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HEALTH CARE AND THE EU: THE LAW AND POLICY PATCHWORK

Governments of European welfare states face an uncomfortable predicament. To transfer their welfare-state obligations to the EU level would jeopardize the political basis of their legitimacy. However, since at least the mid of 1980s the processes of European integration, to which those governments are irreversibly committed, have become increasingly pervasive[1]. As a result, European integration creates a problem-solving gap in that "member governments have lost more control over national welfare policies, in the face of the pressures of integrated markets, than the EU has gained de facto in transferred authority» [11], substantial though the latter may be.

At face value, health care seems to be a case in point to illustrate this predicament. Indeed, with some limited exceptions the European Union has no legal competence to adopt EU law in the field of health care[2], this being a matter of national competence according to the EU's founding or "constitutional" document, the EC Treaty (to be replaced by the Treaty of Lisbon (Treaty of Lisbon, above n. 3.) once it has been ratified by all the Member States. Unsurprisingly, both Member States and EU institutions are heavily bound in their ability and willingness (on account of national interests, political sensitivities and the huge diversity of health care systems in an EU of 27) to issue legislation in this area. Those who are (politically) responsible for health care at the domestic level are faced with a second problem: since the very beginnings of what is now the European Union, other areas of EU law have had unintended effects in health care contexts. The second section of this chapter provides an overview of the main examples of this phenomenon. It involves several areas of EU law. Their effects on health care in the Member States form a

[1] See F. Scharpf, 'A new social contract? Negative and positive integration in the political economy of European welfare states', European University Institute Working Paper RSC 96/44 (1996); R. Dehousse, 'Integration v regulation? On the dynamics of regulation in the European Community', Journal of Common Market Studies 30 (1992), 383–402; G. Majone, 'The European Community between social policy and social regulation', Journal of Common Market Studies 31 (1993), 153–70; F. Scharpf, 'The European social model: coping with the challenges of diversity', Journal of Common Market Studies 40 (2002), 645–70; C. Offe, 'The European model of "social" capitalism: can it survive European integration?', Journal of Political Philosophy 11 (2003), 437–69; M. Ferrera, The boundaries of welfare: European integration and the new spatial politics of social protection (Oxford: Oxford University Press, 2005); L. Moreno and B. Palier, 'The Europeanisation of welfare: paradigm shifts and social policy reforms', in P. Taylor-Gooby (ed.), Ideas and welfare state reform in Western Europe (Basingstoke: Palgrave Macmillan, 2005), pp. 145–71. S. Leibfried, 'Social policy. Left to judges and the markets?', in H. Wallace, W. Wallace and M. Pollack (eds.), Policy-making in the European Union (Oxford: Oxford University Press, 2005), p. 243.

[2] Article 152(5) EC. See, for instance, Case 238/82, Duphar [1984] ECR 523, para. 16; Joined Cases C-159/91 and 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 v. Caisse de Maladie des Employes Prives [1998] ECR 1831, para. 21; Case C-158/96, Kohll v. Union des Caisses de Maladie [1998] ECR I-1931, para. 17; Case C-157/99, Geraets-Smits and Peerbooms [2001] ECR I-5473, para. 44. See also Consolidated Version of the Treaty on the Functioning of the European Union, OJ 2008 No. C115/1, which, if the Treaty of Lisbon of 17 December 2007, OJ 2007 No. C306/1, is ratified, confirms in a new Title I, Article 6, that the EU has competence to carry out actions to support, coordinate or supplement national actions in the fields of 'protection and improvement of human health'.

kind of patchwork, unconnected by legal or policy conference.

In spite of this predicament, the EU has developed since the early 1990s its own health care policies in response to these unintended consequences of the application of EU law in health care settings and their consequent effects on the national health care systems of the Member States. Because the EU has no formal legal powers to develop its own health care law, the EU's emergent health care policy is also something of a patchwork. EU health care law and policy is formed from a variety of provisions that constitutionally "belong" to different policy domains, principally those of the internal market, social affairs, public health, enterprise and economic policy. The third part of the chapter explores the processes through which the various sets of actors representing these five policy domains at the EU level have tried to shape the terms of the EU health care debate and expand their influence upon it.

Both the substance of – and the institutional arrangements for – EU health care law and policy-making are therefore highly displaced, in comparison with national health care law and policy-making, which has its own constitutional structures and established mechanisms. While national health care policy tends to be the domain of national (political or administrative) "health" experts, in the EU context most legal measures and policies that have implications for health care are adopted within institutional structures and procedures that were developed for quite different policy domains. Furthermore, EU-level health care law and policy occupies a highly contested space in the EU's current constitutional settlement. Traditionally understood, EU law and policy-making is legitimated through a constitutional settlement within which powers are formally conferred by the Member States, in a negotiated political settlement represented in legal documents (the EC and EU Treaties) to an institutional triptych of the European Commission, European Parliament and Council of Ministers. In policy areas outside those where the EU has competence to legislate, the Member States enjoy autonomy of action. Recently, however, this binary distinction between EU and national competence has been challenged by the emergence of new governance practices in the EU[3]. By "new governance" we mean "a range of processes and practices that have a normative dimension, but do not operate primarily or at all through the formal mechanism of traditional command and control-type legal institutions"[4]. These apply in areas from which EU competence is formally excluded. But they involve the EU institutions (and especially the European Com-

[3] See F. Scharpf, 'A new social contract? Negative and positive integration in the political economy of European welfare states', European University Institute Working Paper RSC 96/44 (1996); R. Dehousse, 'Integration v regulation? On the dynamics of regulation in the European Community', Journal of Common Market Studies 30 (1992), 383–402; G. Majone, 'The European Community between social policy and social regulation', Journal of Common Market Studies 31 (1993), 153–70; F. Scharpf, 'The European social model: coping with the challenges of diversity', Journal of Common Market Studies 40 (2002), 645–70; C. Offe, 'The European model of "social" capitalism: can it survive European integration?', Journal of Political Philosophy 11 (2003), 437–69; M. Ferrera, The boundaries of welfare: European integration and the new spatial politics of social protection (Oxford: Oxford University Press, 2005); L. Moreno and B. Palier, 'The Europeanisation of welfare: paradigm shifts and social policy reforms', in P. Taylor-Gooby (ed.), Ideas and welfare state reform in Western Europe (Basingstoke: Palgrave Macmillan, 2005), pp. 145–71. S. Leibfried, 'Social policy. Left to judges and the markets?', in H. Wallace, W. Wallace and M. Pollack (eds.), Policy-making in the European Union (Oxford: Oxford University Press, 2005), p. 243.

[4] Article 152(5) EC. See, for instance, Case 238/82, Duphar [1984] ECR 523, para. 16; Joined Cases C-159/91 and 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 v. Caisse de Maladie des Employes Prives [1998] ECR 1831, para. 21; Case C-158/96, Kohll v. Union des Caisses de Maladie [1998] ECR I-1931, para. 17; Case C-157/99, Geraets-Smits and Peerbooms [2001] ECR I-5473, para. 44. See also Consolidated Version of the Treaty on the Functioning of the European Union, OJ 2008 No. C115/1, which, if the Treaty of Lisbon of 17 December 2007, OJ 2007 No. C306/1, is ratified, confirms in a new Title I, Article 6, that the EU has competence to carry out actions to support, coordinate or supplement national actions in the fields of 'protection and improvement of human health'.

mission) in the creation of distinctly normative elements, including non-binding measures such as mutually agreed objectives, indicators and benchmarks, or mandatory reporting mechanisms, which are often embedded in participatory, non-hierarchical and iterative procedures.

Health care law, policy and governance in the EU can thus be understood through a metaphor of a double patchwork. Various parts of long-standing EU law have effects in health care policy settings. The EU institutions, as well as the Member States, have themselves responded to this phenomenon, again using a variety of different policy domains and discourses as their platform. It is our contention that, so far, these patchworks have largely developed in parallel (with governance processes being developed rather defensively in an attempt to soften the consequences of law), but that law and soft modes of health governance are becoming increasingly interwoven, thereby opening the door for hybrid EU policy instruments.

Health is and will continue to be an area within which the competence of the EU institutions is highly constrained. This has been reconfirmed by the Treaty of Lisbon[5]. At the same time, however, health is no longer a "non-topic" for the EU, and neither the EU institutions, nor the governments of the Member States, can now retreat from that position, for how could the EU not be "for" health and health care?

We have described EU health care law, policy and governance as a double patchwork. The limitations of: (a) the political incapacity to adopt "positive" legislation; (b) a longstanding but increasing impact of EU law on national health care systems; and (c) a divided policy space, have triggered "political spillovers pushing consecutive rounds of EU policy initiatives, pressed for by domestic policy-makers, to deal with the unintended consequences" [10]. More particularly, those responsible for health care at the national levels have responded, feeding into the EU's use of the 'governance tool kit' in health care fields. No less than five sets of actors, which we have labelled as "public health", "social affairs", "internal market", "enterprise" and "economic", have crowded the EU health care governance space and have established different (as opposed to integrated) and largely uncoordinated responses, all of which, at least, have the potential to have an impact at the domestic level. So far, law and governance have existed largely in parallel, with governance processes "in the shadow" of legislation. We have seen that, within each of these sets of players, the European Commission, often from a very early stage, set the terms of the debate, including in processes such as the patient mobility processes and the OMC. In other words, governance does not seem to significantly destabilize the independent agency, or even hegemony, of the Commission as the lynch pin of Community law and policy-making. However, there are strong indications now that the different health care processes are "up and running", the Commission's internal divisions may allow the Council and national governments to reassert control. One should recall in this context that, under the United Kingdom Presidency, the Council (daringly) asked for 'more leadership' in the European health care debate. A clear message addressed to the Commission, it seems. And one key actor is quite skeptical: DG Social Affairs has the legal instruments (legal base), but it does not have the legitimate constituency at national level. DG SANCO has privileged relationships with national actors, but it does not have the legal instruments. Result: we have to find a compromise, but for the moment it is a real conflict, a battle for power. Of which we do not see the end yet.

5 See Article 168(7), Treaty on the Functioning of the European Union: 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them'.

Another clear feature of the double EU health care governance patchwork is that public consultations are increasingly used by the European Commission as a tool to legitimize further initiatives and to create ownership of the final proposal among stakeholders. Examples include consultations on the draft strategic guidelines for the new programming period of the Structural Funds, on freeing Europe from exposure to environmental tobacco smoke, on the follow-up to the Court's jurisprudence relating to the reimbursement of medical expenses incurred in another Member State, on health-related information for patients, on how to ensure legal certainty regarding cross-border health care, and David Byrne's electronic Reflection Process in 2004 on the Commission's new EU health strategy. These consultations seem to help to depoliticize debates (which are sometimes even said to be too technical to be discussed among politicians) and thus remain relatively isolated from high profile media or other public scrutiny. And yet, as we have shown, in most cases their effect is significant, as in the case of the Pharmaceutical Forum, which was instrumental in bypassing issues which were rejected in the Pharmaceutical Review.

Another feature of the new EU health care governance patchwork is an increasing interlinking between classical EU law-making and governance processes. Examples of this linkage include the High Level Process of Reflection, which played a key role in pressing the Commission to propose legislation on health services in the internal market. They include the networked governance processes of "Europe against Cancer" feeding into tobacco legislation. They also include the High Level Group on Health Services and Medical Care, which organized pressure to increase EU funding for health care infrastructure through the Structural Funds, and promoted coordination of national health care policies and adopted soft law measures such as the 2005 "EU Guidelines for Purchase of Treatment Abroad", effectively bypassing the lack of legislative guidance from the EU on this issue. Other examples include the Transparency Committee (set up under Directive 89/105/ EEC) [5], which was reactivated because of the information requirements of the Pharmaceutical Forum, and which spilled over into new kinds of cooperation. Thus, new Member States are using the (formal and especially informal) exchanges of information between Committee members (e.g., on the therapeutic value-added of new medicines) "to arm themselves against the invasion of new pharmaceutical products on their markets". Another example is the data protection regulation (covered by Directive 95/46/EC) [5], for which the Commission offers: "to work with the Member States <...> to raise awareness" of the provisions of the Directive that apply to the health care sector. This governance approach presumably sits alongside more classical modes of implementation and enforcement of EU legislation by the Commission envisaged by the Treaty. Taking all these examples together, it will come as no surprise, then, that non-binding measures are far from being perceived as irrelevant by the Member States and that the decision-making process leading to their adoption involves hard politics.

In sum, the cross-fertilization between law and governance seems to point towards the future development of "hybrid" policy instruments: far from abandoning legislative responses, the EU institutions are keen to pursue them alongside the array of governance mechanisms now available to them. A case in point of such "instrument hybridity" [4] is the interlinking between the OMC and the ESF. The scope of the ESF was redirected in 1999, so that the Fund could support, during the 2000–2006 programming period, the newly launched "European employment strategy", another EU governance process launched in 1997 [6]. Even more important in the context of this chapter is that the new ESF Regulation, which determines the tasks of the ESF, the scope of its assistance and the eligibility criteria for the 2007–2013 programming period, explicitly refers to the "open method of coordination on social protection and so-

cial inclusion" [1], of which the health care OMC is now one particular strand. Consequently, there is no reason why in the near future certain elements of the health care OMC would not be taken into account by the Commission, de jure or de facto, to determine whether expenditure is eligible for assistance under the Fund.

What will happen in the future? Most importantly, EU health law and governance will be increasingly interlinked. At first glance, it would seem that we are unlikely to see significant additions to the legislative landscape, in terms of EU law that directly treats the provision of health care in the internal market or competition law. Even if the Commission's proposal for a directive on health care services in the internal market does emerge, it will not significantly change the current position. However, this may be too hasty a conclusion, since support for further legislation may be spurred by the information and new understandings generated through the learning mechanisms of governance procedures, such as the OMC, other forms of policy coordination, and information generation and dissemination drawing on EU funding opportunities. Furthermore, legislation in other fields of EU law that indirectly affects health care systems will continue to be adopted, but the "health care mainstreaming" obligation, which will be further embedded in the Treaty following the Lisbon amendments [2], will be applied more seriously due to the increased visibility of health in the Commission's vista, and because of Member States' increased willingness to discuss health care at the EU level, at least in the context of governance processes. Finally, consistent with the "constitutional asymmetry" thesis, the "negative integration" and destabilizing dynamic of litigation before the Court will continue. But this will only be at the margins and arguably, because the Court is no more blind to governance measures than it is to legislation – and proposed legislation – it will increasingly be inspired by the outcomes of the governance process in its judgements (e.g., perhaps, when interpreting "undue delays", "solidarity" or a definition of "public interest" in the context of cross-border health care services; or an agreed list of justifications for non-discriminatory restrictions on the free movement to provide services, freedom of establishment or free movement of persons).

Non-hierarchical, networked methods of governance, based on shared learning, information collection and dissemination, benchmarking, and so on, are likely to continue to be important, since the EU is likely to continue to use information, influence and incentives, rather than hierarchical law-making and regulation in health care fields. The challenges of non-hierarchical governance that apply in any field will apply perforce in the health care governance arena. How will the relevant actors be included, each with an "equal voice" at the table? At present, EU health care governance remains largely a "closed shop" of high level civil servants, EU officials and experts, and many governance practices are particularly poorly integrated into domestic policy processes. Consequently, (European and domestic) parliamentary overview remains poorly developed. What about Member States where human capacity is scarce, so participation in these processes is more limited than in those better endowed with human capacity? How will the processes be protected from "capture" by powerful interests, be they in the pharmaceutical, tobacco or private health insurance industries? These questions are not only questions for non-hierarchical governance structures – they apply equally in the context of more traditional hierarchical law-making and regulatory processes. Some empirical evidence of longer-standing governance processes suggests that they are being used as an increasingly important trigger for ambitious domestic welfare state reform [8]. It seems that Frank Vandenbroucke was right when he said: "Open co-ordination can and should be a creative process, because it will enable us to translate the much discussed but often unspecified "European social model" into a tangible set of agreed objectives, to be entrenched in European

co-operation. <...> Efficient EU co-operation can help identify and prepare the legislative work [at] both a national and EU level" [7]. The synergies offered by such an integration of law and governance provide the EU with an opportunity to take health care policy forward, while balancing the interests of the internal market and competition, alongside those of "social Europe".

In the final analysis, neither positive nor negative integration in the classical senses will be the dominant mode for EU law or policymaking in the health care context. Rather, we can expect an interaction, or set of interactions, between legislative and governance processes. Although the story we tell in this chapter may be read to imply that the law and policy patchwork is becoming increasingly "joined up", for all the reasons explained here, it will never become a single all-encompassing woven tapestry.

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