a former member of Mattei's cabinet, a former chairperson of the generalist union CSMF (who was also in charge of health issues in the Gaullist UMP), and a managing director in charge of health and social security at the Mutualité.

Thus, throughout the process of creating the HAS, the government policymakers' preference for maintaining the powers for reimbursement decisions played an important role in the agency's institutional design. Although the Mutualité had recommended an agency as a participatory mechanism of societal actors and the delegation of the state's powers in drug reimbursement decisions, far from achieving these ideas in institutional design the incumbent policymakers retained the minister's decision-making powers over reimbursement. And during the parliamentary debate, both government and opposition politicians wanted to make sure that the "scientific" agency would not have any economic roles in reimbursement, which they considered strictly the minister's responsibility.

3. The structure and the process of reimbursement decisions in the mid-2000s

The HAS represented an independent regulatory agency (*autorité administrative indépendante*, or AAI) and was given a legal entity; it enjoyed a high level of formal

[197] See Benoit 2016, 246 for an interview quote on this amendment.
[198] La loi 2004-810 du 13 août 2004 relative à l'assurance maladie.

independence from the ministers in charge of health and social security. Appointment rules followed the template of the AAI in France.[199] Hence two of the eight members of the Board ("collège") of HAS were appointed by the President of the Republic, two by the president of the Senate, two by the president of the National Assembly, and two by the Economic and Social Council. The Board members were appointed by a Presidential decree, for six years with renewal once.[200]. Thus, the HAS did not have a direct delegating relationship with the health ministers. In contrast to health minister's formal predominance over NICE, in managerial terms the HAS had an equal footing with the health minister.

The HAS Committees, such as the Transparency Committee, were also formally independent from the health minister. According to rules as of the launch of HAS, 20 full members of the Transparency Committee with voting rights, chaired by a Board member with expertise in the areas of pharmaceuticals, would be selected based on scientific expertise. The full members were appointed for three years and could serve two further terms. The Committee adopted opinions on drugs based on majority voting. Its 8 advisory members included representatives of the Directorate of the Social Security, the Directorate General of the Health, the Directorate of Hospitalisation and the Organisation of Care, the drug approval agency Afssaps (Agence française de sécurité sanitaire des produits de santé, later renamed as the Agence Nationale de sécurité du Médicament et des produits de santé, ANSM), the directors

[199] For appointment rules in other sectors see e.g. Rose-Ackerman and Perroud 2013, 278.

[200] Art. L 161-42 du CSS. There was a change in this rule from 2017; the Board is now comprised of seven members, of which the president of the Board is appointed by the President of the Republic, three members are appointed by the ministers in charge of the health and social security, and one member each from the National Assembly, the Senate, and the Economic and Social Council. Art. L 161-42 du CSS as amended by Ordonnance n°2017-84 du 26 janvier 2017 - art. 1. The health minister hence now has stronger powers to appoint Board members.

of three main national insurance bodies, and a representative nominated by the pharmaceutical industry association and appointed by the HAS Board.[201]

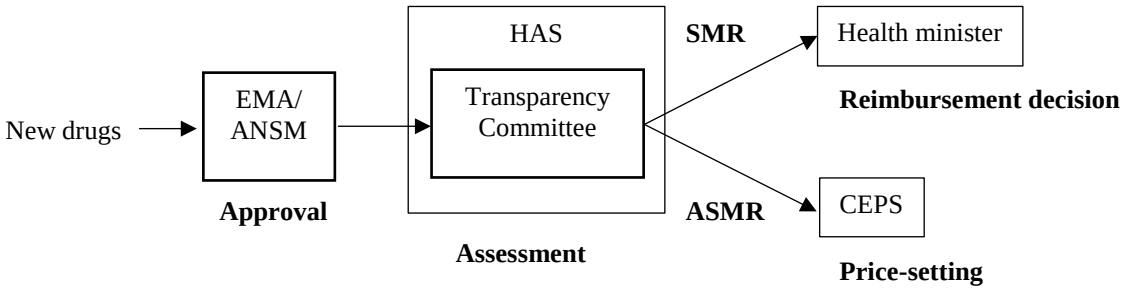

Figure 3.1 Drug pricing and reimbursement process in France

The organisational structure of the Transparency Committee, and in particular its formal independence from the health minister, was a result of decades-long cumulative changes. Originally established by the 1980 decree, the Committee was located within the Ministry of Health. With the creation of the Medicine Agency in 1993, the Transparency Committee was transferred to it, with the agency providing the Committee with a secretariat. But with appointment rules still being held by the health minister, the Ministry's close connection with the Committee continued. Organisational reforms in 2003 and 2004 marked a departure from this structure. First, the 2003 change took place after the Conseil d'Etat annulled the Transparency Committee's negative opinion about vasodilators, which it re-evaluated as part of the de-reimbursement plan, on the grounds of a lack of sufficient reasoning (see Chapter 6).[202] Faced with the significant setback in the de-reimbursement agenda, Health Minister Mattei introduced changes in the Committee's organisational rules to strengthen its scientific profile, hoping to enhance the scientific rigour and reasoning in its assessment.[203] Then, with

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[201] Art. R163-15 du CSS Modifié par Décret n°2004-1398 du 23 décembre 2004 - art. 1 JORF 26 décembre 2004. It should be noted that the composition of the Committee was slightly modified over time. As of 2018 the Committee is now comprised of 21 members with voting rights and 7 consultative members. However, there has not been a fundamental change in its composition.

[202] *Le Figaro* 5 July 2003. cf. *La Tribune* 30 June 2003, *Le Monde* 5 July 2003.

[203] Hence, before the change, 6 of the 13 full members (apart from the chair, the vice chair, and representatives of relevant government department such as DSS (Direction de la sécurité sociale) and Directorate General of Health and Afsapps) of the Transparency Committee were chosen based on clinical, scientific, or economic expertise; the other members were comprised of clinicians and pharmacists selected based on the list of names proposed by the medical professions' association, the pharmacists' association, three main national insurance bodies, and a representative nominated by the

the creation of the HAS in the following year, it became the HAS Board, rather than the minister, which appointed the Transparency Committee members. In short, with the organisational reforms combined with the greater independence of the agency, expert assessments by the Transparency Committee were expected to play an important role in making policy choices on drug reimbursement.

Similar to the relationship between NICE's appraisal committee and its management, the HAS Transparency Committee's assessment process is organisationally separate from its Board. As one observer (a former director of the DSS) put it in the wake of the 2004 reform, "it is hard to see the Board or its members interfere in its [Transparency Committee's] decisions, unless to deprive it of all credibility. However, the opinion of the Transparency Committee will have greater power by having been taken within the framework of the High Authority." (Bras 2004, 972). Thus, although the establishment of the HAS did not fundamentally alter the structure and function of the Transparency Committee itself, the creation of the HAS and the concomitant transfer of the Transparency Committee provided the Committee with a higher level of independence from the Ministry, which was seen to give the Committee's expert assessment extra credibility.

However, as we have seen in the last section, when it comes to procedural rules on reimbursement, the health minister held a firm grip on the final decision. Once either the EMEA or the Afssapps approved a drug based on its benefit/risk ratio, the Transparency Committee assessed its clinical effectiveness, issuing an *Avis* (opinion) on the drug. However, the Transparency Committee's opinion was only advisory; it would inform pricing and reimbursement decisions that the CEPS and the health minister would respectively make (Figure 3.1). The creation of the HAS did not change this core feature in the process of reimbursement decisions.

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pharmaceutical industry. After the change, all the 17 full members with voting rights were experts selected based on scientific competences, while representatives from the government departments and Afsapps, the pharmaceutical industry, and the national insurance bodies played merely an advisory role. Compare Art. R163-15 du CSS Modifié par Décret n°99-915 du 27 octobre 1999 - art. 4 JORF 30 octobre 1999 en vigueur le 5 juin 2000 with the same article modified by Decree N° 2003-922 of 26 September 2003 - art. 1 JORF 27 September, 2003.

It should be noted that the 1999 decree defining SMR had already made a minor change towards reinforcing the committee's independence. It reduced the number of representatives from Cnamts from 2 to one and replaced the slot with experts selected for their scientific expertise. Cf. Laude 2000. Apart from that, however, until 2003 the composition of the Committee had been largely the same since a decree in 1985.

The Transparency Committee issued two types of evaluation of a drug in its opinion, which assessed the improvement in clinical benefit (*Amélioration de service médical rendu* (ASMR) and clinical benefit overall (*Service médical rendu* or SMR). On the one hand, the ASMR rating, consisting of five categories (ASMR I-V), measured the degree of improvement compared to the existing treatments. The rating informed CEPS's pricing decision. On the other hand, SMR, created by the 1999 decree, denoted the actual clinical benefit of a drug. It put a drug into five categories, taking into account the following factors: clinical effectiveness and safety of the medicine, positions within therapeutic strategy (especially the presence or the absence of alternative treatments), severity of the disease, character of the medicine (preventive, curative, or symptomatic), and public health interest. The 1999 decree provided that the SMR ratings would define the level of reimbursement covered by the national health insurance. The same decree also determined that drugs with an insufficient actual clinical benefit would not be reimbursed.[204] Hence, the drugs given "major" (*majeur*) or "substantial" (*important*) SMR ratings would be covered for 65% of the cost, while the drugs with "moderate" (*modéré*) and "low" (*faible*) SMR would be covered for 35%, and drugs with "insufficient" (*insuffisant*) SMR would not be reimbursed.

Once the Transparency Committee issued its opinion on a drug, ASMR and SMR ratings were then used for the parallel process of setting prices and the reimbursement rate, respectively. On the one hand, the CEPS took ASMR ratings into account, among other things, in negotiating prices with drug companies. The Code of Social Security provided that drugs that neither have any improvement in clinical benefit nor save medical costs were not reimbursed by the health insurance.[205] The prices of non-reimbursable drugs were set freely by companies. If a drug was given ASMR V (no improvement) but still recommended for inclusion on the list by the Transparency Committee, the rating would be used for lowering the price or inducing cost-saving measures.[206]

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[204] Art. R163-3 du CSS, I. Modifié par Décret n° 99-915 du 27 octobre 1999 - art. 1. JORF 30 octobre 1999.

[205] Article R163-5 du CSS, I, 2°. Modifié par Décret n°99-915 du 27 octobre 1999 - art. 1 JORF 30 octobre 1999.

[206] For details of pricing rules, Grandfils 2007. Note that the description here is for outpatient drugs. In its opinion on drugs the Transparency Committee also recommended whether a drug should be included for primary care or hospital care. Drugs recommended only for hospital care took a pricing process different from CEPS negotiation, which is applied to outpatient drugs. Prices of hospital drugs were liberalised from 1987; the price was set based on negotiation between firms and individual hospitals. Since 2004, based on a framework agreement between the CEPS and the pharmaceutical industry's association (LEEM), hospital drugs were subject to payment based on Diagnosis-Related Groups except

As to reimbursement, on the other hand, SMR informed setting a drug's reimbursement status, with the health minister having final decision-making powers about including it on the reimbursement list. Prior to the 2004 reform, ministers in charge of health and social security set the reimbursement rate of a drug, in addition to deciding on its inclusion on the reimbursement list. Since 2004, in line with the Mutualité proposal in the preceding year, the reimbursement rate became formally set by the newly established Union Nationale des Caisses d'Assurance Maladie (UNCAM), which was an umbrella body representing health insurance funds and was tasked to negotiate with the state and health care providers. The government conferred UNCAM with powers to define the basket of care reimbursed by sickness funds.[207] This change by the 2004 reform, however, did not result in profound alterations in the allocation of powers in the drug reimbursement process. The powers given to UNCAM for setting reimbursement rate were limited, because the decree already defined the range of reimbursement rate associated with the actual clinical benefit as assessed by the Transparency Committee.[208] And perhaps more importantly, both before and after the reform it remained the health minister who made a final decision on whether a drug was included on the reimbursement list, which was then published in the Official Journal. The registration of a drug on the reimbursement list was valid for five years. At the end of this period, or at any time when significant new information was available, the Committee would reassess a drug, issuing recommendations about whether to maintain it on the reimbursement list.

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for particularly expensive drugs, which are subject to decision by the CEPS. See Chapter 7 for further discussions on pricing for expensive drugs and its implications for the politics of drug rationing.

[207] Importantly, while the government framed this agenda as the delegation of management to UNCAM (see e.g. *Communiqué du conseil des ministres* du 16 juin 2004), in practice the change in governance structure and the role of UNCAM in defining care packages did not mean a shift towards self-governance by the delegating power to social partners in the health insurance funds. On the contrary, The Director-general of UNCAM, a civil servant appointed by the government and also a director of CNAMTS, had extensive power over fund management at the expense of social partners, which had hitherto played a role in management through the board of social health insurance funds. Before the reform, the board of CNAMTS, consisting of employers and employees, had negotiated collective agreements with the medical professions. After the reform it was the Director-general who negotiated and signed the agreements without the involvement of social partners; the board became merely advisory for strategic orientation. The Director-general also had powers to nominate directors of local health insurance funds. The first UNCAM Director-general was Frédéric Van Roekeghem, who was a cabinet member of Douste-Blazy's. Contrary to the initial Mutualité proposal of participatory governance by social partners, UNCAM hence represented a device of greater state control. Bras 2004, 968-969; Hassenteufel and Palier 2005, 17f; Palier 2015, 107-108; Chevreul et al. 2015, 46.

[208] Cf. Grandfils 2008, p.18. The decree (Décret n°2004-1490 du 30 décembre 2004 JORF 31 décembre 2004) provided that the participation rate of an insured person was set at either 30-40% or 60-70% depending on SMR rating.

In short, while the creation of the HAS represented a considerable institutional evolution, the ministerial powers over drug reimbursement decisions were unchanged. Both HAS and the Transparency Committee enjoyed a high level of formal independence from the health minister. During the cumulative changes in organisational rules, the government policymakers enhanced the political independence of the Transparency Committee; they also reinforced the role of experts in the committee's composition. Yet, notwithstanding the stronger independence and experts' roles in issuing the Committee's opinions on a drug's clinical benefit, they remained only advisory; it remained the health minister who had the decision-making powers over the inclusion of a drug on the reimbursement list.

4. Conclusion

The transformation of the institutional landscape in the French regulatory regime for drug funding led to a proliferation of regulatory agencies in the sector. The "agency" phenomenon in the sector has been considered significant for the French institutional structure of policy and politics in two major contexts. First, scholars have considered the French regulatory agencies as a potential departure from the tradition of the sovereign, unitary state, leading to its fragmentation (Rosanvallon 2011, 80; Thatcher 2002, 137; Elgie 2006, 215). Second, scholars have regarded agencies in the health sector as part of reforms that would lead to a break with the governance structure of the Bismarckian welfare state based on the negotiation of social partners (Hassenteufel and Palier 2007). In either perspective, however, through delegation of powers to independent agencies, experts in the agencies were expected to play a prominent role in the policy process.

Yet, the chapter revealed the enduring importance of elected officials in decision-making over drug funding, even in the era of the "regulatory health care state" (Hassenteufel and Palier 2007). Even after elevating the scientific profile of the Transparency Committee and the subsequent reinforcement of formal independence from the health minister as part of HAS, allocations of powers in the reimbursement process remained largely intact. While the health minister's decision was aided by experts' opinion, it was still up to the minister to decide on the inclusion of a drug on the reimbursement list.

A quick comparison of the HAS with NICE would further highlight differences in institutional structures around the agencies, especially the level of political insulation. As an independent agency with its own legal status, HAS had a greater formal independence from

the health minister than NICE, at least in terms of its appointment rules and its legal basis. However, when one looks at the drug reimbursement decision-making process, unlike NICE, whose guidance was the final decision for the NHS, the HAS represents a case of low-level political insulation.

The chapter has shown that the low political insulation in the French drug funding process was a product of deliberative choice made by elected politicians and civil servants. Throughout the policy debates across different episodes of institutional evolution, bureaucrats and ministers systematically preferred maintaining the health minister's political responsibility for drug funding decisions. By drawing a strict demarcation between the "scientific" and the "economic" roles, they tried to justify defending the part played by elected officials in the latter. Ironically, contrary to the Mutualité's wish for greater participation of societal actors in de-reimbursement plans when it proposed the expert-led independent agency that became the HAS, the process of translating the proposals into a concrete institutional structure, far from seeing the retreat of the state, instead saw government convert it into a process whereby ministers retained the crucial powers to set the terms of (de-)reimbursement. Likewise, by excluding reference to sickness funds expenditure, elected politicians ensured that it was solely the health minister (on behalf of the state), not experts, that defined the reimbursement.

Such a defence of the prerogative of the state over reimbursement decisions did not mean that the government did not commit explicit rationing. On the contrary, the low political insulation in the institutional structure was an important part of the incumbent government's policy strategies. The French government exercised a delicate control over the form and magnitude of de-reimbursement and shifting the healthcare costs from the state, by taking into account its political impact. While the successive governments repeatedly resorted to changes in the reimbursement rate and de-reimbursement, they carefully chose both the forms (total de-reimbursement or changes in reimbursement rate, the latter of which would partially shift the cost to complementary insurance and hence make it less visible to the electorate) and the products subject to de-reimbursement. As later chapters shall reveal, the maintenance of the minister's powers for deciding on the boundary of reimbursement would play a key role in policy development even after the establishment of HAS.

Chapter 4 The regulatory state under pressure: England, 1999-2010

English drug funding policy evolved over the course of the 2000s. As Chapter 2 showed, the creation of the regulatory agency NICE took away the health minister's decision-making powers over drug funding to a considerable extent. NICE's guidance on whether a drug should be NHS-funded was authoritative in that the minister did not have the powers to overturn it. NICE's negative guidance thus meant an explicit rationing strategy, which limited the range of drugs funded by the NHS. Yet, policy modification took place through various measures in the latter half of the 2000s, and the trajectory it followed was not linear. These measures, while varied in their instruments, all addressed NICE's explicit drug rationing and were applied to the drugs for certain disease areas, especially cancer. Some were designed to make the conclusion of NICE's guidance faster, while others allowed flexibility in its appraisals to make the drugs that NICE would have not recommended available. Towards the end of the 2000s, we hence saw a partial policy reversal in English drug funding policy. This chapter examines the driving forces behind this partial change.

A key to understanding the trajectory is the role of the endogenous dynamics that stemmed from the high level of political insulation. In the highly politically-insulated setting whereby NICE's guidance meant the final decision for the NHS, NICE defended its policy choices against constant criticisms and policy debates raised by different stakeholders. The criticisms led NICE to develop a consistent, elaborate justification for its policy choices. A highly-insulated setting also helped the imposition of NICE's judgement on societal actors, as elected officials and bureaucrats were not able to challenge the outputs it produced. The high political insulation thus enabled the policy choices for drug rationing that were otherwise too unpopular to make. Yet, such policy choices, once imposed, were subject to intense counter-mobilisation by societal actors from the producer's coalition. Those who sought to challenge NICE's guidance expanded this coalition's base for political mobilisation by raising public awareness of the issue. As politicians' attention was drawn to the rise of public attention, they joined the coalition of producers demanding policy changes. Counter-mobilisation in the public and electoral arenas thus shifted the coalitional balance over policy change. The partial policy change in the late 2000s was a product of public controversy, with the changes being favoured on issues with the greatest magnitude of mobilisation, such as cancer drugs.

The chapter thus demonstrates the role of high political insulation in the post-reform policy development. By generating counter-mobilisation in the public and electoral arenas, high

political insulation created a self-undermining dynamic in the existing policies, and both arenas played a mediating role in this process of endogenous change. Even when attempts at policy changes via organised channels, such as direct lobbying of policymakers, yielded limited results, counter-mobilisation of the producer's coalition via the public and electoral arenas nevertheless still resulted in policy change. By expanding the scope of conflict, those who sought to challenge the existing policies were able to broaden their coalition to the actors outside the decision-making process. The resulting shift in power balance between actors' coalitions led to policy change. The chapter thus highlights a pathway to endogenous change through the public and electoral arenas, stemming from the highly-insulated institutional structure.

This chapter traces the policy development in four steps. First, it examines how the high level of political insulation affected policy choices for drug rationing. The rest of the chapter then studies how the policy choices created counter-mobilisation that took place in different arenas. The second section looks at the industry's challenge mediated by direct or institutionalised linkages to the government, showing its limitation for introducing policy change. The third section examines how counter-mobilisation in the public arena led to policy changes concerning the greater availability of drugs, while the fourth section looks at policy changes that resulted from mobilisation in the electoral arena. In the conflicts channelled through the latter two arenas, we see how controversies generated by the past policy choices played an important role in shaping policy change.

1. High political insulation and policy choices

Over the course of the 2000s NICE's guidance established its authoritative status, both domestically and abroad. But this was hardly the case at the beginning. When NICE started its operation, it found itself surrounded by several other existing actors who already provided expert knowledge and doubted NICE's guidance. Moreover, its task of recommending drugs for the NHS also meant that it must strike a balance between making a new drug available quickly and providing credible rigorous guidance. Not surprisingly, this dilemma led to confrontation with drug companies, on the one hand, which sought to challenge its negative guidance, and with local health authorities, on the other, which doubted its rigour when facing demands for the drugs that NICE recommended. In short, the evolution of NICE was hardly destined at its inception; rather, as this section shows, the consolidation of NICE's authority

within the policy sector is something that it earned through its operation. In particular, a highly-insulated decision-making structure, which excluded elected politicians from its process, helped NICE to develop guidance that was consistent across cases; such consistency, in turn, resulted in the agency earning credibility and institutional reinforcement. This process was facilitated by elite-level policy debates, generated by NICE's own policy decisions, which pushed it to develop elaborate justifications and codify rules that would guide its future decisions.

Early years of NICE and the question of its credibility

From its inception, NICE's guidance provoked controversy and confrontation. The very first appraisal that NICE carried out, in October 1999, on Relenza (zanamivir), a new flu drug by Glaxo Wellcome, set off conflicts between NICE and the pharmaceutical industry. In a decision widely seen as a "test case"[209] for the new agency, NICE recommended not prescribing Relenza for the 1999-2000 flu season on the grounds that there was insufficient evidence for its effectiveness in patients in "high-risk groups", such as the elderly and asthma sufferers[210]; it might review the decision for these groups when additional data was submitted. NICE ruled against making it available for general healthy adults.[211]

The guidance triggered a strong reaction from the pharmaceutical industry. Glaxo protested against the decision, accusing it of contradicting the government's commitment to pharmaceutical industrial policy. It threatened a judicial review and to leave the UK.[212] Other UK-based multinational firms such as AstraZeneca and SmithKline Beecham joined the protest. Through an open letter from the British Pharma Group, which represented the three firms, they accused the decision of "potentially devastating consequences for the future of the British-based pharmaceutical industry". Referring to their earlier warning that NICE would result in damaging impacts on drug sales worldwide and future innovation, they argued: "our worst fears were fully justified". The firms demanded "an urgent meeting" with Prime

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[209] *Financial Times* 3 July 1999.
[210] Glaxo itself had admitted that, in its advertisement to GPs, the clinical effectiveness of the drug for high risk groups had not been established due to the limited number of patients participating in clinical trials. *Financial Times* 4 October 1999; *The Guardian* 4 October 1999
[211] *Financial Times* 1 October, 1999.
[212] *Financial Times* 9 October 1999; *The Independent* 4 October 1999; *The Times* 4 October 1999.

Minister.[213] The largest British firms' position also shaped the reaction of the ABPI, which stated that NICE's "credibility with the industry, both in the UK and abroad, has been seriously damaged".[214]

Health Secretary Frank Dobson supported the guidance. After the submission of additional trials that Glaxo had not completed before the initial appraisal, in late 2000 NICE reversed its initial judgement and recommended Relenza for high-risk groups. It is noteworthy that the Relenza guidance disappointed clinicians for a reason opposite to the industry's. In response to the initial decision, the BMA claimed that Dobson should have given NICE's recommendation legal force and banned the drug. It criticised the government for failing to protect GPs from surging demand for the drug.[215] When NICE revised its appraisal later on and recommended the drug for high risk groups, the BMA chair expressed concerns about "enormous demand";[216] one group of GPs protested against the revised decision, declaring that they would be refusing to prescribe the drug.[217]

The reversal of the judgement about Relenza for high-risk groups raised doubts about NICE's credibility among stakeholders. Several from the medical community, including the dissatisfied BMA, claimed that NICE's credibility was undermined due to the political pressure and the power of the pharmaceutical industry. The title of the *British Medical Journal* (BMJ) editorial following the verdict about Relenza read "The failing of NICE".[218] The same criticism was raised by the payer's side; for local health authorities this was particularly serious because with their fixed budgets NICE's positive guidance meant cutting other treatments and services (e.g. Cookson et al. 2001; HoCHC 2002a, 22-23). Criticisms abounded when the House of Commons Health Committee (HoCHC) held its first inquiry into NICE in 2002. Comments from both the medical and pharmaceutical communities and local health authorities questioned the quality of NICE's guidance; they pointed out what they considered errors and mistakes in appraisals, while advancing the suspicion, as one health authority put it, that

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[213] *Financial Times* 6 October 1999; "UK's NICE turns nasty, rejecting Glaxo Wellcome's anti-flu drug Relenza" *Pharma Marketletter* 11 October 1999.
[214] *Financial Times* 9 October 1999. One informant noted that the fact that the President of ABPI at the time was from Glaxo contributed to the position of the industry as a whole. Interview with an economist, 10.05.2018.
[215] *Financial Times* 9 October, 1999; Yamey 1999.
[216] *Financial Times* 22 November 2000. Cf. "Guidance on Relenza leaves GPs 'vulnerable'" *Pulse* 2 December 2000.
[217] *Financial Times* 8 December 2000. "GPs vote to boycott Relenza on the NHS" *Pulse* 9 December 2000.
[218]Smith 2000, 1363.

"NICE was widely viewed as pursuing a political agenda at the expense of clinical credibility" (HoCHC 2002a, 10). The Committee's report reflected: "NICE clearly operates in an environment populated by information providers who are already established and respected by clinicians. This means that if NICE is not able to produce guidance which clinicians find credible, then it is likely and reasonable that clinicians will use these other sources of information." (Ibid.) It recommended a greater collaboration with the existing "respected" bodies such as the British National Formulary and the *Drug and Therapeutics Bulletin*. In short, far from having an established status, NICE's guidance was subject to doubt, especially given the existence of other knowledge providers that had already earned a reputation among the medical professions. Any efforts for institution building that NICE attempted to make hence must surmount the hurdle of providing justifiable reasoning for its guidance and being seen as a credible regulator, especially in the eyes of different stakeholders who already possessed sector-specific knowledge.

The pattern of policy choices

From its launch, NICE restricted a considerable number of the technologies it appraised. Figures 4.1 and 4.2 show an overview of NICE's decisions based on the list of guidance published on its website. Overall, NICE judged around eight out of ten cases as either "recommended" or "optimised for a subgroup of patients". In the latter, NICE did not refuse a drug altogether, but recommended a restricted use for a smaller subgroup of patients than the one covered by the drug's licence. Between 2000 and 2015, approximately 40% of the drugs (232 of 571 technologies) NICE appraised resulted in some form of restriction compared to its approved usage.[219]

NICE's negative decisions often provoked contestation. One indicator of this may be the number of appeals submitted against decisions. Among 401 technologies appraised from 2000 to 2011, appeals were submitted in 86 cases (see Figure 4.3). Although NICE upheld a

[219] This is based on the total number of the technologies falling in one of the following categories of NICE's guidance: "Not recommended" "Only in Research" "Optimised" or "Terminated". The last category means the appraisal was terminated before its completion as the manufacturer did not submit evidence. Given the PCTs' refusal to fund the treatment during NICE's appraisal, this was considered a form of explicit rationing. If we exclude the technologies falling in this category, about 38% of the technologies (amounting to 208) NICE concluded its appraisal in 2000-2015 received some form of restriction.

substantial proportion of appeals, the majority (52 out of 86 cases between 2000 and 2011) were still dismissed by a panel. Drug manufacturers and patient groups regarded NICE as the "fourth hurdle" to drug access. In a few instances, manufacturers contesting NICE's guidance brought the case to the court. The most notable was the 2007 guidance for Alzheimer's disease drugs, where the Court of Appeal, reversing the earlier High Court ruling, judged that NICE acted unfairly when it refused to supply the manufacturer with the full model used to judge cost-effectiveness.[220]

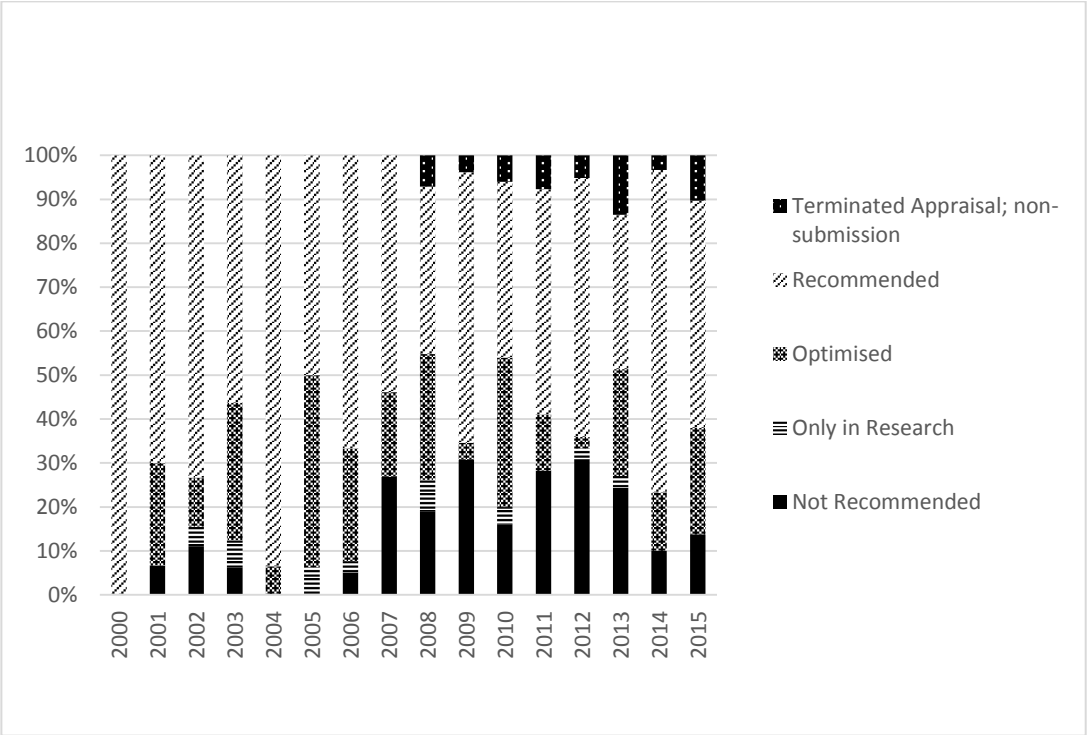

Figure 4.1 The annual distribution of the NICE technology appraisal guidance outcomes (The overall trends in technology appraisal programme)

Source: Author's elaboration based on NICE's technology appraisal data[221]

[220] Dyer 2007. Following the Court's ruling in 2010 NICE updated the guidance and recommended the drugs.

[221] The categories of decision are based on NICE's own descriptions. The full list of guidance is available at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data/appraisal-recommendations

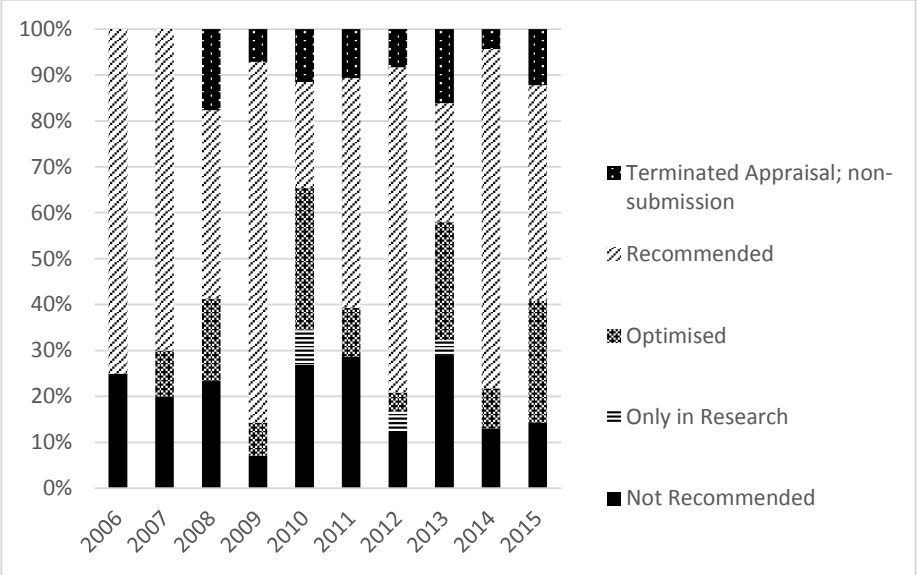

Figure 4.2 The annual distribution of the NICE technology appraisal guidance outcomes (The rapid Single Technology Appraisal process only)

Source: See Figure 4.1.

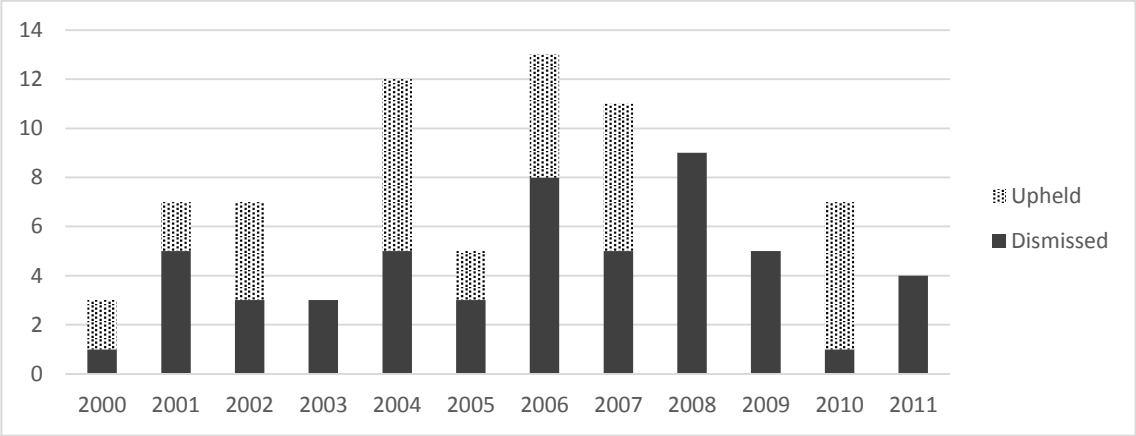

Figure 4.3 Appeal decision outcomes

Source: Compiled based on NICE's website information. [222]

[222] The careful interpretation of the graph is required, because it counts the number of technologies rather than the number of guidances. The same guidance contains a number of technologies (in the case of MTA), and therefore some decisions may be over-represented. For instance, the appeals decided to be "upheld" in 2004 (n=7) was for one particular technology appraisal. I nonetheless used the number of technologies rather than that of decisions, because it was also the case that only some of the technologies within a decision were subject to appeals, and that an appeal may be upheld for some technologies but not in others within the same decision.

Two issues in NICE's impact on explicit rationing at the NHS prove particularly controversial. One was the speed of NICE's guidance. In the mid-2000s, it typically took NICE 18 months to issue guidance. When the drug was licensed but NICE technology appraisal was still not completed, it was the local Primary Care Trusts (PCTs) who made funding decisions. As NICE began operating, it became widely observed that local PCTs tended to wait for NICE's guidance being issued, leading to delay in access to a new drug even though the drug was licensed – a gap that the pharmaceutical industry and patient groups called "NICE blight". This time lag between drug licensing and publication of NICE guidance happened despite a DH circular instructing PCTs not to use NICE as their reason for not funding technologies.[223]

Another criticism was with regard to NICE's negative judgements. Criticisms pointed to how NICE evaluated a drug's benefit in making judgements, and in particular the role of cost-effectiveness. Specifically, NICE used Quality Adjusted Life Year (QALY) to measure how much a medical technology improved both the quantity and the quality of life. The cost per QALY gained, or the incremental cost-effectiveness ratio (ICER), then, indicated cost-effectiveness of a drug. It was initially observed, and then made explicit by NICE, that it used an ICER of £20,000-30,000 per QALY as a threshold range for judging whether a technology was considered "value for money" on the NHS. As NICE itself recognised, there was no theoretical basis for assigning these particular values, and the threshold was therefore arbitrary.[224] Not surprisingly, the threshold became the subject of intense debates and contestation.

The role of the cost-effectiveness threshold was well-observed in practice (Devlin and Perkins 2004; Raftery 2006). By the mid-2000s, it was established that NICE typically gave ICER gained in its appraisal report unless stating that the manufacturer's submission lacked such data. The major reasons why a particular drug was rejected or restricted were either 1) ICER was higher than the above-mentioned threshold; or 2) the manufacturer had not provided evidence showing the drug's clinical or cost-effectiveness. A decision to grant "restricted" use for a subgroup of patient population typically occurred when the ICER calculated for that subgroup proved to be less than the threshold of £20,000-30,000 per QALY.

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[223] HoCHC 2002a, 20.
[224] Rawlins and Culyer 2004, 224; HoCHC 2007, 58-59.

High political insulation and the reproduction of policy and institutions

The high political insulation under which NICE operated contributed to shaping the patterns of policy choices. Within a broad framework given by the Health Secretary, NICE was responsible for developing its own methods and process for technology appraisal. The authoritative status of its guidance for the NHS meant that once it started operation NICE constantly faced contestation of its decisions. Moreover, as an agency operating in a policy area already crowded by actors with expertise and knowledge, NICE was often forced to defend its positions in the face of policy debates and criticisms. Amid these in the dense field of expert audiences, NICE attempted to develop consistency in reasoning in its decisions by deploying its own expert community. Through justification of its policy decisions as being consistent with its precedents, the appraisal process gradually accumulated a set of informal doctrines that the appraisal committee drew on – or what those around NICE sometimes retrospectively called "case laws"[225]. Furthermore, by explicitly codifying such doctrines as they emerged through its operation, NICE attempted to earn credibility in its decisions.

The use of the cost-effectiveness threshold in technology appraisal was a product of such an attempt by NICE to justify its policy choices in the face of criticisms and policy debates. In NICE's early years its appraisal reports did not necessarily cite cost per QALY, partly due to the lack of reliable data on impacts on quality of life.[226] Moreover, as appraisals where NICE referred to cost per QALY of the technologies in question were accumulated, a growing speculation emerged among stakeholders about whether NICE was following a particular threshold of acceptable maximum cost per QALY.[227] NICE was initially reluctant to address the existence of such a threshold.[228] For instance, in 2002 a Technology Appraisal Committee chair stated before the HoCHC that "the Appraisal Committee does not consider the threshold … and has not been given instructions about a threshold and has not discussed a threshold per se at all"[229]; NICE chair Michael Rawlins also maintained before the Health Committee that

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[225] Cf. Chalkidou 2012, 395ff.
[226] Raftery 2001, 1302. Taylor 2002, 168. The 2002 HoCHC inquiry into NICE cited a criticism by a Health Authority, who found that NICE had used cost per QALY in only about a half of its appraisals. HoCHC 2002a, 31.
[227] Devlin and Parkins 2004; HoCHC 2002a, 31-32. For instance, in a joint workshop organised by an independent think tank, The King's Fund, and an ABPI-sponsored think tank, the Office of Health Economics, Towse and Pritcard (2002) argued that NICE was operating an implicit threshold range of £20,000-30,000 per QALY.
[228] Interview with a former NICE appraisal committee member, 03.05.2018; Interview with an economist, 10.05.2018.
[229] HoCHC 2002a (HC 515-I), 31.

"the Institute does not have a cost threshold beyond which a technology would be automatically rejected.", calling the threshold "an urban myth".[230] As the pressure continued to grow, however, Rawlins, in a *British Medical Journal* article co-authored with health economist and NICE vice chair Tony Culyer, set out a threshold range that NICE took into account in its judgements (Rawlins and Culyer 2004). While NICE rejected an absolute threshold for judgement, it elaborated a range of values that changed the probability of rejection. NICE was unlikely to reject a technology if the cost per QALY was below £20,000; the likelihood of rejection on grounds of cost-effectiveness increased if the cost per QALY was above £30,000. As NICE admitted, there was no empirical basis for assigning these particular values to the threshold; it claimed to have arrived at the threshold range through its case-by-case operations (see also Pearson and Rawlins 2005; Rawlins et al. 2010).

NICE not only publicised the threshold range to external actors but also codified it in its internal rules for decision-making. At around the same time as the publication of Rawlins' article, NICE released an updated version of its Guide to the Methods of Technology Appraisal, a guidance document describing methods and concepts used for Technology Appraisals. While the previous 2001 version was criticised for the lack of clarity in how NICE arrived at decisions,[231] the updated guide specified principles and methods for Technology Appraisal judgements in greater detail, including the role of cost-effectiveness.[232] The document clarified that above an ICER of £20,000 per QALY the Technology Appraisal Committee's judgement about acceptability of technology took into account factors such as the uncertainty around calculation of ICER, the innovative nature of the technology, features of the condition and patient population, and (where appropriate) wider societal costs and benefits; and that "above an ICER of £30,000/QALY, the case for supporting the technology on these factors has to be increasingly strong" (NICE 2004, 33). In line with Rawlins' earlier statement mentioned above, NICE thus claimed that it made judgements not solely based on the threshold; rather, it set out how the threshold guided its decision.[233] By responding to policy debates and making the

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[230] Quoted in Littlejohns 2002, 32.
[231] HoCHC 2002a (HC 515-I), 30.
[232] A former member of a NICE working group described the 2004 Methods Guide as "a big leap forward", since its development "involved lots of practitioners in the field … and tried to incorporate a "good science"". Interview with a former NICE Committee member, 03.05.2018.
[233] NICE devoted considerable effort to gaining legitimacy for its guidance through explicit doctrines. In academic and policy debates Rawlins drew on moral theories on procedural justice, especially the criteria of "accountability for reasonableness" – a fair priority-setting process requires publicity, relevance, appeals, and enforcement – as an underlying doctrine for NICE's process. NICE also codified its "social value judgement", a document which was prepared with its layperson's Citizen's Council

threshold range explicit, NICE retrospectively developed rules and doctrines that made its decisions consistent with each other. Such a codification reflected its attempt to justify its policy decisions. Moreover, once established the codification of an explicit threshold not only justified the appraisal committee's past decisions but also constrained future ones as the committee would refer to it in making decisions. It also shifted policy debates among stakeholders from whether NICE had a particular threshold to whether the values of the threshold were adequate and whether the threshold satisfactorily captured the benefits of a drug. All in all, NICE's attempt at earning credibility through clarification of a cost-effectiveness threshold and its consistent application strengthened both institutions and policy orientation.

The high political insulation whereby NICE's guidance was the final decision for the NHS, without elected officials' involvement, strengthened these attempts by NICE at establishing credibility in its decisions. As mentioned in Chapter 2, the Direction issued in 2005 provided that, in performing an appraisal NICE should take into account, among other things, any guidance issued by the Secretary of State. In practice, however, this provision was never used; DH officials' communication with NICE during an appraisal process was mostly about how the former would implement the guidance given the funding obligation for NICE-recommended technologies.[234] Moreover, once NICE issued its appraisal, the Health Secretary's room for manoeuvre was extremely constrained by both rules and standard operating procedures. If NICE recommended a drug, PCTs were legally obliged to make it available within three months. And if NICE did not recommend a drug, little evidence indicates that the Health Secretary attempted to ignore or overturn the guidance. The absence of such an intervention by ministers might be partly due to the lack of procedural rules guiding their action: in contrast to France, where the Health Minister firmly held the final responsibility for reimbursement stipulated by law, in England while ministers formally had powers to issue a decree for the NHS there were few specific procedures for ordering PCTs to fund a drug rejected by NICE. But the lack of specific rules was reinforced by ministers' and bureaucrats' underlying expectation and strategy. A DH official recalled that, while there were a few instances in which ministers had been leaning towards ignoring the fact that NICE had not

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and described the principles that its appraisal committees should follow. Rawlins 2006; Rawlins et al. 2010.

[234] Interview with DH officials, 17.05.2018. There were a small number of cases where ministers issued guidance to waiver the three month funding requirement and delayed the implementation for the training of local clinical staffs and other reasons.

recommended a drug, the Department's officials had warned the ministers that doing so "would undermine NICE and the credibility of NICE".[235] In the end, according to this account, ministers have never instructed the NHS to ignore NICE's negative guidance.

As NICE developed elaborate consistent justification of its decision-making methods, NICE's reputation as an HTA body outgrew initial suspicion of its credibility. An early example of positive evaluation by outside actors was a 2003 report written by the World Health Organization (WHO), which affirmed that "in only four years, NICE has developed a well-deserved reputation for innovation and methodological developments that represent an important model for technology appraisals internationally".[236] The report commended, in particular, "the Institute's commitment to using the rigorous methodology throughout the technology assessment", arguing that "Published NICE appraisals are already being used as international benchmarks—an obvious recognition of their credibility".[237] The same actors who were once suspicious of NICE also reversed their judgement. Following the WHO report, the BMJ published an editorial entitled "The triumph of NICE" – in a contrast to its criticism for NICE's "failing" after Relenza.[238] Likewise, in 2007 when the HoCHC carried out another inquiry into NICE, unlike its previous inquiry that had highlighted stakeholders' doubts about NICE's credibility, it stressed the agency's reputation for "well-established and robust" processes, in addition to its international recognition (HoCHC 2008, 26-27).

Efforts to strengthen the implementation of appraisal continued after the introduction of a funding requirement for NICE-recommended technologies. A 2005 study by the Audit Commission found that only 25% of PCTs implemented technology appraisals within three months (cited in HoCHC 2008, 72). While it was not NICE's remit to ensure PCTs followed its guidance, it made considerable efforts to help local implementation through its newly-created implementation directorate, which assisted PCTs in funding recommended technologies, and through collaboration with Royal Colleges (HoCHC 2008, 71; DH 2008a (Cm 7331), 12-13). The government commitment to ensuring the implementation of NICE guidance and ending the postcode lottery was reiterated in Health Minister Lord Darzi's report for the NHS Next Stage Review in 2008, which set out a decade-long plan for NHS reform.

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[235] Interview with a DH senior advisor, 18.04.2018.
[236] Hill, et al. 2003, 39. NICE invited WHO's Regional Office for Europe to carry out the evaluation in response to HoCHC 2002, which recommended an independent scientific inquiry into NICE.
[237] Ibid.
[238] Smith 2004.

Based on the report's recommendation, the government introduced a legally-binding NHS Constitution, where the right of NHS patients to NICE-recommended technologies was made explicit.[239] The continual strengthening of the funding obligation was made despite the NHS Confederation's criticism that PCTs had to disinvest in other more cost-effective treatments to fulfil it (HoCHC 2008, Ev.180; Maynard et al. 2004). The Darzi Review also led to expansion of the remit of NICE into the area of quality, including providing indicators for the Quality and Outcome Framework (QOF), a primary care pay-for-performance scheme; NICE's budget was also set to be tripled for the next five years to support its expanded roles (Hitchen 2008; cf. Rawlins 2009; Littlejohns et al. 2009). As QOF indicators became aligned with NICE guidance on cost-effectiveness, they were used to give financial incentives to doctors to abide by NICE's decisions. The introduction of the QOF indicators hence placed further control on doctors, in an effort to build them further into the chain of service delivery flowing from NICE's guidance. These expansions may be an indicator of the agency's growing reputation for credible guidance -- a reputation which also provided a prerequisite for strengthening the implementation regime, where NICE guidance was expected to have an authoritative status in health care rationing.

In sum, the operation of the regime exhibits reinforcement of existing institutions and policy orientation. NICE backed more elaborate reasoning for its judgements, trying to make consistent, systematic guidance development in the face of policy debates and criticisms. By doing so it attempted to create credibility as a regulator. The high level of political insulation reinforced such a strategy. All in all, institutional reinforcement went hand in hand with hard policy choices despite – or rather, *because of* – the pressure that NICE confronted.

Gradual rule change for a greater flexibility

However, at around the same time as NICE consolidated its reputation for the credibility of judgement and reinforced its institutions, there was a gradual policy change to make more drugs available more quickly. A number of measures to improve drug access were introduced in the latter half of the 2000s. These measures, while some were more explicit than others, had in mind a particular type of new, expensive treatment—and hence patient population. First, in terms of the speed of its guidance, in 2005 NICE introduced a new appraisal process that

[239] cf. DH 2008b (Cm 7432), 44; *The Guardian* 21 Jan 2009

enabled it to issue guidance more quickly. Unlike the existing technology appraisal process -- now called Multiple Technology Appraisal (MTA) -- which systematically compared several technologies for the same condition, the new Single Technology Appraisal (STA) process was used for a single technology for a particular indication. Moreover, while the existing process involved modelling carried out by an independent academic group, evidence used for the STA was solely based on the manufacturer's submission. These features were aimed at reducing the length of technology appraisal for a new drug close to obtaining a license so that the gap between the licensing decision and the publication of NICE's guidance was closed.

Changes also took place related to cases where NICE issued negative guidance on the grounds of lack of cost-effectiveness, as several measures were introduced to make such drugs available. One such measure was a pricing instrument called a risk-sharing scheme, which was designed to attenuate the uncertainty and high price of new drugs. The 2009 Pharmaceutical Pricing Regulation Scheme (PPRS) formally included a form of such an instrument named the Patient Access Scheme. Under the Scheme, the manufacturer could offer to pay part of the cost of the drugs that NICE otherwise judged as not cost-effective. If the Department of Health agreed a Patient Access Scheme with a company, NICE would then recalculate a drug's ICER to examine whether it was below the cost-effectiveness threshold when taking the scheme into account. Another measure was a set of appraisal criteria that NICE's Technology Appraisal Committee specifically used for drugs for end-of-life (EoL) care. These criteria were introduced in 2009, and applied to "treatments which may be life-extending for patients with short life expectancy, and which are licensed for indications affecting small numbers of patients with incurable illnesses."[240] When a drug met the criteria, NICE's Appraisal Committee would then give a special weighting on the benefit of the drug in making its judgement, which might enable the Committee to recommend a drug exceeding the upper end of the threshold (i.e. £30,000 per QALY). Perhaps the most apparent change in this regard, however, was the Cancer Drugs Fund. Launched in 2010 by the Conservative-Liberal Democrat coalition government, the Fund provided a ring-fenced amount of £200 million annually, within the overall NHS budget, which specifically covered the cancer drugs rejected by NICE. The Cancer Drugs Fund thus enabled overriding NICE's guidance without directly undermining its process.

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[240] NICE, "Appraising life-extending, end of life treatments", July 2009, 1.1. https://www.nice.org.uk/guidance/gid-tag387/documents/appraising-life-extending-end-of-life-treatments-paper2

These episodes of policy change resulted in a significant redistribution of power among different actors – producers, payers, and different patient populations. The remaining sections of this chapter will examine the endogenous forces, generated from the very institutional structures of high political insulation that enabled an unpopular policy choice, which ultimately drove the change.

2. Counter-mobilisation through business-friendly arenas

The following three sections examine how the policy choices for funding or rationing drugs led to counter-mobilisation in different political arenas over the course of the 2000s. By doing so, they examine endogenous sources of policy change for a greater availability of a particular type of drugs on the NHS. Confronted with policy choices that imposed significant costs, drug companies sought to change existing policy orientation on several fronts. Mediated in different arenas, such counter-mobilisation involved distinct strategies and outcomes. This section examines mobilisation efforts channelled through the industry's direct institutionalised access to policymakers, while the next section will explore attempts at mobilisation mediated in the public arena. Finally, Section 4 examines mobilisation in the electoral arena in the 2010 general election.

The first NICE guidance on Relenza in 1999 was also marked by the beginning of the pharmaceutical industry's counter-mobilisation by lobbying the government. Responding to three British firms' call in the wake of the guidance not to recommend Relenza, Prime Minister Tony Blair met with the companies in November. The meeting led to the establishment of the Pharmaceutical Industry Competitiveness Task Force (PICTF), a business-government forum accountable to the Prime Minister. Jointly chaired by Health Minister Philip Hunt and AstraZeneca Chief Executive Tom McKillop and comprised of ministers in charge of Health, Trade and Industry, and the Treasury, among others, as well as representatives of the industry, the forum was tasked to look into ways to strengthen the UK-based pharmaceutical industry's competitiveness.[241] While NICE's impact on the industry and the role of the NHS in supporting international competitiveness remained chief concerns of the Task Force, its scope went well beyond the area of health policy in a narrow sense; it hence examined issues including the UK market and the industry's competitiveness, intellectual property rights,

[241] Joint secretariat, "Pharmaceutical Industry Competitiveness Task Force: Terms of Reference", April 2000.

clinical research, and the EU drug approval regime. Business-government dialogue dedicated to the competitiveness of the pharmaceutical industry continued after the PICTF published its final report in 2001, as the report led to a regular forum called the Ministerial Industry Strategy Group (MISG), which again comprised ministers from the Departments of Health, Trade and Industry, and Treasury and senior industry executives.

Yet despite the existence of such an institutional arena favourable to the industry, the business-government forum did not lead to policy change related to NICE. The PICTF's 2001 report called for a full review of NICE's operation, scheduled in July, which would involve all stakeholders and would address "broader impacts on market access and the resulting competitiveness of the UK as a global player, as well as NHS perspectives".[242] To the industry's disappointment, the government review was subsequently subsumed into the government's response to Ian Kennedy's inquiry into the Bristol Royal Infirmary scandal.[243]

Another business-government forum that channelled the industry's mobilisation was the Bioscience Innovation & Growth Team (BIGT), a group launched in 2003 by the Department of Trade and Industry, in partnership with BioIndustry Association and the Department of Health. It set out "Bioscience 2015", an industrial strategy programme that envisioned the UK medical bioscience sector as a global leader by 2015. BIGT was vocal in challenging NICE's practice. The 2003 "Bioscience2015" addressed impacts of NICE on biotechnology medicines, maintaining that "NICE has an emphasis on mainstream drugs, whereas the bioscience industry often has niche products where the patient numbers involved falls below NICE's economic threshold".[244] In its review of biotechnology research funding in 2006, BIGT's chair, David Cooksey, argued that to accelerate uptake NICE should be involved earlier in the medicine development process. He recommended that the government, regulators, and industry should jointly develop a regulatory process through a pilot project in which NICE was involved in an earlier stage of clinical trials.[245] Furthermore, in the interim review of Bioscience 2015 published in early 2009, Cooksey proposed an independent inquiry into NICE. Referring to the UK's low uptake of cancer drugs compared to other European countries, the

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[242] PICTF 2001, 7. See also "Key task force backs pharmacist prescribing" *Chemist & Druggist*, 31 March, 2001. "UK pharma competitiveness Task Force results announced by Premier Blair" *Pharma Marketletter*, 29 March 2001.
[243] *Financial Times* 13 November 2001. For NICE-related recommendations in the Kennedy inquiry see Chapter 2.
[244] BIGT 2003, 58.
[245] Cooksey 2006, 6. Cf. BIGT 2003, 38.

review argued that "[i]ndustry believes that the way these decisions were reached have been damaging for the industry and their public sector allies seeking to make the UK an attractive location for conducting clinical trials of new medicines."[246] The report hence emphasised that, in addition to assessing NICE's long-term impact on uptake of drugs, the focus of the inquiry should be on the way in which NICE valued medicines so that it could take into account the value of innovation.

In response to Cooksey's call, NICE appointed Ian Kennedy, who, since the public inquiry into the Bristol Royal Infirmary scandal mentioned above, had chaired the Healthcare Commission (the body which replaced CHI in 2004), to carry out a review on appraising the value of innovation at NICE. Contrary to the industry's criticism that had led to the inquiry, the Kennedy Report, published in July 2009, largely supported the methods of appraisal, claiming that the ICER/QALY approach was "quite simply the best tool available to do the job which NICE has been set".[247] He recommended that NICE's appraisal should keep being based on cost per QALY. Moreover, while acknowledging the necessity to review the health-related benefits that NICE considered, he rejected the idea of taking into account wider social benefits that a drug may bring, including easing the burdens of carers, allowing patients to work, or increasing tax revenues.[248] On valuing innovation, Kennedy acknowledged the "societal needs for innovation" and recommended that NICE formulate the definition of innovation, while suggesting ways to make some adjustment in approach to such an "innovation" to incentivise the industry without undermining NICE; in addition to the Patient Access Scheme, ideas for such adjustment included a scheme whereby NICE would agree a higher cost-effectiveness threshold for an innovative medicine for a fixed time.[249] Kennedy's support for its existing approach to appraisal helped NICE defend its practices. In its response to the Kennedy Report NICE argued that it already had flexibility in evaluating the technologies whose cost-per QALY was above the normal threshold, taking into account innovation that may not be well captured in the measurement of cost per QALY.[250] Referring to a stakeholder workshop on the threshold range held earlier that year, it also argued that

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[246] BIGT 2009, 51.
[247] Kennedy 2009, 21
[248] Kennedy 2009, 27-28; cf. "NICE should not take account of drugs' social benefits: Kennedy" *Pharma Times* 23 July 2009; Chaplin 2009.
[249] Kennedy 2009, 36-50.
[250] NICE 2010, 90

changing the threshold was unnecessary.[251] NICE's proposed change was hence in line with other recommendations of the report, most of which were focused on better communication with stakeholders. All in all, to the disappointment of the pharmaceutical industry, which criticised the QALY approach as too narrow to fully capture benefits of a drug, the inquiry did not result in major change. The industry considered it a "missed opportunity".[252]

The increasing attention to NICE's impact on innovation that the industry addressed through lobbying was not limited to the BIGT. In January 2009, Prime Minister Gordon Brown met with representatives of the ABPI, who warned of the fierce international competition that the industry was facing. They advocated measures to protect the industry's scientific base in the UK, which, in addition to changes in taxation and patent legislation, would be aimed at making NICE "a champion of innovation and speed up patient's access to new medicines".[253] The Brown government took pharmaceutical industrial policy seriously, installing senior cabinet members such as Health Secretary Alan Johnson and Business Secretary Peter Mandelson in the MISG, which had usually been led by junior ministers.[254] The summit with the industry led to the creation of yet another government-industry forum: the Office for Life Sciences. Led by Science and Innovation minister Paul Drayson, a founder of a vaccines company and seen as "very much a biotech/pharmaceutical insider"[255], the Office was tasked to set out national initiatives jointly with the industry. As part of its "Life Sciences Blueprint" industrial strategy launched in July, it proposed a scheme which would enable rapid access to certain innovative medicines. In the "Innovation Pass", selected drugs targeting patients with rare conditions but with insufficient data for a NICE appraisal would bypass appraisal and be granted immediate use within the NHS for a limited time period while more data was collected. After this period they would be subject to a regular NICE appraisal. The government allocated the pilot project for the Pass a £25 million budget in the 2010-11 year, and the DH asked NICE to develop the selection criteria.[256] Despite a modest budget, from the industry's perspective the Pass hence represented a potential departure from the existing practice of NICE, which it had seen as the fourth hurdle to new innovative technologies. The pharmaceutical industry considered it as a "precedent of recognising that not all medicines can achieve a positive NICE

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[251] NICE 2010, 30
[252] Clough 2010, 40.
[253] "Drug industry warns PM UK is losing out" *Pharma Marketletter* 28 January 2009.
[254] *The Times* 27 January 2009.
[255] "Kennedy and Drayson: Parallel plans to boost UK's innovation agenda" *Pharmafile* 5 August 2009.
[256] Cohen 2009, 339.

appraisal at launch".[257] For their part, proponents of the existing approach saw it with suspicion. The publication of the Kennedy Report came just after the launch of the Life Sciences Blueprint. Kennedy was critical of the Innovation Pass; if it is adopted, he noted, the use of the Pass for drugs with yet limited evidence must not be "a back-door to approval by NICE".[258]

Thus, despite its repeated attempts the industry's mobilisation through business-government fora resulted in little, or at best modest, policy change. Business actors, with their possession of superior technical expertise and knowledge compared to other actors, are often considered to have an advantage in influencing policy-makers via lobbying and business-government fora. (cf. Culpepper 2010; Dal Bó 2006; McCarty 2014). However, in a policy arena crowded with expert knowledge suppliers who could counter the industry's arguments, the industry's ability to influence policymakers through expertise-based lobbying was attenuated.

One might expect that, in addition to institutionalised access to government departments, another location of the industry's lobbying might be special committees in the legislative branch. Unlike the "iron triangle" metaphor – the closed community among the industry, Congressional committees, and the bureaucracy -- developed in American politics (cf. Lowi 1979), in executive-dominant Britain a prevalent view tends to see the Parliamentary committees of little significance in the policy process. Recent scholars challenge this prevailing image of a weak Parliament, arguing that non-legislative oversight committees such as the House of Commons Select Committees, which are not given legislative roles but are tasked to review government policy, play a significant role in agenda-setting (Benton and Russell 2012; Russell and Gover 2017). If we take into account this revisionist argument, it may be worth a look at whether the pharmaceutical industry's mobilisation efforts effectively shaped the activities of oversight committees in relation to NICE and pharmaceutical policy. Over the course of the 2000s, the HoCHC held inquiries dedicated to NICE twice. However, although improving access to drugs was addressed, the larger concern among the committee members was the pharmaceutical industry's influence on the government and NICE. Following the Vioxx scandal in the US the Committee held a separate inquiry in 2005 into the influence of the pharmaceutical industry.[259] Its members were also critical of the risk-sharing

[257] Clough 2010, 39.
[258] Kennedy 2009, 48.
[259] HoCHC 2005a.

scheme and other measures for flexibility in drug funding policy. The HoCHC's inquiry claimed that the earlier example of the scheme applied to beta interferon was a "costly failure"[260] as its evaluation failed to yield reliable information on the drug's cost-effectiveness. As we shall see later, the Committee criticised EoL criteria as "both inequitable and an inefficient use of NHS resources".[261] In the end, for the same reason as in the mobilisation through business-government fora, business power via the parliamentary channel was moderated by knowledge and counter-arguments supplied by other "expert" actors.

Thus, it is unlikely that the policy changes for a greater flexibility were triggered by the industry's direct lobbying of the government. Rather, as the following sections show, it was a wider mobilisation of societal interests that led to policy change. Such a mobilisation occurred in the public arena, where heightened public attention drew politicians into the producer's coalition. The mobilisation was the most intense around treatments for certain disease groups that were exceptionally salient both among politicians and the general public--such as cancer.

3. Counter-mobilisation in the public arena: Battles over cancer drugs

Cancer drugs exemplify a daunting dilemma of funding drugs through health systems. Despite their often incremental innovation, the latest generation of biopharmaceutical drugs cost much more than existing ones with simpler structures, partly because it targeted a small subgroup of patients or conditions. The sky-rocketing prices and modest improvements in effectiveness tended to result in negative NICE judgements: between March 2000 and March 2015, 40% of the cancer drugs NICE appraised through the STA process were not recommended for use, which was significantly higher than the share of the drugs across areas that NICE did not recommend via STA (24%).[262]

The status of cancer drugs as a defining issue in policy development partly stems from the fact that cancer is perhaps the most politically salient disease area in the UK. Emotionally-gripping stories and hopes for "life-saving" drugs readily enable the media to attract public

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[260] HoCHC 2009, para 118; cf. HoCHC 2008, paras 327ff. See also Raftery 2010 for a critique of the scheme.
[261] HoCHC 2009, para 111.
[262] Source: NICE's website (retrieved 27 June 2015; the statistics on the website has been updated since then). https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/summary-of-decisions

attention. Organised interests were highly vocal; not only the pharmaceutical industry and patient groups, but also charities funding non-commercial research, actively campaigned for making drugs available. Large charities such as Cancer Research UK and Macmillan Cancer Support are among the most resourceful organisations in the entire UK non-profit sector.[263] The mobilisation of these actors for publicity campaigns on the issue helped to raise public attention to it.

To further probe the role of public attention in policy development, and in particular attention to NICE and NICE's guidance for cancer drugs therein, I examine newspaper coverage. This provides a simple but useful proxy to capture variation in salience and public attention to a given issue (cf. Baumgartner and Jones 2010). Figure 4.4 shows longitudinal trends in newspaper coverage related to NICE and NICE's activities in selected disease areas. I use the sum of coverage in *The Times* and *The Guardian*, two national broadsheet papers, to measure the level of public attention. The use of two papers with different ideological orientations -- usually associated with the centre-right and centre-left respectively – has an advantage in tackling biases due to a news source compared to relying on a single one. In terms of disease areas, I look at coverage related to NICE's activities on cancer, Alzheimer's disease, and multiple sclerosis -- three major disease areas in which NICE performed technology appraisal for expensive new drugs and that dominantly affect different types of patient population (mortal, old but not mortal, and predominantly young and chronic respectively) -- and diabetes, a major chronic disease that also affects the risk of several other diseases and hence the subject of a number of NICE's clinical guidelines and public health-related activities in addition to its technology appraisal. To count the newspaper coverage for each topic I first performed searches in each newspaper's database on LexisNexis and then excluded articles unrelated to NICE's work (e.g. Queen's honours, obituaries except those of patient campaigners).

[263] As of writing, both are within top 30 charities in total income. Source: The Charity Commission. http://apps.charitycommission.gov.uk/Showcharity/RegisterOfCharities/SectorData/Top10Charities.aspx

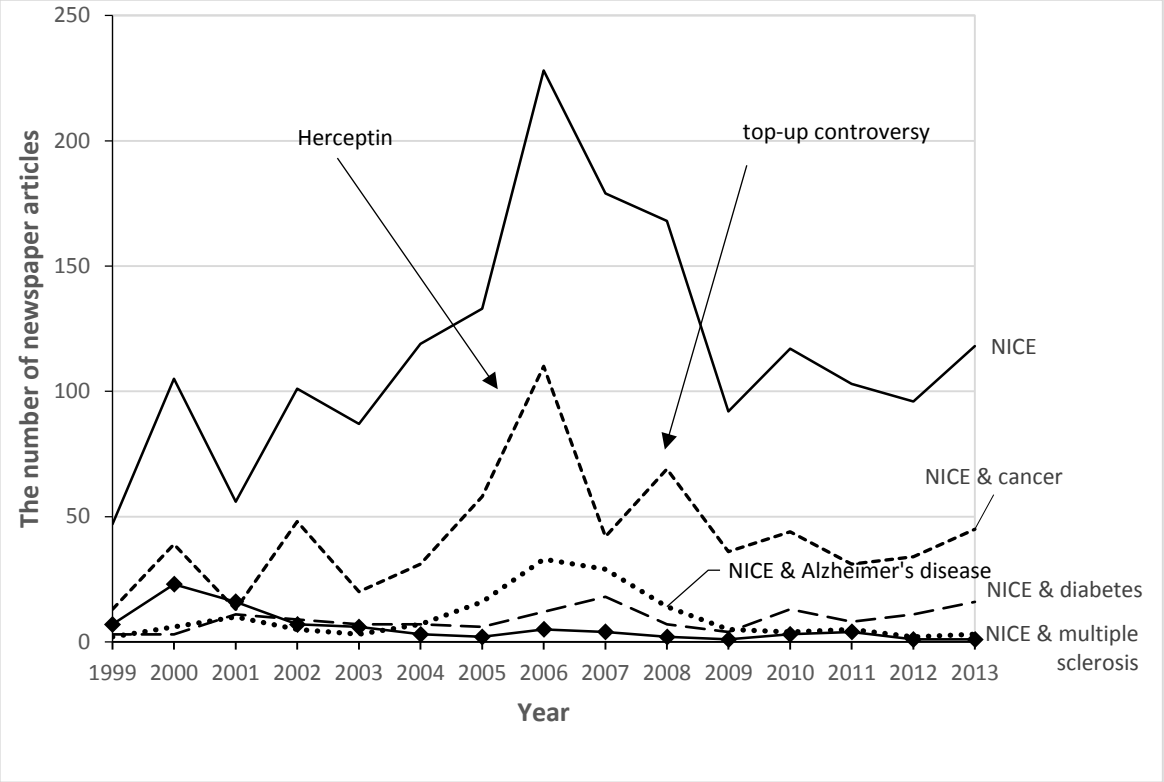

Figure 4.4 Newspaper coverage in *The Times* and *The Guardian*

Source: author's elaboration based on LexisNexis

Several observations stand out. First, the longitudinal trends suggest that NICE drew a significant level of public attention over time but the coverage related to its activities on cancer pushed up the overall coverage of the agency. Within NICE's activities, cancer captured much more significant attention than any other disease areas. Each year, the newspaper coverage on NICE's cancer-related activities accounts for from approximately a quarter to a half of the coverage on NICE as a whole. This hence suggests the special status of cancer in public debates on NICE. Second, the level of public attention appeared to be driven by NICE's guidance on a particular drug. For example, for both multiple sclerosis and Alzheimer's disease the peak year in newspaper coverage corresponds to high-profile cases of NICE's technology appraisal on particular drugs – guidance on beta interferon for multiple sclerosis (2000-2002) and on Alzheimer's disease drugs and a subsequent judicial review on one of them (Aricept, or donepezil) (2006-2007). Apart from these years, public attention to NICE's work in these disease areas was waned. Public attention was hence at least partially endogenous to NICE's guidance; in other words, NICE's guidance triggered public attention. This interpretation also leads us to expect that the exceptionally high level of issue salience in

NICE's activities on cancer compared to other disease areas may not only be due to public attention to cancer per se but also because of NICE's outputs on cancer drugs. Third, and related to this, while NICE's activities on cancer was always important in terms of public attention, the level of issue salience became particularly unprecedented after 2005 and then stayed high throughout the latter half of the 2000s, with its peak being reached in 2006. Indeed, as the rest of the section details, controversies that NICE's activities evoked in the public arena played a significant role in policy development.

A faster guidance: The introduction of Single Technology Appraisal

The timeliness of NICE's appraisal guidance was the subject of policy debates since its early years. As early as 2000, the ABPI had demanded the government to tackle "NICE blight" by pressing local health authorities not to use the lack of NICE guidance as an excuse to issue blanket bans on the drugs awaiting its appraisal.[264] Patient groups made a similar demand.[265] The HoCHC took up the criticism about slow appraisal in its 2002 inquiry into NICE, recommending the agency rearrange its work programme to enable the publication of its guidance closer to the time of drug approval; another inquiry in early 2005 recommended increasing NICE's budget to speed up the process.[266] For its part, NICE underlined the necessity of an early referral to carry out appraisals in parallel to the licensing process, while rejecting curtailing parts of the appraisal process, which, Rawlins argued before the Committee, would lead to less robust judgments or damaging stakeholder participation.[267] Yet tensions were building up. Patient groups criticised NICE over several treatments awaiting guidance. A charity, Cancer BACUP, argued that as of September 2005 there were 23 licensed cancer treatments pending NICE guidance, some of which were due for completion only in 2007.[268]

In November 2005, NICE announced the introduction of a new rapid process, the Single Technology Appraisal (STA). Unlike the existing MTA, which compared several technologies, under STA the NICE appraisal committee would produce guidance for a single drug for a

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[264] "ABPI proposals for NICE, which says it has raised NHS bill by well over L130", *Pharma Marketletter* 30 November 2000.
[265] E.g. Memorandum by Cancer BACUP (NC 26), in HoCHC 2002b, Ev 49.
[266] HoCHC 2002a, 20; HoCHC 2005a, 109.
[267] Rawlins, in HoCHC 2005b (HC 42-II), Ev 369 Q896; see also HoCHC 2002a, 20; HoCHC 2002b, Ev 131 Q374.
[268] Eaton 2005; "UK cancer charity urges NICE reform, as a "life or death issue" for patients" *Pharma Marketletter* 20 September 2005; *The Independent* 21 September 2005. Cf. *The Guardian* 26 May 2005; *The Daily Telegraph* 26 May 2005.

single indication based on the submission from the manufacturer. An independent academic group, the Evidence Review Group, then would assess – or "critique", as several informants around NICE described it – the manufacturer's propositions about the drug's clinical and cost-effectiveness. The process would enable NICE to issue faster guidance, not only because it involved an individual medicine but also because NICE would use a drug company's data as opposed to published materials that were available only after the completion of drug approval. NICE expected that under STA it would develop guidance within 6 months, a much faster timeframe than the existing MTA, which typically took 18 months.

The Single Technology Appraisal process was designed for, and in practice applied to, any technologies for single indications, but cancer drugs had a special weight in its introduction. In both the announcement of STA and the earlier statement made in September that year when NICE's Board agreed to submit a proposal to the Department of Health, the agency's chief executive Andrew Dillon emphasised NICE's responsiveness to criticisms of its slow appraisal process, while explicitly referring to cancer drugs: "We have listened to what patients and healthcare professionals have told us about the need for timely advice on the use of new medicines, particularly for life-threatening conditions such as cancer."[269] This was not merely a rhetorical justification of a new programme; among the first 14 drugs that STA was initially applied to, 13 were cancer drugs.[270]

In fact, NICE's announcement of the launch of STA was made amid an unprecedented level of public controversy around a particular drug: Herceptin (trastuzumab) for the treatment of early stage breast cancer – one of the first drugs that the STA process was used for.[271] Manufactured by Roche, Herceptin was a new generation of targeted therapy that attached a particular protein called HER-2 to interfere with the growth of cancer cells; it was widely seen as a major breakthrough in breast cancer treatment. NICE recommended the drug in 2002 for use in women with advanced metastatic breast cancer; for women with early-stage breast cancer, manufacturer-commissioned clinical trials subsequently discovered a dramatic response. Following Roche's announcement of the trial results in May 2005, patient groups launched a major media campaign to press the government to make Herceptin available as soon as possible. A surge in demand for the drug followed, although at that time Herceptin

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[269] *The Times* September 24, 2005; *BBC News* 23 September 2005.
[270] Mayor 2005; "UK NICE to fast-track major drugs", *Pharma Marketletter* 3 November 2005.
[271] For a detailed timeline of the controversy around Herceptin, see Wood 2014; Syrett 2007, 5-9; Wilson et al. 2008.

had neither been licensed for early-stage breast cancer nor had Roche even submitted evidence for drug approval. The publicity of the issue was escalated in early autumn, when local PCTs rejected a number of requests to fund Herceptin from patients with early-stage breast cancer. A high profile case of a PCT reversing its initial refusal after a patient threatened legal action particularly grabbed media headlines. There was also a notably high level of pressure from elected officials. In July, the government made an early referral of Herceptin to NICE, ahead of its normal work programme, together with Velcade (bortezomib) for multiple myeloma, so that NICE would start preliminary work on developing guidance and issue it as soon as the drug was licensed.[272] As the public pressure reached its peak, Health Secretary Patricia Hewitt promised in October that all early-stage breast cancer patients would have access to the test to assess whether they would benefit from Herceptin.[273] Hewitt declared: "I want the licence for Herceptin to be granted as quickly as possible [...] and to be available within weeks of the licence being given. I share the huge frustration of many women about the delays in getting Herceptin licensed".[274] She also stated that trusts should not refuse to fund Herceptin solely on the grounds of cost.[275] In early November, a PCT reversed its earlier decision not to fund Herceptin after Hewitt demanded the evidence base of the decision and called a meeting with the PCT officials.[276] NICE's announcement on the introduction of STA was thus only weeks after Hewitt's intervention into PCTs. It began appraisal the following February, when Roche submitted an application to the European Medicines Agency. In early June, within weeks of the drug being licensed (itself a "record time"[277] in the EMA's speed of evaluation), NICE released draft guidance that recommended Herceptin for women with early-stage HER-2 positive breast cancer; the final guidance was issued in August.

It is worth noting that Herceptin was clearly an exceptional moment in both levels of public pressure and political intervention in the history of NICE. While cancer patient groups welcomed Hewitt's action, the opposition party and later the bipartisan Health Committee criticised it for undermining NICE's independence by making it difficult not to recommend

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[272] "UK fast-tracks Velcade, Herceptin through NICE" *Pharma Marketletter* 21 July 2005; "Two cancer drugs referred early for NICE evaluation" *Pharmaceutical Journal* 29 July 2005. *BBC News* 21 July 2005.
[273] *Financial Times* 6 October 2005
[274] Quoted in Wood 2014, 12; *The Independent* 6 October 2005; *The Times* 6 October 2005.
[275] *The Guardian* 26 October 2005; *The Times* 10 November 2005; *The Independent* 10 November 2005.
[276] *The Guardian* 9 and 10 November 2005; *The Daily Telegraph* 9 November 2005; *The Independent* 9 November 2005.
[277] *The Independent* 28 April 2006.

the drug.[278] Contrary to the concern several expressed at the time, the kind of intervention that Hewitt took did not become a precedent, and little evidence suggests that a similar ministerial intervention took place in other appraisals. Thus, Herceptin did not change the high political insulation in the drug funding decision-making process.

Yet, the exceptionally high level of public controversy around the speed of drug appraisal in general, and cancer drugs such as Herceptin in particular, helped the agency to justify the introduction of the new programme. To be sure, the introduction of STA was not without criticism. Unlike the comprehensive appraisal based on a systematic literature review that characterised MTA, STA's evidence base was solely the manufacturer's submission on clinical and cost-effectiveness. While this enabled NICE to use confidential data held by the manufacturer, since the manufacture may try to underestimate ICER to get a positive recommendation, concerns were raised about the possibility of biased or less robust appraisal.[279] Given the high stakes for its credibility and robustness and its earlier defence against shortcutting the appraisal process, NICE would change the process only when the pressure led it to believe that its existing process was no longer justifiable. This is not to argue that NICE began developing STA as a response to Herceptin; it is also not an argument that ministerial intervention prompted NICE to develop a new process – this is unlikely, as the NICE Board was presented with a proposal for STA in September, before Hewitt's October intervention with PCTs. Rather, a regulator could risk inducing a change that could potentially damage its appearance on credibility only when a greater cost of non-action might justify the change. NICE was hence not willing to change its practices until it confronted the exceptional intensity in public controversy around Herceptin.

Cancer Reform Strategy and the expansion of STA

The public controversies over NICE's practices were hardly diminished after the introduction of STA. If the exceptional intensity of the Herceptin controversy affected the introduction of STA, the subsequent debates over cancer drug availability further contributed to its expansion. Specifically, debates over the UK's cancer mortality fuelled controversies

[278] HoCHC 2007, 9.
[279] Walker et al. 2007; interview with a former NICE appraisal commmittee member 03.05.2018.

about attributing the blame for lagging cancer drug access and cancer survival to NICE, while policymakers' responses to them led to the expansion of the faster STA process.

In the late 1990s, the Blair government identified the fight against cancer as a prioritised policy problem. Similar to health care rationing, it found a significant regional variation in cancer care performance. The government appointed a prominent cancer physician and academic, Mike Richards, as the National Director for Cancer (dubbed the "Cancer Tsar") to draw up a comprehensive strategy, from prevention, diagnosis to treatment, to improve cancer care. The 10-year Cancer Plan was announced in 2000. NHS cancer care improved in the subsequent years. The National Audit Office's inquiry in 2005 confirmed substantial progress in a range of areas.[280] Richards' 2006 report likewise found that the use of cancer drugs had risen steeply since 2004, with less regional variation.[281] Cancer charities pressed the government to update the cancer plan, and in late 2006 the review process was started.[282]

However, as NICE's guidance provoked contestation, especially since the mid-2000s, the issue of its guidance on cancer drugs became increasingly debated in connection to a persistently higher cancer mortality rate than other European countries. Those who contested technology appraisal and access to new drugs attempted to frame the speed and negative judgement of NICE's guidance as cross-national "health inequality". A watershed in establishing such a connection was the publication of a report in 2005, which highlighted the relationship between patients' access to newly-launched cancer drugs and survival rates. The study, funded by Roche and presented at the European Parliament, was carried out by researchers from the Stockholm School of Economics and the Karolinska Institute in Sweden. The Karolinska Report highlighted "imbalance and inequality" in patients' access to new cancer drugs across Europe depending on the country of residence. Using the cancer mortality database which had resulted from the EUROCARE project, a European Cancer Registry-based study on survival and care of cancer patients, they found that later drug vintage was associated with the increase of the cancer survival rate.[283]

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[280] NAO 2005, 4ff; *The Times* 11 March 2005.
[281] "Richards claims improved cancer drug uptake", *HSJ* 28 September 2006; *The Times* 20 September 2006;
[282] *The Guardian*, 30 November, 2006.
[283] Jönsson and Wilking 2007, Chapter 7. EUROCARE is a multi-wave, international collaborative project for surveying cancer mortality and care for 67 disease groups in cancer.

Throughout the report, the authors were explicitly critical of Britain, especially NICE. Noting that "[n]owhere in the world is the decisive role played by economic evaluations more evident than in the UK," they claimed that NICE's capacity to cope with the growing workload for review and the failure of budgetary allocation to new drugs during the NICE review process "le[d] to further delay for cancer patients in the UK getting access to new innovative drug therapies and this is clearly demonstrated by the comparison of the UK with other countries studied in the report".[284] The report thus maintained, "It was the explicit objective of Nice to avoid any significant delays in bringing innovations to market in the UK. There is yet no evidence that this objective is met".[285]

The Karolinska Report gained wide coverage in the UK media. The timing of publication, which coincided with Patricia Hewitt's intervention on the Herceptin case, capitalised on its news value. The media criticised an "excessive bureaucracy and penny-pinching attitude to life-saving drugs".[286] The media scramble resurged in May 2007 when the updated version of the Report was published in an oncology journal. This time, following the controversies over Herceptin and the ongoing reform agenda on the Cancer Plan, the public attention paid to the issue was even higher.[287] Newspapers, both broadsheets and tabloids, spread the narrative of the "sick man of Europe for providing cancer drugs":[288] Britain was "bottom of the league", and "worst in western Europe" [289] in cancer survival rates, because "British patients are being denied access to life-saving cancer drugs that are widely available in the rest of Europe and the developed world".[290] Although the Karolisnka Report relied on the existing EUROCARE dataset for survival rates, and therefore its key findings were not about the mortality itself, the media played a considerable role in disseminating knowledge not only on drug access but also on lagging survival rates.

The way that newspapers reported the news varied largely along their ideological orientation. Whereas the papers usually associated as right to centre-right drew a rather

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[284] Ibid, iii5
[285] Ibid, iii4.
[286] *The Independent*, 4 October, 2005
[287] The average length of the initial report by three broadsheet newspapers (*The Daily Telegraph*, *The Independent*, *The Guardian*) of the results of the Karolinska Report was 321 words for its original 2005 version; it jumped to 769 words for the 2007 version.
[288] *The Independent*, 10 May, 2007.
[289] Headlines of *The Daily Mail*, 10 May, 2007 (capitalised in original) and of *The Daily Telegraph*, 10 May, 2007, respectively.
[290] *The Independent*, 10 May, 2007.

negative image, the blaming tone was somewhat moderated in coverage by the centre-left *Guardian*. It put down the Karolinska Report with a critical comment from a researcher at the healthcare think tank The King's Fund, who said that "Roche and other drug companies wanted Nice scrapped in order to increase their profits".[291] Yet this kind of remark remained the minority among the overall coverage. The negative tone was not limited to media with a clear pro-Conservative orientation. The *BBC News* headline for the initial report read: "UK 'worst' on cancer drug access."[292] It asked, "Why France is so good at cancer care", where, in addition to the difference in waiting time, it identified access to new cancer medicines as "perhaps the starkest difference in treatment between France and the UK". [293]

In contrast to the media reaction, expert communities reacted to the report in a rather critical tone. Several articles and commentaries questioned it, from its measurement, model and estimation, to its interpretation.[294] As the research was funded by Roche, some also pointed to the commercial motivation behind the report.[295] NICE shared this perception in an attempt at defending itself from the mounting criticisms. NICE's chief executive Andrew Dillon hence publicly condemned the report: "This drug industry-sponsored report is flawed, inaccurate and directly contradicts itself in places'.[296] He pointed to a faster appraisal achieved through Single Technology Appraisal and NICE's implementation programme that assisted PCTs' funding of NICE-recommended technologies.

A further blow to the government came about in August, when results of the latest wave of EUROCARE were released. The results were for two cohorts of patients diagnosed in 1995-1999 and in 2000-2002, meaning that the wave covered patients treated under the early phase of the Cancer Plan, and policymakers hoped for a closing of the gap in the survival rate with other European countries. However, it was revealed that survival rates for several major areas

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[291] *The Guardian*, 10 May, 2007.
[292] *BBC News*, 10 May, 2007
[293] *BBC News*, 17 May, 2007. It is worth noting, however, that the way that BBC framed the issue seems to have changed after this initial reaction. Following the release of results of EUROCARE in August (see below), its news report "Why is the UK lagging on cancer?" emphasised the availability of specialist surgeons and radiotherapy specialists and equipment – a view closer to the position of Mike Richards. It also reported "despair among some cancer specialists that the public gets so agitated about the provision of new cancer drugs while radiotherapy frequently gets short shrift". *BBC News*, 21 August, 2007.
[294] See e.g. Coleman 2006.
[295] Willyard 2007; Coombes 2007.
[296] Quoted in "NICE attacks 'flawed and inaccurate' cancer report", *Pharmafile* May 20, 2007; "UK is "worst country in Europe" for some cancers, the NICE receives most blame", *Pharma Marketletter* 14 May 2007; *Financial Times* 27 August 2007.

of cancer in England remained lower than the European average. Moreover, despite the Cancer Plan, the increase in survival rate remained similar to other countries, without catching up with them. The results inevitably led to questioning performance of cancer policies. As the editor of *The Lancet Oncology* maintained, "Overall, survival for all cancers combined in the UK as a whole is not only below the European average, it is also noticeably similar to some eastern European countries that spend less than one third of the UK's per capita healthcare budget".[297] Not surprisingly, the results again fuelled newspaper reports and parliamentary debates.

The debates over causes of cancer survival rate could have had immediate impacts on policy agenda on cancer, as the Cancer Reform Strategy drafting process, to update the 2000 Cancer Plan, had been underway since the beginning of the year. Yet, key figures reviewing the Cancer Plan did not believe that the uptake of the latest drugs accounted for survival rates. A week after the publication of the Karolinska Report, Cancer Research UK, a charity that formed a partnership role with the government in the review, set out policy goals to be achieved by 2020. In the announcement, the charity highlighted that in the past ten years the cancer survival rate had indicated its sharpest rise since 1971. Referring to the Karolinska Report's criticism, the charity's chief executive nonetheless emphasised "significant improvement".[298] Likewise, while National Cancer Director Mike Richards maintained the necessity of speeding up the appraisal process, he also commented, "Drugs are only one part of the answer." He instead stressed the importance of screening and early detection, based on the idea that the UK's poor results were largely attributable to patients diagnosed at the advanced stage.[299]

This perception of the incumbent policymakers was reflected in the Cancer Reform Strategy announced in December. While acknowledging improvements made since the Cancer Plan, it set out a wider range of goals than the first Plan. It reiterated Richards's idea of prevention and earlier diagnosis as a key to improve survival rates. With regard to treatments, it stressed surgery, pointing out that it cures more patients than any other interventions; an emphasis was also placed on radiotherapy treatment. As to access to chemotherapy drugs, the Strategy largely maintained the existing policy orientation, but advanced an important

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[297] *The Lancet Oncology* 2007.
[298] Cancer Research UK, "Vision for 2020 launched as ten-year survival for cancer doubles in 30 years", May 15, 2007. http://www.cancerresearchuk.org/about-us/cancer-news/press-release/2007-05-15-vision-for-2020-launched-as-ten-year-survival-for-cancer-doubles-in-30-years
[299] Richards 2007. *The Guardian*, 16 May, 2007; *The Independent*, 16 May, 2007; *Financial Times*, 16 May, 2007

proposal. It recommended that, "as a default position all new cancer drugs and significant new licensed indications will be referred to NICE".[300] Acknowledging NICE's effort to improve guidance timeliness via the Single Technology Appraisal, it recommended that the government should "ensure that all appropriate cancer treatments are considered by the Single Technology Appraisal process and that this process works as effectively as possible."[301] The use of STA pledged in the Strategy thus reinforced the policy orientation for rapid appraisal of new drugs. Within the next few years, as Figure 4.4 shows, STA came to be dominant in NICE's technology appraisal programme.

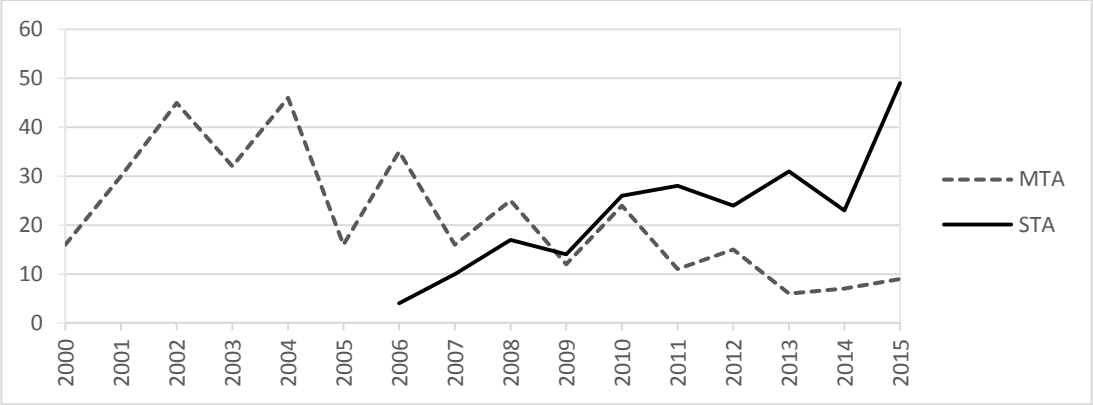

Figure 4.5 The number of technologies processed through rapid Single Technology Appraisal and Multiple Technology Appraisal

Source: author's elaboration based on NICE website information. Note that the graph shows the number of technologies rather than of guidances; since an MTA, by definition, contains several technologies, the dominance of STA can be even starker in terms of the number of guidances.

Thus, the review of the Cancer Plan reinforced both the policy agendas and controversies mediated by public arena. The Cancer Reform Strategy expanded NICE's work on cancer drugs and in particular the use of STA. Moreover, while the controversy over the relationship between cancer mortality and drug access did not result in immediate changes, it shaped subsequent policy debates by drawing public attention to the comparison of UK healthcare's performance with other countries. The contestation took place by offering an interpretation

[300] DH 2007, 64. Bold in original.
[301] Ibid.

about why the UK was lagging in cancer survival rates. It further strengthened the public debate that blamed NICE as a barrier to drug access.

Drug access and the "top-up" controversy

The public controversy over cancer drug availability was further intensified and prompted changes for greater availability through the issue of so-called "top-up" payments. Under the NHS, a patient has to be either a private patient or an NHS patient who receives publicly-funded free treatments for a single visit. In other words, they cannot mix public and private funding by paying privately for certain parts of treatment on top of NHS treatments – or making "top-up" payments. This prohibition of top-up payments was claimed to be based on the founding principle of the NHS in 1948 that "care should be provided to all on the basis of need and not according to ability to pay", which was also stipulated in the Department's code of conduct.[302] However, this ban became subject to public debates as a growing number of patients pressed to obtain the treatments that NICE did not recommend or PCTs refused to fund. For the drugs not recommended or not yet apprised by NICE, local PCTs made funding decisions. If clinicians wished to prescribe the drugs unavailable on the NHS, they could apply to local PCTs for so-called "exceptional funding". Yet in the cases where PCTs declined requests from clinicians, it could lead to demands for private payment while maintaining entitlement to NHS care.

Some patient groups and clinicians had pressed for a reform to lift a ban on top-up payments, which became vocal since the mid-2000s. In 2006, Doctors for Reform, a group of 900 NHS doctors critical of government health policies and supported by a market-oriented think tank Reform, sent an open letter to Prime Minister Tony Blair, calling for an urgent review of the NHS funding structure. It argued that the current tax-funded system would be unsustainable to meet growing patients' needs. It advocated a "mixed-funding system" by drawing on examples of social insurance systems in continental Europe such as France and Germany, which it considered to have more equitable services and higher standards.[303] Health Minister Patricia Hewitt rejected the idea; so did the British Medical Association (BMA) at its annual meeting, on the grounds of continuation of the NHS' "free at the point of delivery" founding

[302] HoCHC (HC194-I) 2009, 13. It was not a written as Direction, thus not legally binding. PCTs can use their discretionary power to accept or reject the guidance.
[303] *The Guardian* 3 April; 5 April, 2006; *The Independent*, 3 April, 2006. *BBC News*, 3 April, 2006.

principle.[304] The advocacy of the group continued. In a report published in 2007, they claimed that free at the point of delivery was a "political mirage", as top-up payments became a growing reality on an ad hoc basis through cases where patients sought to privately receive additional treatments. The group argued, "Without reform to health funding, the use of 'top up' payments is likely to increase due to the upwards pressure on medical costs, the limits to tax financing and, most importantly, the increasing importance of consumer choice".[305]

Throughout the campaign, again, cancer drugs not recommended by NICE became the vantage point. Some private insurance providers announced a scheme for top-up payments that specifically applied to cancer drugs unavailable on the NHS.[306] Tensions grew as it was reported that some patients were planning to take legal action against their PCTs to obtain the right to receive a cancer drug, Avastin (bevacizumab), not yet recommended by NICE.[307] They claimed that they had been threatened with the withdrawal of NHS care if they sought to receive Avastin. The Patients Association backed the legal action. The support was not limited to the patients' side; the NHS Confederation, which represented NHS hospital managers, expressed sympathy saying that denying care for receiving private drugs was "perverse" and against "common sense".[308]

The campaigns for top-up payments gained further momentum in early June 2008. It was triggered by media reports of a bowel cancer patient's death after being withdrawn from free NHS treatments because she had privately purchased a cancer drug, Erbitux (cetuximab), which was neither recommended by NICE and nor NHS-funded – a case subsequently taken up in the House of Commons by a Conservative MP who was also a former shadow health minister.[309] Both the Department of Health and ministers initially denied the possibility of reform, claiming that it would create a two-tier health service.[310] However, facing mounting pressure, Health Secretary Alan Johnson soon changed his position and announced that he had asked Cancer Tsar Mike Richards for a review on top-up payments.[311]

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[304] *The Guardian* 5 April, 2006.
[305] Quoted in *BBC News*, April 23 2007; See Charlson et al. 2007; *The Independent* 23 April, 2007.
[306] *Financial Times*, 29 September 2007.
[307] *The Sunday Times*, 16 December 2007; 26 December 2007; 6 January 2008.
[308] *The Sunday Times*, 23 December.
[309] cf. *The Guardian*, 2 June 2008. See also *Hansard*, 10 June 2008, Columns 50-58WH.
[310] The *Independent* 18 June 2008; *The Daily Telegraph* 14 June 2008; *The Guardian* 18 June 2008.
[311] See *Hansard* 17, June 2008 Columns 787. According to the *Financial Times* (16 June, 2008), there was a signal from Downing Street to change the initial position.

The top-up payments debate inevitably touched upon the issue of whether the NHS's core principle, "free at the point of delivery, regardless of the ability to pay", could be maintained if top-ups were allowed – an issue that Richards himself addressed in the review, by noting that the heart of the issue was the tension between equity and patients' autonomy since the inception of the NHS.[312] Those sympathetic with the core principle of the NHS repeatedly expressed the concern that allowing top-up payments would pave the way for a two-tier health system.

The debate reached its peak in the summer. NICE draft guidance issued in August further fuelled the controversy as it rejected four cancer drugs for renal cell carcinoma on the grounds of insufficient cost-effectiveness.[313] Patients' groups and the pharmaceutical industry pressed for permitting top-up payments. Although the medical professions were "overwhelmingly in favour"[314] of top-ups, the issue was still controversial among them. At its annual conference the BMA voted in favour of a motion that "patients should have the choice to buy additional treatment that is not available on the NHS without being forced to pay for all their treatment privately". But it rejected another motion, with a narrow margin (49.8% vs 50.2%), to demand the government to introduce co-payment immediately. Instead they called for a Royal Commission to review the issue and to allow for wider debate.[315]

Patient groups and charities were also divided. Those who opposed top-up payments argued that the NHS as a whole should be improved so that all patients could get access to these drugs.[316] Some patient groups were actively involved in defining the policy problem. For instance, in its survey Rarer Cancer Forum found a significant variation among PCTs in both the processing of exceptional funding requests and their outcomes, with approval rates ranging from 0 to 100%.[317] It advocated policy reform of NICE to accommodate new cancer drugs,

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[312] Richards 2008, 2.
[313] The four drugs were Roche's Avastin, Beyer's Nexavar (sorafenib), Pfizer's Sutent (sunitinib), and Wyeth's Torisel (temsirolimus). NICE further rejected Revlimid (lenalidemide) for multiple myeloma in October – weeks before the Richards' report was issued.
[314] Richards 2008, 67.
[315] BMA, "Doctors call for Royal Commission to review co-payments", BMA Press Release Archives. http://web.bma.org.uk/pressrel.nsf/wall/1E17A1E156B044DB80257481004D1F59?OpenDocument (Accessed 25 June 2018) See also *The Guardian* 10 July, 2007.
[316] Richards 2008, 67.
[317] The Rarer Cancer Forum, "Taking exceptions: an audit of the policies and processes used by PCTs to determine exceptional funding requests." August 2008.

based on the finding that a significant proportion of exceptional funding requests were for the latest generation. These results were again widely reported.

Political parties' responses also varied. The Liberal Democrats were the first major party to express support for top-up payments.[318] The Conservatives took a notably more cautious approach; their white paper for NHS reform published a year before had denied top-up payments.[319] In the wake of the controversy, though the leader David Cameron reportedly said that he was "tempted" to support top-up payments,[320] the party did not make statement until it finally reversed its previous policy and backed the top-ups.[321] Instead, it launched its own consultation on top-up payments. As we shall see, this inquiry would lead to an electoral pledge to overhaul both NICE and drug pricing.

With more than 400 stakeholder consultation responses, Richards' report released in November addressed the availability of drugs on the NHS. From the outset, Richards explicitly rejected the idea advanced by "a small minority of shareholders" that allowing top-ups would be "a precursor to moving towards an insurance-based system".[322] He instead proposed "a clear framework for how the NHS should handle situations where patients might wish to purchase additional drugs, but also to keep to an absolute minimum the number of patients who will be placed in this position in the future by ensuring that the NHS provides as many clinically effective drugs as possible on the NHS."[323] Thus on the one hand, Richards discussed PCTs' administration of the exceptional funding process and in particular arrangements of top-up payments. But on the other hand, as the title of the report -- *Improving Access to Medicines for NHS Patients* -- suggested, Richards considered the policy problem not only a matter of NHS management but also of drug access. He hence set out an agenda for providing "as many clinically effective drugs as possible on the NHS".

The call to minimise the number of the patients purchasing top-up payments was based not only on results of stakeholder consultation, where the majority of respondents supported comprehensive care within the NHS, but also on policymakers' perception of the scale of the

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[318] *The Times*, 9 September, 2008; *The Guardian* 12 September 2008.
[319] *The Daily Telegraph*, 20 June 2007.
[320] *The Independent* 10 June 2008; The Sunday Times 8 June 2008; *The Daily Telegraph* 10 June 2008; Cf. *The Sunday Times*, 1 June, 2008. Several reports interpreted this deliberate non-commitment to top-ups as Cameron's strategy for positioning the party so that it was not seen as a party of the middle class.
[321] *The Sunday Times* 28 September 2008.
[322] Richards 2008, 2.
[323] Ibid.

issue. According to the Department of Health's survey that the report drew on, it was estimated that there were 15,000 patients each year who asked PCTs for exceptional funding for around 50 drugs, of which 30 were for the treatment of cancer. The largest portion of such requests was for the drugs which NICE had not yet issued technology appraisal guidance on. Richards went on to conclude, "Application for off-label use are largely related to non-cancerous conditions and are numerous. True 'exceptional case' requests for drugs that have been declined by NICE appear to be uncommon".[324]

The fact that the largest category of exceptional funding applications was for drugs not yet appraised by NICE therefore led to reiteration of the idea that speeding up NICE's appraisal process was "extremely welcome" and "strongly supported".[325] By this time, the government's view on the speed of NICE's guidance had converged. When the report was presented, Alan Johnson made a commitment to Parliament that by 2010 NICE would achieve a timeline for issuing technology appraisal guidance as short as six months after receiving an appraisal reference.[326] The controversy over top-up payments thus further reinforced the agenda for faster NICE appraisals.

Perhaps more importantly, the review for top-up payment opened a pathway to policy change. It yielded two immediate modifications. First, Richards' report advocated a "greater flexibility" in NICE's guidance on drugs used near the end of life. This claim was based on the "common perception" that "the value that society places on supporting patients nearing the end of their life is not sufficiently reflected in assessing the cost-effectiveness of new drugs".[327] In response to the recommendation, NICE developed End-of-Life (EoL) criteria in late 2008. It clarified appraisal criteria specifically for drugs for terminal illnesses affecting small numbers of patients. More specifically, it suggested that above £30,000 per QALY, EoL criteria should be applied if (a) the treatment is indicated for patients with a short life expectancy (normally less than 24 months), (b) the treatment offers extension of life (normally

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[324] Richards 2008, 16. Contrary to the high-profile media coverage, the number of withdrawals from NHS care was also limited: at the HoCHC inquiry in the following year, Richards and others stated that there were around 18 cases where PCTs withdrew treatments because patients had purchased additional drugs. Some MPs thus criticised the government for introducing a measure that would potentially form a two-tier health system despite a very small number of cases involved. HoCHC 2009, 14-16.
[325] Richards 2008, 3.
[326] *Hansard*, 4 November 2008, Column 132.
[327] Richards 2008, 42

at least an additional 3 months) compared with current NHS treatments, and (c) the treatments is indicated for small patient populations.[328]

In introducing EoL criteria, NICE developed justifications built around the existing practice in value judgements. As NICE's chair Michael Rawlins clarified before the HoCHC, the NICE appraisal committee had been given "latitude to go above and below it [the threshold of £20,000-30,000 cost per QALY] and that the guidance had made this approach clearer".[329] EoL criteria were intended to make this practice explicit by creating a set of codified rules. At the same time, despite criticism, Rawlins and others around NICE cautiously rejected raising the normal threshold of £20,000-£30,000 per QALY.[330] From NICE's perspective, consideration of EoL fell within the conditions that appraisal committees would give "special weighting" when making judgements of cost-effectiveness.[331] By framing EoL criteria in this way, NICE managed to maintain its strategy of justification based on the consistent application of explicit doctrines.

But what circumstances would justify "special weighting" or "greater flexibility"? NICE's justification was, in line with the Richards report's claim mentioned earlier, that the public place special value on treatments that extend life at the end of life.[332] NICE also drew on its Citizen's Council's meeting in November 2008 about the conditions under which appraisal can deviate from the cost-effectiveness threshold.[333] Such a rhetoric reflected its attempt at justifying policy change through an image of the regulator as responsive to public preferences.

Notwithstanding such a justification, the distributive consequences of the criteria remained controversial. The HoCHC's 2009 inquiry into top-up payments argued that the EoL criteria were "both inequitable and an inefficient use of resources. By spending more on end-of-life treatments for limited health gain, the NHS will spend less on other more cost-effective treatments."[334] This concern was not just theoretical but proved real when the appraisal

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[328] NICE, "Appraising life-extending, EOL treatments, final guidance", January 2009. For details of EoL criteria and practices, Chalkidou 2012.
[329] Cited in HoCHC 2009 (HC194-I), 35.
[330] Rawlins in HoCHC2009 (HC 194-I), Ev41 Q241. Interview with a former NICE appraisal committee, 03.05.2018 2018; Interview with a former NICE official, 04.05.2018. Interview with a NICE senior official, 12.07.2018.
[331] Rawlins et al. 2010, 348.
[332] Rawlins et al. 2010, 348; Interview with a NICE senior official, 12.07.2018.
[333] NICE 2009, 1.3; NICE Citizen's Council 2008, 4. Littlejohns et al. 2009, 421.; Interview with a former NICE official, 04.05.2018.
[334] HoCHC 2009, para 119.

committee began using EoL criteria in practice. Based on the appraisals completed between 2009 and 2011, one study estimates that EoL criteria resulted in substantial loss in QALY (5,933 per year); it cost £549 million annually to fund the drugs recommended based on the criteria.[335]

The other changes for "greater flexibility" that the Richards report recommended concerned approaches to pricing. Such flexibility should be achieved, it argued, in the context of negotiating the Pharmaceutical Price Regulation Scheme (PPRS). Since 2007, the Department of Health had been renegotiating the renewal of the PPRS with the ABPI. The recommendation for flexibility in pricing was also quickly realised. The agreement of the 2009 PPRS included the Patient Access Scheme, a mechanism designed to facilitate patients' access to the drugs that NICE would have otherwise judged as not cost-effective.[336] In fact, this was, too, built on the precedent. Under the label of a "risk-sharing scheme", the Department of Health and drug companies had agreed a mechanism to make a few drugs that were rejected by NICE available. The agreements for each drug were subject to future assessment, thereby mitigating the uncertainty associated with them at the time of launch. In 2002, NICE had rejected beta interferon and glatiramer acetate for the treatment of multiple sclerosis. The manufacturers and the Department of Health agreed to make the drugs available on the NHS as part of 10-year trials, or "monitoring studies", to collect data from clinical practice.[337] Another path-breaking example of a risk-sharing scheme would be the guidance for Velcade (bortezomib) for multiple myeloma in 2007. NICE initially rejected Velcade as the cost per QALY was too high (£38,000). The manufacturer, Janssen-Cilag, subsequently proposed a response-based rebate scheme, whereby the NHS would pay for patients who responded to Velcade; otherwise the manufacturer would pay. An agreement was reached and the proposal was incorporated in NICE's appraisal guidance. In its press-release NICE claimed that it saw risk-sharing schemes as a "win-win solution" for patients and the NHS.[338] It was these earlier

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[335] Collins and Latimer 2013.

[336] DH 2008c, 14ff. The Scheme includes several different mechanisms, from simple confidential discount, to rebate or discount linked to types or outcomes of patients, or doses of drugs.

[337] NICE, "Beta interferon and glatiramer acetate for the treatment of multiple sclerosis, NICE technological appraisal guidance 32", January 2002. http://www.nice.org.uk/guidance/ta32/resources/guidance-beta-interferon-and-glatiramer-acetate-for-the-treatment-of-multiple-sclerosis-pdf

[338] NICE, "NICE guidance on bortezomib (Velcade) is a win-win solution for multiple myeloma patients and the NHS", 27 October 2007. https://www.nice.org.uk/guidance/ta129/documents/2007056-nice-guidance-on-bortezomib-velcade-is-a-winwin-solution-for-multiple-myeloma-patients-and-the-nhs

projects that the PPRS drew on and generalised as the Patient Access Scheme.[339] Although the Department noted that the Patient Access Scheme was an "exception rather than the rule", the number of agreements under the scheme expanded in the subsequent years.[340]

The narrative presented here has highlighted the role of controversies in the public arena in policy change. Through a wider base of political mobilisation that brought politicians into their coalition, those who were sympathetic with the producer coalition successfully shifted ministers' initial position to lift the top-up ban, which led to policy change in drug rationing. Yet one may wonder to what extent NICE itself initiated the change. If Rawlins and NICE publicly stated, *after* the introduction of EoL criteria, that the public place special values on end-of-life drugs and that EoL criteria that went above the threshold were built on existing practices, did NICE also anticipate such change and informally adjust their behaviour *before* the Richards review took place? In such a scenario, recommendation by the Richards review might merely mean a formal endorsement of the changes in practice that NICE had already made. Considering this alternative interpretation is important for the chapter's argument, because it points to an alternative pathway to change. Rather than pressure from outside, via the public arena, leading to the change, according to this interpretation, the change occurred *from within*, either through direct lobbying of NICE or NICE's own anticipated reactions. What looked like a pathway to change through public arena mobilisation might, then, have merely been a spurious correlation.

To consider this possibility, it is useful to look at the cancer drugs for end-of-life conditions that NICE examined *just before* the completion of the Richards review of top-ups. This should serve as a "more likely" case of anticipated behavioural change by the regulator: given the heated debates that policymakers were already facing when the Health Secretary changed his initial position and launched a review of top-up payments, if NICE had anticipated such change and acted beforehand, we should observe some evidence of behavioural change in its appraisals.

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[339] Mike Richards also had these pilot cases in mind when he recommended formulating a more flexible approach to pricing. He explicitly mentioned the examples of Velcade and Lucentis (Ranibizumab) as schemes that the new approach could be based on. Richards 2008, 42. In the case of Lucentis for wet age-related muscular degeneration, NICE initially recommended that its use should not exceed 14 weeks. The subsequently agreed risk-sharing scheme provided that the manufacturer would pay after 14 weeks.

[340] As of June 2015, more than 50 drugs have been approved via Patient Access Schemes, recommended by NICE for NHS treatments. For the list of technologies approved, see: http://www.nice.org.uk/About/What-we-do/Patient-access-schemes-liaison-unit/List-of-technologies-with-approved-Patient-Access-Schemes

Yet, as already mentioned, in August 2008 at the height of debates over top-up payments, NICE's preliminary guidance rejected Sutent (sunitinib) for first-line treatment of advanced and/or metastatic renal cell cancer, alongside another three drugs. Following the introduction of EoL criteria in January 2009, NICE reconsidered its initial judgement to examine whether sunitinib for this condition met EoL criteria. In this case the risk-sharing scheme was also instructed, whereby the manufacturer Pfizer offered a 5% price cut and one free course of treatment (6 weeks), and the NHS would then pay for the treatment in responding patients. Although cost per QALY gained was still £72,000-105,000 per QALY (with a different assumption, £54,400 per QALY) when taking the scheme into account, NICE judged the drug met EoL criteria for the condition, and recommended its use.[341] The other cancer drugs rejected together with Sutent, and a drug rejected even later (Revlimid, or lenalidomide), were also subject to re-examination once the EoL criteria were introduced.[342] While hardly offering a definitive test, even this cursory look hence suggests that the appraisal committee was unlikely to adjust its behaviour before the completion of the Richards review. Indeed, the initial rejection of the drugs, which took place despite ongoing controversy outside the regulator, even further magnified the public controversies and pressures on the agency. NICE thus appeared not to change its policy choice, either until the agency's senior management realised existing practices were no longer justifiable in the face of even greater public and political pressures that the rejection of these drugs triggered, or when the Richards review instructed NICE to review its practice.

In sum, a series of public controversy over cancer drug availability led to gradual policy adjustments. These took place by codifying, clarifying, and thus in effect formally granting, exemptions applied to expensive drugs, especially those for end-of-life conditions such as cancer, alongside the existing technology appraisal.

4. Mobilisation in the electoral arena: The 2010 General Election and the Cancer Drugs Fund

[341] NICE, "Final appraisal determination: Sunitinib for the first-line treatment of advanced and/or metastatic renal cell carcinoma" 9 February 2009. https://www.nice.org.uk/guidance/ta169/documents/sunitinib-for-the-firstline-treatment-of-advanced-andor-metastatic-renal-cell-carcinoma-final-appraisal-determination3

[342] Among them, Revlimid was recommended whereas the other three were not. For an overview of the guidance of the drugs considered for EoL criteria, see Chalkidou 2012, 403.

The rise of public controversies over cancer drug availability over the course of the 2000s not only triggered the Labour government policy response. As the leaders of the opposition Conservative Party drew their attention to the controversy, they also developed reform agendas to capitalise on the issue for their own advantage. The Conservatives' pledge concerning the Cancer Drugs Fund for the 2010 general election was a product of such a response to the public controversies. Generated from the ongoing policy practices, the salient controversy over cancer drug access thus further prompted policy change through mobilisation channelled by the electoral arena.

Electoral pledges on health policy for the 2010 election revolved around the controversies that we saw in the 2000s over drug access, especially for cancer. Both Labour and the Conservatives considered cancer care an important electoral agenda. Consistent with existing policies in the Cancer Reform Strategy, the incumbent Labour Party's emphasis was on earlier diagnosis and intervention. They promised that patients in England would receive results of diagnostic tests for cancer within a week of referral.[343] For its part, the Conservative Party, led by David Cameron, proposed a specialised fund for cancer drugs, valued at £200 million a year, which would fund any cancer drugs licensed since 2005 and which had been recommended for a patient by a specialist.[344]

Both the significant level of public attention to cancer drug availability and the electoral incentive attached to it played a role in the genesis of the Conservative's proposal for the Cancer Drugs Fund. During the opposition years, shadow health secretary Andrew Lansley was a vocal critique of NICE and existing policies about drug access, including NICE blight.[345] This does not mean, however, that the Party was against the reinforcement of NICE in itself. On the contrary, its 2005 plan for NHS reform included expansion of NICE's remit to wider clinical standards of most aspects of healthcare. Lansley maintained "the bureaucratic 'risk' posed by a growth in NICE standards … would be obviated by the fact that they would be 'evidence-based', 'produced in part by those who have to implement them' and take into account 'cost-effectiveness'". [346] Its 2007 white paper proposed strengthening the operational independence of NICE by giving it a statutory base, which may have leveraged the criticism

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[343] Labour Party 2010, 4:3.
[344] *The Times* 6 April 2010; *Sunday Telegraph* 6 April 2010.
[345] For his criticism of UK's lagging cancer survival following the Karolinska Report's publication, see e.g. *Financial Times* 4 December, 2007; *The Daily Telegraph* 4 December 2007.
[346] "Lansley sets out NHS vision" *HSJ* 24 February 2005.

of the Health Secretary's intervention in the Herceptin case. While – perhaps reflecting the Party's past policies – the white paper emphasised bringing the funding decisions back to the hands of clinician-led local commissioning, apart from a general remark that NICE would continue to conduct appraisals of new drugs while "taking into account wider societal costs where appropriate", nothing in the plan suggested an overhaul of NICE especially related to the provision of cancer drugs.[347] Thus, a policy agenda specifically targeting the drugs for a particular disease area such as the Cancer Drugs Fund was likely to have taken shape only after the significant issue salience over cancer drug availability led to the shifting of the Labour government's positions in the late 2000s, where its electoral value drew Conservative leaders' attention with a general election on their horizon. As we shall see in the next chapter, following the general election Lansley unveiled a bold proposal for reforming the drug pricing and reimbursement system, which would fundamentally alter the roles of the government, NICE and the pharmaceutical industry in explicit drug rationing strategy. In this proposal, the Cancer Drugs Fund would be justified as a step towards the far-reaching reform.

Following the Conservatives' electoral victory and the formation of the coalition government with Liberal Democrats, the new government immediately turned the Cancer Drugs Fund pledge into reality. In July it announced the injection of an additional £50 million as an "emergency fund" until the launch of the Cancer Drugs Fund in April 2011. The fund was intended to cover anti-cancer drugs not approved by NICE. In announcing the introduction of the fund, Andrew Lansley, who was now the Health Secretary, noted: "I promised that I would help patients in England get cancer drugs that are readily available in the rest of Europe. It's a scandal that we are strong in cancer research and participation in clinical trials in the UK, yet NHS patients aren't always seeing the benefits from the research swiftly enough".[348] He hence highlighted findings of a report on cross-national variation in drug usage, which was commissioned by the Department of Health and led by England's National Cancer Director Mike Richards -- a mandate that resulted from his own 2008 review on top-up payments.[349] Presented alongside the announcement of the injection of the fund, the report highlighted significant gaps in drug uptake with other countries: among 14 developed countries, the UK

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[347] See Conservative Party 2007, 18.

[348] DH, "£50M additional funding for cancer drugs", Press Release, 27 July 2010. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_117970 The funding of £50 million was sourced by abolishing Labour's plan to provide free elderly care. *BBC News*, 27 July 2010; *The Guardian*, 27 July 2010.

[349] Richards 2010.

ranked high in some areas, such as the use of statins and drugs for acute myocardial infarction, but was ranked low in drugs for certain other diseases, including 11th for dementia, 12th for multiple sclerosis, and 13th for cancer drugs launched within five years.[350] Improving access to cancer drugs was therefore, once again, justified by the claim that Britain was lagging behind other countries.[351]

Subsequently, in October, the government released the Cancer Drugs Fund consultation document. The Treasury Spending Review, having affirmed the Cancer Drugs Fund,[352] confirmed that it would ensure £200 million was available for the Fund each year for three years starting from April 2011. Perhaps most significantly during this process, the DH's impact assessment for the Cancer Drugs Fund, which was required by the Treasury's "Green Book" guidance on appraising public investment, estimated a net loss for NHS patients in the options of both the regionally-administered fund (a £456 million net loss for the three-year period) and the nationally-administered fund (£496 million).[353] It also concluded, against the claim behind the introduction of the EoL criteria in the past and now the Cancer Drugs Fund, that "there is no firm evidence regarding the nature or magnitude of any social preference for treating 'severe' conditions such as cancer."[354]

Thus, although the Conservative Party created the Cancer Drugs Fund through its electoral agenda, it hardly created it from scratch. If the Labour government responded to the public controversy over drug availability – which was itself generated from the very institutional structures around NICE it had created – through EoL criteria and other measures for greater cancer drug availability in the late 2000s, the same salient public debates shaped the Conservative politicians' consideration of their policy agenda. The measures to allow for greater flexibility in cancer drug access having been extended during the last few years of the Labour period, the Conservatives now pushed further in the same direction through the Cancer Drugs Fund. These measures by Labour and the Conservatives resulted in a partial policy reversal from the NICE-led explicit rationing strategy. In this process, political incentives not

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[350] Ibid, 19.
[351] This does not mean the report claimed that the use of cancer drugs was associated with health outcomes such as survival. On the contrary, in line with the Cancer Reform Strategy, Mike Richards stressed that early diagnosis was the main factor to improve cancer survival rate, followed by surgery and radiotherapy, while making it clear that "I honestly do not think that drug usage is linked to survival". *BBC News*, 27 July 2010. According to Timmins (2016, 108), Richards opposed the introduction of the Fund.
[352] HM Treasury 2010 (Cm 7942), 42.
[353] DH 2010c.
[354] Ibid., 16.

only helped Conservative politicians shape the electoral agenda for the Fund by drawing their attention to salient public debates but also enabled them to surmount hurdles in the post-election policy-making process. Policymakers were thus able to override the negative results of the Cancer Drugs Fund's impact assessment because of the significant political incentives involved. In short, endogenous political dynamics stemming from the high political insulation gave rise to both the Labour and Conservatives measures to improve cancer drug access, leading to a partial policy reversal.

5. Conclusion

Throughout the 2000s, the English regulatory state for drug rationing came under significant pressure. As the Relenza case showed, from its inception NICE found itself between the competing criticisms for not making new drugs available and for questioning the credibility and robustness in its guidance. NICE attempted to achieve a delicate balance between these contradictory pressures from different audiences by developing consistent reasoning and elaborate justifications that were made explicit in codified rules. And with the highly insulated institutional setting whereby NICE's guidance was the final decision, ministers dared not overturn NICE's guidance. All of these factors contributed to enabling English policymakers to produce policy choices that would otherwise have been too politically costly.

At the same time, however, such tough policy choices were subject to intense counter-mobilisation over the course of the 2000s. Mediated by the public and electoral arenas, those who sought to change policies managed to widen their base of political mobilisation by elevating public attention to the issue and bringing politicians into their coalition. As a result of the shifting coalitional balance through conflict expansion, from the mid-to-late 2000s the gradual policy reversal began taking place, especially for cancer drugs where the magnitude of counter-mobilisation was the greatest. This gradual change was achieved through a number of measures, including the Single Technology Appraisal, risk-sharing scheme, End-of-Life criteria, and the Cancer Drugs Fund. The measures contributed to making more new expensive drugs (especially for cancer) available on the NHS.

Because different arenas were endowed with different actors and strategic environments, both the industry's strategies for counter-mobilisation and their outcomes varied across policy arenas. When the pharmaceutical industry sought to change existing policy orientation through

lobbying policymakers, the arena it fought in was the full of other elite actors who provided knowledge and expertise. In such an environment, the strategy for achieving policy change was to provide superior knowledge and persuasive reasons to win policy debate battles.

Yet, despite being a powerful actor in the policy process, the industry's ability to win elite battles in policy debates on drug rationing was limited. To be sure, the industry's repeated attempts created institutionalised fora with the government that favoured the industry. Allied with naturally sympathetic industry-related ministries and often involving top-down initiatives by Prime Ministers, such forums provided it with an institutionalised lever for the industrial policy agenda. When it comes to the negative impacts of NICE on the industry, a claim behind creating these forums, however, the business-government forums resulted in little, or at best modest, results. The industry's arguments were often counterbalanced – especially outside of the favourable circle of business-government forums – by the arguments of other actors. In the case of the Kennedy Review, for example, NICE appointed someone experienced in health policy and neutralised the industry's assault. For the same reason, the industry's power to shape bipartisan Parliamentary oversight committees was also limited. At the HoCHC, the industry remained one of many stakeholders. The Committee did give some recommendations that were consistent with the industry's claims – such as a timely NICE appraisal closer to the time of a drug's launch – but the industry was not the sole advocate for the issue. In short, the industry's counter-mobilisation through direct lobbying achieved limited results because it did not manage to overwhelm the policy debates in an area crowded with other elite actors who could advance alternative arguments to its own.

If the industry did not win battles within policy processes involving elite actors, however, it still achieved a partial policy reversal through counter-mobilisation in the public arena. In contrast with the lobbying battles confined to a space involving a limited number of elite actors, when the industry attempted to influence policy via the public arena, it did so by expanding the scope of conflict and bringing actors outside the policy process into their coalition. Those who allied with the industry in the battles about drug access, such as patient groups and charities, helped to expand the coalition base by drawing public attention using varied tactics, from public campaigns and mass media commentary to assistance in judicial reviews. The issue's heightened public attention, which was often intensified through "focusing events" involving particular patients' episodes or specific new drugs, helped to bring politicians into their coalition. The media played an important role during this process of expanding the coalition, since – as shown in the cases of Herceptin and the cancer mortality controversy -- it spread narratives of blame attribution in the public arena about why patients in England could

not get access to the new drugs that those in other countries got, and why the UK was lagging behind other countries in both drug access and health performance. The external pressures arising from intense public attention, then, shifted the position of elected officials who worried about the existing policy orientation's electoral consequences. With their ability to attract greater public attention, cancer drugs occupied a special place both in the magnitude of counter-mobilisation and in the resulting policy changes.

Elected politicians played a pivotal role in these episodes of gradual policy change. As a default, their policy and institutional strategy was to shift the blame for negative decision to NICE. The high political insulation shaped such a strategy of not overturning NICE's guidance. For, in ministers' calculus, overturning NICE's guidance meant taking on the risk of being blamed for undermining NICE's credibility versus claiming the credit for making the drug available, where, as an institutionalised default option, the former always won over the latter. Yet, with the exposure to the intense sustained public pressure through the steep rise in attention, politicians, both left and right, were leaning towards minimising the perceived risk of the blame and giving a greater weight to the credit, and hence responded to the public pressure. Thus, the Labour Health Secretaries, from Hewitt to Johnson, shifted their position to improve access to expensive drugs especially for cancer; the former intervened in the Herceptin case, while the latter initiated changes to lift the top-up ban. The opposition Conservatives, such as Cameron and Lansley, then tried to take over the issue of cancer drug access by pledging the Cancer Drugs Fund. Again, cancer drugs remained special here precisely because they gave a clearer, foreseeable credit to the politicians who were making the changes.

Pressures from the outside environment also played a somewhat subtle role in shaping NICE's behaviours. When NICE began operating, it confronted other actors with expertise and knowledge who questioned its credibility, including the industry, medical and pharmaceutical communities, NHS and academics. Faced with criticisms and policy debates, it deployed its own experts to develop well-elaborated reasoning for its decisions. Under the moderate level of pressure from elite actors within the policy space, NICE then made its detailed rules and doctrines explicit to justify its decisions. By doing so, it attempted to secure consistency in its judgments and credibility as a regulator. Ministers' non-involvement as a default policy strategy further contributed to reinforcing the existing policy orientation. It was only when NICE faced much more intense outside pressure from an enlarged coalition of counter-mobilisation involving not only elite actors but also the public and politicians, that it began adjusting its behaviour, realising that the existing practices were no longer justifiable or

its existence was threatened. Yet, NICE was much more risk-averse in making any changes than politicians; the much greater value it placed on sustaining its credibility and ensuring consistency and rigour in its guidance made NICE resist changes until the last minute. And when NICE finally changed its behaviour – as the cases of EoL criteria and the introduction of STA demonstrated – it then attempted to defend its legitimacy by claiming a retrospective consistency with its existing practices and offsetting the potential loss in any appearance of credibility and rigour, while emphasising the credit due to it as a regulator responsive to public concern about drug availability. Perhaps the slow nature of its response to outside pressure was clearest in the case of the introduction of EoL criteria, where NICE kept rejecting cancer drugs amid intense public controversies surrounding top-up payments, which led to exposing itself to even greater public and political pressures.

The policy development resulted in significant distributive consequences. While NICE's negative guidance imposed significant costs on the users and producers of the excluded technologies in order to achieve a rational resource allocation within the NHS, NICE's positive guidance, with its reinforced enforcement regime, was made at the expense of the NHS commissioners and users of other parts of the NHS as it led to displacement of other treatments and services. The Cancer Reform Strategy's recommendation to refer new cancer drugs to NICE as a default option and the rapid STA process that came to dominate NICE's guidance favoured patients with particular diseases and the manufacturers for expensive new drugs, especially for cancer. To be sure, the magnitude of this displacement effect of NICE's positive guidance was unknown, as is whether, and to what extent, the displacement was offset by the historic increase in the NHS budget during the Labour years. Yet, it is perhaps safe to say that the trend of (re-)distributing towards cancer drug users and producers at the expense of users of other services became even starker when the EoL criteria and the Cancer Drugs Fund were introduced.

More broadly, battles over drug availability in the 2000s revolved around a recurring theme, namely, what values should justify funding drugs? NICE's criteria on cost-effectiveness repeatedly became the subject of intense policy debates and public controversies. Throughout the review of top-up payments and the subsequent introduction of EoL criteria, the underlying justification for a greater flexibility in NICE guidance was that people place special values on life-extending treatments and the way they do so was not captured by cost-effectiveness. Likewise, in the business-government forums one of the central criticisms addressed against NICE's methods, and which led to the Kennedy Review, was that they did not adequately capture the value of innovation. As the next chapter will explore, when the Conservatives took

up these debates on what values a drug should reflect, it would lead to bold policy agendas for overhauling the drug pricing and reimbursement system.

Chapter 5 Bounded policy change in a "hybrid" governance: England, 2010-2016

Policy change leading up to the Cancer Drugs Fund in the late 2000s constituted a partial reversal in the English regulatory state for drug rationing. If the existing regulatory regime created by the early 2000s made NICE's guidance the final decision for drug rationing, the changes that allowed for greater flexibility applied to cancer drugs meant a growing space within the regulatory regime whereby decisions about drug funding were driven by political considerations rather than expert-led appraisal. The Cancer Drugs Fund exemplified such a politician-led decision. When the Coalition Government set up the Fund, the structure of decision-making for drug funding was thus driven by two different logics: on the one hand, NICE continued to appraise drugs based on their clinical and cost-effectiveness, while, on the other, for the cancer drugs that NICE rejected the Cancer Drugs Fund and other measures for allowing flexibility were applied. Through its agenda for a major reform in drug pricing and reimbursement, the Coalition Government set out to push further the boundary between these different, "hybrid" logics of expert- and politician-led governance.[355]

Yet, as this chapter shall show, the Coalition Government's effort did not result in a full policy reversal from the existing expert-led rationing. The agenda for pricing reform was shelved; the Cancer Drugs Fund's budget was expanded but eventually re-reformed, with expert-led logic being brought into its management. The present chapter examines why the Coalition Government's reform agendas only partially materialised.

The chapter argues that the past institutional choices over drug funding created their own beneficiaries, which obstructed the Coalition Government's reform attempts. By stripping NICE of decision-making powers for explicit rationing, the reform agenda would have given back to local-level clinicians the central responsibility for drug provision. At the same time, by making drug prices paid by the NHS reflect a broader value than the cost-effectiveness that NICE used, the government hoped to simultaneously achieve better drug access and reward the pharmaceutical industry for its innovation. Yet, the government's agenda was subsequently stalled in the face of resistance from different political actors, including both clinicians and the pharmaceutical industry. The existing regulatory structure, where the blame for rationing

[355] Note that the "hybrid" mode of governance in regulation used here is different from its common usage of the notion in public policy scholarship. While the latter often denotes the hybridity of public and private logics in public sector organisations, here I mean the hybridity of logics in regulation led by politicians and experts. Cf. Levi-Faur 2012.

of new expensive drugs was attributable to NICE, had benefited clinicians who, while being aided by NICE's expertise, no longer had to face rationing decisions. The pharmaceutical industry had also adapted to the structure centred on NICE as a hurdle for drug access and had changed its business model. Moreover, in addition to losing benefits from the existing pricing regime, such as mid-term certainty and elements of free pricing, the industry feared that it would lose out in the new pricing model that was trying to benefit several different clienteles at the same time. In the absence of a clear foreseeable advantage, the industry opposed the reform, which would shift the accountability for rationing from NICE to clinicians and drug companies.

If the government's agenda for pricing reform failed to materialise due to the opposition of political actors who had adapted to the existing regulatory structure, the Cancer Drugs Fund also faced a momentum for re-reform through its own operation. The Fund's excessive spending, driven by its political logics and little consideration for fiscal monitoring, soon met counter-mobilisation from elite political actors close to the payer's coalitions. The underlying electoral consideration of the Fund meant that it could not be removed once it was installed, but widened mobilisation by the payer's coalition led to a compromise solution under NICE's involvement in the Fund's management. All in all, both in the cases of the value-based pricing reform agenda and the Cancer Drugs Fund, endogenous forces limited the Coalition Government's attempts at shifting away from expert-led drug rationing by NICE.

The present chapter traces the political process of policy reform, from the formation of the Coalition Government's agendas to its negotiations with different political actors. It begins by examining the agenda for a value-based pricing (VBP) system, showing how the government built their reform plan on existing policy debates over drug rationing. It also highlights the radical reallocation of power and responsibility for rationing decision envisioned in the reform and its political implications for different actors, especially clinicians who would be responsible for local rationing decisions. The second section looks at the political process of translating the agenda into a pricing reform negotiation with the industry. It shows how the government failed to convince the industry, who had adapted to the NICE-centred rationing; the government agenda for improving drug access through widening the value that justified NHS drug funding failed to materialise in the face of resistance from the industry and other actors. The third section shows how the operation of the Cancer Drugs Fund endogenously generated the impetus for re-reform, leading to it being partially subsumed into the NICE-led structure of rationing.

1. Value-based pricing agenda

The origins of the agenda

The origin of the agenda for VBP can be traced back to a report written by the competition regulator, the Office of Fair Trading (OFT). In an inquiry report on the PPRS published in early 2007, the OFT called for a major reform replacing current arrangements with a "value-based approach" to drug pricing, one in which price would reflect clinical and therapeutic values.[356] It argued that neither the current profit cap nor the price control under PPRS allowed prices to reflect such values. It found that some drugs widely prescribed within the NHS were up to ten times more expensive than substitutes with similar clinical benefits. As a result, price failed to reward investment. Nor did it ensure value for money for the NHS as it did not use the fund in an efficient way; it estimated over £500 million spent in 2005 could have been used more cost-effectively. Value-based pricing, it claimed, would allow the NHS to use the expenditure in a more cost-effective way, while sending a better signal for investment in future research and development. The OFT gave a positive affirmation to NICE's role in pricing and reimbursement, regarding its technical expertise as "world class standard".[357] It therefore argued that NICE "should play a central role in any value-based pricing schemes".[358] As for new value-based pricing arrangements, while the OFT laid out several options, it preferred an "ex-ante" approach, in which a cost-effectiveness assessment would provide information to set initial prices, subject to later modifications depending on new effectiveness data.

The OFT report started off policy debates among stakeholders. The pharmaceutical industry was generally negative about the report in several respects. In its view, PPRS, with its initial free pricing, had allowed the industry to invest in R&D, which had helped push it towards being the most research-intensive sector in the UK.[359] They feared that the incremental nature of innovation, which was especially the case in later generations of drugs, would be ignored and discouraged if the new pricing scheme was implemented. It also claimed that the

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[356] The OFT 2007. Cf. Towse 2010; Claxton et al. 2008.
[357] Ibid, 67.
[358] Ibid, 94.
[359] The OFT report explicitly rejects this argument that PPRS attracts R&D investment into the UK, as "the R&D allowances under the scheme apply to R&D wherever in the world it is undertaken, not just to R&D incurred in the UK" (4). See the OFT 2007, 44-48.

new pricing mechanism would entail large set-up costs and uncertainty in the business environment. Figures from the sector repeatedly warned about future disinvestment in the UK, thereby trying to pressure the government to reject the proposal.[360]

The OFT report also triggered government action. In August, Health Secretary Alan Johnson announced that the Department of Health would renegotiate PPRS, taking into account and discussing the OFT's reform proposals with the industry.[361] Thus, when top-up payments were proposed and Mike Richards recommended "greater flexibility" in drug access, negotiations in that direction were already under way; his recommendation took over the debate that the OFT's proposal started. In addition to the Patient Access Scheme described in Chapter 4, the revised PPRS set out "new flexible pricing arrangements", which provided drugs initially at low prices and subsequently revised these if there was additional evidence of greater value. In sum, in response to the OFT's agenda setting, the governments opened a path towards changes in drug pricing policy, although those made were modest at the time.

The Coalition Government's agendas for pricing reform

The Conservative Party (especially Shadow Health Secretary Andrew Lansley) subsequently picked up the OFT report's value-based approach to drug pricing. In November 2008, amid the top-up controversy, the Party published a policy document on "a plan to renew NICE", setting out proposals to reform drug funding policy. On explicit drug rationing, along with expanding the use of risk-sharing schemes, it expressed support, albeit still vague, for a progressive move towards "the principles of value-based pricing (VBP) to new medicines".[362] After the 2010 election, the new government's commitment to achieving its pledge on pharmaceutical policies was situated in the broader health care reform context. The underlying idea was to bring back the clinicians' role in decision-making on resource allocation. In its White Paper *Liberating the NHS*, which set out its healthcare reform agenda,[363] the government hence planned to replace the Primary Care Trusts (PCTs) with "commissioning consortia" comprised of GPs, called Clinical Commissioning Groups. On the budgetary

[360] *Financial Times*, Feb. 21, 2007; April 25, 2007. *The Sunday Telegraph*, June 3, 2007.
[361] Department of Business, Enterprise, and Regulatory Reform 2007; Department for Business Innovation & Skills 2009. Cf. *Financial Times*, Aug. 3. 2007. *The Times*, Aug. 3. 2007.
[362] Conservative Party 2008, esp. 4, 24ff. Cf. Carroll 2009, 633.
[363] DH 2010a.

implications of such a shift in the commissioning role from PCTs to GPs, the government claimed, "GPs are well placed to design care packages for patients, which should lead to improved health outcomes and tighter financial control".[364] The Cancer Drugs Fund, which was announced to launch in the following April, was considered as part of the larger reform on clinician-centred healthcare. In the wake of the formation of the new government, it stressed the role of clinicians' judgement in cancer drugs access. The aim of the Fund was thus "to enable patients to access the cancer drugs their doctors think will help them".[365]

Yet, for the Coalition Government, the Cancer Drugs Fund was only an interim measure to bridge the transition to value-based pricing which would replace the existing PPRS upon its expiry at the end of 2013. Lansley argued that "using our cancer drugs fund in the interim, and value-based pricing for the longer-term, we will move to an NHS where patients will be confident that where their clinicians believe a particular drug is the right and most effective one for them, then the NHS will be able to provide it for them." [366] In its consultation document released in December, the government reiterated the idea of improving NHS patients' access to effective drugs by ensuring that price reflects the value it brings.[367] While acknowledging measures that allowed for greater flexibility in drug access, including the Patient Access Scheme and the Cancer Drugs Fund, it claimed that these were not long-term solutions. Likewise, it criticised the current approach to technology appraisals for failing to fully reflect wider societal values, including helping patients back to work and reducing the burden on their carers.

The government laid out broader policy goals for the new pricing system than the current PPRS', including improving patients' access, encouraging innovation, and ensuring value for money.[368] Corresponding to these objectives, the government proposed that in addition to the "basic" cost-effectiveness threshold, like that currently used by NICE, the new pricing threshold should be adjusted by weighting two other factors: a "Burden of Illness" and a

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[364] Ibid., p.9. An independent commissioning board would be established to replace the existing Strategic Health Authority, which, among other responsibilities, would provide commissioning roles outside the usual remit of GPs. *The Guardian*, "Ministers give GPs more power", 12 July 2010; *Financial Times*, "GPs to run £70bn NHS spending in power shift", 12 July 2010. *IHS Global Insight*, "U.K. Coalition Government Outlines Radical Strategy for "Liberating" NHS", July 13, 2010.
[365] HM Government 2010, 25.
[366] *The Guardian*, "Nice to lose powers to decide on new drugs", 29 Oct 2010.
[367] DH 2010b.
[368] Ibid., paras. 2.1; 3.2

"greater therapeutic innovation and improvements".[369] A higher "Burden of Illness" referred to drugs with unmet need or which were particularly severe; "therapeutic innovation" would reflect "any additional health gain not captured by the normal health gain because of the measurement difficulties"[370]. These weightings were, in large part, built on existing measures to allow for a greater flexibility in drug access, and indeed would systematise them. Thus, the emphasis on Burden of Illness reflected the idea underlying End-of-Life criteria as well as the Cancer Drugs Fund; and the greater innovation was the policy goal of the 2009 Innovation Pass[371] and was, as the previous chapter documented, discussed at the government-industry forums and in Ian Kennedy's report. The new system would be applied to branded medicines placed on the market from 2014 – thus generics would not be included -- and in addition to them, the government proposed including some existing drugs, subject to discussion with industry; the medicines already covered by the PPRS were to be subject to a successor scheme, which would be developed alongside VBP.[372]

The proposal meant a major organisational change in the drug pricing and reimbursement process. According to the consultation paper, ministers would, with the advice from expert bodies, define a maximum threshold for the price of a drug to negotiate with the industry. NICE would carry out a "pharmaco-economic assessment" to give advice to ministers and manufacturers; in addition to such a "basic" threshold based on cost-effectiveness analysis, it was proposed that "expert panels", though not specifying details of their composition and status, would review evidence produced by the company to assess weightings for "burden of illness", "therapeutic innovation", and "wider societal benefits" for a new medicine. [373]The company could propose a price, and if this was higher than the government's threshold the company could either lower it or give further supporting evidence for the proposed price. If the company did not follow either of these options, "it would be the company's responsibility to explain to the public why it was not prepared to offer that drug at an appropriate price".[374] And the new GP consortia would take a commissioning role in determining the use of drugs.[375] The government argued that the new scheme would increase the access to medicines, because

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[369] Ibid., paras. 4.5-4.25
[370] Ibid., para. 4.2
[371] Innovation Pass was to be terminated in July 2011 due to its duplication with the Cancer Drugs Fund.
[372] DH 2010b, paras. 4.1.-4.4.
[373] Ibid., paras. 5.2.; 5.6.
[374] Ibid., para. 5.7.
[375] Ibid., paras. 5.11-5.12.

GPs with more clinical autonomy and the consortia can be more flexible in meeting patients' needs: "They [GPs] can be confident that, at a time when consortia have increasing responsibility for NHS resources, the drugs their patients receive reflect value for money."[376]

Thus, the value-based pricing reform proposal would represent a significant departure from the existing allocation of powers and responsibility for drug rationing. NICE, whose guidance meant the final decision for the NHS, would become merely one of the advisory bodies informing the minister, who set drug prices. At the same time, by making it the price taker, the government shifted the accountability—and also the blame -- for denying access to a costly drug to the manufacturer. Finally, by transferring the power of funding decisions to clinician-led local consortia, clinicians would be accountable for their own rationing decisions.

For NICE, the reform meant a major overhaul as its technology appraisal would lose decision-making power over whether a drug should be funded. In October it was reported, first in trade journals and then general newspapers, that Health Minister Earl Howe had stated at an industry-led conference that with the introduction of VBP, NICE would become "somewhat redundant" and the NHS pricing of drugs would reflect "everyone's agreed perspective".[377] It was followed by the Department of Health's confirmation that NICE would focus on "what matters most" [378] --its role would become centred on providing clinicians with clinical guidelines and developing quality standards for health and social care; but it would no longer decide on whether a treatment should be covered by the NHS.[379] Instead, individual GPs and local GP consortia would make the decision, and the central role of NICE would be to issue guidelines to support these clinician-led decisions. Instead of the current mandatory status of the NICE technology appraisal for the PCT, in the new systems it would become a mere advisory role. Likewise, the VBP consultation document stated that NICE would be "the key source of advice on the relative cost-effectiveness of new medicines"[380] in the new pricing systems, and although it acknowledged its expertise and regarded it as playing an important

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[376] Ibid.
[377] "VBP will make NICE cost decisions 'somewhat redundant:' Minister", *Pharma Times* 26 October 2010; *The Guardian* 30 October 2010; *BBC News*, 1 November 2010.
[378] *BBC News*, 1 November 2010.
[379] "What part will NICE play in the future?" *The Pharmaceutical Journal*, 4 November 2010; Chaplin 2011.
[380] DH 2010b, para. 5.3.

role in any new systems, it stated that the details of its role would depend on responses to the consultation. [381]

It should be noted that curtailing NICE's power over rationing went in parallel with shifting its focus and strengthening its legal basis. While the Coalition Government set out to undertake a major "quango cull", reducing 18 arms-length bodies in the health sector to 8 or 10, NICE survived and its remit would be expand to include social care;[382] the government also planned to strengthen its statutory footing by establishing it through primary legislation, the upcoming Health bill based on the White paper, transforming it from its current status as a Special Health Authority, an arms-length body of the Department of Health set up by secondary legislation, to a Non-Departmental Government Body accountable to Parliament. Thus, rather than simply demolishing it, the government would convert the usage of NICE's expertise and analytical capacity while taking rationing decisions away from it.

The majority of the various stakeholders – the pharmaceutical industry, patient groups, clinicians, the NHS and academic communities – were supportive of the broad idea of VBP that linked the price of a drug to the value it delivered. The basic idea itself was also appealing to NICE, as unlike the existing regime where it was only involved in drug pricing indirectly, VBP allowed a form of price-volume agreement whereby NICE would be able to start negotiations with the industry early on.[383] Rather, the problem lay in what it would mean in practice. Several actors highlighted the proposal's lack of details; they also pointed out practical difficulties in implementation, including how to apply the price for different indications with different "values" of the same drug. Given the opacity and potential distributive implications of the agenda, it was not surprising that the pharmaceutical industry was cautious during the months leading up to the adoption of the consultation paper. Some firms were sceptical when the new government announced the agenda, expressing concerns that value-based pricing would lead to administered prices and slower approval, resulting in more price cuts. [384]

Not surprisingly, when the consultation paper was adopted, diverse responses emerged when it comes to specific arrangements of defining "values", notably in terms of who decided them and how values were measured. The two issues were mutually related. For instance, in

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[381] Ibid.
[382] "NICE gets expanded role in quango cull", *Pharmafile* 27 July 2010.
[383] Interview with a former NICE official, 04.05.2018; Interview with an economist, 10.05.2018.
[384] *Financial Times* 27 May 2010.

its written response to the consultation the Association of the British Pharmaceutical Industry (ABPI) argued that, with its focus on "breakthrough" drugs, the proposal overlooked the incremental nature of drug innovation. It emphasised a "co-creation" process between the government and the industry in developing thresholds and weightings, thereby envisaging the PPRS-like government-business negotiations to continue. [385] By contrast, several patient groups worried that, with such a government-business dialogue, patients' voices wouldn't be heard. They advocated for bringing patients into the process of defining the value of a drug.[386] Finally, payers were concerned with the reform's budgetary implications. The NHS Confederation, a representative body of NHS organisations, claimed that "these proposals may drive up the cost of the drug to the NHS without increasing access to treatments," which may result in disinvestment elsewhere, especially effective non-pharmaceutical treatments. They regarded the greater weighting of a higher burden of illness "a contentious and politicised act"; they highlighted weighting innovation would risk "double counting", and questioned whether innovation would be a sufficiently important attribute to merit a premium, claiming that the value of a drug should be cost and clinical-effectiveness. Instead they argued for tasking NICE with developing the approach to value-based pricing, and for developing a process separate from NICE, such as an independent panel, to define the cost-effectiveness threshold.[387]

NICE's role in drug funding policy was also debated. The pharmaceutical industry was active on this issue. In October, ABPI director general Richard Barker called for "a parallel debate on the role and focus of NICE" to the one over VBP: "If we want the NHS and the UK economy to benefit from a vigorous life sciences sector, the reshaping of NICE's remit is an urgent priority".[388] His proposal overlapped with the government position about NICE on several points, such as broadening NICE's definition of values and reflecting early uncertainty in the assessment, refocusing NICE's task on clinical best practice, and most notably not involving NICE in reimbursement negotiations and leaving them to the Department of

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[385] ABPI's response to the consultation, 14 March 2011, 3.
[386] Alzheimer's Society's response to the DH consultation. Patient groups criticised exclusion of patient groups from pricing negotiation. ABPI argued in return that given its global implication, "the negotiation of any new pricing scheme has to be a bilateral negotiation between the industry and the government". "Drug pricing must remain "absolute domain" of companies, says ABPI," *Pharma Times* 15 November 2012. cf. "Cancer charities warn govt over drug price talks", *Pharma Times* 13 November 2012.
[387] NHS Confederation's response to the consultation, n.d.
[388] ABPI, "Reshape NICE remit to fit new 'VALUE' era, says ABPI" http://www.abpi.org.uk/media-centre/newsreleases/2010/Pages/191010.aspx

Health.[389] Barker stressed the idea of business-government dialogue when the DH announced changes to NICE's role, envisioning a system where the manufacturer discussed the price with the DH and NHS, rather than having another body set up.[390] This position was consistent with a later ABPI written response, where it recommended the NHS Commissioning Board's involvement in the access and uptake of medicines priced by the new arrangement.[391]

Patient groups were divided on the proposal to transfer NICE's decision-making power over coverage to local commissioning groups. Some advocated for rethinking NICE's role; in response to the Department of Health's confirmation that NICE appraisal would no longer be mandatory, Macmillan Cancer Support commented that "NICE has too often misread the public mood in rejecting clinically effective drugs for rare cancers".[392] Others were opposed; the Alzheimer's Society response to the consultation document expressed concern that removing the mandatory status of NICE appraisals would see a return to the postcode lottery of the pre-NICE period. They concluded, "We do not feel the case has been made for making NICE guidance optional".[393] Yet others suggested a third alternative: the Multiple Sclerosis Society likewise worried that local decision-making by GP consortia would be "unduly influenced by financial constraints", which would reduce access to treatments, but instead of supporting NICE's current role, it suggested setting up a "central drug fund" to supplement "value-based" prices of treatments in addition to nationally agreed prices paid by GP consortia.[394]

Yet perhaps most importantly, the medical professions strongly opposed the measure to withdraw NICE's power over rationing. Resistance came from clinicians themselves, especially those who were involved in primary care. They feared that the government's idea of putting clinicians on the front line of decision-making, coupled with stripping NICE's power, would result in postcode prescribing whereby GPs would face pressures from patients, and therefore get the blame for rationing.[395] From the outset, the government's agenda

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[389] "ABPI calls for urgent review of NICE remit", *Pharma Times* 21 October 2010; "Drug companies call for NICE remit to be re-examined", *The Pharmaceutical Journal* 21 October 2010.
[390] *Financial Times*, 29 October 2010.
[391] ABPI's response to the DH consultation, 14 March 2011, 5
[392] *BBC News*, 1 November 2010.
[393] Alzheimer's Society's response to the DH consultation. 9 March 2011.
[394] In fact, MS society criticised the Cancer Drugs Fund for taking away funding from elsewhere. "UK's Cancer Fund Criticised for Taking Away Resources from Patients with Other Diseases", *IHS Global Insight* 7 November 2011.
[395] *Financial Times* 8 November 2010, 13 December 2010; *The Guardian* 29 October 2010; "GPs face chaos as NICE's role shifts", *GP Magazine*, 24 September. 2010.

provoked counter-mobilisation among General Practitioners.[396] The Royal College of General Practitioners claimed that the removal of NICE's responsibility would result in patients "shopping around" to receive treatments, inflating the drug budget, and placing individual GPs in "invidious positions with regard to patients" when making decisions. They warned that the proposal would erode the trust of patients in doctors and ultimately in the NHS.[397] The British Medical Association's written response likewise warned that "leaving the commissioners to make decisions on specialist drugs could widen 'postcode rationing' and the pillorying of commissioning groups".[398] These strong reactions against clinician-led rationing were also seen in the wider health agenda, including reactions to the government White Paper and debate over the incoming Health bill.[399]

The counter-mobilisation by clinicians appeared to have influenced the subsequent fluctuation in the government's position. In June 2011, the government stated that patients would retain "the right to drugs and treatments recommended by NICE" after the introduction of value-based pricing in 2014.[400] GPs welcomed the reversal, who, as NICE's chair Mike Rawlins put it, "wanted a 'blame quango' to be responsible".[401] To be sure, the government's position about NICE's role remained unclear in the subsequent years; and it was not until 2013 when, in response to the HoCHC's inquiry into NICE, the government officially maintained that NICE would be given "a central role in the value-based pricing system" by not only assessing cost-effectiveness but also undertaking the "full value assessment" of a drug, that its reversal about NICE's role was confirmed.[402] Still, clinicians' opposition, driven by the fear of getting the blame for rationing, represented a considerable obstacle to the agenda of stripping NICE of its role in explicit rationing decisions.

The government confirmed its commitment to advancing its policies. In April 2011, it launched the operation of the Cancer Drugs Fund. With the electoral mandate and mostly

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396 "GPs face chaos as NICE's role shifts", *GP Magazine* 24 September 2010.
397 Royal College of General Practitioner's response to the DH consultation. 14 March 2011.
398 Cited in "BMA attacks value-based drug pricing plan" *GP Magazine*, 15 April 2011. Other parts of medical communities advanced a similar criticism in their written responses, including the Academy of Medical Royal Colleges (a body that comprises the Medical Royal Colleges and the Faculties) and the Royal College of Nursing.
399 Cf. Klein 2013b.
400 "NICE to Retain Reimbursement Endorsement Powers in Revised NHS Reform Plans" *IHS Global Insight* 20 June 2011; *Financial Times* 17 June 2011
401 *Financial Time*s 17 June 2011. Tellingly, the title reporting this change on a GP's trade journal reads, "Consortia freed from role in rationing of healthcare" *GP magazine* 24 June 2011.
402 DH 2013a, 4.

positive reactions to its consultation, the design of the fund was largely unchanged from the initial porposals: it took a "regional" approach, allocating money through clinically-led panels of local Strategic Health Authorities (SHAs); and based on a "population-based approach" to decision-making, SHAs developed "priority lists" of drugs to be routinely available through the fund, which was regularly updated. Likewise, in July, the government responded to the stakeholder consultation, noting that the proposed objectives of value-based pricing gained "broad support". It stated its preference for "negotiated agreement" with the industry, similar to the current PPRS, announcing that the negotiation would begin "sometime in 2012".[403]

2. The political trajectory of value-based pricing

Value-based pricing, however, struggled to materialise in the subsequent years. The government launched its negotiation with the ABPI in August 2012. In the joint statement the government declared its wish that "value-based assessment is carried out as fully as possible, as early as possible", and that the arrangement should be "stable and not bureaucratic" to make it predictable for the company.[404] Towards the end of 2012, the Department of Health organised a series of workshops with NICE and different stakeholders to draw up directions for the values.[405] Meanwhile, in the HoCHC's inquiry into NICE, MPs criticised the government for failing to clarify the new arrangements years after initiating the consultation: "There is a lack of clarity around the whole issue which has persisted for too long. Decisions need to be taken, and the details of the scheme made public," claimed Stephen Dorrell, the committee chairperson.[406] The resulting report stated, "We do not regard it as acceptable that the arrangements for value-based pricing have still not been settled and that those who will have to work with those arrangements are still unclear about what value-based pricing will mean in practice."[407] This concern was widely shared among stakeholders and, as the deadline for the new scheme was approaching, by the end of that year speculation arose as to whether VBP would take place or PPRS would continue, as well as about what role NICE would play

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[403] Cf. "VBP scheme to go ahead, says govt," *PharmaTimes* 19 July 2011.
[404] DH/ABPI n.d. "Joint DH/ABPI statement on arrangements for pricing branded medicines from 2014" https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212902/Joint-DH-ABPI-statement-on-arrangements-for-pricing-of-branded-medicines-from-2014.pdf
[405] DH 2013a, 4.
[406] *Financial Times*, 16 January 2013.
[407] HoCHC 2013 (HC 782), 4.

therein.[408] Nobody except the Department of Health and the ABPI knew the answer since their PPRS negotiations were confidential.

The government's response to the growing concern was to hand NICE the task of defining values. As already mentioned, in response to the Health Committee's report, the government announced in March 2013 that NICE would be responsible for assessing the full value of a drug.[409] This implied that NICE would be tasked to assess not only the clinical and cost-effectiveness as it currently did, but also broader benefits valued in the new pricing arrangement. Subsequently, in June, the government announced that it had directed NICE to develop the method for assessing "full value", and given NICE terms of reference. It also noted that value-based pricing would be introduced in January 2014.

Despite the stated commitment of the government, however, the agreement between the government and the ABPI reached in November did not represent a shift to value-based pricing. The new PPRS would launch in 2014 and run for the five years. As was the case for the previous PPRS, it would give companies the discretion to decide on the prices of drugs. At the same time, the new PPRS would introduce a cost-containment deal -- a fixed cap on NHS drug expenditure, on which the ABPI president Deepak Khanna stated, "It should not be underestimated how difficult this will be for the industry".[410] NHS spending on prescription drugs, which was £12 billion in 2011/12, would be kept flat for the first two years, followed by a growth rate allowing for up to 2% increases for the next three years. The industry would be required to pay back in order to hold the growth of the expenditure at the allowed rate, which was set at 3.74% of estimated total sales in 2014.[411] Alongside PPRS, government also introduced the statutory pharmaceutical price regulation scheme, which covered branded medicines by companies who chose not to participate in the voluntary PPRS. It imposed a compulsory price cut of 15%, which appeared to threaten companies into joining the PPRS. As to Value-based Assessment, the new PPRS document noted that NICE would be working on the broader definition of value, which, according to the Department of Health, would be

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[408] *Financial Times* 13 March 2013.
[409] DH 2013a, 4; DH, "Press release: NICE to assess value of medicines from 2014", 21 March 2013. https://www.gov.uk/government/news/nice-to-assess-value-of-medicines-from-2014
[410] *Financial Times* 7 November 2013.
[411] A company with sales below £5 million in the previous year was exempted from the payback scheme. The industry criticised that the exemption did not cover companies with NHS sales between £5 and £25 million, which "will find this extremely tough", said ABPI chief executive Stephen Whitehead. "New PPRS pact unveiled" *Pharma Times* 6 November 2013.

introduced in autumn 2014 after public consultation.[412] The document also stated that the basic cost-effectiveness threshold that NICE used for its appraisal would be "retained at a level consistent with the current range" for the five years covered by the new PPRS.[413] In sum, the government and the industry failed to arrive at agreement on value-based pricing and continued the existing PPRS based on profit-based control with tight fiscal terms imposed on the industry.

Why did value-based pricing fail to materialise? For several reasons the industry's position never got closer to the government's VBP proposal. First, the industry's preference was to retain elements of PPRS that were favourable to it, notably free pricing. In starting negotiations for VBP, ABPI chief executive Stephen Whitehead stated, "We would like there to be a single holistic scheme that is low on bureaucracy, efficient, patient-focused and reflects an element of freedom of pricing which we have with PPRS because it's profit controlled."[414] The preference for PPRS-like free pricing appeared stable throughout the period. The industry repeatedly warned that under the new pricing arrangement Britain would lose its attractiveness as an early launch market. The industry was concerned the introduction of pricing control and lowering the list price in the UK would result in the drop of the price globally, since the UK is used as a reference country for pricing drugs in a number of other countries.[415] They repeatedly claimed that UK drug prices were among the lowest in Europe, and "already a good value for money", referring to the recent PPRS report to Parliament.[416] From such a perspective, VBP was seen as a threat to the free pricing system.

The industry was also against the emphasis on the local-clinician-centred decision in the value-based pricing proposal as it would generate significant uncertainty over volumes. This would be compounded by the increase in local marketing costs, especially because by that time the operation of NICE had already changed the business structure. The past business model of the pharmaceutical industry that emphasised marketing at local clinicians had been replaced by the increasing focus of its resources on research demonstrating cost-effectiveness to meet

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[412] "UK government and pharma industry unveil new Pharmaceutical Price Regulation Scheme", *IHS Global Insight* November 7, 2013.
[413] DH 2013b, 4.9.
[414] *The Daily Telegraph* 21 September 2011.
[415] *Financial Times*, 7 November 2013.
[416] The report stated that the price was substantially dropped in 2007/08, due to currency fluctuation (DH 2012). A report written for the pharmaceutical industry gave a similar picture. O'Neil et al. 2011. On the industry's claim see also *Financial Times* 21 June 2013.

NICE's appraisals.[417] The industry did not favour the reform as it would force companies to re-localise its now-centralised resources. The industry's institutional adaptation to NICE-centred rationing thus further diminished the appeal of the government's proposal.

Furthermore, the industry remained unconvinced by the government's claim that VBP would contribute to industrial policy. Again, they warned repeatedly throughout the agenda-setting and negotiation process that the government's proposal did not understand the value of incremental nature of innovation. The industry remained negative about the notion of the proposal's emphasis on wider societal benefits, such as production and employment, as it feared that by weighting wider societal benefits when measuring the value of a drug, end-of-life treatments such as cancer drugs and drugs for the old – drugs that were much of the industry's focus at the time and aimed at incremental improvement rather than curing the disease or getting people back to work -- were disadvantaged.[418] Conversely, from the government's perspective, by looking only at the upside that a drug could bring, the industry did not understand the notion of the opportunity costs of funding the drug – a notion that is required by the Treasury Green Book.[419] While the Coalition Government introduced a number of measures to stimulate innovation through tax credits and others instruments, the industry hence considered VBP to contradict these emphases on industrial policy. The ABPI's response to the VBP consultation argued for a more "joined-up approach" to the industrial policy, creating a more explicit reference in VBP to the government's industrial strategies for the life sciences sectors.

In the absence of the reward as part of the industrial policy, and given the loss of pricing freedom and increase in uncertainty, to the pharmaceutical industry VBP appeared as just a strategy for shifting the blame for rationing from NICE to the industry. As one industry observer put it, "instead of putting NICE in the hot seat when it recommends denying access to a drug the new regime will put onus back on the industry—patients will be knocking on company doors for that essential explanation of why a price doesn't measure up to bringing it to market".[420]

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[417] Interview with an economist, 10.05.2018; Interview with a former NICE official, 04.05.2018.
[418] Interview with an economist, 03.05.2018; Interview with a DH senior advisor, 18.04.2018.
[419] Interview with a DH senior advisor, 18.04.2018.
[420] Upton 2012, 39. An informant close to the industry made a similar comment. Interview with an economist, 10.05.2018.

Turning to the government side, we can see its position shifting away from the industry. Some changes can be observed in the DH's response to the 2013 HoCHC's inquiry into NICE, which confirmed NICE's role in full value assessment. First, the idea of having "expert panels" separated from NICE to examine such broad benefits appeared to have been abandoned by this point, and among the stakeholders who responded to the 2010 consultation, government's position on institutional design seemed to be getting closer to the NHS Confederation's as the purchaser. Second, in contrast with the government's emphasis in its 2010 consultation paper and contrary to the industry's continued advocacy, innovation was dropped from the weighting of the threshold of a drug. On "incorporating a broader assessment of a medicine's benefits and costs", the government claimed that NICE would be "taking into account factors such as burden of illness and wider societal benefits" but never made reference to therapeutic innovation.[421] The reference to innovation appeared not to have returned in the subsequent terms of reference given to NICE. Finally, the government statements came to give more emphasis on cost control than innovation. Hence, when the government tasked NICE to develop the assessment of a drug's broader value, Health Minister Earl Howe justified the mission by stating that, "We cannot simply spend more and more on drugs – this would mean spending less and less elsewhere."[422] Moreover, this remark was reportedly made in the context of taking steps to achieve savings of GBP 20 billion from the NHS by the next election.[423]

In sum, contrary to its initial rhetoric of improving access and encouraging innovation, the government failed to convince the industry that moving from PPRS to VBP would achieve them. Although the fiscal climate and the fall in drug prices might well be prerequisites, they always existed during this period, and hence did not automatically result in the policy outcome. Rather, the policy preference of the industry remained diverged from that of the government, and the latter in balancing different policy goals failed to steer its direction towards linking the measure to the industrial policy in a convincing enough way for the industry to support it. It was not surprising, then, when an industry negotiation participant reportedly commented, "We

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[421] DH 2013a, 4. Behind the scenes, DH officials were struggling to define "innovation" as a separate weighting, since all the impacts of drugs were supposed to be counted in other criteria. Interview with a DH senior advisor, 18.04. 2018.
[422] Department of Health and The Rt Hon Earl Howe, "Press release: Expert body given responsibility to look at the benefits medicines bring to wider society", 20 June 2013. https://www.gov.uk/government/news/expert-body-given-responsibility-to-look-at-the-benefits-medicines-bring-to-wider-society
[423] *The Times* 20 June 2013.

are perplexed and confused by the inconsistent messages."[424]A comment from a think tank funded by the industry represented the widespread sense: "Doctors, charities and the media may see value-based pricing not as something in which the government believes, but rather as a way [to hide behind] jargon and intellectual dishonesty . . . to justify what will increasingly feel like largely arbitrary rationing of expensive drugs."[425]

NICE's full value-based assessment (VBA) struggled too. The government terms of reference stated that "burden of illness" and "wider societal benefits" should be incorporated in the NICE appraisal. There was an explicit reference to End-of-Life criteria, which should be taken into account within the weight of burden of illness; Wider Societal Benefits were measured based on the shortfall of productivity and consumption as a result of the condition. The government's intention behind this emphasis on Wider Societal Benefits was that the VBA should take into account not only impacts on the NHS but also on wider public policy such as employment and production. Yet, NICE was struggling to operationalise these considerations. There was little evidence that supported these weightings; and NICE was concerned that they could result in gender or age discrimination –an unintended consequence that would run counter to the NHS' equity principle.[426]

In January 2014, NICE refused to incorporate the concept of "Wider Societal Benefits", as the concept could result in prioritising the young over the old. Although any approach to wider societal benefits would "inevitably take age into account to some degree", it argued: "regardless of the way the proposals in this paper are incorporated into the appraisal process, NICE will not allow age itself to tip the balance of a recommendation against the use of a treatment".[427] It instead proposed an alternative concept called "Wider Societal Impacts", which, instead of measuring production and consumption, measures absolute shortfall of QALYs resulting from the condition. NICE would set a maximum weight of 2.5 accumulated by Burden of Illness and Wider Societal Impacts, which meant the threshold of £20,000 per QALY would be increased to £50,000 per QALY.

The proposal for value-based assessment that NICE put forward in March attracted much criticism from different stakeholders. The consultation gathered 900 responses, the

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[424] *Financial Times*, 21 June 2013.
[425] Cited in *Financial Times* 7 May 2013.
[426] Interview with a NICE senior official, 12.07.2018.
[427] "NICE rejects 'wider societal benefit' test for new drugs" *Pharma Times* 26 January 2014.

overwhelming majority of which were negative. Patient groups strongly opposed the proposal, especially on the ground of discriminating against older patients.[428] The industry worried that incorporating EoL criteria into Burden of illness might result in reduced availability.[429] It argued against the fixed threshold of £50,000 per QALY.[430] Both the industry and patient groups preferred to retain EoL criteria. Most notably, in its consultation response the Department of Health stated that it now wished to retain the current approach to EoL criteria, with the maximum of £50,000 per QALY.

In response to the consultation, NICE decided to shelve the proposal; it stated that there would be no change in appraisal methods and EoL criteria would be retained. In the end, with the inevitable discrimination as a result of the weighting being expected, NICE preferred to keep its existing case-by-case approach rather than to make the appraisal Committee hard-wired to the assessment weighting.[431] NICE presented this withdrawal as a call for a "wider review of the NHS' arrangements for supporting innovation and evaluating and adopting new treatments." It claimed, "it's clear that just changing NICE's methods will not overcome concerns about how the NHS accesses new treatments". The proposal put forward in the statement included the creation of "an office for innovation" inside NICE to work early with the company from development to evaluation, and a "more productive sharing of risks".[432] Indeed, this emphasis on regulatory communication, early entry and a "wider review" somewhat resonated with what the industry was calling for since it allowed more flexibility in entry.[433] While welcoming such an initiative, the ABPI kept advocating reform of NICE's appraisal methods.

In short, while NICE attempted to reconcile various imperatives while meeting the government's requests when translating the government's agenda into a concrete proposal for assessment, it was not able to create political compromise among different stakeholders. With

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[428] *Financial Times* 27 March 2014; cf. Cancer Research UK, Comments to NICE's consultation. https://www.cancerresearchuk.org/sites/default/files/policy_june2014_cruk_proforma_tamethodsreview_response.pdf

[429] "NICE proposals on value-based assessment of new medicines criticised" *The Pharmaceutical Journal* 27 June 2014.

[430] "ABPI comments on NICE's Value Base Assessment consultation." 27 March 2014.

[431] Interview with a NICE senior official, 12.07.2018.

[432] NICE, "NICE calls for a new approach to managing the entry of drugs into the NHS", 18 September 2014; *Financial Times*, 17 September 2014.

[433] NICE chief executive Andrew Dillon reportedly sensed "a willingness on the part of the industry to work with NICE on developing new models for drug pricing and appraisal that encourage uptake of new medicines without busting the health budget." Cf. *Financial Times*, 17 September 2014.

the massive criticism upon receiving the task to establish the full value assessment – a task that one informant close to the industry aptly called "a hospital pass"[434] – NICE now passed back the ball to the government by calling for a "wider review". The pharmaceutical industry's advocacy for allowing flexibility in a drug's market entry and its attempt at seizing the opportunity to reform NICE was also seen in the policy debate on the Cancer Drugs Fund, to which the chapter now turns.

3. The political trajectory of the Cancer Drugs Fund

The organisation of the Cancer Drugs Fund's operation reflected the government's policy to put clinicians at the centre of decision-making. As discussed above, the Fund was initially run by local clinician-led panels at Strategic Health Authorities for its allocation, with regional priority lists of drugs routinely available. In early 2013, NHS England changed this policy on listing drugs; instead it would draw up a single national list of cancer drugs available from the Fund.[435] This change was again intended to tackle regional variations in the Fund. The national list would be written by the Clinical Reference Group for Chemotherapy at NHS England. The management of the Fund at the national level was led by the National Cancer Drugs Fund Panel within the Group, mostly comprised of clinicians, pharmacists, and patient representatives.

As the negotiation over value-based pricing generated doubts about its feasibility, patient groups also expressed concerns about the future of the Cancer Drugs Fund, which would be expiring in March 2014. In September 2013, the government announced that the Fund would continue to run until 2016. Prime Minister David Cameron declared that the Fund was a "massive success", showing his willingness to continue it beyond 2016 should he be re-elected.[436]

Ironically, however, as a fiscal consequence of its "success", the operation of the Fund increasingly found itself the subject of political battles. In the first two years, the Fund was underspent; but it started exceeding the budget in the 2013/14 year, with £32 million overspent.

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[434] Interview with an economist, 10.05.2010.
[435] "Cancer Drugs Fund changes will end regional variation in access" *The Pharmaceutical Journal* 5 April, 2013; NHS England, "New Single drug fund list to bring fairer system for cancer patients" 4 April 2013. https://www.england.nhs.uk/2013/04/cdf/
[436] *BBC News*, 28 September 2013.

In August 2014, the Department of Health announced that the Fund's annual budget was increasing from £200 million to £280 million a year until 2016. At the same time, with the proposal from the CDF Panel, NHS England decided to ask the Panel's experts to re-evaluate drugs on the list.[437] "To ensure patients continue to have access to the best innovative treatments now and in the future, we must re-evaluate some of the drugs on the list,"[438] stated the CDF chair, the oncologist Peter Clark, noting that the Fund had a "minority of drugs of much less clinical value". Sharing the critique that the Fund had allowed companies to keep prices high, he recognised that the Fund "offered an alternative funding source on price terms, which in some cases have represented poor value".[439] At the same time, NHS England sought options to develop "greater alignment between CDF and NICE".[440] The alignment of the two bodies was also advocated by NICE, with its chief executive Andrew Dillon stating that NICE could take over the Fund's work.[441]

The budgetary situation was increasingly alarming to NHS policymakers. NHS England had a deficit of around £500 million, and the planned target surplus to offset the deficit fell short by £184 million in the 2014/15 year, with two-thirds of the overspend being reportedly attributed to the CDF.[442] This should have alerted policymakers to tackle the CDF, since government was trying to close the gap of a forecast £30 billion in spending by the 2020/21 year.[443]

The re-evaluation of drugs at the CDF resulted in rationing. The NHS intended removing not only drugs with lesser clinical benefit from the list but also effective but "excessively priced" ones unless the price was reduced.[444] It would hence leave the manufacturer the option of cutting the price of a drug so that it could remain on the list. In January 2015, NHS England announced that it would withdraw eight drugs from the list and reduce another eight drugs' indications to be covered by the CDF. In total, 25 out of 85 indications would be removed in March 2015. It also estimated it would save £80 million through negotiated price cuts to retain

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[437] *Financial Times* 28 August 2014; Hawkes 2014.
[438] NHS England, "NHS England sets out plan for a sustainable Cancer Drugs Fund" 28 August 2014. https://www.england.nhs.uk/2014/08/cdf-plan/
[439] *Financial Times*, 28 August 2014.
[440] NHS England, "NHS England sets out plan for a sustainable Cancer Drugs Fund" 28 August 2014.
[441] *The Times*, 16 October 2014.
[442] "Cancer drugs fund threatens NHS England's bottom line," *HSJ* 5 November 2014.
[443] *Financial Times* 5 January 2015.
[444] "Expensive drugs to be cut from cancer drugs fund," *HSJ* 11 November 2014; *The Times*, 15 December 2014.

drugs.[445] At the same time, the Fund's budget was again increased: it became £340 million per year, 1.7 times larger than the initial £200 million budget. The NHS forecast, however, that the Fund's spending would reach £410 million for the 2014/15 year.[446]

The delisting announcement triggered strong reactions from patient groups and drug companies. In March it was announced that a few drugs retained their positons after appeals from companies. In September, 16 drugs for 23 indications were delisted. Roche's drug Kadclya (trastuzumab emtansine) – which cost £90,000 per patient and was controversial since NICE had rejected it in 2014 - was later that year announced to back on the list, as a result of price negotiations between the industry and the NHS amid a petition for the company to lower the price.[447] Patient groups hence blamed not only NHS England for removing drugs from the Fund but also pharmaceutical companies for their drugs' prices.

During the controversy, there appeared some convergence of views among different organised interests, the government, and the NHS that the Cancer Drugs Fund was fiscally unsustainable; that it was also a temporary fix; and that greater alignment between NICE and the CDF would be a possible means of reform. Notably, while deploring the delisting decision, the ABPI stated that the Cancer Drugs Fund was just a "sticking plaster" and emphasised the role of NICE: it called for an "urgent reform of NICE" to allow for more flexibility over expensive drugs.[448] The industry's advocacy for NICE reform persisted throughout the debate; early on, in 2014 in response to the announcement of boosting the Fund, while welcoming the increased budget the ABPI called for "the development of sustainable aligned solutions involving NICE, NHS England, and the industry working together".[449] ABPI hence also wanted the integration of the CDF within NICE, and saw this as an opportunity to realise their policy goals for reforming NICE appraisals.

The electoral logic behind the creation of the Fund meant it was again a subject during the 2015 General Election. While the Conservatives pledged for the continuation of the Fund, the Labour Party proposed to set up a "cancer treatment fund" with a budget of £330 million per year, which would cover not only drugs but also radiotherapy and surgery – an emphasis consistent with their policies in the 2000s. Thus, even though the Fund remained heavily

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[445] "Cancer drugs fund receives surprise £60m boost, "*HSJ* 13 January 2015.
[446] *The Times*, 5 September 2015.
[447] *BBC News* 4 November 2015.
[448] Hawkes 2014; *The Guardian* 8 August 2014.
[449] ABPI, "ABPI comments on Government's decision to boost the CDF", 28 August 2014.

criticised for its overspending and stakeholders believed it unsustainable, the budgetary vehicle's policy legacy kept attracting office-seeking politicians, regardless of their partisanship, who in turn continued to prioritise cancer care over others.

In November 2015, NHS England proposed a reform of the Cancer Drugs Fund after its expiry in March 2016. Building on the idea of integrating the CDF within NICE, it proposed making the Fund "a 'managed access' fund for new cancer drugs, with clear entry and exit criteria".[450] In addition to recommendation and rejection, NICE would give a conditional recommendation, whereby the CDF would fund the drug for a pre-determined period during which further evidence would be collected. At the end of the period the drug would be subject to a further NICE appraisal in light of the new evidence gathered. NICE would give initial draft guidance prior to drug approval, and issue final guidance within 90 days after the Marketing authorisation.[451] Hence, these designs intended to enable patients' early access to the Fund, while attempting to limit overspending. The managed access fund proposed was consistent with recommendations from the new Cancer Strategy that the NHS accepted earlier in July, which was drawn up by the Independent Task Force chaired by Cancer Research UK.[452] Its report summarised the perception of incumbent policy-makers: "… because it has also enabled some pharmaceutical companies to bypass NICE cost-effectiveness assessments, it is widely acknowledged that it is no longer sustainable or desirable for the Cancer Drugs Fund to continue in its current form". Part of the solution, it hinted, would be for it to "continue to be a national fund to make new cancer treatments available prior to NICE assessment or which are subject to a conditional approval". Meanwhile, Cancer Research UK itself publicly advocated for early access to the Fund. In sum, the agenda for a managed entry fund was a reflection of converged views between NICE and the NHS (and the CDF) and some cancer charities close to the incumbent policymakers – the latter two remained largely similar to the policy community seen in the debate over the 2007 Cancer Reform Strategy that we saw in the last chapter.

In addition to the policy debate among actors inside the policy sector, fiscal consequences of the operation of the Fund triggered reactions from actors outside the sector. In 2015, the National Audit Office stepped in to investigate the CDF. It highlighted that despite the deficit

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[450] NHS England and NICE 2015, 8.
[451] Ibid.
[452] Cancer Taskforce, n.d. 38-39.

the DH and the NHS England did not take action until November 2014; and that despite their initial pledge, they did not monitor patient outcomes for those who received funding from the CDF.[453] The NAO report was followed by the House of Commons Public Accounts Committee hearing, which criticised the management of the Fund.[454] It urged the NHS to "take tough decisions to ensure that the Fund does not overspend", while asking the DH to draw "lessons" from the Fund's negotiations with companies to ensure a fair price and value for money. These critiques did not seem to affect the content of the reform agenda that had already taken shape, but helped the Department of Health and the NHS to justify tightening the fiscal grip on the use of the Fund in the post-enactment phase when they faced resistance from the industry.

The resulting reform adopted in February 2016 was largely unchanged from the original proposal. Under the new Fund, a joint group of NHS England and NICE called the CDF Investment Group, would, based on recommendation from NICE, decide a drug's entry to the Fund, determine a managed access agreement, and monitor use. Despite the industry's wishes to seize the opportunity to reform NICE, NICE's appraisal was largely unchanged. The ABPI responded with disappointment, once again calling for "the wholesale reform" of NICE.

4. Conclusion

Although the Coalition Government envisioned a far-reaching reform that would have changed the structure of drug rationing through value-based pricing, it confronted different political actors, including drug companies and doctors. In the end, the value-based pricing agenda yielded little concrete results, and drug pricing in England continued to operate under the PPRS' framework of profit-based control. What was left was the Cancer Drugs Fund, whose introduction was justified as an intervening step towards more comprehensive reform. Despite its budgetary overload gathering criticism, the electoral logic behind the introduction of the Fund meant that once it was introduced it was hard to remove; by remodelling it as a fund to manage drugs' early entry to the market, NICE, the industry, NHS, and cancer patient groups reached a negotiated settlement, which continued to favour cancer patients through their improved drug access.

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[453] NAO 2015.
[454] House of Commons Public Accounts Committee 2016.

The story behind the fall of the value-based pricing agenda revealed the power of the past choices. Both clinicians and the pharmaceutical industry adapted to the existing regulatory structure centred on explicit drug rationing led by NICE. Clinicians opposed the agenda because it would mean a return to postcode prescribing whereby local clinicians must make rationing decisions. Against the government's rhetoric of clinical autonomy and clinician-centred provision of care, clinicians no longer want to take back that responsibility. Likewise, part of the reasons drug companies opposed the reform was that they had also changed their business model in response to the existing regulatory structure centred on NICE. Through political actors' institutional adaptation, existing institutional arrangements of drug rationing hence created their own support basis, which in turn limited policy reversal.

At the same time, the trajectory of policy debates in the early 2010s showed the role of the "blame game" in shaping political struggles over an unpopular policy such as rationing. While the government would shift public accountability and the accompanying blame for rationing decision from NICE to clinicians and drug companies, hoping that it would lead to more drugs being available, neither of them would take on that burden. In the end, the agenda's demise meant the continuation of the final decision on drug funding being shared by NICE (for new drugs that it appraised) and local NHS commissioners (for the others). Ironically, although the Cancer Drugs Fund facilitated drug access and benefited drug manufacturers, it also implied the diffusion of responsibility and blame for drug rationing. The existence of a Fund that could override NICE's judgement failed to incentivise manufacturers to reduce their prices. The episode of removing drugs from the CDF suggests that unlike the earlier period of blaming NICE, patient groups started blaming not only the NHS for rationing drugs but also drug companies for putting high prices on the drugs that in turn led to the rationing. The continued role of the CDF as an instrument for early access may hence hint at the coming of the era in which the blame for expensive drug access is shared by both the payers and producers.

The English regulatory state for drug rationing has, in the past two decades, experienced pendulum swings between movements for expert-led logic and for politician-led logic of rationing. The two chapters that examined the policy trajectory revealed the endogenous forces that created these swings. While NICE's high political insulation enabled otherwise politically costly decisions based on experts' judgements, it also generated a greater magnitude of counter-mobilisation that led to political reactions. In the process, the regulatory regime was exposed to constant high-profile conflicts and salient political battles channelled through the public and electoral arenas. At the same time, however, the political reactions did not lead to a full reversal either, because the expert-based decision of the regulatory regime created its

own beneficiaries by facilitating actors' adaptation through its day-to-day interaction in the realm of the organised channel of politics. It was these interactions between the different political arenas that shaped the policy trajectory.

Chapter 6 Ministers' choices in low political insulation: France 1999-2016

French drug funding policy has remained a site of political struggles since the late 1990s. After the Socialist Jospin government defined actual clinical benefits as the criteria for drug reimbursement, the successive governments attempted to apply the criteria to exclude the drugs that an expert committee judged clinically ineffective from the reimbursement list. Given the persistently high drug consumption in France, the government considered de-reimbursement a major tool for rationalisation of drug funding. With the establishment of the independent agency HAS, one might expect that, with its greater formal independence from the health minister, the HAS expert committee charged with drug assessment played a greater role in shaping the trajectory of drug funding policy.

But the low political insulation of the decision-making – that is, the institutional arrangements whereby the health minister held the final decision-making powers over drug funding – meant that even if the expert committee concluded that a drug was ineffective and therefore should not be funded by national health insurance it was still up to the elected official how to react to the experts' opinion. As Chapter 3 has shown, the demarcation of powers between the minister and the expert committee was a key issue throughout policy debates over institutional arrangements of drug funding leading up to the creation of HAS; and both before and after the creation of HAS, the health minister always had the formal decision-making powers over the admission of a drug to the reimbursement list. Drawing on diverse cases of the drugs that were subject to the HAS expert committee's evaluation, this chapter examines the consequences of the low political insulation for policy choices over drug funding.

The chapter argues that, in an institutional setting with low political insulation, the anticipated political costs of a policy decision shaped ministers' policy choices over whether to de-reimburse a drug. In making such choices about a drug that experts have judged clinically ineffective, a minister takes into account the likely negative impacts of their policy decision on both the manufacturer and consumers of the drug. If the minister believes that the political implications of de-reimbursing the drug are too significant she chooses, against the experts' opinion, to maintain the reimbursement of the drug. The chapter finds that the establishment of HAS did not lead to a fundamental change in this ministerial strategy. Even though the independent regulator's autonomy-seeking behaviour led to open conflicts with ministers, as long as the latter had the final say on drug funding ministers' consideration of the political costs of a negative policy choice alone could still override the agency's judgements. Nor was

the ministers' behaviour altered after a major drug scandal, which was itself a partial by-product of ministers' choice to avoid de-reimbursement in the low political insulation environment. The chapter thus argues that ministers' considerations of the political costs that a policy decision might trigger, and hence the magnitude of the blame the minister might receive for making a negative decision continues to plays a role even after the advent of the French "regulatory health care state" (Hassentefel and Palier 2007).

With regard to the overall argument of the thesis, the present chapter thus shows how low political insulation enabled elected politicians to prevent an unpopular decision from being made. By anticipating its likely political impacts, in a setting with low political insulation ministers can use their decision-making powers to avoid making an unpopular policy choice.

The chapter draws on diverse cases of drug assessment made by the Transparency Committee. It uses variation across different attributes of a drug in terms of the losses that a decision to de-reimburse it can impose on drug companies and on consumers; it also makes a before-after comparison of organisational changes like the creation of the HAS and specific events like a drug scandal. Through these cross-sectional and temporal comparisons, the chapter considers when a health minister chooses to override experts' judgement and keep making a drug reimbursable. Based on these case studies, it then discusses the role of political costs in ministers' policy decisions in the context of low political insulation.

1. The pattern of drug assessment

The Transparency Committee evaluates all the drugs, both new and existing, to issue its opinion. As noted in Chapter 3, it gives a drug one of four SMR ratings in accordance with the drugs' actual clinical benefit, namely "Substantial", "Moderate", "Low", and "Insufficient". In its 1999 decree, the Jospin government defined SMR as the criteria for drug reimbursement.[455] The decree also provided that drugs with insufficient clinical benefit would not be reimbursed. After the Transparency Committee issues a positive opinion on a drug, the health minister has the power to include the drug on the reimbursement list through a ministerial order.

[455] Décret n° 99-915 du 27 octobre 1999 relatif aux médicaments remboursables et modifiant le code de la Sécurité Sociale.

In practice, the Committee relatively rarely gave a negative opinion. The overwhelming majority of its opinions on new drugs and new indications for existing drugs judged that drugs had a "substantial" actual clinical benefit (Table 6.1). The drugs were usually then reimbursed at 65%. By contrast, each year, 10-20% of opinions that it gave fell under the categories of either "low" or "insufficient" SMR. The negative opinions for new drugs attracted neither public attention nor controversy. General newspapers rarely reported them, and little evidence suggests that public debates erupted over the non-admission of these drugs. The decisions to refuse adding new drugs to the list are hence largely invisible. The dominance of "substantial" SMR reflected HAS's assessment criteria based on actual clinical benefit; unlike England, cost-effectiveness was not used to inform reimbursement decisions.

Year / **SMR**	2010	2011	2012	2013	2014
Substantial	275	208	207	176	192
Moderate	33	22	24	17	34
Low	15	11	21	6	12
Insufficient	17	19	31	15	23
Total	325	260	283	214	235

Table 6.1 The Transparency Committee's opinions on drugs for primary and extended indications

Year / **The type of demand**	2011	2012	2013
Initial inclusion	219	216	169
The extension of indication	22	32	31
Renewal and re-evaluation (incl. referral and self-referral)	557	459	276
Others	194	163	144
Total	992	870	620

Table 6.2 The number of demands that the Transparency Committee processed

Source: Ibid.

Yet, the picture is different when one takes into account the re-evaluation of existing drugs on the list. After admission to the reimbursement list, the Committee looks into the dossier to renew the inclusion every five years; the Committee can also conduct re-evaluations in an ad hoc manner based on the minister's referral or its own self-referral. Outputs of the committee include substantial amounts of these renewals and re-evaluations (Table 6.2). As we shall see in the next section, in contrast to new drugs the process is much more political and controversial, as the Committee's re-evaluation and the minister's decision on "de-reimbursement" – the removal of a drug from the reimbursement list -- takes place under the cross-cutting pressures of different interests.

2. The politics of de-reimbursement

This section examines policy decisions about de-reimbursement. It considers when politicians choose to de-reimburse a drug after the Transparency Committee has recommended doing so. This section compares policy decisions about diverse cases of drugs taken at different times to ensure both variation across drugs and over time. Longitudinal variation enables us to examine the effects of organisational change, such as the creation of HAS, and specific events, like a drug scandal, on policy choice. It also allows us to look at other factors that are commonly discussed in the literature and might be affecting policy choices, such as parties in government. In addition, looking closely at the process of the politics of re-evaluation over time has a methodological merit in assessing the evolution of policies and institutions. A comparison between different drugs that belong to different periods may raise a question of whether the observed variations in policy decisions are attributable to differences in the nature of drugs or activities of the regulator. This is especially the case given the magnitude of changes in medical technologies over the past decades: a drug launched in 1990 can be very different in its complexity from a drug launched in 2010. By contrast, a longitudinal comparison across regulatory activities for the renewal and revaluation of the same drug at different times, by keeping the drug to be evaluated constant, enables us to consider how experts evaluated the same drug differently over time and how the actor configuration might affect policy choices.

A de-reimbursement decision can impose visible costs on different types of actors. Politicians may consider these costs, and weigh them against the benefits of following experts' advice in making a de-reimbursement decision. As a result of such calculations, politicians

may not choose to follow experts' opinion and avoid de-reimbursement. Table 6.3 describes different stakes and political costs associated with de-reimbursement decisions.

		Costs on consumers/patients	
		High	Low
Costs on domestic firms	High	(a) de-reimbursement plan e.g. vasodilators (b) osteoarthritis drugs	(c) Multaq
	Low	(d) Alzheimer's disease drugs	Most of the new drugs with low SMR

Table 6.3 Different political costs of a de-reimbursement decision

The Y-axis of the table denotes the political costs of de-reimbursement imposed on domestic manufacturers. A de-reimbursement decision can impose a serious drop in sales on the manufacturer of a drug. It may even threaten the survival of the firm if the turnover of the drug accounts for a large part of the company's revenue, which was often the case for small and medium-sized manufacturers in France. Politicians may well be concerned about the impacts of negative decisions on the company given its contribution to the local and national economy. This axis can also indicate the possibility of lobbying by domestic firms. In France, anecdotes abound on how domestic drug companies are connected with political elites inside the government. It is hard to empirically detect whether such a network advantage of domestic firms affects ministers' considerations, but we can still expect that they may have better access to decision-makers and hence be able to bring politicians' attention to the costs associated with de-reimbursement.

For its part, the X-axis implies political costs on consumers by removing drugs from the reimbursement list. Several factors could affect the political costs in this dimension. First, the extent of the use of the product may affect the political costs on consumers. As the literature on welfare state retrenchment has pointed out, because the existing benefits of the welfare state create its own beneficiaries, groups who have benefited from a medication may oppose

removal of the drug (Pierson 1994). Hence generally speaking, other things being equal, products that are widely used may have higher costs than products that are not yet reimbursed or prescribed a lot. The lack of public debates about decisions not to include new drugs with an insufficient SMR rating on the reimbursement list mentioned above (the south-east quadrant of the table), in contrast to the mobilisation against removal of drugs already on the list that we shall see later, may reflect this variation. Second, and related to this, the magnitude of the opposition of beneficiary groups can also vary depending on the profile of beneficiaries. If de-reimbursement is imposed on well-resourced tightly connected groups in the population, it can generate a greater counter-mobilisation against the decision. Political costs may thus depend on the mobilisation of patient groups and doctors who are against de-reimbursement. Third, inherited policy goals and government programmes also affect the political importance of maintaining a drug on the list. The government can prioritise certain diseases that they consider politically important over others. In France, this prioritisation takes the forms of specific disease-based plans and of the exemption from co-payments of certain chronic disease patients. Finally, significant concerns over a drug's safety may lower the perceived benefits of keeping it on the list. It is hard to measure and include such concern; yet, for instance, warnings issued on the side effects of a drug may discount the political costs of removing it from the list.

This section considers diverse cases of policy decision that vary in their political costs. It allows us to explore how elected officials' considerations of different political costs attached with de-reimbursement of drugs affect political dynamics and policy decisions.

(a) The re-evaluation plan, 1999-2012

In 1999, Socialist Employment Minister Martine Aubry ordered the Transparency Committee to re-evaluate 4,490 medicines reimbursed by the Sickness Fund.[456] At the same time, Aubry's 1999 decree formally changed the criteria of reimbursement, explicitly codifying the SMR rating. The underling idea was to establish a greater coherence between therapeutic effectiveness, based on scientific evaluation, and reimbursement status, given by the Social Security. Experts from the committee concluded that while 840 drugs had "moderate" or "low" SMR, 835 drugs (18.3%) were judged to have "insufficient" clinical benefit.[457]

[456] *Les Echos*, 22 November 1999; *Le Monde* 7 August ; 22 April 1999.
[457] *Le Monde* 21 July 2001; 2 June 2001; *Le Figaro* 8 June 2001. The figures indicated here are the final results of re-evaluation, which was completed in 2001. The first phase of evaluation examined 1,176 drugs released in September 1999, among which 286 drugs were judged as having insufficient SMR.

However, the de-reimbursement of the products with insufficient clinical benefit turned out to be difficult for Aubry. In addition to resistance from the industry, the industry minister Christian Pierret pressured her not to remove the products by emphasising the negative impacts on employment.[458] In the end, Aubry did not resort to immediate de-reimbursement, and instead called for price reductions. An arrêté (ministerial order) in August 2000 laid down that the prices of 658 drugs with insufficient SMR would be reduced by up to 20% for three years,[459] while the reimbursement rate of 60 drugs (vasodilators) would be reduced from 65% to 35%. The government claimed that this measure was just a first step towards total de-reimbursement; it emphasised that products with insufficient SMR would be removed from the list in three years. Firms thus avoided the worst-case scenario of outright de-reimbursement of their products.

Reactions of pharmaceutical companies to the plan varied significantly within the sector. On the one hand, somewhat surprising support came from foreign manufacturers. In July 2000, shortly before Aubry's reform was announced, the LIR (Laboratoires internationaux de recherche), an organisation representing 14 international companies operating in France, such as GlaxoWellcome, Bayer, and AstraZeneca, among others, pressured the government by complaining that no concrete measures were yet taken.[460] De-reimbursement would, according to them, allow "freeing up a space for innovation and new treatments for diseases". On the other hand, French firms resisted the measures. In particular, those affected most were some 200 family-owned small and medium-sized companies (so-called "independent" firms) that relied on a few products. Among them, firms with more capacity (e.g. Servier, Ipsen, Pierre Fabre, and Fournier) attempted to accelerate strategies for overseas alliances and merger and acquisitions.[461] According to their criticism, the de-reimbursement policies would not lead to cost containment; on the contrary, as prescriptions would be switched to "more expensive and even more dangerous" products, it would lead to an increase in the healthcare cost.[462]

Cf. *Le Monde* 18 September 1999. The drugs with insufficient SMR mainly consist of vasodilators, magnesium-based products, and bronchial fluidifiers.

[458] *Les Echos* 10 July 2000.

[459] Products included veintonics, magnesium-based products and respiratory immune stimulants, 10% of diarrheic treatments and 1% of antibiotics.

[460] *Les Echos* 10 July 2000. *Le Figaro* 11 July 2000.

[461] *Le Monde* 29 July 2000.

[462] Jacques Servier in *Pharma Marketletter* 13 May 1998. Servier criticised the government's reimbursement policy as the result of a "small and effective lobby", which he believed removed their drugs from the reimbursement list. This criticism therefore may be related to the cleavage between domestic and international firms.

Similar dynamics were repeated after Élisabeth Guigou replaced Aubry in 2000. Once the final results of the evaluation were released in 2001, they opened up inter-ministerial battles.[463] As the 2002 Presidential election was approaching, the government was not willing to move on to de-reimbursement. Guigou did not make profound reforms and kept piecemeal adjustments such as a gradual reduction of prices. In July 2001, she announced a 2-19% price reduction, which would generate a saving of 900 million euros.[464] Price negotiation resulted in an 8% reduction for drugs as a whole. In contrast with the domestic-international divide in the industry over the de-reimbursement plan, Guigou's price-reduction agenda faced the united front between the LIR and the domestic pharmaceutical industry's association, the Syndicat national de l'industrie pharmaceutique (SNIP), as this time the drugs subject to price reduction included those essential for certain pathologies. The LIR called the plan "a dramatic signal for discouragement to innovation, and hence research".[465]

Aubry's and Guigou's plans resulted in court battles. After Servier filed a legal appeal against de-reimbursement of its product, in June 2003 the Conseil d'Etat ordered annulment of the reduction of the reimbursement rate from 65 to 35% for its two vasodilators.[466] It was followed by another ruling to annul the reduction for another 10 drugs, as it considered that the Committee's advice was not sufficiently reasoned.[467] The annulment prompted the minister to reorganise the Transparency Committee. Facing a significant setback in the de-reimbursement plan, Health Minister Jean-François Mattei stressed the reinforcement of the process' "transparency and rigour", with more emphasis on clinical expertise, and with more precise criteria to be applied.[468] The organisational change of the Transparency Committee to reinforce its scientific profile was thus a result of this event.

After the May 2002 Presidential election put an end to the Cohabitation, newly-appointed health minister Jean-François Mattei (UMP) set out agendas for healthcare reforms. Based on the perception that attempts at spending controls since the 1990s had failed, he placed a greater emphasis on patients' responsibility in healthcare. The underlying notion was that the health

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[463] *Le Monde*, 2 June 2001. Finance Minister Lauren Fabius, in addition to Florence Parly and Christian Pierret, junior ministers of finance and industry respectively, reportedly criticised Guigou's price reduction plan. cf. *Le Monde* 12 Sepember 2001.
[464] *Le Monde* 11 July 2001; *Le Monde* 24 August 2001.
[465] *Le Monde* 11 July 2001. Cf. *Le Figaro* 11 July 2001.
[466] Duxil (vasodilator) and Trivastal (a treatment for Parkinson's disease). Cf. *Le Figaro* 8 July 2003; *Le Monde* 5 July 2003.
[467] *Le Figaro* 24 July 2003.
[468] *Le Figaro* 5 July 2003.

budget deficit was caused by medical consumerism as a form of patients' moral hazard. The emphasis on the patient's responsibility were reflected in agendas such as raising the fees for physicians' home visits, the increase of patients' co-payments (*ticket modérateur*) for treatments and drugs, and the alignment of the reimbursement rate with available generic medicines. The last agenda was announced in April 2003, in which from October 172 drugs' reimbursement prices would be fixed at their generic price. The measure was expected to save 100 million euros every year. To encourage sales of generics, the government set the profit margins for generic sales for pharmacies at 10% against 3% for branded medicines.[469] These agendas fuelled considerable controversies. For instance, patient co-payment was later negatively regarded by the HCAAM (Haut Conseil pour l'Avenir de l'Assurance Maladie), in the course of preparing agendas for the Douste-Blazy healthcare reform in 2004, as "it results in a form of insidious rationing of care, therefore it gives up taking on advances of science and medical technologies".[470]

The idea that moral hazard hinders cost containment also embodied drug reimbursement policy. In terms of the de-reimbursement plan, therefore, Mattei further pushed agendas inherited from his predecessors. In April 2003, Mattei announced a ministerial decree in which the reimbursement rate for 617 drugs with moderate or low SMR would be reduced from 65% to 35%. The announcement was issued without prior consultation with medical unions and mutual funds. It provoked considerable criticism, as these drugs included medicines that were widely prescribed.[471] The Mutualité (the federation of complementary health insurance bodies, which cover co-payment) opposed the change in the reimbursement rate. The largest generalist association, the CSMF, also claimed that while they were in favour of de-reimbursement of drugs with an insufficient SMR, it was against the change in reimbursement rate, arguing that drugs should be either reimbursed if they were useful, or de-reimbursed if not.[472] With regard to the drugs with insufficient SMR, Mattei had earlier begun the consultation process for de-reimbursement.[473] In July 2003, Mattei announced that 650 out of the 835 drugs that were judged as having insufficient SMR in Aubry's re-evaluation plan should be totally removed from the list. The measure was estimated to achieve a saving of 1.4 billion euros. He declared his commitment to implementing the first wave of operations in October 2003, which applied

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[469] *Pharma Marketletter* 24 June 2003; 7 October 2002. *Le Figaro* 25 September 2002;
[470] HCAAM 2004, 13.
[471] *Le Monde*, 24 April, 2003.
[472] *Le Monde* 01 October 2002; *Les Echos* 24 April 2003.
[473] *Le Figaro*, 25 September 2002; 26 September 2002.

to 84 drugs. These were mainly traditional medicines, some of which were considered dangerous. Mattei also planned another two waves to complete the de-reimbursement, which was taken over by his successors, following the adoption of the 2004 healthcare reform.

Yet, even after the establishment of HAS in the 2004 Douste-Blazy reform, an evaluation by an expert committee did not make imposition of de-reimbursement easy. The second wave of the de-reimbursement agenda arose in 2005. In September, HAS recommended de-reimbursement of 221 products with insufficient SMR. It argued that the withdrawal of the reimbursement of these products had no proven negative impact on the quality of care, and it emphasised the necessity of ensuring national solidarity and providing access to the most effective treatments.[474] As a commentator maintained, as the new independent agency's first evaluation, this recommendation was expected to be "symbolically strong but easy to defend because of no possible scientific debate".[475] However, the government preferred not to remove the products from the list; instead, it proposed to create a new class with a reimbursement rate of 15%. Among the de-reimbursement targets, the new class was applied to veintonics, a treatment for heavy legs. HAS disagreed with the new reimbursement rate. It claimed that the products in question had been removed in Germany, Italy, Spain, and Luxemburg by 2004. It also pointed out that a French patient consumed eight times more products with an insufficient SMR than a Canadian or British patient, which cannot be explained by demographic and pathophysiological structures.[476] Health Minister Xavier Bertrand nevertheless decided to keep 62 veintonics reimbursed at 15% until January 2008 before they were removed.[477] Another 156 drugs (282 branded pharmaceuticals) were removed from the list in March 2006.[478]

The subsequent wave of de-reimbursement shows a similar open conflict between the agency and the minister. In October 2006, HAS issued a recommendation for the third wave of de-reimbursement measures. A major difference between this wave and the previous ones is that this time it targeted prescription-only drugs. It recommended that 145 drugs judged to have insufficient SMR ratings, accounting for 575 million euros (among which 345 million euros were covered by the obligatory health insurance), should be removed from the list. The primary share of the de-reimbursement comprised vasodilators used for multiple indications.

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[474] *Le Monde*, 15 September 2005. *Le Figaro* 16 September 2005.
[475] Ibid.
[476] *Le Monde*, 26 September 2005.
[477] *Le Monde*, 30 September 2005.
[478] *Le Monde*, 2 March 2006.

As for the drugs whose benefits were judged as insufficient in some indications but not in others, HAS advised their removal from the list for the former indications.

However, Health Minister Xavier Bertrand announced that he would not follow HAS's opinion. He justified this decision by maintaining that his role was "to take into account the social reality" as opposed to HAS's "scientific assessment".[479] The minister emphasised the consideration of the existence of alternative treatments, especially for old people. Thus, 48 of the 89 drugs (mainly vasodilators) would maintain the same reimbursement rate of 35% while reducing their prices up to 20%; the other 41 drugs would be removed from the reimbursement list from January 2008, after a one year transition period during which the reimbursement rate would be reduced to 15%.[480] The Mutualité regretted the decision. It suggested that its subsidiaries should no longer pay for the drugs reimbursed at 15%. For its part, Les Entreprises du médicament (LEEM) (the pharmaceutical industry's association, formerly named SNIP) criticised the "massive" price reduction.

Successive ministers continued to adopt de-reimbursement measures. For the 2010 Social Security Financing Law, Health Minister Roselyne Bachelot decided to create a reimbursement rate of 15% for drugs with low and insufficient SMR. Based on this new reimbursement rate, an additional wave of de-reimbursement measures took place in 2010 based on HAS' 2006 evaluation, where the reimbursement rate for 150 products with low or insufficient SMR was reduced from 35% to 15%.[481] The creation of the new reimbursement rate, however, meant that these products with insufficient clinical benefits again avoided total de-reimbursement.

Yet, ministers' reluctance to implement total de-reimbursement was subsequently reversed. In January 2011, Health Minister Xavier Bertrand announced that 126 products with insufficient SMR would be de-reimbursed.[482] According to the Cour des comptes' report that year, the minister planned to de-reimburse all drugs presenting insufficient SMR. Bertrand's announcement was also backed by President Nicholas Sarkozy, who clarified that a product must be de-reimbursed if it is not effective.[483]

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[479] *Les Echos*, Oct. 26, 2006. Cf. *Les Echos*, Oct. 20, 2006.
[480] *Les Echos*, Oct. 26, 2006; *Le Figaro*, Oct. 26, 2006.
[481] *Le Monde*, April 17, 2010.
[482] *Les Echos* 1. Feburary 2011.
[483] *Le Parisien*, 21 January 2011.

Why was the same minister, who repeatedly refused to follow experts' advice in the previous rounds of re-evaluation, eager to de-reimburse all the drugs with insufficient SMR? The timing of the decisions suggests that this was to do with an ongoing drug scandal. In late 2010, the minister ordered the IGAS (Inspection générale des affaires sociales) to investigate Mediator, a diabetes drug manufacturer by Servier. Having obtained approval for diabetes but widely prescribed for controlling appetite, Mediator was alleged to have caused between 500 and 2,000 deaths since 1976, until it was withdrawn from the market in 2009. As the Transparency Committee had judged Mediator's SMR insufficient in 1999 but the drug had nevertheless remained reimbursable throughout successive de-reimbursement plans, the scandal was not only seen as a significant blow to the drug safety regulatory regime but also to pricing and reimbursement, and in fact to policies related to the pharmaceutical sector as a whole. In that autumn the Cour des comptes deplored that the measure for de-reimbursement had not been implanted. It criticised the lack of transparency in the reimbursement decision by emphasising that ministerial decisions contradicted experts' opinion.[484] In the meantime, a further re-evaluation by HAS was progressing, and it was decided that at least some of the drugs were to be de-reimbursed in early 2012.

In short, the agenda for de-reimbursement based on experts' evaluation took a decade-long process to implement after Aubry's plan in 1999. Ipsen's Tanakan, a drug based on gingko for old-age memory problems may exemplify this incrementalism of de-reimbursement measures. As already noted, the threat of de-reimbursement would be felt especially severely by a family-owned company such as Ipsen, since Tanakan was its second best-selling drug (11% of the company's turnover), the 54th most prescribed drug in France, representing 55 million euros in reimbursement payments in 2006.[485] Tanakan had been put on the list of drugs with insufficient SMR in Aubry's 1999 plan. The reimbursement rate was reduced from 65% to 35% in 2001, which was annulled subsequently by the 2003 ruling of the Conseil d'Etat.[486] HAS included Tanakan on the de-reimbursement list again in 2006, based on the re-evaluation that its SMR rate was "insufficient". Yet, like another 47 drugs, it was not withdrawn from the reimbursement list immediately and was still reimbursed at 35%; instead, the government decided to reduce the price. Meanwhile, Ipsen launched additional clinical trials involving 2,800 patients, which continued until 2010, trying to demonstrate Tanakan's effectiveness in

[484] Cours des comptes 2011, 119-120.
[485] *Les Echos* 13 Octpber 2006.
[486] *Les Echos* 13 October 2006; *Les Echos* 20 October 2006.

the treatment of Alzheimer's disease.[487] This sort of "buying -time" tactics might have helped Ipsen to prepare for the expected loss of Tanakan's turnover; it was reported to have boosted research and development and improved production capacity, especially looking to expand its presence in overseas markets.[488] In 2010, Tanakan's reimbursement rate was reduced further to 15%.[489] In the following year, HAS again judged that Tanakan had an insufficient SMR and would not be reimbursable, recommending withdrawal from the list.[490] Tanakan was finally removed from the list in February 2012[491].

The case of the re-evaluation plan shows that political costs on both the domestic producers and consumers played a role in decisions. On the one hand, domestic French firms, which were the main expected losers of the decision, mobilised against de-reimbursement, which successfully shaped the minister's policy choice. The mobilisation was transmitted through either the rival ministries' intervention, as shown in Aubry's and Guigou's plans, or direct lobbying. Consideration of the loss imposed on the domestic industry was also confirmed in interviews. A senior civil servant who was involved in Gigou's plan mentioned a meeting with a group of independent firms including Servier, Pierre Fabre, Ipsen and others, which claimed that thanks to their new research several new drugs were in the pipeline and asked the minister to wait. "We need a bit of time, we can't murder the French industry".[492] On the other hand, in some cases doctors protested against de-reimbursement. A former member of HAS said that "some front-line doctors" protested when HAS conducted the 2005 re-evaluation, as they were blamed by patients for prescribing useless drugs.[493] As a result of pressure from both interests, ministers were reluctant to impose de-reimbursement.

(b) Osteoarthritis drugs

Another case that involved considerable stakes for both patients and French domestic firms was drugs for osteoarthritis. Osteoarthritis is said to affect 9-10 million people in France,

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[487] *Les Echos* 24 October 2006; *Les Echos* 20 March 2007; *Les Echos* 4 July 2007.
[488] *IHS Global Insight* 4 June 2007.
[489] *Les Echos*, Feb 26, 2010 ; April 19, 2010. *Le Monde*, April 17, 2010.
[490] *Les Echos*, 11 November 2011.
[491] For the announcement, see http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-02/accompagnement_des_mesures_de_deremboursement_de_medicaments_fevrier_2011.pdf Cf. *Le Figaro Économie*, January 30, 2012.
[492] Interview with a former DSS official, 10.11. 2016.
[493] Interview with a former member of HAS, 30.9. 2016.

especially people older than their 40s.[494] In 2008, the Transparency Committee judged that the actual clinical benefit of Pierre Fabre's Structum for the treatment of hips and knees was insufficient. The drug remained reimbursed at 15%, but it was de-reimbursed in December 2011. Pierre Fabre complained, in particular, that whereas Structum was judged insufficient, its competitors were judged as having low SMR. It claimed that instead of saving expenditure de-reimbursement of Structum would cost the health insurance more, because the prescription would be transferred to its more expensive competitors.[495] It appealed to the Conseil d'Etat but was not successful.[496]

But the fate of Structum's competitors turned out to be unkind too. In January 2013, HAS published an opinion recommending the de-reimbursement of several anti-inflammatories, symptomatic slow-acting drugs for the treatment of osteoarthritis (drugs based on glucosamine, chondroitin, diacerein, and avocado and fish oils), including Chondrosulf (manufactured by Génévrier), ART 50 (by Negma), Piascledine (by Expansience) and Zondar (by Niverpharma) – the drugs named as the main competitors for Pierre Fabre's Structum. This recommendation, itself followed several rounds of re-evaluation. In 2002, several of the nine drugs were judged as low SMR based on re-evaluation, which led to reimbursement at 35%. In the 2008 re-evaluation of the drug the committee also judged them as low SMR, though the committee gave the manufacturer the condition of a two-year study to examine their effects on reducing the consumption of anti-inflammatory steroids. The reimbursement rate was reduced to 15% following the creation of this new reimbursement rate in 2010. In September 2011, the Director of Social Security further referred them to the Transparency Committee, and the conclusion of the committee reiterated that it would re-evaluate the drugs once the results of the trial came out.[497] Based on the re-evaluation in January 2013, the Committee issued a negative opinion about the inclusion of the drugs in the reimbursement list. The Health Minister moved on to

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[494] Aflar's website. Cf. http://www.aflar.org/l-arthrose

[495] *Le Figaro*, 11 Oct. 2011. *La Tribune* 7 October 2011. Cf. CT. « Synthèse d'avis de la commission de la transparence » available at http://api.vidal.fr/data/avis/com/vidal/data/avis/090026e580229716.pdf

[496] *La Tribune* 7 October 2011. Conseil d'État, Juge des référés, 30/11/2011, 353633, Inédit au recueil Lebon. https://www.legifrance.gouv.fr/affichJuriAdmin.do;jsessionid=5AC9BE55BD3B9BD96E5FF8C3BF1505AC.tpdjo06v_1?oldAction=rechExpJuriAdmin&idTexte=CETATEXT000024942888&fastReqId=1628858398&fastPos=15

[497] ART 50 mg, gélule, Avis de la CT du 09 janvier 2013, 2-5. https://www.has-sante.fr/portail/upload/docs/application/pdf/2013-02/art50_ri2012_avis2modifie17jan2013_ct12263.pdf

issue a ministerial order in May removing the drugs from the list. In July, however, the Conseil d'Etat suspended the order on the grounds that HAS had not re-evaluated all the specialities of the same class of drugs, including some other glucosamine-based products, as required in the Code of Social Security. Meanwhile, in November, based on the ANSM's re-evaluation of the risk/benefit ratio of the drugs, the EMA's Pharmacovigilance Risk Assessment Committee recommended suspension of drugs containing diacerein (among the drugs mentioned above, ART 50, Zondar and their generics) due to the side effects of severe diarrhoea and potential liver damage.[498] After the Transparency Committee judged that other glucosamine-based products had insufficient SMR, in January and March 2015 the Health Minister removed all the drugs mentioned above as well as the other glucosamine-based products that HAS judged to have insufficient clinical benefit.

The decision had a severe impact on the manufacturers, as they were all small and medium-sized firms and osteoarthritis drugs accounted for significant part of their sales. Facing the risk of de-reimbursement, one of the manufacturers, Expanscience, was reported to have axed 119 positions from their 750 employers.[499] After de-reimbursement of its drug, Génévrier shifted its resources to its biotechnology subsidiary to survive.[500]

Patient groups and rheumatologists mobilised against the decision. The patient group Aflar (L'Association française de lutte antirhumatismale) claimed that although the drugs only had low-to-moderate therapeutic effectiveness they improved patients' quality of lives. It launched a major campaign to protest against de-reimbursement, including sending open letters to Health Minister Marisol Touraine and President François Hollande and running petitions, the latter of which gathered more than 160,000 signatures.[501] Overall, however, these mobilisations did not seem to affect the results.

After Mediator

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[498] EMA, "PRAC recommends suspension of diacerein-containing medicines." 6 December 2013. http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Diacerein/Recommendation_provided_by_Pharmacovigilance_Risk_Assessment_Committee/WC500154013.pdf
[499] *Le Parisien* 31 August 2012.
[500] *Actu Labos* 12 September 2012. *Les Echos* 2 March 2015.
[501] *Aujourd'hui en France* 16 March 2015.

(c) Multaq

Sanofi-Aventis's drug Mutaq, an antiarrhythmic medication for the treatment of atrial fibrillation (irregular rhythms in the heartbeat), provides an interesting case to illustrate how the government reacted to the heightened salience of drug safety in a crisis situation. Manufactured by the national flagship company, Multaq was seen as a potential "future blockbuster" while it was developed. As a number of its medicines' patents were to expire by 2012, Sanofi-Aventis considered Mulaq strategically important. One estimate indicated that the drug's sales would be $1.4 billion in 2014.[502] We would hence expect the producer interest's stakes over Multaq to be high. Multaq was approved for marketing authorisation in November 2009.

Multaq was launched on the French market in October 2010. The Transparency Committee's assessment disappointed Sanofi-Aventis. In March, it was reported that the Committee initially judged that the drug had only a moderate SMR; it also gave an ASMR of 5 (no improvement). These results implied that the drug would be reimbursed at 35%, and the price negotiation was unlikely to be in favour of the manufacturer as the drug was unlikely to be given a generous price compared to its competitor – a drug produced in 1967, with an expired patent.[503] The leadership of Sanofi-Aventis urged the committee to hold a hearing, and as a result the final version of the opinion gave a substantial SMR.[504] The new drug was hence reimbursed at 65%. The company had to accept a very much lower price than in other European countries.

In January 2011, however, it was reported that according to the US Food and Drug Administration (FDA) in very rare cases the drug caused severe liver damage, and in two cases patients treated by Mulaq required liver transplantation.[505] Following the FDA notice, the EMA recommended a warning and precautions about the drug. In particular, it recommended the examination of the liver function of the patient before and over the course of the treatment and discontinuation of the treatment in case of signs of liver damage. It also launched a re-examination of the drug's risk-benefit ratio.[506]

This safety warning coincided with the "storm" of the Mediator scandal. The IGAS investigation report on Mediator had just come out on 15 January. During the same week, as

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[502] *La Tribune* 14 Jan 2011. Cf. *Le Figaro* 22 March 2010.
[503] *La Tribune* 22 March 2011; *Le Monde* 24 March 2010.
[504] *Les Echos* 16 June 2010.
[505] *Les Echos* 17 January 2011.
[506] *Les Echos* 24 January 2011. *L'Agence France Presse* 21 January 2011.

part of the response to the scandal, Minister Bertrand ordered the Afssaps to publish the list of 76 drugs currently subject to follow-up examination in national pharmacovigilance by the end of the month. In practice, the list meant drugs were put under reinforced surveillance within the risk management plan, which became obligatory for all new molecules after a major drug scandal took place in the United States in 2004 involving Vioxx, an arteritis drug. The Afssaps director reassured the public that the list was not a "black list" of dangerous drugs and it would not affect patients currently taking them. The minister's order to publish the list may hence indicate his attempt at managing the public reaction after the Mediator scandal. Multaq was also put on the published list.

Faced with the EMA alert, HAS' Transparency Committee decided to re-evaluate Multaq. In June the committee judged that it did not have sufficient clinical benefit. Minister Xavier Bertrand did not oppose the experts' advice; in July he stated that he had "decided to change the rules: if opinions are made by the scientists, the minister will be bound to follow the opinion, unless [s/he] wants to oppose [it] with a reasoned opinion".[507] The decision to remove Multaq did not surprise the press; a month earlier the minister stated at the press conference for the reform of pharmacovigilance in response to the Mediator scandal that he would follow experts' advice "without hesitation nor trembling". Bertrand also ordered the Afssaps to reinforce the surveillance of Multaq. In November, Multaq was de-reimbursed. Following its re-evaluation, the EMA, for its part, confirmed in September that Multaq had a positive risk/benefit ratio. The drug was hence not withdrawn, but the EMA also recommended restricted use of Multaq after consideration of alternative treatments.

(d) Alzheimer's disease drugs

The 2011 and 2016 re-evaluations of four drugs for the treatment of Alzheimer's disease, including Aricept (manufactured by Eisai), Ebixa (by Lundbeck), Exelon (by Novartis), and Reminyl (by Janssen-Cilag), provide another case of the post-Mediator dynamics over drug de-reimbursement. It also illuminates the role of inherited policy programmes in politicians' consideration of de-reimbursement's political costs.

Alzheimer's disease is a highly important disease area from a political perspective, and the drugs in question occupied an important place within the therapeutic strategy. The stake for

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[507] *Le Monde* 18 July 2011.

patients of the drugs was high -- among 800,000 patients of Alzheimer disease in France about 300,000 patients were estimated to be prescribed one of the four drugs, with an annual cost of 260 million euros covered by the Sickness Fund.[508] Successive governments had prioritised combatting Alzheimer's disease. Alzheimer's disease was one of the chronic diseases included in the Affections longue durée (ALD), which exempted certain chronic disease patients from co-payment for treatments. For patients admitted to the ALD the drugs were reimbursed at 100%. Moreover, Alzheimer's disease was also one of the few areas for which the government had introduced disease-based national "plans", alongside cancer and palliative care. During the 2008 Presidential election Sarkozy pledged to create a plan for Alzheimer's disease, which was launched after the election. The plan set out a comprehensive strategy ranging from research and development, and clinical guidelines to disease management. Costs imposed on consumers by excluding drugs from the list can hence be very high. At the same time, none of the drugs in question were produced by domestic firms. Although the Alzheimer's disease plan was pledged in part as a response to domestic firms' campaign during the 2008 Presidential election, the grand research and development projects associated with the plan would not be themselves affected by de-reimbursement of these drugs. Few comments were made by domestic firms or LEEM in the wake of public debates over the potential de-reimbursement of the drugs.

The case of Alzheimer's disease drugs suggests attempts by the regulator to act autonomously in response to the crisis situation. In 2011, HAS launched a re-evaluation of four existing Alzheimer's disease drugs on the market. The re-evaluation was based on a "self-referral" (*une autosaisine*), which allowed HAS to re-evaluate the drug based on its own agenda. This agenda reflected its response to the Conseil d'Etat's annulment of the earlier guidelines due to undeclared conflicts of interests. The re-evaluation's timing was perhaps also related to the context of the Mediator scandal. Given these hostile situations for the regulatory agency's credibility, HAS attempted to restore its reputation through the re-evaluation agenda.

These four drugs were given "substantial" SMR in the previous evaluation in 2007, and were covered at 100% for ALD patients. Several studies had questioned the therapeutic efficacy of the drugs in slowing the progression of the disease. Moreover, there was a concern

[508] *Le Figaro* 9 March 2011. *La Croix* 2 March 2011.

about side effects associated with them. An independent pharmaceutical journal, *Prescrire*, had reported increased risk of cardiac side effects and sometimes deaths.[509]

The re-evaluation process became salient, as a leaked document from HAS' working group revealed the possibility of de-reimbursement: some of the assessors recommended judging the drugs of "insufficient" SMR, while others considered the drugs "low" in their clinical benefit.[510] Patient groups, including French Alzheimer's Society, and specialist doctors advocated for not removing the drugs. Before the conclusion was announced, Health Minister Xavier Bertrand reassured the public that the drugs would not be removed, and that they would keep being reimbursed at 100% for ALD patients.[511] The HAS concluded that the four drugs were evaluated as "low" SMR and ASMR 5 (no improvement).[512] As a result, the reimbursement rate for the four drugs was reduced from 65% to 15%; ALD patients they were still reimbursed at 100%. HAS director Haroussou deplored the "interference" and "pressures" during the consultation. He publicly criticised "these grand neurologists, of whom you could wonder if they are influenced by pharmaceutical companies, and who had better care about scientific impact of medicines rather than looking for mediagenic impacts".[513]

Five years later, another round of HAS's re-evaluations in 2016 provoked yet another controversy. Once again, the Transparency Committee judged that actual clinical benefit of the drugs was "insufficient". Health Minister Marisol Touraine (PS), however, decided to not to follow the committee's opinion and to maintain the drugs on the list. She explained the decision by maintaining that since the disease did not have an available cure she first wanted to establish the "care protocol".

These decisions not to de-reimburse the drugs were made despite mobilisation and campaigns *for* de-reimbursement. There was considerable criticism and mobilisation among consumer interests and generalist doctors against the decision. Not only a group of doctors who were critical of pharmaceutical policy, such as those around the journal *Préscrire*, but

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[509] Cf. *La revue Prescrire* 2008.
[510] *La Croix*, 11 October 2011.
[511] *Les Echos* 24 October 2011; *Le Monde* 25 October 2011.
[512] *Le Monde* 28 October 2011. HAS recommended that the prescription of the drugs should be limited to six months with one possible renewal after re-examination; an extension beyond one year must be decided in consultation with the caregiver and patient (if possible), following a joint meeting with a multidisciplinary team including physician, geriatrician or neurologist and psychiatrist. Cf. http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-01/alzheimer_19102011_synthese.pdf http://www.has-sante.fr/portail/upload/docs/application/pdf/2013-01/ebixa_ct_10677.pdf
[513] *Le Monde*, Oct. 28, 2011.

also major medical associations mobilised against maintaining the reimbursement of the drug. Together with the *Préscrire*, one of the generalist associations, MG France, had campaigned for de-reimbursement of the drugs since 2011, emphasising their cardiac risk. The largest generalist union, CSMF, was also against the minister's decision. In April 2017 when the government announced its intention to raise fees for neurology consultations, it claimed that the announcement was to avoid deciding on the issue of de-reimbursement of the Alzheimer's disease drugs. They stated: "We regretted that the minister limits herself to a pre-electoral political communication, thus delaying making a decision on a certain sensitive and very worrying subject".[514]

The case of Alzheimer's disease drugs thus shows how the existing policy programmes that reflect policy priorities affect elected officials' policy choices. The result is somewhat surprising, as even after the Mediator scandal, when the public might have become more sensitive to safety concerns, and despite worries expressed by both doctors and groups of consumers about the drugs' risk, considerations of anticipated political costs imposed on domestic programme beneficiaries alone can override such concerns.

3. Discussions

Comparisons across different episodes concerning drugs yield insights into determinants of the minister's de-reimbursement decisions (for a summary of the cases, see Table 6.4). First, both types of political cost –on domestic industry and on consumers – informed ministers' behaviours. The effect is by no means deterministic. There is some evidence that consideration of domestic producers had substantial impact on the minister's decisions in re-evaluation plans, but even in the absence of the domestic business aspect, as in the case of Alzheimer's disease drugs, with a very high level of costs on consumers, the minister did not choose to de-reimburse a drug.

514 http://www.csmf.org/actualites/2017-04-12-000000/plan-alzheimer-un-joli-tour-de-magie-de-madame-la-ministre

Year/ Case [*1]	Drugs	Costs on domestic producer	Costs on consumers/patients				Minister	Minister's decision
			Patient group /doctors [*2]	Population covered	National priority	Safety concern [*3]		
2000 (a)	658 drugs w/insufficient SMR	High		High	No	No	Martine Aubry (PS)	Avoid immediate de-reimbursement Price reduction 60 vasodilators: 65% -->35%
2001 (a)	Drugs w/ insufficient SMR	High		High	No	No	Elisabeth Guigou (PS)	Avoid de-reimbursement Price reduction
2003 (a)	(a) 617 drugs w/moderate/low SMR (b) 84 old drugs w/ insufficient SMR (diverse)	High	Generalists against the reduction of the reimbursement rate	High	No	No	Jean-François Mattei (UMP)	(a) 65% --> 35% (b) de-reimburse
2005 (a)	145 drugs w/insufficient SMR (eg veintonics)	High	Doctors against de-reimbursement	High	No	No	Xavier Bertrand (UMP)	Override the Transparency Committee (CT) advice: Creation of 15% for veintonics until 2008 De-reimburse 156 drugs
2006 (a)	221 products w/ insufficient SMR (eg vasodilators)	High	Doctors against de-reimbursement	High	No	No	Xavier Bertrand (UMP)	Override CT advice: 48 drugs: reimburse at 35%; price reduction 41 drugs: reimburse at 15% before de-reimbursement in 2008
2009 (a)	150 products w/ low/insufficient SMR	High		High	No	No	Roselyne Bachelot (UMP)	Legalise the rate of 15% for low/insufficient SMR
2011 (a)	126 drugs w/insufficient SMR	High		High	No	***No***	Xavier Bertrand (UMP)	Follow CT advice: de-reimburse
2011 (b)	Structum (osteoarthritis)	High		High	No	***No***	Xavier Bertrand (UMP)	Follow CT advice: de-reimburse
2013-15 (b)	9 osteoarthritis drugs	High	Patient groups against de-reimbursement	High	No	Yes (some of the drugs)	Marisol Touraine (PS)	Follow CT advice: de-reimburse

2011 (c)	Multaq (for atrial fibrillation)	High	N/A	Low	No	***Yes (EMA warning)***	Xavier Bertrand (UMP)	Follow CT advice: de-reimburse
2011 (d)	4 Alzheimer's disease drugs	Low	- Patient groups/specialists against de-reimbursement - Generalists for de-reimbursement	High	Yes	***Yes (no official warning)***	Xavier Bertrand (UMP)	Override CT advice
2016 (d)	4 Alzheimer's disease drugs	Low	- Patient groups/specialists against de-reimbursement - Generalists for de-reimbursement	High	Yes	Yes (no official warning)	Marisol Touraine (PS)	Override CT advice

*1) Alphabet denotes case groupings used in Table 3: (a) re-evaluation (b) osteoarthritis drugs (c) Multaq (d) Alzheimer's disease drugs

*2) Reported opposition appeared in more than 3 independent sources among general newspapers during the studied period

*3) Yes/No means safety concerns specific to the particular specialities. ***Bold*** cells are under a high level of public attention to drug safety in general immediately after the Mediator scandal

Table 6.4 Policy decisions on de-reimbursement

Source: Author's elaboration

For each dimension of political costs, we also see some more nuanced pictures. On the one hand, comparison of the re-evaluation plan and osteoarthritis drugs suggests the necessity of a further investigation into more specific effects of the domestic industry. In both cases, the firms affected were all domestic independent firms and the drugs were of a similar type – high volume ones with insufficient clinical benefits. They also involved counter-mobilisation by doctors and patient groups. However, firms were more successful in shaping the minister's choice in the re-evaluation plan than in the case of osteoarthritis drugs. One possible interpretation is that in the former, it involved much larger number of drugs and the industry association formed a more united front to defend their interests, whereas in the latter case firms were competing with each other within one disease area. Another possibility is that after the Mediator scandal, with increased public attention to safety concerns on drugs and a more critical view of the existing regulatory regime, elected politicians were becoming more cautious about whether not to follow experts' opinions; they might give a greater consideration to the risk of getting the blame for refusing experts' outputs, which might lead to negative consequences like Mediator. This somewhat optimistic speculation of the impact of a scandal might be the case, especially because at least two of the osteoarthritis drugs had reported safety concerns. Yet, the available evidence does not allow us to make conclusive claims.

On the other hand, in terms of political costs on consumers, doctors and patient groups' mobilisation against de-reimbursement at least played a role in the re-evaluation plan, though in the case of osteoarthritis drugs it did not seem to have significant effects in stopping ministers from de-reimbursing the drugs. Yet perhaps the clearest impacts of costs upon consumers are shown in the case of Alzheimer's disease drugs, where the drugs conveyed significant political importance and policy priority due to inherited policy programmes. Conversely, the effects of consumer groups' and doctors' criticism *against* keeping reimbursing drugs were limited at best, even in the post-Mediator period. Even if we take the optimistic hypothesis about public criticism on the existing regime mentioned above – that ministers were generally more cautious in choosing not to follow experts' outputs in the post-Mediator period – the perceived political importance of keeping the Alzheimer's disease drugs on the list was still great enough for the minister to override experts' outputs.

Second, in terms of ministers' blame-avoidance strategies, ministers used various tactics to avoid politically costly choices. They delayed implementation of de-reimbursement; they incrementally reduced the reimbursement rate of drugs instead of choosing to remove them; they reduced the price of the drug; and they created a new reimbursement rate. The use of

price reduction as an alternative to de-reimbursement shows how existing institutional structures in the policy sector gave a range of available policy instruments and options that policymakers could use; it also suggests the continued role of the state in policy-making that we see in other French policy sectors.

Third, concerns on drug safety issues had substantial impacts on politicians' behaviours at least during the period of intense public salience immediately after the investigation into the Mediator scandal. In the de-reimbursement decisions in 2011 over drugs with insufficient SMR and of Multaq, the minister, who was trying to turn the blame on the government for the scandal to his own credit by reforming the system, attempted to address the issue of clinically ineffective drugs. By contrast, only a few months later, the same minister chose not to remove Alzheimer's disease drugs from the reimbursement list, despite the risks highlighted by consumer groups and medical associations. To be sure, unlike the Multaq case, there was no official EMA warning. Yet, the minister could have been sensitive about safety matters given his earlier commitment after the scandal, and given -- as the next chapter shall show – his own initiatives for ongoing policy debates over reforming pharmaceutical regulation. Thus the overwhelming political importance of drugs in existing programmes overshadowed the Alzheimer's disease drugs' safety risk.

Fourth, cross-case comparisons show that some of the conventional accounts of the welfare state reform, such as partisanship, played little role in the politics of de-reimbursement. Both ministers from left- and right-wing parties were extremely reluctant to de-reimburse the same Alzheimer's disease drugs. Parliamentary debates during the re-evaluation plan also indicate that both parties, while in opposition, criticised de-reimbursement, and when they were in power, they kept putting de-reimbursement on the agenda but were reluctant to actually implement them. This confirms the idea that the politics of drug de-reimbursement is the politics of blame-avoidance, where partisanship played a less important role (cf. Pierson 1994).

In addition to cross-case comparison, longitudinal comparisons of the same drugs across different occasions of re-evaluation show how an independent regulator tried to develop autonomy. Generally speaking, each re-evaluation of the same drugs was becoming "tougher" than the previous round of evaluation. As several cases show, since the establishment of HAS it openly challenged the minister, or at least did not hesitate to disagree with them. To be sure, after drugs have been on the market for a while more evidence is available to assess their clinical effectiveness. In addition, the picture of increasing scrutiny may partly be consistent

with the evolution of the Committee's use of SMR. In rating a drug's clinical benefit, the Transparency Committee's assessment hinges greatly on two factors including the severity of the pathology and the place of the drug in the therapeutic strategy. According to the then chair of the Committee, over time assessment placed increasing emphasis on the latter. Whereas traditionally a drug for serious diseases was almost certainly recommended for reimbursement, this was no longer the case. With the arrival of new drugs since the 1990s the Committee looked more into the intrinsic value of the drug rather than the disease area (Bevenot 2011). Yet, in addition to drugs being on the market and the evolution of the committee's criteria, the case studies here highlight the agency's autonomy-seeking behaviours. In an attempt at setting its own agendas, the Committee used instruments such as self-referral (the cases of Alzheimer's disease drugs, Multaq) and conditions attached with reimbursement (the case of osteoarthritis drugs). Attempts at autonomous actions were even clearer after the Mediator scandal and the annulment of earlier guidelines due to conflicts of interests. To restore confidence, the agency attempted to set its own agendas, which resulted in open disagreements with ministers in the case of Alzheimer's disease drugs.

However, while such an autonomy-seeking behaviour of the agency might have affected public debates, as the cases of the re-evaluation plan and the Alzheimer's disease drug show most vividly, they did not necessarily result in changing the minister's decisions, especially when these involve greater political costs of de-reimbursement. Minister's decisions were shaped more by avoiding the blame for de-reimbursement, and the blame was felt more heavily when the decision was expected to impose significant costs on different beneficiaries.

4. Conclusion

This chapter examined how low political insulation reduced the occurrence of an unpopular policy choice such as explicit drug rationing. Where elected officials had the final decision-making powers over drug funding, they could choose whether to follow the expert body's outputs. They were able to selectively override the experts' outputs by looking at the political costs that a decision was likely to generate. Drawing on different cases of the politics of drug assessment, the chapter considered when health ministers chose to override the Transparency Committee's judgement to make a drug available. It found that elected politicians took into account anticipated negative impacts of their policy choice on both the domestic pharmaceutical industry and the consumers of a given drug. These considerations were

significant enough to induce elected officials to engage in blame-avoiding behaviour, choosing not to follow the Committee's judgement. To avoid total de-reimbursement of the drugs that the Transparency Committee judged clinically ineffective, elected politicians used a number of alternative tactics, including partial and incremental reduction of reimbursement rates, price reductions, and the creation of a new reimbursement rate. While the creation of HAS gave the Transparency Committee a greater formal independence from the health minister, it did not fundamentally alter this dynamic. Although HAS did not shy away from openly disagreeing with health ministers, as long as the latter had the decision-making powers, their considerations of political costs still have crucial impacts on policy decisions. Likewise, the increasing public concerns about drug safety following the Mediator scandal had at best only a limited impact on politicians' considerations behind their policy choices. The outbreak of the scandal indeed prompted elected politicians' reactions, making them de-reimburse the drugs with insufficient clinical benefit -- as shown in the cases of the 2011 wave of de-reimbursement measures and Multaq. However, even after the scandal the consideration of the risk of blame for removing a politically important drug – like drugs for Alzherimer's disease -- alone could still overwhelm political calculation. Overall, these findings highlight the role of elected officials' anticipated blame-avoidance strategies in preventing unpopular policy choices in a less-insulated setting. Such a strategy continued to be crucial for policy even after the reform that created the regulatory state institutions.

One caveat of the present chapter's analysis is that I examined the cases where the Transparency Committee issued a negative opinion, and hence treated the Committee's opinion as given. But as Table 6.1 showed, negative opinion is rather rare – 80-85% of the time the Committee gave "substantial" SMR ratings. The relative lack of selectivity in SMR rating – especially compared to the English counterpart we saw in Chapter 4 – was at least partly due to the fact that, unlike NICE, the Transparency Committee evaluates clinical effectiveness but not cost-effectiveness of a drug. Especially since the mid-2000s, as the pressure to rationalise spending and the arrival of expensive new drugs continued, debates over changing the criteria for HAS' evaluations emerged among elite political actors; the next chapter will examine these political struggles. As the chapter shall show, the lack of rule change, together with the absence of unpopular decisions for individual drugs demonstrated in the present chapter, contributed to policy continuity in French drug funding policy.

Chapter 7 Rationalisation without rationing: France, 2004-2016

French drug funding policy has been marked by continuity despite changes in external circumstances. As the previous chapter demonstrated, health ministers selectively refused to follow the HAS expert committee's judgement about a drug's clinical effectiveness to avoid an unpopular policy choice such as explicit rationing. By limiting the occurrence of explicit rationing, the ministers' policy choice over individual drugs' funding contributed to policy continuity. But the battles over drug rationing took place not only at the level of decisions over individual drugs but also at the level of rules that guide these decisions. As the government addressed healthcare costs and the arrival of expensive new drugs, especially since the mid-2000s HAS' evaluation criteria that underpinned reimbursement decisions were increasingly debated among elite political actors. As this chapter shall show, however, the existing evaluation criteria, which allowed funding of the overwhelming majority of drugs, largely persisted. In terms of both policy practices over individual drug and rules that guide the practices, drug funding policy thus exhibited continuity, with limited occurrence of an explicit rationing strategy.

This chapter explores the politics of changing rules. It considers why there has been little change in the reimbursement rules, despite the pressure on the healthcare budget driven by expensive drugs, focusing events that sparked policy debates, and the periodic rise of a policy agenda put forward by its proponents – seemingly a perfect recipe for policy change. In addition to the bureaucratic politics and turf battles, the chapter proposes that elected politicians' blame-avoidance, linked with low political insulation, contributed to policy continuity. Given their decision-making powers and accompanying political responsibility for explicit rationing, elected officials were reluctant to adopt a reform that may lead to taking the blame for rationing decisions. As a result of their inaction, policy responses to drug expenditure largely took place through existing institutionalised arenas and instruments. In the absence of conflict expansion to outside actors, the policy reactions kept the power balance between coalitions intact despite changes in the external environment.

The chapter first briefly revisits the existing pricing and reimbursement regime consolidated by the mid-2000s, where the pricing control and price-volume agreement established themselves as a key mechanism of resource allocation and the state's control over drug expenditure. It then looks at the attempts to change pricing and reimbursement rules,

notably the initiatives to incorporate medico-economic evaluations in drug funding decisions. It shows how, despite favourable conditions for policy change, the bureaucratic politics as well as the lack of incentives for the minister to enact a reform, both stemming from the low political insulation of the locus of drug funding decisions, limited expansion of the role of such evaluations. The chapter then turns to the consequences of the lack of fundamental reforms, especially by looking at the policy response to the arrival of expensive drugs.

1. Controlling drug spending through pricing

Before examining the efforts to reform reimbursement rules, it is useful to revisit key features of the pricing and reimbursement system at around the time when HAS was established. If the reimbursement decision-making powers held by the minister based on HAS's opinion was one pillar of the process, the other was the role of the inter-ministerial committee CEPS in pricing negotiation. As mentioned in Chapter 3, the CEPS negotiates drug prices with the manufacturer, using the HAS's evaluation of the drug's improvement in clinical benefit indicated in the ASMR rating from I (major improvement) to V (no improvement). It is important to note, in this regard, that the CEPS was not only the interlocutor with the industry to set the price but also came to play a major role in controlling drug spending and resource allocation.

The Committee's role in controlling spending was played through its price-volume agreement with the industry. The framework agreement, which was negotiated between the CEPS and the pharmaceutical industry's association LEEM every 5 years, defined the terms of repayments that companies had to make. From 1999 the government's annual repayments under the framework agreement became aligned with the ONDAM (L'objectif national des dépenses d'assurance maladie), the national target for health insurance fund expenditure. Established in 1996 by Juppé's healthcare reform plan, under the ONDAM each year the parliaments voted on the target spending growth for Social Security. If drug sales exceeded the target growth rate of spending corresponding to ONDAM, known as the L rate, then the company had to give rebates on them.

The Committee steered the balance between the health policy and the industrial policy goal. Through its collegial structure among different ministries, and led by the Chair held by a senior bureaucrat, it achieved a partial autonomy from any of the ministries. This, together with mid-

term framework agreements, enabled the Committee to send more credible signals to companies investing in the French market. From the industry's perspective, while the framework agreements imposed tight control, they provided stability and certainty in terms of the industry's production strategy.[515] Moreover, the Committee set up measures explicitly designed to incentivise companies and reward their investments. Hence, from the 2003 framework agreement onwards, "innovative" drugs with ASMR I-III were given a "European" price, which was set in reference to other European countries. This price hence contrasted with traditional pricing control, which was often criticised for setting prices lower than other countries'. Conversely, for the overwhelming majority of the drugs, which fell in ASMR IV or V, the price was kept under tighter control.[516] The Committee hence rewarded the producers of innovative drugs while supressing spending on the vast majority of drugs.

Clawback credits under the CSIS (Conseil stratégique des industries de santé) were another example of the government's attempt at using the CEPS as a vehicle of industrial policy measures. The business-government forum established in 2004 was based on an initiative by the Ministry of Finance and Economy and the Cour des Mines, which had proposed a forum similar to the Pharmaceutical Industry Task Force in Britain (see Chapter 4).[517] Among other agendas for stimulating R&D through public-private partnership and other instruments the CSIS set tax credits distributed through the CEPS. Awarded to companies investing in European countries, these provided tax exemption from the price-volume agreement rebate.

In sum, the CEPS not only set the prices of individual drugs but also played a key role in the government's control over drug resource allocation, especially through its framework agreement with drug companies. It provided a major channel of negotiation between the industry and the government, reconciling different policy goals associated with funding drugs. Through the operation of these spending controls, the CESP consolidated and reinforced its institutional status within the state.[518]

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[515] On the role of the CEPS in industrial policy, Nouguez 2014. See also Renaudin 2011 for the CEPS chair's account of the rationales behind the Committee's policy.
[516] About 90% of the drugs HAS assessed were given ASMR V (no improvement).
[517] Masson 2002, 41-42. See also the Conseil Général des Mines 2004.
[518] Thus for instance, the 2004 LFSS abolished ministers' veto powers against the Committee's decisions. Renaudin 2011, 424.

The Committee's price-volume agreement the was a powerful tool of spending control, and the government managed to meet overall spending policy goals intended to be achieved through pricing instruments. Over the second half of the 2000s, drug spending growth was coming into line with the allowed spending growth target that they set out in ONDAM (see Figure 7.1). Price reduction remained powerful throughout the 2000s. As the Cour des comptes pointed out in its 2011 report, measures targeting clinicians and pharmacists were less successful, including diffusion of generic drugs.[519] The Cour also pointed out that the government was even less successful in controlling hospital drugs, the majority of which CEPS did not have direct control over (see Section 3). The relative success in supressing spending through price-volume agreements set a precondition within which policy debates over changing rules for drug pricing and reimbursement took place.

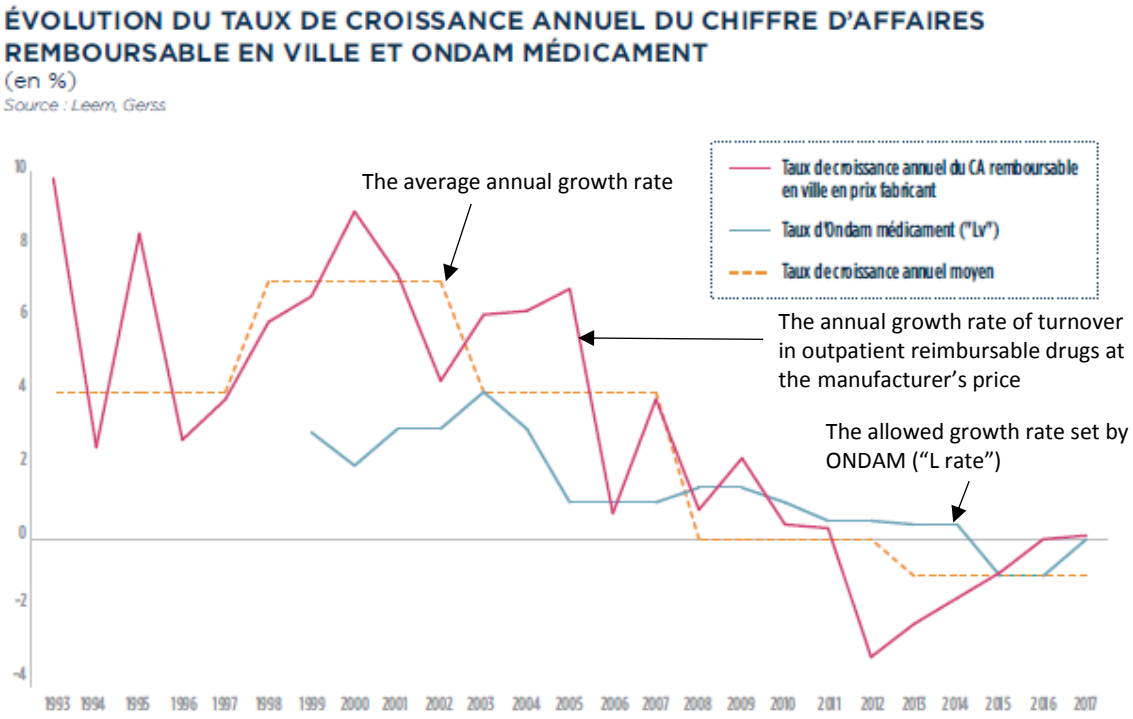

Figure 7.1 The annual growth of turnover in outpatient drugs and the ONDAM growth target

Source: Adapted from LEEM's website, added English labels. (https://www.leem.org/chiffre-daffaires)

[519] Le Cour des Comptes 2011, esp.143-144.

2. The limits of the bureaucrat-led attempts at policy change: Policy debates over reimbursement rules and the use of medico-economic evaluation

The French criteria for drug reimbursement and pricing were the subject of policy debates among elite actors inside and outside the state, especially since the mid-2000s. While the existing criteria based on SMR (actual clinical benefit) enabled generosity in patients' access to new technologies, the budgetary implication of unlimited access alarmed policymakers who were closer to the payer's position. In particular, from the perspective of rational spending, the lack of information on cost-effectiveness and its missing linkages with decisions on prices or funding of drugs were considered problematic. Economic expertise also played only a secondary role in medical evaluation and clinical guidelines at ANAES, which emphasised "medicalised" control and clinical expertise (see Chapter 3).

Political actors located in different parts of the state supplied policy ideas about reforms on assessment based on SMR and ASMR, especially whether, often explicitly referring to NICE, France should incorporate some form of economic evaluation in drug pricing and reimbursement; the Cour des Comptes, for instance, was a long-term critic in this respect. In its 2004 report on Social Security it complained that "neither the transparency committee, refocused on its mission of the medical expertise, nor the CEPS, whose mission is to regulate prices, at present undertake the crosscutting mission of medico-economic analysis of this sector, which involves evaluating cost-effectiveness ratio of drug candidates for reimbursement". [520] In its 2007 report, the Cour further recommended the reform of reimbursement criteria and a more regular revision of the reimbursement list, both of which should take into account medico-economic evaluation.[521]

Politicians in the legislative branch also periodically paid attention to this issue. After the ONDAM gave budgetary control of Social Security to the parliaments, they set up a committee called les missions d'évaluation et de contrôle de la Sécurité sociale (MECSS) as a routine monitoring device for social spending. The committee was hence sympathetic with the idea of rationalising resources through changing pricing and reimbursement rules. For instance, in

[520] Le Cour des Comptes 2004, 315.
[521] Le Cour des Comptes 2007, 305.

2008 the Senate MECSS report expressed concerns about the high level of drug consumption and recommended a greater selectivity in SMR based on the criterion of public health interest.[522] Besides routine attention to budgetary issues through institutionalised procedures, focusing events involving a drug scandal further drew legislators' attention to drug reimbursement. For instance, when the Senate committee discussed the pharmaceuticals market in response to the 2004 Vioxx affair, alongside other issues concerning expertise and autonomy, the report also quoted the Cour des Comptes' remark about the lack of medico-economic assessment.[523] Perhaps more importantly, in the 2011 report on the Mediator scandal the Senate rapporteur proposed radically reforming the pricing and reimbursement system. It proposed abolishing the SMR, recommended transferring the formal powers for reimbursement decisions from the minister to the Transparency Committee, and suggested CEPS incorporate medico-economic evaluation into pricing by transferring HAS's mission on medico-economic evaluation to CEPS.[524] Little evidence indicated that any of the recommendations significantly changed the government's course of action regarding its policy agendas. The non-legislative information reports, which were intended to help senators to monitor the government's activities, remained toothless. A more direct attempt by the Senate to control the agenda was made through the use of legislative powers concerning the Social Security Financing Law (LFSS). For instance, the Senate rapporteur proposed an amendment to the LFSS for 2011, which would make the CEPS take into account medico-economic evaluation in 2010; it was subsequently withdrawn when the health minister objected.[525] The executive government's dominant power vis-à-vis the parliaments implies that, apart from transmitting public attention to the issue to the incumbent government during crisis moments or being cited later to justify claims made in various executive branch reports, the Senate proposals little affected the government's policy agendas.

A more likely actor to initiate changes in drug pricing and reimbursement rules was the executive government, in particular the bureaucracies in charge of the sector. The role of senior Ministry of Health bureaucrats, especially those from the Directorate of the Social Security, is worth mentioning. These bureaucrats invested their careers in specialising in

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[522] L'Assemblée Nationale 2008, 42-43.
[523] Hermange and Payet 2006, 30-31.
[524] Hermange 2011.
[525] Le Sénat, Séance du 13 novembre 2010 (compte rendu intégral des débats), Article 36 septies (nouveau). https://www.senat.fr/seances/s201011/s20101113/s20101113009.html#section1297

health policy and moved around the Ministry, and together with the ministerial cabinet and relevant Grand Cours, such as the IGAS (Inspection générale des affaires sociales) and the Cour des Comptes, played a key role in the government's agenda-setting forums like the Haut Conseil pour l'Avenir de l'Assurance Maladie (Hcaam).[526] Thus for instance, the 2006 report by Hcaam mentioned the necessity of examining the economic approach in more detail.[527] The following year's report argued that "the issue of health economics expertise, its institutional and legal framework as well as the development of its resources, has not been sufficiently addressed in the context of reforms".[528] These diagnoses expressed in the forums were followed by the government's agenda in the context of the Social Security Financing Law for 2008. Regretting that HAS's recommendations did not establish the care priorities, it proposed broadening HAS's expertise to medico-economic evaluation; explicitly referring to other countries' experiences, including England and Germany, the government stressed that HAS acquiring an analytical capacity would lead to "a greater selectivity in care".[529]

The call for medico-economic evaluation favoured payers -- the obligatory and complementary insurance bodies -- who had a natural interest in optimising social spending. For instance, the UNCAM/CNAMTS director Frédéric Van Roekeghem -- a position served by a senior official – had long called for taking into account medico-economic evaluation.[530] The CNAMTS also suggested that a possible means of reform was to give UNCAM the right to refuse products that failed to demonstrate cost-effectiveness.[531]

At around the same time, another group of bureaucratic actors advocating the use of medico-economic evaluation was also emerging within HAS. In 2006, HAS set up an internal working group for economic evaluation, the Commission for the Evaluation of Health Strategies, with the appointment of Lise Rochaix, the only health economist among the Board's members. Health economists and pharmaco-epidemiologists within HAS actively sought to address non-clinical dimensions of evaluating health technologies. Their early

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[526] Genieys and Hassenteufel 2015; Genieys and Smyrl 2008 for these elite bureaucrats' career trajectories and their agenda-setting role in healthcare reform in general; Benoit 2016, 438 for the role of DSS bureaucrats in the 2008 LFSS to introduce the HAS mission for medico-economic evaluation.
[527] Hcaam 2006, 18.
[528] Hcaam 2007, 76.
[529] *Les Echos* 22 October 2007; "France's HAS to become more like UK's NICE" *Pharma Marketletter* 22 October 2007.
[530] E.g. *Les Echos* 21 March 2005. Hermange and Payet 2006, 279.
[531] Le Cour des comptes 2007, 264.

efforts included conceptual work related to "public health interest", a criterion included in the SMR by the 1999 decree, whereby the Committee sought to broaden the concept to take into account "collective and societal dimensions" in assessing benefit of drugs.[532]

The Social Security Financing Law for 2008 provided that HAS would issue "medico-economic recommendations and opinions on the most efficient strategies for treatment, prescription or care management".[533] HAS set up the Commission Evaluation Economique et de Santé Publique (CEESP) in charge of the mission, which succeeded the Commission for the Evaluation of Health Strategies. In contrast to the Transparency Committee dominated by clinicians, the 25 members of the CEESP consisted of economists and academics from other diverse disciplines in social sciences and humanities, including sociologists, and ethicists, among others, as well as a patient representative. The HAS Board Chair Degos justified such a multi-disciplinary composition of the committee by emphasising that evaluations must be made not only of therapeutic efficacy but also economic, sociological and ethical aspects.[534]

Having got official backing as a HAS mission, the CEESP's effort to promote medico-economic evaluation was set in motion.[535] The broad provision for this mission within the LFSS remained relatively ambiguous in terms of how evaluation was conducted and for what purpose; the Committee took advantage of this to expand their activities. Notably, CEESP Chair Lise Rochaix took a leadership role in "building bridges with different people".[536] Such efforts for coalition building were made on several fronts. Through medical evaluation and public health recommendations made for different clients in the government, it demonstrated the usefulness of medico-economic evaluation to different policymakers.[537] The Committee also leveraged the network of comparable agencies in other countries to reinforce its analytical

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[532] Benamouzig 2010, 198. The notion of public health interest was originally intended to give "a joker to the decision-maker" to enable a political decision to reimburse drugs that would be useful for public health policy goals. It was then taken up by pharmaco-epidemiologists at the Directorate General of Health to develop it into a population-based approach to evaluation based on real world data. Health economists at HAS inherited this intellectual legacy. Bas-Théron et al. 2011, 42; Benamouzig 2010, 197; Interview with a HAS CEESP member, 14.10.2016. Interview with an IGAS official, 26.10.2016; Tabuteau 2006, 246-247.
[533] Article 41 LFSS http://www.legifrance.gouv.fr/eli/loi/2007/12/19/BCFX0766311L/jo/article_41
[534] *Le Monde* 5 July 2008, quoted in Benamouzig 2010, 15.
[535] Hassenteufel et al. 2018, 91-94 for the CEESP's role in the introduction of medico-economic evaluation.
[536] Interview with a HAS CEESP member, 14.10. 2016.
[537] Ibid.

capacity by facilitating information exchange. At the European Network for Health Technology Assessment, the regulatory network of HTA agencies across European countries, HAS took a lead role in the working group for the development of the Relative Effectiveness Assessment, which addressed joint development of methods of drug evaluation. There was also "unexpected" support from the new Board Chair of HAS Jean-Luc Harousseau, who arrived in 2011 and was sympathetic to the use of medico-economic evaluation despite being a physician an oncologist.[538]

The CEESP's attempts at capacity and coalition building can also been seen in its development of methods. In October 2011, the CEESP issued its methodological guide to medico-economic evaluation.[539] The elaboration of the guidance document was itself a product of their efforts to promote their work through consultation with different stakeholders as well as public consultation. Its methods shared some key features with those of NICE, including the use of QALY to measure impacts of health intervention and the EQ-5D questionnaire to measure quality of life. Through its activities, health economists within HAS thus sought to push the role of medico-economic evaluation further.

Different political actors' efforts to introduce changes in the drug pricing and reimbursement rules gained momentum following the Mediator scandal. The heightened public attention to pharmaceutical regulation opened up conflicts over the pricing and reimbursement rules in the public arena. In the wake of the scandal, the government was exposed to intense public pressure that blamed the government. This prompted the government to take visible action addressing pharmaceutical policy that could appeal to the public. Notably, Health Minister Xavier Bertrand attempted to turn the blame on the government to his credit, by actively taking an initiative for large-scale reforms in the pharmaceutical sector.[540] In February 2011, he launched the National Drug Forums (Les assises national du médicament), large-scale consultations involving different stakeholders, which discussed agendas for reforming diverse aspects of pharmaceutical regulation. In the subsequent months, a plethora of reports were presented by different political actors, who tried to make their voices heard during the intense public scrutiny of the issue. Those who advocated changing pricing and reimbursement rules pushed their agendas. As already

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[538] Ibid.
[539] HAS 2011.
[540] On Bertrand's responses to the Mediator scandal leading up to the Bertrand law see Smith 2017.

mentioned, the Senate proposal involved radical organisational changes including the transfer of decision-making powers for reimbursement from the government to the Transparency Committee and the use of medico-economic evaluation in pricing decisions; for its part, the Mutualité proposed amending the decree implementing medico-economic evaluation to increase the selectivity over the admission to reimbursement.[541]

The HAS also used this opportunity to push for the use of medico-economic evaluation for pricing and reimbursement decisions. In its submission to the Drug Forums, it proposed reinforcing consideration of "nonclinical criteria in the framework of public health interest", especially by introducing "the criteria of efficiency" in its opinion used for pricing and reimbursement decisions. Highlighting that the public authorities' referrals to HAS on medico-economic evaluation had so far not been focused on conditions for reimbursement but on support for "medicalised" control through clinical guidelines, it argued that "HAS is ready for such an evolution that involves strengthening its advice given to the decision makers through a medico-economic dimension".[542]

This time, however, in addition to the actors who had promoted agendas for reforming drug funding during the pre-scandal period, the IGAS pushed HAS's advocacy for medico-economic evaluation and changes in the pricing and reimbursement systems. In the wake of the Mediator scandal, the IGAS produced a number of reports and investigations into aspects of pharmaceutical policy. In its report on experts in health issued in spring 2011, IGAS recommended that the government should strengthen medico-economic evaluation at HAS.[543] Furthermore, in its report on proposals for reforming the pharmacovigilance system in response to the Mediator scandal, the IGAS proposed far-reaching institutional reforms of the pharmaceutical regulatory regime as a whole. The report involved not only reforms on drug approval and post-marketing surveillance but also radical organisational changes in the pricing and reimbursement regime. Criticising the "opacity" of price-setting by the CEPS and the lack of collaboration between the CEPS and HAS, the report proposed merging CEPS with HAS to create "*NICE* à la française"[544], which would be in charge of both pricing and reimbursement; it recommended the new HAS to integrate medico-economic evaluation into

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[541] La Mutualité « Plan pour le médicament proposé par la Mutualité Française », March 2011, esp. 20
[542] HAS n.d. « Les assises du médicament. Haute autorité de santé – Axes d'amélioration », 5.
[543] Bas-Théron et al. 2011, 25.
[544] Bensadon et al. 2011, 88-89. Italics for NICE in original.

reimbursement criteria, replacing SMR and ASMR. The minister would still retain the decision-making powers, but would have to explicitly explain to the public the reasoning behind not following the evaluation.[545]

Yet, in the subsequent bill proposed by minister Xavier Bertrand, which became the so-called Bertrand law, otherwise extensive measures to reinforce the Afssaps's independence from the industry, regulation of conflicts of interests and physicians-pharmaceutical industry relations, and pharmacovigilance systems, did not touch on the pricing and reimbursement regime.

Political actors who advocated medico-economic evaluation yet sought to achieve their agenda via the LFSS bill.[546] The LFSSS for 2012 gave a legal basis to the CEESP as a regulatory committee. In the following year, the ministerial order set out the CEESP's roles and the usage of medico-economic evaluation in decision-making. The CEESP was tasked to produce medico-economic evaluations for drugs, which would inform pricing negotiations. The subjects of evaluation were drugs with ASMR I-III (so-called "innovative drugs") and drugs with significant impact on the healthcare budget, and the CEESP were to produce evaluation of the drugs' cost-effectiveness. In a process separated from the Transparency Committee's work on opinions on drugs, the CEESP's advice was to be sent to the CEPS. Thus, in contrast to the far-reaching institutional reforms that the IGAS envisioned, and a greater role on medico-economic evaluation therein, changes in organisational and procedural arrangements for drug funding after the Mediator scandals were limited. The CEESP's medico-economic evaluation was given some limited roles in drug pricing but none in reimbursement; and installing the new evaluation in the process involved little change in existing organisational arrangements, with the expectation that the medico-economic evaluation would be designed to operate within the existing institutional framework centred on price-volume agreement rather than altering it. Despite the very favourable conditions for those advocating policy change – bureaucrats seeking to achieve policy innovation, a major scandal as a focusing event, and a credit-claiming minister who want to introduce high-profile reforms in pharmaceutical policy – the reform did not lead to a rupture in existing institutions and policy.

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[545] Ibid., 88.
[546] Le Cour des comptes 2011, 127, 144.

To understand the timing and the limits of the bureaucrat-led attempt at policy change, it is useful to look at the constraints the bureaucrats faced. These partly lay in bureaucratic politics. First, there was said to be rivalry between the Transparency Committee and the CEESP. The rivalry was based not only on disciplinary differences between the "scientific" – meaning clinical in the French pharmaceutical policy –and "economic" approaches to evaluation but also on their organisational turfs.[547] Assessments by the two committees were conducted in parallel as separate processes, whereby the two committee did not collaborate with each other. The Transparency Committee, dominated by clinicians, was reluctant to accept the expanding role of medico-economic evaluation. It did not see CEESP's initiatives, such as those related to public health interest, favourably.[548] Building supporting coalitions inside and outside HAS, including the newly-appointed Board Chair Harousseau, was hence crucial for those who advocating medico-economic evaluation to overcome the internal political hurdle within HAS.

For a long time, the CEPS was also against the use of medico-economic evaluation for pricing and reimbursement decisions. For instance, when the government set out HAS's role in medico-economic evaluation in 2008, Noël Renaudin, who served as the CEPS Chair for more than a decade from 1999, pointed out in an interview with a trade journal that while the method of the medico-economic analysis was universal, its usage would differ depending on "the culture of care". He hence argued, explicitly referring to NICE, that refusing treatments because their cost per QALY was too high "would not be acceptable to French society" – the latter instead considered care albeit with expensive medicines as an important part of "collective solidarity". [549] For him, medico-economic evaluation could be useful for therapeutic strategy and hence a tool to control demand-side costs, such as doctors' prescriptions, but not supply-side ones, such as pricing. Yet, such a cultural and normative justification seems to go hand in hand with the motivation of defending CEPS's organisational turf. After the Mediator scandal, Renaudin was replaced by Gilles Johanet, a former CNAMTS director who underwrote the Jospin government's healthcare reforms. Johanet was more sympathetic to medico-economic evaluation, considering that one cannot set prices without

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[547] On tensions between the two groups of experts in pharmaceutical policy, Robelet 1999; Ansaloni et al. 2017.
[548] Interview with a HAS CEESP member, 14.10.2016.
[549] « Noël Renaudin, président du CEPS : « A chacun son rôle ! » », *Pharmaceutiques* September 2008, 16

taking QALY into account.[550] If such a shift in the ideational acceptance allowed HAS and allied interests to surmount the political barrier, in contrast to IGAS' reform proposal, the use of medico-economic evaluation was still operating within the institutional arrangements, rather than upsetting CEPS' role as the sole negotiator and decision-maker for drug pricing.[551] One would expect that the CEPS would oppose measures constraining the discretion it enjoyed, let alone the ones like the above-mentioned proposal by the IGAS to abolish it.

What about ministers in charge of reimbursement decisions? They appeared to distance themselves from the possibility of a fuller use of medico-economic evaluations in reimbursement decisions, especially those like NICE's.[552] For instance, during the National Assembly debates leading up to the adoption of the 2008 LFSS that expanded HAS's missions to medico-economic evaluation, health minister Roselyne Bachelot explicitly noted that "I am against integrating the concept of quality-adjusting life-years into the indicators of medico-economic efficiency, like NICE," because "it does not match the culture that HAS draws inspiration from".[553] This reluctance did not change during the dramatic moment following the Mediator scandal. In a stark contrast with widely publicised actions for radical reforms in drug approval and surveillance, Bertrand did not appear to visibly push medico-economic evaluation agendas.

If ministers were not keen on the use of medico-economic evaluations for reimbursement, HAS also set itself boundaries for its pursuit of the agenda. While promoting the use of medico-economic evaluation for drug pricing and reimbursement, leaders of the agency never sought to gain decision-making powers; nor did they want to establish an explicit cost-effectiveness threshold, as in England, where outputs of medico-economic evaluation became

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[550] Caniard 2013, 65.

[551] According to Benoit (2016, 456-459), incoming CEPS president Dominique Giorgi, who further replaced Johanet in 2012, played a key role in setting the boundary of the use of medico-economic evaluation during the decree's preparation.

[552] For instance, during the Senate debate leading up to the LFSS for 2008, health minister Roselyne Bachelot dispelled the concern by a senator that "as in England, otherwise useful drugs are excluded from reimbursement on mere medico-economic criteria". She attempted to reassure senators by stating that HAS would not issue medico-economic opinions systematically, and it would do so with caution where the question of care strategy arose; she also argued that "medico-economic evaluation does not interfere with the level of management of the new treatment". Sénat, Séance du mercredi 14 novembre 2007 (compte rendu intégral), 4743-4744.

[553] L'Assemblée nationale, Compte rendu analytique officiel. Séance du jeudi 25 Octobre 2007, 3ème séance. Projet de loi de financement de la sécurité sociale pour 2008, article 19. http://www.assemblee-nationale.fr/13/cra/2007-2008/026.asp

the critical reimbursement decision criteria. On the contrary, they attempted to differentiate themselves from the English model by trying to dispel negative connotations associated with rationing that were especially inspired by the experience of NICE. Hence, in introducing medico-economic evaluation, HAS President Laurent Degos argued that the "French way" of medico-economic evaluation would not lead to rationing, by contrasting it with NICE:

> "Other countries, like the United Kingdom, have chosen to define thresholds beyond which an expenditure is no longer considered to be collectively justified. At HAS, we consider that it is not for us to decide what our society is willing to spend on the health of its members. The independent economic evaluation we will carry out will concern the service that a certain product or act of health renders to the community, and then it is up to the politician to decide on the merits of the expenditure in relation to the service rendered."[554]

He emphasised in the same interview that the aim of medico-economic evaluation was to "rationalise but not to ration", as if anticipating the prevailing negative reactions and attempting to reassure the public and the industry. Likewise, while Degos's successor, Harousseau, strongly supported the CEESP's effort to incorporate medico-economic evaluation, he also carefully tried to differentiate HAS's image from that of NICE as a rationing body. In 2013, when the CEESP's assessment was about to start operating, at an industry-led conference sponsored by the business newspaper *Les Echos*, Harousseau emphasised the differences between French medico-economic evaluation and that of NICE. He argued that it was "out of question" to make decisions based on the threshold of cost per QALY, because "it would be contrary to the French tradition of broad access to therapeutic innovation".[555] Even Lise Rochaix, the CEESP Chair, in an interview with the trade journal *Pharmaceutiques*, ruled out the possibility of using the explicit cost-effectiveness threshold for a decision; cost per QALY would instead be "useful information for clarifying a decision" that took place in "open discussion".[556] The decision-making powers with explicit criteria that NICE represented was thus seen as neither politically feasible nor normatively justifiable.

How can we understand both the ministers' and HAS's unwillingness to use medico-economic evaluation for reimbursement decisions? With the decision-making powers in their hands, one would expect that elected politicians may not be keen on enacting a change in rules that could lead to more controversial decisions. Unlike drug safety surveillance rules and

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[554] *Le Monde* 04 July 2008.
[555] « La France ne s'inspirera pas du NICE britannique » *Actu Labos* 5 juin 2013.
[556] "Une méthode différente du NICE anglais", *Pharmaceutiques* Octobre 2009, 68-69.

conflicts of interest with high visibility and a wide appeal to the public in the post-Mediator context, changing pricing and reimbursement was unlikely to generate credit for the minister to claim. On the contrary, as long as the minister held the political responsibility for reimbursement decisions, they would be the one getting the blame for a negative decision. When the political costs of negative decisions are high, a minister would prefer a negotiated settlement to refuse a drug rather than a blunt decision which may lead to a public backlash. Even though they only have an advisory status, changing the reimbursement rules used by HAS could lead to constraints on the minister's room for manoeuvre. At the same time, a minister would be reluctant to delegate the decision-making powers to the agency either, because it would mean losing the powers for budgetary control of the healthcare system.

This ministerial responsibility for rationing decisions, in turn, set the boundary about what the independent agency pursued. From the agency's perspective, the institutional arrangements within which the minister had the decision-making powers allowed the agency to build analytical capacity, while leaving political decisions to the minister. The ongoing controversies over NICE further strengthened such views. Given the unpopularity of rationing and a system with formal and political responsibility of the minister, there was little incentive for the agency to challenge the existing institutional order to take up the decision-making powers.

The trajectory of HAS's proposal for reforming the method of drug assessment in the subsequent years further illustrates how the bureaucratic politics and lack of ministerial efforts obstructed attempts at policy change. Based on the initiatives of the CEESP's health economists, in early 2012 HAS proposed replacing the SMR/ASMR ratings-based pricing and reimbursement criteria with a more integrated method. The proposed new criteria, called ITR (Index Thérapeutique Relatif), would inform both pricing and reimbursement decisions. Unlike SMR, it provided a fuller comparative assessment among different drugs using medico-economic evaluation on real-world data. The ITR was proposed to be legislated for in late 2012 for the 2013 Social Security Financing Law bill.

However, the agenda did not materialise as HAS envisioned and subsequently disappeared from the public radar. The IGAS report on ITR in 2013, which was not made public until 2015, concluded that reform was "not urgent and must not be brutal", and instead recommended that HAS should take "a reform trajectory" to keep discussing the methods. One of the major criticisms against the new approach it highlighted was "the lack of flexibility": "the approach

appears rather 'technocratic'", the report pointed out, "the process appears more directive … leaving little room for debate and nuances".[557] Such a criticism of "automatism" mirrored debates over the use of cost per QALY for reimbursement decisions. There was little sign of the initiative being subsequently taken up by the minister. During debates inside the government, neither the health minister nor the Transparency Committee supported ITR.[558] The Transparency Committee was reluctant to change its method. According to one participant of the discussions, the Committee members claimed that it should not be the "scientific" Transparency Committee but the "political" minister who took reimbursement decisions.[559]

In the subsequent years, policy debates over reimbursement rules were periodically brought back to the minister's attention as the arrival of expensive drugs put the existing regime's heavy reliance on pricing negotiation under strain. Again, heightened attention to drug prices related to a specific drug created such a momentum. In 2014, the arrival of a new Hepatitis C drug, Sovaldi (sofosbuvir), captured national headlines across European countries. The drug, developed by the American manufacturer Gilead, was widely seen as a breakthrough treatment for Hepatitis C, and was said to have 90% cure rate. However, in the US it cost $84,000 for 12 weeks' treatment. Unlike the controversy over expensive cancer drugs targeting a narrow specific subpopulation of patients, Sovaldi could treat a wide population of Hepatitis C patients and would result in an even more serious budgetary impact; Hepatitis C affected 200,000 people in France. The government consulted a group of experts about the treatment strategy; they recommended that patients with a severer stage, as well as specific subpopulations of patients (such as pregnant women) should be prioritised. HAS' Transparency Committee gave the drug "substantial" SMR and ASMR II ratings (except for patients infected with a specific type of virus, for which it was rated ASMR III).[560] The drug was initially put through the Temporal Authorisation (ATU) outside the usual drug approval and pricing and reimbursement regime. Under the terms of ATU it was approved for patients with severe conditions. The CEPS negotiations with Gilead managed to achieve the lowest price in Europe, at 56,000 euros. In the meantime, the government set out a specialised contribution scheme, which would tax the producer when the drug sales exceeded the

[557] Dahan 2013, 20.
[558] Interview with an IGAS official, 28.10. 2016. Interview with a member of HAS CEESP, 14.10.2016.
[559] Interview with an IGAS official, 28.10. 2016.
[560] CT, « Avis de la CT du 14 mai 2014 : Sovaldi ».

budgetary ceiling. The rebate ceiling was initially set at 450 million euros for the 2014 year and 700 million euros after that. After the ATU period ended, health minister Marisol Touraine decided to expand Sovaldi's use. The initial authorisation for restricted access was criticised for rationing. As the Polton report (see below) put it, "it was the first time that a curative medicine was rationed because of its price".[561]

HAS's effort to push the agenda for changing assessment methods had been continuing in the intervening years. HAS Board Chair Harousseau, who argued that "SMR becomes obsolete", sought to revive the agenda for ITR. Regretting that the item was not included in Touraine's health law proposal, he attempted to incorporate it in the bill for the 2015 LFSS.[562] In November 2014, during the LFSS debate the Senate proposed an amendment to replace SMR and ASMR with ITR. The health minister opposed it; she emphasised that, during the test phase of the new mechanism, "consensus" had been reached among actors, including HAS, that ITR was not suitable. She was countered by senators, who argued that Harrouseau wholeheartedly supported the amendment.[563] The amendment passed the Senate but did not survive the National Assembly.

Yet the arrival of innovative and expensive drugs like Sovaldi posed a clear challenge to policymakers. While defending her position against ITR at the Senate, Touraine admitted the necessity to reconsider the reimbursement criteria. She mentioned an ongoing IGAS mission on medico-economic evaluation, while noting that she would ask relevant public bodies such as ANSM, HAS, and CEPS as well as health insurance bodies to make concrete proposals for reforming assessment methods. The IGAS report, issued in December 2014, recommended the use of medico-economic evaluations not only for pricing but also for reimbursement decisions, while avoiding the establishment of an explicit cost-effectiveness threshold.[564] In the following year, the health minister asked CNAM (Caisse nationale de l'assurance maladie) director Dominique Polton to review methods of evaluation in the drug reimbursement system.

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[561] Polton 2015, 153.
[562] « Medicament : la HAS veut en finir avec le service médical rendu, et relance l'ITR» *Le Quotidien du medicin* 29 September 2014.
[563] Le Sénat, Séance 14 novembre 2014 (compte rendu intégral des débats), articles additionnels après l'article 47. https://www.senat.fr/seances/s201411/s20141114/s20141114012.html#s1_Niv3_art_Articles_additionnels_aprT
[564] Jeantet and Lopez 2014, esp. 61-63.

As the minster wrote in the letter of mission, "if it is important to ensure the access to future therapeutic innovation for all the patients who need it, it is equally essential for the public authority to ensure the long-term sustainability of solidarity-based financing of health expenditure. The arrival of new treatments of Hepatitis C has perfectly illustrated, in the past months, the difficulty to find a balance between these two imperatives." [565]

The Polton report, published in autumn 2015, proposed a reform of the reimbursement rate, among other items. It pointed out a number of difficulties arising from the complexity of the SMR and ASMR ratings, calling for their simplification; and while it recognised medico-economic evaluation, it argued that its current use was not sufficiently developed to meet its objective of judging cost-effectiveness. As one scenario of reform, it recommended setting out a unique reimbursement rate of 50-60% instead of the current reimbursement rates of 65%, 30%, and 15%. She also suggested, similar to the idea behind ITR, a single indicator based on comparative evaluation called VTR (valeur thérapeutique relative) that would replace ASMR and SMR. Minister Touraine quickly dismissed the former possibility, as she found abolishing the reimbursement rate of 15%, which was, as noted in the previous chapter, created to avoid the total de-reimbursement of ineffective drugs, "too sensitive". [566] She preferred de-reimbursement on a case-by-case basis. Subsequently, despite the Senate's call for reform and the support for VTR expressed by Harousseau's replacement as the Board Chair of HAS,[567] the Socialist government never took up the proposal again during its tenure.

Thus, regarding the allocation of decision-making powers politicians dared not take up a blame-gathering reform like changes in reimbursement rules. The lack of incentives for politicians, combined with the bureaucratic politics of actors and agencies defending their turfs, helped reproduce existing institutions and policies. Limited opportunities for conflict expansion to broaden reform coalitions, apart from extraordinary moments like a drug scandal, meant that the reform effort was not driven by public pressure or politicians' responsiveness to issues. As soon as public attention waned, vested interests entrenched in the existing institutions took over the political struggle to obstruct a reform, while elected officials had little incentive to overcome the political blockages. As the case of Sovaldi has shown, one of

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[565] Polton 2015, 165.
[566] *Les Echos* 9 September 2015, 13 August 2015 ; *Le Monde* 8 September 2015. Cf. *Le Figaro* 13 August 2015; *Libération* 13 August 2015.
[567] Barbier and Daudigny 2016, 73ff ; Le Sénat, Comptes Rendus de la Commission des Affaires Sociales du 9 janvier 2017. Audition de Mme Agnès Buzyn.

the consequences of such institutional reproduction and inaction, despite technological advances, can be seen in policy responses to expensive new drugs, to which the chapter now turns.

3. The consequences: Policy continuity despite the arrival of expensive drugs

The inaction of the government over changing the reimbursement rules had major implications for its policy strategies to tackle healthcare costs. A consequence of the absence of reforms and sustained conflict expansion to outside actors was that the government kept relying on the existing price-volume agreement where it had a strong lever. While the arrival of expensive new drugs meant the issue of their pricing was increasingly debated in the mid-2010s, the government tried to tackle the issue within the institutionalised framework of existing measures. Overall, it attempted to rationalise resources through existing instruments, especially the price-volume agreement, without resorting to explicit rationing.

The reimbursement status of expensive medicines in France, such as those for cancer, multiple sclerosis and others, contrasts sharply with those in England. Most cancer drugs judged as not cost-effective by NICE are rated "substantial" in actual benefit in France; as hospital medicines prescribed for chronic disease patients they were usually reimbursed at 100%. In spite of the arrival of expensive drugs and the resulting pressure on healthcare expenditure, policymakers were extremely reluctant to set out drastic reforms to the pricing and reimbursement system. Hence, policy debates over expensive drugs, including for cancer on the "liste en sus" (a supplementary list) further illustrates how, in the absence of radical reforms that might lead to explicit rationing, policymakers attempted to adapt to these budgetary pressures.

The government made considerable efforts to ensure access to cancer care. Like in England, cancer occupied a special place within the government's programmatic priorities. An apparent reflection of such a priority was the creation of disease-based plans. Before the 2002 Presidential Election, Jacque Chirac proposed launching a "cancer plan", which constituted a comprehensive plan related to clinical research, prevention, diagnosis and care. It would set up the Institut National du Cancer, an agency tasked to coordinate strategies ranging from management of care to funding of research. The cancer plan, started in 2003, was expanded in the subsequent phases (2003-2008, 2009-2013, and 2014-2018). The Cour des comptes was

rather critical of the "explosion" in drug expenditure and volume, pointing out the "absence of economic pilotage".[568] Similarly, the National Assembly Finance Committee's report in 2006 criticised the "exponential" increase in costs: a 54.7% increase in the expenditure on cancer funded by the Sickness Fund between 2003 and 2005.[569]

The government's prioritisation of cancer drug access was also reflected in hospital drug pricing reform. The pricing and reimbursement of hospital drugs were regulated under a different framework from ambulatory care; their pricing was liberalised and unregulated between 1987 and 2003. The 2004 Douste-Bulazy hospital sector reform introduced a new payment framework called the tarification à l'activité (T2A) based on the Diagnosis Related Group, which was further elaborated and implemented by the Hospital Plan in 2007. The T2A framework allocated resources based on the grouping of drugs into similar therapeutic classes, regardless of individual drug specialities, thereby incentivising physicians to prescribe cheaper medicines in the same group. However, to ensure patients' access, orphan drugs and particular costly drugs put on the list issued by the Ministry of Health were exempted from the T2A framework, called the "liste en sus".

Categories	**Pricing**
Outpatient drugs	CEPS-company negotiation
Hospital drugs included in T2A	Liberalised (1987-2003); pricing based on T2A (2004-)
Hospital drugs exempted from T2A ("liste en sus")	CEPS-company negotiation (2004-)

Table 7.1 Different pricing methods for different types of drugs

Source: Adapted from Grandfils (2008)

The creation of the *liste* favoured cancer drug access. A report by the IGAS pointed out that the spending on the *liste* was particularly concentrated on cancer: five cancer drugs accounted for about 50% of the *liste* paid in a sample region in the first half of 2011.[570]

[568] Le Cour des Comptes 2008, 11-12, 109-111.
[569] *Les Echos*, July 6, 2006.
[570] Duhamel and Morelle 2012, 15.

Moreover, it drew attention to the fact that, in terms of spending, about a half of drugs on the *liste en sus* were evaluated by HAS as of little or no therapeutic improvement (ASMR IV or V).[571] Furthermore, it was reported that CEPS' prices for these particular drugs were more expensive than those in England, where pricing was freely set by the pharmaceutical industry under the Pharmaceutical Price Regulation Scheme. Accordingly, the IGAS criticised the drug pricing policy's inconsistency , claiming that "public policy to foster drug innovation, particularly with regard to cancer, appears excessively favourable to pharmaceutical companies".[572] Likewise, in his report for the 3rd wave of the cancer plan, the oncologist Jean-Paul Vernant warned the health minister about the extremely high prices of new treatments, calling for measuring the economic impact of the innovative medicines.[573]

Policy reactions to the arrival of expensive drugs largely relied on existing instruments under the price-volume agreement framework. Spending growth on drugs was negative in 2012 and 2013 for the first time in history (see Figure 7.1). In Autumn 2014, through the Social Security Financing Law for 2015 – when the issue of drug prices triggered by Sovaldi was highlighted -- the government expected the price reduction of drugs would yield 900 million euros of savings; the permitted growth rate of sales used for rebate scheme would be kept as low as -0.1% for three years; and, while the application of the growth rate had formerly been limited to ambulatory care drugs, it was now expanded to hospital drugs on the *liste en sus* and given temporal authorisation, the latter measure being adopted in response to Sovaldi. As Prime Minister Manuel Valls recognised earlier that year, "price reduction has been very strong. We reach its limits".[574] He considered generic policy as a margin of manoeuvre -- a claim that resonated with the Cour des comptes's repeated diagnosis, which highlighted the persisting lags in the penetration of generics in France behind other European countries.[575]

Vigorous control through drug pricing was made despite the resistance of the pharmaceutical industry. It argued that the consumption level was already becoming the same as in other European countries, emphasising that France was no longer an exception.[576] In

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[571] Ibid, 49.
[572] Ibid, 3.
[573] *La Croix* 6 November 2013.
[574] *Le Figaro* 14 April 2014.
[575] E.g. Le Cour des comptes 2011, 129ff.
[576] See e.g. Leem, n.d. « PLFSS 2016 : 10 Raisons De Faire Autrement » https://www.leem.org/sites/default/files/Livret%20.pdf

April 2014, when Marisol Touraine unveiled her plan to save 3.5 billion euros of drug spending over the next three years, LEEM, backed by the employer's federation Mouvement des entreprises de France, attempted to protest. LEEM temporally suspended its participation in the CSIS.[577]

If Sovaldi triggered political attention to the issue of pricing expensive drugs, the continuous arrival of other expensive drugs alarmed policymakers. The CNAM 2015 annual report warned that "The advent of new treatments for hepatitis C has provoked a shock wave in all health systems. For the first time, the question of access to drug innovation has arisen not for developing or emerging countries, but for the richest countries".[578] Among other proposals, the CNAM recommended a "cleaning work" of liste en sus. In that autumn, the Social Security Financing Law for 2016 included a saving measure through the removal of drugs from the *liste*. The following March health minister Touraine issued a decree, setting out the terms for removing drugs. It specified that 1) drugs other than those rated "major" or "substantial" SMR or 2) drugs rated ASMR V, and some of drugs rated ASMR IV, were subject to removal.[579] Cancer patient groups, such as the Ligue contre de cancer, and cancer specialists denounced the decision, but they also blamed the industry for overly expensive "unfair" drug prices. Before the decree was issued, 110 oncologists sent an open letter to the minister, arguing that the new cancer drugs' excessively high prices threatened patients' equality of access to treatments.[580] Based on the re-evaluation of SMR and ASMR by HAS, 5 drugs were removed from the list in August 2016, which was expected to save 205 million euros in 2016.

Thus, apart from a covert form of rationing such as removal from the *liste en sus*, policy adjustments took place in a piecemeal manner, often strengthening budgetary control over the industry. The Social Security Financing Law for 2017 showed continuation of this trend. It set out stricter mechanisms, including regulation of the contribution from rebates, a new budgetary ceiling for temporal authorisations, and others. The industry denounced the

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[577] *Agence France Presse* 14 May 2014.
[578] *Les Echos* 2 July 2015.
[579] See Ministère des Solidarité et de la Santé, « Prise en charge des médicaments à l'hôpital : précisions sur le décret « liste en sus » », 25 March 2016. https://solidarites-sante.gouv.fr/archives/archives-presse/archives-breves/article/prise-en-charge-des-medicaments-a-l-hopital-precisions-sur-le-decret-liste-en
[580] *Le Figaro* 15 March 2016; *Les Echos* 16 March 2016 ; *Le Monde* 26 March 2016.

measures that targeted it, claiming that of the savings of 10 billion euros achieved in the health insurance during the last three years, 5 billion euros had come from the pharmaceutical industry.[581] As a policy more favourable to the industry, the government established the Fonds pour le Financement de l'Innovation Pharmaceutique. With an initial reserve of 876 million euros per year and a relatively generous allowance of a 5% annual increase, the fund would specifically cover particularly expensive drugs, such as hospital drugs on the *liste en sus*, drugs with temporal authorisation, and the retrocession of hospital drugs in ambulatory care, so that it stabilised expenditure.[582]

In sum, the government attempted to tackle the arrival of expensive drugs largely through existing instruments. It managed to maintain the existing regime's features, which allowed access to expensive new drugs without explicit rationing. Moreover, vigorous operation of the price-volume agreement further diminished incentives for elected politicians to set a fundamental reform in pricing and reimbursement criteria that might lead to limiting access. While episodes of the individual expensive drugs still alarmed policymakers, who enabled piecemeal adjustment, the lack of sustained exposure to salient public debates enabling conflict expansion and mobilisation of political actors advocating more far-reaching reforms meant that the policy adjustment occurred within the existing regime, anchored by the existing power balance within the institutional arrangements. At the same time, however, this continuation of high level of access to drugs does not necessarily mean that the pharmaceutical industry won the behind-closed-doors political negotiations. Ironically, the industries often lost out when facing strong control through pricing instruments. The industry did not have effective means to counter-mobilise through expanding their coalition, as long as the negotiations took place through existing organised channels exclusively comprising of drug companies and the government. Overall, through making adjustments largely through the existing channel the state held a strong grip over the negotiations with the industry.

4. Conclusion

[581] Leem, communiqués de presse 4 October 2016. http://www.leem.org/leem-interpelle-les-pouvoirs-publics-sur-des-nouveaux-mecanismes-de-regulation-qui-risquent-de-frein
[582] *Les Echos* 23 September 2016.

The trajectory of the battles over rule changes in French drug funding policy showed several "near-miss" events that may have led to more drastic change. We saw the emergence of different policy elites willing to introduce a greater role of medico-economic evaluation, while we witnessed a major drug scandal and episodes related to specific drugs as focusing events that could have given an impetus to reform. Yet, the existing institutions and policies demonstrated persistence and adaptability in the face of these forces. The present chapter showed that a key to understanding the surprising lack of reform was the absence of conflict expansion. Without such an expansion, which leads to a changing coalitional balance, the existing institutions' structures preserve the power balance of their defenders. Limited opportunities to expand the conflict in a sustained manner meant that policy adjustment was through negotiated settlement among different political actors entrenched in the existing institutions – among different bureaucratic organisations and policy elites inside and outside the state and between the state and the pharmaceutical industry. Such a piecemeal adjustment largely operated through existing organised channels of politics, not through public or electoral arenas.

Where did this lack of shifts in coalitional balance come from, then? The present chapter proposed a possibility that the low level of political insulation limited the opportunity for conflict expansion and coalitional shifts. It did so by showing that ministers did not attempt to enact a reform that might generate blame on them without any clear credit to claim. When combined with the findings of the last chapter, the present study offers a perspective on how low political insulation affected policy persistence through shaping ministers' behaviours. At the level of policy choices about individual drugs, as Chapter 6 explored, the low political insulation enabled ministers to avoid making politically costly decisions when experts issued negative opinions. The present chapter showed that impacts of the low political insulation on ministers' behaviour can also operate at the level of the rules defining the policy choices. The low insulation discouraged ministers from taking up a rule change that was likely to generate more negative opinions by experts and increase the chances of politically costly decisions. Both contributed to policy persistence, preventing the government from committing explicit rationing. In the process, politicians managed to contain conflicts in the existing institutional channels.

The findings of the chapter also highlight regulatory agencies' behaviours under different levels of political insulation. Health economists at HAS pushing medico-economic evaluation acted much like those at NICE: they elaborated guidelines and methods, they tried to build

coalitions among different audiences, and they sought for autonomy and bureaucracy-induced policy innovation. Yet, against an oft-made assumption that bureaucrats would seek to gain greater authority, HAS did not push further to gain reimbursement decision-making powers. Whilst the existing institutional structures conferred to ministers the unpopular decisions of explicit rationing, the bureaucrats did not dare to challenge the existing institutional structure to expand their own powers. The existing institutional structure hence also limited the magnitude of bureaucracy-led policy change.

The persistence of existing institutions does not necessarily mean that they did not adapt in the face of changing external environments. On the contrary, the French case showed elasticity in its policy adjustment using existing institutionalised instruments. With the lack of fundamental reforms, the policymakers tackled the arrival of expensive medicines largely through existing instruments such as pricing control, without resorting to explicit rationing. The functioning of the existing institutions, even when facing expensive drugs, in turn, deprived of a further factor that may have led to changes in the pricing and reimbursement rules: the focusing event that would have alerted political actors to the urgency of reforms.

French policy adjustment generated substantial redistributive consequences; the partial de-reimbursement led to a distributive transfer whereby complementary insurance (and patients) on drug companies had to bear the cost of policy adjustment, whereas the burden of price reduction was borne by the industry; but blame-avoidance and a gradual reduction of reimbursement rates meant that the imposition of costs on companies was gradual and on a negotiated basis. In the process, conflicts between payers' and producers' coalitions were tackled by government-led negotiated settlements.

Chapter 8 Conclusion

This study, based on the study of explicit drug rationing policies, examined policy development after reforms to create regulatory agencies. The proliferation of regulatory agencies and other non-majoritarian institutions in Europe has attracted much attention in the past few decades. Notwithstanding the regulatory state thesis's claim that sees this proliferation as a sign of the transformation of state-society relations, however, insufficient attention has been paid so far to the trajectories after the creation of agencies. The thesis takes up drug funding policies as an example of the regulatory policies where, in line with the regulatory state thesis, the reforms to create agencies may disrupt the existing governance structure and their unpopularity may create moves both towards and against non-majoritarian institutions. By comparing the divergent trajectories of drug funding policy in England and France, this study examined endogenous sources of policy development in the post-reform period.

This study argues that a source of the divergent trajectories lies in the locus of decision-making over drug funding. Specifically, it contends that political insulation, namely, the degree to which elected politicians are excluded from decision-making has important implications for the post-reform political dynamics and policy development. A high political insulation generates self-undermining dynamics whereby unpopular policy choices create generate counter-mobilisations that expand conflicts to outside actors. By contrast, a low political insulation limits opportunities for such conflict expansion, contributing to policy continuity.

This concluding chapter brings together the main findings from the case studies laid out in the preceding chapters to provide the thesis's main arguments. First, it synthesises the key findings from the comparative case studies, summarising the trajectories after regulatory reform. Second, it discusses the underlying mechanisms behind the trajectories. Third, based on these discussions, it considers the study's broader implications for the scholarship of regulatory politics and historical institutionalism. The thesis ends by reflecting on the study's implications for debates on the regulatory state and depoliticisation.

1. A summary of the findings from the case studies

Through comparative analyses of drug rationing policies in England and France since the late 1980s, this study shows: (i) that in the two countries policymakers used different institutional and policy strategies in tackling a loss-imposing policy choice such as drug rationing – the strategies that can be found in the two countries' low versus high political insulation in decision-making process; (ii) and that the different degrees of political insulation identified above endogenously structured their own political dynamics, shaping distinct post-reform trajectories.

Two blame-avoidance strategies

Government policies often involve decisions that impose significant visible losses on different societal actors. In making such a policy, which is likely to generate blame on the incumbent government, policymakers devise different strategies. Through the study of drug rationing policies in England and France, the thesis identified two such strategies that policymakers could use that involve non-majoritarian institutions. On the one hand, policymakers can create a highly insulated locus of decision-making where powers are delegated to non-majoritarian institutions. The high political insulation enables elected politicians to shift the blame for the outcomes of unpopular decisions to the regulatory agencies. On the other hand, policymakers can design a less-insulated locus of decision-making where elected officials retain powers in their own hands. Such a setting enabled ministers to block regulatory agencies' outputs when they felt following the outputs would entail too much political cost; the low political insulation hence prevented unpopular decision from taking place. These two distinct strategies to deal with blame-gathering policy choices were thus both *institutional* and *policy* strategies in that they rested on the particular institutional structures, which in turn shaped policymakers' practices in their policy choice.

Chapters 2 and 3 described the emergence of these distinct strategies that were found in the countries' sectoral institutional arrangements. In both countries, the history of explicit rationing strategies triggered salient loss in electoral terms, generating strong incentives for incumbent politicians to avoid the blame for explicit rationing decisions. Such electoral incentives hence would constitute a background condition for institutional reforms. When it comes to designing the decision-making process, however, elected politicians in the two countries preferred remarkably divergent strategies. In England, incumbent politicians, both Conservative and Labour, repeatedly refused to address the national government's responsibility for rationing. The creation of NICE implied that it would no longer be the

minister but the agency who assumed authority over whether the NHS would fund the new drugs subjected to NICE's appraisal. The subsequent rule modification further minimised the room for manoeuvre after NICE issued its guidance; ministers hence had few powers in their hands to affect policy outputs. By contrast, in debating the designs of the French decision-making process both left- and right-wing incumbent politicians tried to draw a clear demarcation line between regulatory agencies' "scientific" role, to make assessments, and "political" decisions, to include drugs on the reimbursement list, the latter of which they claimed could only be made by health ministers. In both the cases of the Medicine Agency and the inter-ministerial pricing committee, CEM in the 1990s and HAS in the 2000s demonstrated that, time and time again, ministers claimed the powers and final responsibility for reimbursement decisions. Even if HAS and the Transparency Committee were granted strong formal independence from the health minister, the locus of decision-making remained largely intact. It always remained the ministers who had the powers to make the final decision over whether the national health insurance funded a drug.

In most instances covered in this study the incumbent governments in both countries played a crucial role in establishing regulatory agencies and designing the different insulation of the drug funding decision-making locus. The two countries' national institutional structures, with a strong executive branch vis-à-vis both the legislative branch and societal actors, meant that the incumbent government was largely able to impose its preferences on the design of the regulatory reforms.[583] Thus in France, when the Mutualité proposed an independent agency in the area of health, it envisioned a greater participation of societal actors and retreat of the state from important decisions such as drug de-reimbursement as a form of explicit rationing strategy. Yet, when the government took up the proposal and translated it into a concrete agenda for HAS, far from state retreat and a participatory mechanism, it maintained or even reinforced the executive government's powers at the expense of societal actors. Likewise, in England, while the opposition parties (Labour under the Major Conservative government and Conservatives under the Blair Labour government) and generalist doctors demanded the incumbent national government to address its responsibility for rationing, the Blair

[583] Perhaps a major exception was the French Socialist government's proposal in 1991 where the minority government was not able to pass its bill for an inter-ministerial pricing committee and was forced to withdraw it when confronting the opposition-controlled legislative branch; the successive Gaullist government (Balladur in 1994 and Juppé in 1996) restored virtually the same agenda for the committee and successfully formalised it.

government designed a highly-insulated setting by creating NICE; the feature of high political insulation was further reinforced during the agency's early years of operation through the mandatory funding of NICE-recommended technologies.

Trajectories after regulatory reforms

The findings of this study suggest how institutional arrangements with varying degrees of political insulation guided divergent policy choices for drug reimbursement. As Chapter 6 showed, the low level of political insulation in decision-making in France, where ministers held the final responsibility for reimbursement, allowed ministers not to follow the Transparency Committee's conclusions if they found de-reimbursement of the given drug too politically costly. This remained unchanged after the establishment of HAS. By contrast, in England, Chapter 4 demonstrated that without the powers to overturn NICE's technology appraisal outputs the highly insulated decision-making process in the 2000s enabled otherwise politically costly decisions.

But the different policy choices in the two countries generated distinct political dynamics in the post-reform period. By shaping the forms of political conflicts between payers and producers and by changing the coalitional balance, policy choices affected policy development. Generated from their different policy choices, the two countries differed in their *form* of political conflict in that they involved political actors who used distinct mobilisation strategies that were consequential to policy change and the arenas by which the conflicts were mediated. Over time, the different forms of conflict led the English and French drug funding policies to follow divergent trajectories.

The policy trajectory in England involved salient political battles channelled by the public and electoral arenas that were consequential to a partial policy change. The highly-insulated decision-making over reimbursement made NICE's outputs the final policy decisions for the NHS. Despite the reputation and the credibility that NICE's technology appraisals enjoyed, however, policy decisions generated counter-mobilisation once negative policy decisions had accumulated. Drug companies and patient groups broadened their coalitional base of counter-mobilisation, calling on support from citizens and politicians by drawing public attention to the losses imposed by the policy decisions. Chapter 4 demonstrated how the rise of public attention and pressures on the incumbent government drove the introduction and expansion of

measures to improve NHS drug availability such as the Single Technology Appraisals, risk-sharing scheme, End-of-Life criteria, and the Cancer Drugs Fund; it also highlighted that these rule changes were a product of pressures emerged from outside the insulated decision-making process for reimbursement. Starting from the mid-2000s under the Labour government, these measures specifically targeted high-cost drugs for particular areas, especially cancer, where the counter-mobilisation through the public arena was greatest. The Conservative Party's Cancer Drugs Fund agenda in the 2010 general election was largely built on this coalition for counter-mobilisation formed during the Labour period.

While the electoral mandate enabled the Coalition government to achieve a partial policy reversal through the Cancer Drug Fund, it did not end up achieving the full-scale reversal as envisioned in its value-based pricing agenda. Ironically, as Chapter 5 showed, the Coalition government was less successful in navigating the organisational realm of politics than the politics via public and electoral arenas like the Cancer Drugs Fund, partly due to the positive feedback that the existing policy created in relation to drug companies and doctors. Both drug companies and doctors had adapted to the existing structure whereby NICE took the central responsibility for rationing of new expensive drugs. Doctors were freed from their rationing responsibility while aided by NICE's expertise; drug companies shifted their resources to clear the regulatory hurdle set by NICE. Both actors, therefore, opposed value-based pricing, which attempted to shift the accountability (and the blame) for explicit rationing decisions from NICE to doctors and drug companies. Moreover, the Cancer Drugs Fund was also subject to the momentum for re-reform through its own operation. With its weak fiscal monitoring and inflationary spending underlined by its political logic, the Fund invited counter-mobilisation from the payers' side, whose coalition expanded to other actors inside the government such as the National Audit Office. The re-reform led to a compromise that put the Fund under the management of NICE. In the end, endogenous forces limited the Coalition government's agenda for shifting away from NICE-centred rationing decisions.

In France, by contrast, policy choices in a low political insulation setting prevented unpopular policy choices. In the absence of policy-triggered conflict expansion to outside actors, the government-led negotiations with organised interests contributed to policy continuity. As Chapter 6 showed, low political insulation allowed ministers, who anticipated the political costs entailed, to selectively de-reimburse the drugs that the Transparency Committee judged as insufficient in clinical benefit. To avoid total de-reimbursement, ministers used various tactics, including delaying de-reimbursement, creating a new

reimbursement rate, or lowering the prices of drugs with insufficient clinical benefit. Through such soft-landing tactics based on partial or selective de-reimbursement, elected politicians sought to deflect the blame that a total de-reimbursement decision would have evoked, while lessoning negative impacts on domestic firms and constituencies. The public controversy triggered by the Mediator scandal opened the possibility of coalition expansion to outside actors through the public arena, but the effect was only temporary. Soon after the scandal ministers, both left and right, returned to the existing strategies for de-reimbursement and rationing, despite even generalist doctors becoming less sympathetic to the producers' coalition.

Another effect of the low political insulation concerned the policy debates over changing drug funding rules, as Chapter 7 examined. While some bureaucrats within the Ministry of Health and health economists within HAS repeatedly attempted to incorporate medico-economic evaluation to HAS' assessment, and despite allied voices of actors outside the sector-specific policy process, such as the Cour des Comptes, the self-reinforcing dynamic of existing criteria, emphasising clinical rather than economic expertise, meant that attempts at introducing economic criteria had to confront hurdles inside the government and the clinician-dominated HAS. Even if the proponents of reform managed to surmount these organisational hurdles, especially aided by the temporary conflict expansion after the Mediator scandal, the low political insulation whereby the final decision-making powers laid with the minister meant that ministers had a stronger incentive not to create political controversies surrounding HAS's evaluation and reimbursement decisions. Any changes in criteria that would increase the agency's political responsibility and make a difference to policy outputs thus entailed resistance from ministers and civil servants, while clinicians inside HAS continued to resist taking on such a responsibility.

All in all, the incumbent politicians in France managed to reduce the potential conflicts that could arise as a result of explicit rationing strategies. By doing so, they confined the policymaking process to existing government-business relations. But this avoidance of "noisy politics" and blame-generating policies does not mean that the industry was the winner of the drug rationing battles. On the contrary, the same government strategy to minimise conflict implied that, by reducing the possibility to expand the producer coalition, drug companies were deprived of the ability to mobilise against the government-imposed policy measures. In an attempt at controlling healthcare expenditure, instead of resorting to explicit rationing, the government extensively used pricing control where it historically had a stronger power over

drug companies. The institutionalised price-volume negotiations, which largely limited actors' access to only drug companies and the pricing committee, CEPS, meant that the drug firms had a limited capacity to overturn its existing weak position by allying with other actors.

2. Drivers of post-reform trajectories

By tracing policy trajectories over time, I examined how institutional arrangements for drug funding endogenously shaped subsequent development by creating their own political dynamics. This section discusses mechanisms linking the institutional arrangements to the post-reform period trajectories, including politicians' consideration of political cost, counter-mobilisation through different arenas, and mobilisation in support of policy continuity.

Before considering the mechanisms driving the trajectories, it is worth noting that any arguments that can be developed from a comparative study of the two countries within a single sector, like the present one, has obvious limitations. This study is largely a theory-building rather than a theory-testing exercise, with analytical priorities being placed on identifying mechanisms rather than delineating their scope conditions. The nature of the research design and the evidence collected for this study do not allow me to fully develop conditions under which the mechanisms affect policy development, which can be a task for future research.

But the key claims and findings of this study – that regulatory reforms endogenously create divergent trajectories, and that policymakers' different blame-avoidance strategies anchored by different degrees of political insulation affect these trajectories in an important way – may operate in different terrains in the two countries and beyond. In France, Bezes (2008; see also Bezes et al. 2013)'s study on administrative reform shows that elected politicians and central government civil servants resisted delegating political and economic powers – a finding that is similar to this study's observation of the emergence of low political insulation. Such low political insulation can also be found in many areas of "risk" regulation in France and other continental European countries as well as at EU level, with the form of separating roles between "risk assessment", which is seen as a task for a "scientific" regulator, and "risk management", which is considered the government's role (e.g. Vogel 2003). Borraz et al. (2006)'s study on food safety regulation in France likewise documents open disagreements between the independent agency and ministers, and the latter's reluctance to implement controversial outputs of the agency -- a dynamic comparable to the consequences of low

political insulation for subsequent policy choices we saw in Chapter 6. For its part, high political insulation also appeared to create its own dynamics in different areas. In England, Heims and Lodge (2018) highlighted widespread discontent against the regulatory state in economic regulation, where regulation has a command-and-control style with direct, hierarchical enforcement by regulatory agencies. Considering further scope conditions of the present study and the origins of different institutions and blame-avoidance strategies –given the similar dynamics found in other sectors—can be a future research agenda.

Political costs and the post-reform political dynamics

This study emphasised the role of political insulation in shaping different policy choices and trajectories over time. The varying degrees of political insulation guided different policy choices, which created the distinct political dynamics that led to divergent policy development over time. A key factor that conditions the chain of events linking political insulation to policy development is (both anticipated and real) political costs of the policy decision over rationing.

As Chapter 6 showed, in France, where the institutional arrangements had low political insulation, the anticipated political cost guided ministers' policy choices about whether to follow the Transparency Committee's opinion to exclude a drug with insufficient clinical benefit from the reimbursement list. It shows that anticipated losses, on both consumers and domestic manufacturers, informed politicians' calculation of political cost. It suggests such considerations played an important role in ministers' policy choices. The effect of anticipated political cost remained significant even after the creation of HAS, with its greater independence from the minister, and the Mediator scandal, the latter of which temporarily made ministers more sensitive to drug safety risks.

Political costs also played an important role in shaping post-reform trajectories in the institutional arrangements with high political insulation. The effects took place by conditioning how policy choices, which high political insulation enabled, created political conflicts. Chapter 4 showed how the societal distribution of political costs affects the magnitude of counter-mobilisation triggered by the policy choice over explicit rationing. It shows that, with its greater concentration of groups affected by the decisions and time-intensive "focusing events" that decisions can trigger, cancer generated the greatest counter-mobilisation involving the public arena. The different magnitudes of counter-mobilisation

across disease areas shaped variation in policy changes, where measures to improve drug availability specifically applied to cancer drugs but not others.

It is worth noting that in both countries, the blame-avoidance strategies anchored by consideration of political costs seemed to operate across different parties in government. In England, both the Conservatives and Labour accused the incumbent national government of refusing to take responsibility for healthcare rationing when they were in opposition. However, once in power both parties were reluctant to address the rationing debates, while expanding the programme of expert Health Technology Assessment. There were indeed some differences between the two parties in terms of their preferred institutional arrangements involving experts: the Conservative governments in the 1990s and 2010s preferred local decision-making and clinical guideline development, whereas Labour in the 1990s and 2000s emphasised expert guidance by a national-level agency such as NICE. Yet, the arrangements endorsed by the two parties do share one crucial feature: that politicians tried to delegate decision-making to others, either to local-level managers and doctors (in the case of the Conservatives) or the national-level agency (in the case of Labour), thereby freeing themselves from taking politically-costly decisions. The longitudinal analyses of the study also found how policy legacies in the Labour period affected the Coalition government's agenda for the Cancer Drugs Fund and value-based pricing. Indeed, the partial policy reversal to improve the availability of drugs began during the closing years of the Labour government, especially through the introduction of End-of-Life criteria. Rather than creating it from scratch, the Conservative party exploited the existing electoral coalition for counter-mobilisation, generalising the policy measures largely built in the Labour period.

In France, both the Gaullist and Socialist parties committed to de-reimbursement plans while in government, but criticising the same plans when they were not. For instance, although it was the Socialist Jospin government who launched drug re-evaluations by the Transparency Committee in 1999 and committed to de-reimbursing drugs with insufficient clinical benefit, the succeeding Gaullist government in the 2000s took over the de-reimbursement plan and continued its commitment in the successive waves. Along the way, health ministers from both parties tried to avoid total de-reimbursement; they selectively de-reimbursed drugs that the Transparency Committee judged as not clinically effective. A similar example of both left- and right-wing governments refusing to follow experts' advice and thus keeping treatments available includes Alzheimer's disease drugs. Despite the mobilisation *for* de-reimbursement by some generalist doctors' associations, in addition to HAS's repeated evaluations of the

drugs deeming them not sufficiently effective, ministers' concerns about the anticipated political costs of de-reimbursement, driven by the disease's electoral significance and existing government programme policy priorities, overrode the Committee's opinion. As a result, both Gaullist and Socialist ministers chose to keep the drugs reimbursed.

All in all, throughout the study I have emphasised the role of elected officials' political and electoral incentives, anchored by different institutional arrangements, in shaping the executive government's strategies for explicit rationing. Regardless of the incumbent government's ideological and socio-electoral base, these political incentives guided elected officials' consideration of loss-imposition when deploying explicit rationing strategy. And the way in which elected officials can offset such anticipated political losses that an explicit rationing decision would be likely to provoke differed more across countries than across partisanship within a country. The thesis suggested the variety of such blame-avoidance strategies used by elected officials: in England, it was expert decisions in the highly insulated locus of decision-making, and in France it was ministers' avoidance of politically costly decisions.

Counter-mobilisation, coalition expansion and endogenous policy change

The present study argues that different levels of political insulation affect the forms of political conflicts, including the possibility of conflict expansion and the arenas by which the conflicts are mediated. The different forms of conflicts, in turn, play an important role in shaping post-reform trajectories as they change the coalitional balance between producers and payers. Specifically, the preceding chapters showed how producer coalition actors attempted to expand their base of mobilisation against explicit rationing policies through conflict expansion in the public and electoral arenas, and how the counter-mobilisation affected policy development.

By emphasising the role of coalition expansion in policy change, this study suggested a mechanism of change that differs from the often-invoked account of policy change via business's lobbying. A long-standing approach in political economy has emphasised business's power to shape policy-makers' choices behind closed doors, evoking such images as the "iron triangle" (cf. Lowi 1979). Recent works have revived this interest in business power through direct lobbying. Culpepper (2010) has stressed that business can exert influence in policy through lobbying policymakers when the issue is not publicly visible.

Likewise, the prominent "regulatory capture" literature argues that regulations are prone to benefit the regulated industry's interest at the expense of the public's (Stigler 1971; Carpenter and Moss 2014). These research programmes share a common image of the mechanisms behind policy change: business should be able to transmit its preferences on policy process effectively through closed venues, such as bureaucracy, regulatory agencies, and specialised legislative committees; the process of policy and rule changes in regulation should occur from *within*, where captured policymakers create or change rules in business interests' favour, without the involvement of the actors outside the "closed circle", such as diffused interests with less mobilising capacity and access to policymakers. Given the both academic and popular image of the powerful "Big Pharma" lobby, one might expect that the pharmaceutical sector should represent an "easy" case of policy change through direct lobbying.

In fact, the narratives of the two countries were replete with lobbying activities by drug companies, who attempted to change the rationing policy. As a major cost bearer of the government's explicit rationing strategies, the pharmaceutical industry actively sought to counteract both individual regulatory decisions and overall policy orientations by lobbying policymakers. In some cases, drug companies reached sympathetic ears inside the government. Perhaps the clearest products of the pharmaceutical industry's tactic of allying with sympathisers within the government were the government-business fora. In both countries, drug companies' counter-mobilisation against the explicit rationing strategy resulted in the creation of favourable forums exclusive to the government and the industry. In addition to actively promoting the industrial policy, which may offset the political costs imposed by rationing and other loss-imposing policies, through such forums the government actors sympathetic to the industry actively sought to change the overall direction of drug pricing and reimbursement policy in the industry's favour. Examples of such attempts include repeated criticism by British business-government fora, such as the Pharmaceutical Industry Competitiveness Task Force and Bioscience Innovation & Growth Team, against NICE's technology appraisals, and their recommendation for an inquiry into NICE; and R&D credits which were distributed through the CEPS as a result of the French business-government forum CSIS. Given the lobbying literature's emphasis on "arena shifting", i.e. shifting the locus of policy-making to an arena favourable to business influence, as a mechanism of business's power over public policy (cf. Culpepper 2010; Baumgartner and Jones 2010), the business-government fora in the two countries might reinforce the expectation that policy development in England and France should be driven by the industry's direct lobbying of policymakers.

Yet, the experiences of policy development in England and France showed several limits to the pharmaceutical industry's counter-mobilisation through such "inside lobbying" tactics. In both countries, business-government fora sympathetic to drug companies did not lead to major policy changes in drug rationing. In England, the result was at best modest; although the 2009 Kennedy inquiry into NICE recommended a pilot project on the role of innovation in NICE appraisals, overall it affirmed the existing criteria based on cost-per-QALY and recommended that the agency should not consider wider societal benefits (Chapter 4). And as Chapter 5 documented, although the innovation criterion was indeed incorporated in the subsequent agenda for value based-pricing, it did not materialise as the industry had wished and was later abandoned. In France, the pharmaceutical industry's capacity to change the course of policy through lobbying was even more limited. Throughout the period examined, the industry often lost in the business-government negotiations over price-volume agreements. Despite its discontent at bearing the burden of healthcare spending control, the industry was largely unable to overturn its existing weak position through negotiation.

The policy development narratives suggested mechanisms that limited the impacts of business's attempt to policy change through lobbying. One mechanism was expertise independent from the industry (cf. McCarty 2014). Both the business power and regulatory capture theories tend to assume the industry's superior expertise and a resulting information asymmetry between industry and government as a source of the former's dominance (Culpepper 2010; Dal Bó 2006). But the information asymmetry could be attenuated when the industry's claim was countered by other providers of knowledge. By providing knowledge and expertise to counteract the industry's claims, experts who are more sympathetic to the payer's side could counteract elite level policy debates, helping the incumbent government to justify the existing policies. Hence, for instance, the attempts by business-government fora to change NICE appraisals by calling for an inquiry were unsuccessful because the NICE-appointed rapporteur made a positive conclusion about NICE's technology appraisal methods (Chapter 4).

Another mechanism, which is also related to such elite-level policy debates, can be found in the policy process' procedural rules (cf. Moss and Carpenter 2014). Administrative requirements, such as impact assessment and cost-benefit analysis, limited the range of policy options that the government was able to deploy; like counter-expertise to the industry, they also helped the government to justify its policies in elite-level debates. For instance, impact assessment requirements constrained policymakers in drawing agendas for Value-based

Pricing, which failed to meet the industry's demands (Chapter 5). In contrast, when significant and immediate electoral credit was involved, such as the Cancer Drugs Fund, politicians were able to override impact assessment results (see Chapter 4). The contrasting experiences of the Coalition government's two policy agendas hence again indicate the importance of electoral and political factors, and of building a broader coalitional base involving public and politicians as an alternative strategy for mobilisation against an explicit rationing policy.

Indeed, even if the industry was not successful in the lobbying battles with elite policymakers, its efforts to counter-mobilise against drug rationing policy still resulted in policy change at times, especially when it expanded its societal coalitional base.[584] This coalition expansion involved both other organised interests, such as clinicians, and actors in the public arena, such as the public and politicians. On the first front – medical professionals – in some cases drug companies allied with clinicians in their counter-mobilisation. For example, in England, industries were more successful in their opposition against the 1985 Limited List, when doctors also opposed it, than the 1992 Limited List, when doctors' resistance had waned (see Chapter 2). And the possibility of successful alliance-building for counter-mobilisation partially depended on government strategies themselves. In the latter case, the government took more accommodationist strategies with doctors from the beginning, thereby successfully taming their potential resistance to its agendas.

Another, perhaps more consequential, coalition strategy for counter-mobilisation involved the public and electoral arenas. The producer's coalition – drug companies and disease-based patient groups – were successful in counter-mobilisation when it gained political and electoral currency. It did so by raising public attention to the issue and widening its political base by bringing politicians into the coalition. In England, as Chapter 4 showed, NICE's decisions on cancer drugs triggered a much greater magnitude of counter-mobilisation than any other areas.

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[584] Stating this does not mean that coalition expansion is a *superior* or *more effective* tactic of drug companies to influence policy than direct lobbying. The thesis does not examine relations between different lobbying tactics. What this study can say at most is that even when attempts at direct lobbying were not successful the industry may have indirect means to counter-mobilise against policy through coalition expansion. Theoretically, if we follow Schattschneider (1960)'s framework, coalition expansion is a tactic that a losing side of the battle may use. Yet the thesis did not test or develop this claim fully. To do so we need a more systematic process tracing of the strategies of the industry's side and its interaction with policymakers. Hence the relationship between different counter-mobilisation strategies that the drug company can use – e.g. how different strategies such as inside and outside lobbying interact with each other – requires further research. For an explicit treatment of the superiority of institutional access to coalition strategy in interest group mobilisation, see Grzymała-Busse (2015) on the church's influence in policymaking in the Western world.

It is important to reiterate the finding that the rising public attention to NICE's activities on cancer drugs appeared endogenous to NICE's guidance. As the pressure through the public arena increased, elected officials adjusted their positions, introducing policy change to improve the availability of drugs. In France, among the drugs the Transparency Committee judged as insufficient in clinical benefit, ministers tended to be more reluctant to take de-reimbursement decisions when the disease area was of higher programmatic and political priority -- such as Alzheimer's disease. The reluctance was somewhat surprising, given that after the Mediator scandal elected officials would have been more cautious about keeping drugs with insufficient benefit on the reimbursement list, and also that not only an independent pharmaceutical journal, which had long been critical of the government's policies, but also major generalist doctors' associations were against keeping the drugs on the list. In both countries, the alliance-building in organised interest politics, such as clinicians mentioned above, was an integral part of these episodes of counter-mobilisation, because in these battles, in addition to patient groups, some specialist doctors sympathetic to drug companies played a key role by acting as authoritative "experts" to raise public awareness of the issue and to affect policy debates in public arenas, amplifying the magnitude of the counter-mobilisation.

The study's emphasis on the role in policy change played by coalition expansions in the society means that, instead of originating from inside the policy process captured by business, policy changes took place from *outside* the existing drug rationing decision-making process. Chapter 4 showed that a partial policy reversal in England, such as End-of-Life criteria, was less to do with the agency-drug company interaction or the agency's anticipated reaction than with the rising public pressures on elected politicians. In a losing battle over elite-level policy debates and regulatory decisions, actors from the producer coalition could still counteract when they managed to steer debates and build broader coalitions in the public and electoral arenas.

In sum, different arenas in the political system played important roles in mediating and expanding political conflicts to outside actors. It is worth highlighting here that the opportunities for conflict expansion that would be consequential to policy change depended on the existing institutional arrangements, notably the degree of political insulation. In France, ministers' responsibility for reimbursement decisions enabled them to prevent unpopular policy decisions. The prevention of costly policy decisions that would later trigger conflict expansion in the public and electoral arenas – the dynamic that we saw in England – meant that there were less opportunities to expand the coalition in order to change the existing policy

orientation. As we shall see, this lack of opportunities for coalition expansion is further compounded by the institutions' feedback effects on different organised actors in both the state and society, such as bureaucracies and agencies, drug companies and doctors.

The bureaucracy, policy feedback, and the endogenous policy continuity

If endogenous forces that undermine existing policies through conflict expansion are a key mechanism that this study has advanced, it also identified endogenous forces that contributed to the persistence of existing policies. Specifically, this study showed how the activities of bureaucratic actors, through their operation, generate self-reinforcing feedback. Bureaucratic actors, such as regulatory agencies, ministerial departments, and inter-ministerial committees, contributed to policy continuity in several ways. First, at the most general level, bureaucratic actors maintained a certain extent of organisational and personnel continuation across different governments.

Second and perhaps more importantly, policy continuity was a product of regulatory agencies' own actions. A regulatory agency does not stand still after its creation; through its day-to-day functioning it produces policy outputs to fulfil its core tasks, while deploying experts and expertise to justify the outputs. The study documented the feedback effects from regulatory agencies to their experts, expertise, and their rule-making behaviours; it showed how these effects helped institutional defence against counter-mobilisation, thereby contributing to policy continuity. One such mechanism was regulators' codification of rules to both justify their decisions and make them decisions consistent. This was especially the case for NICE, which, with its highly insulated setting, was positioned at the forefront of explicit rationing decisions. Once it began operating, NICE confronted criticisms from different societal actors against its policy decisions. In response, NICE deployed its own expert network to develop elaborated rules and doctrines, including the cost-effectiveness threshold, based on its operational practices. NICE also actively participated in elite-level policy debates to explain the rationales behind its guidance (Chapter 4).

NICE's elaboration and justification of its policy decisions was coupled with a related feedback mechanism concerning the reproduction of experts and expertise. In both countries, different regulatory criteria underlined distinct experts and expertise that they deployed. NICE not only drew on but also strengthened the network of health economists through its operation.

At HAS, its criteria for pricing and reimbursement relied on clinical expertise were both reinforced by, and reinforced, its clinician-dominated composition. When HAS's health economists attempted to incorporate medico-economic evaluation within the agency's drug assessment, they hence confronted an internal organisational barrier in the clinician-dominated HAS (Chapter 7). Thus in both countries, the self-reinforcing dynamics of regulatory rules and expertise limited attempts at policy change.

But at the same time, the agencies' actions were bounded by the existing institutional structures that organised relations among actors. The boundary of agencies' organisational development set by the institutionalised power balance was at times further justified by normative or doctrinal claims. In France, such a justification took the form of the demarcation between scientific regulators and politicians, and the refusal of medico-economic evaluation for reimbursement criteria based on a cultural or normative claim – an argument that prevailed among ministers, civil servants, and HAS. The argument to refuse the use of medico-economic evaluation for reimbursement decisions was as much normative as political in that it contributed to organisational defence of vested interests, such as the CEPS and ministers, which enabled them to prevent politically costly decisions, following the example of NICE (Chapter 7).

The activities of regulatory agencies generated further feedback effects on societal actors through their regulatory interactions. Where the regulator became a substantial hurdle to drug access, such as NICE, we observed the societal actors' adaptive behaviour. Such a feedback effect through the interaction of the regulator with societal actors generated forces in favour of policy continuity, as it led clinicians and drug companies to oppose the value-based pricing agenda (Chapter 5). In France, by contrast, such effects of the regulatory agency's activities on societal actors' adaptive behaviour did not appear to be as prominent in the episodes of policymaking as in the English counterpart. This absence underscores the possibility that the ability of regulatory activities to encourage societal actors' adaptation to the existing policies might be conditioned by its significance as a regulatory hurdle.

Finally, in a complex regulatory space, such as drug pricing and reimbursement, involving multiple actors and organisations, neighbouring institutions can affect actors' positions (Pierson 1996, 2004; Hall 2016). In France, the CEPS's powerful spending control through price-volume agreements with the industry meant that a minister had even less incentives to enact a politically controversial reform that might upset the existing reimbursement regime

(Chapter 7). In England, where the drug companies perceived a benefit from the existing pricing regime through the PPRS, they opposed the value-based pricing agenda, which was considered to deprive them favourable conditions they had enjoyed for decades (Chapter 5).

3. Theoretical implications

The thesis brought together the regulatory politics and historical institutionalism literatures to develop arguments about the post-reform trajectories. With regard to the regulatory politics literature, I engaged with a prominent but empirically underexplored claim of the regulatory state thesis that the creation of regulatory agencies in Europe represents a key part of the transformation of state-society relations. In terms of the historical institutionalist literature, I built on its approach to endogenous change, notably its emphasis on institutions' coalitional underpinnings. I also drew on the literature's focus on policy feedback and the mediating role of arenas to analyse the impacts of past policy choices on policy development. By drawing on these two bodies of literature, which had remained largely separate, this study sought to enrich both areas of inquiry.

Scholars of regulatory politics have extensively examined sources of delegating decisions and the independence of a regulator. This study has focused on a different aspect, that is, the effects of non-majoritarian bodies on subsequent policy development. It widened the institutional scope of analysis by looking at a broader set of political battles that are not limited to regulator-politician or regulator-regulatee relations; it expanded the temporal scope of the analysis by tracing mid-term policy development that goes beyond individual regulatory rulemaking. By expanding both the institutional and temporal horizons of the analysis, this study has sought to advance research on regulatory politics and endogenous change on several fronts.

First, it advances the notion of political *insulation* and its impacts on subsequent policy development. The regulatory politics literature has paid much attention to the political *independence* of regulatory agencies (cf. Thatcher and Stone Sweet 2002; Gilardi 2009). This is an undoubtedly important dimension, especially given the scholars' major concern about democratic accountability of non-majoritarian institutions. But in seeking to understand the implications of regulatory agencies for post-reform dynamics, we run the risk of drawing misleading conclusions if we overlook the role of the locus of the day-to-day decisions that

allocate powers among actors – who is in charge and how they share regulatory space during the policy process. Indeed, HAS enjoyed a greater formal independence from the health minister than NICE. In contrast to the health minister's predominance to NICE in its appointment rules and its legal foundation, the HAS Board was appointed by the President and the legislative branch – hence it had at least an equal footing to the health minister. But that greater independence did not translate itself into the agency's responsibility in policymaking. Instead, what played a crucial role in the trajectories were the rules about allocation of powers that actors sharing the regulatory space should follow in a given decision-making process. It was these day-to-day interactions in the regulatory space that generated significant feedback effects, both positive and negative, on subsequent counter-mobilisations or mobilisations of actors, which affected policy development. In generating momentums for undermine or reinforcing the existing policies, the varying degrees of political insulation have resulted in far-reaching distributive consequences among different political actors. This attention to the organised relations among political actors throughout the decision-making process broadly resonates with a classic idea of interdependence of actors sharing "regulatory space" – an idea that different European national traditions have shaped distinct allocations of powers and ways of interdependence among the state and organised interests (Hancher and Moran 1989; cf. Crouch 1986). The findings of the thesis suggest the analytical merits of not only focusing narrowly on regulatory agencies but also looking at the broader decision-making process and power relations between different organisational actors therein.

A second and related lesson from looking at the decision-making process and how actors share the political space throughout it is about the role and the capacity of the state in public policy. This study's coalition-based institutional approach showed how political actors within the state attempt to impose costly decisions on its citizens and organised interests, and what shapes different political strategies for loss-imposition. Examining different actors within the state – such as ministers, regulatory agencies, ministerial bureaucracies – and their strategies for linking up with different societal actors with different policy goals enabled me to examine the role of shifting conflicts and political coalitions in shaping the trajectories; and how the conflicts and coalitions are themselves a product of sectoral institutional structures that allocate powers among actors in the decision-making process. In doing so, this study joins the recent call for analytically disaggregating the state into different organisational entities and their roles in policymaking (Morgan and Orloff 2016). The long-standing tradition of state-society relations, which the idea of political and regulatory space mentioned above rests on,

looks at how different linkages between the state and organised interests affect governments' distinct policy strategies (Katzenstein 1976; Weir and Skocpol 1985; Hall 1986).

The present study further extends this line of thinking about the relations between the state and societal actors to the different actors *within* the state and their linkages with societal interests. Conceptualising actors within the state in this way and examining their role in policymaking entailed some surprising findings that are otherwise not well captured. For example, the narrative of the thesis highlighted how the French government attempted to steer different goals through its policy strategies, and along the way how the domestic industry often lost out through the government's imposition of those strategies. The resource allocation role of government-led pricing control, and the weak power of business to overturn the existing policy orientation, meant that the government shifted the costs of economic adjustments onto the industry by using pricing mechanisms. This finding may run counter to the established image of the "strong" French state as an active promoter of its domestic industry (cf. Cohen 1992; Hayward 1995). The apparent paradox can be resolved once one differentiates the capacity of the state from its preferences or policy goals and examines how the latter can vary among different actors within the state. The French state was indeed powerful vis-à-vis societal actors, but it could use its power for different societal purposes. And these different purposes are shaped by how coalitional balance between the different state actors linking up with societal actors, which is at least partially constrained by the existing sectoral institutional structures. The different actors within the state played a pivotal role throughout this coalition management in that their act of balancing different, often contradictory, policy goals that the different actors from the government-private coalitions carried shaped the orientation and changes of policy.

Policymakers' shifting attempts at balancing coalitions were also seen in the English case. The regulatory state, with its highly insulated decision-making, yielded the capacity of policymakers to impose politically costly decisions on the industry as well as citizens; but as an unintended consequence of such loss-imposition, later policymakers had to confront greater political pressures channelled through public and electoral arenas. Such conflict expansions and changing coalitional balances prompted ministers to shift positions in terms of the prioritisation of different policy goals and changes in their own coalitional base; it also empowered some actors within the state while discouraging others, as the Cancer Drugs Fund temporary showed. In the end, however, the rebalancing of coalitions did not mean one policy orientation completely took over another. As the narrative of the Coalition government's

failed attempts at value-based pricing and the re-reform of the Cancer Drugs Fund shows, existing institutions shaped changes in policy orientations. As societal actors such as drug companies and doctors adapted to the existing process, their support for it obstructed a policy reversal; likewise, the government actors and procedures built in the existing institutions constrained the policy swing, including the Department of Health's draft agenda for widening societal values in drug evaluation that failed to meet the industry's wishes, and the National Audit Office's inquiry into the Cancer Drugs Fund. Along the way, different actors within the state, responding to ongoing political dynamics, created a particular balance of different policy orientations in the government policy strategies at a particular time. In sum, looking at how the different actors within the state, whose power balance was a product of the allocation of institutionalised decision-making powers, create and maintain coalitions with different societal actors can enable us to capture the capacity, as well as policy strategies, of the state to impose costly decisions.

Finally, this study advances a coalition-based account of endogenous development (Mahoney and Thelen 2010). It shows how policymakers' blame-avoidance strategies, linked with political insulation, shape endogenous development – a mechanism of endogenous change that has been underexplored in the literature. Through its inquiry into the battles over drug rationing across different arenas, the study broadly resonates with the recent call by historical institutionalist scholars to look beyond major legislative battles and the adoption of bills that political scientists tend to be preoccupied with (Hacker et al 2015; Hacker and Pierson 2010) In their recent conceptual work on endogenous change, Hacker et al. (2015) encourage scholars to examine "hidden" changes. Inquiries into mechanisms of endogenous hidden changes such as "drift", i.e. institutional stasis in a changing environment, and "conversion", i.e. altering the purpose of institutions without changing rules, they argue, "expand our range of vision by prompting us to adjust not just what kind of changes we are looking for but where we are looking for it and whom we expect to produce it" (204). By paying attention not only to salient legislative and electoral battles but also to bureaucracies and courts, and by examining how organised interests induce changes through these arenas, which are less publicly visible, they call for a research programme that integrates institutional changes with studies of public policy and administration, law and courts – studies that have tended to be separate from inquiries in comparative politics. This study broadly shares its interests with this line of analytical endeavour in that it examines multiple institutional locations and looks at mechanisms that can only be manifested over a substantial period of

time. It also shares the underlying idea of a coalition-based account of institutions: that institutional or policy continuity requires ongoing mobilisation of political support and that gradual institutional changes are often driven by shifts in its coalitional base -- an underlying structure on which institutions can have a "partially bite" (cf. Capoccia 2016, 1100).

At the same time, however, the study highlights a mechanism that differs from the image of hidden changes that the scholarship on endogenous change is advancing. By examining how a particular feature of sectoral structures, such as political insulation, creates distinct blame-avoidance strategies, it shows how policy arenas such as bureaucracy and regulatory agencies can expand or constrain the coalitional base of political mobilisation through different politics channels. In contrast to the image of hidden changes where organised interests alter institutions through regulatory agencies and other channels within elite-level politics, the mechanisms that the present study proposes are based on the interaction between different arenas involving both elite and mass politics. The salient battles and coalition expansion through public and electoral arenas in England contributed to policy change; the absence of the opportunities for such conflict expansion contributed to policy continuity in France.

An analytical lesson for the scholarship on endogenous change is that in examining endogenous sources of change, we need to look at *both* hidden "quiet" and "noisy" visible politics in order to fully understand policy changes that involve bureaucratic enforcement, in particular how the different arenas of politics, with their varying degrees of electoral involvement, interact with each other. This claim that the thesis has developed here hence has a broader implication for a classic and ongoing debate in comparative political economy over the relative roles of organised interest politics versus electoral politics in distributive issues (Beramenti et al. 2014; Hacker and Pierson 2010). This study shows, despite remaining a comparative study in a single sector, how policymaking in the realm of the former – the interaction of state organisations, such as regulatory agencies and bureaucracies, with organised interests in drug pricing and reimbursement – can shape whether conflicts are contained within organised interest politics or spill over into the parliamentary-electoral channel of politics. This last point concerning the roles of different channels in politics in post-reform dynamics brings us back to the opening question about the consequences of the regulatory state and the implication of this study for debates over depoliticisation and regulatory reforms.

4. A final note: The regulatory state, depoliticisation, and democratic politics

This study was motivated by the question of the trajectories following regulatory reforms to create non-majoritarian institutions. Notwithstanding the regulatory state and depoliticisation theses' claims that non-majoritarian institutions can disrupt the existing governance structure and undermine party democracy in Europe, empirical work on post-reform trajectories has remained underdeveloped. This study uses explicit drug rationing policies as a window into the post-reform political dynamics, studying endogenous drivers of policy development.

The study's conclusion casts doubt about a teleological understanding of the history of the regulatory state. When referring to the regulatory state as a disruptive, institutional innovation to the existing state-society relations, both the theorists of the regulatory state and depoliticisation appeared to assume a linear trajectory of reinforcing the policies that accompanied the creation of non-majoritarian institutions. The findings of the thesis challenge such an assumption. It argues that under certain conditions, far from strengthening its depoliticised mode of governance, a non-majoritarian institution can itself become a source of *greater* politicisation, generating self-undermining dynamics. This study identified political insulation as a factor that conditioned such a dynamic, arguing that high political insulation creates a distinct form of political conflicts involving counter-mobilisation through public and electoral arenas. Against the assumed linear post-regulatory reform trajectories, it stressed divergent paths of regulatory policies through the endogenous political dynamics mediated by different arenas.

To be sure, this study's argument against a linear policy development and its findings on self-undermining forces are hardly novel. In his classic essay on public participation, Hirschman (1982) pointed out how disappointment and discontent generated by ongoing practices lead to turnabouts between private and public spheres of collective behaviours (see also Hood 1994, 15). In a way, through its examination of opportunities of conflict expansion this thesis identifies a more concrete mechanism that drives the endogenous forces behind the long-term cyclical movements that Hirschman once highlighted. The thesis shows that, as the English case demonstrated, an institutional arrangement for decision-making insulated from politics may pull itself into the public sphere, leading to conflicts and instability. Conversely, with the absence of such opportunities for conflict expansion, as the French case showed,

decision-making remained largely contained in elite-level political bargains that took into account decisions' likely political and electoral costs, contributing to policy continuity.

These divergent paths of both the post-regulatory-reform politics and policy in drug rationing thus highlight tensions between non-majoritarian institutions and the political dynamics in public and electoral arenas. As Hall (2013) has argued in his recent essay on the democratic legitimacy of the EU, governing not only involves choosing a policy option among several but also entails "mobilizing consent for the choices among those affected by the policy" (432).[585] For Hall, the problem of the EU – another paradigmatic case of the regulatory state thesis -- is that, while it has developed a capacity to create compromises through institutionalised channels, for its increasingly political tasks involving profound distributional implications among its citizens it has failed to create compromises and obtain the political consent of those affected through democratic arenas. More generally, governments are engaged in coalition-building and mobilisation of consent among societal actors through different, organised and electoral, political arenas. Sometimes, the imperative of coalition-building in one arena may give rise to contradictory forces in the other (see Hall 1986, 273).

As a policy choice that deeply affects citizens' well-being and the state's resource allocation, the case of explicit drug rationing policies thus represents a challenge to coalition-building in different arenas following the creation of regulatory institutions. A highly-insulated, regulator-led decision, while making a difficult policy choice possible, can be susceptible to political discontent. But a politician-led decision can also create its own consequences for resource allocation and well-being of citizens, by prioritising some patients or constituents over others based on political and electoral consideration and downplaying experts' evidence-based opinions. The different consequences of regulatory reform thus pose a political dilemma involving difficult policy choices for post-reform regulatory politics.

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[585] Hall's claim here was based on Beer (1969)'s classic conceptualisation of mobilisation of political consent through interest group politics and party politics in Britain.

Appendix: List of Interviewees

England

Senior Economic Advisor, Department of Health	18/04/2018
Former Senior Official, NICE	30/04/2018
Health economist; Former member, NICE Appraisal Committee	03/05/2018
Former Senior Official, NICE	04/05/2018
Economist, the Office of Health Economics think tank	10/05/2018
Officials, Department of Health	17/05/2018
Senior Official, NICE	12/07/2018

France

Health policy scholar; Former member, HAS	30/09/2016
Health economist; Member, HAS CEEPS	14/10/2016
IGAS official; Member, Aubry's cabinet	26/10/2016
IGAS official	28/10/2016
IGAS official; Former senior official, DSS	10/11/2016

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