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The rise of the regulatory state in health care: a comparative analysis of the Netherlands, England and Italy

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Abstract: In a relatively short time, regulation has become a significant and distinct feature of how modern states wish to govern and steer their economy and society. Whereas the former 'dirigiste' state used to be closely related to public ownership (e.g. hospitals), planning (volume and capacity planning) and centralised administration (e.g. fixed prices and budgets), the new regulatory state relies mainly on the instrument of regulation to achieve its objectives. In this paper, we wish to relate the rise of the 'regulatory state' to the path-dependent trajectories and institutional legacies of discrete European health-care systems. For this purpose, we compared the Dutch corporatist social health insurance system, the strongly centralised National Health Service (NHS) of England and federal regionalised NHS system of Italy. Comparing these three different health-care systems suggests that it is indeed possible to identify a general trend towards the rise of the regulatory state in health care in the last two decades. However, although the three countries examined in this paper face similar problems of multilevel governance of networks of third-party payers and providers, each system also gives rise to its own distinct regulatory challenges.

1. Introduction

In his seminal article on the rise of regulation in Europe, Giandomenico Majone pointed at the paradoxical development that the creation of the internal market in Europe and the privatisation of public services had not led to deregulation, but instead, to such an increase in regulation that it was even appropriate to speak about a distinct 'regulatory state' (Majone, 1994). Majone's regulatory

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state thesis was soon accompanied by a growing body of literature that presented itself under the label of 'regulatory capitalism' and that broadened the analysis of regulatory reforms to other areas at varying levels and in varying segments of the globalised economy (Levi-Faur and Jordana, 2005). In a relatively short time, regulation had become a significant and distinct feature of how modern states govern or steer their economy and society, that is, via rule making and rule enforcement. Whereas the former 'dirigiste' state used to be closely related to public ownership (e.g. hospitals), planning (volume and capacity planning) and centralised administration (e.g. fixed prices and budgets), the new 'regulatory' state relies mainly on the market and the instrument of regulation, to achieve its objectives (Majone, 1994).

Does this trend of market-oriented reforms together with regulatory reforms also hold for European health-care systems? In the last two decades, in many European countries, governments have introduced quasi-market arrangements in their health-care systems, that is, a system in which health-care services are provided within a competitive market context, but one that is carefully controlled and regulated by the state to avoid inequalities (Le Grand and Bartlett, 1993). In this paper, we ask to what extent and in what ways these quasi-market – regulatory – reforms in European health-care systems can be related to the institutional legacies of different health-care systems and how these regulatory reforms have contributed to strengthen government's capacity in health-care systems. In Section 2, we argue that for a thorough understanding of regulatory reforms in health care, it is necessary to go beyond functional arguments and to look for the institutional legacies of different health-care systems. For this purpose, we compared regulatory reforms in three countries: the Dutch corporatist social health insurance system, the strongly centralised National Health Service (NHS) of England and the regionalised NHS system of Italy. In Section 3, we relate different regulatory challenges to the institutional legacies of the three health-care systems examined in this paper. In Section 4, we examine the regulatory challenges that accompanied the market-oriented reforms in the 1990s and 2000s. We end this paper with a number of considerations.

2. The regulatory state and institutional capacity

The rise of the regulatory state and the transition from welfare capitalism towards a system of regulatory capitalism fit into the broader transformation from 'government' to 'governance'. The accompanying search for new mechanisms of social coordination between the state and society, in order to ensure political control, accountability and societal support, led to a growing theoretical and empirical interest in issues of governance and regulation (Majone, 1994; Pierre and Peters, 2000; Moran, 2003). Whereas 'governance' can be used for several different institutional orders (including spontaneous coordinated action) with multiple centres or networks (Rhodes, 1997; Offe, 2009), regulation is more

restrictedly confined to the 'sustained and focussed control, exercised by a public – independent – agency, over (private) activities that are socially valued' (Majone, 1994). The emphasis on *socially valued activities* distinguishes regulatory regimes from the criminal justice system, whereas the reference to *sustained and focussed control* suggests that regulation is more than simply passing a law or setting the rules. Regulation is also about setting standards, gathering information, inspection, measuring and monitoring performance and finally enforcement (Power, 1997; Moran, 2003). Finally, the reference to *specialised* and *independent agencies* is justified not only by the need to develop specialised expertise in highly complex and technical matters, but also by the necessity to free these agencies from partisan politics and party political influence (Majone, 1994). Independent regulatory agencies are not only supposed to be more efficient in rule making but they are also believed to be better capable to withstand short-term political pressures. Hence, the creation of independent regulatory agencies would greatly enhance the institutional capacity of the government to deal with technically complicated and politicised issues. The downside is – of course – that this *post-political* search for effective regulation results in a diminution in direct political control and democratic accountability (Hirst, 2000; Thatcher and Sweet, 2002).

It should be emphasised here that Majone's original notion of the 'regulatory state' was related to the development of the European Union (EU) as a supranational state. The rise of regulation in the EU can be explained by the fact that as a supranational entity, the EU lacks the traditional interventionist and redistributive capacities of the modern welfare state. The term 'regulatory state', however, can also be applied to the post-war welfare state where it refers to the withdrawal by the state from direct public ownership and new regulatory agencies created in the *shadow* of the hierarchical state (Moran, 2003; Levi-Faur, 2006). These regulatory agencies are not necessarily restricted to public control over private activities, but also over state and non-profit actors who are delegated responsibility for delivering social services (Hood and James, 2000).

Health care then becomes an interesting case for the analysis of regulatory reforms for a couple of reasons. First, given the specialised nature of medical care, delegation and professional self-regulation have always been part of the 'governance repertoire' of governments in their attempts to govern health-care systems (Tuohy, 2003; White, 2009). The regulatory challenge in health care is rooted in the complex agency relationships in the medical sector. Think of the control and supervision of quality of care that has traditionally been delegated to specialised agencies equipped with the skills and information needed to assess quality in medical performance. But in the last two or three decades the regulatory challenge in European health-care systems has been substantially increased with the introduction of market-oriented reforms. Many European countries have experimented with (quasi-) market-oriented reforms, which has made their regulatory challenge considerably more complex as governments now also need to monitor the competitive strategies and rent-seeking behaviour

of third-party payers and health-care providers (both public and private). However, the re-distributive and stabilisation function of governments has not diminished in importance. Hence, regulatory reforms may be needed to enhance the institutional capacity (power and resources) of the government vis-à-vis organised interests, but these reforms need to address multiple objectives in an increasingly complex configuration of third-party payers and health-care providers, operating at multiple levels of the health-care system. It is also because of these institutional configurations that we expect a large amount of variation in regulatory reforms across European health-care systems.

In the remainder of this paper, we examine how three European countries with different institutional legacies have dealt with the regulatory complexity of their health-care system in the face of market-oriented reforms. England used to have the most centralised NHS system, but in 1991, the Thatcher government introduced the internal market and successive Labour governments have further developed the internal market (Bevan and Robinson, 2005). By contrast, the Dutch corporatist state has always been dependent on private actors for the delivery of public goods and services. In the 1990s and 2000s, the Dutch went further than any other country by incorporating a system of regulated competition in their Bismarckian health-care system (Helderman *et al.*, 2005). Italy presents us with an even more complicated story as it is one of the few countries that transformed from a health insurance system into a national health service (SSN). Moreover, this was accompanied by devolution in government from the national level towards the regional level (France and Taroni, 2005). This again can be contrasted with the English NHS, which is still marked by a tight vertical and centralised line of control from the Department of Health.

3. Institutional legacies and regulatory challenges

Prior to the 1990s, regulation was already part of the governance-repertoire in the three health-care systems under examination. But each country had to deal with its own distinct set of regulatory challenges related to institutional principles (or architecture) underlying its health-care system. In each health-care system, the locus of power and the balance of power within the government and between the government and societal interests, determined in an important way the regulatory challenge at stake.

3.1 England: from dirigiste towards a regulatory state

The NHS system in the United Kingdom was, prior to 1991, an archetype of what Majone referred to as a 'dirigiste' state: public ownership (hospitals), planning (volume and capacity planning) and centralised administration (global budgets). The NHS continues to be free at the point of delivery funded by taxation; with salaried hospital specialists as employees of, and General Practitioners (GPs) as

independent contractors with, the NHS; and the private sector's role for short stay care is marginal. For the first 30 years of the NHS, the emphasis by both Labour and Conservative administrations was tackling inequities in access to health care and seeking to improve services that had been neglected (for the elderly, mentally ill and 'mentally handicapped'). Equity was sought from 1948, by making access to services free at the point of delivery and controlling the distribution of GPs and from 1977, by allocating resources for hospital and community health services to health authorities on an equitable basis based on their populations' estimated relative need. Planning was the means of tackling neglected services (Bevan *et al.*, 1980; Webster, 1988; Klein, 2007).

Following the election of the Conservatives under Margaret Thatcher, the government sought to make the NHS more efficient and moved away from the 'dirigiste' state with the introduction of the 'internal market' in 1991 (Secretaries of State for Health, Wales, Northern Ireland and Scotland, 1989), which was intended to lead to competition between providers of care but not between District Health Authorities (DHAs), which may be seen as local insurers in which enrolment was determined by place of residence. This meant that DHAs no longer funded providers in a hierarchical arrangement but contracted with them. Providers became NHS Trusts independent of health authorities, but directly accountable to Ministers, and were funded by a system in which 'money followed the patient'. GPs could opt to become GP fundholders, who contracted for diagnostic and elective services and managed budgets for these services and their own prescribing costs (Bevan and Robinson, 2005; Klein, 2007). As part of the policies of the internal market, new kinds of audit were introduced into the NHS: of value for money by the Audit Commission (until this passed to the Healthcare Commission in 2004); and medical audit by doctors (Klein, 2007). Although this meant the demise of the 'dirigiste' state, there was little development of a regulatory state as the Department of Health in effect fulfilled most of the regulatory functions.

From 1997, the Labour government following its election abolished the idea of provider competition and GP-fundholding (on grounds that this had created a two-tier NHS) retained the purchaser/provider split and initially sought a 'third way' between 'command and control' and a market (Secretary of State for Health, 1997). The legacies of that failed search were the creation of two important regulators (Klein, 2007; Bevan, 2011). First, the National Institute for Clinical Excellence, which recommends guidelines and whether (mainly new) treatments ought to be made available for the NHS based on assessments of their cost-effectiveness. This regulator aimed to end the perceived problem of 'postcode rationing'. Second, the creation of an independent quality regulator in the NHS: the Commission for Health Improvement (CHI).

From 2000, the Labour government sought to improve NHS performance by a systems of 'targets and terror' and 'naming and shaming' (Secretary of State for Health, 2000). CHI took over from the Department of Health publication of

an assessment of performance of NHS organisations in annual 'star ratings'. Those NHS organisations that performed well were granted 'earned autonomy', whereas those that performed poorly were subject to heavy monitoring and their chief executives were at risk of being sacked (Bevan and Hood, 2006).

From 2002, the government developed the 'new Labour market' of provider competition with pluralism in delivery (Secretary of State for Health, 2002). The rationale was that regulation by targets could only improve NHS performance from appalling to mediocre: for a high-performing NHS markets driven by patient choice were required (Barber, 2007; Le Grand 2007). The Labour government created a new status for high-performing NHS Trusts, independent of the Department of Health, as NHS Foundation Trusts, which were subject to approval and regulation by a new regulator, Monitor. Additionally a small number of Independent Sector Treatment Centres were created to provide diagnostic and elective services and good value for money (Secretary of State for Health, 2002; Audit and Health Care Commission, 2008). CHI, which had been designed to regulate the NHS, was replaced by the Healthcare Commission, with the objective of creating a 'level playing field' in regulating quality of care in NHS and independent providers. From 2009, the Healthcare Commission was in turn replaced by the Care Quality Commission (CQC), which is responsible for regulating quality of public and private providers of health and social care (Bevan, 2011). The Department of Health also created the Co-operation and Competition Panel (CCP), in 2009, as an independent advisory body to the Department of Health, Monitor and NHS-funded stakeholders. CCP also makes recommendations on formal cases to the Department on mergers, acquisitions, joint ventures and other transactions between NHS organisations, complaints on the conduct of service providers and commissioners and disputes over procurement and advertising (Department of Health, 2010a). Two key functions remained with the Department of Health: the allocation of resources to purchasers and the setting of hospital prices at standard national tariffs. We consider below the extent to which the Coalition government's proposals for the NHS in England (Secretary of State for Health, 2010) move it further towards a 'regulatory' state.

3.2 The Netherlands: between corporatism and etatism

The Dutch health-care system is a classical example of a Bismarckian corporatist health insurance system with predominantly public financing and a private delivery of health care in which national associations of health-care providers, insurers, trade unions and employers play an important intermediary role (Okma, 1997; Van der Grinten, 2001; Helderman *et al.*, 2005). Although a corporatist state may also rely on planning and centralised administration, it differs from the 'dirigiste' state on the aspect of public ownership. In the corporatist state, the state is dependent on private actors for the delivery of public goods and services. Care is provided by independent professionals (GPs, independent specialists and

physiotherapists) and by private institutions (hospitals, home-care organisations and nursing homes). In the course of the development of the post-war welfare state, the Netherlands evolved from being a predominantly decentralised unitary state towards a highly centralised unitary state, combining both corporatist and etatist policy arrangements (Helderman *et al.*, 2005). Except for the supervision of quality, which was – and still is – the exclusive task of the state funded but independent Inspectorate for Health Care and its predecessors, corporatism was present nearly everywhere in Dutch health care.

Dutch health care has always been governed by several boards and councils and many of these used to include representatives from the health-care sector and independent experts. One of these is the Sickness Fund Council (*Ziekenfondsraad*), established in 1949 in order to administer the Sickness Fund Decree. In 1964, the Council was converted into a more formalised council composed of the representatives of employers and employees, representatives of the sickness funds, their contract partners (the health-care providers) and independent members appointed by the Crown (Okma, 1997; Helderman, 2007).

Health-care prices used to be regulated by the Central Office on Hospital Prices (COZ), founded in 1965 with the enactment of the Hospital Prices Act. According to this Act, hospital price setting was to be determined by negotiations between the sickness funds and hospitals, and approved by the COZ. In 1982, the COZ was converted into the Central Negotiating Board Tariffs Health Care (COTG), which was charged with the task of implementing the Health Care Tariffs Act (*Wet Tarieven Gezondheidszorg*). The representatives of sickness funds and private health insurers, however, had little incentive to negotiate the lowest possible prices (Schut, 1995). Sickness funds were fully and retrospectively reimbursed for their members' medical expenses and the private health insurers had more of an interest in *high* rather than low health-care prices because rising health-care expenditure would push up their income from premiums (given the inelastic demand for health care).

The problems with the COTG can be taken as an example of more general problems of corporatist governance in the Netherlands in the 1970s and 1980s (Hemerijck, 1992). Although the Minister of Health was formally entitled to give binding instructions to the COTG, in practice, the legal basis for hierarchical instructions by the Minister turned out to be quite narrow (Schut, 1995; Helderman, 2007). From the 1970s onwards, the need to rationalise volume and capacity planning and to contain expenditures on health care entailed a greater independence of these semi-public boards in order to avoid state-capture by the organised interests of health insurers and providers. It is mainly because of a tight system of supply-side regulation and budget caps that the government succeeded in gaining control over health-care expenditure, as a result of which the proportion of GDP spent on health services has remained stable at around 8.5% throughout the 1980s (Organisation for Economic Co-operation and Development (OECD, 2000). But these hierarchical interventions led on their

turn to a growing dissatisfaction among physicians and hospitals. In the mid-1980s, the post-war corporatist relationships between the government, the health-care insurers and the health-care providers were under serious pressure.

From the late 1980s onwards, successive Dutch coalition governments have worked on the development and implementation of a national health insurance scheme, complemented with a system of regulated competition in the health insurance and health-care provision market. The reforms started with the advisory report of the Dekker committee in 1987. The Dekker Committee was an ad hoc committee, selected on the basis of individual merit rather than corporatist representation of health insurers, hospital, physicians and social partners. The Dekker Committee published its advice in March 1987 under the significant title '*Willingness to Change*' (Commissie Dekker, 1987) in which it proposed to replace all separate health-care financing schemes by one mandatory national health insurance scheme, while a system of regulated competition should create the incentives for both health insurers and providers to improve the efficiency and quality of health-care delivery. The legal distinction between sickness funds and private health insurers would have to be abolished so that both would be allowed to offer 'basic' benefits as well as optional supplementary health insurance. This was finally implemented in the Health Insurance Act (ZVW) of 2006. Prior to 2006, more than 60% of the population fell under the Sickness Fund Act but the remainder had to take out private insurance coverage. After 2006, 100% of the population was required to have mandatory private health insurance.

3.3 Italy: regional sovereignty vs central responsibility

An important event in Italy's post-war history is the abolition of the Bismarckian health insurance system and the creation of the National Health Service (Servizio Sanitario Nazionale – SSN) in 1978. This latter was modelled in important ways on the British NHS with overarching principles of universalism, comprehensiveness of care, progressive tax funding and maximisation of resource efficiency. Italy had provided health protection through a system of sickness funds, not unlike the Netherlands. But in comparison with the Netherlands, the Italian funds were less stable financially, running chronic deficits and having to be periodically bailed out by the state. The majority of hospitals and ambulatory clinics were independent and themselves debt ridden mainly due to chronic delays in reimbursement by the sickness funds. In contrast with the Netherlands, moreover, centralised government and corporatism had a bad reputation in Italy, mainly because of their association with Fascism. The 1948 Italian Constitution had already provided for 21 regions and autonomous provinces to be created. In the case of health care, the combination of regionalism and the health-care model chosen in 1978 was to have important consequences for the regulatory arrangements eventually adopted.

The original blueprint of the SSN seemed to intend that the principal locus of power be at the centre: for example, levels of aggregate health spending were to be set by Parliament, rather than endogenously within the health sector, and to be funded by a central block grant. The regions would be responsible for setting broad policy in their territory and for allocating the state transfer among the new Local Health Authorities. To begin with, the new regions were probably incapable of doing much else since they lacked a professional civil service with a regional ethos and had to make do with demotivated staff from the defunct sickness funds and from the central ministries downsized after regionalisation. The real operational power was to lie with local government. Day-to-day administration of the SSN would be overseen by a local management board made up of nominees of local authorities reflecting the political party composition of their elected assemblies. The aim here was to promote 'democratic participation' and put an end to a tradition where the hospitals and medical barons had set spending patterns. But the management boards quickly degenerated into political machines, generating systematically waste and inefficiency, clientelism and even at times corruption (Ferrera, 1995).

Most hospitals were nationalised with the creation of the SSN, but one of the many deals struck to get the health reform bill through Parliament allowed teaching, research and certain ecclesiastical hospitals to remain independent but with the right to contract with the SSN. In addition, the Constitution's protection of free enterprise meant that the SSN – unlike the British NHS in 1946 – could not unilaterally absorb private health facilities. This meant, for example with hospital care, that in many geographical areas and in many specialties, the SSN relied to a significant degree on private providers, between 15% and 20% on average and a third and over in a few regions (Neri, 2009). Pluralism in provision implies pluralism in demand and, although many regions disputed the legality of this, in practice SSN patients enjoyed significant freedom of choice of provider. According to the SSN statute, private operators were not supposed to compete with public providers, but rather complement them. C*onventions* negotiated between the state and regions and the organisations representing the private providers set out the obligations and rights of the parties involved. These conventions were essentially rudimentary contracts, incomplete leaving ample room for opportunistic behaviour. *De facto*, private operators competed among themselves and with public providers for SSN patients. External transaction costs borne by the SSN were probably low given the scarce resort to contract, but the internal transaction costs associated with large highly vertically integrated organisations were likely quite high.

Attempts by the centre to solve these problems by direct intervention encountered legal obstacles. Numerous Constitutional Court sentences in the 1980s recognised the regions' sovereignty over organisational and administrative matters, including matters concerning the local health authorities. The fact that competition was not officially envisaged meant that no need was felt

for recognition to control it. The principle regulatory route taken to tackle local poor performance, provided of course that audit can be considered regulatory, was the promotion of the internal and external audit. Perhaps the most innovative initiative was the regional College of Auditors created by national legislation in 1982 to supervise the more than 650 Local Health Authorities. Regional laws set the investigative mandate of the College, the financial and human resources it enjoyed to carry out its activities, frequency of controls, powers of access to information and health authority facilities, and there were wide interregional differences in all these aspects. The thrust of its audit activity tended however to regard regularity and conformity. The College, however, was a hybrid in that it was responsible to both the Ministry of Treasury and to the region. (France and Prisco, 1986) and also, formally, was considered an internal organ of the Local Health Authority.

The Colleges of Auditors jostled for room in a crowded field. Other organs with audit powers included: the national Court of Accounts, the Inspectorate General of Finance of the Treasury, the Central Planning Directorate and the Anti-Fraud Unit, both of the Ministry of Health, and finally the inspection services of the single regions. All tended to emphasise regularity and conformity over performance. A form of 'audit chaos' was being created that is overlapping or duplication of auditing combined with serious audit gaps (Buglione and France, 1990). Toward the end of this period the central state began the slow process of building up its technical capacity to control sub-central government, which would become a decisive factor in the post-2000 period. Forces in and outside Parliament had began to lobby for reform as early as 1983. But the 1978 arrangements would essentially remain intact for over a decade (France and Taroni, 2005).

4. Market-oriented reforms and their regulatory challenges

Summing up, by 2010 the NHS in England had moved away from a 'dirigiste' state but had not moved into a 'regulatory' state. The Dutch state was locked in by the need to incorporate societal interests in the governance of health care vis-à-vis the call for hierarchical planning of services and central regulation of prices in order to contain health-care expenditures. The result was a rather complicated mixture of supply-side regulation, hierarchical interventions and corporatist bargaining. And in Italy, institutional capacity was seriously weakened by the interdependencies between the central state and the regions.

4.1 England: the regulatory impacts of provider markets

Market-oriented reforms in the English NHS created three interrelated regulatory challenges: the regulation of quality, prices and the functioning of the 'market'. In the 'internal market', there was no external regulatory oversight of quality.

Provider competition was intended to be on both price and quality, but there was little comparative information on either. The regulatory rule for prices was that these ought to equal costs. To remedy the lack of pressure on DHAs as purchasers, because of the absence of purchaser competition, the government regulated DHAs by the Purchaser Efficiency Index that required them to reduce costs per episode by 3% each year and also put pressure on them to reduce waiting times.

In the 'new Labour' market, the Healthcare Commission regulated and reported on quality of public and private providers. Tariffs for providers were set by the Department of Health in the system of 'Payment by Results'. This was modelled on the US Prospective Payment System by Diagnosis-Related Groups (DRGs). The objective was that competition be on quality and not on price.

Studies of these different markets have generally worked within one of two paradigms (Kuhn, 1962). Analyses of the impacts of the markets on the various players have generally concluded that both markets were ineffective. Econometric analyses, in contrast, claim to find a causal relationship between greater intensity of competition and *reduced* hospital quality in the 'internal market', and *improved* hospital quality in the 'New Labour market'. In these analyses, hospital quality is principally measured by hospital mortality rates, which Bevan and Skellern (2011) argue do not measure quality of services for which hospitals compete and different outcomes from these markets reflect their different regulatory designs. But sadly in each, scandals over poor quality of care emerged.

In the late 1990s, a series of notorious scandals, including that of excess deaths following paediatric cardiac surgery at the Bristol Royal Infirmary, highlighted the need for an external regulator of quality (Abbasi, 1998; Bevan, 2008). The introduction of pluralism in, and competition between, providers, from 2002, meant a dramatic shift in the role of the regulator of quality. In 1997, as the government abandoned the policy of competition and pluralism of providers, CHI was seen as the regulator responsible for quality assurance in NHS providers based on inspections of each organisation organised around a visit. The objective of creating a 'level playing field' for the regulation of quality by public and private providers was seen to require moving to a system of 'light touch' regulation. The Healthcare Commission assessed quality based on routinely available data and self-declarations by trusts, which were supposed to be validated by a sample of inspections. There were weaknesses in the system of 'light touch' regulation by the Health Care Commission and it failed to work in harmony with monitor, the regulator of foundation trusts. Monitor approved the application for Mid-Staffordshire NHS Foundation Trust when it was being investigated by the Health Care Commission, which revealed a scandal in quality of care that has been the subject of three enquiries and is currently the subject of a public enquiry (Bevan, 2011). The Healthcare Commission was in an ambiguous position being both responsible for quality improvement and also, in effect, a regulator of public and private providers eligible to enter into the NHS market. The Coalition

Government removed that ambiguity for CQC: its role is only the latter. Unlike its predecessors, CQC charges all providers a fee to be registered.

In 2010, the new Conservative-Liberal Coalition Government in its White Paper *Liberating the NHS* (Secretary of State for Health, 2010), proposed the abolition of the remaining bureaucratic hierarchical arrangements of the NHS in England, which suggests a transformation into a 'regulatory state'. Purchasing would be done by GP consortia. The remaining NHS Trusts would become NHS Foundation Trusts. A new NHS Commissioning Board will regulate purchasing and allocate their resources. Monitor would become the economic regulator and set tariffs. CQC, the regulator of quality, would also provide a new independent consumer champion, HealthWatch England to inform patients of quality of care (Department of Health, 2010b). The House of Commons Public Accounts Committee (2011) raised questions over accountability in these proposed reforms. These proposals have been revised (Department of Health, 2011): including clinical commissioning groups replacing GP consortia and Monitor becoming responsible for competition and integration. It is, however, unclear as to how regulatory roles will develop between the Secretary of State for Health, the NHS Commissioning Board and the other regulators, and hence the extent to which the English NHS will move into a 'regulatory state'.

4.2 The Netherlands: towards a model of 'regulated' competition

Different from in England, where the internal market was more or less introduced overnight, the Dutch reforms evolved in a much more gradual and incremental way (Schut, 1995; Helderman *et al.*, 2005). Already in 1992, the regional monopolies of the sickness funds were abolished, and sickness funds were permitted to define their own geographical market. At the same time, sickness funds were required to have biennial open enrolment periods, during which enrollees were free to switch between sickness funds, irrespective of their health status. The main effect of these initial steps had been a large number of mergers between health insurers (sickness funds as well as private health insurers) and between hospitals, and a considerable reinforcement of regional co-operation among health-care professionals, such as GPs, pharmacists and physiotherapists. These market dynamics in turn required the development of specialised regulatory agencies aimed at safeguarding competition and consumer protection and equity.

The regulatory reforms that followed need to be understood within the context of two more general developments in the Dutch welfare state in the 1990s. Already in 1994, the Cabinet of the Social Democrat Prime Minister Wim Kok initiated a series of reforms aimed at reducing the number of corporatist advisory bodies in various segments of the welfare state by terminating the participation of sectoral interest groups. In the second half of the 1990s, many administrative boards and advisory councils were successfully reformed so

that partisan interests were no longer formally represented. Second, as a product of European integration and the Cabinet's programme of introducing more competition into social services sectors, a new stringent Competition Act was adopted in 1998 under the responsibility of the Ministry of Economic Affairs and to be monitored by the Dutch Competition Authority (NMa). Given that competition – although still a marginal phenomenon – was now part of the health-care policy system as well, the NMa was assigned the role of 'market-umpire' in Dutch health care.

Most regulatory reforms that were undertaken, however, were not aimed at creating new agencies, as in England, but at converting the formerly corporatist bodies into semi-independent regulatory boards. The convergence between sickness funds and private health insurers, for example, had important consequences for the corporatist structure of the Sickness Fund Council. In January 2000, the Sickness Fund Council was converted into the Health Care Insurance Board (CVZ), governed by nine independent members appointed by the Minister of Health. It became responsible for the management of the Central Health Insurance Fund from which the risk-equalization subsidies are paid to the health insurers. The CVZ has the authority to instruct health insurers on administrative procedures, the registration of their enrollees, the collection of statistics, annual reports and the conditions of service staff. In addition, the Board has to inform the Minister of Health about all matters concerning the health insurance market and issues of equity related to the mandatory basic package.

In the 1990s, supervision of health-care insurers was placed in the hands of the Supervisory Board for Health Care Insurance (*College van Toezicht op de Zorgverzekeringen*, CTZ), whereas health-care prices used to be regulated by the COTG. Under the market-oriented reforms in the 1990s, the COTG has been converted into to the Board for Health Care Tariffs (CTG), now consisting of nine independent members appointed by the Minister of Health, similar to the composition of the CVZ mentioned above. In October 2006, both the CTG and the CTZ were integrated in the newly erected Dutch Health Care Authority (*NZa: Nederlandse Zorg Autoriteit*), which is now the most important market regulator in Dutch health care. Although there is some redundancy between the NZa and the NMa, the government felt that it needed a specialised agency to prepare and monitor the conditions for regulated competition in health care, including supervising health insurers and health-care providers; examining whether the information that purchasers provide to their potential enrollees is complete and truthful; whether the offered insurance packages are in accordance with the law; and to ensure transparency and consumer information in the market (Ministry of Health, Welfare and Sports (VWS, 2003).

With the enactment of the new ZVW on 1 January 2006, the formerly bifurcated health insurance system has finally been replaced by a single mandatory national health insurance scheme, which guarantees universal access to basic health-care services to be provided by both the former sickness funds and

the private health insurers (Helderman, 2007). The reforms led to a full convergence of non-profit sickness funds and for-profit health insurers operating within a universal National Health Insurance regime on a national health insurance market. The new ZVW was complemented with the Health Care Market Organization Act, which regulates the newly created health insurance market and health-care provision market. Today, the Dutch health insurance market is dominated by four large insurance companies (NZa, 2010), monitored by three semi-independent regulatory agencies. Although the Minister of Health Care remains ultimately responsible for their functioning and for any political decision concerning health care, they have deliberately been located at arms length of the Ministry in order to free them from partisan politics and to enable them to develop specialised expertise. Once created, these agencies started to play an active role in the further development of regulated competition in Dutch health care. In a number of important decisions, for example, the NMa has forbidden horizontal price-fixing and market-sharing agreements, entry regulations and collective contracting practices by GPs, physiotherapists, pharmacists and other independent medical practitioners. Another example is the development of Diagnosis Related Treatment Combinations (DRGs) and the active role that the NZa played in this. Initially, the development of the DRGs was left to the professional associations of physicians. But when these came up with no less than 30,000 different DRGs, the government decided to bypass the professional associations and to ask the NZa to develop a more transparent system with a smaller number of DRGs.

To conclude, the conversion of formerly corporatist bodies into newly created independent regulatory agencies, assigned to different regulatory objectives in health care, can be interpreted as a transformation from a predominantly corporatist structured system towards a more regulatory managed health-care system. The creation of semi-independent regulatory agencies probably did ease the way for the government to pass through major policy change in the 1990s and 2000s. This does not imply the end of the deeply rooted practice of formal and informal consultations and negotiations between governmental actors and organised interest groups in Dutch health care. In a small country such as the Netherlands, where organised interests meet each other regularly, it is virtually impossible (and also unwise) to 'exit' the health policy arena for any involved stakeholder (Okma and de Roo, 2009). But it is also true that there is an inherent tension between the economic logic of the (quasi-) market and corporatism in the sense that the interdependencies and collaborative practices that fit in with the logic of corporatism come close to what an economist, following the logic of the market, would label as cartelisation (Streeck and Schmitter, 1985). The creation of semi-independent regulatory agencies may find its justification in the increasingly cumbersome balance between public and private interests in Dutch health care. But whether these newly created semi-independent agencies are more immune from capture by market forces, than the state was from organised interest forces in the former corporatist system, remains to be seen.

4.3 Italy's two speed devolution model

In the early 1990s, Italy was caught in a severe political and financial crisis, which opened a window of opportunity for drastic reforms (France and Taroni, 2005). Legislation in 1992 and 1993 confirmed the power that the regions had accumulated *de facto* over the 1980s. The legislation also transferred to the regions the responsibilities that local government had had in health care. The aim was to clarify the locus of responsibility for spending and, therefore, for funding health care. The new inter-governmental division of labour allocated the task of promoting the performance of the SSN to the regions. The health policy developments in Italy bore a (superficial) resemblance to policy innovations in England: internal markets in health care and the New Public Management. But a crucial difference between the two countries was that the English reforms were centrally designed and executed while in Italy, for constitutional reasons, central government plans had necessarily to be contained in *framework* legislation. The responsibility for detailed specification and implementation of the reforms was the competence of the region. The purchaser–provider split was far less marked in Italy and there was no GP-fundholding, but services were to be paid for by the Health Care Enterprises (which replaced the local health authorities) using DRG based tariffs for hospital care. SSN markets were further opened to private providers, and competition between public and private providers for SSN patients was not only formally recognised but also encouraged.

A distinction must be made here between these government functions that the regions took over with devolution and the regulatory function, which they began exercising after 1993. Much of the implementation of reform was concerned, on the one hand, with improving existing managerial capacity at the regional and local level and on the other with creating regulatory capacity *ex novo*, the need for which was probably perceived only after the event. The Health Care Enterprise was given strong managerial autonomy and headed by a general manager appointed by, and accountable to, the region. Regulation required now that there was competition between providers, creating a need for payment systems, accreditation, contracts and agreements and quality control. In the following years, an imposing body of regional legislation was approved regulating accreditation and the organisation and management of Health Care Enterprises (Mapelli, 2007).

Regional regulatory models differed considerably one from another. Some regions stood out for the energetic use they made of their autonomy while others were distinguished by their inertness. The central authorities in Rome were quick in recognising the need for well designed tariff systems, but were dilatory in pressing the regions for accreditation arrangements and mechanisms for controlling private providers (Falcitelli and Langiano, 2004; Arcangeli, 2010). Most regions welcomed technical guidance from the central level (Ministry of Health and through the National Agency for Regional Health Services), but overall they opposed state attempts to impose national tariff ceilings and to

restrict region-specific tariff policies. Where the state did act with alacrity was in the enactment of the essential care levels (*livelli essenziali di assistenza* – LEAs), a national health entitlement, aimed at preventing the regions from cutting back services provided. In 2001, the LEAs were granted constitutional status and became operational after the state and regions agreed on how these levels were to be defined and financed (Torbica and Fattore, 2005).

Regional regulatory activity further intensified in the new century. Some regions, like Emilia–Romagna, and Umbria were energetic in setting rules, standards and guidelines and in enforcing compliance (Camera dei Deputati, 2003–2010). Instead, Lombardia tended to adopt a hands off approach, limiting itself to defining the prerequisites for accreditation, leaving most other matters to its health-care enterprises (Arcangeli, 2010). The state promoted increased regulatory action by the regions in the hope that it would improve resource utilisation and help to contain expenditures. For the same reason, over the decade some major revenue sources were ceded to the regions and in 2000 a government plan was published for an ambitious form of fiscal federalism (Arachi and Zanardi, 2004). The aim seems to have been to shift the blame from central government to the regions for unpopular measures taken to eliminate deficits (e.g. increasing taxes or patient co-payments). This worked for a while as real public health spending fell, but the deficits reappeared and state bailing-out of the regions resumed (Bordignon and Turati, 2009).

To conclude, the manner in which regulation of health care has evolved in Italy has depended crucially on its decentralised system of government and the state of inter-governmental relations. In the early years of the SSN, the state limited its intervention to the promotion of internal and a kind of external audit. The introduction of internal markets, although quite limited, encouraged a regulatory orientation although there was considerable interregional disparity. It was attempted to alleviate the effects of decentralised government by voluntary cooperation, but this produced only limited results. Once again a certain similarity exists between Italy and England with national government treatment of regions in Italy mirroring the English approach to high and poor performing providers. Regions with high state capacity that manage expenditures within their budgets are granted autonomy to innovate. The state uses its financial leverage instead to persuade/compel the chronic deficit spenders to encourage them to use well-stocked regulatory tool boxes. These asymmetrical arrangements permit 'two speed devolution', appropriate for a country such as Italy, characterised by a regionalist form of government and by significant divergence in levels of economic development and administrative capacity.

5. Conclusions

In this paper, we have focussed on the regulatory reforms that accompanied the creation of quasi-market arrangements in health care in the last two or

three decades. We asked to what extent in what ways the introduction of market-oriented policies in the health-care systems under examination has indeed been accompanied by the rise of more – independent – regulatory agencies. In all three countries, regulatory reforms were aimed at strengthening governments' institutional capacities to protect or promote public interests in increasingly complex configurations of third-party payers, providers and lower government levels. It is therefore no surprise that the shape and impact of these regulatory reforms have largely been determined by the institutional legacies of the specific health-care system and the constitutional structure of the country at stake. This is consistent with a growing body of comparative studies of regulatory reforms in which it is argued that the content and shape of regulatory reforms can only be understood within the context of existing state–society relations and the institutional legacies of different policy sectors in different countries (Levy and Spiller, 1994; Majone, 1999; Thatcher, 2002; Levi-Faur, 2006).

The preceding sections on the Netherlands, England and Italy give stories of the distinct nature of the development of regulation within each country. In all three countries, we saw indeed that regulation was seen as a necessary corollary to the creation of quasi-market arrangements. For example, opening up SSN markets to private providers in Italy made it necessary to devise authorisation and accreditation arrangements, establish DRG-based tariff systems, contracts or purchasing agreements between purchasers and providers. In England, and to a lesser extent in Italy, regulatory reforms were accompanied with the adoption of New Public Management type instruments. The Netherlands is different from the United Kingdom and Italy, mainly because of its smaller geographical size, it territorially unitary system of government and its system of corporatist private interest governments. With the enactment of the National Health Insurance, the Netherlands is now one large health insurance market with no regional barriers. The conversion of formerly corporatist bodies into independent regulatory agencies, operating at arms length from the Ministry of Health and independent from societal interests, can be interpreted as the gradual transformation from a predominantly corporatist governed system towards a regulatory health-care system. But the role of the Dutch state goes far beyond being simply an umpire of 'level-playing fields'. It needed a specialised agency (the Health Care Authority) next to the DMa to deal with the health-care specific aspects of the market (e.g. the development of a DRG-system) and it also created new collective arrangements (the Central Health Insurance Fund) in order to safeguard equity and solidarity in Dutch health care.

Bevan and Van de Ven (2010) compared the then extant regulatory arrangements of the provider market in England and the market for both insurers and providers in the Netherlands and concluded that in England, unlike in Netherlands, 'the government remains direct responsible for the many activities of insuring, providing and regulating health care' (p. 359), which makes it more difficult for English ministers to move from rowing to steering publicly financed health care. These are

path-dependent outcomes that reflect their different institutional arrangements when governments in both countries sought to introduce markets in their health-care systems. These institutional differences also had consequences for the implementation of regulatory reforms. This is starkly illustrated by the implementation of the provider market. In England, the purchaser–provider split was implemented in two years (1989–1991) and was not seen to require new regulators (regulatory activities were performed by the Department of Health), whereas in the Netherlands the need to develop an adequate regulatory system within a predominantly corporatist state meant that the implementation of their market reforms took no less than 20 years. Many of the newly created regulatory agencies in the Netherlands were in fact the successors of formerly corporatist bodies. In Italy, the implementation of regulatory reforms depended crucially on its decentralised system of government and the regional differences in administrative capacities.

In general, regulatory reforms seem to fit in better with structuring and coordinating state–market configurations (on the public–private dimension) than with how intra- and inter-governmental relations are structured and coordinated within so-called 'general-purpose jurisdictions' (Marks and Hooghe, 2005). This could explain why regulatory reforms are more developed in the Netherlands than in England and Italy, where regulatory reforms are more of an ad-hoc nature. Italy differs from England and the Netherlands as having different systems of governance within a single country: is it meaningful to talk of an Italian SSN or are there emerging 21 different versions? In the UK funding for its national health system comes mainly from national taxation, while in Italy it is done with a mix of national and regional taxes. The differences within Italy and between the countries of the United Kingdom have evolved over time, with unresolved questions over the design of a system of governance for the regions of Italy and the countries of the United Kingdom. A common problem in both countries is that they operate with systems of multilevel governance along a territorial dimension but that their systems of regulation have not been developed to recognise this.

To what extent then have these regulatory reforms altered the conventional division between Bismarckian and Beveridgian health-care systems? Is there any sign of convergence towards a regulatory health-care state? The regulatory reforms that we have examined in England, the Netherlands and Italy were related to the creation and introduction of quasi-market arrangements. But these newly created quasi-markets were in turn shaped by the institutional legacies of each of these three health-care systems. As a consequence, the structure of these newly created markets and the composition and interdependencies of various stakeholders and their assigned functions and roles are different as well. As a counterfactual thought experiment, we could hypothesise that if choice of purchaser (local insurer) would be introduced within the single payer scheme of the NHS, in ways similar to the Dutch health insurance system, we could perhaps expect more convergence between regulatory systems as well (Bevan and Van de Vent, 2010). We see some signs of this in the United Kingdom with the creation of Monitor as an economic

regulator. But, there still remain important differences along the inter- and intra-governmental dimensions of each of these three countries. Could, for example, the region of Lombardia in Italy also go down this path, while other regions stayed with a system in which geographically defined local health authorities ran providers? This poses complex questions for the future design of regulation of health systems with such large differences in their principles of governance and the accompanying institutional capacities that governments have at their disposal.

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