FREEDOM TO PROVIDE HEALTH CARE SERVICES WITHIN THE EU: AN OPPORTUNITY FOR A TRANSFORMATIVE DIRECTIVE

Tamara Hervey[*] *& Louise Trubek*[**]

In the context of free movement of health care services, "the classic Community method" (CCM) of regulation through harmonized internal market law, underpinned by Treaty-based litigation, has failed. At the same time, a plethora of new governance activities concerned with health care have grown up in the EU. This article argues that the current situation represents an opportunity to develop and design, ex ante, a new Transformative Directive on health care services. The Transformative Directive would articulate the formal legal rules on cross-border receipt and provision of health care services in the EU. At the same time, the Directive would set up a framework for creating non-binding norms through participatory mechanisms, such as those found in new governance processes that already exist in other areas of EU law. The Directive would represent an example of a transformative relationship between law (the CCM) and new governance, where the procedures and institutions of new governance and traditional law are structurally designed as an integrated system, each element of which relies on the other for its success.

[*] Professor of Law, University of Sheffield, United Kingdom.
[**] Clinical Professor of Law, Director of Health Law Project, University of Wisconsin-Madison, United States. This Article was 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 New Governance Law Taskforce II Conference, May 26–27, 2006, University College London; in particular David Trubek, Joanne Scott, Grainne de Búrca, Kenneth Armstrong and Diamond Ashiagbor.

INTRODUCTION

In the context of free movement of health care services, "the classic Community method" (CCM) of regulation through harmonized 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.[1] At the same time, a plethora of new governance activities concerned with health care have grown up in the European Union (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."

I. OUT WITH THE OLD AND IN WITH THE HYBRID: A TRANSFORMATIVE DIRECTIVE ON HEALTH CARE SERVICES

A. The Failure of the Classic Community Method and the Potential of New Governance

The failure of the CCM in the context of health care services can be attributed to two main reasons. The first belongs in the realm of practical politics. It is relatively easy to create a single EU-wide market in goods and services (the internal market) through "negative integration," by enforcing the directly effective internal market Treaty provisions through litigation. 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 EC[2] procedure, a qualified majority of votes in Council and the support of the European Parliament are necessary for the adoption of legislation.

The proposed Bolkestein Services Directive[3] represents a clear example of these difficulties. The original proposal generated much opposition, both from civil society and from EU institutions. A public demonstration against the proposal (virtually unheard of in EU political life), organized by NGOs and a broad coalition of left political parties, took place in Brussels on June 4, 2004.

---

[1] *Amended Commission Proposal on Services in the Internal Market*, COM (2006) 160 final (Apr. 4, 2006) [hereinafter *Amended Bolkestein Proposal*].

[2] Treaty Establishing the European Community, art. 251, Nov. 10, 1997, 1997 O.J. (C 340) 3 [hereinafter EC Treaty].

[3] *Commission Proposal on Services in the Internal Market*, COM (2004) 2 final (Mar. 5, 2004) [hereinafter *Bolkestein Proposal*].

The European Parliament's report of December 2005 incorporates fundamental changes to the proposal, including scrapping the keystone "country of origin principle"[4] from the text. This principle was one of the elements of the proposal most criticized by those concerned with the application of the proposal to health care services.[5] The country of origin principle was seen as opening the floodgates to a deregulatory race to the bottom, or leveling down in quality standards and professional qualifications requirements in the European health care sector. Such a phenomenon was highly unattractive, 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 pay for lapses of quality of health care within their public provision, either by providing compensation, or by providing further treatment to remedy the health problems caused by the lapse of quality.[6] This push towards leveling down was seen as a lost opportunity for the EU, whose work, according to these critics, should be geared towards the objective of "upwards" convergence or harmonization.

More fundamentally, though, critics of the proposal in terms of its application to health care services concentrated on the challenge that the proposal implied to the public understandings of health care in the European context. In Europe, health care is not viewed 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 healthcare 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, other than in the context of cross-border receipt of health care services, or movement of health care professionals. The Treaty Establishing the European Community (EC Treaty, 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 organization and delivery of health services and medical care."[7] The European Court of Justice (Court, ECJ) has consistently affirmed that the organization and

---

[4] The principle would have provided that service providers established in any Member State of the EU could have lawfully offered their services across the EU, so long as they complied with the regulatory requirements of the Member State in which they were established. The principle was controversial because regulatory standards for services, including health care services, vary widely across the Member States. Those Member States with higher standards were concerned that service providers from Member States with lower standards would use this competitive advantage to undercut their service providers, and also, potentially jeopardize consumers of the services, whom the standards are designed to protect.

[5] *See generally* David. Rowland, David. Price, & Allyson M.. Pollock, *Implications of the Draft European Union Services Directive for Health Care*, 364 LANCET 1200 (2004) (Eng.).

[6] It is already the case that the public health care systems of the Member States treat patients who have medical problems caused by lapses in quality of treatment on the part of health care professionals, including medical negligence, in the private sector.

[7] EC Treaty art 152.

delivery of health care services is the responsibility of the Member States.[8] This lack of competence results in the well-recognized "constitutional imbalance" arising from the relative ease of negative integration compared to positive integration.[9]

In the cross-border health care context, this "constitutional imbalance" 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 destabilizing 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 recognized that Member States may have an "objective public interest"[10] 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,[11] the financial viability of such social security systems[12] and consumer protection[13] (consumers here being the patients). Nevertheless, due to the nature of litigation processes in general, and the Article 234 EC reference procedure in particular, such a rebalancing will always be incomplete.

However, "new modes of governance,"[14] have much to offer to the problem of governing cross-border health care within a legally pluralist European Union.

---

[8] *See* Case 238/82, Duphar BV and Others v. Netherlands 1984 E.C.R. 523, ¶ 16; Case C-159/91, Poucet and Pistre v. Assurances Générales de France, 1993 E.C.R. I-637, ¶ 6; Case C-70/95, Sodemare and Others v. Regione Lombardia, 1997, E.C.R. I-3395, ¶ 27; Case C-120/95, Decker v. Caisse de Maladie des Employés Privés, 1998 E.C.R. I-1831, ¶ 21; Case C-158/96 Kohll v. Union des Caisse de Maladie des Employés Privés 1998 E.C.R. I-1931, ¶ 17; Case C-157/99, B.S.M. Geraets-Smits v. Stichting and H.T.M. Peerbooms v. Stichting, 2001 E.C.R. I-5473,¶ 44; Case C-372/04, Yvonne Watts v. Bedford Primary Care Trust, 2006 E.C.R. I-4325, ¶ 146.

[9] STEPHEN WEATHERILL, LAW AND INTEGRATION IN THE EUROPEAN UNION (1995); Wolfgang. Streek, *Neo-Voluntarism: A New European Social Policy Regime?*, 1 EUR. L. J. 31 (1995); MIGUEL POIARES. MADURO, WE THE COURT: THE EUROPEAN COURT OF JUSTICE AND THE EUROPEAN ECONOMIC CONSTITUTION (1998).

[10] Case 205/84, Commission v. Germany, 1986 E.C.R. 3755, ¶ 30; Case C-288/89, Antennevoorziening Gouda and Others v. Commissariaat voor de Media, 1991 E.C.R. I-4007, ¶ 27; Case C-76/90, Säger v. Dennemeyer, 1991 E.C.R. I-4221,¶ 15; Case C-275/92, Her Majesty's Customs and Excise v. Schindler, 1994 E.C.R. I-1039, ¶ 58; Case C-272/94, Michel Guiot and Climatec SA, 1996 E.C.R. I-1905; *Decker*, 1998 E.C.R. I-1831; *Kohll*, 1998 E.C.R. I-1931; *Geraets-Smits and Peerbooms*, 2001 E.C.R. I-5473; Case C-368/86, AbdonVanbrackel and Others v. Alliance Nationale des Mutualités Chrétiennes, 2001 E.C.R. I-5363; Case C-8/02, Ludwig Leichtle v. Bundesanstalt für Arbeit, 2004 E.C.R. I-2641; *Watts*, 2006 E.C.R. I-4325.

[11] *Guiot and Climatec*, 1996 E.C.R. I-1905.

[12] *Decker*, 1998 E.C.R. I-1831; *Kohll*, 1998 E.C.R. I-1931; *Geraets-Smits and Peerbooms* 2001 E.C.R. I-5473; *Vanbraekel*, 2001 E.C.R. I-5363; *Leichtle*, 2004 E.C.R. I-2641; *Watts*, 2006 E.C.R. I-4325.

[13] *Commission v Germany*, 1986 E.C.R. 3755, ¶ 30; *Gouda*, 1991 E.C.R. I-4007, ¶ 27; *Säger*, 1991 E.C.R. I-4221,¶ 15; *Schindler*, 1994 E.C.R. I-1039, ¶ 58.

[14] Joanne Scott & David M. Trubek, *Mind the Gap: Law and New Approaches to Governance in the European Union*, 8 EUR. L. J. 1 (2002); Oliver Gerstenberg & Charles F. Sabel, *Directly-Deliberative Polyarchy: An Institutional Ideal for Europe?, in* GOOD GOVERNANCE IN EUROPE'S INTEGRATED MARKET (C. Joeges & R. Dehousse eds., 2002); Joanne Scott & Jane Holder, *Law and New Environmental Governance in the European Union, in* LAW AND NEW GOVERNANCE IN THE EU AND THE US (Gráinne de Búrca & Joanne Scott eds., 2006); Charles F. Sabel & Jonathan Zeitlin, *Learning from Difference: The New Architecture of Experimentalist Governance in the EU* (paper presented at Law in New Governance Workshop, University College London, May 2006).

Member States share a need to respond to common problems in their health care systems, while simultaneously protecting the values represented by the "European Social Model."[15] Nevertheless, Member States must manage to protect these values within the context of their Treaty obligations to create and sustain an internal market characterized, *inter alia*, by the free movement of services and by a situation of formally limited EU-level competence. New governance can offer "bottom up" solutions to complex social problems, where "top down" regulation has either failed to deliver, or where it is constitutionally unavailable.[16] This is exemplified in the EU's institution of an "open method of coordination" (OMC) in health and long term care,[17] 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 new governance type structures engaging with health care in the EU, in particular the work of the High Level Group on Health Services and Medical Care.[18] Moreover, health is a policy sector that has historically drawn heavily on self-regulatory structures,[19] 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 new 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

---

[15] David M. Trubek & James S. Mosher, *Alternative Approaches to Governance in the EU: EU Social Policy and the European Employment Strategy*, 41 J. COMMON MKT STUD. 63, 64 (2003), state that the European social model represents:

> [A] commitment to expansive benefits, relative wage and income equality, and coordinated bargaining by organized interest groups where it existed, and to spread it to where it was missing. Although the term underplays the diversity among west European states, it is used in official and academic circles and represents a desire to maintain protection in those countries that have advanced welfare states and expand it in those that do not.

[16] *See, e.g.*, THE OPEN METHOD OF COORDINATION: THE EUROPEAN EMPLOYMENT AND SOCIAL INCLUSION STRATEGIES (Jonathan Zeitlin, Phillipe Pochet, & Lars Magnusson eds., 2005). Also see the works cited in the OMC Bibliography, *available at* http://eucenter.wisc.edu/OMC/open12.html.

[17] *Commission Communication on 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 (Apr. 20, 2004). This was endorsed by the Employment, Social Policy, Health and Consumer Affairs Council in October 2004. *See also Commission Communication on the Future of Health Care and Care for the Elderly: Guaranteeing Accessibility, Quality, and Financial Viability*, COM (2001) 723 final (Dec. 5, 2001); JOINT REPORT BY THE COMMISSION AND THE COUNCIL ON SUPPORTING NATIONAL STRATEGIES FOR THE FUTURE OF HEALTH CARE AND CARE FOR THE ELDERLY, Council Doc. 7166/03 (Mar. 10, 2003).

[18] *See* Tamara Hervey, *The European Union and the Governance of Health Care*, *in* LAW AND NEW GOVERNANCE IN THE EU AND THE US, *supra* note 14.

[19] *See generally* HEALTH PROFESSIONS AND THE STATE IN EUROPE (Terry Johnson, Gerry Larkin, & Mike Saks eds., 1995).

benefits of experimentalism without retreating totally beyond the legal constraints that help to secure democratic values in the EU's governance processes. Charles Sabel and Jonathan Zeitlin[20] 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."[21] 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."[22] 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,"[23] the new architecture of EU governance may be said to operate neither through 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"[24] of the CCM. The case law of the European Court of Justice on the subject shows the unsatisfactory nature of case-by-case *ex post* procedures for a complex and evolving policy area. In our view, this situation has created a climate in which relevant actors have strong vested interests in participating in soft law structures and in adhering to the norms that they create.

Given the interface between internal market entitlements and social rights, which in some Member States are 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 European Court of Justice, 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 and then revised in the light of technological or other societal changes. Second, litigation based on the direct effect

---

[20] Sabel & Zeitlin, *supra* note 14.

[21] Joshua Cohen & Charles Sabel, *Directly Deliberative Polyarchy* 4 EUR. L. J. 314 (1997); Gerstenberg & Sabel, *supra* note 14.

[22] Sabel & Zeitlin, *supra* note 14, at 49.

[23] *Id.* at 50–51.

[24] *Id.*

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 summarize, we take the view that European citizens are not well served by having the question of when Member States may diverge from the obligations of Article 49 EC in their health care systems resolved by the European Court of Justice. This is because the European Court of Justice 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 jurisprudence in terms of the cases actually brought before it. The court-centered approach creates an opportunistic, piecemeal, litigation-based, unstable legal situation, in which, the main winners are those who are equipped to litigate. European citizens would be better served by having 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. The guidelines would be developed by reflexive discussion of all relevant stakeholders brought around the table and coordinated by the European Commission. There would be a coordinated exploration of the benefits that cross-border health care can bring to European health care systems, with their fundamental principles and values.

B. The Legal Context on Freedom to Provide Services

Any legislation seeking to regulate the free movement of health care services within the EU must take into account the three possibilities for free movement of services:[25] the service provider (the health care professional) moves, the service itself (the medical treatment or health care) moves, or the service recipient (the patient) moves.[26] All three have potential application to the health care situation, but our main focus for the purposes of this Article 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, the cross-border health care 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 in order to clear waiting lists in UK hospitals, or used general practitioners from other EU Member States to cover unpopular working times under the NHS 'Out of Hours' scheme.[27]

---

[25] CATHERINE BARNARD, THE SUBSTANTIVE LAW OF THE EU: THE FOUR FREEDOMS 331–33 (2004).

[26] All of these three types of cross-border health care services are also found in the United States of America, where they tend to be referred to as "medical tourism" or "offshoring." *See* Thomas. R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities* 14 ANN. HEALTH L. 205 (2005).

[27] Roger Boyes, *Striking Doctors on the March in Germany*, THE TIMES (UK), Jan. 19, 2006, *available at* http://www.timesonline.co.uk/article/0,,13509-1995603,00.html; Press Release, Paramedic UK, Casualty Busier after GP Service Changes (Sept. 2004), *available at* http://www.paramedic.org.uk/news_archive/2004/09/News_Item.2004-09-10.3211/view; Press Release, Portsmouth NHS Trust, Patients

The second possibility for free movement of services—where the service itself moves, but the provider and recipient remain in different Member States—could be utilized in the provision of e-health. The nascent market in cross-border e-health in the EU has not yet had significant impact on national health care provision, or the regulation of public health service providers.[28] However, there is scope for such an impact to arise in the future. In the *DocMorris* case,[29] the European Court of Justice 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, although the *DocMorris* case concerned free movement of *goods*, free movement of services would be engaged by such cross-border receipt of e-health care services.

The final possibility for engagement of free movement of services—where the service recipient moves—is the best known. The service recipient may be an individual patient who seeks health care in another Member State where the service is to be paid for by his or her 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, and spending less money on the co-payment element of the health care.[30]

Free movement of service recipients may also be engaged where groups of patients move, such as 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), 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.[31] The aim of the HLG is to "improve top level coordination among EU members on a broad range of health issues."[32]

Benefit from European Initiative (Aug. 1, 2003), *available at* http://www.portshosp.org.uk/news/aug03_pr.asp.

[28] E-HEALTH AND THE LAW (Stefaan Callens ed., 2003).

[29] Case C-322/01, Deutscher Apothekerverband e.V. v. DocMorris, 2003 E.C.R. I-14887.

[30] This type of free movement of services is illustrated by cases such as Case C-158/96, Kohll, 1998 E.C.R. I-1931; Case C-157/99, Geraets-Smits and Peerbooms, 2001 E.C.R. I-5473; Case C-368/86, Vanbraekel, 2001 E.C.R. I-5363, ¶ 42; Case C-385/99, V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij, 2003 E.C.R. I- 4509; Case C-56/01, Inizan, 2003 E.C.R. I-12403; Case C-8/01, Leichtle, 2004 E.C.R. I-2641; Case C-145/03, Keller v. INSS, 2005 E.C.R. I-2529; Case C-372/04, Watts, 2006 E.C.R. I-4325.

[31] "DG SANCO" is the Directorate General—like a government department—of the European Commission that is concerned with health and consumer protection.

[32] Letter from Robert Madelin, Director General for Health and Consumer Protection, HLG/2004/1 (May 4, 2004), *available at* http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2004_001_en.pdf.

C. The Current Legal Position

The current legal position of a patient seeking health care in another Member State is governed by the interactions between Regulation 1408/71/EEC[33] (to be replaced by Regulation 883/2004/EC),[34] 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.[35] If the health care sought by the patient has been "authorized"[36] by the home Member State under Regulation 1408/71/EEC, Article 22 (c), the patient is entitled to health care ("benefits in kind")[37] provided by the host institution on behalf of the home institution, or cash benefits to pay for such health care. This kind of cross-border health care is administered under the E112 scheme. Under the scheme, benefits in kind are to be reimbursed at the rate of the home state,[38] but only for benefits that are provided in the home state.[39] 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), is the patient has a right to receive "necessary care"[40] in the host Member State. Necessary care is defined as 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."[41] Where the host Member State gives benefits in kind, they are to be provided "as though the patient were insured"[42] in the host Member State. If the patient paid up front, then the home Member State must reimburse the patient or his or her heirs.[43] It is not clear whether this principle applies to non-urgent care, although it probably does not.[44]

In some circumstances, either under the legislative scheme, or in terms of the Treaty provisions, Member States may lawfully refuse authorization for cross-border health care. For instance, if either (i) the treatment is not among those provided for by the legislation of the home Member State; or (ii) 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 authorization may lawfully be refused (provided that the Treaty rules are not thereby infringed).[45] So, for instance, a new, experimental treatment

---

[33] 1971 O.J.(L 149) 2.

[34] 2004 (L 166) 1. This measure will come into effect when the implementing legislation has been adopted. *See also Commission Proprosal for a Regulation of the European Parliament and of the Council Laying Down the Procedure for implementing Regulation (EC) No 883/2004 on the Coordination of Social Security Systems*, COM (2006) 16 final (Jan. 31, 2006).

[35] See Figure 1, *infra*, for a summary.

[36] Regulation 1408/71/EEC, *supra* note 33, art. 22(c).

[37] *Id.*

[38] Case C-368/98, Vanbraekal, 2001 E.C.R. I-5653.

[39] Commission Regulation 1408/71/EEC, *supra* note 33, art. 36.

[40] *Id.* art. 22(a).

[41] *Id.*

[42] *Id.*

[43] Case C-145/03, Keller v. INSS, 2005 E.C.R. I-2529, ¶ 69.

[44] Tamara Hervey, *The Current Legal Framework and the Right to Seek Health Care Abroad*, CAMBRIDGE Y.B. EUR. L. STUD. (forthcoming, 2007).

[45] Commission Regulation 1408/71/EEC, *supra* note 33, art. 22 (2)

may not 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 authorization system itself is lawful, in the sense that the Treaty rules are not thereby infringed). Another example where authorization 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."[46] Each patient must be assessed on a case-by-case basis.[47] The European Court of Justice has also applied these rules in the context of considering justifications for restrictions—which include national rules to protect consumers, national rules to safeguard the social protection provided by national social security systems, or the financial viability of national social security systems—under Article 49 EC.[48] A third example, which applies where hospital care is concerned, is that prior authorization for treatment may be refused in pursuit of an objective public interest, such as protecting the financial stability and balance of a national health care system.[49]

However, if authorization has not been lawfully refused, or the terms of the authorization scheme are unlawful, then the patient enjoys a right, based on the "direct effect" [50] of EU law, to have the medical treatment reimbursed by the home Member State. Examples of unlawful refusal of authorization, or terms of authorization schemes that are unlawful, include the following:

(i) A scheme is unlawful if non-hospital care is available without authorization in the home Member State, but authorization is required for such care in a host Member State.[51] This is clearly a "restriction"[52] 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.

(ii) In principle, a scheme is unlawful if hospital care is available without authorization for care in a hospital with which the national sickness fund has an agreement, but authorization is required where the hospital does not have such an agreement, as such hospitals are more likely to be in other Member States.[53] However, the European Court of Justice 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

---

[46] C-157/99, Geraets-Smits and Peerbooms, 2001 E.C.R. I-5473, ¶ 103; Case C-385/99, V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij, 2003 E.C.R. I-4509, ¶ 89; Case C-56/01, Inizan, 2003 E.C.R. I-12403, ¶ 45.

[47] Case C-372/04, Watts, 2006 E.C.R. I-4325.

[48] *See supra* notes 10–12.

[49] *See* Case C-120/95, Decker v. Caisse de Maladie des Employés Privés, 1998 E.C.R. I-1831; Case C-158/96 Kohll, 1998 E.C.R. I-1931; *Geraets-Smits and Peerbooms*, 2001 E.C.R. I-5473; Case C-368/86, Vanbraekel, 2001 E.C.R. I-5363; *Müller-Fauré and Van Riet*, 2003 E.C.R. I-4509; Case C-8/01, Leichtle, 2004 E.C.R. I-2641; *Watts*, 2006 E.C.R. I-4325.

[50] *See* Case 26/62, NV. Algemeine Transporten Expeditie Onderneming, 1963 E.C.R. 1.

[51] *Kohll*, 1998 E.C.R. I-5363.

[52] EC Treaty art. 49.

[53] *Geraets-Smits and Peerbooms*, 2001 E.C.R. I-5473, ¶¶ 67–69.

effort to guarantee a rationalized, stable, balanced and accessible supply of hospital services."[54]

(iii) Combining 1 and 2 above, a scheme is unlawful if authorization is required for non-hospital care only with a provider with whom the health insurance body has not contracted. Such a scheme is unlikely to be justified by the financial impact on the home Member State's health care system.[55]

(iv) A scheme is unlawful where authorization for health care and the associated costs of health care (board, lodging, travel, visitors' tax) in an institution of 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" [56] there. Such a condition, by its very nature, has the effect of inhibiting cross-border receipt of health care services. Again, in principle, the scheme could be justified.

(v) A scheme is unlawful if the level of payment is lower where the health care is sought in another Member State.[57] Such a situation 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*[58] this was found not to be the case. There, the patient was in fact entitled to authorization 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, the application of the Treaty to support cross-border patient care would not give rise to a *greater* financial burden for the home Member State.[59]

(vi) A scheme is unlawful if the basis on which authorization is given is by reference only to national professional circles within the home Member State. EU law requires that the assessment of whether authorization is granted be by reference to international medical science.[60] Here, questions arise about how one determines the views of "international medical science,"[61] given the constant developments in the understanding of disease and treatment and significant cultural differences between medical professionals across the EU, and indeed the world.

(vii) If authorization may be refused when 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"[62] then when this is not

---

[54] *Id.* ¶ 81; *Müller-Fauré and Van Riet*, 2003 E.C.R. I-4509, ¶ 82.

[55] *See Müller-Fauré and Van Riet*, 2003 E.C.R. I-4509, ¶¶ 93–98.

[56] Case C-8/01, Leichtle, 2004 E.C.R. I-2641, ¶¶ 36, 42.

[57] Case C-368/86, Vanbraekel, 2001 E.C.R. I-5363.

[58] *Id.*

[59] *Id.*

[60] C-157/99, Geraets-Smits and Peerbooms, 2001 E.C.R. I-5473, ¶ 94.

[61] *Id.*

[62] *Geraets-Smits and Peerbooms*, 2001 E.C.R. I-5473, ¶ 103; Case C-385/99, V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij, 2003 E.C.R. I- 4509, ¶ 89; Case C-56/01, Inizan, 2003 E.C.R. I-12403, ¶ 45; Case C-372/04, Watts, 2006 E.C.R. I-4325.

the case, refusal to authorize is unlawful. "Undue delay" must be determined by reference to the individual patient.[63]

(viii) A scheme is unlawful if the authorization scheme requires that the patient wait for authorization, including challenging a refusal of authorization before the courts, *before* undertaking the treatment. The European Court of Justice has confirmed this, both in the context of authorization under Regulation 1408/71/EEC[64] and in the context of Article 49 EC.[65] 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.

(ix) A scheme is unlawful if the authorization scheme or system is not procedurally transparent and accessible, and subject to judicial review, that is to say, based upon reasoned articulations of decisions made concerning authorization.[66] Where authorization schemes lack transparency and reviewability, the ability of patients to enforce their rights in EU law is compromised. This lack of enforceability 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, because EU law entitles some patients to reimbursement for health care to which they would not otherwise be entitled. Neither is a Member State wholly in control of cross-border receipt of health care 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 proportionality.[67] Although the law is complex, that is not the problem here. Rather, as the operation of national health care systems evolves, such as when 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 EU law will itself constantly evolve. This situation represents an undesirably high degree of uncertainty for the regulatory landscape in this field.

---

[63] *Watts*, 2006 E.C.R. I-4325.

[64] Case C-368/86, Vanbrackel, 2001 E.C.R. I-5363, ¶ 34.

[65] Case C-8/01, Leichtle, 2004 E.C.R. I-2641, ¶¶ 55–59.

[66] *Geraets-Smits and Peerbooms*, 2001 E.C.R. I-5473, ¶ 103, ¶90; *Müller-Fauré and Van Riet*, 2003 E.C.R. I-4509, ¶ 85; *Inizan*, 2003 E.C.R. I-12403, ¶ 48; *Watts*, 2006 E.C.R. I-4325.

[67] *See, e.g.*, Case C-76/90, Säger v. Dennemeyer, 1991 E.C.R. I-4221; Case C-180/89, Commission v. Italy (Tourist Guides), 1991 E.C.R. I-709.

D. Opportunities and Threats

The current legal position gives rise to a number of potential opportunities and threats. Those who see the litigation surrounding the free movement of patients as a *threat* to national health (insurance) systems focus, in particular, on the impact of the litigation on the stability and internal balance of national health (insurance) systems and the viability of their social goals.[68] 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 sustaining 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. Closure of hospitals could jeopardize 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 recognized 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*[69] imply that decisions about cost-effectiveness may no longer be kept within the closed territory-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. In effect, states use hospital waiting lists as a tool to constrain spending. Waiting lists also arise as a logical consequence of decisions about resource allocation. Cases such as *Müller-Fauré*[70] and *Watts*[71] imply some loss of control at a 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 centers of excellence for highly specialized treatments, and in foreign tourist centers. 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.[72] Moreover, Member States share common challenges to their

---

[68] *See, e.g.*, Rita Baeten, *European Integration and National Healthcare Systems: A Challenge for Social Policy*, 8 INFOSE 1 (Nov. 2001) (Belg.), *available at* http://www.ose.be/files/infose/infose8EN.pdf; Yves Jorens, *The Right to Health Care Across Borders*, *in* THE IMPACT OF EU LAW ON HEALTH CARE SYSTEMS 83 (Martin McKee et al. eds, 2002).

[69] *Geraets-Smits and Peerbooms*, 2001 E.C.R. I-5473.

[70] *Müller-Fauré and Van Riet*, 2003 E.C.R. I-4509.

[71] *Watts*, 2006 E.C.R. I-4325.

[72] *See* KARIN LOWSON ET AL., YORK HEALTH ECONOMICS CONSORTIUM, EVALUATION OF TREATING PATIENTS OVERSEAS—FINAL REPORT (2002), *available at* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005742; LUIGI BERTINATO ET AL., WORLD HEALTH ORGANIZATION ON BEHALF OF EUROPEAN OBSERVATORY ON HEALTH SYSTEMS

national health care systems, including the need to ensure quality of care, the need to assess technological developments in terms of their comparative therapeutic efficiency[73] 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 must also be met in the context of an EU internal market for health care services. These opportunities suggest that new governance mechanisms could provide a means to capitalize on the benefits of common action at the EU level in a field where the CCM is not available, either in law, or in practice.

E. The Contours of a Transformative Directive

We see the current unsatisfactory 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.

The first component would articulate the formal substantive legal rule in highly abstract and simple terms. Using the Water Framework Directive,[74] which aims to achieve good water quality by the end of 2015, as a guide, the basic formal legal rule should be simple and general, and should read as follows: "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 use this basic language and nothing else 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 European Court of Justice under Article 234 EC. This would leave in place all the resultant uncertainty of the current legal position and unrealized 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 that the CCM alone will deliver in this instance.[75]

AND POLICIES, POLICY BRIEF: CROSS-BORDER HEALTH CARE IN EUROPE (2005), *available at* http://www.mig.tu-berlin.de/files/2005.publications/2005.bertinato.l.pdf.

[73] JOHN ABRAHAM & GRAHAM LEWIS, REGULATING MEDICINES IN EUROPE: COMPETITION, EXPERTISE AND PUBLIC HEALTH (2000).

[74] Council Directive 2000/60, 2000 O.J. (L 327) 1. *See* Holder & Scott, *supra* note 14; David Trubek & Louise Trubek, *New Governance and Legal Regulation: Complementarity, Rivalry, or Transformation*, 13 COLUM. J. EUR. L. 539 (2007).

[75] We reach this conclusion in light of the experience of the Bolkestein Services Directive, Directive 2006/123/EC on Services in the Internal Market, 2006 O.J. (L376) 36; the constitutional position of

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 new governance institutions and mechanisms, which form a framework for creating rules, to breathe life into the formal legal provisions. Such a framework would be established, not primarily through litigation processes, but through the generation of soft law through iterative participatory processes. Thus, what emerges is an opportunity for a hybrid form of old and new governance. The roles played by formal, hard, old law in this hybrid are to create a framework rule, to bring to bear certain constitutional values and rights, and to set legal duties relating to the new governance processes. The new governance processes operate to generate and exchange information and data, to develop guidance, and to review, test, and validate practice.[76]

Following the model of the water quality Common Implementation Strategy, as outlined by Joanne Scott and Jane Holder[77] and David Trubek and Louise Trubek[78] 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 XBHCS Strategy already exist in informal mechanisms. 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 HLG, 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) would report. The working groups would be required to bring in expertise 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 element of our proposal builds on the practices operating within the OMC and also those of the HLG. For instance, the existing Guidelines on Cross-Border Block Purchasing, developed by the HLG, do bring in expertise and examples of good practice from all relevant levels of governance 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.

---

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."

[76] *Id.* at 215–24.

[77] *Id.* at 224–33.

[78] Trubek & Trubek, *supra* note 74.

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 new governance. Without generation and exchange of comparable data, there can be no peer review and no reflexive learning, which are at the very heart of new governance. As in the case of the Environmental Impact Assessment (EIA) Directive,[79] 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 to enable the testing and validation of different national practices.

In terms of guidance development, the strategic coordination group—the successor to the HLG—would determine what detailed guidance would be necessary to develop general formal legal rules in the proposed Transformative Directive. This would be carried out in consultation and collaboration with the working groups. A number of types of guidance may be envisaged. Guidelines could elaborate the notion of "undue delay".[80] Standards by which Member States may refuse to authorize new therapeutic treatments could be set. Guidelines could elaborate the bases for cross-border health care block purchasing either where patients move,[81] 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. These guidelines could include, for instance, the measures of data protection, privacy, and confidentiality that are to govern cross-border health care services, and to which quality/professional standards, such as duties to give information, apply.[82] Guidelines could be developed on malpractice and near miss reporting, and on continuing professional education.

Thirdly, 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 the convergence of national practice around certain quantifiable environmental

---

[79] Council Directive 85/337, 1985 O.J. (L 175) 40 (as amended). The Directive requires an environmental impact assessment to be carried out for certain projects which have a physical effect on the environment. The environmental impact assessment must identify the direct and indirect effects of a project on the following factors: man, fauna and flora, soil, water, air, climate and the landscape, interaction between the aforementioned elements, and the material assets, and cultural heritage.

[80] Case C-372/04, Watts v. Bedford Primary Care Trust, 2006 E.C.R. I-4325

[81] Some of this work has already been done by the HLG.

[82] For example, whether a hospital is obliged to give statistical information on the therapeutic outcomes of its operations.

standards. In the context of the XBHCS Strategy, the aim would instead 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, in order 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 centers 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 new 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 be open and transparent. There would be an obligation to publish the data on which any guidelines would be 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 and national ministries), health care providers (hospitals and health care professionals), and health care recipients (patients). Scott and Holder note "some vagueness"[83] on matters of participation in the case of the Water Directive—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*.[84] Setting the new 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.[85] Finally, the reflexive mechanism set up by the Transformative Directive would *itself* be revisable.

---

[83] Scott & Holder, *supra* note 14, at 228.

[84] It should be pointed out that the Commission was already meeting informally with water directors—Member State representatives with overall responsibility for water policy, usually the head of the water division in the ministry responsible for the environment—before the Water Framework Directive was proposed, and that the Commission proposed the common implementation strategy.

[85] On the relationship between new governance and fundamental social rights, see generally Nicholas Bernard, *A "New Governance" Approach to Economic, Social and Cultural Rights in the EU*, *in* ECONOMIC AND SOCIAL RIGHTS UNDER THE EU CHARTER OF FUNDAMENTAL RIGHTS (Tamara Hervey & Jeff Kenner eds, 2003); SOCIAL RIGHTS AND MARKET FORCES: IS THE OPEN COORDINATION OF EMPLOYMENT AND SOCIAL POLICIES THE FUTURE OF SOCIAL EUROPE? (Olivier De Schutter & Simon Deakin eds., 2005).

II. OBJECTIONS / PROBLEMS

A number of objections to, or problems with, our proposal, may be foreseen. 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 summarized as the accountability issue, the resources/efficiency issue and the participation issue. We cannot do full justice to these general issues in the context of this single Article. They are elaborated much more fully in the general literature on new 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 accountable the actors making 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 a retrospective version of accountability—that is, narration, debating the issues, and evaluation of the process by external actors, which may be in the form of passing judgment on the process,[86] the Transformative Directive offers no solutions. The mechanisms envisaged and the norms that they would develop, would essentially be soft and would *themselves* escape formal judicial review. However, wherever the soft norms developed would essentially constitute an instrumentalization of the contours of Article 49 EC, in the context of cross-border health care services, national 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 legally required to narrate the reasons for their decision, in a transparent manner. 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, which report 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 objection is that a significant network may seem an unnecessary structural elaboration, but it may appear less elaborate 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 of health care services while preserving the values of European health care systems at a time of technological and regulatory change. In addition, many of the mechanisms we envisage *are already in*

---

[86] *See* Carol Harlow & Richard Rawlings, *Promoting Accountability in Multi-level Governance: A Network Approach* (European Governance Papers, Paper No. C-06-02, Apr. 7, 2006), *available at* http://www.connex-network.org/eurogov/pdf/egp-connex-C-06-02.pdf; Mark Bovens, *Analysing and Assessing Public Accountability—A Conceptual Framework* (European Governance Papers, Paper No. C-06-01, Jan. 16, 2006), *available at* http://www.connex-network.org/eurogov/pdf/egp-connex-C-06-01.pdf.

place and the proposed Transformative Directive would simply formalize their existence and the terms of reference within which they work.

On the participation issue, as Stijn Smismans has noted,[87] more heterarchical, horizontal, and flexible modes of governance do not necessarily imply more participation and inclusion regarding the involvement of all stakeholders. There is a danger in the proposed XBHSC Strategy that those actors who 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 such would be the case. For instance, the civil society groups involved in the consultation that led to the setting up of the HLG were all groups which had already worked closely with the Commission. Indeed one of these groups was set up by the Commission, which could suggest a semi-closed network.[88] However, to counteract this excluding tendency, 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, the baseline of litigation based on Article 49 EC would remain. 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 only be persuasive and 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 could be used by stakeholders who feel that the existing new governance guidelines fail to sufficiently take into account their interests and thereby, destabilize the new governance process, so that a new, still reflexive, settlement is reached.[89]

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.[90] Scharpf points out that while, in the Member States, "economic policy" and "social protection"[91] 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 equality does not exist at the 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

---

[87] Stijn Smismans, *New Modes of Governance and the Participatory Myth* (European Governance Papers, Paper No. N-06-01, Mar. 7, 2006), *available at* http://www.connex-network.org/eurogov/pdf/egp-newgov-N-06-01.pdf.

[88] Hervey, *supra* note 18.

[89] *Cf.* Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 HARV. L. REV. 1015 (2004).

[90] Fritz Scharpf, *A New Social Contract? Negative and Positive Integration in the Political Economy of European Welfare States*, 2002 (EUI Working Paper No. RSC 96/44, 1996).

[91] Fritz Scharpf, *The European Social Model: Coping with the Challenges of Diversity*, 40 J. COMMON MKT. STUD. 645, 647, 655-58 (2002).

also the case for national social protection policies recognized as representing best practice by the OMC, or equivalent processes.

Scharpf's skepticism about the OMC as an appropriate response to the "constitutional imbalance" between what he terms "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."[92] We disagree. The internal market *need not necessarily* be only an economic construct. Indeed, internal market law already accommodates "social protection" interests.[93] For instance, it does so where the European Court of Justice recognizes objective public interest justifications, such as the financial stability of national health care systems, for national rules that *prima facie* infringe on 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" domain in terms of his dichotomous structure.[94] 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 of March 2002[95] set three principles for reform of social protection systems, including health care, the European Commission set three broad objectives for an OMC in health and long

---

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] European Council meetings are high level meetings with the Heads of State and Government of the Member States of the EU, and their foreign ministers. They set the overall agenda for the European Union. The European Commission builds on this agenda-setting in its policy making activities.

term care.[96] 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. Under "access to health and long term care" the reports cover the range of services included or the extent of health care coverage; 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. The concept of "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. Under "financial sustainability of health and long term care," the reports consider the general economic and social situation; the aging population; inducing responsible individual behavior, such as reducing obesity, promoting healthy use of alcohol, and 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.[97] Along with the OMC on social inclusion and the OMC on pensions, the OMC health and long term care is now being brought forward as part of the streamlined OMC on social protection and social inclusion.

Regarding efficient or "joined up" governance,[98] 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 in the paragraph above, in order to bring within the scope of the Transformative Directive 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.[99] 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(5) 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."[100] If the Transformative Directive included giving powers to the EU to govern the organization and delivery of health services and medical care, the Directive

---

[96] *See Commission Communication on 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 (Apr. 20, 2004).

[97] European Commission, *Memorandum of the Social Protection Committee—Review of Preliminary National Policy Statements on Health Care and Long-term Care* 20–27 (Nov. 30, 2005), *available at* http://ec.europa.eu/employment_social/social_protection/docs/spc_ltc_2005_en.pdf.

[98] "Joined up" governance is the idea that law and policy makers pay attention to the activities of other law and policy makers who operate through different institutional structures, but deal with aspects of the same policy issues. The idea calls for holistic approaches that see all dimensions of a particular policy problem and seek to coordinate responses to that problem.

[99] *Cf.* EC Treaty arts. 52, 95.

[100] *Id.* art. 152(5).

would then be vulnerable to legal challenge through judicial review on the grounds of lack of competence.[101]

One possible counter-argument to such a challenge would involve an extensive interpretation of free movement of health care services and what this interpretation then requires in terms of EU-level regulation. However, this line of argument failed in the *Tobacco Advertising* case.[102] 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,[103] 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, this approach 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,[104] would therefore almost certainly be needed for the Transformative Directive.

III. 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 European Court of Justice 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.[105] To adopt a transformative hybrid of old and new governance would mean to recognize the failure of the CCM and the promise of new governance, but at the same time gain the benefits of agreeing on a legal text. This transformative hybrid would be explicitly constructed as a framework for participative rule-making within broad substantive and procedural legal principles. Adopting the Transformative Directive will not mean that the regulatory problem of cross-border health care is now solved. 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 reflexive guidelines generated thereafter.

---

[101] *Cf. id.* art. 230.

[102] Case C-376/98, *Germany* v. *Parliament and Council (Tobacco Advertising)*, 2000 E.C.R. I-8419.

[103] Opinion 2/94 of the Court, Opinion pursuant to Article 228(6) of the EC Treaty (Accession by the Communities to the Convention for the Protection of Human Rights and Fundamental Freedoms), 1996 E.C.R. I-1759.

[104] EC Treaty art. 137(2)(a).

[105] *See Amended Bolkestein Proposal, supra* note 1. The Commission has undergone a consultation process, to which, the response deadline was January 31, 2007. *Commission Communication Regarding Community Action on Health Services*, SEC (2006) 1195/4 (Sept. 26, 2006). The results of this process are available at http://ec.europa.eu/health/ph_overview/strategy/results_consultation_en.htm.

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 may be broadly termed new governance. For the purposes of this article, we are influenced in particular by the methodological framework elaborated by David Trubek and Louise Trubek in their contribution to this collection,[106] by the data on EU environmental governance described therein, and also by Joanne Scott and Jane Holder.[107] The Environmental Impact Assessment (EIA) Directive and the Water Framework Directive (WFD) are both described as instances where law is transformed by its relationship with new governance. The EIA Directive is structured to provide "the tools for iterative evaluation and adaptation."[108] 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." Here "the law . . . structures procedures for conflict resolution or problem-solving."[109] 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."[110] 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."[111] The result is a transformative relationship between old and new governance, in which the new supplements the old, and the old is constructed both to embrace and mandate the new.

Our view that there is an opportunity for a Transformative Directive on cross-border health care services rests 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. Rather, there is an apparently messy multi-actor regime, coordinated through EU level structures, but penetrating to the Member States' national governance structures. The regime also penetrates to lower levels of governance, where these institutional settings and actors need to be brought to the table to resolve complex social problems. Such complex social problems are 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.

Our proposed Transformative Directive on health care services would represent an example of "transformation"[112] 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

---

[106] Trubek & Trubek, *supra* note 74.
[107] Holder & Scott, *supra* note 14.
[108] *Id.* at 215.
[109] Trubek & Trubek, *supra* note 74, at 548.
[110] Holder & Scott, *supra* note 14, at 224.
[111] *Id.* at 226–27.
[112] Trubek & Trubek, *supra* note 74.

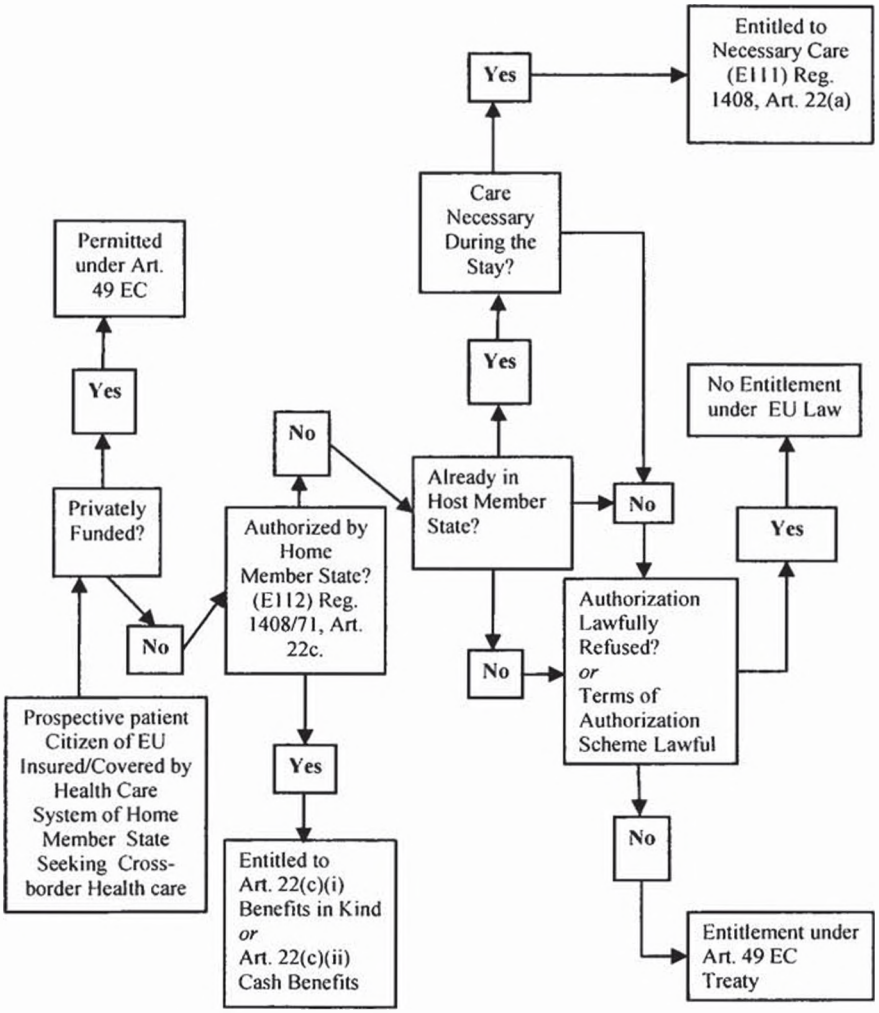
other for its success. The result would be a mutually reinforcing process which eschews the traditional legal dichotomy between law-making and its implementation and enforcement.[113] This approach sees the hybrid of old and new governance as bringing altered roles for legal norms and institutions. It both draws on the lessons of the "law-in-context" literature,[114] 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.[115]

[113] It builds on, but goes beyond the "New Old Governance" (NOG) identified by Scott & Trubek, *supra* note 14, 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 bolted on.

[114] *See generally* THE LAW AND SOCIETY READER: READINGS IN THE SOCIAL STUDY OF LAW (Stewart Macaulay et al. eds., 1995); LAW IN SOCIAL THEORY (Roger Cotterrell ed., 2006).

[115] *See* Neil Walker, *EU Constitutionalism and New Governance*, *in* LAW AND NEW GOVERNANCE IN THE EU AND THE US, *supra* note 14; Gráinne De Búrca & Joanne Scott, *Introduction: New Governance, Law and Constitutionalism*, *in* LAW AND NEW GOVERNANCE IN THE EU AND THE US, *supra* note 4; Neil Walker, *Late Sovereignty in the European Union*, *in* SOVEREIGNTY IN TRANSITION (Neil Walker ed., 2003); Miguel Poaires Maduro, *Contrapunctual Law: Europe's Constitutional Pluralism in Action*, *in* SOVEREIGNTY IN TRANSITION (Neil Walker ed., 2003); Neil Walker, *The Idea of Constitutional Pluralism*, 65 MOD. L. REV. 317 (2002).

Figure 1: Entitlements of EU Citizen Patients Seeking Cross-border Health Care.[116]



[116] Hervey, *supra* note 44.