



Project no. CIT1-CT-2004-506392

NEWGOV **New Modes of Governance**

Integrated Project
Priority 7 – Citizens and Governance in the Knowledge-based Society

The European Union and the Governance of Health Care

reference number: LTFIa/D3e

Due date of deliverable: February 2006
Actual submission date: 23rd February 2006

Start date of project: 1 September 2004

Duration: 48 months

Organisation name of lead contractor for this deliverable:
European University Institute. Report prepared by Tamara K. Hervey, University of Nottingham, UK.

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Summary

This paper, using a case-study of the health-care sector, employs an understanding of the notion of “governance” as the use of legal and political authority, wealth and information, to exercise control in the management of relationships and resources in the pursuit of social and economic ends. Through this case-study, the paper explores the changing roles of law in EU governance processes and the EU’s constitutional construct, and highlights some uncertainties or problems with our understandings of “new” governance in the EU. It concludes: a) that the “traditional” conceptualisations of EU (constitutional) law, and its relationships with national legal regimes, do not capture the wide variety of governance processes brought to bear in the EU context of health governance but that our accounts of the roles of law in the governance of Europe need to take account of law’s roles in containing “soft convergence” processes (persuasive coordination, provision of funding, and collection and dissemination of information), as well as in the more visible “new governance” processes, especially the OMC; b) that far from abandoning “old governance” legislative responses, the EU institutions, especially the Commission, are keen to pursue them, *alongside* the array of new governance mechanisms now also available; c) that litigation, at least in this sector, remains a core site for the contestation of core ideological (“constitutional”) values within the EU’s juridical construct, and that this constitutional rebalancing, along with the various governance responses to the resultant instability, deserves the attention of EU (constitutional) lawyers, in terms of both its processes and its substantive policy outcomes.

Contents

I. INTRODUCTION	3
II. THE EU AND THE GOVERNANCE OF HEALTH CARE	4
II.1 THE KOHLL LITIGATION.....	5
II.2 A “HIGH LEVEL REFLECTION PROCESS” AND COMMISSIONER BYRNE’S REFLECTION PROCESS	8
II.3 “IF IT MOVES, HARMONISE IT”: REGULATORY “OLD GOVERNANCE” RESPONSES	9
II.4 “MONEY, MONEY, MONEY”: CONVERGENCE THROUGH EU FUNDING, DATA COLLECTION AND DISSEMINATION	10
II.5 “C’MON, C’MON, LET’S GET TOGETHER”: “PERSUASIVE CONVERGENCE”	12
II.6 A HEALTH CARE OPEN METHOD OF COORDINATION	13
II.7 “REFLECTING THE WILL OF THE CITIZENS AND STATES OF EUROPE”: THE CONSTITUTIONAL REFORM.....	14
III. GOVERNANCE, LAW AND EU CONSTITUTIONALISM	17
III.1 ROLES OF (EU) LAW: BEYOND HARMONISATION	17
III.2 CONSTITUTIONALISM	21
a. <i>Institutional balance</i>	23
b. <i>Legitimacy</i>	24
c. <i>Participation</i>	24
III.3 BACKSTOP OR KICKSTART? CONSTITUTIONAL VALUES.	26
IV. CONCLUSION	27

I. Introduction*

Within the European Union, the organisation and delivery of health care services is the responsibility of the Member States. So affirm both the EU's Constitutional Treaty¹ and its "constitutional court", the European Court of Justice.² Yet the case study described in this paper paints quite a different picture, in which the European Union is becoming increasingly involved in the governance of health care. Here, "governance" means the use of legal and political authority, wealth and information, to exercise control in the management of relationships and resources in the pursuit of social and economic ends.³ Through the health care case study, the paper explores the changing roles of law in EU governance processes and the EU's constitutional construct, and highlights some uncertainties or problems with our understandings of "new" governance in the EU.

Health care makes a good case study for three main reasons. First, health care is a field of governance in which (any significant) EU activity and involvement is relatively new. This allows isolation and analysis of particular "moments of governance" or catalysts for emerging processes, at least to some extent free from the "background interference" of several years of EU governance activity. Second, health care is a field which presents complex problems, especially in the context of the various challenges to the "European social model" that currently occupy national social welfare systems in European states. Considering the EU's involvement here may illuminate the potential of different types of governance mechanisms, and mixes of such modes of governance, in tackling such social problems.⁴ Third, many of the various EU "modes of governance"⁵ are present in the field. In the EU, health care is also a policy area in which governance can be said to be strongly "multi-level", in the sense of involving interactions between sub-national, national, EU, and transnational institutions and actors. The case study shows the operation of various different modes and levels of governance within the lens of one policy area of activity.

Following this brief introduction, the main body of the paper (2) is a narrative exploration of the explosion in EU involvement in the governance of health care. The starting point for the narrative is a relatively recent development in EU internal market litigation (the *Kohll* litigation). After explaining the significance of this litigation (2a), as a catalyst for the inception of various other governance processes (2b), the narrative traces each, by reference to the docu-

* I am grateful to the participants in the conference *New Governance and Constitutionalism in Europe and the US*, Cambridge, 19-20 July 2004, especially Louise Trubek, for their helpful comments and suggestions. I would also like to thank my colleague, Tom Poole, although I have not been able to incorporate many of his valuable suggestions at this stage. The usual disclaimer applies.

¹ Article III-278 (7) CT.

² See, for instance, Case 238/82 *Duphar* [1984] ECR 523, para 16; Cases 159 & 160/91 *Poucet and Pistre* [1993] ECR I-637, para 6; Case C-70/95 *Sodemare* [1997] ECR I-3395, para 27; Case C-120/95 *Decker* [1998] ECR I-1831, para 21; Case C-158/96 *Kohll* [1998] ECR I-1931, para 17; Case C-157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473, para 44.

³ In the EU context, the term "governance", as opposed to "government", is useful as it avoids the implication that the EU is, or is becoming, or should become, a (federal) state. More importantly, it also allows us to capture the rich insights of political science literature, such as that on policy-networks, and multi-level governance, and to move away from an exclusive focus on the "classic Community method" of governance, as outlined in the Commission's *European Governance: A White Paper* COM(2001) 428. See J Scott and D M Trubek, 'Mind the Gap: Law and New Approaches to Governance in the European Union' 8 ELJ (2002) 1; C Scott, 'The Governance of the European Union: The Potential for Multi-Level Control' 8 ELJ (2002) 59.

⁴ Here the paper echoes the findings of several of the other papers in this collection.

⁵ See T Hervey and J McHale, *Health Law and the European Union*, (Cambridge, CUP, 2004), chapter 2.

mentary records. The modes of governance at issue include harmonising regulation (2c); explicit constitutional reform (the Constitutional Treaty) (2g); a proposed “open method of coordination” (2f); “persuasive convergence” through EU-coordinated cooperation (2e); and funding, information collection and dissemination (2d). The paper then considers the different and changing roles for (constitutional) law within these various modes of governance (3), noting in particular that “traditional” conceptualisations of EU “constitutional law” capture only part of the story about governance processes applicable to health care in the EU. Finally, the paper touches on a number of hermeneutical and normative problems that arise for EU legal scholars from the specifics of the case study. Many of these have echoes in the other contributions to this collection.

II. The EU and the governance of health care

The starting point for this paper’s story of EU health care governance is a relatively recent development in EU internal market litigation, concerning the freedom to receive and provide cross-border services within the EU (the *Kohll* litigation).⁶ In adopting this as the starting point for the narrative, the case study foregrounds certain processes of “hard” law, in particular that of adjudication, rather than other explanatory factors, for instance those focussed more on “softer” legal mechanisms, or indeed political power. The reference to internal market litigation situates the analysis, at least at its inception, within the assumptions of “traditional” EU constitutionalism, and the “classic Community method” of governance.⁷ Here, the EU’s constitution operates in a “top-down” mode, with distinct spheres of competence between EU institutions and those of the Member States and regional or even local actors. Indeed, much of the negative response to the (actual or potential) substantive outcomes of the *Kohll* litigation⁸ can only be understood within this traditional framework.

⁶ There are other related litigation developments, in fields such as the free movement of goods (Case 215/87 *Schumacher* [1989] ECR 617; Case C-120/95 *Decker* [1998] ECR I-1831); free movement of health care services themselves across borders (Case C-322/01 *Deutscher Apothekerverband v 0800 DocMorris and Waterval* 11 December 2003, nyr in ECR); and, potentially, EU competition law (but see Cases C-264/01, C-306/01, C-354/01 and C-355/01 *AOK Bundesverband and others* 16 March 2004, nyr in ECR).

⁷ Some of the “classics” here include S Weatherill, *Law and Integration in the European Union*, (Oxford, Clarendon, 1995); M Poiras Maduro, *We The Court: The European Court of Justice and the European Economic Constitution* (Oxford, Hart, 1998); J H H Weiler, *The Constitution of Europe* (Cambridge, CUP, 1999); F Scharpf, *Governing in Europe: Effective and Democratic?* (Oxford, OUP, 1999); and A Stone Sweet, *Governing with Judges: Constitutional Politics in Europe* (Oxford, OUP, 2000).

⁸ See, for instance, V Hatzopoulos, ‘Health Law and Policy: The Impact of the EU’, forthcoming in *Selected Courses of the Academy of European Law 2003* (Florence/Oxford, EUI/OUP, 2005); Y Jorens, ‘The Right to Health Care Across Borders’ in R Baeten, M McKee and E Mossialos, (eds), *The Impact of EU Law on Health Care Systems* (Brussels, PIE Peter Lang, 2003); E Steyger, ‘National Health Care Systems Under Fire (but not too heavily)’ 29 LIEI (2002) 97; A P Van der Mei, ‘Cross-Border Access to Health Care within the European Union: Some Reflections on *Geraets-Smits and Peerbooms* and *Vanbraekel*’ 9 MJ (2002) 1; V Hatzopoulos, ‘Killing National Health and Insurance Systems but Healing Patients?’ 39 CMLRev (2002) 683; R Baeten, ‘European Integration and National Healthcare Systems: a challenge for social policy’ 8 infose November 2001, 1; J Nickless, ‘Were the European Court of Justice decisions in *Kohll* and *Decker* right?’ 7 (1) *eurohealth* (2001) 16; T Van der Grinten and M de Lint, ‘The impact of Europe on healthcare: The Dutch case’ 7 (1) *eurohealth* (2001) 19; W Palm, J Nickless, H Lewalle and A Coheur, *Implications of Recent Jurisprudence on the Coordination of Health Care Protection Systems* Summary Report produced for DG Employment and Social Affairs (Brussels, AIM, 2000); K Sieveking, ‘The Significance of the Transborder Utilisation of Health Care Benefits for Migrants’ 2 *European Journal of Migration and Law* (2000) 143; C Garcia de Cortazar, ‘*Kohll* and *Decker*, or That is Somebody Else’s Problem’ 6 *European Journal of Health Law* (1999) 397; A Cabrai, ‘Cross-border medical care in the European Union-Bringing down a first

However, in this study, the *Kohll* litigation is not read as the end point or outcome, but rather as a key catalyst for the inception of various other (“new” and also less new) governance processes, which, if carried through, will alter the conceptual map within which we situate the EU’s involvement in the governance of health care. Most of these other governance processes do not fit easily within a traditional construct of EU constitutionalism. Their elaboration (2) will inform the contours of a framework for analysis of what various modes of “new governance” might mean for the roles of (constitutional) law, in relation to EU health care governance (3).

II.1 The *Kohll* litigation

Article 49 EC provides that “restrictions” on the freedom to provide services within the EU “shall be prohibited”. Originally, it was tacitly assumed that the material scope of Article 49 EC did not extend to “public services”, such as health care services, because the essential characteristic of a “service” – that it be provided for “remuneration” – was not present.⁹ However, in a series of rulings beginning in 1998, the European Court of Justice (ECJ) has found that, in some circumstances, health care reimbursed under a national social security scheme may fall within Article 49 EC.¹⁰ So, for instance, the ECJ has found that a system requiring prior authorisation where treatment is sought from a health care provider with whom the insurance fund has not entered into an agreement (which would in practice include health care providers in other states) constitutes *prima facie* a “restriction” in the sense of Article 49 EC.¹¹ According to the doctrine of direct effect,¹² a litigant may enforce her rights in primary EU law (here, Article 49 EC) before national courts. The significance of this interpretation of the Treaty is that, *prima facie*, individual patients may enforce a right to have health care, given in another Member State, reimbursed by the national health (insurance) system of their home Member State.

wall’ 24 ELRev (1999) 387; ‘EU patients entitled to treatment abroad’ *Irish Times* 13 July 2001; ‘Ruling frees NHS patients to seek treatment abroad’ and ‘A healthy opportunity’ *The Sunday Times* 15 July 2001; ‘NHS may pay for EU care’ *Independent on Sunday* 15 July 2001.

⁹ The essential characteristic of remuneration is that it constitutes consideration for the service in question; Case 263/85 *Belgian State v Humbel* [1988] ECR 5365, para 17. However, remuneration need not come directly from the recipient of the services; Case 352/85 *Bond van Adverteerders* [1988] ECR 2124.

¹⁰ Case C-158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931, para 29, applying to *extramural* health care (taking place outside a hospital); the principle applies also where *intramural* health care (within a hospital) is reimbursed by a national sickness insurance fund, even where such reimbursement is on the basis of regulated pre-set scales of fees; Case C-157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473 paras 55-58; Case C-368/86 *Vanbraekel* [2001] ECR I-5363, para 42; see also Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509; Case C-8/02 *Leichtle* 18 March 2004, nyr in ECR. The ECJ has not yet ruled on the application of the Treaty to the provision of health care services under a national health system financed largely by public taxation. The English High Court has ruled that the principles developed by the ECJ in *Geraets-Smits* and *Müller-Fauré* do apply in the context of the UK NHS, funded largely through public taxation; see *R (on the application of Yvonne Watts) v Bedford Primary Care Trust and Secretary of State for Health* [2003] EWHC 2228 (Admin), 1 October 2003. This case has now been referred to the ECJ under the preliminary rulings procedure, Article 234 EC.

¹¹ Case C-385/99 *Müller-Fauré* supra n 10, paras 37-45, para 103.

¹² A central, Court-developed part of the process of “constitutionalisation” of EU law, in the traditional constitutional mode. See, for example, B de Witte, ‘Direct effect, supremacy and the nature of the Legal Order’, in P Craig and G de Búrca, (eds), *The Evolution of EU Law* (Oxford, OUP, 1999).

However, the potentially disruptive effects of the extension of Article 49 EC to national health care systems¹³ are mitigated by a number of factors. The first is the structure of Article 49 EC itself, and the other internal market provisions of the Treaty, as interpreted by the ECJ. Potentially, Article 49 EC may be read as an essentially deregulatory mechanism of governance. Indeed, deregulation based on litigation may be seen as the quintessential mode of “old governance” in the EU – the “grandmother of old governance”. However, the Member States of the EU do not have a tradition of neo-liberal economics with which classical market deregulation is associated. Rather, the Member States of the EU have tended to reflect a “social market” tradition, in which public intervention in the free operation of markets is accepted and indeed expected, either as required to prevent various “market failures” (social values as “market perfecting or correcting”), or as to promote values of social justice as ends in themselves.¹⁴ The ECJ has taken account of the “social market” tradition, by constructing the internal market as more than a simple deregulatory space. One element of this jurisprudence is the development of the principle that restrictions on the freedom to provide and receive services may be *justified* in various circumstances.¹⁵

¹³ These concern the impact of the rulings on the stability and internal balance of national health (insurance) systems, and the viability of their social goals. Certain Member States, for instance, those Member States that provide higher standards of service, better value for money, a greater choice for patients, or whose medical profession enjoys a high reputation, might experience an unpredictable influx of patients. This may have an impact on standards of national health care provision for nationals, for instance longer waiting lists. The rulings may have a detrimental effect on health care planning and capacity maintenance States calculate their health care needs by reference to their populations. Too much movement of patients might result in overburdening of some hospitals, and corresponding under use of others, possibly leading to closures. This could jeopardise the social principle of effective health care accessible to all, which underpins the national health (insurance) systems of all Member States. The ability of patients to access (and be reimbursed for) innovative treatments that might not be recognised as reimbursable within their home state may imply a loss of control over the reimbursement of such new and “unproven” treatments. Thus, decisions about cost-effectiveness in terms of determining which treatments are to be reimbursed within a particular national health (insurance) system may no longer be kept within the “closed” national system, with its own “home-grown” experts, but must be subject to exogenous assessment. Ultimately, the decision to reimburse certain types of treatment, and not others, in the context of limited overall resources for health care, constitutes a choice to allocate resources to meet the health care needs of one part of the population rather than another. The same reasoning applies to the use of EU law by litigants seeking to avoid waiting times for health care services under their national health (insurance) systems. States use hospital waiting lists in effect as a tool to constrain spending. Waiting lists also arise as a logical consequence of policy decisions about resource allocation. The ability of certain (litigious) patients to utilise EU law in these circumstances may be regarded as an inappropriate judicial interference with political processes. There are also concerns about the assumption of the Court in *Kohll* that a similar standard of health care applies across the EU. It is not clear whether different quality standards with respect to treatment in hospitals could be used to justify a refusal to reimburse, on the grounds that Member States may justify additional national regulatory measures if these are essential for protection of public health. In general, then, these kinds of pressures may jeopardise the overall structure of national health (insurance) systems, their financial and administrative arrangements, and questions of access to and quality of treatment.

¹⁴ On deregulation, the internal market and the EU’s socio-economic constitution, see for instance Póitres Maduro, *supra* n.*; F. Scharpf, (*Governing*), *supra* n 7; on social law in particular, see S. Deakin, ‘Labour Law as Market Regulation’ in P. Davies et al (eds), *European Community Labour Law: Principles and Perspectives* (Oxford, Clarendon, 1996); G Majone, ‘Which social policy for Europe?’ in Y Mény, P Muller and J-L Quermonne, (eds), *Adjusting to Europe: The impact of the European Union on national institutions and policies* (London, Routledge, 1996); W Streek, ‘Neovoluntarism: A New European Social Policy Regime?’ 1 ELJ (1995) 31.

¹⁵ Relevant objective public interest justifications include the social protection provided by national social security systems (Case C-272/94 *Guiot and Climatec* [1996] ECR I-1905); the financial viability of such social security systems (Case C-120/95 *Decker* [1998] ECR I-1831; Case C-158/96 *Kohll* [1998] ECR I-1931; Case C-

Second, the disruptive potential of the *Kohll* litigation is significantly mitigated by the juridical structure within which such litigation takes place. The principles of internal market law, including its scope (here, application to health care systems), have been developed in the context of the ECJ's power to give authoritative interpretations of EU law under Article 234 EC. Article 234 EC involves a reference from a national court to the ECJ for a "preliminary ruling" in a case concerning a question of EU law, before final resolution of the case at the national level. Thus the principles enunciated by the ECJ are given effect in national legal orders by national courts. The Article 234 EC procedure cuts both ways.¹⁶ On the one hand, it requires national courts to apply EU law within their own legal orders – embodying the idea that "every national court is an EU court". This means that the detailed working out of the processes of integration (here, the application of Article 49 EC to health care systems) is removed from the highly visible political arena, where differences in approach may be extremely difficult to reconcile, to the judicial arena, where solutions are reached by an "impartial" body, relatively shielded from public scrutiny. Here, respect for the rule of law and the authority of courts help to ensure compliance with EU-level norms. This is particularly so where *national* courts actually apply EU law, which is the case with directly effective provisions such as Article 49 EC. On the other hand, under Article 234 EC, national courts retain an important "gatekeeping" control, in that they are the ultimate arbiters of any litigation, and indeed of whether to refer to the ECJ at all.¹⁷ The crucial part of any litigation involving the free movement of patients based on rights in Article 49 EC, that is, the question of justification, is, technically at least, a question of fact for the national court.¹⁸

Granted therefore, the potentially disruptive effects of the extension of Article 49 EC to national health care systems are significantly mitigated. However, even so, the *Kohll* litigation, within the construct of directly effective EU internal market law, significantly raises the levels of uncertainty for governments of Member States, and other relevant actors (such as health care providers, insurance funds), in terms of the application of EU law to their norms and practices in health care provision and its reimbursement. Both rational actor-oriented, policy-network and institutionalist accounts of EU governance processes would tell us to expect a response to such uncertainty, be that explained by reducing the (transaction) costs associated with uncertainty; or by network or institutional opportunism. Drawing on the discourses of these different explanatory accounts for EU governance processes,¹⁹ the *Kohll* litigation may

157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473; Case C-368/86 *Vanbraekel* [2001] ECR I-5363; Case C-8/02 *Leichtle* 18 March 2004, nyr in ECR); and consumer protection (Case 205/84 *Commission v Germany* [1986] ECR 3755, para 30; Case C-288/89 *Gouda* [1991] ECR I-4007, para 27; Case C-76/90 *Säger* [1991] ECR I-4221, para 15; Case C-275/92 *Schindler* [1994] ECR I-1039, para 58).

¹⁶ See, in general, T Tridimas, 'Fragmentation, Efficiency and Defiance in the Preliminary Reference Procedure' 40 CMLRev (2003) 9-50.

¹⁷ But see Case C-224/01 *Köbler* [2003] ECR I-10239, in which the Court held, for the first time, that a national supreme court (the Supreme Court of Austria) should have referred a case under Article 234 EC (or rather, should not have withdrawn a reference).

¹⁸ See G Davies, 'Health and Efficiency: Community Law and National Health Systems in the Light of *Müller-Fauré*' 67 MLR (2004) 94.

¹⁹ Over time, the explanatory discourse on EU "integration" has been overlaid by a discourse about the EU as a system of governance. See, for example, K Armstrong, 'Legal Integration: Theorizing the Legal Dimension of European Integration' 36 JCMS (1998) 155; K Armstrong, 'The New Institutionalism' in P Craig and C Harlow, (eds), *Lawmaking in the European Union* (Deventer, Kluwer, 1998); K Armstrong and S Bulmer, *The Governance of the Single European Market* (Manchester, MUP, 1998); Scharpf, supra n 7; G Majone, *Regulating Europe* (London, Routledge, 1996); G Majone, 'A European regulatory state?' in J Richardson, (ed), *European Union: power and policy-making* (London, Routledge, 1996); G Marks, L Hooghe and K Blank, 'European Integration from the 1980s: State-Centric v. Multi-Level Governance' 34 JCMS (1996) 3;

be read as a catalyst for the bringing into play of a number of modes of governance with which the EU is now engaging in the governance of health care.

II.2 A “High Level Reflection Process” and Commissioner Byrne’s Reflection Process

The initial most visible institutional and governmental response at EU level to the *Kohll* litigation came in the Health Council²⁰ of 26 June 2002. The Council invited health ministers and representatives of civil society to take part in a “high-level process of reflection” on patient mobility and health care developments in the EU. This “High Level Reflection Process” (HLRP) took place during 2003, and played an important agenda-setting role, with the final Report²¹ containing some 19 recommendations, which are now being carried forward in a number of ways. The HLRP Report focuses on five themes, the fourth of which – “reconciling national health policy with European obligations” – explicitly concerns the need to respond to the *Kohll* litigation. The Report highlights the legal uncertainty concerning the application of EU rules to health care systems, and various possible responses are mooted. These include: Treaty reform; secondary legislation; Commission communications; Member State initiatives and bilateral cooperation; and a permanent cooperation mechanism at EU level.

The Commission formally responded to the HLRP Report in April 2004, in COM(2004) 301 final,²² which suggests 12 areas where the EU could take matters forward. Interestingly, the press release on COM(2004) 301²³ highlights only three elements of the “package” – better provision of information to patients; establishing an OMC on the reform of health care; and an “action plan” on “*e-health*” – none of which involves “old” or regulatory modes of governance. Perhaps this is related to the contentious nature of EU involvement in health care governance, a matter which was being played out in the negotiations for the Constitutional Treaty (see below, 2h), at the same time as COM(2004) 301 was being drawn up. In fact, a number of other modes of governance are also covered, including proposed EU-level legislation on the mutual recognition of professional qualifications, enforcement of existing EU-level harmonisation legislation on data protection in the health care field, re-routing of EU public health funding for research on the motivations for cross-border patient mobility, and re-routing of EU structural funding towards health care infrastructure and skills development, especially in the new Member States. COM(2004) 301 also covers the use of Commission communications (soft law measures) to clarify the legal position in response to the uncertain-

G Marks et al, *Governance in the European Union* (London, Sage, 1996); J Richardson, ‘Policy-making in the EU: Interests, Ideas and Garbage Cans of Primeval Soup’, in J Richardson, (ed), *European Union: power and policy-making* (London, Routledge, 1996); S Hix, ‘The Study of the European Community: The Challenge to comparative Politics’ 17 *West European Politics* (1994) 1; M Jachtenfuchs, ‘Theoretical Perspectives on European Governance’ (1995) 1 ELJ 115; J Peterson, ‘Decision-Making in the European Union: Towards a Framework for Analysis’ 2 *Journal of European Public Policy* (1995) 1; special issue of the *European Law Journal*, Volume 8, No 1, edited by Scott and Trubek; Commission, *European Governance: A White Paper* COM(2001) 428 final.

²⁰ In spite of the lack of formal competence in the field, the Health Ministers of the Member States of the European Union have been meeting regularly at least since the mid 1980s.

²¹ High Level Reflection Group, High Level Reflection Process on Patient Mobility and Healthcare Developments in the European Union HLPR/2003/16, 9 December 2003.

²² *Communication from the Commission Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union* COM(2004) 301 final.

²³ P/04/508 21 April 2004.

ties raised by *Kohll*. In fact, this part of COM(2004) 301 does not appear to fully encapsulate all the elements of the relevant ECJ rulings.²⁴

Furthermore, Commissioner David Byrne²⁵ launched his own electronic Reflection Process in July 2004. The Byrne Reflection Process (BRP) was guided by a strategy paper, ostensibly seeking the views of governments and civil society, but also strongly articulating the Commissioner's vision for "a new EU Health Strategy".²⁶ Byrne's strategy paper has a strong emphasis on mainstreaming health into all EU policies, on multi-level participation, and, in a significant departure from the HLRP, a strong and explicit linkage of health and economic growth,²⁷ bringing health into the Lisbon agenda, and related processes. Both COM (2004) 301 and especially the BRP suggest an independence of action on the part of the Commission that needs to be taken into account in assessing the implications of the follow-up to the HLRP (see 3 below).

II.3 "If it moves, harmonise it"²⁸: regulatory "old governance" responses

The HLRP Report and COM(2004) 301 both propose certain elements of "old governance" as a response to the *Kohll* litigation. Also, alongside the HLRP, the EU legislature was quietly agreeing a consolidation of the principal legislative measure governing the implications of the free movement of persons for national social security systems, which of course include health care systems, Regulation 1408/71/EEC.²⁹ The Commission identified three further areas where "old governance" could apply: a proposed new directive on the free movement of services,³⁰ one on the free movement of medical professionals, and the enforcement of the data protection directive in the field of health care.

In terms of the latter, data protection is covered by Directive 95/46/EC.³¹ This is binding EU secondary legislation, which sets harmonised standards of data protection within the Member States – in other words, it is a classic piece of "field occupation" by EU law.³² The Commis-

²⁴ The Commission states that "Any hospital care to which you are entitled in your own Member State, you may also seek in any other Member State ...", see, COM(2004) 301 final, p 7. In fact, at least one of the relevant cases, *Geraets-Smits and Peerbooms*, concerns the receipt of hospital care to which the patient *would not have been entitled* in his home state.

²⁵ Commissioner for DG SANCO until 22 November 2004, when Commissioner Markos Kyrianiou took over under the Barroso Commission.

²⁶ D Byrne, 'Enabling Good Health for all: a reflection process for a new EU Health Strategy' 15 July 2004, http://europa.eu.int/comm/health/ph_overview/strategy/health_strategy_en.htm.

²⁷ "Europe [sic] needs a paradigm shift from seeing health expenditure as a cost to seeing effective health policies as an investment. Europe should look at what health puts in to the economy and what illness takes out", Byrne strategy paper, above n *, p 6.

²⁸ See C Barnard, *The Substantive Law of the EU* (Oxford, OUP, 2004), p 535.

²⁹ Regulation 883/2004/EC, OJ 2004 L 166/1.

³⁰ COM(2004) 2 final.

³¹ OJ 1995 L 281/31.

³² The Directive aims to ensure that the level of protection of the rights and freedoms of individuals with regard to data protection is equivalent in all Member States; preamble, recital 8. As noted in recital 10, EU-level harmonisation in this area must not result in any lessening of the protection afforded by national laws concerning the right to privacy. See Case C-101/01 *Lindqvist* 6 November 2003, nyr in ECR, para 96. However, Member States do retain a certain "margin for manoeuvre" in implementing the Directive; preamble, recital 9. Although the Directive sets out basic principles and standards with respect to the lawfulness of data processing, it is left to the Member States to set the precise conditions within which such processing is lawful; Article 5.

sion observed in COM(2004) 301 that the implementation of the provisions of the Directive in the health care sector in Member States may need some work. To this effect, the Commission offers to “work with the Member States ... to raise awareness of these provisions”.³³ This is somewhat different from the classical modes of implementation and enforcement of EU legislation by the Commission envisaged by the Treaty, and indeed by the Directive itself,³⁴ and presumably would sit alongside the possibility of enforcement through Article 226 EC or the direct effect of the Directive’s provisions.³⁵

In COM(2004) 301, the Commission took the opportunity to promote an existing proposal for legislation to amend the directives on the mutual recognition of professional qualifications.³⁶ The proposal is regarded as highly problematic, both in general and specifically in the health care sector.³⁷ Problems with the proposal in this sector centre around questions of notification of professional malpractice procedures and confidential exchange of information relevant to the free movement of professionals. Perhaps to soften the ground, the Commission refers to an EU-funded Belgian project (“Sysex”), which has done some preparatory work here. This highlights linkages between the classic Community method of governance, and other methods of governance, including through use of EU funding.

II.4 “Money, money, money”: convergence through EU funding, data collection and dissemination

The HLRP Report, COM(2004) 301 and the BRP Report all envisage the use of EU funding, including to collect and disseminate relevant data, as a mechanism for responding to the *Kohll* litigation. The HLRP Report called for a refocussing of the EU’s structural funds, towards health infrastructure development and health status improvement, and some skills development, especially in the new Member States. The Commission responded that the EU already supports investment in health, and that this will be continued. Investment in skills development is presented as essential, as, if insufficient human capacity is built over the forthcoming years, the freedom of movement (of medical professionals, patients or both) implied by inter-

³³ COM(2004) 301 final, p 13.

³⁴ Articles 22-24. However, Article 27 provides that Member States and the European Commission are required to promote both national and EU-level codes of conduct in relation to specific sectors. This approach fits well with the turn to “new” modes of governance in the EU.

³⁵ See Cases C-465/00, C-138/01 and C-139/01 *Österreichischer Rundfunk* [2003] ECR I-4989, para 101. For an application of the Directive in the context of “health care information”, see Case C-101/01 *Lindqvist* 6 November 2003, nyr in ECR.

³⁶ COM(2002) 119 (amended by COM(2004) 317) on mutual recognition of professional qualifications. Council reached political agreement on a common position on 18-19 May 2004, with the German and Greek delegations voting against; the common position was adopted on 21 December 2004; the European Parliament forecasts adoption in June 2005.

³⁷ In the UK, for example, health and social care regulators have argued that the new proposals may result in harm to patient safety, noting for example, the element of the proposal that health professionals be allowed to practice in another Member State for a period of up to 4 months per year without having been registered with the host Member State’s regulating authority. See R Watson, ‘GMC opposes EU proposal to allow greater freedom of movement for doctors’ 325 *BMJ* (2002) 795. In Ireland, the health regulatory bodies – the Medical Council, Dental Council, Opticians Board and the Pharmaceutical Society of Ireland – all called upon the Tanaiste to stop the proposed Directive which would enable health practitioners to practice in Ireland without any registration there. They were concerned that a health professional who had been struck off in another Member State could practice in Ireland without having registered. See <http://www.nursingboard.ie/ABANews/Directive19NOV02.html>. The European Parliament supported these concerns: see ‘EU work plan puts patients at risk’ 18 July 2002 <http://www.bbc.co.uk/1/hi/health/>; ‘EU rejects foreign doctors plan’ 27 November 2003 <http://www.bbc.co.uk/1/hi/health/>.

nal market law may mean skills shortages in the poorest Member States. This is also presented as a justification for EU-level information sharing about capacity planning, and subsequent coordination of policy (see 2e below).³⁸

Second, COM(2004) 301 identified “health technology” as the largest contributor to escalating costs of European health care systems. Evidence-based analysis of new health care technologies (in comparison with existing (cheaper) therapies) is carried out at national level, in a fragmented way. The only EU-level work here is that of the “Transparency Committee” under Directive 89/105/EEC.³⁹ The Commission suggests a coordination of “collaboration and projects already assisted under the public health programmes” through a “coordinating mechanism”, implying a blend of funding and “new governance” through coordination. However, in the first instance, only a study on such a mechanism will be commissioned. The language in this part of COM(2004) 301 suggests a sense that this response to *Kohll* is, in the view of the Commission at least, unlikely to attract sufficient support to be taken forward. This reflects the long-standing lack of a true “single market” in pharmaceuticals across the EU.⁴⁰

Third, one of the key opportunities arising from the *Kohll* litigation is the possibility of developing “European centres of reference”, offering highly-specialised treatments for patients with rare diseases, and offering a focal point for research and information dissemination. These would be appealing for individual Member States lacking the financial or human capacity to provide such specialised treatment. A clear “EU value added” can be seen here, consistent with the principle of subsidiarity. Similarly, the *Kohll* litigation offers opportunities for cross-border health care provision to be developed in border regions,⁴¹ and in fact, this is happening to some extent already, in the EU-supported “Euregios”. Funding from the public health programme is to be directed to evaluation of the Euregio health projects, to assess the most successful in terms of cooperation on health care.⁴² The implication is that convergence of national approaches, based on these models of best practice, would follow. The public health programme is also to support research on the motivations for cross-border health care. This will presumably be used to inform decisions in the context of other governance processes, including the “old” regulation and “new” methods, such as the OMC.

COM(2004) 301 notes that the lack of interoperability of health care information systems across Europe represents a significant barrier to reaping the benefits of cross-border health care. The public health programme is to be used to begin the process of developing an EU-wide “Health Information and Knowledge System”. However, the Commission’s enthusiasm

³⁸ Information sharing allows for planning. Current trends show critical shortages in health care professionals in the near future. “If the overall numbers and specialisations of health professionals are not adequate, this still represents a serious risk for health systems across the Union, with the impact being felt hardest in the poorest Member States. In this context, it will be difficult for any one country to invest in training health professionals without knowing other countries will do likewise.” Therefore the Commission invites the Member States to consider a “concerted strategy”.

³⁹ Directive 89/105/EEC on the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance schemes OJ 1989 L 40/8. On the limited practical effect of the Directive, see Hervey and McHale, *supra* n 5, pp 323-327; L Hancher, ‘Creating the Internal Market for Pharmaceutical Medicines: An Echternach Jumping Process?’ (1991)28 CMLRev 821.

⁴⁰ See Hervey and McHale, *supra* n 5, chapter 8.

⁴¹ See A Coheur, ‘Integrating care in the border regions’ 7 (4) *eurohealth* (2001) 10; R Busse ‘Border-crossing patients in the EU’ 8 (4) *eurohealth* (2002) 19.

⁴² COM(2004) 301 final, p 9 “The Commission plans to support a project under the public health programme to evaluate Euregio health projects and to assess the most successful regions in terms of cooperation on health care”.

in this context needs to be seen in the light of the significant systemic inertia that would have to be overcome to attain such a system. The Commission is also using its “*e-Europe 2005*” action plan in this area.⁴³ One strand of *e-Europe 2005* is the “*e-health* action plan”,⁴⁴ which will provide EU funding for a number of developments. For instance, an EU “electronic health card” is to be developed, involving a common approach to patient identifiers and electronic health record architecture.⁴⁵

COM(2004) 301 proposes a “health systems information strategy”, which will be taken forward through the public health programme, and the *e-health* action plan. The Commission is to contribute to developing health information systems ranging from local networks through to “Europe-wide systems for spotting emerging health threats”. In order for such a Europe-wide system to function, compatibility of national and local data systems feeding into it will be essential. The Commission is to work with the European Medicines Evaluation Authority (EMA) towards a pharmaceuticals information strategy, which will include developing a database containing a harmonised set of information on all licensed medicines in the EU.⁴⁶ The process of developing such a database may prompt convergence in national practice in terms of data collection and presentation. In general, the Commission also plans to collect and disseminate data from within primary health care and hospital sectors. Where funding is also used for information gathering at EU level, this provides the Commission with a significant lever, in terms of its own information, rather than being reliant on national sources of information, either slow to arrive or non-existent, or potentially filtered through national administrative institutions.

II.5 “C’mon, c’mon, let’s get together”: “persuasive convergence”

Although the HLPR Report is at pains to stress that “the organisation and financing of health-care and social protection systems” are the responsibility of Member States,⁴⁷ nevertheless, it concludes that “exchanges of best practice would be valuable for all Member States”.⁴⁸ To this end, the HLPR Report suggests a permanent cooperation mechanism at EU level. This is echoed by COM(2004) 301⁴⁹ and the BRP Report.⁵⁰ The motivation for this is partly expressed by reference to the *Kohll* litigation,⁵¹ but also by reference to common challenges to national health care systems from technological development, ageing populations and rising public expectations.

⁴³ Commission, *eEurope 2005: An Information Society For All An Action Plan to be presented in view of the Sevilla European Council, 21/22 June 2002*, COM(2002) 263 final.

⁴⁴ Commission, *e-Health – Making Healthcare Better for European Citizens: An Action Plan for a European e-Health Area*, COM(2004) 356.

⁴⁵ According to the Commission, this card is to be rolled out in 2008.

⁴⁶ COM(2004) 301 final, p 12.

⁴⁷ It devotes several paragraphs to this assertion, setting out a long list of national responsibilities. The *Kohll* rulings are read as recognising “the need for Member States to be able to plan health services to ensure access ... avoid undermining the financial balance of the social security system, and control costs ...”

⁴⁸ COM(2004) 301 final, p 10.

⁴⁹ “[a] consensus has ... developed that a framework at European level to facilitate cooperation and to shape developments is needed, but is lacking”, COM(2004) 301 final, p 4.

⁵⁰ “There is overwhelming support for the Commission’s role in steering exchange of best practice” BRP Report, p 5.

⁵¹ Community law gives patients mobility entitlements, but their exercise is difficult in practice, so cooperation of Member States would help; the consequences of the litigation for national health care systems are unclear, this can also be alleviated by cooperation.

Under Article 152 (2) EC, the Commission has now decided to establish a “High Level Group on Health Services and Medical Care” (HLG on HS&MC), of senior officials from Member States, chaired by the Director General of DG SANCO, in order to drive this process of cooperation and coordination. It will call on external experts, as necessary. Other stakeholders are to be involved only indirectly, not as full members.⁵² In many of its work areas,⁵³ EU funding will also be used to support policy developments, and some may also (or instead) be taken forward by the OMC.

II.6 A health care Open Method of Coordination

The HLRP Report mooted the possibility of a “health care OMC” as a response to the uncertainty arising from the *Kohll* litigation. At the same time as COM(2004) 301, the Commission issued COM(2004) 304 final⁵⁴ proposing such an OMC, covering both health and social care. The focus of COM(2004) 304 differs from that of COM(2004) 301. The opening paragraph sets the tone, situating European social and health protection systems as “an important part of the European social model”. COM(2004) 304 also recalls the EU’s pedigree in promoting convergence of social protection objectives and policies,⁵⁵ rather than stressing the need for a response to a new situation.

Recalling that the Barcelona European Council, March 2002, set three principles for reform of social protection systems, including health care, COM(2004) 304 sets objectives based on these principles. The principles are: ensuring access to care, on the basis of universal access, fairness and solidarity; promoting high quality care; and ensuring the financial sustainability of health care and social protection systems. These are high sounding principles, to which all interested actors can easily sign up. The Employment, Social Policy, Health and Consumer Affairs Council endorsed the OMC’s principles in October 2004. However, the detail of how such social entitlements are delivered currently varies widely between Member States, and an OMC process in the field of health care will face significant challenges.⁵⁶

⁵² “Civil society stakeholders from the health sector should also be involved on a regular basis, in particular through the European Union Health Forum. Representatives of regional and local authorities with responsibility for health care should also be able to contribute, as in most Member States the responsibility for providing health services is at regional or local level.” COM(2004) 310, p 16.

⁵³ COM(2004) 301 envisages a number of areas of activity, including exchange of best practice on “provision of information to patients on how to get treatment in other Member States, and get your NHS to pay for it”; exchange of information on networks of health experts and centres of excellence across the EU; cooperation to “ensure that where Europe does have an impact on health or health systems, it does so in a positive way”; identifying common elements in national statements on the rights and duties of patients; exchange of information and cooperation on capacity-sharing, by a pooling at EU level of experience gained by existing local initiatives in cross-border health care; drawing up a contractual framework for healthcare purchasing; data sharing between Member States on health care professionals, their specialisms, distribution and mobility (in collaboration with the Commission and “relevant international organisations”); and coordinating assessment of new health technologies.

⁵⁴ *Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the “open method of coordination”*. See also Commission communication, *The future of health care and care for the elderly: guaranteeing accessibility, quality, and financial viability* COM(2001) 723 final; Joint report by the Commission and the Council, *Supporting national strategies for the future of health care and care for the elderly* Council Doc 7166/03, 10 March 2003.

⁵⁵ In particular, by reference to 1992 Council Recommendation 92/442/EEC on the convergence of social protection objectives and policies.

⁵⁶ See R Busse, ‘The “OMC” in European health systems’ <http://www.tu-berlin.de/fak8/ifg/mig/files/2002/lectures/pdf/Lisbon3105-RB.pdf>.

OMC processes in other areas place significant reliance on the identification of “hard” quantitative objectives and indicators, in particular as a basis for the evaluation and benchmarking stage of the process. However, it is extremely difficult to compare national health systems of the Member States, given their independent historical, cultural and institutional contexts, and the multidimensional aspects of health care. If a health OMC is to be effective, extreme caution will be needed in the formulation of indicators and the interpretation of results. Of the three principles on which the objectives of the health OMC are based, only the financial sustainability of national health (insurance) systems is readily susceptible to quantification. What cannot be so easily quantified is “best practice”, in terms of not simply more efficient health care provision, but a more “patient-centred” approach to health care provision.

Moreover, the health OMC faces opposition in Council and national parliaments,⁵⁷ to the effect that the case for an OMC process has not been persuasively made by the Commission. Council’s October 2004 conclusions make clear that the OMC is to have a “light touch”, and should not impose excessive administrative burdens. National health ministries must be directly involved. Overlaps between existing EU institutions and processes⁵⁸ must be avoided.

Indicators, on which the OMC will be based, are to be developed from 2004, by reference to work done originally under the action programme on health monitoring⁵⁹ and subsequently the public health programme.⁶⁰ All Member States are to submit, by March 2005, “preliminary reports” on the challenges facing their systems. The Commission will analyse these and propose “development and reform strategies” for 2006-09. The first “Joint Report” will be adopted in 2007.

II.7 “Reflecting the will of the citizens and States of Europe”:⁶¹ The constitutional reform

At the same time as the HLRP was carried out, the governments of the Member States were considering the latest version⁶² of the EU’s evolving “constitutional document”, the Constitutional Treaty (CT).⁶³ The CT has now been agreed, but of course has to be ratified by national constitutional processes in each Member State before it enters into force.⁶⁴ One of the aims of the CT is to clarify the division of competences between the EU institutions and those of the

⁵⁷ See, eg, UK Parliament House of Commons Select Committee on European Scrutiny, Thirty-Second Report, 28 October 2004.

⁵⁸ The Social Protection Committee; Employment Committee, Economic Policy Committee and HLG on HS&MC.

⁵⁹ Decision 1400/97/EC OJ 1997 L 193/1.

⁶⁰ Decision 1786/2002/EC OJ 2002 L271/1. See the European Community Health Indicators projects 1 and 2, 1998-2001, and 2001-2004; P G N Kramers, ‘The ECHI Project’ 13 *European Journal of Public Health* (2003) 1.

⁶¹ Article I-1 CT.

⁶² On the EU constitution as process, see J Shaw, ‘Postnational constitutionalism in the European Union’ 6 *Journal of European Public Policy* (1999) 579; B de Witte, ‘The Closest Thing to a Constitutional Conversation in Europe: The Semi-Permanent Treaty Revision Process’ in P Beaumont, C Lyons and N Walker, (eds) *Convergence and Divergence in European Public Law* (Oxford, Hart, 2002).

⁶³ For details on the novel “constitutional convention” method, see G de Búrca, ‘The Drafting of the European Union Charter of Fundamental Rights’ 26 *ELRev* (2001) 126; K Lenaerts and M Desomer, ‘New Models of Constitution-Making in Europe: The Quest for Legitimacy’ 39 *CMLRev* (2002) 1217.

⁶⁴ Article IV-447 CT.

Member States.⁶⁵ The division of competences within the EU is a highly politicised area of EU constitutional law, reflecting concerns about “creeping competence”, the extension of EU competence into ever wider areas.⁶⁶ The context here is the uncertain legitimacy of the EU as a “*demos-less*” polity, exercising powers once exclusively held by the democratically legitimated sovereign entities of its Member States.⁶⁷

The general concerns about the division of competences in the EU are reflected in microcosm in the context of the EU’s involvement in health care, and, more generally, health policy. In the CT, “common safety concerns in public health matters” are explicitly deemed to be a matter of “shared competence”.⁶⁸ This was probably seen as desirable,⁶⁹ in the light of the ECJ’s apparent constraining of Article 95 EC as a basis for Community public health competence, in the *Tobacco Advertising* ruling.⁷⁰ By contrast, the “protection and improvement of human health” is stated to be an area where the EU may take only “supporting, co-ordinating or complementary action”.⁷¹ In such areas, national laws may not be harmonised.⁷² It is likely that most elements of governance of health care systems would not fall within the terms “common safety concerns in public health matters”, as “public health” enjoys a specific meaning in this context.⁷³ However, health care governance probably does fall within “the protection and improvement of human health”. Thus, the Treaty implies a basis for mecha-

⁶⁵ The necessity of such a clarification is particularly associated with German legal and political commentators, see J Schwarze, ‘Constitutional Perspectives of the European Union with Regard to the Next Intergovernmental Conference’ 8 *European Public Law* (2002) 241. See also U di Fabio, ‘Some Remarks on the Allocation of Competences between the European Union and its Member States’ 39 *CMLRev* (2002) 1289.

⁶⁶ Legally speaking, this happens because the precise extent of Community competence is not always easy to determine, for a number of reasons. Community competence includes *implied competence*, where the Treaty does not grant an explicit power, but requires the achievement of an objective (Cases 281, 283-5, 287/86 *Germany v Commission* [1987] ECR 3203). Competence in a particular field is rarely exclusively allocated to the EU institutions, but is most often *shared* with national institutions, leading to boundary disputes about the proper limits of Community competence, expressed in legal terms by reference to the principles of subsidiarity and proportionality (Article 5 (2) and (3) EC). Some legal basis provisions may be expressed in very *general* terms, leaving doubt as to their precise scope in a particular context (See, in particular, Article 308 EC). Along with Article 95 EC, this is explicitly mentioned in the Laeken Declaration as a possible site for adjustment by the Constitutional Convention; see G de Búrca, G. and B deWitte, ‘The Delimitation of Powers between the EU and its Member States’ in A Arnull and D Wincott, (eds), *Accountability and Legitimacy in the European Union* (Oxford, OUP, 2002), at 204. The European Court of Justice has not developed a complete doctrine of the allocation of powers between Member States and EU institutions. De Búrca and de Witte contrast the position with respect to other elements of European constitutional law, where the Court has developed quite comprehensive jurisprudence.

⁶⁷ For a starting point on the (copious) literature on the subject, see P Craig and G de Búrca, *EU Law: Text, Cases and Materials* (Oxford, OUP, 2002), chapter 4; P Craig, ‘The Nature of the Community: Integration, Democracy and Legitimacy’ in P Craig and G de Búrca, (eds) *The Evolution of EU Law* (Oxford, OUP, 1999) pp 23-50; A Arnull and D Wincott, (eds), *Accountability and Legitimacy in the European Union* (Oxford, OUP, 2002); Scharpf, *supra* n 7; Weiler, *supra* n 7; Weiler and Wind, *supra* n 7, especially M Póitres Maduro, “Europe and the constitution: what if this is as good as it gets?” therein; N Walker, (ed), *Sovereignty in Transition* (Oxford, Hart, 2003).

⁶⁸ Article I-14 CT.

⁶⁹ See M Giannakou, member of the Constitutional Convention, ‘Thoughts on the EC Treaty provisions regarding public health’ CONTRIB 229 CONV 536/03, 4 February 2003.

⁷⁰ Case C-376/98 *Germany v Parliament and Council (Tobacco Advertising)* [2000] ECR I-8419.

⁷¹ Article I-17 CT.

⁷² Article I-12 (5) CT.

⁷³ See, generally, Hervey and McHale, *supra* n 5, chapter 3.

nisms of “new governance” in health care, for instance, the HLG on HC&MT or the health OMC. It also strongly implies the exclusion of EU “old governance” mechanisms from the health care field.

Probably more importantly, the “internal market” is also an area of shared competence. As we have seen, the catalyst for the EU’s recent increased involvement in health care is internal market litigation, and the Commission seeks to respond utilising internal market legal bases where it proposes “old governance” measures, such as a new directive on services (2c). Therefore, to a large extent, these provisions, although presented as intending to constrain “creeping EU competence” in the health field, appear to simply consolidate the existing position.

However, on its face, the CT attempts to constrain “creeping competence” in the health field, by explicitly stating that responsibility for health care systems is a matter of national competence. This clause originated as a proposed addition to Article III-122, which refers to “services of general interest”, and is in Title I of Part III CT on “provisions of general application”. The proposal gained initial support from over 10 Member States. This would have read:

“1. The Constitution shall in no way prejudice the responsibilities of the Member States for the determination of their policies, organisation and delivery of health services and medical care provided within the framework of a social security scheme.

2. The responsibilities of the Member States referred to in paragraph 1 shall include in particular the management of health services and medical care and allocation of resources to them, and standards applied.”

However, in the Irish draft, the clause was moved to Article III-278 (7). It now reads:

“Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them ...”

A number of observations may be made. Legally speaking, the location of a provision in a legal text may make a difference to its interpretation. So, here, the earlier version, under Title I, would have had a stronger effect than a provision later in the Treaty. The final version limits “Union action”, whereas the earlier version limits “the Constitution”. While it is not entirely clear what the legal significance of this distinction might be, one possible interpretation is that “Union action” predominantly relates to action of the legislative and administrative institutions of the EU; that is, its main focus is secondary legislation. “The Constitution” seems to be wider, including within its focus the primary text of the CT itself. The (perceived) challenge to the organisation of national health systems comes *inter alia* from the application by the ECJ and national courts of the Treaty provisions on freedom to provide and receive services. These remain essentially unchanged in the CT.⁷⁴ While the final text might limit the ability of the Commission, for instance, in the development of a health OMC, the earlier text seems to at least attempt to go further towards encouraging the ECJ to develop a different approach to the scope of the directly effective Treaty provisions on the internal market.

⁷⁴ Articles III-144-150 CT.

Nevertheless, the overall thrust of the CT is that health care is a matter for Member States. “Organisation and delivery of health services and medical care” is to be the responsibility of the Member States, and the CT explicitly states that the “Union shall respect” such responsibilities. This is reflected in the list in Article I-17, of “areas of supporting, co-ordinating or complementary action”, which, as we have seen, strongly implies the exclusion of EU “old governance” mechanisms from the health care field. However, unlike the earlier text proposed for Article III-122, the current provision does nothing to curtail the application to health care systems of the “grandmother of old governance” – that is, deregulatory internal market litigation.

III. Governance, law and EU constitutionalism

What does the health care case study reveal about the changing roles of law in the context of the EU’s new governance processes? What do these mean for the EU’s constitutional arrangements? What hermeneutical or normative uncertainties or problems do “new governance” mechanisms bring? The final section of this paper brings together some preliminary observations on these inter-related questions from the health care case study, and draws some parallels with other contributions to this collection.

III.1 Roles of (EU) law: beyond harmonisation

EU lawyers have tended to downplay the significance of EU Treaty law that requires cooperation on the part of Member States, focussing only on the negative aspects of policy areas where regulatory harmonisation is explicitly excluded. The implication is that policies where the EU plays a “supporting, co-ordinating or complementary” role are not very important. A focus on new governance methods challenges that assumption. Also, EU lawyers have only recently begun to consider the significance of soft EU law.⁷⁵ The health care case study shows how the legal obligations of Member States to cooperate or participate in new and persuasive convergence governance structures (OMC; EU-coordinated cooperation) (2f; 2e); funding, information collection and dissemination (2d)) and the use of soft interpretative norms (2b) may underpin future significant Europeanisation effects, through indirect or voluntary policy convergence, and may affect the articulation and dissemination of legal norms and values within the EU’s constitutional order.

First, the roles of law in OMC include the imposing of procedural obligations to report within certain timeframes, and provide information within certain parameters. Soft law generated under OMC persuades rather than coerces national actors to conform to European standards; although national or sub-national actors may adopt hard law in response to OMC processes. In the health care context, OMC faces particular difficulties in translating indicators with respect to the *quality* of care into the process. It is here that relationships between an OMC process on health care, and a *right* to access quality health care may come into play.⁷⁶ Relations between the OMC process and (fundamental) rights in EU law have been elaborated in a number of contributions to the literature.⁷⁷ Bernard has argued that the OMC process may

⁷⁵ See L Senden, *Soft Law in European Community Law* (Oxford, Hart, 2004). For early exceptions, see F Snyder, ‘Soft law and institutional practice in the European Community’ EUI Working Paper LAW No 93/5; K C Wellens and G M Borchardt, ‘Soft law in European Community Law’ 14 ELRev (1989) 267.

⁷⁶ See J Zeitlin, ‘Opening the Open Method of Coordination’ Committee of the Regions Conference, 30 September –1 October 2002, <http://www.cor.eu.int/pdf/omc/zeitlin.pdf>.

⁷⁷ See, in particular, N Bernard, ‘A “New Governance” Approach to Economic, Social and Cultural Rights in the EU’ in T Hervey and J Kenner, *Economic and Social Rights under the EU Charter of Fundamental*

provide an opportunity for the EU to pursue a social rights agenda, by reference to the fundamental social rights contained in the EUCFR.⁷⁸ Such social rights would include a “right to health care” (Article 35 EUCFR). OMC may then provide an alternative framework to litigation, within which the contested relationships between the internal market and the “European social model” may be resolved.

Obviously it is too soon to assess the policy content outcomes of the proposed health OMC. To the extent that the OMC process is successful in tackling the similarly complex social problems of unemployment and social exclusion, and to the extent that health care can be likened to those policy areas, a health OMC may be a fruitful mechanism of governance in the EU. For instance, OMC may provide the framework for resolving uncertainties about relationships between economic indicators (such as health as a driver of economic growth) and human rights-based values (such as health as a human right),⁷⁹ through comparison of the relative success of locally or regionally developed health policy blends of the values of the internal market and the “European social model”.

Second, one of the key Treaty obligations of the Commission, often underplayed by “old governance” and traditional constitutional accounts of the EU, is to foster cooperation between the Member States in various policy areas.⁸⁰ When describing these policies, legal commentators often focus on the “negative” aspects of their legal bases, in particular the fact that harmonisation of national policies through binding EU level norms, such as directives, is explicitly precluded by the Treaty. However, these legal bases also include *positive* obligations on the Member States, to liaise with the Commission and to coordinate policies and programmes accordingly. Thus, national policy in the relevant field may not lawfully develop in a vacuum, but multi-level coordination and cooperation is required by EU “constitutional” law.

Further, such legal bases formally grant the Commission a general power of initiative to propose measures which will promote cooperation between the Member States in those areas, potentially leading to convergence of national policies. In the health field, Article 152 (2) EC is an example of such a legal basis provision. It provides that “Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes” in the areas of “improving public health, preventing human illness and diseases, and obviating sources of danger to human health”,⁸¹ and gives the Commission competence to “take any useful initiative to promote such coordination”. The extent to which those areas include governance of health care systems is highly contentious in the EU context (2g). Nevertheless, the Commission has taken several initiatives to promote policy coordination in the governance of health care systems, including the establishment of the HLG on HS&MC (2e), the Byrne Reflection Process (2b) and the health OMC (2f).

Rights: A Legal Perspective (Oxford, Hart, 2003); K Armstrong, ‘Tackling Social Exclusion through OMC: Reshaping the Boundaries of EU Governance’ in T Börzel and R Cichowski, (eds), *State of the Union: Law, Politics and Society* (Vol 6) (Oxford, OUP, 2003), 170; F Scharpf, ‘The European Social Model: Coping with the Challenges of Diversity’ 40 *JCMS* (2002) 645.

⁷⁸ *Supra* n 77.

⁷⁹ The BRP Report highlights problems with the interpretation of health as a driver of economic growth, observing that values such as health as a human right may be underemphasised as a consequence. BRP Final Report, p 3.

⁸⁰ See, for example, Article 99 EC on economic policy; Article 127 EC on employment; Article 137 (2) (a) and 140 EC on social policy; Article 149 EC on education; Article 151 EC on culture.

⁸¹ Article 152 (1) EC.

Third, EU law plays a crucial role in legitimating the disbursement of EU funding, which can also promote Europeanisation through voluntary convergence. Although the EU's budget is modest,⁸² the EU institutions have traditionally used the provision of financial incentives to promote the integration process. This mode of governance, largely neglected by legal scholarship, involves the use of the wealth of governing institutions to achieve policy aims.⁸³ Where funding is used to generate and share information, there are close links with technocratic modes of governance. Although a long-standing technique of governance in the EU context, the use of funding to promote particular policies, or steer developments, including the adoption of hard law, at national level, now deserves greater attention from EU legal scholars,⁸⁴ in the context of “new governance” discussions.

The EU, through its research and technology policy, has funded medical research since the mid 1980s.⁸⁵ The public health programme⁸⁶ also provides funding for medical research, and other matters concerned with health care delivery. A key element of these programmes is the sharing of best practice across borders, and the forging of networks in particular fields, in order to provide a forum for shared knowledge and expertise. Over time, it may be that the experiences of collaboration may feed into national policy processes, thus prompting gradual convergence or “Europeanisation” of national policies, or, ultimately, laws. From this convergence of approaches, EU level financial support may also lead to the adoption of principles or values that eventually feed through to EU level legislation,⁸⁷ or other modes of governance, such as OMC. For instance, the public health programme has been used to develop health indicators, that are likely to form the basis of the health OMC (2f).

Judicial review of Commission action disbursing EU funds is a failsafe legal mechanism of last resort to ensure disbursement consistent with agreed goals and parameters,⁸⁸ although strict *locus standi* rules make this an impractical route for challenge to or participation in the

⁸² It is important to be clear about the size of the EU's budget. The idea, at times perpetuated by the British media, of swathes of “Brussels bureaucrats” is a gross exaggeration. In fact, the European Commission employs fewer people than a large county council in England; see A Hayes, ‘The EU and Public Health beyond the Year 2000’ 4 *eurohealth* (1998) 2. The EU budget represents only a fraction of levels of public spending in the Member States. It is obvious from this that the EU, as currently constituted, cannot possibly replace health spending in the Member States. The EU's redistributive interventions in the health field are small-scale, in the totality of health spending across the EU as a whole.

⁸³ The technique of government by *dominium*; see T Daintith, ‘The Techniques of Government’ in J Jowell and D Oliver, (eds), *The Changing Constitution* (Oxford, OUP, 1994); see further, T Daintith and A Page, *The Executive in the Constitution: Structure, Autonomy and Internal Control* (Oxford, OUP, 1999); see also Claire Kilpatrick's paper, Bruno de Witte's paper** cross refer**. What the EU does not fund is also relevant; see for instance the Commission's refusal to fund stem cell research under the Framework Six Programme; for further information see T Hervey and H Black, ‘The European Union and the governance of stem cell research’ 12 *Maastricht Journal* (2005) 3.

⁸⁴ For exceptions to the trend of neglect, see, for example, J Scott, *Development Dilemmas in the European Community* (Buckingham, Open University Press, 1995); J Scott, *EC Environmental Law* (London, Longman, 1998); J Kenner, ‘Economic and Social Cohesion: The Rocky Road Ahead’ (1994) LIEI 1.

⁸⁵ See Council Resolution on the first framework programme of research OJ 1983 C 208/1; Decision 85/195/EEC establishing a multiannual research action plan in the field of biotechnology, OJ 1985 L 83/1, which included the use of biotechnology in health care.

⁸⁶ Decision 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) OJ L 271/1.

⁸⁷ See, for instance, the case of “orphan medicines” (for treating disorders affecting not more than five in 10 000 persons), discussed in Hervey and McHale, supra n 5, p 244-245.

⁸⁸ Case C-106/96 *UK v Commission (Poverty IV)* [1998] ECR I-2729.

formation of those goals for any other than the “privileged” applicants of EU institutions and Member States.⁸⁹ Further, in policy areas where governance is shared between EU and (sub)national levels, the legal structure of Article 230 EC may preclude the use of litigation as a “good governance” check.⁹⁰ Non-litigation routes to promote mechanisms of good governance, including principles of good administration, or value-for-money standards, may have a more significant role.

A governance mechanism closely related to the use of funding is the collection and dissemination of data at EU level, either by the Commission, or by specialist EU agencies, such as the EMEA. In certain circumstances, the Commission is obliged in EU law to collect and disseminate data across the EU.⁹¹ Member States, under the “duty of sincere cooperation”,⁹² are obliged to cooperate in this process. Where data collection is mandated at EU level, the need to produce standardised and comparable data sets in order to fulfil obligations in EU law may give a significant push towards convergence of national practices towards a “Europeanised” standard. For instance, if the Commission and EMEA develop standardised health systems information data sets, to prepare for and respond to emergent health threats, as is being proposed (2d), then national, regional or local administrations will be obliged to provide data in the “Europeanised” form.

Changes in data collection or dissemination practices may reveal information that affects the policy-making process at national levels. Further, the enhanced ability of individual citizens, or NGOs, to compare data across Member States may increase opportunities not only for political pressure, but also for litigation strategies, at national or sub-national levels. For instance, several Member States have recently adopted statements of “patients’ rights”. The Commission proposes the EU-level collection of information on the rights of patients,⁹³ in order to promote cross-border health care – both to increase patient confidence in health care in other Member States and to assist in the formation of contractual relationships between health care funds in one Member State with health care providers in another. Comparisons of rights enjoyed by patients in other Member States may throw light on (perceived) deficiencies in particular Member States, increasing political pressure for reform. It may also provide alternative interpretations of patients’ rights, bringing opportunities to challenge existing national interpretations of provisions common to several Member States, by reference to interpretations in legal systems of other Member States. This is particularly so within the context of common membership of the Council of Europe, with the ECHR and European Social Charter, both of which include rights relevant to health care, and indeed the provisions of the EUCFR, now part of the CT.⁹⁴ The Commission’s collection and dissemination of informa-

⁸⁹ Article 230 EC; Case 25/62 *Plaumann* [1963] ECR 95; Case C-50/00P *Unión de Pequeños Agricultores (UPA) v Council* [2002] ECR I-6677

⁹⁰ For instance, Article 230 EC implies the identification of “an act of the EU institutions”. So where, for instance, the Court finds that there is no such act (see, eg, Case T-461/93 *An Taisce* [1994] ECR II-733) then judicial review will not be available. In a new governance setting, where responsibilities of public and private actors at different levels may be imprecisely defined, these types of problems are exacerbated.

⁹¹ For example, in employment (Article 128 EC); social policy (measures based on Article 137 (2) (a) EC); education (Article 149 (2) EC).

⁹² Article 10 EC.

⁹³ Either through the High Level Group on Health Services and Medical Care or by the OMC.

⁹⁴ For further discussion, see T Hervey, ‘The right to health in EU law’ in T Hervey and J Kenner, (eds), *Economic and Social Rights under the EU Charter of Fundamental Rights* (Oxford, Hart, 2003) 193-222; T Hervey, ‘We don’t see a connection: the “right to health” in the EU Charter and European Social Charter’ , in

tion, for instance on patients' rights may, in time, lead to comparisons between national systems within the EU, and cross-fertilisation of standards development and interpretation of the content of various elements of a "right to health care" recognised in the CT.

Finally, the Commission uses interpretative communications (soft law) in dialogue with the ECJ and national courts, in order to determine the contours of EU "hard law". Although the Commission has no formal constitutional authority to determine the scope or content of EU law (that being for the ECJ or national courts), such communications may have significant persuasive effects.⁹⁵ Communications may structure social or economic behaviour as if they were binding legal norms, in that individuals may rely on them in arranging their affairs. This may be seen with the Commission's communication COM(2004) 301 final on the *Kohll* ruling (2b). It remains to be seen whether the Court will be persuaded to develop its jurisprudence consistently with this communication, so as to remove the application of *Kohll* in situations where the patient would not have been entitled to the particular hospital care at issue in her home state. In a classical constitutional framework, this type of use of soft law might offend the doctrine of separation of powers,⁹⁶ to the extent that the Commission (an administrative/legislative institution), acting in a quasi-judicial role, may be "usurping" the judicial function. However, the EU has always accommodated this role of soft law,⁹⁷ and the increased prominence of new governance simply brings into the spotlight an existing governance mechanism, reminding lawyers of the relevance of non-binding legal norms in exercising control in the management of relationships and resources in the pursuit of social and economic ends.

III.2 Constitutionalism

The health care case study reveals strongly that the CT's formal articulation of the constitutional norm to the effect that the governance of health care is a matter for Member States is at odds with the emerging practice that suggests various sites at which the governance of health care is becoming, or at least may become, "Europeanised". It is difficult to read the CT as a "brake" on the emerging health care governance practices discussed above, as there is little evidence that the CT seeks to deal directly with the inter-relationship between the internal market and health care, which is what would be required to end "competence creep" in this policy area. Starting with the obvious and simple observation that written constitutional texts do not necessarily capture operative constitutional norms and practices, what does this mean for EU constitutionalism?

At least in the health care context, the "creeping competence" discourse represents genuine concerns about the legitimacy of governance, in terms of both process and outcome. These reflect not only generic constitutional concepts, such as accountability or protection of individual rights, but also sector-specific interests or values, such as the equal access of citizens to

B De Witte and G de Búrca, (eds), *The Protection of Social Rights in Europe: Changes and Challenges*, (Oxford, OUP, forthcoming 2005).

⁹⁵ The Commission has used such soft law measures in internal market law; see Commission Communication concerning the consequences of the judgment given by the Court of Justice on February 20, 1979, in Case 120/78 *Cassis de Dijon* OJ 1980 C 256/2; and in the field of competition law, for instance, see M Cini, 'The soft law approach: Commission rule-making in the EU's state aid regime' 8 *Journal of European Public Policy* (2001) 192; Senden, *supra* n 75, pp 143-148.

⁹⁶ On the problems of applying a traditional "separation of powers" approach to EU governance, see C Joerges, 'The Law's Problems with the Governance of the European Market', in C Joerges and R Dehousse, *Good Governance in Europe's Integrated Market* (Oxford, OUP, 2002), especially pp 19-22.

⁹⁷ See Senden, *supra* n 75.

public health care provision, the solidarity of health care systems, and effective use of public resources for health care delivery. In the European context, these can be characterised as “constitutional values”, in that they form a relatively stable and agreed foundation, within which politically contentious and non-stable policy decisions about health care are made.⁹⁸

The health care case study suggests that a reliance on a traditional, allocation of powers, constitutional model for the EU may prove profoundly problematic in ensuring constitutional protections, at least in a policy area such as health care governance. Such a model implies, *inter alia*, an EU-Member State hierarchy, within which it is essential to “get right” the formal allocation of competences; (at least symbolic) lines of accountability of separate “executive” institutions to elected representative institutions;⁹⁹ delegation of authority from legislative to executive actors; a regulatory structure where individually enforceable legal norms are the ones that matter; control of regulatory activity and acts of relevant institutions through judicial review. If our constitutional model assumes that health care governance is a matter for Member States, there is a danger that questions about the protection of constitutional values in the new governance arrangements operating in the EU escape constitutional scrutiny. If the EU’s constitution tells us that health care is a matter for Member States, then we can safely leave scrutiny to national constitutions. The very involvement of the EU in the governance of health care suggests that this particular model of EU constitutional law simply does not capture the processes at play: the practice of governance has been decoupled from the nation state, and cannot be readily recoupled.

Rather, the health care case study implies that we need a constitutional model which accommodates heterarchy of legal authority;¹⁰⁰ within which competence is shared and competences are exercised within multilevel governance mechanisms; within which various actors participate in governance, rather than acting as agents for a delegating authority; where non-enforceable legal norms matter;¹⁰¹ and where control mechanisms take into account all of the above, and, therefore, must go beyond judicial review. The relationships between governance institutions within that multilevel system need to be understood not simply within a binary EU-national government framework. For instance, the Commission is proposing further cooperation between health care providers on capacity sharing, observing that a number of cross-border capacity sharing arrangements already exist, and that the bodies involved have worked out how to tackle problems of cross-border cooperation. These projects have grown up out of local initiatives (2d). The Commission is now suggesting a cooperation mechanism that goes directly from local to EU level (either through HLG on HS&MC, or through OMC) cooperation, and that bypasses both Council, and national executives and parliaments altogether. The challenge for EU constitutional law is to encapsulate such interactions within its framework of analysis, so as to ensure that constitutional norms are protected therein. The details of such

⁹⁸ See M Tushnet, *The New Constitutional Order* (Princeton, Princeton University Press, 2003).

⁹⁹ See eg P Lindseth, ‘Delegation is Dead, Long Live Delegation: Managing the Democratic Disconnect in the European Market-Polity’ in C Joerges and R Dehousse, (eds) *Good Governance in Europe’s Integrated Market* (Oxford, OUP, 2002)

¹⁰⁰ See, for instance, N MacCormick, *Questioning Sovereignty* (Oxford, OUP, 1999); N Walker, ‘Late Sovereignty in the European Union’ and M Poiaras Maduro, ‘Contrapunctual Law: Europe’s Constitutional Pluralism in Action’, in N Walker, (ed), *Sovereignty in Transition* (Oxford, Hart, 2003); N Walker, ‘The Idea of Constitutional Pluralism’ 65 *MLRev* (2002) 317-59.

¹⁰¹ See Senden, *supra* n 75.

a framework are not developed here,¹⁰² but the health care case study suggests its contours include institutional balance, legitimacy and participation.

a. Institutional balance

One possible narrative from the health care case study, drawing on institutionalist/rational actor accounts, would present the Commission's "purposive opportunism"¹⁰³ arising from the application of new governance mechanisms in health care governance. According to this narrative, new governance does not significantly destabilise the independent agency, or even hegemony, of the Commission as the linch pin of Community law and policy making. For instance, the change of emphasis from the HLRP Report in COM(2004) 301 and even more so the BRP (which adds the Commission-led linkage of health with the Lisbon agenda) may be read as Commission "recapturing" the policy initiative from the Member States or Council, and indeed from the civil society participants in the HLRP. The Commission's long-standing use of the wealth of government, and technocratic governance techniques, blending judicious use of EU funding and information coordination (2d), coupled with OMC (2f) situates the Commission as a central driver and clearing house for generation and dissemination of policy ideas, allowing the Commission control over these governance processes. This narrative would raise classical concerns about the Commission's vulnerability to "capture". Not new, these are even made explicit in the BRP Report, which suggests that the health agenda may be susceptible to capture by powerful interests in the food, tobacco or pharmaceutical industry.¹⁰⁴

However, the health care case study also supports a more subtle narrative, in which Council, national governments and even parliaments (although perhaps not civil society) seek to reassert control, with some success. This arises, for instance, in the institutionalisation of coordination and cooperation, through comitology, such as the HLG on HS&MC (2e). This classical form of executive governance in the EU's constitutional order allows for flexibility, but without national administrations ceding to the Commission all control of governance processes. Its critique is well-known in EU legal literature.¹⁰⁵ Another example is the health OMC (2f). National parliaments and Council are sceptical about the need for an OMC in this field at all. The difficulty of quantifying elements of health care makes OMC processes difficult to apply. The upshot is that Council has rewritten this OMC to leave a large margin of discretion to Member States, possibly to the extent that operating an OMC process at all may not be an efficient use of administrative resources, and it may in the end be quietly dropped, or allowed to wither through *de facto* lack of real participation.

¹⁰² cross refer some of the more 'general' chapters

¹⁰³ This is well-represented in existing literature – see, for instance, Armstrong and Bulmer, *supra* n 19.

¹⁰⁴ BRP Report, p 4.

¹⁰⁵ See C Harlow, *Accountability in the European Union* (Oxford, OUP, 2002), especially chapter 3; M Andenas and G Türk, (eds), *Delegated Legislation and the Role of Committees in the EC* (The Hague, Kluwer, 2000), especially G Schäfer, 'Linking Member State and European Administrations – The Role of Committees and Comitology', and A E Toeller and H C H Hofmann, 'Democracy and the Reform of Comitology' therein; C Joerges and E Vos, (eds) *EU Committees: Social regulation, law and politics* (Oxford, Hart, 1999), especially G Ciavarini Azzi, 'Comitology and the European Commission' therein; E Vos, 'The Rise of Committees' 3 ELJ (1997) 210; K St Clair Bradley, 'The European Parliament and Comitology: On the Road to Nowhere' 3 ELJ (1997) 230; R Pedler and G Schäfer, (eds), *Shaping European Law and Policy: The Role of Committees in the Political Process* (Maastricht, European Institute of Public Administration, 1996); K St Clair Bradley, 'Comitology and the Law: Through a glass, darkly' (1992) 29 CMLRev 691.

The health care case study suggests that the EU's constitutional concept of institutional balance¹⁰⁶ may provide a framework within which the relative powers of at least EU-level institutional actors may be held in fruitful tension. One potential response to the problems of comitology in EU constitutional law has been through the concept of "institutional balance".¹⁰⁷ However, new governance raises questions about the application of institutional balance in a context of multilevel activity, where local, regional and national institutions also share competence and shape policy development. What kind of entitlement to "institutional balance" could form a platform for empowerment of (excluded) civil society groups, where new governance structures imply their participation? Could an entitlement to "institutional balance" prevent the quiet dropping of a health OMC?

b. Legitimacy

A number of the US participants in the conference that preceded the publication of this collection observed that the use of new mechanisms of governance to solve complex social problems in any other than neoliberal ways appears to require the application of these new mechanisms of governance "under the radar", that is, relatively isolated from high profile media or other public scrutiny. While a fixation with neoliberalism is not so entrenched in European political life, elements of this "under the radar" phenomenon appear also in the EU health care case study, for instance, in the use of Article 234 EC as site for deregulatory litigation (2a), and consequent governance responses to instability thereby created; or in the press release on COM(2004) 301 (2b), which highlighted only the "soft" and cooperative, and not the normative, governance responses proposed by the Commission.

Whilst the "under the radar" phenomenon may be desirable in terms of policy outcomes, it raises questions about traditional constitutional understandings of legitimate governance, through representation of informed citizens by law-makers, accountability of executives to elected legislatures, and so on. Questions arise as to whether the participatory elements of new governance offer sufficient legitimacy to compensate for the lack of informed debate among a wider citizenry. There is also a concern about the generation and application of fundamental constitutional values (see below).

c. Participation

One feature of "new governance" is said to be a move from representation towards participation. As in the US case,¹⁰⁸ the EU involvement in health care governance reveals the emergence of novel institutional structures that may enhance participation in governance processes. In particular, a health OMC will presumably draw on a wide range of "partners", for instance, in developing its benchmarks and indicators, and feeding back instances of good practice into the policy loop. If the health OMC moves ahead, various relevant actors, such as health care funds, hospitals, health care professionals and patients, are likely to be included in the various stages of the OMC process.

Participation applies at all policy stages, including policy initiation. The application of new methods to health care governance suggests a focus on representation of a wider range of interested actors, even at the policy initiation stage, as participators in agenda-setting. The

¹⁰⁶ See K Lenaerts and A Verhoeven, 'Institutional Balance as a Guarantee for Democracy in EU Governance' in C Joeges and R Dehousse, *Good Governance in Europe's Integrated Market* (Oxford, OUP, 2002).

¹⁰⁷ Although in fact the ECJ has declined to find the comitology system "unconstitutional", see Case 25/70 *Koster* [1970] ECR 1161 and Case 302/87 *European Parliament v Council (Comitology)* [1988] ECR 5615.

¹⁰⁸ See L Trubek, 'New Governance Practices in US Health Care', in this collection.

membership of the agenda-setting High Level Reflection Group included not only health ministers and the European Parliament, but also other key stakeholders, that is, representatives of patients, professionals, providers and purchasers of health care. Rather than bringing in a wider range of stakeholders later in the policy cycle, in particular, in the implementation of EU law phase under the “traditional” construction of EU law, stakeholders were involved from the very beginning. The use of new governance methods here may help to avoid, for instance, “agency capture” of the Commission by entrenched interests, for instance, those of the pharmaceutical industry, reflecting a generalised concern framed in terms of the representativity of the EU’s agenda-setting institutions and processes.

On the other hand, the HLRP only met for a year. The real work of taking the detail of the policy forward will be done by the HLG on HS&MC, which excludes civil society as full members, even though they were included at the High Level Reflection stage. It also also excludes parliaments (European and national) except in the most indirect ways. This seems to be a return to an older mode of governance for the EU.¹⁰⁹ This is also exemplified in the health OMC. OMC is said to offer significant changes to sites for participation, and in particular to link sub-national with EU levels. However, for the health OMC, Council has explicitly written in the direct participation of national health ministries, thus removing the possibility of bypassing that national site of governance and control.

The health care example raises questions about who the “representatives of civil society” are, especially where they interact “at EU level”. For instance, the “civil society” members of the High Level Reflection Group were International Mutual Association (AIM); Standing Committee of the Hospitals of the EU (HOPE); European Health Management Association (EHMA); European Patients Forum (EPF); European Social Insurance Partners (ESIP); Standing Committee of European Doctors (CPME). All are EU-wide networks of national representatives of civil society, so by definition operate at a distance from individual patients, health care professionals and health care funders and purchasers within the Member States, although all can claim representativity indirectly through national organisations which form their membership. It is unclear how the members of the High Level Reflection Group were selected. However, they are all groups which had already worked closely with the Commission, which could suggest a “semi-closed” network, again reverting to potential problems of “capture”. In the case of one group, the “European Patients’ Forum”, the group itself owes its existence to a request from the Commission that such a group be created.¹¹⁰ One potential role for the law here is to allow challenge to the processes by which “civil society” groups become “insiders” in EU governance processes,¹¹¹ and a counterbalance to the power of the EU institutions, especially the Commission, in effect to require civil society to structure and present itself in a way which is appealing to the EU institutions, rather than self-chosen.¹¹²

¹⁰⁹ The legal basis of the HLG on HS&MC is also interesting – unlike the Social Protection Committee, which has a Treaty basis in Article 144 EC, it is set up by Commission Decision.

¹¹⁰ “The European Patients’ Forum should be seen as a response to recent calls by the European Commission and other EU institutions to have one pan-European patient body to address and be consulted on issues concerning the interests of patients in the European healthcare debate.” <http://www.europeanpatientsforum.org>.

¹¹¹ The inclusion of other EU-wide networks excluded from EU-level processes has already arisen in the context of Case T-135/96 *UEAPME* 1998 ECR II-2335.

¹¹² See generally, G De Búrca and N Walker, ‘Law and Transnational Civil Society: Upsetting the Agenda?’ 9 *ELJ* (2003) 387.

III.3 Backstop or kickstart? Constitutional values.

Several of the contributors to this collection observe that “new governance” often emerges within a pre-existing framework of hard law, suggesting that such a framework may be one of the drivers of new governance phenomena.¹¹³ Hard law provides the framework, or backstop, within which experimentation and problem-solving among relevant stakeholders may flourish, and lead to desired or efficient policy outcomes. Hard law, including litigation, can also be used to destabilise entrenched institutional arrangements that are failing to achieve their objectives,¹¹⁴ thereby “kickstarting” new governance arrangements. The roles of such legal “backstopping” rules include promoting accountability and ensuring adherence, in the context of experimental devolved governance, to centrally-agreed broad policy goals.

The EU health care case study is consistent with the observation that various new governance mechanisms follow from particular types of hard law rules, and in particular with the observation that litigation may play a destabilising role, such that existing entrenched actors and institutions are enticed or forced into new ways of interacting and using new problem-solving mechanisms. One interesting element of the responses to the *Kohll* litigation is the extent to which policy discussions that were not strictly indicated by the uncertainties raised are now included in EU health care governance. The *Kohll* litigation seems to have “kickstarted” various broader policy discussions, in particular based on solving of shared problems in the provision of health care within the “European social model” in the 21st century.

Much of the legal commentary criticising the *Kohll* litigation has been on the basis that the application of the law of the internal market to health care provision in the Member States of the EU destabilises the financial arrangements for national health care provision. This is presented as undesirable. In contrast, a “new governance” reading of such destabilisation suggests that it should rather be embraced, as opening up opportunities for the application of governance mechanisms that will generate more efficient policy outcomes.

However, new governance mechanisms in themselves provide only the *processes* within which policies are generated, and, potentially, new soft and hard regulatory norms are adopted.¹¹⁵ In the context of complex social problems, such as how to continue to provide universal access to quality health care, in the current European context, unless new governance moves towards agreed objectives, in terms of normative standards, then applying internal market law to public services that have hitherto been considered to be outside of “the market” may turn out to be more destabilising than is desirable. Whether the European Court of Justice, or indeed national courts, are able to provide the contours of such normative standards in the context of health care provision, remains to be seen, although certain values, for instance, solidarity, appear to be consistently appearing in the jurisprudence.¹¹⁶ Under ‘old governance’, although we may not agree with the precise contours of these backstopping values, at least we know which institutions and mechanisms (largely, courts and litigation, with the possibility of legislation where Community competence allows) are responsible for generating them.¹¹⁷ Under “new governance” arrangements, it is less clear whence these values emanate.

¹¹³ See, in particular, Bradley Krakkainen; ? Susan Sturm**check**

¹¹⁴ See C F Sabel and W H Simon, ‘Destabilization Rights: How Public Law Litigation Succeeds’ 117 *Harvard Law Review* (2004) 1015.

¹¹⁵ See, eg, O Gerstenberg and C F Sabel, ‘Directly-Deliberative Polyarchy: An Institutional Ideal for Europe?’ in C Joeges and R Dehousse, *Good Governance in Europe’s Integrated Market* (Oxford, OUP, 2002).

¹¹⁶ T Hervey, ‘Social solidarity: a buttress against internal market law’ in J Shaw, (ed), *Social Law and Policy in an Evolving European Union* (Oxford, Hart, 2000) 31.

¹¹⁷ **Cross refer Grainne de Búrca’s paper**

In the context of health care, Community competence is highly contested, and there is no equivalent of the framework directive(s) present in the race equality or environmental spheres. In this case, new governance can offer opportunities, but it also presents risks that core values, against which new governance mechanisms are framed, are developed and perpetuated by institutions and other actors that escape (to some extent) *both* classical *and* “new” modes of accountability and representativity or participation.

IV. Conclusion

What emerges clearly from the health care case study is that the “traditional” conceptualisations of EU (constitutional) law, and its relationships with national legal regimes, do not capture the wide variety of governance processes brought to bear in the EU context, certainly in the case of governance of health care. “Europeanisation” is so much more than deregulatory litigation with a bit of top-down harmonisation, implemented by national administrations, wherever formal competence provisions allow. Our accounts of the roles of law in the governance of Europe need to take account of law’s roles in containing “soft convergence” processes, such as persuasive coordination, provision of funding, and collection and dissemination of information, as well as in the more visible “new governance” processes, especially the OMC.

What is also clear is that “old governance” still plays an important role. This paper’s narrative is of a governance space opening up for the EU in the wake of the archetypal “old governance” mechanism – internal market litigation. Far from abandoning “old governance” legislative responses, the EU institutions, especially the Commission, are keen to pursue them, *alongside* the array of new governance mechanisms now also available. The extent to which the Commission can exploit all such possible sites for governance is subject to constitutional principles of institutional balance, as well as the practicalities of the Commission’s limited resources.¹¹⁸

The health care case study shows that litigation remains a core site for the contestation of core ideological (“constitutional”) values (such as equality and solidarity of citizens) within the EU’s juridical construct. This finding merely confirms in the context of services much of the existing “EU constitutional literature”, citing litigation on free movement of goods.¹¹⁹ The possibility of individual legal challenge to national welfare settlements, even at the fringes, affects the balance of powers between EU and national or even sub-national institutions in the health care field. This constitutional rebalancing, along with the various governance responses to the resultant instability, deserves the attention of EU (constitutional) lawyers, in terms of both its processes and its substantive policy outcomes.

¹¹⁸ For instance, given the lack of a single market in pharmaceuticals, evidence-based analysis of new health care technologies is a possible site for Europeanisation, but the Commission is decidedly lukewarm on this (2d).

¹¹⁹ See Póiares Maduro, *supra* n 7; Weatherill, *supra* n 7; J H H Weiler, ‘The Community System: The Dual Character of Supranationalism’ 1 YEL (1982) 257.