

Freedom to provide health care services within the EU: An opportunity for a Transformative Directive.

Tamara Hervey, University of Sheffield, UK and Louise Trubek, University of Wisconsin-Madison, USA.*

1. Introduction

In the context of free movement of health care services, ‘the classic Community method’ (CCM) of regulation through harmonised internal market law, underpinned by Treaty-based litigation, has failed. Most recently and spectacularly, this is evidenced by the dropping of health care services from the general ‘Bolkestein’ services directive (COM(2006) 160). At the same time, a plethora of ‘new’ or ‘experimentalist governance’ activities concerned with health care have grown up in the EU. These include the use of the ‘open method of coordination’ (OMC) in the field of health care; the establishment of structures to encourage cooperation among health ministers at EU level; and the focusing of EU funding on activities that encourage sharing of information and collaborative practices among various professional groups operating in health care fields.

This article argues that the current situation of the failure of ‘the old’ and the emergence of ‘the new’ represents an opportunity to develop and design, *ex ante*, a transformative hybrid between the two. Our proposed hybrid solution – a ‘Transformative Directive’ – has much to offer in terms of developing and circulating solutions to the problems arising from managing health care provision in the context of an internal market and Europe’s ‘social model’.

2. Out with the old and in with the old/new hybrid: a Transformative Directive on health care services

(1) The failure of the classic Community method ... and the potential of experimentalist governance

The failure of the CCM in this context can be attributed to two main reasons. The first belongs in the realm of practical politics. It is relatively easy to bring about the internal market through ‘negative integration’, through litigation enforcing the directly effective internal market treaty provisions. It is much more difficult to gain the requisite political will to create the internal market through ‘positive integration’, by adopting EU level legislative measures (Regulations and Directives). Even under the Article 251 procedure, a qualified majority of votes in Council and the support of the European Parliament are necessary for the adoption of legislation.

* Paper presented at Law in New Governance Law Taskforce II Conference, 26-27 May 2006, University College, London. Supported in part by the European Union Center of Excellence at the University of Wisconsin-Madison, which is funded by the European Commission. We are grateful for the comments and suggestions made by participants at the conference, in particular David Trubek, Joanne Scott, Gráinne de Búrca, Kenneth Armstrong and Diamond Ashiagbor.

The proposed Bolkestein services directive (COM(2004) 2 final) represents a clear example of these difficulties. The original proposal generated a significant head of steam in terms of opposition, both from civil society and from the institutions of the EU. A public demonstration, organised by NGOs and a broad coalition of left political parties, against the proposal (virtually unheard of in EU political life) took place in Brussels on 4 June 2004. The European Parliament's report of December 2005 incorporates fundamental changes to the proposal, including scrapping the keystone 'country of origin principle' from the text. This principle was one of the elements of the proposal most criticised by those concerned with the application of the proposal to health care services (see, for example, Rowland, Price, Pollock, 2004). The country of origin principle was seen as opening the floodgates to a deregulatory 'race to the bottom' or levelling down in quality standards and professional qualifications requirements in the European health care sector, a highly unattractive phenomenon not only in terms of patient safety or rights, but also in terms of efficiency, especially in the context of national health care systems which 'pick up the tab' for lapses of quality of health care within their public provision. This push towards levelling down was seen as a lost opportunity for the EU, whose work, according to these critics, should be towards the objective of 'upwards' convergence or harmonisation. More fundamentally, though, critics of the proposal in terms of its application to health care services concentrated on the challenge the proposal implied to the public understandings of health care in the European context. In Europe, health care is not seen as being provided as a commodity, but as meeting a social need. A services approach puts too great an emphasis on patient (service recipient) choice at the expense of solidarity. This may further exclude the already under-empowered within national health systems (the elderly, the mentally ill, those from social groups who do not traditionally engage with dialogue on or take an active part in decisions relating to their health care). Thus the freedom of services approach, under the CCM, offends against fundamental values of European health care systems, in particular, efficiency, solidarity and equality of access.

The second reason for the failure of the CCM to govern cross-border health care services in the EU has a more normative and indeed constitutional basis. The European Union lacks formal legal competence to regulate health care more generally, other than in the context of cross-border receipt of health care services, or movement of health care professionals. The Treaty explicitly provides in Article 152 EC that 'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care'. The European Court of Justice has consistently affirmed that the organisation and delivery of health care services is the responsibility of the Member States.¹ This results in the well-recognised 'constitutional imbalance' arising from the relative ease of negative integration compared to positive integration (Weatherill, 1995; Streek, 1995; Scharpf, 1996; Maduro, 1998).

¹ 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; Case C-372/05 *Watts* 16 May 2006, para 146.

In the cross-border health care context, this leads to a situation where the creation of the internal market in health care services, through private litigation, raises significant uncertainties for relevant actors, especially the governments of the Member States, and their health care institutions. It is true that such internal market litigation plays a role in rebalancing the push from negative integration that would imply free cross-border receipt of health care services irrespective of its destabilising impact on the values underpinning territorially-based national health care systems, such as solidarity and equality of access to health care. In particular, the European Court of Justice has recognised that Member States may have an ‘objective public interest’ in restricting the free movement of health care services across EU borders. Relevant objective public interest justifications include the social protection provided by national social security systems;² and consumer protection³ (‘consumers’ here being the patients). Nevertheless, such a rebalancing will always be incomplete, due to the nature of litigation processes in general, and the Article 234 EC reference procedure in particular.

More positively, ‘new modes of governance’, in particular ‘experimental federalism’ (Sabel and Gerstenberg, 2002; Scott and Holder, 2006; Sabel and Zeitlin, 2006) have much to offer to the problem of governing cross-border health care within a legally pluralist European Union. Member States share a need to respond to common problems in their health care systems, and at the same time to protect the values represented by the ‘European Social Model’. Nevertheless, Member States must manage this within the context of their Treaty obligations to create and sustain an internal market characterised *inter alia* by the free movement of services, and of a situation of formally limited EU-level competence. Experimental federalism can offer ‘bottom up’ governance solutions to complex social problems, where ‘top down’ regulation has either failed to deliver, or where it is constitutionally unavailable (see, e.g., Zeitlin, Pochet, Magnusson, 2005).⁴ This is exemplified in the EU’s institution of an open method of coordination (OMC) in health and long term care⁵ which aims to ensure access to care, on the basis of universal access, fairness and solidarity; to promote high quality care; and to ensure the financial sustainability of health care and social protection systems. All of these are at least potentially engaged by the application of the free movement of services provisions to national health care services. There are also other ‘experimentalist governance’ type structures engaging with health care in the EU, in particular the work of the High Level

² 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-157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473; Case C-368/86 *Vanbraekel* [2001] ECR I-5363; Case C-8/02 *Leichtle* [2004] ECR I-2641; Case C-372/04 *Watts* 16 May 2006.

³ 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.

⁴ See the works cited in the ‘OMC bibliography’ <http://eucenter.wisc.edu/OMC/open12.html>.

⁵ European Commission, *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”* (COM(2004) 304 final). Endorsed by the Employment, Social Policy, Health and Consumer Affairs Council in October 2004. 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.

Group on Health Services and Medical Care (see Hervey, 2006). Moreover, health is a policy sector that has historically drawn heavily on self-regulatory structures (see, for example, Johnson, Larkin and Saks, 1995), and thus governance mechanisms that involve the relevant actors in norm setting ‘from within’, rather than the imposition of norms ‘from above’ are likely to be particularly appropriate in this context.

However promising ‘experimentalist governance’ might be in the field of cross border health care in the EU, it must take its place within internal market law. Moreover, the sites and actors involved in the emerging ‘new governance’ of EU cross border health care are highly disparate and indeterminate, in particular when compared to more stable ‘new governance’ structures such as the European Employment Strategy. Therefore, rather than adopting *either* old (CCM) *or* new (OMC and the like), *both* the old and the new could be harnessed together in novel hybrid structures that retain the benefits of experimentalism without retreating totally beyond the legal constraints that help to secure democratic values in the EU’s governance processes. Sabel and Zeitlin (2006) highlight the centrality of the ‘framework regulation/directive’ in the new governance architecture of the EU. As they see it, the roles of the framework regulation/directive are to set basic principles, objectives, and parameters, and to establish legal duties of transparency and accountability in the sense of ‘directly deliberative polyarchy’. The framework regulation/directive sets legal obligations requiring accountability in the sense of requiring an explanation, not only to a central authority, but also, ideally, to peers. Along with penalty defaults, which are a means to induce participation in ‘soft law’ processes and respect for their outcomes, the framework regulation/directive creates not rules, but ‘frameworks for creating rules’ (Sabel and Zeitlin, 2006: 49). Where ‘the patent unworkability of official solutions – the failures, if you like, of rules made by anything like traditional means ... makes the mere threat of imposing them so effective a device for inducing the parties to deliberate in good faith’ (Sabel and Zeitlin, 2006: 50-51), the new architecture of EU governance may be said to operate through neither soft nor hard law alone, but through a hybrid of the two.

These observations are reflected in the context of governing cross-border health care within a legally pluralist European Union. The story of the Bolkestein services directive shows ‘patent unworkability’ of the CCM. The case law of the Court of Justice on the subject (see below) shows the unsatisfactory nature of case-by-case *ex post* procedures for a complex, and evolving, policy area. In our view, this has created a climate in which relevant actors have strong vested interests in participating in soft law structures, and in adhering to the (soft) norms which they create.

Given the interface between internal market entitlements and (fundamental) social rights (in some Member States, expressly guaranteed in constitutional documents), the cross-border receipt of health care is not the type of issue that it is appropriate to leave to the CCM. Even if a CCM-type health care services directive were adopted (which may not be a practical political reality), its interpretation would remain within the context of Article 49 EC, and the final arbiter of its meaning and scope would remain the European Court of Justice. The inefficiencies and constraints of the litigation process, especially the Article 234 EC procedure, are particularly problematic. Courts may not be the best

institutions at which to resolve complex social problems such as the tension between the ability of patients to receive health care in other Member States, and the territorial solidarity, and financial sustainability, of national health care systems. Litigation before the ECJ, under Article 234 EC, suffers at least two deficiencies in this respect. First, it frames the issue in terms of a once-off *ex post* adversarial process, in which there is one winner and one loser, not an iterative, deliberative process in which the optimal accommodation of all relevant interests is reached, for the time being, and revised in the light of technological or other societal changes. Second, litigation based on the direct effect of Article 49 EC may be skewed towards what we might call ‘internal market interests’, rather than those represented by the discourse of fundamental social rights, in that the Treaty’s structure proceeds from the assumption that all freedom of movement is to be permitted, unless its restriction can be objectively justified.

To put it very simply is to ask this. Wouldn’t European citizens rather have guidelines about how and when Member States may diverge from the obligations of Article 49 EC in their health care systems, when patients move across borders, by reflexive discussion of all relevant stakeholders brought around the table and coordinated by the European Commission, than the vagaries of the European Court of Justice, which takes the national context(s) into account only to the extent that these are explained in the reference, and, of course, can only develop its law in terms of the cases actually brought before it? Wouldn’t European citizens rather have a coordinated exploration of the benefits that cross-border health care can bring, within the context of European health care systems, and their fundamental principles and values, than an opportunistic, piecemeal, litigation-based, unstable legal situation, in which the main winners are those who are equipped to litigate? In both cases, we take the view that European citizens would prefer the former option.

(2) The legal context on freedom to provide services

Any legislation seeking to regulate the free movement of health care services within the EU needs to take account of the three possibilities for free movement of services (Barnard, 2004: 331-3). These are either the service provider (the health care professional) moves; or the service itself (the health care) moves; or the service recipient (the patient) moves.⁶ Each of these has at least potential applications to the health care situation, but for the purposes of this article, our main focus is the third possibility.

The first situation is where health care professionals from one Member State provide a temporary service in another Member State. This may be an individual health care professional, with an established base elsewhere in the EU, who seeks to provide cross-border health care services on a temporary basis. Alternatively, it may be planned by national health authorities. For instance, some NHS trust hospitals in the UK have flown in teams of German surgeons for a weekend, to operate in UK hospitals, in order to clear waiting lists, or under the NHS ‘Out of Hours’ scheme, NHS trusts have used general

⁶ All three of these types of cross-border health care services are also found in the USA, where they tend to be referred to as ‘medical tourism’ or ‘offshoring’, see McLean, 2005.

practitioners from other EU Member States to cover unpopular working times, especially weekends and evenings.⁷

The second possibility for free movement of services to be engaged – where the service itself moves, but the provider and recipient remain in different Member States – could apply in the provision of ‘e-health’. As far as we know, the nascent market in cross-border e-health in the EU has not yet had any significant impact on national health care provision, or the regulation of public health service providers (Callens, 2003). However, there is scope for this to arise in the future. In the *DocMorris* case,⁸ the Court considered whether the cross-border activities of an internet pharmacy breached the Treaty provisions on free movement of goods. It is quite feasible to provide the service of health care electronically – patients may seek ‘e-consultations’ with health care professionals. In principle, therefore, free movement of services would be engaged by such cross-border receipt of ‘e-health care’ services.

The third and final possibility for engagement of free movement of services – where the service recipient moves – is the best known in the context of cross-border health care in the EU. The service recipient may be an individual patient, seeking health care in another Member State, where the health care is to be paid for by their own national health (insurance) system. The reasons for seeking cross-border health care in this context include avoiding waiting times in the home Member State, accessing different types of treatment, or spending less money on the co-payment element of the health care.⁹

Alternatively, free movement of service recipients may be engaged where groups of patients move, for instance in the case of cross-border contracting for block purchase of health care. This has been the focus of one of the working groups of the High Level Group on Health Services and Medical Care (HLG on HS&MC), a body established by the Commission under Article 152 (2) EC, and welcomed by Council in June 2004. The High Level Group consists of senior officials from Member States, and is chaired by the Director General of DG SANCO. The aim of the HLG on HS&MC is to ‘improve top level coordination among EU members on a broad range of health issues’.¹⁰

(3) The current legal position

⁷ Boyes, R, ‘Striking doctors on the march in Germany’ 19 January 2006 <http://www.timesonline.co.uk/article/0,,13509-1995603,00.html>; Paramedic UK, 2004, ‘Casualty Busier after GP Service Changes’ September 2004, http://www.paramedic.org.uk/news_archive/2004/09/News_Item.2004-09-10.3211/view; Portsmouth NHS Trust, 2003, ‘Patients benefit from European initiative’ News and Press Releases 1 August 2003 http://www.portshosp.org.uk/news/aug03_pr.asp.

⁸ Case C-322/01 ECR I-14887.

⁹ This type of free movement of services is illustrated by cases such as Case C-158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931; Case C-157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473; Case C-368/86 *Vanbraekel* [2001] ECR I-5363, para 42; Case C-385/99 *Müller-Fauré/Van Riet* [2003] ECR I-4509; Case C-56/01 *Inizan* [2003] ECR I-12403; Case C-8/01 *Leichtle* [2004] ECR I-2641; Case C-145/03 *Keller*, [2005] ECR I-2529; Case C-372/04 *Watts* [2006] ECR I-4325.

¹⁰ Letter from Robert Madelin, DG SANCO, 4 May 2004, Ref HLG/2004/1.

The current legal position of a patient seeking health care in another Member State is governed by the interactions between Regulation 1408/71/EEC¹¹ (to be replaced by Regulation 883/2004/EC¹²), which coordinates national social security schemes, of which national health (insurance) systems are a part; and Article 49 EC, which prohibits restrictions on freedom to provide (and receive) services within the EU. (See the flowchart for a summary.) If the health care sought by the patient has been “authorized” by the home Member State under Regulation 1408/71/EEC, Article 22 (c), the patient is entitled to health care (‘benefits in kind’) provided by the host institution, on behalf of the home institution, or cash benefits to pay for such health care. This is administered under the E112 scheme. Benefits in kind are to be reimbursed at the rate of the home state,¹³ but only for benefits in kind that are provided in the home state.¹⁴ Cash benefits are to be provided at the rates of the home state, even if the two states agree that the host state will provide them. If the patient is already in the host Member State, then under Article 22 (a), there is a right to receive ‘necessary care’ in the host Member State, that is treatment ‘which become[s] necessary on medical grounds during a stay in the territory of another Member State, taking into account the nature of the benefits and the expected length of the stay’. Where the host Member State gives benefits in kind, this is to be ‘as though the patient were insured’ in the host Member State. If the patient paid up front, then the home Member State must reimburse the patient (or the heirs).¹⁵ It is not clear whether this principle applies to non-urgent care, although it probably does not (Hervey, 2007).

In some circumstances, either under the legislative scheme, or in terms of the Treaty provisions, Member States may lawfully refuse authorisation for cross-border health care. For instance, if either 1) the treatment is not among those provided for by the legislation of the home Member State; or 2) the treatment can be given within the time normally necessary for obtaining the treatment in the home Member State, taking account of the patient’s current state of health and the probable course of the disease, then authorisation may be lawfully refused (provided that the Treaty rules are not thereby infringed).¹⁶ So, for instance, some new, experimental treatments may not (yet) be provided for by the legislation of a particular Member State. In those circumstances, the home Member State may lawfully refuse to authorize the treatment (provided that the authorisation system itself is lawful). Another example where authorisation may be lawfully refused is if there is treatment available in the home Member State ‘which is the same or equally effective for the patient’ and ‘can be obtained without undue delay’.¹⁷ This must be assessed on a case-by-case basis.¹⁸ The Court has also applied these rules in the context of considering justifications for restrictions under Article 49 EC. A third example, applying where hospital care is concerned, is that prior authorisation for treatment may be refused in

¹¹ OJ Sp. Ed. 1971 II p 416.

¹² OJ 2004 L 166/1. This measure will come into effect when the implementing legislation has been adopted, see COM(2006) 16.

¹³ Case C-368/98 *Vanbraekal*.

¹⁴ Regulation 1408/71/EEC, Article 36.

¹⁵ Case C-145/03 *Keller*, para 69.

¹⁶ Regulation 1408/71/EEC, Article 22 (2).

¹⁷ Case C-157/99 *Geraets-Smits/Peerbooms*, para 103; Case C-385/99 *Müller-Fauré/Van Riet*, para 89, Case C-56/01 *Inizan*, para 45.

¹⁸ C-372/04 *Watts*.

pursuit of an objective public interest, such as protecting the financial stability and balance of the national health care system.¹⁹

However, if authorisation has not been lawfully refused, or the terms of the authorisation scheme are unlawful, then the patient enjoys a right based on the ‘direct effect’ of EU law²⁰ to have the medical treatment reimbursed by his or her home Member State. Examples of unlawful refusal of authorisation, or terms of authorisation schemes that are unlawful, include the following:-

1. If non-hospital care is available without authorisation in the home Member State, but authorisation is required for such care in a host Member State.²¹ This is clearly a ‘restriction’ on the free movement of services in the sense of Article 49, as it discriminates on grounds of nationality between home and host providers of the service. Such a scheme would be contrary to Article 49 EC, unless justified by an objective public interest.
2. In principle, if hospital care is available without authorisation for care in a hospital with which the national sickness fund has an agreement, but authorisation is required where the hospital is not one with which the national sickness fund has entered into an agreement, as such hospitals are much more likely to be in other Member States.²² However, the Court found that such a restriction was justified, according to the objective public interest of protecting ‘all the planning which goes into the contractual system in an effort to guarantee a rationalized, stable, balanced and accessible supply of hospital services’.²³
3. Combining 1 and 2 above, if authorisation is required for non-hospital care only with a ‘non-contracted’ provider. This is unlikely to be justified by reference to the financial impact on the home Member State’s health care system.²⁴
4. Where authorisation for health care, and the associated costs of health care (board, lodging, travel, visitors’ tax), in an institution in a host Member State is subject to the condition that a medical professional has determined that this health care is ‘absolutely necessary outside the [home state] on account of the greatly increased prospects of success’ there.²⁵ Such a condition, by its very nature, has the effect of inhibiting cross-border receipt of health care services. Again, justification would be available in principle.
5. If the level of payment is lower where the health care is sought in another Member State.²⁶ This is also a ‘restriction’ on the freedom to provide services, as the lower level of payment is likely to deter patients from seeking provision in another Member State. Again, such a scheme may potentially be justified, although in *Vanbraekel* this was found not to be the case, as the patient was in

¹⁹ See Case C-120/95 *Decker*; Case C-158/96 *Kohll*; Case C-157/99 *Geraets-Smits/Peerbooms*; Case C-368/86 *Vanbraekel*; Case C-385/99 *Müller-Fauré/Van Riet*; Case C-8/01 *Leichtle*; Case C-372/04 *Watts*.

²⁰ See Case 26/62 *Van Gend en Loos* [1963] ECR 1.

²¹ Case C-158/96 *Kohll*.

²² Case C-157/99 *Geraets-Smits/Peerbooms*, paras 67-69.

²³ Case C-157/99 *Geraets-Smits/Peerbooms*, para 81; Case C-385/99 *Müller-Fauré/Van Riet*, para 82.

²⁴ See Case C-385/99 *Müller-Fauré/Van Riet*, paras 93-98.

²⁵ Case C-8/01 *Leichtle*, para 36; 42.

²⁶ Case C-368/86 *Vanbraekel*.

- fact entitled to authorisation under Regulation 1408/71/EEC, and thus, given that the amount that would have been paid out had the treatment been given in the home Member State was higher, it could not be claimed that the application of the Treaty, to support cross-border patient care, would give rise to a *greater* financial burden for the home Member State.
6. If the basis on which authorisation is given is by reference only to national professional circles within the home Member State. EU law requires that this be by reference to international medical science.²⁷ Questions arise here about how one determines the views of ‘international medical science’, given the constant developments in understandings of disease and treatment, and significant cultural differences between medical professionals across the EU, never mind the world.
 7. It follows from the principle that authorisation may be refused if there is treatment available in the home Member State ‘which is the same or equally effective for the patient’ and ‘can be obtained without undue delay’²⁸ that if this is not the case, then refusal to authorize is unlawful. ‘Undue delay’ must be determined by reference to the individual patient.²⁹
 8. If the authorisation scheme requires that the patient wait for authorisation, including challenging a refusal of authorisation before the courts, *before* undertaking the treatment, this is unlawful. The Court has confirmed this both in the context of authorisation under Regulation 1408/71/EEC,³⁰ and in the context of Article 49 EC.³¹ To find otherwise would be to violate the practical effect of the provisions of EU law, in particular their direct applicability and supremacy over incompatible national norms.
 9. If the authorisation scheme or system is not procedurally transparent and accessible, and subject to judicial review, that is, reasoned.³² Where authorisation schemes lack transparency and reviewability, the ability of patients to enforce their rights in EU law is compromised. This violates the principle of *effet utile*, or the ‘useful effectiveness’ of EU law.

The combination of the legislation, Treaty provisions and case law, as interpreted by the European Court of Justice, results in the position that a Member State is not wholly in control of the cross-border receipt of health care by its own patients (EC law entitling some patients to reimbursement for health care to which they would not otherwise be entitled) or by patients from other Member States seeking access to care in that Member State. It also represents a position of significant legal uncertainty, especially in that the question of justification – which essentially determines the extent of national control – is subject only to the broad principles of non-discrimination, equivalence and

²⁷ Case C-157/99 *Geraets-Smits/Peerbooms*, para 94.

²⁸ Case C-157/99 *Geraets-Smits/Peerbooms*, para 103; Case C-385/99 *Müller-Fauré/Van Riet*, para 89, Case C-56/01 *Inizan*, para 45; Case C-372/04 *Watts*.

²⁹ Case C-372/04 *Watts*.

³⁰ Case C-368/86 *Vanbraekel*, para 34.

³¹ Case C-8/01 *Leichtle*, paras 55-59.

³² Case C-157/99 *Geraets-Smits-Peerbooms*, para 90; Case C-385/99 *Müller-Fauré/Van Riet*, para 85; Case C-56/01 *Inizan*, para 48; Case C-372/04 *Watts*.

proportionality.³³ The problem is not that the law is complex here (although it is). The problem is that, as the operation of national health care systems evolves, for instance as Member States seek greater efficiencies, or redistribution of resources in pursuit of equality, the question of whether exclusion of cross-border health care in various situations is consistent with EC law will itself constantly evolve. This represents an undesirably high degree of uncertainty for the regulatory landscape in this field.

(4) Opportunities and threats

The current legal position gives rise to a number of (potential) opportunities and threats. Those seeing the free movement of patients litigation as a *threat* to national health (insurance) systems focus in particular on the impact on their stability and internal balance and the viability of their social goals (see, for example, Baeten, 2001; Jorens, 2003). In particular, the current legal position gives scope for detrimental effects on national health care planning and capacity maintenance, both of which are crucial to the sustaining of quality standards and values of social equity in health care provision. States calculate their health care needs by reference to their populations. Too much movement of patients might result in the 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 of the EU. 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. Cases such as *Geraets-Smits* imply that decisions about cost-effectiveness may no longer be kept within the ‘closed’ territorially-based national system, with its own ‘home-grown’ experts. The same reasoning applies to the use of Article 49 EC litigation by patients seeking to avoid long waiting times for treatment in their home Member States. States use hospital waiting lists in effect as a tool to constrain spending. Waiting lists also arise as a logical consequence of decisions about resource allocation. Cases such as *Müller-Fauré* and *Watts* imply some loss of control at national level over the use of hospital waiting lists. These types of threats contribute to the uncertainty arising from the litigation based on Article 49 EC, which is one of the factors that make an EU-level governance response appropriate.

At the same time, the opening up of the internal market in health care services may give rise to a number of beneficial *opportunities*. Publicly funded cross-border health care provision could be beneficial in a number of specific instances, such as in border regions, in centres of excellence for highly specialised treatments, and in foreign tourist centres. For Member States with over-capacity in their national health care systems, access from patients in other Member States could result in a more efficient use of resources overall. Some Member States are funding treatment packages for their patients to travel to other Member States, as a means of alleviating waiting times (Lowson, et al, 2002; Bertinato et al, 2005). Moreover, Member States share common challenges to their national health care systems, including the need to ensure quality of care; the need to assess

³³ See, eg, Case C-76/90 *Säger* [1991] ECR I-4221; Case C-180/89 *Commission v Italy (Tourist Guides)* [1991] ECR I-709.

technological developments in terms of their comparative therapeutic efficiency (Abraham and Lewis, 2000); and the obligation to continue to provide equal and universal access to health care on the basis of need, in times of ageing populations and contracting public spending. All of these challenges need to be met also in the context of an EU internal market for health care services. These opportunities suggest that new governance mechanisms could provide a means to capitalise on the benefits of common action at EU level, in a field where the CCM is not available, either in law, or in practice.

(5) The Contours of a Transformative Directive

We see the current situation as presenting an opportunity for a ‘Transformative Directive’ on health care services. This Directive would have two main components. The first would be an articulation in directive form of the formal legal rules on cross-border receipt and provision of health care services in the EU. The second would be a framework for creating non-binding norms through participatory mechanisms, such as found in the OMC and other ‘new governance’ processes already existing in EU law.

Turning to the first component of the Transformative Directive, this would articulate the formal substantive legal rule in terms of high abstraction and simplicity. By analogy with the Water Framework Directive, (see Scott and Holder, 2006), which aims to achieve ‘good’ water quality by the end of 2015, the basic formal legal rule should be simple and general:- ‘Free movement of health care services is permitted in the internal market, unless its restriction is justified by objective public interests’. It should also reflect, perhaps in its preamble, both the ‘European social model’ with respect to health care, and the construction of health care as a ‘fundamental social right’ in many European constitutions, as well as the Council of Europe’s European Social Charter. The notion of ‘objective public interest’ is of course to be interpreted in the light of this position.

However, to leave matters along these lines would simply be to replicate the Treaty provision in not much more detail. Under the CCM, the interpretation of such a formal rule in a directive would be a matter for national courts, with the possibility of reference to the ECJ under Article 234 EC. This would leave in place all the resultant uncertainty of the current legal position, and unrealised potential for common action. In addition, the problems of applying Article 49 EC to national health care services, which resulted in the collapse of that provision in the Bolkestein services directive, suggest a need for further intervention in the operation of the internal market and its legal constructs. We do not believe, in the light of the experience of the Bolkestein services directive, the constitutional position of healthcare in EU law, and the need to provide a flexible, diverse and plural settlement of the balance between health care services as part of the internal market and health care services as part of the social solidarity responsibilities incumbent upon governments of all EU Member States, within the ‘European social model’, that the CCM will deliver in this instance.

Therefore, turning to the second component of the Transformative Directive, in addition to the very simple formal substantive legal rule, the Transformative Directive would establish a set of ‘federal experimentalist’ institutions and mechanisms, (a framework for

creating rules) to breathe life into the formal legal provisions, not (primarily) through court-based litigation processes, but through iterative and participative soft law generation. What we see, therefore, is an opportunity for a hybrid form of old and new governance, where the roles played by (formal, hard, old) law are to create a framework rule, to bring to bear certain constitutional values and rights, and to set legal duties relating to information and data generation and exchange; development of guidance; and review, testing and validation of practice (Scott and Holder, 2006: 229).

Following the model of the water quality ‘Common Implementation Strategy’, as outlined by Scott and Holder (2006: 227-8), and taking account of the ‘new governance’ activity already taking place in the EU, especially the OMC on health and long term care, we envisage the *structure* of a ‘new governance’ mechanism – say, the ‘cross-border health care services strategy’ (XBHCS Strategy) – operating at three coordinated levels. Working groups would operate at the level of technical detail. They would report to a strategic coordination group, chaired by the Commission and including participants from each Member State. This group would receive and discuss the working groups’ reports, and coordinate their different activities. An intergovernmental steering group would take overall policy decisions to drive the process.

The seeds of this ‘cross-border health care services strategy’ already exist in informal mechanisms, largely unrecognised by formal legal measures. The health ministers of the Member States, who would comprise the steering group, have been meeting since at least the 1980s in the context of the Council of Ministers. They have steered both the EU’s legislative process and the open method of coordination, where applied to health care. The High Level Group on Health Services and Medical Care, consisting of senior officials from Member States, and chaired by the Director General of DG SANCO, would become the strategic coordination group, to which ad hoc working groups (already part of the HLG on HS&MC) would report. The working groups would be required to bring in expertise and examples of good practice from all relevant levels of governance in the European Union, right down to the level of an individual hospital or other health care institution. This builds on the practices operating within the OMC, and also those of the High Level Group on Health Services and Medical Care. For instance, the existing Guidelines on Cross-Border Block Purchasing, developed by the High Level Group on Health Services and Medical Care, do just this, in that they collect examples of cross-border contracts between hospitals in a database which is accessible to all European Union hospitals that might seek to use them.

The overall *aims* of the ‘XBHCS Strategy’ would be two-fold. The XBHCS Strategy would develop guidelines on when Member States may diverge from the principle of free movement of health care services, essentially through elaborating ‘objective public interest’, thus dealing with the *threats* arising from cross-border health care services. The Strategy would also aim to enable individual patients, hospitals, health care professionals and funding/administrative bodies to benefit from the *opportunities* for efficiency that cross-border receipt of health care services provide.

The *activities* of the XBHCS Strategy would be three-fold. Following Scott and Holder's taxonomy, the XBHCS Strategy would (i) generate and exchange information and data; (ii) develop guidance; and (iii) review, test and validate practice.

Generation and exchange of information and data are central to experimental federalism. Without generation and exchange of (comparable) data, there can be no peer review, and no reflexive learning, the very heart of experimental federalism. As in the case of the EIA Directive, or the legal bases of the OMC, we see an opportunity for the Transformative Directive to set out legal duties to generate and to report on relevant information, to develop appropriate guidance, and duties to enable the testing and validation of different national practices.

In terms of guidance development, the strategic coordination group – the (successor to the) High Level Group on Health Services and Medical Care – would determine what detailed guidance would be necessary to 'put the flesh on the bones' of general, formal legal rules in the proposed Transformative Directive. This would be carried out in consultation and collaboration with the working groups. Types of guidance could include elaborating the notion of 'undue delay'; or setting standards by which Member States may refuse to authorise new therapeutic treatments; the bases for cross-border health care block purchasing either where patients move (some of this work has already been done by the HLG on HS&MC), or where the services of health care professionals from another Member State are purchased on a temporary basis, or even where the health care service itself moves. For instance, what measures of data protection, privacy and confidentiality; quality/professional standards; malpractice and 'near miss' reporting; continuing professional education; duties to give information (for instance on therapeutic outcomes); would govern these cross-border health care services?

Thirdly, in terms of peer review, the XBHCS Strategy would mandate structures of peer review (like those envisaged for the OMC in health care and long term care). These would need to be a little different from the peer review in the environmental field, where the aim is convergence of national practice around certain quantifiable environmental standards. In the context of the XBHCS Strategy, the aim would be to gain benefits for the EU as a whole, and its patients, from cross-border health care, without losing the quality, solidarity and equality of access that are potentially in jeopardy if unregulated cross-border activity proliferates. So, for instance, we might envisage publication and peer review of hospitals' statistical success and failure rates, so that patients can move, and purchasing authorities can make their choice of provider, with more complete knowledge of the service they will receive. This might be especially pertinent for hospitals seeking to become centres of excellence in rare diseases; hospitals in border areas; and hospitals where high numbers of non-national patients are likely to seek their health care services, such as in geographical retirement areas, or tourist destinations.

Building on the value of a 'hybrid' of old and new governance, and in particular the roles for (hard) law in reifying certain constitutional values in experimentalist governance processes, there is an opportunity for the Transformative Directive to *mandate certain standards* for the XBHCS Strategy. These would aim to promote both 'procedural' and

‘substantive’ constitutional principles. The procedural principles would include transparency and participation. Thus the proposed Transformative Directive would require that the working methods of the XBHCS Strategy were open and transparent. There would be an obligation to publish the data on which any guidelines were developed, the minutes of meetings, and of course the guidelines themselves. The proposed Transformative Directive would also require participation of the main necessary stakeholders. These are health care funding institutions (social insurance funds; national ministries); health care providers (hospitals, health care professionals) and health care recipients (patients). Scott and Holder note ‘some vagueness’ on matters of participation in the case of the Water Directive (2006: 228) – there is an opportunity in a Transformative Directive to promote greater clarity and precision than is present in the environmental context, which has grown ‘organically’, rather than being designed *ex ante*.³⁴ Setting the experimentalist governance structures within the scope of a Transformative Directive also gives an opportunity to articulate (probably in its preamble) the ‘substantive’ constitutional principles of the ‘right to health care’, on the basis of equality of access and solidarity. All actors in the XBHCS Strategy would be under an obligation to respect these principles (on the relationship between experimentalist governance and fundamental social rights, see, for instance, Bernard, 2003; de Schutter and Deakin, 2005). Finally, the reflexive mechanism set up by the Transformative Directive would *itself* be revisable.

3. Objections/problems

A number of objections to, or problems with, our proposal, may be envisaged. Some of these are specific applications of more general objections to new modes of governance (or even governance itself, as opposed to government). The main general objections may be summarised as the accountability issue; the resources/efficiency issue and the participation issue. We cannot do full justice to these general issues – accountability, use of resources, participation – in the context of a single article. They are elaborated much more fully in the general literature on experimentalist governance. However, some brief observations are merited.

In the context of the proposed Transformative Directive on cross-border health care services, the accountability issue essentially asks what mechanisms are in place to hold to account the actors taking decisions within the process (the working groups, the strategic coordination group (essentially a comitology type committee) and the intergovernmental steering group). In the sense of retrospective giving of account – that is, narration; debating the issues; evaluation/passing judgment, by external actors to the process (Harlow and Rawlings, 2006, following Bovens 2006), the Transformative Directive idea offers no solutions. The mechanisms envisaged, and the norms that they would develop, would be essentially soft, and would *themselves* escape formal judicial review. However, wherever the soft norms developed essentially constitute an instrumentalisation of the contours of Article 49 EC, in the context of cross-border health care services, national

³⁴ Although it should be pointed out that the Commission was already meeting informally with water directors before the Water Framework Directive was proposed, and the Commission proposed the ‘common implementation strategy’.

practices based upon them would formally speaking remain subject to review for consistency with the EC Treaty. Still, given their legal pedigree within the Transformative Directive, the legal argument that those norms should be treated as consistent with Article 49 EC would be highly persuasive. Moreover, the actors involved would be subject to peer review, and would be required to narrate the reasons for their decisions, in ways which would be legally required to be transparent. This would allow political actors to contest the decisions reached. We would also add that hierarchical and court-based models of accountability tend to overstate their practical effectiveness.

The efficient use of resource issue focuses on the question of whether the creation of an elaborate network of working groups, reporting to a central body, with full transparency, is really an efficient use of the resources of government, in terms of resolving the questions raised by cross-border receipt of health care services. Our response to this is that this may seem an unnecessary structural elaboration, but this may appear less so in the context of the resource expense of the CCM approach and, in particular, law-making through litigation, which is a highly inefficient means of resolving the question of how to allocate health care resources within an internal market in health care services, and at the same time preserving the values of European health care systems, at a time of technological and regulatory change. We would also add that many of the mechanisms we envisage *are already in place*, and the proposed Transformative Directive would simply formalise their existence and the terms of reference of their working practices.

On the participation issue, as Smismans (2006) has noted, more heterarchical, horizontal and flexible modes of governance do not necessarily imply more participation and inclusion in terms of involving all stakeholders. There is a danger in the proposed XBHSC Strategy that those actors that are already empowered within the EU's governance structures will become entrenched and further empowered. There are some indications in the existing, informal governance structures that this would be the case. For instance, the civil society groups involved in the consultation which led to the setting up of the High Level Group on Health Services and Medical Care were all groups which had already worked closely with the Commission, and indeed, in the case of one of them, was set up by the Commission, which could suggest a 'semi-closed' network (Hervey, 2006). However, to counteract this, the Transformative Directive presents an opportunity to mandate, from the beginning, a process of reflection on the composition and working practices of the XBHCS Strategy. Furthermore, and more significantly, of course, the 'baseline' of litigation based on Article 49 EC remains. Although as noted above the implication would be that the soft norms developed under the XBHCS Strategy are consistent with Article 49 EC, ultimately this position would be only persuasive, not determinative. Therefore, an opportunity for litigation based on an argument that the guidelines failed to take into account important interests or factors would remain. This type of litigation can be used by stakeholders who feel that the existing new governance guidelines fail to take into account their interests sufficiently, and thereby destabilise the new governance process, so that a new, still reflexive, settlement is reached (Sabel and Simon, 2004).

Other objections to our proposal are more specifically related to its context, and in particular the constitutional contours of the European Union, and the ways in which the internal market has developed and interacted with national social policies, including national health care policies. We see two such problems: the ‘constitutional imbalance issue’ and the ‘competence issue’.

The notion of the ‘constitutional imbalance’ between social Europe and the internal market is well-established, notably through the work of Fritz Scharpf (1996; 2002). Scharpf (2002: 647; 655-658) points out that while, in the Member States, ‘economic policy’ and ‘social protection’ policy enjoy the same constitutional status, the direct effect and supremacy of internal market law, in the absence of equivalent EU social law, mean that this is not the case at EU level. Rather, national social protection policies remain vulnerable to challenge through private or Commission-sponsored litigation, on the basis that they infringe internal market or competition law. This is the case also for national social protection policies recognised as representing ‘best practice’ by the OMC, or equivalent processes.

Scharpf’s scepticism about the OMC as an appropriate response to the ‘constitutional imbalance’ between ‘the economic’ and ‘the social’ in the EU’s legal order rests upon a construction of the internal market *acquis* as being only about ‘economic policy’, and not also about ‘social-protection policy’. We would tend to disagree. The internal market *need not necessarily* be only an economic construct. Indeed internal market law already accommodates ‘social protection’ interests, for instance where the Court recognises objective public interest justifications, such as the financial stability of national health care systems, for national rules that *prima facie* infringe internal market law.

The proposal Scharpf promulgates as likely to rebalance the constitutional imbalance between the internal market and the social is to combine framework directives with OMC. This is in many respects similar to our suggestion for a Transformative Directive on cross border health care services. However, Scharpf’s proposed framework directives are firmly within the ‘social’, in terms of his dichotomous structure. In particular, they are to be based on Article 137 EC. Thus our Transformative Directive differs from Scharpf’s proposal, in that we envisage a dual legal basis (internal market and social policy), thereby embedding the ‘social protection’ aspects of cross-border health care services firmly *within* the construct of the internal market, rather than seeing these two concepts as constitutionally counterposed to one another. The Transformative Directive would thus provide a basis upon which, for instance, courts would be required to balance the interests of patients in being able to move freely with the interests of national health care systems in preserving values such as solidarity, financial viability and equal access, in the light of the detailed norms developed by relevant stakeholders as to the proper balance. This balancing exercise would be undertaken *within* the legal category of internal market law. Furthermore, the dual legal basis for the Transformative Directive would strengthen the constitutional position of the OMC health and long term care, by bringing its scope within that of the internal market.

A dual legal basis is also indicated by the final issue of concern: the competence issue. Put bluntly, this objection to our proposal is represented by the question:- How does the XBHCS Strategy, mandated by the Transformative Directive, relate to the (already existing) OMC health and long term care? To explain this issue, it is necessary to elaborate a little on the OMC health and long term care.

Recalling that the Barcelona European Council, March 2002, set three principles for reform of social protection systems, including health care, COM(2004) 304 set three broad objectives for an OMC in health and long term care based on these principles. The objectives 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. The Employment, Social Policy, Health and Consumer Affairs Council endorsed the OMC's principles in October 2004. Each Member State produced a preliminary national report in 2005 on their policies, practices and plans with respect to each of these principles. These preliminary reports cover a very wide range of health care policy issues. Access to health and long term care covers the range of services included or how comprehensive care is; the financial burden of care; geographical disparities of supply in health and long term care; constraints of staffing; waiting times; primary care, referral systems and care coordination; patient information; and health status and health inequalities. Quality of care covers mechanisms and policies for improvement of care quality standards; monitoring systems; assessment and evaluation of clinical and social interventions; care coordination; and patients' involvement and choice. Financial sustainability of health and long term care covers the general economic and social situation; the ageing population; inducing responsible individual behaviour, such as reducing obesity, promoting healthy use of alcohol, avoiding tobacco, for classic disease patterns; strengthening incentives for rational use of resources; technology development; and improving funding to the health and long term care sector.³⁵ Along with the OMC on social inclusion and the OMC on pensions, the OMC health and long term care is now being taken forward as part of the streamlined OMC on social protection and social inclusion.

If one thinks in terms of efficient or 'joined up' governance, the XBHCS Strategy would need to be part of, or at least closely coordinated with the 'pillar' on health and long term care within the streamlined OMC on social protection and social inclusion. However, looking at the list above, in order to bind in the types of issue that the OMC health and long term care has begun to look at would involve a legal basis for the Directive beyond the free movement of services (Articles 95 and 52 EC). In the environmental field, there is a separate substantive legal basis provision in Article 175 EC. Not only is this not the case in the health care field, but Article 152 EC explicitly states that 'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care'. If the Transformative Directive included giving powers to the EU to govern the organisation

³⁵ European Commission, DG Employment, Social Affairs and Equal Opportunities, *Review of Preliminary National Policy Statements on Health Care and Long-term Care* Memorandum of the Social Protection Committee, 30 November 2005.

and delivery of health services and medical care, the Directive would then be vulnerable to legal challenge through judicial review on the grounds of lack of competence.³⁶

One possible counter-argument to such a challenge would involve an extensive interpretation of free movement of health care services and what this then requires in terms of EU-level regulation. However, just this sort of argument failed in the *Tobacco Advertising* case.³⁷ A second possible counter-argument would be based upon the (implied) competence of the EU to embed and protect constitutional values and principles (such as transparency, participation and fundamental (social) rights). However, Article 6 TEU and the jurisprudence of the European Court of Justice with respect to the EU's competences in the field of fundamental rights,³⁸ suggest that fundamental rights act as a constraint on EU action, rather than as a positive basis for action. Therefore, this would seem an unlikely basis for a directive seeking to embed protection of fundamental procedural and substantive social rights in the governance of cross border receipt of health care. In any event, it would require the use of Article 308 EC, which may be politically impractical. It follows that a dual legal basis, including that on which the OMC on social protection and social inclusion is based (Article 137 (2) (a)), would therefore almost certainly be needed for the Transformative Directive that we envisage.

4. Broader Methodological/theoretical implications

It will be apparent that the inspiration for this article comes from our engagement with a number of scholars in the EU and US who are interested in what has been variously named 'new governance', 'experimentalist governance', 'democratic experimentalism', or 'directly deliberative polyarchy'. For the purposes of this article, we are influenced in particular by the methodological framework adopted by Joanne Scott, drawn from the field of EU environmental law. In a contribution to De Búrca and Scott's *Law and New Governance in the EU and US* (2006), Scott and Holder conceptualise the governance arrangements surrounding the EU's Environmental Impact Assessment (EIA) Directive and Water Framework Directive (WFD) in terms of Sabel and Gerstenberg's 'directly deliberative polyarchy' (Sabel and Gerstenberg, 2002). The EIA Directive is structured to provide 'the tools for iterative evaluation and adaptation' (Scott and Holder, 2006: 215). It requires regular information exchange between the Member States and the Commission. The Commission must issue implementation reports, which *inter alia* must propose amendments to the workings of the EIA Directive, to ensure it is being applied in a 'sufficiently coordinated manner'. These informational requirements

'underpin an approach to governance which is well-suited to conditions of complexity and diversity. This approach makes a virtue out of necessity, harnessing disagreement and diversity as resources for innovation and learning. These tools exemplify ... the distinctive character of European federalism, which rests increasingly upon coordination not harmonisation, and upon supervised decentralisation.' (Scott and Holder, 2006: 216)

³⁶ Article 230 EC.

³⁷ Case C-376/98 *Germany v Parliament and Council (Tobacco Advertising)* [2000] ECR I-8419.

³⁸ Opinion 2/94 *Re Accession of the Community to the European Human Rights Convention* [1996] ECR I-1759.

In addition to these types of requirements, the WFD has spawned a doctrinally informal ‘governance forum, which is committed to the pooling of information and experience, and to the elaboration of standards for comparing local achievements’ (Scott and Holder, 2006: 224). This, in the form of the ‘Common Implementation Strategy’, ‘provides for an “open method of cooperation” between the Member States, and between the Commission and the Member States, in the implementation of the Directive’ (Scott and Holder, 2006:226-7). The result is a ‘hybrid’ between old and new governance, in which the new supplements the old, and the old is constructed both to embrace and mandate the new.

Thus, our view that there is an opportunity for a ‘Transformative Directive’ on cross border health care services rests first and foremost on a construction of the European Union as a legally pluralist system, within which competencies and responsibilities are shared between EU, national and sub-national institutions. Here there is no ‘sovereign’, and no settled vertical or horizontal division of competences, but rather an apparently messy multi-actor regime, coordinated through EU level structures, but penetrating to the Member States’ national, or even lower, levels of governance where these institutional settings and actors need to be ‘brought to the table’ to resolve complex social problems, such as those at issue both in the case of environmental protection and in the case of managing cross-border movement of health care services in the EU’s internal market and territorially-based public national health care systems.

Within this system, formal legal rules are formulated at a high level of abstraction, but they are elaborated through a coordinated system of stakeholder multiparty dialogues. These dialogues result in soft law measures that are both revisable, and yet normative in both aspiration and effect. These norms render concrete, for the time being, the abstract formal legal rules, even though, being soft law, they are not technically legally enforceable as such. The actors involved in the process are ‘socialised’ by their participation, and this socialisation, coupled with the understanding that ‘old style command and control’ governance simply will not produce a workable or desirable outcome, prompts convergence around agreed soft norms. At the same time, a system of reporting is coordinated centrally, which allows the creation and dissemination of data, permitting peer review. Review of practice against the activities of peers prompts further change at the operational level, which then feeds through in an iterative process of norm creation, self-assessment, and norm revision. The soft norms are taken into account where courts (both national courts and the ECJ) are faced with challenges to Member State action on the basis that it is inconsistent with Treaty norms on free movement of services. The scope of permitted divergence from the Treaty norms on free movement (on the basis, for instance, that there is a justification for a practice of a national health care system based in social solidarity) is thus significantly clearer than at present. It is developed through deliberation of relevant stakeholders, taking into account the widest possible context, rather than through litigation, which by its very nature can only take into account the contexts of the particular legal claim being heard. At the same time, however, these rules are not ossified in a series of ‘snapshot’ judicial decisions. The whole system itself is also reflexive, in that its working practices, parties, conceptualisation of the problems at hand, and data on which those problems are approached, are subject to regular review, and thus incremental change. Moreover, they

are destabilised, in the sense that ‘constitutional’ litigation may at any time prompt a more radical departure from current practice, for instance by bringing new actors to the table or reviewing the data on which decisions are made.

Secondly, then, the proposal is also grounded in emergent theoretical understandings of the roles of law and new governance, and hybrid forms thereof, in a pluralist legal order (de Búrca and Scott, 2006; Trubek and Trubek, 2006). According to the ‘classical’ methodological perspective on EU law, the roles for law in the CCM include the management of the various interests at issue in the creation of the internal market, where questions such as those relating to risk or redistribution of resources are no longer totally within the control of national authorities. EC law, in part through secondary legislation, but in particular through litigation processes, finds a balance between the free movement of the factors of production and the protection of ‘objective public interests’ that may be placed in jeopardy by totally unregulated, neoliberal free movement. The CCM also envisages law as delivering democratic values such as accountability, through the judicial review of acts of administrative or governmental bodies. By contrast, experimentalist governance perspectives, and hybrid perspectives, envisage new, or at least additional, roles for law. Again following Scott and Holder, these are implicit in the notion of ‘embedded constitutionalism’ (Loughlin, 2003), where ‘the practice of governance has spawned a process of constitutionalisation from within, and a settling of expectations around certain core values; transparency, participation, accountability and the like’ (Scott and Holder, 2006: 238). The ‘law-ification’ of the practices of experimentalist governance in the EU – its foundation and revision being based on agreement between the Commission and the Member States, its encapsulation in documentary form, its expression in normative terms – creates expectations of behaviour to which relevant actors adhere. Moreover, over time, the hybrid of old and new may generate processes of functional spill-over that result in the formal articulation of these core values as legal (and ultimately enforceable) principles (see Scott and Holder’s discussion of comitology, 2006: 239-240). Thus, in brief, we reject the notion that ‘new governance’ is somehow extra-legal, but rather hold that ‘law’ extends beyond the classic ‘command and control’ and ‘principal-agent’ models implicit in the CCM.

Finally, the ‘Transformative Directive’ would represent an example of ‘transformation (hybridity)’ (Trubek and Trubek, 2006: 4) of old and new governance, where the procedures and institutions of ‘new governance’ and ‘traditional law’ (here the CCM) are structurally designed as an integrated system, each element of which relies upon the other for its success. The result would be a mutually reinforcing process which eschews the traditional legal dichotomy between law-making and its implementation and enforcement.³⁹ This approach sees ‘hybridity’ of old and new governance as bringing altered roles for legal norms and institutions. It both draws on the lessons of the classical ‘law-in-context’ literature, and responds to the opportunities presented by newer literature embracing the meanings and significance of law and governance in a legally pluralist constitutional system such as that of the European Union (Walker, 2006; de

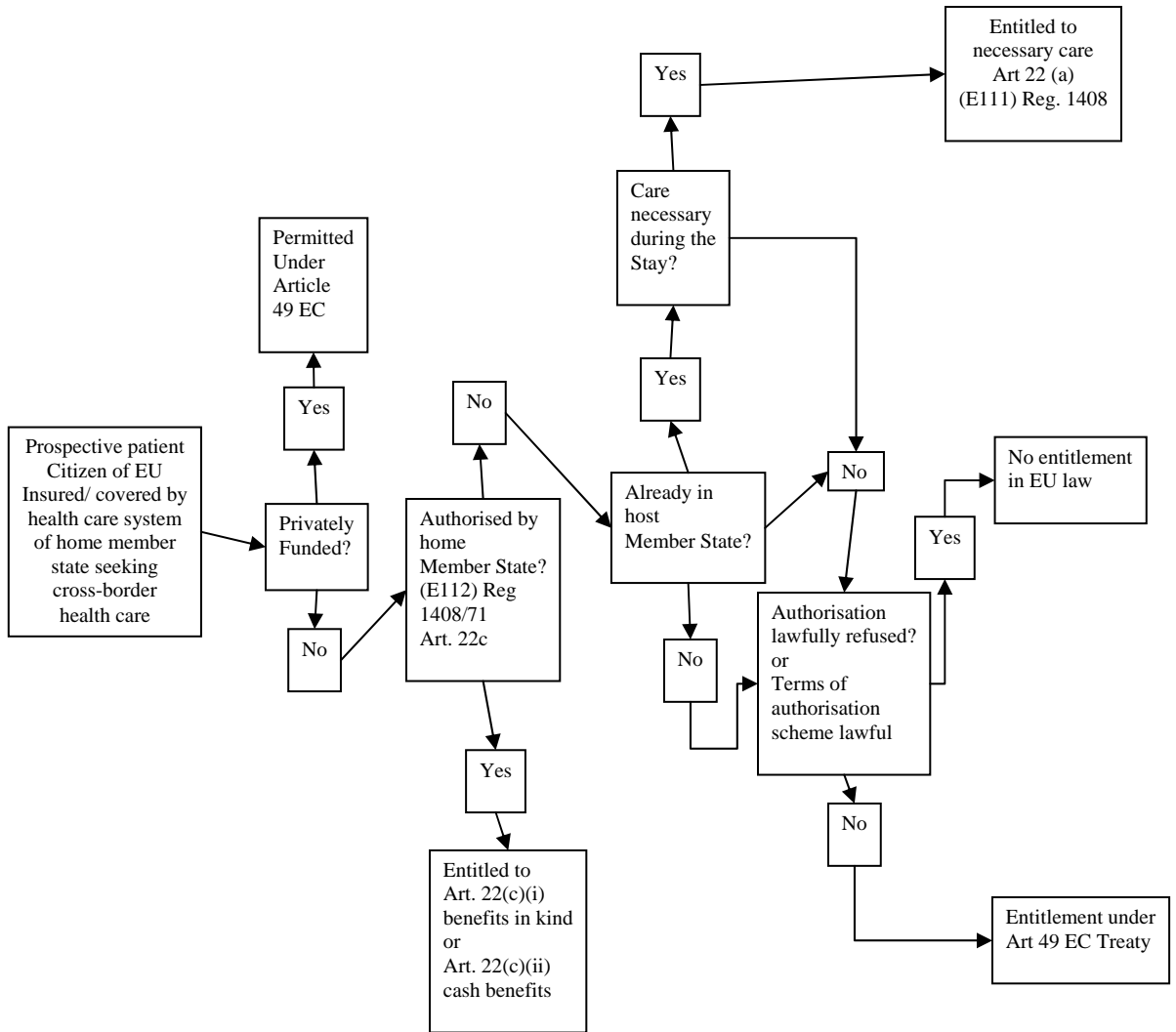
³⁹ It builds on, but goes beyond the ‘New Old Governance’ (NOG) identified by Joanne Scott and David Trubek (2002), in that the basis of the hybrid is truly mutually respecting of both CCM and ‘new governance’, not simply essentially CCM, with some ‘new governance’ bolt on.

Búrca and Scott, 2006; Walker 2003; Maduro, 2003; Walker, 2002). The new would transform the old, for instance, by making it more effective. The old would transform the new, for instance, by making it subject to certain legal (and enforceable) duties. The inclusion of values expressed as social rights within a legally binding text, as constraining new governance processes, may help to answer some of the objections to the use of OMC-type processes (Scharpf, 2002) within European social governance.

5. Conclusion

The failure of the Bolkestein Services directive to cover cross border health care services has opened up an opportunity for the consideration of alternative governance arrangements. The uncertainty and inappropriateness of leaving to the ECJ and national courts questions related to the application of Article 49 EC to national health care services suggest that there is likely to be political support for some kind of EU-level response. The Commission has indicated that it intends to take the issue forward (COM (2006) 160 final).⁴⁰ However, to recognise the failure of the CCM, and the promise of experimentalist governance, but at the same time to gain the benefits of agreeing a legal text, would mean to adopt a transformative hybrid of old and new governance. This would be explicitly constructed as a framework for participative rule-making, within broad substantive and procedural legal principles. Adopting the Transformative Directive will not be the end of the regulatory problem, leaving only ‘implementation’ to follow. The ‘meat’ of the legal text – the solutions to the problems raised by cross-border health care within the EU, and the ways of benefiting from the opportunities it presents – will come from the formally soft, but in reality adhered to, reflexive guidelines generated thereafter.

⁴⁰ The Commission is currently undergoing a consultation process, the deadline for responses to which is 31 January 2007, see http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/comm_health_services_comm2006_en.pdf. The results of this process may be signalled in the Commission’s interim report on the Internal Market in the 21st Century, to be presented to the Council in March 2007.



Entitlements of EU citizen patients seeking cross-border health care (Hervey, 2007).

Bibliography

- Abraham, J and G Lewis, 2000 *Regulating Medicines in Europe: Competition, Expertise and Public Health* (London: Routledge).
- Baeten, R 2001, 'European Integration and National Healthcare Systems: a challenge for social policy' 8 *infose* 1 (November).
- Barnard, C, 2004, *The Substantive Law of the EU: The Four Freedoms* (Oxford: OUP).
- Bernard, N, 2003, 'A "New Governance" Approach to Economic, Social and Cultural Rights in the EU' in T Hervey and J Kenner, eds, *Economic and Social Rights under the EU Charter of Fundamental Rights* (Oxford, Hart).
- Bertinato, L, R Busse, N Fahy, H Legido-Quigley, M McKee, W Palm, I Passarani and F Ronfini, 2005, *Policy Brief: Cross-border Health Care in Europe* (Brussels, World Health Organisation on behalf of the European Observatory on Health Systems and Policies).
- Callens, S, ed, 2003, *E-Health and the Law* (London, the Hague, New York, Kluwer Law International).
- De Búrca, G and J. Scott, 2006 'New Governance, Law and Constitutionalism' in G. de Búrca and J. Scott, eds, *Law and New Governance in the EU and US* (Oxford: Hart).
- De Schutter, O and S. Deakin (eds) (2005) *Social Rights and Market Forces: Is the open coordination of employment and social policies the future of social Europe?* (Brussels: Bruylant).
- Gerstenberg, O and C F Sabel, 2002, 'Directly-Deliberative Polyarchy: An Institutional Ideal for Europe?' in C Joeges and R Dehousse, *Good Governance in Europe's Integrated Market* (Oxford: OUP).
- Harlow, C and R Rawlings, 2006, 'Promoting Accountability in Multi-Level Governance: A Network Approach' *European Governance Papers (EUROGOV)* No C-06-02, <http://www.connex-network.org/eurogov/pdf/egp-connex-C-06-02.pdf>.
- European Commission, Ministero della Salute, Italy, Veneto Regional Government, Italy, and European Observatory on Health Systems and Policies, *Cross-Border Health Care: Challenges and Perspectives*, Venice, Italy, 26-27 October 2005
<http://www.regione.veneto.it/Organizzazione+Regionale/Sede+di+Bruxelles/Settori+di+Intervento/Sanit%C3%A0/CONFERENCE+ON+CROSSBORDER+HEALTH+CARE.htm>.
- Hervey, T, 2006, 'The European Union and the Governance of Health Care' in G de Búrca and J Scott, eds, *Law and New Governance in the EU and the US* (Oxford, Hart).
- Hervey, T, 2007, 'The current legal framework and the right to seek health care abroad', *Cambridge Yearbook of European Legal Studies* (forthcoming)
- Joeges, C and R Dehousse, 2002, *Good Governance in Europe's Integrated Market* (Oxford: OUP).
- Johnson, T, G Larkin and M Saks, eds, 1995, *Health Professions and the State in Europe* (London, Routledge).

- Jorens, Y, 2003, '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 Pieter Lang).
- Loughlin, M, 2003, *The Idea of Public Law* (Oxford, OUP).
- Lowson, K, P West, S Chaplin, J O'Reilly, 2002 *York Health Economic Consortium Document; Final Report; Evaluation of Treating Patients Overseas* (York: YHEC).
- Maduro, M P, 1998, *We the Court: The European Court of Justice and the European Economic Constitution* (Oxford: Hart)
- Maduro, M P, 2003 'Contrapunctual Law: Europe's Constitutional Pluralism in Action', in N. Walker (ed), *Sovereignty in Transition* (Oxford: Hart).
- McLean, T R, 2005 'The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities' 14 *Annals of Health Law* 205-264.
- Rowland, D, D Price and A Pollock, 'Implications of the draft EU services directive for health care' *The Lancet* Vol 364, 2 October 2004.
- Sabel, C F and W H Simon, 2004 'Destabilization Rights: How Public Law Litigation Succeeds' 117 *Harvard Law Review* 1015.
- Sabel, C F and W H Simon, 2006 'Epilogue: Accountability without Sovereignty' in G. de Búrca and J. Scott, eds, *Law and New Governance in the EU and US* (Oxford: Hart).
- Sabel C F and J Zeitlin, 2006, 'Learning from Difference: The New Architecture of Experimentalist Governance in the EU', paper presented at the workshop on *Law in New Governance*, University College London, May 2006.
- Scharpf, F, 1996, *A New Social Contract? Negative and Positive Integration in the Political Economy of European Welfare States* EUI Working Paper RSC 96/44.
- Scharpf, F, 2002, 'The European Social Model: Coping with the Challenges of Diversity' 40 *Journal of Common Market Studies* 645-670.
- Scott, J and D Trubek, 2002, 'Mind the Gap: Law and New Approaches to Governance in the European Union' 8 *ELJ* 1.
- Scott, J and J Holder, 2006, 'Law and New Environmental Governance in the European Union' in G. de Búrca and J. Scott, eds, *Law and New Governance in the EU and US* (Oxford: Hart).
- Smismans, S, 2005, 'Reflexive Law in Support of a Directly Deliberative Polyarchy: Reflexive-Deliberative Polyarchy as a Normative Frame for the OMC' in O. de Schutter and S. Deakin (eds) *Social Rights and Market Forces: Is the open coordination of employment and social policies the future of social Europe?* (Brussels: Bruylant).
- Smismans, S, 2006, 'New Modes of Governance and the Participatory Myth' *European Governance Papers (EUROGOV)* No N-06-01, <http://www.connex-network.org/eurogov/pdf/egp-newgov-N-06-01.pdf>.
- Streek, W, 1995, 'Neo-voluntarism: A New European Social Policy Regime?' 1 *ELJ* 31.

Trubek, D and L Trubek, 2005, 'Hard and Soft Law in the Construction of Social Europe: the role of the OMC' 11 *ELJ* 343-364.

Trubek, D and L Trubek, 2006, 'The Coexistence of New Governance and Legal Regulation: Complementarity, Rivalry or Hybridity? Paper for Workshop *The Rise of New Governance and the Transformation of Law* University of Wisconsin, Madison, 21-22 April 2006.

Walker, N, 2002, 'The Idea of Constitutional Pluralism' 65 *Modern Law Review* 317-359.

Walker, N, 2003, 'Late Sovereignty in the European Union', in N. Walker (ed), *Sovereignty in Transition* (Oxford: Hart).

Walker, N, 2006, 'Constitutionalism and New Governance in the EU: Rethinking the Boundaries' in G. de Búrca and J. Scott, eds, *Law and New Governance in the EU and US* (Oxford: Hart).

Weatherill, S, 1995 *Law and Integration in the European Union* (Oxford, OUP).

Zeitlin, J, P Pochet, with L Magnusson, eds, 2005 *The Open Method of Coordination: The European Employment and Social Inclusion Strategies* (Brussels, PIE Pieter Lang).