

1 *Health systems governance in Europe: the role of European Union law and policy*

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1. The scope and aims of this book

This volume assesses the impact of European Union (EU) policy and law on Member States' health systems and their governance in a number of key areas. In so doing, it builds on two earlier books¹ that sought to assess the changing legal and policy dynamics for health care in the wake of the European Court of Justice's (ECJ) seminal rulings in the *Kohll* and *Decker* cases.² These books showed that, despite widely held views to the contrary, national health care systems in the EU were not as shielded from the influence of EU law as originally thought.³ The explicit stipulations of Article 152 EC (as amended by the Amsterdam Treaty) that health is an area of specific Member State competence, and implicit understanding of the subsidiarity principle where policy is undertaken at the lowest level appropriate to its effective implementation, proved not to be the 'guarantees' of no EU interference in national health care services that they were often held to be. As the raft of legal cases and degree of academic attention that followed have shown, *Kohll* and *Decker* were certainly not the 'one-offs' many policy-makers hoped they would be.⁴ In fact,

¹ M. McKee, E. Mossialos and R. Baeten (eds.), *The impact of EU law on health care systems* (Brussels: PIE-Peter Lang, 2002); E. Mossialos and M. McKee (with W. Palm, B. Karl and F. Marhold), *EU law and the social character of health care* (Brussels: PIE-Peter Lang, 2002).

² Case C-120/95, *Decker v. Caisse de Maladie des Employes Privés* [1998] ECR 1831; Case C-158/96, *Kohll v. Union des Caisses de Maladie* [1998] ECR I-1931.

³ T. Hervey and J. McHale, *Health law and the European Union* (Cambridge: Cambridge University Press, 2004); M. McKee, E. Mossialos and P. Belcher, 'The influence of European Union law on national health policy', *Journal of European Social Policy* 6 (1996), 263–86.

⁴ K. Lenaerts and T. Heremans, 'Contours of a European social union in the case-law of the European Court of Justice', *European Constitutional*

they are widely held to have set precedent in terms of the application of market-related rules to health care, which in turn ‘allowed the EU into’ the health care arena. As the growing number of national level analyses of the impact of EU law on health care systems highlight,⁵ it is clear then that careful scrutiny is needed in future in order to ensure the balance between creating and sustaining the internal market and the maintenance of a European social model in health care. So, ten years on from *Kohll* and *Decker*, how has the EU health care landscape changed, and what now are the pressing issues? These are two of the underlying questions with which this book is concerned.

In addressing such questions, and particularly in view of the need to balance the internal market with the European social model in health care, it is worth noting that there are three EU policy types, as discerned by Sbragia and Stolfi.⁶ Market-building policies emphasize liberalization and are generally regulatory, reflecting the ‘Community method’⁷ and with a leading role for the European institutions. These are the typical internal market, trade, competition and commercial policy related rules, including those around economic and monetary union (EMU). Market-correcting policies aim to protect citizens and producers from market forces and tend to be redistributive rather than regulatory, thereby involving intergovernmental bargaining. The Common Agricultural Policy and EU Structural Funds are examples. There are also market-cushioning policies, which are again regulatory in nature, and, as they are intended to mitigate the harm that economic activities can bring to individuals, are shared EU–Member State competences. We see this in the case of environmental policy

Law Review 2 (2006), 101–15; E. Mossialos and W. Palm, ‘The European Court of Justice and the free movement of patients in the European Union’, *International Social Security Review* 56 (2003), 3–29.

⁵ See, for example, D. Martinsen and K. Vrangbaek, ‘The Europeanization of health care governance: implementing the market imperatives of Europe’, *Public Administration* 86 (2007), 169–84.

⁶ A. Sbragia and F. Stolfi, ‘Key policies’, in E. Bomberg, J. Peterson and A. Stubb (eds.), *The European Union: how does it work?* Second edition (Oxford: Oxford University Press, 2008).

⁷ The ‘Community method’ refers to the institutional operating mode for the first pillar of the European Union and follows an integrationist logic with the following key features: the European Commission has the right of initiative; qualified majority voting is generally employed in the Council of Ministers; the European Parliament has a significant role reading and co-legislating with the Council; and where the European Court of Justice ensures the uniform interpretation and application of Community law.

and occupational health and safety. Economic integration, which began with market-building policies, has, given the pressure it exerts also in other areas, seen the development of market-correcting and, now, market-cushioning policies at EU level. This implies a recognition of the welfare and social policy impacts of policies taken from an otherwise economic perspective.

In view of the *Kohll* and *Decker* ‘fallout’, and given the considerable autonomy exercised by the Commission in this area, our focus in this book is on the first category of policy – market-building – and the effects this has on health policy. We seek to examine these effects, what they mean from the perspective of EU law and the ECJ’s role, and their impact on Member State health care systems. In particular, competition law, which is a core EU policy area (where the Commission can be very active), falls under the market-building category and has a profound impact on EU health policy. Market-correcting and market-cushioning policies are not so relevant to health policy given that the EU has little direct competence here – with some ECJ rulings corresponding to the former, and some aspects of public health falling under the latter.

Involving a cadre of leading experts, this volume thus proposes an interdisciplinary treatment of the subject-matter, drawing primarily from the legal and policy spheres. Aimed at an informed audience, the contributors offer a critical examination in crucial and emerging areas of EU law and health care, as well as assessing potential policy implications given changing governance dynamics⁸ at the EU level. Among the more specific questions and issues addressed are: what are key areas of concern in health care and law at the EU and Member State levels? How is the Court’s role viewed and how has it developed? What do the increasing number of EU soft law instruments and measures

⁸ By ‘governance’, we mean all ‘steering’ carried out by public bodies that seeks to constrain, encourage or otherwise influence acts of private and public parties. We also include structures that ‘delegate’ the steering capacity to non-public bodies (i.e. professional associations). By ‘steering’, we mean to include binding regulatory measures (laws) and other measures that are sometimes called ‘new governance’ measures – that is, ‘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’. See G. de Búrca and J. Scott, ‘Introduction: new governance, law and constitutionalism’, in G. de Búrca and J. Scott (eds.), *New governance and constitutionalism in Europe and the US* (Oxford: Hart, 2006).

mean for health care? What challenges and opportunities exist? And what might the future hold in terms of reconciling continued tensions between economic and social imperatives in the health (care) domain? The book thus provides not only a broad understanding of the issues, but also analyses of their specific interpretation and application in practice through the use of issue-specific chapters/case-studies. And while it is clear that such a volume cannot be exhaustive in its coverage, and some issues or policy areas have not been included, each chapter addresses a topical area in which there is considerable debate and potential uncertainty. The chapters thus offer a comprehensive discussion of a number of current and emerging governance issues, including regulatory, legal, 'new governance' and policy-making dynamics, and the application of the legal framework in these areas.

The remainder of this chapter is divided into two sections. The first offers an initial snapshot of the current status of health (care) policy in the EU before examining specific challenges facing policy-makers. While the focus of the book is less about theory than about the legal situation and its policy impact, some elements from the relevant theoretical literature are raised in order to help better set the scene. These relate to the different (in part explanatory) perspectives on how policies have developed (why and why not) and where the constraints lie. The second section reflects the structure of the remainder of the volume, providing an introduction to the content of each chapter, as well as an in-depth discussion of the main findings and policy relevance in each case. This opening chapter is therefore written both as an introduction to the book, and as a key contribution to the volume in its own right.

2. EU health policy: contradictions and challenges

Health policy in the European Union (EU) has a fundamental contradiction at its core. On the one hand, the EC Treaty, as the definitive statement on the scope of EU law, states explicitly that health care is the responsibility of the Member States.⁹ On the other hand, as Member State health systems involve interactions with people (e.g. staff and patients), goods (e.g. pharmaceuticals and devices) and services (e.g. provided by health care funders and providers), all of which are granted freedom of movement across

⁹ Article 152(5) EC.

borders by the same Treaty,¹⁰ many national health activities are in fact subject to EU law and policy.¹¹ For instance, when national health systems seek to purchase medicines or medical equipment, or to recruit health professionals – what would appear to be clear local health care policy choices – we see that their scope to act is now determined largely by EU legislation.¹² Further, when the citizens of a Member State travel outside their national frontiers, they are now often entitled to receive health care should they need it, and have it reimbursed by their home (national) authority. We thus have a situation where national health care systems officially fall outside EU law, but elements relating to their financing, delivery and provision are directly affected by EU law.

In addition to this overarching contradiction, the EU has, since the 1992 Maastricht Treaty, been required to ‘contribute to the attainment of a high level of health protection’ for its citizens.¹³ This is an understandable and important objective in its own right, and there is compelling evidence that access to timely and effective health care makes an important contribution to overall population health – so-called ‘amenable mortality’.¹⁴ But, notwithstanding the EU’s commitment to various important public health programmes and initiatives, how are EU policy-makers to pursue this goal of a high level of health attainment when they lack Treaty-based competences to ensure that national health systems are providing effective care to their populations? How can they ensure that health systems promote a high level of health and, indeed, social cohesion, and that they comply with the single market’s economic rules (particularly regarding the free movement principles) when health care is an explicit Member State competence?

In this regard, EU health (care) policy can be seen to be affected by what Scharpf terms the ‘constitutional asymmetry’ between EU policies to promote market efficiency and those to promote social

¹⁰ Articles 18, 39, 43, 28 and 49 EC.

¹¹ McKee, Mossialos and Baeten (eds.), *The impact of EU law*, above n.1; Mossialos and McKee, *EU law and the social character of health care*, above n.1.

¹² Hervey and McHale, *Health law*, above n.3; McKee, Mossialos and Belcher, ‘The influence of European Union law’, above n.3.

¹³ Article 3(1)(p) EC.

¹⁴ E. Nolte and M. McKee, *Does health care save lives? Avoidable mortality revisited* (London: Nuffield Trust, 2004).

protection.¹⁵ That is, the EU has a strong regulatory role in respect of the former, but weak redistributive powers as requisite for the latter. This can be ascribed to the Member States' interest in developing a common market while seeking to retain social policy at the national level. More widely, this conforms with Tsoukalis' view that while welfare and solidarity remain national level prerogatives, many issues affecting the daily life and collective prosperity of individuals are dependent on EU level actions, mainly in economic policy spheres.¹⁶ This reflects what he identifies as the 'gap' between politics and economics in the EU system: 'the democratic process of popular participation and accountability has not caught up with this development [an expanding EU policy agenda driven primarily from an economic perspective]'.¹⁷ Rather than a strong political base, therefore, the EU system relies on an increasingly complex institutional arrangement, a growing depoliticization of the issues, and rules set by legislators and experts. This gap is an important reflection on the EU as a whole – in part encompassing what others have identified as the 'democratic deficit' of the EU¹⁸ – and appears of especial relevance to health and social policy where the economic impetus has set much of the path in the absence of a Treaty-based (political) mandate.

In the health (care) arena, we further see that the constitutional asymmetry is exacerbated by a dissonance between the Commission's policy-initiating role in respect of single market free movement concerns and the Member States' right to set their own social priorities. Wismar and colleagues have noted the 'subordinate role' of health within the broader European integration process,¹⁹ and others have highlighted that health policy in the EU has, in large part, evolved within the

¹⁵ F. Scharpf, 'The European social model: coping with the challenges of diversity', *Journal of Common Market Studies* 40 (2002), 645–70.

¹⁶ L. Tsoukalis, *What kind of Europe?* (Oxford: Oxford University Press, 2005).

¹⁷ *Ibid.*, 42.

¹⁸ For a detailed discussion on the merits and failings of the democratic deficit argument in respect of the EU, see A. Follesdal and S. Hix, 'Why there is a democratic deficit in the EU: a response to Majone and Moravcsik', European Governance Papers (EUROGOV) No. C-05–02 (2005), www.connex-network.org/eurogov/pdf/egp-connex-C-05–02.pdf.

¹⁹ M. Wismar, R. Busse and P. Berman, 'The European Union and health services – the context', in R. Busse, M. Wismar and P. Berman (eds.), *The European Union and health services: the impact of the single European market on Member States* (Amsterdam: IOS Press, 2002).

context of the economic aims of the single market programme.²⁰ This has led to a situation in which the Member States have conceded the need for the EU to play a role in health (care), even if only a limited one, and in ill-defined circumstances. As Tsoukalis' view on the politics–economics 'gap' allows us to highlight, this is in part because the EU continues to lack a sufficient political base, not just in health policy but across the board. It has also seen an ad hoc development of measures and, crucially, an ongoing tension between economic and social priorities in the provision of health care. This is in stark contrast to environmental protection, as another area of EU policy, where the EU is given explicit competence under Title XIX of the EC Treaty.²¹ This is not to equate health/social policy and environmental policy. But it is simply to highlight that a greater policy mandate for areas outside (though related to) the single market could be accorded to the EU via the Treaties if desired, and that the asymmetry need not be as clear or as limiting as it appears to be for health. This suggests a redefinition or, at least, a reorganization and re-prioritization of health at the EU level, and one that would change current policy-making dynamics.

A. Constraints and parameters: theoretical perspectives on EU health policy-making

Beyond the constitutional asymmetry, which represents an overarching constraint on the development of health (care) policies, there are other perspectives that are useful in explaining the conditions under which policies can be pursued and implemented. And while a theoretical treatment of the issues or the development of an encompassing conceptual framework²² is not our aim, we can discern three main perspectives that can help us to better understand where policies can or cannot be agreed.

²⁰ See, for instance, W. W. Holland, E. Mossialos and G. Permanand, 'Public health priorities in Europe', in W. W. Holland and E. Mossialos (eds.), *Public health policies in the European Union* (Aldershot: Ashgate, 1999); B. Duncan, 'Health policy in the European Union: how it's made and how to influence it', *British Medical Journal* 324 (2002), 1027–30.

²¹ Articles 174–6 EC.

²² The evolution of the European Community into an organization with supranational qualities has been explored extensively in the academic literature on European integration. For an analysis of the theories and debates that emerged see, for example, B. Rosamond, *Theories of*

The first is a group of rationalist perspectives,²³ where, for instance, Wilson's 'politics of policy' typology²⁴ provides a useful illustrative backdrop.²⁵ Here, policy-making is divided into four categories according to the costs and benefits to the affected stakeholders: majoritarian politics (diffuse/diffuse); client politics (diffuse/concentrated); entrepreneurial politics (concentrated/diffuse); and interest group politics (concentrated/concentrated). In the case of EU health (care) policy, we can define the main stakeholders as the Commission (in some cases, specific Directorates-General), the Member States and, to a degree, the European Court of Justice and industry (in particular, the health-related industries). These actors all have vested interests – often in specific outcomes – and either directly contribute to, or else indirectly affect, policy development. If we are to consider key elements of the EU's current health policies and competences, we see that aspects of public health policy are majoritarian; much pharmaceutical policy is client-based; occupational health and safety or even food safety is entrepreneurial; while the Commission has very little say over those areas that are interest group-oriented and thus fall within the purview of the Member States. It may be the case that aspects of soft law, and the open method of coordination in particular (see below), can play a role in addressing issues within this latter category.

European integration (Basingstoke: Macmillan, 2000); M. Cini and A. Bourne, *European Union studies* (Basingstoke: Palgrave Macmillan, 2006); M. Eilstrup-Sangiovanni, *Debates on European integration* (Basingstoke: Palgrave Macmillan, 2006); I. Bache and S. George, *Politics in the European Union* (Oxford: Oxford University Press, 2006), Chapters 1–4. See also E. Mossialos and G. Permanand, 'Public health in the European Union: making it relevant', LSE Health Discussion Paper No. 17 (2000), for a discussion specific to EU health competencies in respect of theories of European integration.

²³ T. Börzel and T. Risse, 'When Europe hits home. Europeanization and domestic change', *European Integration Online Papers* 4 (2000), <http://eiop.or.at/eiop/texte/2000-015a.htm>; Bache and George, *Politics in the European Union*, above n.22, Chapters 1–2.

²⁴ J. Q. Wilson, *The politics of regulation* (New York: Basic Books, 1980).

²⁵ This is an approach that has already been used to explain the development and orientation of EU public health policy. See Mossialos and Permanand, 'Public health in the European Union', above n.22; G. Permanand and E. Mossialos, 'Constitutional asymmetry and pharmaceutical policy-making in the European Union', *Journal of European Public Policy* 12 (2005), 687–709.

Given our interest in EU law specifically, as the Court's role in health policy is primarily oriented towards free movement, we see that client-based and entrepreneurial politics are the most feasible avenues of action for the Court (e.g., anti-discrimination or cross-border care). The Court steers clear of majoritarian and interest group politics, such as where financial benefits or other redistributive policies are involved, and where it is for the Member States to agree between themselves. Indeed, the Court may deliver judgements relating to the nature of the Member States' social security systems, but has not sought to rule against them in addressing issues such as reimbursement and pricing, except from an EU-wide free movement perspective.²⁶

A second group of perspectives is oriented around constructivism,²⁷ one where the gradual development and building up of capacity and policies is possible. We see this best reflected in the so-called 'new modes of governance' approaches, where Member States seek mutual learning and progress on sensitive and potentially partisan issues via benchmarking and sharing of best practices. The open method of coordination (OMC) is a clear example, and is in stark contrast to the interest group dynamic under the politics of policy view, where the Member States may engage directly with one another, albeit behind the scenes rather than in a transparent manner, and often without much concrete evidence of change. Issues of entrepreneurial politics, with their concentrated costs but diffuse benefits, may also lend themselves to the OMC.

A third view is the broader one represented by the 'grand' international relations theories of European integration. Intergovernmentalism,²⁸ for instance, which asserts the pre-eminence of the governments of the Member States in the integration process (i.e.,

²⁶ Case C-238/82, *Duphar v. Netherlands* [1994] ECR 523. The *Duphar* case has been widely invoked to support the argument that Community law does not detract from the powers of the Member States to organize their social security systems. See D. Pieters and S. van den Bogaert, *The consequences of European competition law for national health policies* (Antwerp: Maklu Uitgevers, 1997).

²⁷ Börzel and Risse, 'When Europe hits home', above n.23; Bache and George, *Politics in the European Union*, above n.22, pp. 27–8, 43–7.

²⁸ A. Moravcsik, 'Preferences and power in the European Community: a liberal intergovernmentalist approach', *Journal of Common Market Studies* 31 (1993), 473–524.

that national governments remain very much at the helm in deciding the course of Europeanization), distinguishes between issues deemed to be of high politics (defence, foreign policy) and those of low politics (economic interests, welfare policy). The latter are much easier to secure Member State agreement on than the former. And while the distinction would not appear to hold true for health policy as an ostensibly low politics issue over which agreement should be reachable, it is the case that Member States are more or less agreed on the social welfare underpinnings (low politics) but not so over the health care planning and financing elements (high politics). It is these latter elements that in large part represent the stumbling blocks given the loss of national control and consequent budgetary implications of EU competence here. In the case of neo-functionalism,²⁹ as the other grand international relations theory in respect of the European Union, we see that its central tenet of ‘spillover’ also carries some explanatory value. Spillover asserts that the pressure to integrate or harmonize in one sector can spill over or demand similar integration in another sector; this seems most relevant to the economic and free movement imperatives of the single market programme, which extended into social policy areas as well. For instance, we have seen how, in order to avoid a situation of social and ecological dumping,³⁰ and to establish a level playing field for business, the European Community sought to pre-emptively avoid a weakening of countries’ health and safety legislation by explicitly strengthening such legislation for coal and steel workers under the original European Coal and Steel Community (ECSC) and European Economic Community (EEC) Treaties. This has since evolved to broader health protection for EU citizens more widely. These bird’s eye view perspectives often miss the detail, particularly at the level of policy-making itself, but they do help us to understand the broader roles and interests of different stakeholders – be they those of the European institutions or of stakeholders within the Member States – and they help to establish an overall contextual backdrop to the more immediate political and legal discussions.

²⁹ E. Haas, *The uniting of Europe: political, social and economic forces* (Palo Alto: Stanford University Press, 1968).

³⁰ V. Eichener, ‘Effective European problem-solving: lessons from the regulation of occupational safety and environmental protection’, *Journal of European Public Policy* 4 (1997), 591–608.

In addition to the constraints represented by these perspectives, it would appear that the EU health (care) legal and policy framework is itself more broadly grounded around free movement rights and rules and principles pertaining to non-discrimination on grounds of nationality. For the most part, legislation and policies thus have to do with entitlements to free movement and ‘negative integration’. This implies the removal of (national regulatory) obstacles to market access, as opposed to positive integration that involves the EU-level approximation of laws and standards, which then replace the different national frameworks. Whether relating to trade, imports, services, free movement or foreign providers, the majority of EU initiatives can be viewed from this free movement rights and non-discrimination perspective. It should not, therefore, be surprising that this is often the view taken by the Commission when seeking to enact policies.

Again, we are not proposing a definitive theoretical framework for understanding how EU health (care) policies have evolved or within what parameters they can or cannot develop; it is not clear that any single framework will be able to do this. But we do see each of the perspectives mentioned above, despite their individual limitations, as capable of helping us better understand the dynamics and constraints at play, which are in addition to the overriding constitutional asymmetry. That is, they help to establish the contextual backdrop to the interplay between interests and actors, and to shape the parameters within which the patchwork of health competences can be executed.

B. Taking EU Policy forward?

The development and application of a prospective and coherent EU legal framework to address the issues mentioned here, including a bridging of the asymmetry and economics–politics gap, if seen as desirable, would face a number of hurdles. In the first place, and reflecting the societal preferences of their citizens, Member States have chosen different ways to organize their health care systems. The overall design of any system is often based on specific national histories, such that commonly accepted norms are important.³¹ So,

³¹ J. Figueras, R. Saltman and C. Sakellarides (eds.), *Critical challenges for health care reform* (Buckingham: Open University Press, 1998); A. Oliver and E. Mossialos, ‘Health system reform in Europe: looking back to see

while social insurance systems require an existing set of relationships between employers, trade unions and government, national health services imply a different relationship – one in which social partners play a less prominent role and governments become more important. Patterns of funding reflect views about the balance between individual and collective financing of health services, as well as the amount of redistribution that each society believes to be desirable. Methods of provision reflect views on the balance between professional and organizational autonomy and the role of the state in ensuring effective treatment and an equitable distribution of facilities. The ways in which these varying goals are achieved highlight differing interpretations about the legitimacy of regulation, incentives and other levers to bring about change. And, while the Member States' systems are often thought of as falling within broad categories, such as Bismarckian or Beveridge, it is important to note that each national health care system is in fact unique. An EU-level 'policy' or legal framework would need to take account of such differences, and not seek to minimize or de-emphasize them.

Despite the challenges posed by these differences, a further difficulty for policy-makers in fact stems from a similarity between the Member States' health systems. Among at least the longer standing EU Member States, there is a common model or approach to health care provision based on social solidarity and universal coverage. This approach has several important features that distinguish health care from a normally traded good or service, and this complicates the application of economic rules to the governance³² of health care. In particular, the European social model is based on a complex system of cross-subsidies, from rich to poor, from well to ill, from young to old, from single people to families, and from workers to the non-active.³³ This model has continued to attract popular support, reflecting the historical

forward?', *Journal of Health Policy Politics and Law* 30 (2005), 7–28; E. Mossialos, A. Dixon, J. Figueras and J. Kutzin (eds.), *Funding health care: options for Europe* (Buckingham: Open University Press, 2002).

³² See above n.8 for our understanding and use of the term governance throughout this volume.

³³ This is not to suggest a clear definition of the European social model – see below n.58 – but to acknowledge its importance as an underpinning set of values or approach among EU Member States.

necessities from which it emerged and the deeply rooted values of solidarity in Europe.³⁴ It also recognizes that a market for health care is inevitably imperfect; individuals may not always be in the best position to assess their health needs, whether because they are unaware of the nature of their health need or are simply unable to voice it effectively. In part as a consequence, Member States have explicitly stated in the Treaties that the organization and delivery of health services and medical care remains a matter of national competence.

Yet it is clear that health care cannot be ignored by European legislators and policy-makers. Health care is not something that stands alone, isolated from the wider economy. In fact, many individual elements of health care are, entirely reasonably, subject to market principles. For instance, with the exception of some vaccines and drugs with specialized applications related to national security, governments generally do not produce or distribute pharmaceuticals. Health facilities purchase equipment, whether clinical or otherwise, on the open market. Both medical equipment and technology are freely traded internationally. Many health professionals are self-employed, engaging in contracts with health authorities or funds. Patients may pay for treatment outside the statutory health care system, either in their own country or abroad. Pharmaceuticals or technology are traded across borders, and their production, distribution and purchase are all legitimately governed by the provisions of the single market. Health care workers also have free movement, and Member States cannot simply exclude providers from another Member State without objective justification. Indeed, given the failure of many Member States to produce or retain sufficient numbers of their own health care professionals, they are often desperately in need of those from elsewhere in Europe and

³⁴ See P. Taylor-Gooby, 'Open markets and welfare values', *European Societies* 6 (2004), 29–48; S. Stjernø, *Solidarity in Europe: the history of an idea* (Cambridge: Cambridge University Press, 2005). Indeed, health care is increasingly complex, creating major informational asymmetries that present scope for opportunistic exploitative behaviour by providers and thus reflect a need for effective systems of regulation and oversight. For these reasons, all industrialized countries have taken an active role in the organization of health care. Even the United States has established a substantial public sector, covering about 40% of the population, to address at least some of the more obvious symptoms of market failure.

abroad.³⁵ All of these matters are entirely legitimate subjects for the application of internal market and competition law; indeed, the ‘fundamental freedoms’ enshrined in the Treaties require that such transactions be transparent and non-discriminatory on grounds of nationality.

At the same time, it needs to be recognized that policies developed to sustain the principle of solidarity, with its complex system of cross-subsidies, are especially vulnerable to policies whose roots are in market principles. Unregulated competition in health care will, almost inevitably, reduce equity because of the incentive to select those whose health needs are least, making it difficult or expensive for those in greatest need to obtain cover. Risk adjustment systems can be established, but are far from perfect, especially in an intensely competitive environment.³⁶ Cost containment policies may be based on restricting supply, such as the number of health facilities.³⁷ Such policies may be undermined if patients can require their funders to pay for treatment elsewhere. Policies that address the issue of informational asymmetry may involve selective contracting with providers, but this requires the existence of agreed uniform standards. Concerns about information have also caused European governments to reject policies, such as direct-to-consumer advertising of pharmaceuticals, which may seem superficially to redress this asymmetry, on the basis of empirical evidence that it is often misleading and drives up health care costs while bringing few if any benefits to patients. This is, however, clearly an interference with the working of the market. In other words, even for those elements of health care that are covered by internal market provisions, both the Member States and the EU acknowledge that the effects of the market must be constrained.

As a result of such concerns, EU Member States have now explicitly stated that equitable effective health care systems are a means

³⁵ S. Bach, ‘International mobility of health professionals: brain drain or brain exchange?’, Research Paper No. 2006/82, UNU-World Institute for Development Economics Research (2006); and M. Vujicic and P. Zurn, ‘The dynamics of the health labour market’, *International Journal of Health Planning and Management* 21 (2006), 101–15.

³⁶ W. van de Ven *et al.*, ‘Risk adjustment and risk selection in Europe: 6 years later’, *Health Policy* 83 (2007), 162–79.

³⁷ E. Mossialos and J. Le Grand (eds.), *Health care and cost containment in the European Union* (Aldershot: Ashgate, 1999).

of promoting both economic growth and social cohesion in Europe. This is reflected, for instance, in the Council Conclusions on common values and principles in European Union health systems of 2006.³⁸ There is, therefore, a broad consensus on basic values that would underpin a so-called ‘European health policy’. For instance – and perhaps most fundamentally – while greater efficiency is welcomed, there is little interest in radical reforms that risk changing (undermining) the welfare-state constellation.³⁹ European health care systems have survived largely intact in the face of undulating economic fortunes. And, where fundamental changes have been attempted, they have often failed or been rejected by a public that places a high value on the underlying concept of social solidarity. In considering a wider role for the EU, therefore, it is important to bear in mind the value placed by Europe’s citizens on the social model that they have helped to create at home. This allows us to ask whether policies that emerge at the EU level, and the impact of EU law on national health care systems, are consistent with these values. For while Majone has argued that, ‘rather than undermining the achievements of the welfare state, [the European Union] is in fact addressing many quality-of-life issues which traditional social polices have neglected – consumer protection and equal treatment for men and women, for example’,⁴⁰ the issue is that, especially in relation to health, it is doing so often in the context of spillover rather than in a proactive fashion.

An important outcome of the lack of clarity and, in some cases, conflict between the objectives of national and EU policies is the emergence of a leading role for the European Court of Justice in the field of health (care) policy. In a series of seminal decisions, the Court

³⁸ Council Conclusions on common values and principles in European Union health systems, OJ 2006 No. C146/1. These Conclusions are also reflected in European Commission, ‘Proposal for a Directive of the European Parliament and the Council on the application of patients rights in cross-border health care’, COM (2008) 414 final, 2 July 2008. We see also a broader political commitment expressed by European member states in the 2008 World Health Organization’s Tallinn Charter on Health Systems, Health and Wealth, Tallinn, 27 June 2008, www.euro.who.int/document/E91438.pdf.

³⁹ See T. Hervey, ‘The European Union’s governance of health care and the welfare modernization agenda’, *Regulation and Governance* 2 (2008), 103–20.

⁴⁰ G. Majone, ‘The European Community between social policy and social regulation’, *Journal of Common Market Studies* 31 (1993), 153–70, at 168.

has set crucial precedents in areas such as patient mobility and the reimbursement of medical costs. Through its ‘teleological’ approach to the interpretation of very general Treaty and legislative texts, and given the institutional constraints upon the EU legislature already highlighted, the Court can in fact be seen to be setting policy directions, and doing so on the basis of ‘atypical cases’ within the single market and, to some extent, competition law rules.⁴¹

The thrust of the Court’s role is to fill in gaps that have developed in the creation of the single market. The peculiar status of health policy – both an economic and social concern, and with (de facto) shared EU and national levels of competence – means in essence that an unelected and unrepresentative body is in large part constraining the context in which decisions may be taken on social policy matters in relation to Member States’ health systems.⁴² Moreover, such decisions and the policies they subsequently generate, involving the EU legislative and administrative institutions, are generally subject to scrutiny by people who often have little idea of what they will lead to. Most single market-related policies, even those relevant to health care, will be initiated by the European Commission’s Directorate-General for Internal Market and Services, debated by the Member States’ economic or competition ministers at their Council meeting, and in turn examined by the European Parliament’s committees on the internal market or industry, before being forwarded for approval. Those with an interest or expertise in health care or public health usually have little say. This, in part, reflects the constitutional asymmetry between EU policies that promote the single market and those that promote social protection, but so too the lack of recognition within the Treaty framework that health is in fact an area of shared competence (contrast environmental policy). The result is a patchwork of health competences, legal provisions and measures, some with a market-oriented focus and others with more social solidarity underpinnings, and increasing areas of tension between the EU

⁴¹ E. Mossialos and M. McKee, ‘Is a European health care policy emerging?’, *British Medical Journal* 323 (2001), 248; M. McKee and E. Mossialos, ‘Health policy and European law: closing the gaps’, *Public Health* 120 (2006) Supp: 16–21; and G. Permanand, ‘Commentary on “health policy and European law: closing the gaps”’, *Public Health* 120 (2006), Supp: 21–2.

⁴² G. Permanand, ‘Commentary on health policy and European law’, *Public Health* 120 (2006), Supp: 21–2.

legislature (and the Court) and the Member States in the area of health (care) policy.

The patchwork and the resulting tension are further manifest in concerns over the potential erosion of the social values intrinsic to European health care systems, as raised earlier.⁴³ It is feared that, via the strict application of EU law – particularly as a means of redressing gaps in the single market rules – solidarity will become a secondary priority behind, for example, free movement or free competition. We see this particularly in the impact of competition law on the regulation of public and private actors involved in providing health care. Indeed, competition law has been shown to impact on public services in general⁴⁴ – the impact on health needs more exploration – and there are limits on the provision of state aid and indirect subsidies via both primary and secondary legislation.⁴⁵ And, while competition law may not apply in certain cases, such as those involving ‘services of general economic interest’, the question is whether this will in turn be thinned via further policies and case-law. Unsurprisingly, some commentators would argue the former, while others foresee the latter.

Overall, therefore, there is a gap in the EU approach to health (care) policy, especially in relation to the delivery and funding of health care services. The Treaties state that it is a matter for Member States, yet it is clear that many aspects are within the ambit of EU law. Member States decide the goals they wish to pursue, such as equity and more effective care, and must then find mechanisms by which to do this that are consistent with EU law. The inability of the legislative bodies of the EU to deal with the issues that arise, or to deal with them in a way that takes account of the specificities of health systems, means that it has often fallen to the Court to make law as it goes along. Moreover, much of the relevant EU law has emerged from rulings that have either arisen from considerations in other sectors, or by addressing only the issues in a single case, thereby leaving issues of

⁴³ T. Hervey, ‘EU law and national health policies: problem or opportunity?’, *Health Economics, Policy and Law* 2 (2007), 1–6.

⁴⁴ T. Prosser, *Competition law and public service in the European Union and the United States* (Oxford: Oxford University Press, 2005).

⁴⁵ V. Hatzopoulos, ‘Health law and policy: the impact of the EU’, in G. de Búrca (ed.), *EU law and the welfare state: in search of solidarity* (Oxford: Oxford University Press, 2005).

broader applicability unresolved. All of this suggests that there is a need for a clear future health care policy agenda in the EU.

This must be an agenda that can reconcile the often conflicting imperatives already highlighted, but that also respects the wide diversity that exists. Ideally, it would allow the Member States to cooperate where necessary and to learn from each other on the basis of best practices and evidence-informed approaches. Such an agenda should aim to ensure that the EU's citizens benefit from health care systems that concomitantly support solidarity and economic growth. In pursuing such an agenda, however, policy and law-makers will also need to be aware that a deregulation-oriented approach to the rules of the single market will, if not sensitively applied, undermine the social principles upon which European health care systems, and the European social model in general, are based.

In view of not just the policy issues and difficulties, but so too the environment, constraints and (theoretical) perspectives outlined above, it becomes necessary to take a closer look at the impact of EU law and the rulings of the European Court of Justice, and what the response and results have been. This is the primary purpose of this book. We do so because the Court is seen by many as a driving force behind the health care policy agenda in the context of the constitutional asymmetry, and is playing this role through the strict and potentially insensitive application of the single market rules. Does the Court sufficiently take into account the peculiarities of health care (that is, as more than a simple product or commodity subject to normal market rules)? Are the Member States' interests and their diversity respected and, indeed, reflected in decisions? How have EU policy-makers responded? And what measures are being pursued to 'soften' the Court's role, or at least lessen its impact on solidarity and social policy grounds? Indeed, Scharpf's broad constitutional asymmetry view is useful in understanding the tension between market-enhancing and market-correcting policies, but it perhaps underplays the influences, over time, of ideas that become embedded in (internal market) law and policy-making processes – this includes the jurisprudence of the Court – among which are the traditionally non-market based conceptions of public health care provision in European contexts.⁴⁶ This book considers such questions, and

⁴⁶ See Hervey, 'The European Union's governance', above n.39.

asks about the wider impact of EU law and governance on national health care systems.

3. EU Law and (the erosion/protection of) national social policies

As the process of Europeanization⁴⁷ continues, a gradual redrawing of national and European identities and a (partial) dismantling of Member State social policy would appear to be following.⁴⁸ Welfare systems seem to have become insufficient in the face of growing difficulties to the task of balancing national commitments to the welfare state and EU internal market objectives. Welfare and the internal market may therefore be juxtaposed as incompatible, but, at the same time, both ideals are central tenets of European identity and valued by EU citizens. Consequently, it is often argued that an EU-level equilibrium between market efficiency and social protection policies is necessary.⁴⁹ Although some theorists focus on the inherent limitations of EU governance and the need for decentralized decision-making, others emphasize EU capabilities to both influence Member State welfare priorities⁵⁰ and to protect them in global contexts. In this regard, a stronger role for the EU in welfare contexts is perhaps envisaged.

Three main roles are ascribed to the modern state: regulation, redistribution and stabilization – essentially, a need exists for market-building,

⁴⁷ For a useful overview of the uses of ‘Europeanization’ in research on the EU, see I. Bache and A. Jordan, ‘Britain in Europe and Europe in Britain’, in I. Bache and A. Jordan (eds.), *The Europeanization of British politics* (Basingstoke: Palgrave Macmillan, 2008), pp. 12–5; C. Radaelli, ‘Europeanization: solution or problem?’, in M. Cini and A. Bourne (eds.), *European Union studies* (Basingstoke: Palgrave Macmillan, 2006).

⁴⁸ For example, S. Leibfried and P. Pierson, *European social policy: between fragmentation and integration* (Washington: Brookings, 1995); M. Ferrera, *The boundaries of welfare: European integration and the new spatial politics of social protection* (Oxford: Oxford University Press, 2005); T. Hervey, *European social law and policy* (London: Longman, 1998).

⁴⁹ P. Taylor-Gooby, ‘Introduction. Open markets versus welfare citizenship: conflicting approaches to policy convergence in Europe’, *Social Policy and Administration* 37 (2003), 539–54.

⁵⁰ See, for instance, F. Scharpf, *Governing in Europe: effective and democratic?* (Oxford: Oxford University Press, 1999), on the one hand; and B. Eberlein and D. Kerwer, ‘New governance in the European Union: a theoretical perspective’, *Journal of Common Market Studies* 42 (2004), 121–42, on the other.

market-correcting and market-cushioning public policy – but the rise of the European Union as what Majone calls a ‘regulatory state’ (a state-like body with regulatory powers to create the internal market) was intentionally not accompanied by the development of a corresponding set of redistributive mechanisms or financing capacity.⁵¹ Although the EEC had (and the EU still has) modest redistributive powers in the context of the Common Agricultural Policy (CAP), the Structural Funds (European Regional Development Fund, European Social Fund), and its poverty and social inclusion programmes, the amounts involved are insignificant in comparison with national welfare budgets. This imbalance between market-building and market-correcting/cushioning competences at the EU level suggests that the EU’s contribution to social policies is likely to be to undermine their provisions over time. It also allows us to ask what options are available to the Member States given the otherwise primarily economic (market-building) nature of the EU’s health competences.

Indeed, because of this imbalance, many national governments are hesitant to engage in dialogue about the Europeanization of welfare. They fear that closer integration will mean loss of national gate-keeping control over welfare entitlements. Nonetheless, discussions of inputs (who gives) and outputs (who gets) are an important component of a state’s legitimacy vis-à-vis its citizens, and the EU – where it fulfils these state-like functions – is no exception.⁵² The EU’s founding Treaties, as interpreted by the Court, have established a rudimentary ‘constitutional’ definition of EU citizenship based on safeguarding fundamental civil, political and social rights, though enforcement and implementation are left to the national level. This suggests the existence of a baseline EU-level moral commitment to social solidarity,⁵³ and most Europeans profess a commitment to the ideals of equality, cooperation and helping those in need;⁵⁴ social solidarity appears a

⁵¹ G. Majone, ‘A European regulatory state’, in J. Richardson (ed.), *European Union: power and policy-making* (London: Routledge, 1996); G. Majone, *Regulating Europe* (London: Routledge, 1996).

⁵² F. Scharpf, ‘Problem-Solving Effectiveness and Democratic Accountability in the EU’, Max Planck Institute for the Study of Societies Working Paper No. 03/1 (2003).

⁵³ J. H. H. Weiler, ‘A constitution for Europe? Some hard choices’, *Journal of Common Market Studies* 40 (2002), 563–80.

⁵⁴ Ferrera, *The boundaries of welfare*, above n.48.

source of pride in the national identity of many Europeans.⁵⁵ And while the evolution of a dual European and national identity is underway, national allegiances still supersede EU loyalty for most citizens. Ferrera considers this tendency a reflection of people's conceptions of national boundaries. Yet European integration is challenging such spatial boundaries as borders are continuing to open as a result of the single market.⁵⁶ Where identity evolves to take into account these new spatial conceptions, an EU-level version of values, such as solidarity and equal access to welfare based on need, may become articulated, and eventually embedded in EU law and policy.

Some degree of solidarity has already been evidenced between subnational regions within the EU, due in part to EU supranational patronage, for instance, through the EU's Structural Funds.⁵⁷ These activities of the EU might diminish the role of national governments as gatekeepers of social policy, and may result in tensions between different geographical areas, if 'those who give' resent giving to 'those who get', as we do see in respect of the CAP. But an EU-level commitment to a shared social welfare policy may equally have positive effects, such as encouraging innovation and efficiency. In the context of global trade, EU-level solidarity may contribute to shoring up the 'European social model'⁵⁸ vis-à-vis alternative welfare models in the rest of the world (such as the approach to welfare and health care found in the United States), though this is not clear. The implication of this observation is that the EU's contribution to national social policies is likely to be to protect 'European' welfare values over time. Or else, as Majone has described it, the 'social Europe' of the future, based also on key jurisprudence from the Court,

⁵⁵ Weiler, 'A constitution for Europe?', above n.53.

⁵⁶ M. Ferrera, 'European integration and national social citizenship: changing boundaries, new structuring?', *Comparative Political Studies* 33 (2003), 611–52.

⁵⁷ Ferrera, *The boundaries of welfare*, above n.48.

⁵⁸ There is no formal legal definition of the 'European social model'. For a discussion of the meaning of the phrase, see T. Hervey, 'Social solidarity: a buttress against internal market law?', in J. Shaw (ed.), *Social law and policy in an evolving European Union* (Oxford: Hart, 2000), 31–47, in which is also cited Commissioner Flynn's speech to the Conference on 'Visions of European Governance', Harvard University, Cambridge, MA, 2 March 1999: '[t]he European Social Model ... has been conceived and is applied in many different ways. ... All the variants reflect and respect two common and balancing principles. One is competition ... the other is solidarity between citizens.'

'will be, not a supranational welfare state, but an increasingly rich space of social-regulatory policies and institutions'.⁵⁹

We can discern two types of challenges to EU-level articulations of the values of social solidarity, or development of EU social policy. The first concerns the wide variety in approaches to welfare and the economic disparities between the Member States. Establishing a common EU-level social and health policy framework would be challenging in view of the great disparities that exist between Member States in ability to pay for health and social services and also in varying conceptions of social solidarity. Four broad regional models of welfare solidarity exist within the EU: Scandinavian, Anglo-Saxon (the United Kingdom and Ireland), Continental and Southern European.⁶⁰ Additionally, new Member States have attempted to reconcile communist legacies and, in some cases, post-communist worldviews, with free market principles. These groups of countries differ in their sources of funding, relative levels of taxation, social service spending, priorities and contribution rates.⁶¹ Inevitably, solidarity evokes varying levels of commitments, inputs and outputs in different nations.⁶² And, for the newer Member States, given their different traditions of welfare and state development, and recent changes in priorities, is their adherence to social protection and social solidarity still as strong (or likely to remain as strong)? Conversely, rich Member States may fear that EU social citizenship could also lead to increased supranational redistribution between Member States, while relatively poorer nations might worry that EU regulation would place unduly lofty demands given limited resources, funding and capacity. EU-level social policy (set at the more generous welfare levels that arguably only the richer Member States can afford) here becomes a form of protectionism for the wealthier EU Member States.⁶³ However, we might observe that similar challenges pose barriers to the creation of an EU-level environmental policy, and yet such a policy exists.

The second type of challenge to the feasibility of developing EU-level social policy concerns the as-yet (and perhaps always to be)

⁵⁹ Majone, 'The European Community', above n.40, 168.

⁶⁰ G. Esping-Anderson, *The three worlds of welfare capitalism* (London: Polity Press, 1989); Scharpf, 'The European social model', above n.15; J. Alber, 'The European social model and the United States', *European Union Politics* 7 (2006), 393–419.

⁶¹ Scharpf, *Governing in Europe*, above n.50.

⁶² Weiler, 'A constitution for Europe?', above n.53.

⁶³ Hervey, *Social Solidarity*, above n.58, p. 8.

brittle concept of supranational solidarity. Although EU citizenship and EU solidarity can be seen to have a discernible influence on the legal and political stage, at least at the level of political discourse, for most citizens national loyalty still takes precedence over EU loyalty. This may, in part, be due to the fact that EU citizenship seems defined primarily in terms of free movement rights and anti-discrimination rules, where some countries initially favoured including citizenship and human rights in the Treaties, while others were less supportive.

For instance, the 1992 Maastricht Treaty granted EU citizens political rights, the right of free movement, the right to diplomatic protection and the right to appeal to the European Parliament. Following this, while several Member States supported further strengthening of citizenship rights, under German and French impetus, the United Kingdom instead pushed for a ‘partnership of nations’. Amsterdam represented something of a disappointment to those favouring stronger citizenship provisions. The result of this still inconclusive understanding of EU citizenship may be the diminished loyalties that are evidenced towards foreigners and immigrants from within the EU (i.e., neighbouring Member States).⁶⁴ Fears of ‘EU benefit tourism’ could spur increasingly protectionist national responses and a restriction of welfare entitlement eligibility.⁶⁵ Indeed, a balancing act must occur between voices against the entry of foreign migrants and the outsourcing of domestic firms with petitions to opt out of social insurance policies or to enter domestic markets.⁶⁶ The *Pierik* rulings⁶⁷ clarified that authorization for treatment abroad was always to be granted when the treatment in question could not be given at home, irrespective of the coverage rules of the insurance scheme and of financial considerations. In a reaction to these rulings, the Member States forced a restrictive amendment of the

⁶⁴ Ferrera, *The boundaries of welfare*, above n.48.

⁶⁵ M. Ferrera, ‘Towards an ‘open’ social citizenship? The new boundaries of welfare in the European Union’, in de Búrca, *EU law and the welfare state*, above n.45.

⁶⁶ See the cases of Case C-438/05, *The International Transport Workers’ Federation and The Finnish Seamen’s Union* [2007] ECR I-10779; Case C-341/05, *Laval* [2007] ECR I-11767; and Case C-346/06, *Rüffert* [2008] ECR I-1989.

⁶⁷ Case 117/77, *Bestuur van het Algemeen Ziekenfonds Drenthe-Platteland v. G. Pierik* [1978] ECR 825; and Case 182/78, *Bestuur van het Algemeen Ziekenfonds Drenthe-Platteland v. G. Pierik* [1979] ECR 1977.

relevant Regulation,⁶⁸ effectively blocking a Court-led stream of negative integration.⁶⁹ Additionally, political mobilization to sway rulings of the Court has also been evidenced – for example, the French Government’s campaigns in the *Poucet and Pistre* case (see below).⁷⁰ Repeat litigation,⁷¹ delay tactics and deliberate non-compliance have also been seen, such as the Spanish request for further clarifications around cross-border health service provision.⁷²

However, even without a centralized and coherent EU social policy framework, and irrespective of whether one is now or will ever be feasible, the boundaries of welfare are already being blurred as a result of EU internal market and other policies. The evolution of EU citizenship without a complementary EU welfarist framework decreases the legitimacy of the EU as a regulatory state and is subtly changing national welfare policies without transparency or careful consideration at either the EU or national levels.⁷³ The European regulatory state brings theoretical and practical challenges that must first be addressed in relation to social protection and European conceptions of redistributive justice.

We can identify five main areas of Europeanization that have restricted national welfare systems: economic and monetary policy; internal market policies; EU employment law; EU law on the free movement of human beings (including movement of workers and citizens within the EU, and immigration and asylum); and health related regulation (including environmental law and public health).⁷⁴ The EU’s economic and monetary union policy adjusts exchange rates based on average conditions in the Eurozone, thus divesting Member States of the ability to adjust exchange and interest rates in relation to internal

⁶⁸ Council Regulation 1408/71/EEC on the application of social security schemes to employed persons and their families moving within the Community, OJ 1971 Sp.Ed. Series I, p. 416.

⁶⁹ Ferrera, *The boundaries of welfare*, above n.48.

⁷⁰ Joined Cases C-159/91 and 160/91, *Poucet and Pistre* [1993] ECR I-637.

⁷¹ Such as in the context of German legislation on ‘minimal workers’.

⁷² J. Sylvest and C. Adamsen, ‘The impact of the European Court of Justice case law on national systems for cross-border health services provision’, Briefing Note, DG Internal Policies of the Union, IP/A/ALL/FWC/2006–105/LOT 3/C1/SC1 (2007).

⁷³ Ferrera, *The boundaries of welfare*, above n.48.

⁷⁴ Scharpf, *Governing in Europe*, above n.50; G. de Búrca, ‘Towards European welfare?’, in de Búrca, *EU law and the welfare state*, above n.45.

economic conditions. This has the potential to further encumber and punish countries with slow growth, while serving to exacerbate highly inflationary economies that may be overheating.⁷⁵ The budgetary commitments required by economic and monetary union imply increased financial pressure on national welfare systems.⁷⁶

Internal market policies have fostered increased EU liberalization, deregulation policies and competition laws.⁷⁷ Economic integration has been promoted through legal mechanisms like deregulation. The EU Treaties prohibit restrictions on the provision of cross-border services and the movement of goods.⁷⁸ These directly-effective Treaty provisions are enforceable by individual litigation ('negative integration'). Even if these goods or services are affiliated with domestic social programmes, like government-sponsored health care or subsidized pharmaceuticals, directly effective EU Treaty law on free movement or competition is still applicable in principle, if these activities are deemed to be 'economic' and not purely welfare-based services.⁷⁹ This application of market models in welfare contexts seems to contradict European welfarist principles such as equal access and solidarity. EU internal market and competition law restrict the use of numerous Keynesian policies, such as increased state level employment and other traditional tools designed to cushion and boost economies in recession. Thus, EU internal market and competition law reduces the number of strategies a domestic government can use to stimulate its economy. As a result, instead of increased spending on social programmes, policy-makers may resort to supply-side measures like welfare reductions or tax cuts.⁸⁰

EU employment law has attempted to prevent discrimination and protect employment rights, and a large body of EU worker health and safety legislation has been adopted, including employment rights during restructuring, non-discrimination clauses and directives on working

⁷⁵ Scharpf, 'The European social model', above n.15.

⁷⁶ P. Pestieau, *The welfare state in the European Union: economic and social perspectives* (Oxford: Oxford University Press, 2006), pp. 116–24.

⁷⁷ B. Eberlein and E. Grande, 'Beyond delegation: trans-national regulatory regimes and the EU regulatory state', *Journal of European Public Policy* 12 (2005), 89–112.

⁷⁸ Article 49 EC; Article 28 EC.

⁷⁹ Scharpf, 'The European social model', above n.15.

⁸⁰ Hervey, 'The European Union's governance', above n.39.

time.⁸¹ However, EU regulators may not have considered the long run implications of such decisions, particularly as they apply to welfare institutions, which are often among the largest employers within a Member State. The increased cost of compliance with EU employment law may also have the effect of squeezing public welfare budgets.

Measures of EU law based on the protection of the rights of mobile workers⁸² or, more recently, the emergent ‘citizenship of the EU’,⁸³ have influenced the movement of people in the EU. Such principles of free movement law, as applied to human beings, also affect domestic welfare programmes. Countries with generous social systems may reduce benefits in response to increased immigration or tighten eligibility regulation.⁸⁴ The creation of a mobile ‘European’ labour force is changing boundaries and eroding social sovereignty within Member States. This has resulted in the evolution of (semi) sovereign welfare states⁸⁵ within an EU regulatory structure, and a new era of governance and complexity.⁸⁶

Finally, the obligations to comply with EU-level health-related regulation (in fields such as environmental law, food law and communicable diseases law) may restrict the ability of individual Member States to tailor responses to these threats to public health to their national (or even local) specificities. The need to comply with EU-level information-gathering, monitoring and reporting requirements alone – while it may be entirely appropriate, given the need to have a European (or even global) response to many public health threats – does require Member States to deploy human and other resources in ways that would not be mandatory were they not Member States of the EU.

⁸¹ See C. Barnard, *EU Employment Law* (Oxford: Oxford University Press, 2006).

⁸² Article 39 EC; Council Regulation 1612/68/EEC on freedom of movement for workers within the Community, OJ 1968 No. L257/2.

⁸³ Article 17 EC; Directive 2004/38/EC of the European Parliament and the Council on the right of citizens of the union and their family members to move and reside freely within the territory of the Member States, amending Regulation 1612/68/EEC and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC, OJ 2004 No. L229/35.

⁸⁴ S. O’Leary, ‘Solidarity and citizenship rights in the Charter of Fundamental Rights of the European Union’, in de Búrca, *EU law and the welfare state*, above n.45.

⁸⁵ Leibfried and Pierson, *European social policy*, above n.48.

⁸⁶ G. Majone, ‘The regulatory state and its legitimacy problems’, *West European Politics* 22 (1999), 1–24.

As already noted, the jurisprudence of the European Court of Justice plays a pivotal role in EU-level law and policy-making, including in those areas just mentioned. The Court enjoys the exclusive power to provide authoritative interpretations of EU law, which is supreme and applies in preference to contradictory national law.⁸⁷ For instance, the Court has safeguarded the rights of transnational EU workers to social assistance entitlements⁸⁸ and cross-border health care access,⁸⁹ corresponding unemployment benefits and child support for migrant workers have been established,⁹⁰ along with the rights of other groups such as students.⁹¹ Consequently, Court decisions have eroded national competence in several key areas of social policy, such as control over beneficiary restrictions, consumer choice in benefits consumption, coverage of non-national workers and access to foreign providers. Nonetheless, certain social rights gaps have not been accounted for by Court rulings in these areas, such as unemployed spouse benefits, children's access to social insurance schemes and discrimination against non-traditional family structures like homosexual couples. Such omissions, more or less mandated by the structure of internal market law, and the Court's limited jurisdiction (in this context, to hear references from national courts on questions of the interpretation of EU law under Article 234 EC), indicate that the Court's rulings focus primarily on protecting active members of the labour force.⁹² Most Court rulings have focused on the concerns of relatively well-off income groups.⁹³ Better educated people with greater financial resources may have an easier time navigating through any court system, and the European Court of Justice is no exception. As a result, without explicit EU social legislation guaranteeing the rights of marginalized groups, leaving matters to the Court may unintentionally disadvantage those people who need social protection the most. In addition, it remains the case that the 'ambiguous' understanding of what a social dimension to Europe would mean, as

⁸⁷ Article 220 EC; Article 234 EC; Case 26/62, *Van Gend en Loos* [1963] ECR 1.

⁸⁸ Case C-456/02, *Trojani* [2004] ECR I-7573

⁸⁹ Case 159/90, *Grogan* [1991] ECR I-4741; Case C-120/95, *Decker*, above n.2; Case C-158/96, *Kobll*, above n.2.

⁹⁰ Case C-85/96, *Martinez Sala* [1998] ECR I-2691.

⁹¹ Case C-184/99, *Grzelczyk* [2001] ECR I-6193; L. Conant, 'Individuals, courts, and the development of European social rights', *Comparative Political Studies* 39 (2006), 76–100.

⁹² Conant, 'Individuals, courts', above n.91.

⁹³ Ferrera, 'European integration', above n.56.

already highlighted by Majone in the wake of the Treaty of Rome, remains in place. For while it is clear that neither a single (common) market, nor rulings by the ECJ can facilitate a ‘social Europe’, the question remains as to what extent the Member States are willing to themselves engender such a concept.

4. The role of the European Court of Justice in health care

Moving from such wider social policy questions to the Court’s role in respect of health care specifically, many regard the Court’s rulings in the *Kohll* and *Decker* cases as something of a *Wendezeit* – a turning point in European health policy development. From the point of view of health care policy, the decisions were an unanticipated ‘endogenous shock’, surprising many people, and policy-makers in particular, and they certainly contributed to the establishment of a so-called ‘critical juncture’⁹⁴ in European health policy (at least in terms of becoming high profile cases). But, from the point of view of existing EU internal market law, *Kohll* and *Decker* did not represent anything new. The application of internal market (in this case, freedom of movement) rules to health services had already been recognized.⁹⁵ Regulation 1408/71/EEC⁹⁶ on the application of social security schemes to employed persons and their families moving within the EU, already allowed for health care to be provided in another Member State in specific circumstances. As part of its justification in delivering its decisions in *Kohll* and *Decker*, the Court reaffirmed the Regulation.⁹⁷ Just as importantly, the Court had already applied principles of internal market law in health care contexts. The

⁹⁴ S. Greer, *Power struggle: the politics and policy consequences of patient mobility in Europe* (Ann Arbor: University of Michigan School of Public Health, 2008); S. Greer, ‘Choosing paths in European Union health services policy: a political analysis of a critical juncture’, *Journal of European Social Policy* 18 (2008), 219–31.

⁹⁵ Joined Cases 286/82 and 26/83, *Luisi and Carbone v. Ministero del Tesoro* [1984] ECR 377, para. 16.

⁹⁶ Regulation 1408/71/EEC of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community, OJ 1971 No. L149.

⁹⁷ The Court also held that, while the national Luxembourg rules that were being used to implement Regulation 1408/71 were in violation of the free movement principles under Articles (ex) 28–30 of the Treaty, the Regulation itself was not in violation.

1981 *Duphar* ruling⁹⁸ on the basis of the reimbursement of medicines (resulting in the wide-spread use of negative and positive lists in Europe), affirmed the Member States' right to organize their social security systems as appropriate. In the 1984 *Luisi and Carbone* case,⁹⁹ the Court established that tourists, business travellers, students and patients could travel to another Member State as a 'recipient of services'; the economic elements of free movement were thus already recognized as incorporating health services, falling within (then) Article 60 EEC (now Article 49 EC). As such, the extent of the Court's reference to the free movement provisions in *Kohll* and *Decker* should really not have been unexpected. Moreover, and more generally, the Court was in fact doing exactly what it is mandated to do – that is, to interpret and apply the available hard law (that is, the EC Treaty) in order to fill gaps uncovered by legal challenges.

A characterization of the Court's role as filling gaps is perhaps a statement of the obvious. We have already noted the confused and piecemeal status of health care policy in the EU. As such, the logic of the system would seem to be about plugging holes, smoothing inconsistencies and moving where possible in order to overcome the challenges and tensions mentioned earlier. Perhaps the real question in respect of the Court's role, therefore, is how the Court fills those gaps. Indeed, its role in interpreting the application of EU law in specific circumstances towards filling these gaps raises concerns. This is the case because these Court decisions establish generalized interpretations of the Treaty rules, which become precedents that must be applied in all similar circumstances. Moreover, there is a wide-spread concern that, in doing so, the Court has expressed an apparent leaning towards the application of internal market principles, or the adoption of an economic perspective, at the expense of either a more Member State-oriented approach (a wider 'margin of discretion' for Member States) or a more balanced interpretation of the place of welfare within the internal market. This is, however, perhaps an oversimplification of the position. The Court does try to balance the place of welfare within the internal market, by recognizing that the internal market is not simply a deregulated economic space, but one where social (and other non-economic, such as environmental) dimensions are also embedded in market-correcting or market-cushioning measures. Moreover, it is

⁹⁸ Case C-238/82, *Duphar v. Netherlands* [1994] ECR 523.

⁹⁹ Joined Cases 286/82 and 26/83, *Luisi and Carbone*, above n.95, para 16.

not just the Court that is ‘interfering’ in national health care policy. The Commission, too, has sought to use internal market principles in this way. For instance, the ‘Bolkestein’ Directive (and certainly its early drafts), were an attempt to free up the cross-border provision of services (including health care services) via internal market mechanisms, in particular the ill-fated ‘country of origin’ principle.¹⁰⁰

The Court has determined that some ‘public’ provisions of welfare services, such as health care, are not exempt from the Treaty’s free movement and competition law. Member States remain competent to organize their health care systems as they see fit, but they must do so in ways consistent with EU law.¹⁰¹ Cross-border medical treatment is permitted in most cases, and, in many cases, the public purse is obliged to compensate the patient for treatment received in another Member State. In such a manner, the precedent of increased patient choice and mobility in alignment with EU internal market objectives was established. However, the Court has also sought to maintain the principles of solidarity, such as in the *Poucet and Pistre* ruling,¹⁰² in which it was held that exit from compulsory national insurance schemes was not allowed on the basis of competition law,¹⁰³ and in the *Albany* case, in which it ruled that the sectoral pension scheme under question carried out an essential social function within the Dutch system.¹⁰⁴ Additionally, we see in such cases that public insurance monopolies have also been exempted from competition rulings with certain stipulations. The Court has also shown sensitivity in its interpretation of the term ‘undertaking’ where the Member States’ organization of their social systems around

¹⁰⁰ According to the ‘country of origin’ principle, a service provider providing services anywhere in the EU would be subject only to the regulatory controls of their ‘home state’ – that is, the Member State in which they were established. This principle did not survive in the ‘Services’ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ 2006 No. L376/36, as finally adopted.

¹⁰¹ We see the point made by Damjanovic and De Witte, that the Lisbon Treaty makes welfare *values* far more pertinent at the level of EU policy-making, but that this is not reflected in a commitment to the future evolution of EU welfare *integration*. D. Damjanovic and B. De Witte, ‘Welfare integration through EU law: the overall picture in the light of the Lisbon Treaty’, EUI Working Paper LAW 2008/34 (2008).

¹⁰² Joined Cases C-159/91 and 160/91, *Poucet and Pistre*, above n.70.

¹⁰³ Hatzopoulos, ‘Health law and policy’, above n.45.

¹⁰⁴ Case C-67/96, *Albany International v. Stichting Bedrijfspensioenfonds Textielindustrie* [1999] ECR I-5751.

the principle of solidarity is concerned.¹⁰⁵ And there have, of course, been several instances where the Court has specifically and explicitly qualified its decisions on the basis of non-economic policy objectives.

For instance, in *Preussen-Elektra*, a landmark 2001 ruling,¹⁰⁶ the Court upheld a German requirement that electricity distributors purchase from renewable energy suppliers at fixed minimum prices (where suppliers then compensated them), stating that this was not incompatible with the free movement of goods under internal market rules. Recalling the point made at the outset of this chapter, because commitment to environmental protection is explicitly included in the EU competences (see Title XIX EC), the Court was able to consider two equally footed EU-level policies: commitment to the environment versus internal market pricing stipulations.¹⁰⁷ Such a framing suggests that the explicit inclusion of social objectives in the EC Treaty could similarly help balance national policies promoting social protection, and reflects the Court's ability to be sensitive to a balanced approach to the internal market, particularly where the EC Treaty encourages it to do so. The Court also took into account that a further 'aim' of the German measure was public health protection. It is, of course, to be acknowledged that, like health, environmental policy is itself also a unique case. Nonetheless, other examples where the Court's approach to internal market law (including competition law) and welfare is more balanced include the Irish *BUPA* decision, where the Court of First Instance defended the state compensation scheme,¹⁰⁸ holding that it did not amount to state aid but rather a service of general interest within the scope of Article 86(2) EC, and *Kobll* and *Decker* themselves, where ensuring the financial sustainability of the social protection system was regarded as an important consideration. The Court has also referred to the Charter of Fundamental Rights in some instances.¹⁰⁹ Such cases may not be the norm, but it does need to be asked to what extent can the Court be expected to raise equity

¹⁰⁵ H. Schweitzer, 'Competition law and public policy: reconsidering an uneasy relationship. The example of Art. 81', EUI Working Papers 2007/30 (2007).

¹⁰⁶ Case C-379/98, *Preussen-Elektra AG v. Schleswig AG* [2001] ECR I-4473.

¹⁰⁷ Scharpf, 'The European social model', above n.15.

¹⁰⁸ CFI Judgement in Case T-289/03, *BUPA and Others v. Commission*, [2008] ECR II-81.

¹⁰⁹ Case C-173/99, *The Queen v. Secretary of State for Trade and Industry, ex parte Broadcasting, Entertainment, Cinematographic and Theatre Union*

and solidarity approaches to health care when these are only vaguely mentioned in the EC Treaty? The point to be made, therefore, is that the Court acts within the parameters available, and that it is responsive to Treaty amendments in policy areas other than internal market and competition law, as well as the 'background' of legislation, soft law, governance and policy activity. The Court's primarily internal market and free movement-oriented roles do, however, reflect its inability and unwillingness to address issues of a majoritarian politics nature.

Further, as the Court's role is to interpret and apply the rules that the Treaty sets out, then the argument may be made that it is not the Court that is responsible for making the rules per se, but the Member States as the *Herren der Verträge*. For, while the Court's decisions may bring prominence to an issue and focus attention, and may even go further than anticipated, the Court is not setting the rules as much as it is working within them. So, if the governments of the Member States are 'unhappy' with the Court's interpretation and application of the Treaties, can it not legitimately be asked whether they themselves are not at least in part responsible? Indeed, can such 'problems' not be addressed via new legislation? As Alter points out:

[I]f Member States cannot sway the interpretation of the Court, they may still be able to change the European law itself. This would not necessarily be an affront to the Court, nor would it necessarily undermine the Court's legitimacy. The political system is supposed to work by having legislators draft and change laws, and courts apply laws.¹¹⁰

During the 1990s, for instance, we saw the Member States move to protect specific practices with regard to private health insurance. As the legal framework for medical insurance was becoming clearer and more specific, the Member States were able to agree on and secure partial legislative exemptions aiming to protect social objectives. In future, we may also see the Member States actively move to protect practices that would otherwise constitute a violation of competition law, such as by subsidizing pharmacists to move into more rural areas.

(*BECTU*) [2001] ECR I-04881; and Joined Cases C-122/99 and C-125/99, *PD and Sweden v. Council* [2001] ECR I-4319.

¹¹⁰ K. J. Alter, *Establishing the supremacy of European law: the making of an international rule of law in Europe* (Oxford: Oxford University Press, 2001).

However, while in theory it should be easier now to change regulations and directives than in the earlier days of the EEC, because of the possibilities offered by qualified majority voting in the Council,¹¹¹ in practice we see that few Court interpretations have provoked legislative action to reverse the thrust of the decision. Alter notes that this is because:

[M]ost decisions of the European Court of Justice ... affect Member States differently, so there is no coalition of support to change disputed legislation ... After enough time passes, and enough protests or attempts to challenge ECJ jurisprudence lead nowhere, political passivity sets in ... Inertia undermines the political will to effect change, and passivity is taken as a sign of tacit support.¹¹²

Although not our focus here, it is perhaps worth noting that Dehousse goes further, emphasizing that ‘the tendency towards juridification may help to weaken the legitimacy of the integration process as a whole’.¹¹³ Supposedly neutral debates on the interpretation of EU law considerably weaken the political process, and this adds to the perception of a democratic deficit in the EU more generally (even if the deficit itself is not a view shared by all scholars of European integration).¹¹⁴ This offers opportunities to opponents of integration to claim that citizen’s democracy is replaced by a form of ‘judicial democracy’. Dehousse also points out that, because ‘ECJ rulings may easily be perceived as intrusions calling into question the choices and traditions of national communities’, the same process nonetheless enables EU law to protect individual rights against the decisions of national

¹¹¹ G. Tsebelis and G. Geoffrey, ‘The institutional foundations of intergovernmentalism and supranationalism in the European Union’, *International Organization* 55 (2001), 357–90.

¹¹² Alter, *Establishing the Supremacy*, above n.110.

¹¹³ R. Dehousse, ‘Constitutional reform in the European Community: are there alternatives to the majoritarian avenue?’, *West European Politics* 18 (1995), 118–36.

¹¹⁴ See, for example, G. Majone, ‘Europe’s “democratic deficit”: the question of standards’, *European Law Journal* 4 (1998), 5–28; A. Moravcsik, ‘In defense of the “democratic deficit”: reassessing the legitimacy of the European Union’, *Journal of Common Market Studies* 40 (2002), 603–34; C. Crombez, ‘The democratic deficit in the European Union: much ado about nothing?’, *European Union Politics* 4 (2003), 101–20; Follesdal and Hix, ‘Why there is a democratic deficit’, above n.18.

administrations.¹¹⁵ The point to be stressed, therefore, is that, in view of the joint decision trap, where sub-optimal policy outcomes tend to result, it is extremely difficult in practice for the Member States to reverse any Court advances that are based on the Treaty.

Given the Court's role, the parameters of the constitutional asymmetry, and recognizing the difficulties in overcoming Member State differences, EU policy-makers sought to reach their policy goals through alternative approaches, such as the development of transnational regulatory agencies. Attempts have also been made to strengthen the normative aspirations of 'social Europe' through 'new governance methods', employing soft law such as the open method of coordination (OMC). Such soft laws may be a first step in reconciling the constitutional asymmetry of the EU 'regulatory state', but their long run effectiveness and legitimacy remain in question.

5. New forms of governance and the role of soft law

Given the fundamental contradictions EU health (care) policy is confronted with, linked to the reluctance of Member States to transfer power in this field to the EU, while, at the same time, EU internal market policies might have adverse effects on national social policies, other policy approaches have developed over time, including in the field of health care. A wide variety of phenomena are associated with the concepts of 'new modes of governance', and the ambiguity of the notion may have contributed to its abundant popularity. Most do, however, refer to the relationship between state intervention, on the one hand, and societal autonomy, on the other.¹¹⁶ 'New governance' refers to policy-making that is less prescriptive, less committed to uniform approaches and less hierarchical in nature.¹¹⁷ In this section, we will shed light on the role of new modes of governance in EU health care policies. We will first consider the use of supranational agencies

¹¹⁵ R. Dehousse, 'Integration through law revisited: some thoughts on the juridification of the European political process', in F. Snyder (ed.), *The Europeanisation of law: the legal effects of European integration* (Oxford: Hart, 2000).

¹¹⁶ O. Treib, H. Bähr and G. Falkner, 'Modes of governance: a note towards conceptual clarification', Eurogov Paper No. N-05-02 (2000), available at www.mzes.uni-mannheim.de/projekte/typo3/site/fileadmin/wp/abstract/N-05-02.htm.

¹¹⁷ See Chapter 4 in this volume.

as part of the new governance architecture, and then discuss the soft law instruments as non-legally binding EU rules of conduct, with a focus on the open method of coordination.

Looking first at the EU's use of supranational agencies, many of the current twenty-nine agencies have an impact, even if not direct competences, in health (care) policy fields. The two most relevant are the European Medicines Agency (EMA), established in 1993, and the European Food Safety Authority, established in 2002 (EFSA).¹¹⁸ Supranational agencies were set up primarily in response to the need to serve the 1992 Single Market Programme, where it became increasingly clear that the Commission had neither the functional nor technical expertise, far less the resources, to address the number of tasks associated with governing the internal market. It is also the case that the Member States were not in favour of any strengthening or expansion of the Commission. With independent regulatory agencies becoming an increasingly popular choice for governments at home, it was an approach that could be 'sold' to them, particularly so as these agencies were, on the one hand, decentralized, outside of the Commission bureaucracy and acting independently and, on the other, bodies that would regulate primarily in terms of gathering and disseminating information, without therefore interfering directly in Member State affairs. The European agency model was thus one that was more intergovernmental/technocratic than supranational. Not only did the agencies' management boards comprise Member State representatives, but the agency structure involved national regulatory authorities with the EU agency at the centre.¹¹⁹

None of the EU agencies are independent regulators in the sense of national regulatory authorities. Nonetheless, they do fill one or more governance roles, such as development of EU standards in the internal market;¹²⁰ information collection;¹²¹ and the implementation of

¹¹⁸ The afore-mentioned public health agency, as an 'executive agency' of the EU, is established for a limited time in order to administer the implementation of a specific Community programme and is not therefore a regulatory authority in the manner of the other EU agencies. The Executive Agency for the Public Health Programme is thus mandated to run from 1 January 2005 until 31 December 2010.

¹¹⁹ Dehousse, 'Constitutional reform', above n.113.

¹²⁰ For example, the European Medicines Agency.

¹²¹ For example, the European Environment Agency.

specialized programmes.¹²² Despite their lack of executive powers, the use of agencies has been seen as filling the ‘regulatory gap’ at the EU level in terms of requiring the Member States, via their national regulatory authorities, to work together, rather than acting individually. The EU’s agency model enables collective decisions to be taken that might otherwise have been hampered by the Member States’ opposition to any further centralization of authority in the Commission. This ‘softer’ approach can therefore be seen as part of the ‘new modes of governance’ view of contemporary EU policy-making, marking a shift away from the long-standing, essentially top-down, rule-based ‘Community method’. In this regard, many of the agencies represent the formalization into a single structure of what had previously been a series of loosely connected committees. This single committee structure can then work independently of both the Commission and the Member States – though this is not to say that the main committees are not subject to pressures from both, nor that their decisions or recommendations have never reflected these pressures – a fact that, in turn, generates its own credibility.

Essentially, an EU agency needs to be legitimate at both the EU and national levels, along with being effective at carrying out its assigned tasks. Many EU agencies have questionable power and legitimacy, leading to variability between Member States and decentralization.¹²³ Both the EMEA and EFSA rely on independent committees comprised of national experts to undertake assessments and work closely with the Member State agencies. Taking the risk assessment function away from the individual national bodies and assigning it to the relevant EU-level scientific committee or panel thus represents an attempt to depoliticize health protection and foster credibility in scientific decision-making in the EU. Nevertheless, in terms of their legitimacy at the EU and national levels, while EMEA is, in the main, well regarded, EFSA, even accounting for its relative youth, is regarded as weaker. This reflects the fact that the Commission tends to ‘interfere’ to a higher degree in the latter agency’s work, where the College of Commissioners reviews the agency’s recommendations. It also reflects that the Commission’s decisions

¹²² For example, the Executive Agency for Health and Consumers.

¹²³ Despite it not being an EU agency, it is worth highlighting in this context that, although DG SANCO is especially well regarded among national stakeholders, its lack of a clear legal competence to propose measures concerning health care hampers its abilities to effect comprehensive EU regulation change. Hervey, ‘The European Union’s governance’, above n.39.

are put to the Council of Ministers for a vote, which introduces national sensitivities and politics into the food (safety) and agriculture sectors, as well as a high degree of politicking. This contributes to the agency's opinions being regarded as less credible than those of the EMEA. Nevertheless, the use of independent expert committees through hub and spoke arrangements via the agencies can be seen as part of the new governance architecture in the EU, as well as reflecting the EU health care governance 'patchwork'.¹²⁴

Staying with the new modes of governance discussion, but moving perhaps a step beyond the agencies' policy-affecting role, soft law encapsulates non-legally binding EU rules of conduct.¹²⁵ There are three main categories of soft law: (a) preparatory information, including action programmes and communications; (b) interpretive and decisional tools intended to provide guidance in the application of EU law; and (c) policy coordination and steering instruments.¹²⁶ Such distinctions are often blurred in reality, as often soft law can evolve over time, including into hard law. For example, what began as a briefing on cancer screening evolved into a national policy steering instrument.¹²⁷

The case can be made, relying on a constructivist approach, rather than the rational actor explanations that underpin intergovernmental explanations of EU-led policy change, that soft law can set the stage for policy change, through, for example, policy learning and sharing of best practice, by increasing dialogue and raising awareness. But limitations to effective policy learning arise due to financing disparities, differing capacities and asymmetric power between those 'at the table' in the process of articulating soft law measures. Without adequate financing mechanisms to back EU-led soft law suggestions for change, national policy change is unlikely. Even with adequate funding, best practice exchange between countries is not a given – measures pursued by one country will not

¹²⁴ See Chapter 2 in this volume.

¹²⁵ L. Senden, *Soft law in the European Community* (Oxford: Hart, 2004); L. Barani, 'Hard and soft law in the European Union: the case of social policy and the open method of coordination', *The Constitutionalism Web-Papers* No. p0011 (2006).

¹²⁶ Greer, 'Choosing paths', above n.94.

¹²⁷ L. G. Trubek, M. Nance and T. Hervey, 'The construction of a healthier Europe: lessons and questions for EU governance from the fight against cancer', 26 *Wisconsin International Law Journal* (2008), 804–43.

automatically work in another due to varying underlying conditions, especially if the ‘learner’ does not have the ability to facilitate change.¹²⁸ Also, a middle of the road approach attempting to balance multiple development models may not be as efficient as pursuing one clear and well-coordinated strategy.¹²⁹ Member States may also have the tendency to push forward soft laws that align with their own domestic agendas, rather than policies that might better benefit the EU as a whole. Additionally, powerful lobbies such as the pharmaceutical sector appear to have had success at getting their concerns on the EU soft law agenda, as evidenced by the Pharmaceutical Forum.

The alignment of the requisite legal elements and key stakeholder buy-in were important factors in the success of such examples.¹³⁰ Ensuring that soft law is being developed and distributed to decision-makers at the national level is also critical. Speed of uptake at the national level may also be affected by how controversial the subject matter is: contrast, for instance, the European Platform for Action on Diet and Physical Activity and the work of the High Level Group on Health Care in the internal market. On the other hand, soft laws such as those promulgated through EU-level cancer and AIDS public health programmes, funded by EU sources, have provided extremely helpful research, guidelines and tools since inception. There is also evidence that such programmes provide positive incentives for national governments to improve the quality and support of corresponding domestic initiatives.¹³¹

Although such EU public health programmes may be well received, Member States are quite sensitive to EU interference in welfare domains like health care. Overall, despite the lack of formalized EU welfare policies, a patchwork of law, governance and policy, especially in the areas of public health, employee protection and cross-border health care provision, is evident. The combination of formalized EU regulation, Court rulings and the introduction of soft laws, leads to

¹²⁸ B. Eberlein, ‘Formal and informal governance in Single Market regulation’, in T. Christiansen and S. Piattoni (eds.), *Informal governance in the EU* (Cheltenham: Edward Elgar, 2004); Alber, ‘The European social model’, above n.60.

¹²⁹ Alber, ‘The European social model’, above n.60.

¹³⁰ Scharpf, ‘The European social model’, above n.15.

¹³¹ Trubek, Nance and Hervey, ‘The construction of a healthier Europe’, above n.127.

'hybrid' policy channels.¹³² Such 'amalgam' policies can help effect change and may be more politically feasible than policies relying solely on traditional regulatory (or redistributive) methods.

The open method of coordination (OMC) is the best-known example of soft law. The OMC, seen as a new mode of governance, serves to promote comparative evaluations of EU Member States' performance based on the voluntary sharing of information, dissemination of best practices and 'learning by monitoring'.¹³³ Although lacking formal sanction capabilities, the OMC establishes a benchmarking framework that respects national diversity and employs 'peer pressure tactics' (e.g., 'naming and shaming') to promote learning and achieve progress. It involves the European Commission as something of a broker or facilitator between Member States, with the burden of work falling to transnational networks of policy experts. The introduction of the OMC has prompted much debate over the role of such soft laws in EU governance.

Proponents contend that a 'gradual hardening' of OMC goals can be evidenced by the growing incorporation of social protection considerations in judicial rulings and in increased national implementations of soft laws.¹³⁴ They also point out that so-called 'hard law' may not, in practice, necessarily result in change on the ground, and that 'bottom-up' decision-making that engages those who will be responsible for actually implementing the decisions on the ground may be much more effective in practice than hard (but not necessarily observed) law. It is certainly the case that, with the EU political system dependent on consensus and (qualified) majority opinion, a dynamic based on peer pressure and benchmarking may help to move policy forward in intractable areas or those that are otherwise normally off-limits.

Sceptics of the use of soft law in this context raise five broad objections. They point out that soft law lacks specificity, enforceability and the ability to establish a concrete plan of action, fearing that it cannot counterbalance the hard laws defined around the internal market.¹³⁵ As Tsoukalis summarizes: '[i]n a political system consisting

¹³² D. Trubek, P. Cottrell and M. Nance, 'Soft Law,' 'Hard Law,' and *European Integration: Toward a Theory of Hybridity* (Madison: European Union Center of Excellence, University of Wisconsin, 2005).

¹³³ Scharpf, 'The European social model', above n.15.

¹³⁴ Ferrera, *The boundaries of welfare*, above n.48.

¹³⁵ Trubek, Cottrell and Nance, 'Soft Law', above n.132.

of (semi-) sovereign states, which retain in most cases the monopoly of implementation of joint decisions, discretion and brainstorming are usually a poor substitute for rules'.¹³⁶ Second, given a scenario of 'competitive solidarity', such soft laws may not be able to assuage tension between competing regions.¹³⁷ Third, soft law also bypasses traditional accountability mechanisms, such as public forums, which decreases transparency and may lead to an 'expert-ocracy' of sorts, as the process is often detached from the constituency of the EU citizen, and from traditional representative democratic bodies, such as parliaments.¹³⁸ This again reflects (and reinforces) the politics–economics gap already mentioned. The Lisbon Strategy, for instance, set out to make the EU the 'most competitive and dynamic knowledge-based economy in the world' by 2010. Notwithstanding the financial crisis ongoing at the time of writing, there has been but limited progress towards achieving this goal. Fourth, the application of the OMC to health care, in particular, raises a number of questions, particularly in respect of benchmarking and the extent to which demonstrable outcomes or cumulative progress can be ascertained.¹³⁹ The difficulties surrounding the health care strand of the social protection OMC, and the fact that the development of even base-line indicators has been significantly slower than in other strands of this OMC, further confirm these concerns. Fifth, Scharpf contends that the OMC cannot achieve constitutional parity due to the vulnerable state of national social protection policies in relation to economic integration objectives.¹⁴⁰ Using the Scandinavian welfare model as a case-study, Scharpf concludes that even such best-practice welfare models could hypothetically be dismantled by a Court ruling based on internal market free movement or competition law. However, others believe that the internal market's legal structure takes both economic and social protection considerations into account, and Hervey

¹³⁶ Tsoukalis, *What kind of Europe?*, above n.16, p. 34. He does, however, acknowledge that soft law approaches, and the OMC in particular, 'may have wider application in some new policy areas where national governments want to preserve a wide margin of discretion'. While not a new policy area, this designation would seem to apply to health policy.

¹³⁷ Trubek, Cottrell and Nance, *Soft Law*, above n.132.

¹³⁸ Ferrera, 'European integration', above n.56; M. Bovens, 'New forms of accountability and EU governance', *Comparative European Politics* 5 (2007), 104–20.

¹³⁹ McKee and Mossialos, 'European health care policy', above n.41.

¹⁴⁰ Scharpf, 'The European social model', above n.15.

therefore maintains that elements of social protection can be firmly embedded in EU regulation of the internal market¹⁴¹ – although this is not to say that they have (yet) been so embedded, in all circumstances where this might be desirable.

The difficult questions of whether soft laws are legitimate and effective must also be asked. In relation to legitimacy, many uncertainties persist. From misgivings about the very concept of EU-level solidarity, to tensions around the viability of soft and hard laws coexisting, and questions about the democratic nature of this non-consensus driven process, the legitimacy of soft policy is not guaranteed.¹⁴² The flexible nature of soft law also makes it almost impossible to gauge its effectiveness.¹⁴³ Additionally, clarification is necessary around whether soft law efficacy is measured by its influence on national level policy change, institutional restructuring and/or vague conceptions of mutual learning.¹⁴⁴ Nonetheless, soft laws can be considered a ‘democratic experimentation’ of sorts that, albeit far from perfect, may be a critical first step in establishing EU-level social policy.¹⁴⁵ Hard laws in the realm of social Europe may not be politically tenable at this point in time, and a process like the OMC could help stakeholders gradually realize the need for (and possibly effectiveness of) enhanced EU-level social policy, including in health care fields. So, while soft laws, including the OMC, have the potential to be an important first step and to help shape national policies, it does not appear that soft law alone can resolve the constitutional asymmetry. Further, as Jorens notes, ‘we should take care. In case we really want to guarantee that social policy

¹⁴¹ T. Hervey and L. Trubek, ‘Freedom to provide health care services in the EU: an opportunity for “hybrid government”’, *The Columbia Journal of European Law* 13 (2007), 623–45.

¹⁴² B. Eberlein and D. Kerwer, ‘Theorising the new modes of European Union governance’, *European Integration Online Papers* 6 (2003), available at <http://eiop.or.at/eiop/texte/2002-005a.htm>; J. Zeitlin, ‘Social Europe and experimentalist governance: towards a new constitutional compromise?’, in de Búrca, *EU law and the welfare state*, above n.45.

¹⁴³ See, on the methodological impossibility of discerning whether national policy changes are attributable to the OMC, S. Borrás and B. Greve, ‘Concluding remarks: new method or just cheap talk?’, *Journal of European Public Policy* 11 (2004), 329–36, at 331–3.

¹⁴⁴ Zeitlin, ‘Social Europe and experimentalist governance’, above n.142.

¹⁴⁵ C. Sabel and J. Zeitlin, ‘Learning from difference: the new architecture of experimentalist governance in the EU’, *European Law Journal* 14 (2008), 271–327; Eberlein and Kerwer, ‘Theorising the new modes’, above n.142.

is a productive factor on an equal basis with economic and employment policy, there is a need for a better regulatory framework.¹⁴⁶ This is the case in order to ensure that social objectives are not (implicitly) governed by economic or fiscal factors, for the extent to which the OMC can either bring tangible developments in health care policy at the EU level, or even lead to hard law more generally, remains unclear.

6. Key areas of EU legal and policy developments in health: the structure of the book

This section serves to apply the various elements of the above discussion to specific areas – current and emerging – in EU law and health care. These areas reflect the individual chapters of the book, and each subsection in the following provides a brief synopsis of the relevant chapter, as well as a more detailed examination of the policy questions and implications at hand.

The volume is roughly divided into two parts. Chapters 2–6 consider, broadly speaking, governance and policy-making arrangements at the EU and Member State levels in view of the impact of EU law on health. Chapters 7–15 then address individual areas of contention or interest given the incursion of EU law – primarily relating to free movement, but also competition law – and its effect on policy-making and outcomes. All of the chapters address both the tension between economic and social priorities in health care given the impact of EU law, and the impact on national health systems (in terms of issues raised and effects brought to bear). The discussion begins with a more detailed and critical exploration of the legal, governance and policy-making patchwork touched upon above.

A. The legal–policy patchwork

Chapter 2 provides an in-depth examination of the different EU-level responses to the myriad issues facing the Member States as the effects of EU law (and of European integration more widely) on their health care systems are felt. Taking as their starting point the somewhat paradoxical situation that national policies are increasingly influenced

¹⁴⁶ Y. Jorens, ‘The evolution of social policy in the European Union’, *Polityka Społeczna* (2005), 26–9.

by EU legislative instruments and policies at the same time that EU level welfare policy is purposefully weak, Tamara Hervey and Bart Vanhercke explain how a 'patchwork' of EU law and policy has developed in relation to health care. An increased appreciation of the effects of European integration on national health care objectives has evolved over time, and the chapter provides an overview of this phenomenon. It makes the case that an EU health care policy sphere is evolving that balances formal EU legislation and judicial rulings, EU soft modes of governance, and defensive national level responses.

Providing something of an historical perspective, the chapter begins with an overview of formal EU laws around public health policy. The direct and unintended consequences of other EU laws and court cases on national health care systems are then critically assessed and numerous examples are provided. Specifically, the role of internal market, competition, social and employment law are evaluated. The fourth section explores the processes through which various sets of actors attempt to shape the EU health care debate. Five sets of key player are identified, which are labelled as 'public health', 'social affairs', 'internal market', 'enterprise' and 'economic' actors, who have crowded the health care arena and established various uncoordinated responses with varying impacts at the domestic (and, indeed, EU) level.

Public health is a separate policy domain from health care, but there is, of course, a high degree of overlap. EU public health policy is based on Article 152 of the EC Treaty, equipping the EU with instruments to regulate at the supranational level. Specifically, EU public health programmes, such as those on cancer and HIV/AIDS, appear to have had a positive impact, especially in increasing awareness of high priority health issues throughout the EU. The programmes' budgets, though modest, have nonetheless provided guidelines and positive incentives for change at the national health care policy level, especially in research and development. As a result, the public health programmes, administered by the Directorate-General for Health and Consumer Protection (DG SANCO), provide a platform from which health care governance can springboard.

EU legislation relating to other policy areas and decisions of the Court provide further avenues and legal instruments that have had profound influences on national health care systems. Despite a small budget, the extensive regulatory powers of the EC Treaty in internal

market law have had a significant influence. Specifically, the principle of free movement of goods, services and professionals has been applied to the health care arena. Despite exceptions such as the ‘protection of the health and life of humans’ under Article 30 EC, and additional recognition of ‘objective public interests’, the encroachment of internal market law on national health care policies has occurred. The Court has attempted to balance such public interest with market objectives, but its jurisprudence has more explicit market-promoting guidelines in comparison to more vague welfare-promoting objectives.

Some formal regulation has been adopted concerning the manufacture, marketing and sale of pharmaceuticals and biomedical devices, as well as consumer protection measures (e.g., tobacco laws). It appears that the success of EU regulatory measures is contingent on the formal legal power to adopt such EU-level standards and the corresponding political will. Promoting competition and protecting services of general interest are also primary objectives of EU internal market policy. Articles 81 and 82 EC may apply to governmental services like health care, which has had repercussions on national health care and places a burden of proof on domestic governments, such as in respect of services of general economic interest (and this, in turn, depends on how these services are considered), as discussed in Chapters 7–9. Additionally, EU social and employment law, intended primarily to protect EU workers and promote non-discrimination, have also had unintended consequences in the health care setting. For example, the Working Time Directive’s application to medical professionals may hamper domestic delivery of care.

In such a manner, the freedom of domestic stakeholders to organize their national health care systems is restrained by the growing influence of EU law, but the EU has limited specific legal competence in the health care field. Defensive responses to protect solidarity-based national models of health care by a multitude of actors and institutions have been evidenced. Nonetheless, health care has slowly but unmistakably found its way onto the EU agenda. A key initial milestone was the adoption of soft law such as the 1989 Community Charter of Fundamental Social Rights for Workers; Commission white papers on social protection have also played an instrumental role. Other Commission communications have spurred debates on topics like reducing costs, ageing and pensions. High profile court cases have also kick-started political momentum around social protection,

especially in health care. And the EU Treaties have afforded various Directorates-General greater legitimacy, such as the increased role implied for DG SANCO under the Amsterdam Treaty.

'Enterprise' players, such as the pharmaceutical industry, have also played a profound role in pushing forward agendas such as competitiveness, direct-to-consumer advertising and transparency in pricing and reimbursement. The launch of the G10 Medicines Group to foster competitiveness is an example of a new informal mechanism that largely enables the Directorate-General for Enterprise and Industry (DG Industry) to weaken the position of the institutions involved in the legislative process on pharmaceuticals. Increasing awareness of such 'back door' internal market-promoting approaches and their influence on national health care systems is occurring. Nonetheless, EU level intervention remains very politically sensitive. National health ministers and DG SANCO have struggled to implement soft law recommendations such as those of the High Level Process of Reflection on Patient Mobility, or to implement the 'Concerted Strategy on Health Care for the Elderly'. Member States often seek to delay the processes. The European Commission succeeds in pushing soft law like the OMC forward by employing simple strategies such as shifting the wording of Council mandates from referencing 'health care' to 'health and long-term care for the elderly'.

Health will continue to be a highly constrained area of EU competence. But awareness of the influence of EU regulation on health care continues to increase. The case is made that greater governance does not appear to significantly destabilize the independent agency of the Commission, and public consultation is seen as a tool to legitimize further initiatives like soft law and legally-binding directives. The increasing interlinkage between classical EU law and new governance processes is evidenced. Such cross-fertilization is fostering hybrid policy instruments; however, it does not appear that such patchworks will result in a single unified EU approach to health care.

B. Agencies and health (care) policy-making

In Chapter 3, Govin Permanand and Ellen Vos look at the reasons behind the increasing number and influence of EU-level agencies, before focusing on the two with the most direct relevance to national health systems: the European Medicines Agency (EMA)

and the European Food and Safety Authority (EFSA). They highlight a general trend amongst European policy-makers to turn to executive or regulatory agencies that are outside of the Commission structure as a means of addressing specific areas of EU policy. The agencies are also seen as a means of generating objective assessments and disseminating information and examples of best practice. More widely, the chapter also considers agencies from the perspective of their being a central element in the new experimentalist governance architecture of EU policy-making, and considers the pharmaceuticals and foodstuffs agencies as examples in practice.

The authors trace the evolution of EU competence in health and the Europeanization of pharmaceutical and food safety as precursors to the eventual emergence of EFSA and the EMEA. The discussion looks at EU-level initiatives, the impact of the single market, and health crises in the respective domains, highlighting how this dual health protection and internal market facilitation role is reflected in both agencies' mandates and their execution of regulatory functions. These mandates are then examined in detail, especially their risk analysis functions. This reflection on their operations is tied to the EU's principles of good governance. The chapter thus offers a comparative analysis of the two agencies, considering their real and potential impact on Member State health systems. Throughout, concerns are raised around the independence, accountability and strength of both agencies, especially as their spheres of influence increase. The chapter further raises the question as to whether the agency approach, which is seen as a constituent element of new modes of governance approaches (see Chapter 4 in this volume), is likely to be relevant to other health-related areas as well.

The wider development of Community health competences can, however, be seen as a backdrop to the emergence of the EMEA and EFSA in terms of how health has permeated the EU agenda in the first place. Here, the discussion looks at the 1992 Maastricht Treaty's allowance of public health protection, the 1997 Treaty of Amsterdam's emphasis on human health safety, and ECJ rulings on the free movement of health care services and professionals. In identifying milestones in the development of the two agencies, we see that specific legislation and monitoring guidelines addressing the pharmaceutical sector, at both the national and EU levels, were first adopted in the aftermath of the thalidomide case. 'Mutual recognition' procedures aimed at reducing trade barriers

to increase the speed of entry of new medicines were introduced in 1975 and further augmented by the 1986 Single European Act's emphasis on the free movement of goods, services and capital. Meanwhile, specific food safety oversight began in 1974 with the creation of a risk assessment body and was first seriously questioned in the wake of the bovine spongiform encephalopathy (BSE) crisis with the reorganization of scientific committees under the Directorate-General for Consumer Policy and Health Protection of the Commission (now DG SANCO). A new Community approach thus began to evolve with the adoption of the 2002 General Food Law¹⁴⁷ to address safety concerns and the creation of the centralized EFSA. Tension between balancing the objectives of the EU internal market, such as free movement and competition, and health safety is thus evidenced in both policy domains, and both agencies' remits reflect this in their regulatory mandates. Nonetheless, a bias towards market policy is suggested, indicating a need to better serve public health interests more directly.

The mandates and functions of the EU regulatory agencies reflect considerable variability in degree of authority, ranging from collecting and disseminating information, acting in an advisory capacity to the Commission and/or Member States, and providing direct oversight and guidance. As regards the medicines and foodstuffs agencies specifically, the underlining aims are shown to include securing political commitment for long-term goals in health, addressing uncertainties and risk analysis, enhancing credibility through greater independence from policy-makers and increasing efficiency. In this regard, both agencies are shown to be similar in their focus on guaranteeing product accessibility and safety, along with meeting consumer expectations by effectively communicating potential risks. Yet, while the EMEA is shown to be a 'strong' agency by virtue of its proximity to the Commission (where the Commission accepts the EMEA's opinions in the form that they are delivered), EFSA is shown to be comparatively weak, as its recommendations do not carry similar weight. A further crucial difference between the agencies lies in the timing of regulatory interventions: pharmacovigilance tends to focus especially on *ex ante*

¹⁴⁷ Regulation 178/2002/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 No. L31/1.

regulation, while foodstuff testing generally occurs *ex post* market distribution. Regarding the latter, an increasing trend towards pre-market control is, however, the case.

Despite the agencies' need to be seen as credible, independent and accountable, and to espouse good communication practices, the chapter shows that both reveal some shortcomings in these areas. Even if not in the opinion-generating procedures *per se*, it is suggested that the influence of the governments of the Member States, the Commission and industry on the agencies may be too high, though understandable given their role in also promoting the single market. So, while both agencies attempt to maintain their independence – efforts have been made to strengthen the declaration of interests of agency committee and panel members, and greater public involvement has been sought, for example, through the EMEA's introduction of consumer and doctor representatives on its management board – we see that neither agency is immune to politics. This is especially the case for EFSA, where the communication of risk assessment findings is extremely political and challenging. Additionally, there are potential conflicts of interest in relation to industry sponsorship. Here, it is interesting to note that the instructive capacities of EMEA in helping to guide applicants on what is needed for a successful marketing authorization go considerably beyond that undertaken at a national level or by the United States Food and Drug Administration. Increased transparency is pivotal in building consumer trust, but also a challenge in light of commercial secrecy. And the fact that neither agency is entirely free from EU and national level politics – that the science is not properly divested from the politics – is also identified as an area of potential concern, given that both purport to protect public health according to the highest independent scientific standards. Overall, therefore, better balance between the agencies' commitment to hard science, stakeholder priorities and public opinion must be achieved.

The chapter also treats the agencies as part of the broader new modes of governance approach. As such, there are lessons to be learned from their design, their involvement of interests and their functioning in practice. This is especially the case given their impact on national health care systems. Can such agencies help to forward the more deliberative and participatory policy-making approaches required to address sensitive issues in health and health care? The discussion does not offer an unequivocal answer – it is not clear that one

exists. But the discussion does strike a cautionary note in nonetheless endorsing the view that the agencies have an important role to play and may serve as something of a model for better balancing between the free movement of goods and public health priorities.

C. Health care and the EU: the hard politics of soft law

The shift away from the ‘classic Community method’ of regulation to more incorporative and less prescriptive approaches has led to an increasing literature of so-called ‘new modes of governance’ in the EU. Soft law, in general, and the OMC – the most institutionalized form of soft law – in particular, have so far been used with some success in various areas of social policy. Are these modes of governance relevant to health policy (making) in terms of helping to breach the constitutional asymmetry between EU-level regulatory internal market law and lack of redistributive power in welfare contexts? For, while the OMC may be useful in helping to overcome national divergence via a shared bottom-up approach, it is nevertheless grounded in an EU legal framework, which seeks deregulation of national markets and the promotion of competition. The question of how to achieve overall convergence while promoting individual competitiveness, and how to then balance this with appropriate and shared social protection guidelines, are among the challenges facing policy-makers who seek to use the OMC approach in health (care) policy.

Taking as their starting-point the conceptual difficulties and rather ambiguous definitions that mark much of the new modes of governance and soft law literature, in Chapter 4 Scott Greer and Bart Vanhercke seek to offer some clarity by focusing on four questions. What is new governance? Why and how has new governance developed in health care? Finally, they ask what it may do now in view of the challenges and sticking-points already mentioned several times. They discuss the new governance concept within the context of soft law more generally, and offer a case-study of OMC, as applied to health care, in terms of its theoretical origins and application in practice.

The authors highlight that specifying what new governance is and what is not ‘new governance’ is not an easy task given the degree of networked policy-making that characterizes the EU polity. Nonetheless, the Commission’s increased use of: (a) green and white papers, action

programmes and information communications; (b) more formal communications, guidelines and frameworks for action; and (c) steering instruments such as the OMC or the High Level Group on Health Services and Medical Care reflects this less hierarchical and more deliberative approach.

The OMC, as officially laid out at the Lisbon Summit in 2000, is envisaged as an incremental mode of securing Member State approval towards achieving consensus in areas that have otherwise defied harmonization. Via a commitment to agreed goals, benchmarking of progress towards these goals, reporting mechanisms and sharing of best practices, Member States can help each other develop and pursue measures towards promoting convergence among them.

The authors found that the new governance mechanisms emerged as a result of competition between different sets of actors to frame EU health policy as an economic (internal market), social or health policy issue, and that this developed as a reaction to the development of EU law and decisions by the Court, as well as the pressures of Economic and Monetary Union (EMU). The direction of Court decisions both created an EU competency and gave it a concrete form – the internal market (patient mobility), state aids, competition and public procurement law. That form did not reflect the priorities, values or the expertise of health systems or welfare states. Consequently, health ministries and health interest groups were at least grudgingly receptive to the Commission when it proposed new governance mechanisms such as the OMC and the High Level Group on Health Services and Medical Care. The emergence of soft law with regard to health care is thus the result of bargaining between different sets of strategic actors, each with specific, sometimes conflicting, interests. The authors found some evidence that illustrates that soft law is considered by some and in some cases to ensure compliance with Court rulings (where soft law is seen as a tool to implement hard law), whereas, in other circumstances and by other actors, soft law is sometimes used to avoid specific legislation on health care (e.g., through engaging and occupying the Commission).

The chapter outlines the necessary conditions for successful new governance. Drawing on the work of Sabel and Zeitlin,¹⁴⁸ they substantiate that the first condition is uncertainty – i.e., lack of agreed

¹⁴⁸ Sabel and Zeitlin, 'Learning from difference', above n.145.

solutions (or problems) – which is the case in health. The second is a lack of hierarchy, with no single actor having the capacity to impose its own preferred solution. These two criteria are fertile grounds for networks. The third criterion is an unattractive penalty default for failure – i.e., something worse that will happen if the experimental governance fails, a destabilization regime. The authors consider the progressive submission to internal market law as extended in an unpredictable, case-by-case manner to be the penalty for lack of action. The ultimate question is, however, whether any of the soft law instruments will prevent the penalty default. This is not clear. The authors do, however, suggest that the Court has shown itself to be sensitive to the political consequences of its decisions. Furthermore, it is not clear that new governance mechanisms would have to actually affect health systems or policies in order to ‘head off’ the Court. New governance might affect policy without staving off the expansion of internal market law, and it might equally deter the Court and the Directorate-General for the Internal Market and Services (DG MARKT) without affecting a single doctor or patient.

Looking at the likely future of new governance, the authors conclude that the benefits for the EU institutions and Member States are sufficient to keep new governance alive, even if they might not be sufficient to carry the day for the social or health framing of EU health policy. New governance tools might be abandoned if Member States do not get adequate use out of them or if one or more EU institutions dislike the consequences. However, the Commission is the most active EU institution, and its fragmentation and internal competition generally enhance its entrepreneurialism. Therefore, the authors conclude that it is likely to continue to offer new governance mechanisms. New governance might do better than survive if new governance seems likely to prevent the ‘default penalty’ of internal market law. Conversely, if the OMC turns out to be a way to discuss health policy while the Court is rewriting the fundamental rules of the game, Member States might lose interest. But even if they never replace the Community method, and fail as the countermove to Court jurisprudence, the different mechanisms fulfil multiple functions, such as strengthening networks, contributing to epistemic Europeanization and shaping political consensus.

D. Public health in the EU

In Chapter 5, Tamara Hervey, Martin McKee and Anna Gilmore highlight that, at the same time as the EC Treaty enshrines the exclusive right of the Member States to set their own national health care policies, so too do they establish a set of obligations for the EU vis-à-vis public health requirements. Although the inherent difficulty (if not contradiction) in this position has been raised in Chapter 1, this chapter explores the range of competences exercised at the EU level in public health protection of EU citizens. The chapter sets out the legal framework, discussing the Treaty and the regulations governing the EU's public health programmes. It examines the challenges faced by the EU in developing public health policy through two case studies: communicable diseases and tobacco.

Throughout the chapter, the authors highlight the tensions with which the EU is confronted while discharging its obligations to develop and implement public health policy. The first tension relates to its positioning between nation states and international organizations. The EU lacks the public health expertise, resources and experience of international bodies. It also lacks the capacity – in particular, the financial and human resources – of a state, which would enable it to deliver public health policies. The chapter illustrates that, as a result, in some respects, the EU acts, or attempts to act, as if it were an international public health organization. In other respects, the EU acts, or attempts to act, as if it were a state. What emerges is a series of partially-connected EU laws and policies that have various effects on public health. Secondly, the EU has obligations concerning the protection and promotion of public health, but the organization and delivery of health care services is the responsibility of the Member States. Yet, in practice, public health measures can reduce the burden of disease falling on health care systems, while health promotion is a core function of a health care system. In practical terms, this can make it difficult to ascertain what is or is not within the scope of EU law. The third tension is between the imperative to promote public health and those elements designed to create the internal market. And finally, within the European Commission, one Directorate-General (DG SANCO) has a specific responsibility for public health, but many policies that might be considered to be directly relevant to public health are located elsewhere, often reflecting other priorities and

underpinned by different values. For instance, DG SANCO has the responsibility to ensure that the EU is ‘mainstreaming’ health protection, by ‘ensuring a high level of human health protection’ in all its policies and activities, implying a duty to conduct health impact assessments of EU policies. However, DG SANCO’s capacity to do so is extremely limited. The authors substantiate that, until these tensions can be resolved, if this is possible, the EU institutions, with their limited resources, will find it very difficult to develop a comprehensive public health policy.

The chapter further analyses how the powers of the EU in the field of public health extended mainly as a reaction to failings to address serious crises such as the BSE crisis or health scandals such as the one on the distribution and transfusion of HIV-infected blood and blood products. While Article 152 EC explicitly prohibits the adoption of binding EU-level laws designed to protect and improve human health, it has allowed the EU to develop its own public health programmes. According to the authors, it is difficult to assess the overall impact of the public health programmes, as they lack specific goals against which success can be measured. Furthermore, the extent to which the results of projects are subsequently embedded into national practices or fed into EU law and policy-making is unclear.

In order to illuminate some of the other means by which the EU fulfils its obligation to ‘improve public health’, the chapter examines policies with regard to communicable disease. The progressive dismantling of borders within Europe, with the resultant increase in mobility of people and goods, has greatly increased the opportunity for the spread of infectious diseases. There are, however, various safeguards in the Treaties that have been developed in subsequent legislation. Court rulings and specific legislation have clarified this further, allowing obstacles to the free movement of products where there is genuine doubt about the risk to health, or to the free movement of persons, although the circumstances in which the latter may be done are extremely limited. Article 152 EC provides the legal basis for establishing proactive mechanisms to combat communicable diseases. The EU accordingly established in 2004 a European Centre for Disease Prevention and Control (ECDC) to provide structured, systematic responses to the threats from communicable diseases and other serious health threats in Europe.

The chapter illustrates the wide spectrum of different roles for EU law and policy that are at play, ranging from regulation through the

provisions of internal market law, through to soft law and the use of information to exercise control and effect change. At the more 'regulatory' end of the spectrum, Article 152 EC expressly excludes the ability to take harmonizing measures for public health purposes. On the other hand, restrictions on the free movement of persons and goods, in pursuit of protection of public health, are permitted within internal market law. There is EU-level regulation of the contents of products, and the labelling of products, that involve or may involve a public health risk. The chapter shows, however, a lack of 'fit' between the EU legal bases and the public health aims. Measures adopted under Article 95 EC must be proportionate (i.e., they must not go further than necessary in achieving the aim of ensuring the smooth functioning of the internal market). The EU may not lawfully use internal market law simply to achieve public health goals. This has left them open to challenge by lobbies, as illustrated through the major Tobacco Control Directives since 1989, which have all been challenged by the tobacco industry and its allies.

At the other end of the spectrum, there are areas where it is believed, according to the authors, that greater interaction between members of the public health community, supported by the EU, has played a role in the diffusion of ideas leading to convergence of national policies without any direct involvement of the EU institutions. The EU has exercised influence through information collection, dissemination, development of best practice and networking. As illustrated by the EU's activities in communicable disease control, the authors suggest that the judicious use of relatively small available funds, in carefully selected policy areas, can lead, through their own successes and also external pressures, to large scale, more integrated sets of policy-making tools and institutions, supported by a long term financial framework.

The authors conclude that, faced with the responsibility of developing public health policy, in the context of insufficient resources and competences to develop the full range of policies and practices that make up national public health and insufficient expertise and experience to become an international public health actor, the EU has adopted a piecemeal approach, based on the 'art of the possible'.

E. Fundamental rights and their applicability to health care

In Chapter 6, Jean McHale considers how and, indeed, whether fundamental human rights principles may be utilized in developing

EU law and policy in health. She looks, first, at how principles of fundamental human rights have been developed at the European level, both in respect of the Council of Europe (i.e., the European Court of Human Rights, the European Social Charter and the European Convention on Biomedicine) and the European Union (i.e., the Charter of Fundamental Rights of the European Union). The discussion considers their impact – real and potential – on health and health care in the Member States and raises, with examples, the potential conflicts between such initiatives and national laws, particularly in ethical and religious issues. Second, the chapter outlines the recently endorsed EU Charter of Fundamental Rights and newly created Fundamental Rights Agency. It further considers what impact, if any, they will have in general and on health and health care specifically. The discussion here is oriented around the question of whether an ‘EU approach to fundamental rights in health and health care law’ will develop.

With health and health care not explicitly delineated in the various human rights declarations relevant to the EU Member States (though they are implied or mentioned in passing), their impact has, in the main, been limited to legal challenges in related areas. These include abortion and the right to life, suicide and euthanasia, assisted reproductive technologies, access to care, and limitations placed on, for example, persons with HIV/AIDS. Nonetheless, the Charter of Fundamental Human Rights (agreed in 2000 and adopted in amended form by the Member States in 2007 within the context of the Lisbon Treaty)¹⁴⁹ has the potential to make more of an impact. For instance, the Commission will be able to challenge Member States should it perceive them to be in breach of the Charter in areas within the scope of EU law, and it may result in more (EU and national) legislation being framed in the language of fundamental rights. However, the aspirational language used, along with the considerable scope afforded in interpreting elements of the seven titles and fifty-four articles of the Charter suggests a degree of uncertainty. Indeed, Article 35, which is entitled ‘Health Care’, is broad-ranging, if not simplistic, in citing access subject to national laws and the need for the EU to take health into account when developing policies.

¹⁴⁹ The Lisbon Treaty entered into force on 1 December 2009.

Increased rhetoric and better-informed debate – an area in which the new Fundamental Rights Agency’s primarily information-gathering and dissemination role can play a part – may not necessarily amount to a tangible (long-term) impact. Indeed, the agency is not designed to monitor human rights in the Member States. It is not to be a human rights ‘watchdog’: it cannot cite Member States or address citizens’ complaints, and will be more focused on coordination within and between Member States over human rights issues. Additionally, while there is no specific reference to health or health care in the agency’s mandate, health care has, in 2008, been added as a ‘thematic area of work’. This reflects that some areas of its work in respect of discrimination (whether based on sex, race or ethnic origin, religion or belief, disability, age or sexual orientation, etc.), the rights of the child, and the respect for private life and protection of personal data have carried some health impact. The agency’s work around health rights – mainly concerning access by minority groups or others excluded – has been oriented around (non-) discrimination. Given its limited mandate, therefore, the agency’s work here is primarily in disseminating what the Member States are or are not doing. For instance, it highlights good and bad implementation of the EU’s anti-discrimination legislation or good practice in tackling racism and discrimination (including as relates to health care). And an overall conclusion of this work is that the agency urges Member States, as well as the EU more generally, to encourage cultural sensitivity in the health care workforce.

Despite the Charter and the Agency, therefore, it remains unclear whether a health care dimension to fundamental rights in the EU, or a fundamental rights dimension to EU health care policy, will develop. While both Charter and Agency will contribute to greater awareness, and may have the longer-term effect of moving human rights from a soft to hard law context, perhaps their primary contribution may be in terms of the use of new modes of governance in the context of health and health care law and policy-making – that is, they will engage the Member States and other actors in a deliberative process to deal with complex and controversial issues in a sensitive manner towards enabling agreement and progress. For instance, if the Agency can contribute to better embedding the Charter into decision-making contexts, we may see more explicit EU policy emerge in the future.

F. EU competition law and public services, including health care

Chapters 7–9 analyse the applicability of EU competition rules to national health systems, and whether the case-law and Commission policy statements provide sufficient guidance to resolve the dilemmas that such an application raises. As the authors remind us, the creation of the single internal market characterized by open competition has been and remains an important tenet of European Union policy. Public services in many Member States are characterized by the principles of solidarity and citizenship, which may make the application of internal market and competition principles inappropriate. In Chapter 7, Tony Prosser first considers to what extent health services are subject to the competition norms of the internal market. Following from this, Julia Lear, Elias Mossialos and Beatrix Karl in Chapter 8 then ask when competition law applies to health care organizations. In Chapter 9, Vassilis Hatzopoulos considers how the rules of public procurement and state aid affect the organization of Member State health care systems. Neither the European Court of Justice, the Court of First Instance nor the Commission have defined sufficiently unambiguous responses to these questions.

The most important Treaty provisions for this purpose are Articles 81, 82 and 86 EC governing competition, and Article 87 EC covering aids granted by states. Article 81 bans cartel agreements, activities and practices that aim to or somehow affect the prevention, restriction or distortion of competition within the common market. Article 82 prohibits abuse of a dominant position by one or more undertakings. The term ‘undertaking’ is not defined in the Treaty, but case-law indicates that it does not matter whether the entity is public or private; the defining factor is whether the entity is engaged in economic activity. These rules make it difficult for market participants to attempt to coordinate activities with other market players or to attempt to exploit their monopoly position. Article 86 addresses both the activities of Member States directly and organizations involved in services of general economic interest. In the case of public undertakings and bodies given exclusive or special rights, Member States must not make or maintain in force measures contrary to Treaty rules, notably in relation to competition. Article 86(2) allows for an exemption from competition rules for services of general economic interest where market failures cannot

be effectively remedied with market-based solutions. Article 87 EC prohibits Member States from granting public resources in a form that distorts or threatens to distort competition by favouring certain undertakings. Public funds must either be distributed following a competitive tender based on objective and transparent criteria, or must be specifically evaluated under the Treaty rules on state aids.

Within this context, Chapter 7 focuses on the conflict between economic policy and public services within EU law. The health sector offers an interesting case-study of this dilemma, as some Member States have begun to mix markets and solidarity-based provision of care. The evolving test for services of general economic interest is another point where the Court must determine whether the health sector should be subject to the rules on competition. Chapter 8 takes the next step in the analysis and offers cases from the Court, national courts and the national competition authorities to illustrate the complexities of applying EU competition law to the health sector. Since Regulation 1/2003/EC¹⁵⁰ modernized and decentralized enforcement authority, the protection of EU competition law by national courts and national competition authorities has created the opportunity for greater scrutiny of health care markets. Chapter 9 then explains the links between public procurement and state aid rules and further dissects the implications for financing, planning and contracting for health services.

The competition provisions are based on the argument that competitive markets are the best means of achieving two objectives: maximizing economic efficiency and augmenting consumer choice. Since the health care sector is plagued by market failures, including information asymmetry, moral hazard and uncertainty, Member States have traditionally defined policies to fund and provide services in an attempt to minimize these problems. Competition law may apply where governments mix markets and solidarity-based provision of health services. The distinction between social and economic activities used in the determination of whether competition law applies may seem intuitive at first glance. However, as the complexity of case-law around the health sector demonstrates, it is often unclear to what extent EU competition law is engaged when national health

¹⁵⁰ Council and European Parliament Regulation 1/2003/EC on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ 2003 No. L1/1.

systems have introduced elements of competition. Some public health providers compete with private organizations for privately paying patients, such as between health care trusts in the United Kingdom, or some public hospitals in Finland. In other systems, private providers fulfil public service obligations under the principle of solidarity, such as health insurers in the Netherlands and Ireland. In many cases, there is no clear distinction between a service based on social solidarity and one based on markets and competition. As many of the examples have not been tested within legal proceedings, the question as to whether competition law applies has not been answered.

Once the determination that competition law applies has been made, prohibited conduct includes anti-competitive agreements or associations between undertakings and abuse of dominant positions. Numerous examples exist of agreements between pharmaceutical companies unlawfully colluding to fix prices, or of professional associations illegally encouraging their members to engage in unlawful concerted actions or raising anti-competitive barriers to entry. Some agreements are excluded from the prohibition, such as those resulting from state delegation of sovereign powers or where the restriction is deemed proportionate to protect a legitimate national state interest. Where an undertaking is dominant in a given market, it is prohibited from abusing that dominance to distort competition, as in the case where pharmaceutical companies exploit their market influence by engaging in predatory pricing, as seen in the *Napp* case.¹⁵¹

Another complication in the application of EU competition law is Article 86(2), which allows for a partial exemption of competition rules in cases where a Member State has proactively delineated the activity as a service of general economic interest to obtain immunity from competition law principles, for instance with regard to state aid, as the Court of First Instance held in the *BUPA* case.¹⁵² Similarly, the Commission's White Paper on services of general interest affirms the importance of universal services for social and territorial cohesion and the need to respect the diversity of different types of services as defined

¹⁵¹ Case 1001/1/1/01, *Napp Pharmaceuticals v. Director General of Fair Trading* [2002] CompAR 13.

¹⁵² Case T-289/03, *British United Provident Association Ltd (BUPA) and Others v. Commission* [2008] ECR II-81.

by Member States. It is currently the role of Member States, rather than the Commission and EU law, to promote public service values and good governance in services of general interest. The Commission will only interfere with the Member States' discretion in cases of manifest error. However, there is still a role for the Commission to play by providing legal guidance on cross-cutting issues, such as the state aid rules, further developing sector-specific policies and monitoring and evaluating services on a sector-by-sector basis.

Although the national competition authorities of some Member States have been investigating and prosecuting health sector cases throughout the 1990s (including Finland, Italy and Germany), national authorities became much more active after the entry into force of Regulation 1/2003/EEC in May 2004.¹⁵³ Due to the Regulation's delegation of enforcement to national authorities and the proximity and familiarity of domestic legislation, competition authorities have had the opportunity to pursue anti-competitive practices in the health market with greater frequency than the Commission. As a result of decentralization tendencies, the role of the Commission has evolved from primary enforcer to steward of competition enforcement. The Commission has, in turn, begun to focus on priority setting, enforcing state aid rules and ensuring consistency among the national authorities through the European Competition Network. The scope of authority and financial resources delegated to the authorities varies among Member States, which could lead to a number of problems that have yet to be publicly evaluated by the Commission. Several Member States have employed their competition authorities to comment on health reform legislation and to make recommendations regarding market failures, for instance, leading to rising costs of pharmaceuticals.

The extent to which public procurement and state aid rules affect the organization of national health systems depends on the regulatory techniques used by Member States. The rules on state aids in Article 87 EC prohibit the use of public funds either indirectly through advantages or directly through subsidies, unless the Commission approves the grant following a notification procedure. The rules on public procurement defined in Directives 2004/17/EC and 2004/18/EC¹⁵⁴ require that public contracts are awarded following stringent

¹⁵³ Regulation 1/2003/EC, above n.130.

¹⁵⁴ For procurement in the utilities sector, Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the

conditions of publicity, transparency, mutual recognition and non-discrimination. While the rules of public procurement apply to public contracting entities, state aid rules apply where state resources are transferred to undertakings. Therefore, the rules apply in principle alternatively, and not simultaneously.

The Court formalized this link between the two sets of rules in the *Altmark* case,¹⁵⁵ holding that financial support does not constitute a state aid when four conditions are met cumulatively. The *Altmark* test requires: (a) clearly defined public service obligations; (b) compensation defined in advance in a transparent and objective manner; (c) stipulation that remuneration does not exceed costs; and (d) compensation that must be determined on the basis of an analysis of the costs that a typical undertaking, which is well run, would have incurred if the efficient provider had been found through a competitive tendering procedure. These criteria were most recently used, in a modified form, in the Irish *BUPA* case.¹⁵⁶ The Commission's Communication on the *de minimis* rules¹⁵⁷ limited the application of public procurement rules to contracts falling below a minimum threshold. The Communication goes on to explain the four principles of public procurement: non-discrimination, transparency, proportionality and mutual recognition. The so-called 'Altmark Decision'¹⁵⁸ considers public service compensation to small size service providers and hospitals to be lawful state aids, which need not be notified to the Commission. This Decision and related Commission publications have clarified state aid rules to an extent, but have fallen short of clearly delineating when hospitals or other health system providers are exempted as services of general interest. In an

procurement procedures of entities operating in the water, energy, transport and postal services sectors, OJ 2004 No. L134/1; and the 'General' Procurement Directive, Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, OJ 2004 No. L134/114.

¹⁵⁵ Case C-280/00, *Altmark Trans GmbH* [2003] ECR I-7747.

¹⁵⁶ Case T-289/03, *BUPA v. Commission*, above n.152.

¹⁵⁷ European Commission, 'Interpretative Communication on the Community law applicable to contract awards not or not fully subject to the provisions of the public procurement directives', OJ 2006 No. C179/2.

¹⁵⁸ Commission Decision 2005/842/EC on the application of Article 86(2) of the EC Treaty to state aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, OJ 2005 No. L312/67.

effort to promote fairness, the Court has defined and the Commission has clarified the rules, requiring burdensome analyses rather than identifying with precision which entities qualify as ‘contracting authorities’ and which circumstances meet the *Altmark* requirements.

These rules will impact upon health systems depending upon the choices Member States make regarding the funding of health care. How the state defines the split in financing infrastructure versus costs associated directly with patient care could have an effect on how contracts should be tendered. Lack of transparency in cost calculation by private providers frustrates systems of public tendering. The ‘Altmark Decision’ raises a number of questions concerning the funding of hospitals entrusted with public service obligations. What is the state’s obligation to monitor hospitals to determine whether these organizations fulfil their missions allowing for some reasonable profit, and what recourse must the state take if a hospital fails? If the organization qualifies as a contracting entity, there are still some circumstances where competitive tenders are not required. An example is if no contractual relationship exists because the services are provided between two public entities. What the discussion in this chapter thus shows us is that the general Treaty rules on prohibiting discrimination and restriction of free movement will continue to apply, and thereby result in continued confusion, without positive integration and measures to promote harmonization in the area of health care provision.

G. Private health insurance

In Chapter 10, Sarah Thomson and Elias Mossialos examine the impact of specific internal market laws and policies on the regulation of private health insurance, for the move into private health insurance at the EU level is itself a product of spillover from internal market-oriented policies, reflecting market-enhancing (-building) intentions on the part of the Commission. In 1992, the EU adopted the Third Non-life Insurance Directive¹⁵⁹ to facilitate the free movement of insurance services. The Directive prohibits insurance monopolies and requires equal treatment of insurers, along with forbidding

¹⁵⁹ The third ‘Non-life Insurance’ Directive, Council Directive 92/49/EEC on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance, OJ 1992 No. L228/23.

national governments from demanding ex ante claims approval or systematic supervision of policy conditions and premiums. Article 54 of the Directive includes specific rules for health insurance that constitute a 'complete or partial alternative' to statutory national health insurance plans provided by social security systems. In such cases, the Directive grants an exception and permits governments to impose material (as opposed to merely financial) regulation in the interest of the general good. Examples of permissible measures include open enrolment, community rating, standardized benefits packages and risk equalization schemes. The chapter analyses areas of uncertainty in interpreting the Directive, focusing on the lack of clarity around when and how governments may invoke Article 54 to justify intervention in health insurance markets. It also questions the Directive's capacity to promote consumer and social protection in health insurance markets. Analysis is based on discussion of case-law referred to the European Court of Justice under Article 234 EC concerning private health insurance and infringement procedures initiated by the European Commission under Article 226 EC.

The chapter provides evidence suggesting that material regulation is acceptable so long as private health insurance substitutes for cover that would otherwise be provided through social security. In allowing intervention under such circumstances, the Directive appears to support access to private health insurance where it contributes to social protection. The chapter argues that supplemental private health insurance may also enhance social protection – for example, if it covers reimbursement of user charges or health services excluded from a narrowly-defined statutory benefits package. However, the Directive's framework deems material regulation of such complementary private health insurance to be inappropriate. The Directive may therefore constrain government attempts to ensure access to supplementary private health insurance. This could, in turn, undermine social protection, particularly if insurers have incentives to deter people in poor health from purchasing private cover. Dissonance between recent Court decisions concerning the Irish market¹⁶⁰ and current European Commission infringement proceedings against Slovenia imply continued uncertainty in interpreting Article 54.

Other outstanding issues that the authors highlight include the extent to which private health insurance can be seen as a service of general

¹⁶⁰ Case T-289/03, *BUPA v. Commission*, above n.152.

economic interest (SGEI) – exempt from competition rules under Article 86(2) EC – and the degree to which the SGEI argument can be used to justify differential treatment of insurers. It is argued that the Directive's emphasis on financial regulation may not sufficiently protect consumers in markets where health insurance products are highly differentiated, potentially leading to risk selection and/or consumer confusion. Information problems appear to be growing in health insurance markets in some countries, but the Commission has yet to establish mechanisms to monitor anti-competitive behaviour by insurers.

As the chapter points out, the Directive reflects the regulatory norms of its time. When it was first introduced, the European Commission may have been convinced that Article 54 would provide ample scope for governments to protect consumers in substitutive markets, while in markets regarded as supplementary, the benefits of deregulation (increased choice and competition resulting in lower prices) were perceived to outweigh concerns about consumer protection. These assumptions are more problematic now, partly because there is no evidence to suggest that the expected benefits of competition have materialized, and also due to increased blurring of the boundaries between normal economic activity and social security. The latter is no longer the preserve of statutory institutions or public finance, but a result of increased complexity around welfare systems that is likely to bring new challenges for policy-makers. Greater obscurities around the public–private interface in health insurance give rise to challenges that the Directive does not seem equipped to address at present. In light of these complexities, it is suggested that it is perhaps time for a new debate about how best to update the Directive.

H. Free movement of services

In Chapter 11 on the free movement of services, Wouter Gekiere, Rita Baeten and Willy Palm focus on the direct application of the Treaty provisions on the freedom to provide services and the freedom of establishment to health care. The discussion considers the impact and extent to which the application of these rules to health care goes far beyond the issue of patient mobility and the reimbursement of health care costs received in another Member State. It illustrates how regulation in the health care sector is increasingly scrutinized as a potential obstacle to free movement, and considers that almost any regulatory or institutional

aspect of health care provision can potentially be challenged under the free movement rules. The authors explore the conditions under which the Court accepts health care regulator justifications related to safeguarding public interests and clarify that, even for such measures, actions must be proportional. It becomes clear from the analysis that health authorities face a relatively high burden of proof, and that providing sufficient evidence to justify public intervention under the free movement rules is challenging. Regulatory bodies must demonstrate that general measures are also justified in single cases for an individual provider, and they are required to demonstrate what would happen if the measure were dropped. The authors then analyse the legislative process in a search for policy answers to the legal uncertainty and to the threat of a slippery slope of deregulation arising from these developments. They explain the complexity of the policy process and analyse why policy initiatives thus far have not succeeded in delivering appropriate answers.

The threshold for the application of free movement of services regulations on health services is relatively low. Furthermore, recent Court case-law shows that free movement rules come into play even if the regulatory measure that is under scrutiny lacks a specific potential cross-border element.¹⁶¹ Nonetheless, as the chapter shows, the application of free movement rules in the field of health care is not unconditional. The Court is aware that important market failures might occur and the sustainability of national systems could be threatened when health care is delivered in an unregulated setting. The protection of public health, as well as the sustainability of national health care and the related social protection systems, are recognized as public interest objectives, which can serve as legitimate justifications for obstacles to free movement.

The true challenge rests not as much in the identification of the public interest objectives, but rather in providing the proof that the measures do not exceed what is necessary and that the result cannot be achieved by a less restrictive alternative. Member States will have to provide sufficient evidence demonstrating that the non-application of a restrictive measure in a particular case would jeopardize the public interest objective. Providing evidence of what would hypothetically

¹⁶¹ Case C-55/94, *Gebhard* [1995] ECR I-4165, Case C-8/96, *Mac Quen* [2001] ECR I-837; and Case C-294/00, *Deutsche Paracelsus Schulen v. Gräbner* [2002] ECR I-6515.

occur without the restriction is problematic. Furthermore, even if a rule is generally justifiable, this does not automatically validate its application to every specific situation. As a consequence, health authorities face a relatively high burden of proof. The internal market approach dealing with individual services, and the structure of individual litigation relying on directly effective Treaty rules (negative integration), make it very difficult to consider the health system in its totality and ensure coherence in the government's role as a public payer or purchaser. As a consequence, there is a risk that the free movement provisions might lead to creeping deregulation in this intricately regulated sector.

Actors have gained an awareness of what is at stake in a piecemeal fashion. It appears to be extremely difficult to find an adequate policy response to these developments. The complexity of the issues at stake, the absence of a clear legal framework in the Treaty to deal with these questions and an inherent inertia stalling efforts to fundamentally change the rules of the game all play an important role. Furthering this challenge, stakeholders have discordant concerns, objectives and interests.

Governments of Member States are concerned with losing their steering capacity. However, codification of cross-border health care regulation would engage them to determine what aspects of health system organization and financing should be declared compatible with free movement under what conditions and which to exclude. Although, in principle, the Member States may favour EU-level legislation, in practice national policy-makers become extremely reluctant once concrete proposals have to be discussed. They seem to be caught in the paradox that, in order to safeguard their national autonomy, they have to accept some EU-level interference in their national policies.

Beyond the issue of patient mobility, the European Commission seems neither able nor willing to provide guidance on the specific application of the free movement rules to health care services. It is internally divided between the differing objectives and responsibilities of the Directorates-General, and is limited by its constrained powers. The power relations within the Commission reflect the respective importance of the Treaty provisions on which the areas of expertise of each Directorate-General are based. The voice of DG MARKT thus outweighs the voices of DG SANCO or the Directorate-General for Employment, Social Affairs and Equal Opportunities in the policy debates.

Health care regulation will thus inevitably come under increasing scrutiny on the grounds of its compatibility with the rules on freedom of service provision. The long-term effects thereof are rather unpredictable. Developments are likely to create more diversity in health care provision and increasingly fragmented health care systems. More choice for patients and providers might challenge public support for equity and the solidarity principles underpinning national systems.

I. Free movement of patients

Modest in size but high on the political agenda, attention surrounding patient mobility within the EU has gathered momentum over the last ten years. Two procedures for patients seeking medical treatment outside the state of affiliation now exist in parallel – one designed by Member States, acting through the EU legislature, in the form of Regulation 1408/71/EEC,¹⁶² and one emerging as the Court applies the principles of free movement to health care.¹⁶³ This creates a complex legal picture. Compared to the traditional social security coordination mechanism, Court jurisprudence has created an alternative Treaty-based procedure with a different legal basis, and different conditions in terms of access to and reimbursement of care. Member States have been slow and reluctant to adapt to the new situation, and the revision of the social security coordination framework did not succeed in incorporating both procedures or in simplifying the existing Regulation.

In Chapter 12, Willy Palm and Irene Glinos analyse these issues ten years after the *Kohll* and *Decker* rulings,¹⁶⁴ and in the aftermath of the Commission's proposed directive on cross-border health care.¹⁶⁵ The focus of numerous Court rulings in this area has been on permitting the cross-border movement of patients and the subsequent reimbursement of their costs by the home health care budgets, at the same

¹⁶² Regulation 1408/71/EEC, above n.97.

¹⁶³ Case C-120/95, *Decker*, above n.2; Case C-158/96, *Kohll*, above n.2; Case C-157/99, *Geraets-Smits and Peerbooms* [2001] ECR 5473; Case C-385/99, *Müller-Fauré* [2003] ECR 4509; Case C-372/04, *Watts* [2006] ECR I-4325; Case C-444/05, *Stamatelaki* [2007] ECR I-3185.

¹⁶⁴ Case C-120/95, *Decker*, above n.2; Case C-158/96, *Kohll*, above n.2.

¹⁶⁵ European Commission, 'Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care', COM (2008) 414 final, 2 July 2008.

time as seeking to entrench the right of the Member States to organize their social security systems as they see fit. This seems somewhat odd when the Member States are reticent about 'health tourism', given the health care budgetary strains it implies. Differing national interpretation and implementation of the Court's rulings are a further complication. Deregulation of access to health care and free movement of patients may seem a good idea in principle, but it is not clear that it is desirable, far less widely evidenced, in practice. Nevertheless, we now see growing interest in a set of patients' rights that are valid across the EU and that go beyond the more traditional issues of financing to covering quality of care, liability and compensation, conflict of laws, etc. The chapter addresses these issues, while also considering the need to balance the interests of the individual with the broader equity and access requirements for all EU citizens.

In order to first set the scene, the chapter reviews the status and evolution of the social security coordination mechanism and the case-law of the Court, illustrating how the Court in consecutive rulings has reinterpreted and by-passed Regulation 1408/71/EEC. By defining medical activities as falling within the scope of the freedom to provide services, the Court has reduced Member States' scope for denying cover of treatment in another Member State and has created an alternative Treaty-based route to access health care services outside the state of affiliation. At the same time, the European Commission has pursued its own political agenda, first pushing for 'more market' in health care by including health services in the Horizontal Services Directive,¹⁶⁶ then proposing a Community framework on cross-border health care.¹⁶⁷

Under pressure to admit internal market rules into national health care systems and as the potential effects of Court judgments slowly dawn on them, Member States have had to adjust. At the national level, governments have adopted new legislation in conformity with the jurisprudence. At the EU level, efforts to retake control of the situation have, however, remained limited. Initiatives have amounted to high-level debates and non-binding guidelines, as Member States are unable to agree on what action to take in the

¹⁶⁶ European Commission, 'Proposal for a European Parliament and Council Directive on services in the internal market', COM (2004) 2 final, 5 March 2004

¹⁶⁷ European Commission, 'Proposal', above n.165.

form of hard law. Moving from this broader discussion, the chapter illustrates what the changing legal and policy environments at the EU and national levels have meant for EU citizens deliberately seeking treatment in another Member State and for those in need of care while temporarily abroad. For both groups, the possibilities to access care outside the state of affiliation have significantly increased as a result of the Court rulings and of developments in the field adopted by health care actors. The scope of prior authorization has been challenged, as has Member States' control over cross-border movements and ensuing costs. Potential tensions between national health policies and the values underlying European health systems, on the one hand, and Member States' obligations under EU law and the free movement of services logic, on the other, have emerged. This might explain why patient mobility has attracted considerable political attention over the years. Despite its limited extent, it has left health systems more exposed to the pressures of the internal market.

The pursuit of more EU-level governance on patient mobility is motivated partly by legal uncertainty as to the application of internal market rules to health care, and partly by diversifying mobility patterns and behaviours. The debate on patient mobility has changed to include issues such as quality of care, liability, responsibility and safety of care received abroad. These need to be addressed together with attempts to clarify the legal context. Following the exclusion of health care from the Services Directive in 2006, the Commission has finally been able to put forward an adapted legislative proposal incorporating flanking measures. The wording remains somewhat vague and the approach minimal, considering the diversity among health systems. It remains to be seen whether the proposal will, in fact, add clarity to outstanding legal issues or even reassure Member States concerned with their control over patient flows and financial implications.

Other developments are likely to entail challenges of a different kind. Increasingly aware patients, commercial incentives for health care stakeholders, novel possibilities through e-health and differing national legislations on interventions with important bioethical dimensions are likely to raise new legal and ethical questions. An EU-level framework should ideally be able to respond and adjust to

evolving trends, and it is not clear that these proposals adequately account for this.

The question of who is steering the policy of increased mobility has become inescapable. Governments initiated the debate, but the European Commission has gradually taken over the reins of the process, albeit with different aims and methods depending on which Directorate-General is involved. While stakeholders and the European Parliament have succeeded in removing health services from a horizontal directive on services, high level groups involving Member States have found it difficult to come up with a suitable framework instead. Patients, administrators and actors are left without clear guidance in an environment of procedural and legal complexity and uncertainty. As long as policy makers do not fill the gap, the Court is bound to do so by continuing to apply primary and secondary EU law to the field of health care.

J. The status of e-health in the EU

E-health – defined here as the application of information and communication technologies across a range of functions that affect the health care sector – has grown and proliferated in recent years. At the same time, the European Commission has become increasingly interested in consolidating the EU as an information society. In Chapter 13, Stefaan Callens examines the place and role of e-health in the EU. Treated as a now important component of the single market, e-health is supported by the Commission as enabling higher quality, effective health care that is safe, empowering and accessible for patients and cost-effective for governments. The Commission thus appears to be pursuing numerous initiatives around e-health that are generating a potential legal framework for indirectly governing health systems. In the chapter, Callens therefore analyses how EU rules related to e-health have an important effect on national health care players and systems.

Given the breadth of understanding that surrounds the e-health concept, the chapter first provides a broad view and establishes some initial parameters. The second part of the discussion outlines key areas of e-health and the corresponding legislation that exists within the EU. The evolution of directives with relevance to e-health is described, and the influence on national health care

programmes is then assessed along with current EU policies related to e-health. Callens' focus is on five directives relating to: data protection; e-commerce; medical devices; distance contracting; and electronic signatures. The third part of the chapter then looks at other current EU deliberations and policies in e-health – specifically, new (legal) challenges regarding e-health applications, guidelines on the reimbursement of telemedicine and liability issues vis-à-vis telemedicine – and considers how (in practice and in theory) EU rules related to e-health are affecting national health systems and health care players.

The European Commission sees e-health as central to making the EU a leading information society. More specifically, e-health is seen as a mechanism or instrument to restructure and promote citizen-centred health care systems, as well as promoting greater cooperation between actors in the health arena. The Commission is embracing e-health as an approach that also respects diversity in language and culture among its Member States, while enabling higher quality, cost- and clinically-effective care that is participatory and empowering. In this regard, the Commission's view on e-health broadly comprises: (a) clinical information systems; (b) telemedicine and home care, including personalized health systems and remote patient monitoring, teleconsultation, telecare, telemedicine itself and teleradiology; (c) integrated national and regional health networks, distributed electronic health record systems and associated services (e.g., e-prescriptions and e-referrals); and (d) secondary use non-clinical systems (e.g., support systems such as billing). These developments are interesting given that the EU has no formal competences in health care, a fact that also explains the Commission's considerable interest in pushing the area forward as a means of developing competence. A case is thus made that a more detailed legal framework governing e-health is necessary, especially in light of its influence on health care systems. Specific consideration of all vested interests, such as data protection, public health, quality and continuity of care, cost, etc., is therefore required.

At the same time as the number of initiatives and interest grows, Callens shows that e-health raises tricky questions relating to (data) privacy and confidentiality, liability and, potentially, competition law within the context of European Union rules. The EU has had legislation on data protection in place since 1995 (Directive

95/46/EC).¹⁶⁸ While, on the one hand, the Directive emphasizes the fundamental rights and freedoms of the individual in respect of confidential personal information being protected and secure, on the other it aims to promote the free movement of secure personal data within the internal market in instances where required or desirable. Additionally, many health care players do not always appear to know how to comply with the Data Protection Directive and may need further guidance. Taking the case of health grids, the chapter shows how ethical challenges emerge in implementation due to data sharing responsibilities across multiple controllers. The development of rigorous guidelines is pivotal in this example. The storing of genetic data on computers also raises an interesting dilemma in terms of ensuring privacy in genetic screening, but supplemental guidelines remain vague and ineffectual.

In the area of liability, the EU has several pieces of legislation in place to protect consumers from poor quality products. As such, the General Liability for Defective Products Directive (85/374/EEC)¹⁶⁹ may apply to e-health in some instances, so too may the General Product Safety Directive (2001/95/EC).¹⁷⁰ But, as e-health is not a traditional consumable in that it has several faces – for example, as consumer product, software application, medical device or Internet service – no single legislative approach is exhaustive in respect of liability considerations. Similarly, for EU competition law, there are numerous rules on specific elements (undertakings, services of general interest, regulatory competition, etc.), all of which are relevant, in different ways, to e-health (and the provision of health care in general). As is shown in the chapter, this all contributes to a somewhat confusing picture. For instance, specific questions arise in respect of whether, in shopping around, purchasing and drawing up contracts with specific suppliers for e-health services, health care providers are to be classified as engaging in economic activities or whether they are instead acting

¹⁶⁸ The ‘Data Protection’ Directive, Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281/31.

¹⁶⁹ Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ 1985 No. L210/29.

¹⁷⁰ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ 2002 No. L11/4–17.

as public entities. All of these issues may have impacts on, and raise concerns for, patients, clinicians and the medical profession more generally, producers, suppliers, purchasers and national governments.

In order for e-health to deliver on the promises of its exponents, or help to address the Commission's concern to promote cost-effective, patient-centred systems, the EU will need to address these data protection, liability and competition concerns in a firm manner. For, as Callens argues, the existing legal framework is often vague and remains unfinished in many areas. Questions surrounding the reimbursement of e-health activities and applications, and the (no-fault) liability issue in particular, will need solving. It is not yet clear that the Commission has the tools, far less the consensus, at hand to do this.

K. EU law and health professionals

In Chapter 14, Miek Peeters, Martin McKee and Sherry Merkur examine health professionals' mobility in the EU. Advantages of the free movement of health workers include increased quality of specialized care, greater collaboration in highly complex procedures, improved access for patients living close to national boundaries and allowances for professionals to move across borders. Potential drawbacks include exacerbating the 'brain drain' of medical professionals from new Member States, challenges in rotational programmes in western European countries and compromised continuity of care, especially for chronic disease management. A case is made that uncertainties around health professional mobility must be adequately addressed in order to legitimize this practice to EU citizens, and the unintended consequences of EU law in the unique realm of health care must also be carefully considered.

This chapter begins by analysing the EU legal framework within which health professionals operate, focusing specifically on the arrangements for worker mobility between Member States. Critically assessing both old and new legislation, the benefits, challenges and shortcomings, particularly in relation to patient safety, are addressed and extensive examples are provided. The Working Time Directive¹⁷¹ is also examined in great detail to highlight the immense impact of EU legislation not specifically directed at the health sector.

¹⁷¹ European Parliament and Council Directive 2003/88/EC concerning certain aspects of the organisation of working time, OJ 2003 No. L299/9.

This chapter is contextualized to highlight the effects and unintended consequences of the EU's deficient legal basis for health care, as well as the piecemeal role the Court has been forced to play. A case is made that mutual recognition and coordination of professional requirements has enabled increased cross-border mobility, but that such free movement also evokes concerns over professional qualifications and patient safety. The legal framework must strike a balance between the benefits of professional mobility and the safeguarding of quality by working to resolve current shortcomings and legal uncertainties.

Examples reviewed in this chapter include the lack of coordination of disciplinary proceedings, continuing educational requirements and cross-border reimbursement, along with the need for a clear definition of 'services' and increased clarity around telemedicines. Ethical issues also surround this question, related to the different ethos in different Member States, such as abortion or euthanasia practices, and different language certifications for various types of medical professionals. The legitimacy and oversight of minimum training requirements is also a source of great contention. The misgivings of European citizens around health worker mobility can be assuaged by increasing the transparency and oversight of training quality, along with resolving the remaining legal issues highlighted above.

The application of non-discrimination on grounds of nationality in the health care setting is also a challenging feat given the vagueness of guidelines offered in the Doctors' Directive.¹⁷² Greater transparency and administrative oversight is needed, especially in coordinating medical education requirements. Balancing access to medical education with allowances for national priority-setting objectives is also necessary, such as safeguarding that an adequate number of medical professionals from a Member State's home country are educated. A challenge lies in the varying national interpretations and viewpoints surrounding acceptable levels of state intervention and regulation of health professionals. The Working Time Directive¹⁷³ highlights that the European legislature does not always take account of the specific characteristics of and implications for the health care sector. Through specific case studies, it is suggested that the implementation of the Directive will

¹⁷² European Parliament and Council Directive 2005/36/EC on the recognition of professional qualifications, OJ 2005 No. L255/22-142.

¹⁷³ Directive 2003/88/EC, above n.171.

pose a threat to the staffing of hospitals, especially more remote and smaller facilities. The *SIMAP* and *Jaeger* cases,¹⁷⁴ in particular, have placed restrictions on varying Member State definitions of ‘working time’, in ‘on-call’ and ‘stand-by’ hours especially. Although the standardized 48-hour week and other requirements are intended to be implemented in 2009, the Member States can request a (further) delay and also allow individual workers to opt out of such restrictions. Several Member States have implemented such opt-out clauses in health care, and the United Kingdom has enabled all workers to do so. In spite of the fact that the Council has finally, in June 2008, reached a political agreement on ‘on-call’ time, stipulating that inactive on-call time does not have to be regarded as working time unless national law or a collective agreement so provides,¹⁷⁵ the European Parliament and Council have failed to find a compromise in the conciliation process. This is the first time that no agreement could be found via conciliation since the Amsterdam Treaty, which significantly extended the scope of the codecision procedure. Although enacted with good intentions, to help safeguard EU worker safety, the special nature of the health care sector makes such restrictions extremely difficult. The challenge rests in finding a balance between the objectives of promoting efficiency, equity, quality and access both for patients and medical professionals.

L. EU pharmaceutical policy and law

In Chapter 15, Leigh Hancher analyses the specific case of pharmaceuticals in the EU – an area where the clash between the EU’s health considerations and economic interests is especially acute, and that has a direct impact on health care policy in the Member States. Hancher takes as her starting point that the EU’s involvement in pharmaceutical policy reflects two, not always concordant, faces. First is the health protection face, through the promotion of innovation and enabling the market access of only those medicines that are deemed safe and effective. The second face is in the provision of incentives and a regulatory environment that is conducive to

¹⁷⁴ Case C-303/98, *SIMAP* [2000] ECR I-7963; Case C-151/02, *Jaeger* [2003] ECR I-8389.

¹⁷⁵ www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lisa/101031.pdf.

a competitive pharmaceutical industry in Europe. In using the EU's aims to balance these two faces as the thread that keeps the various elements of her detailed discussion together, Hancher outlines the development and exercise of EU competence in respect of what she terms the 'regulatory pathway' – that is, licensing according to strict criteria – and the 'market pathway' – that is, the conditions under which medicines are made available in the Member States. The considerable imbalance between the EU's influence over the former in comparison to the latter is developed in detail, and the impact of each on three types of competition within the sector – therapeutic, generic (inter-brand) and intra-brand – is examined in view of recent changes and developments.

Looking at recent developments in the 'regulatory pathway', the chapter highlights legislative changes made with regard to widening the coverage of and speeding the marketing authorization processes for patented medicines. Within the context of these 2005 changes, attention is also given to generic competition and the major changes introduced by the Commission. In addition to such *ex ante* regulation, the Commission has also sought stricter *ex post* controls on certain practices of the research-based industry. Here, the discussion focuses on the application of EU competition law in respect of the Commission's fine of AstraZeneca for abuse of a dominant position – where it had tried to delay the market entry of generic versions of its best-selling proton pump inhibitor Losec – and the recent sector-wide inquiry that was instigated by concerns over insufficient enforcement of generic competition.

The discussion then considers recent developments in the 'market pathway' on the post-authorization of prescription medicines – specifically, pricing and patient information, which are traditionally the preserve of the Member States. The still-controversial practice of parallel trade in medicines is examined in view of the Commission's position that it remains a lawful form of trade, and the manufacturers' attempts to develop strategies to diminish its impact. Specific court rulings are profiled here, as well as Member State decisions.

Given the issues identified, the chapter then considers the emergence of the Pharmaceutical Forum as a mechanism to address competing challenges, and to do so in a way that ensures wide-spread stakeholder support. The discussion considers the Forum's potential role in developing both faces of EU pharmaceutical policy in tandem rather

than in competition. This development can be seen as an example of the more incremental and discursive approach assumed under the new modes of governance discussion (see Chapter 4 in this volume). The discussion also touches on clinical trials and pharmacovigilance in view of a two-part consultation process, which is expected to result in the development and adoption of proposals that will introduce changes to the EMEA's roles and that will have repercussions for national systems as well.

For, while generic manufacturers have been offered opportunities, such as now being able to conduct research and development prior to patent expiry (an EU equivalent of the United States 'Bolar provision')¹⁷⁶ and a more efficient registration system, the overall time that they are required to wait before registering their products has been increased. These types of trade-offs reflect quite clearly the Commission's attempts to balance public health interests (access to affordable medicines), with measures to promote innovation and ensure a productive pharmaceutical industry in the EU.

More importantly, however, the two pathways are no longer as distinct as previously. The growing intersection between them is raising a host of challenges for national and EU-level stakeholders; challenges which may impact and have repercussions upon national policy-making.

7. Conclusions

By way of conclusion, we seek to raise some questions on the internal market/social solidarity trade-offs touched upon throughout this discussion, and which lie at the heart of the chapters to follow. These chapters discuss many of the places in health care policy where a blurring of 'social security' (associated with non-market, non-competitive

¹⁷⁶ The United States provision is an exemption that enables generic manufacturers to conduct research before the relevant patent expires without infringing the patent, and consequently to place the product on the market immediately the relevant patent expires. It was introduced in §271(e) (1) of the Hatch-Waxman Act 1984, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 15 USC §§ 68b-68c, 70b (1994); 21 USC §§ 301 note, 355, 360cc (1994); 28 USC § 2201 (1994); 35 USC §§ 156, 271, 282 (1994), which was the legislative overruling of the decision in *Roche Products v. Bolar Pharmaceuticals*, 733 F.2d 858 (Fed. Cir. 1984).

structures, constrained within geographical borders, collective responsibility and redistribution – a matter for Member States) and ‘normal economic activity’ (associated with markets and competition, free movement across borders, individual rights and regulation – a matter for the EU’s internal market) has occurred. Indeed, where such blurring occurs and health care – which has otherwise been founded upon a stark distinction between these two opposing concepts – interfaces with EU law and policy, there are important challenges. Part of the challenge for the future, then, is to reconceptualize this relationship (social security/welfare as *part of* the internal market) so as to develop robust and helpful contributions from EU law and policy to health systems governance in Europe.

Health care systems in the Member States are evolving in response to rising costs, rising population expectations and ageing societies. The choice of reform or policy options adopted in response to these changes may fall under the scrutiny of the Commission, under soft law mechanisms or the Court applying economic legislation. In any case, Member States can no longer rely on the EU’s inertia in the field of health policy. Once a Member State shifts its health services from a model based essentially on solidarity to one including market-based principles, the uncertainty surrounding the scope of application of EU law could result in unintended consequences. Such reforms may unintentionally broaden the market’s influence on health services, despite the dampening effect of the ‘services of general economic interest’ clause in the EC Treaty.

The leveraging of best practices and other soft law techniques must be carefully considered in the context of each situation. Specific allowances for the protection of comprehensive national welfare systems and the simultaneous capacity building of new Member State welfare systems need to be inbuilt into long-term EU strategies. To achieve this, additional EU enforcement capabilities, along with appropriate incentive structures, are necessary. Additionally, neither increased regulation nor soft law will resolve underlying national disparities in power, financing and capacity. The safeguarding of strong welfare systems in wealthier nations and simultaneous strengthening of social structures in new Member States is a challenging goal necessitating a new transformative approach. Social protection and equality can best be augmented by establishing a robust and transparent supranational policy framework, and one that can counterbalance the

acquis of EU internal market regulation. EU free-market ideals like patient choice resonate in many Court rulings and other aspects of EU regulation. However, the counterbalancing mention of solidarity and other welfarist principles appear to be less pronounced in much EU regulation.¹⁷⁷

Having opened this chapter by highlighting the contradiction inherent in EU health policy and the constraints imposed by Scharpf's 'constitutional asymmetry', it has now become clear that this is not the whole story. First, there is always an interplay between trade and health interests, and not just at the EU level but also within the Member States themselves. The chapters that follow provide evidence of this. Second, there is clearly some flexibility at hand for an emerging EU health policy to incorporate welfare principles such as solidarity and equality of access based on medical need – as indicated in the discussion regarding the patchwork – in terms of the Court's role, and in possibilities for soft law. Moreover, there is perhaps scope for market-cushioning policies, in which the Member States can, despite the considerable implementation problems, shape them in a manner appropriate to their needs. The 'asymmetry' does not have to mean that policies cannot be implemented in a proactive manner: this is not a black and white view.

Still, the EU's constrained competence in health care does result in a tendency towards more internal market or competition regulatory elements rather than a clear *health care* policy focus or approach. Again, the constrained competence to adopt formal legal measures implies the use of incentives and very small scale redistributive policies, and an increased potential role for soft law mechanisms. And the Court's unwillingness to move into areas of majoritarian or interest group politics further hampers developments here. Additionally, the strength of the internal market as a basis for action, and the internal institutional structure of the Commission, mean that the Commission will always find it easier to give priority and greater attention to trade and free movement. Yet even measures based on free movement within the internal market can promote a high level of health protection.¹⁷⁸ What is clear in respect of the current 'asymmetry', however,

¹⁷⁷ Eberlein and Grande, 'Beyond delegation', above n.77.

¹⁷⁸ See, for instance, the Toy Safety Directive, Parliament and Council Directive 2005/84/EC amending for the 22nd time Council Directive 76/769/EEC on

is that long-term planning and a coherent policy framework would mitigate some of the negative impacts of the patchwork approach that otherwise results. We might point to the successes of EU environmental protection policy, where there is explicit Treaty stipulation of Community competences. At the same time, it is not immediately clear how best to bridge or remedy the gap between politics and economics in the health arena; at least not without making changes at the level of the Treaty.

The new modes of governance, soft law and open method of coordination, in particular, have been forwarded as a means to address the gap (these modes of governance have also been used with some degree of success in combination with hard laws in EU environmental policy). While such approaches have the potential to bring dividends in respect of Member States' and other stakeholders' mutual learning and in being an inclusive and deliberative dynamic, this is first contingent on the OMC and other soft law approaches generating meaningful results. Compared to internal market law, the OMC is still in something of an embryonic stage, and its results are therefore somewhat uncertain. One visible output is perhaps the proposal for a directive on the application of patients' rights in cross-border health care.¹⁷⁹ But it is worth asking whether this really is (or ought to be) a priority for the EU rather than for the Member States, such as through using ordinary 'conflict of laws' rules, which is what currently applies to questions of liability, etc. It can certainly be argued that there are more compelling (public) health issues to be addressed at the EU level, especially those relating more to the determinants of health. This is not to say that health care activities emanating from an EU level, whether via the OMC or otherwise, are unhelpful. Establishing a legal, or even soft law, framework is not a bad thing per se, and it need not necessarily erode social solidarity (but this depends on the Member States).

That said, some activities of the EU legislature have proved less helpful in terms of promoting robust health care policies for the future. For example, the private health insurance provisions do not provide for standardization of products, nor for monitoring competition rules

the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles), OJ 2005 No. L344/40.

¹⁷⁹ European Commission, 'Proposal', above n.166.

in the market. And, while the Commission's lack of capacity here is a limiting factor, this lack of a quality element to EU level policies is a common theme. In the pharmaceutical sector, for instance, we see much attention paid to the important issue of facilitating the industry's registration of new products, but other important issues such as comparative clinical trials or the use of comparative efficacy data by the EMEA (raised but not followed through) are less rigorously pursued.

Two further topical examples relate to the work of the European Centre for Disease Control (ECDC) and the issues of revalidation/recertification of health professionals. The ECDC continues to develop slowly and, despite its mandate to cover chronic diseases, this has not sufficiently been addressed. The formal justification for the establishment of the ECDC was Article 152 EC, but to what extent is it really executing a public health mandate? And, while the EU has done a great deal to seek the standardization of professional qualifications and to promote patient choice (including to cross-border care), the quality of care has not been given comparative attention – there are no provisions in respect of continuing professional development or quality of assessment of health professionals in the EU. Internal market legislation and policies thus concern qualifications and minimum standards, but they rarely tackle quality or what the Member States are doing within their own borders.

In terms of the Commission's own priorities and scope for action, again consider the disproportionate emphasis put on cross-border movement for patients compared to other areas. There is little to suggest that the currently miniscule number of individuals affected by, or likely to make use of, easier cross-border access to health care will increase dramatically with the new legislation. Moreover, it bears asking who the likely beneficiaries of such a policy are going to be: those with the most pressing health and clinical needs, irrespective of socioeconomic status, or those who are better-informed and with more means to be able to make use of it? The same is the case with the mobility of health workers, where much emphasis continues to be placed upon enabling free movement, such as through promoting the recognition of qualifications. Notwithstanding (some) Member States' fears, and the Commission's interest here, there have been changes in the patterns of labour flows generally, but net mobility has remained steady and at a fairly muted level. According to Hantrais,

for instance, EU policies on the recognition of qualifications or the coordination of social protection systems have had some impact on formal obstacles to mobility. But other difficulties associated with linguistic and cultural traditions have mitigated this.¹⁸⁰ Again, why is the emphasis not on quality of care to patients by ensuring healthcare professionals remain competent and up-to-date? Surely it is here, rather than in promoting mutual recognition of qualifications, that EU policy-makers can make a greater contribution to the high level of health protection for European citizens called for under Article 152. Overall, therefore, in contrast to the level of attention paid to such areas where the Commission's competences are not yet well-defined, it remains regrettable that the Commission is not more proactive in respect of public health where it has a relatively clear mandate to act under Article 152. Yet, even here, much policy is driven by externalities rather than through concerted action by the Commission itself (e.g., the 'knee-jerk' establishment of the ECDC or the development of tobacco control policies). Acknowledging the practicalities of coordinating across Directorates-General and securing support, quite simply, there appears little initiative and forward-thinking by the Commission, not even where room to act exists.

The development of hybrid approaches incorporating soft and hard laws, judicial rulings, EU agencies and national policies in a patchwork arrangement has been referred to several times through this discussion and is the explicit focus of the next chapter. Currently, such a mix of supranational and domestic policies may be the most politically feasible option. At the same time, however, such an ad hoc approach is unlikely to be effective without in-built incentivizing structures. Additionally, the development of a clear framework and the formation of an explicit EU welfarist structure to assist in decision-making and EU regulation are other pivotal success factors. An explicitly legally adopted baseline set of social objectives to be applied to health care law and policy emerging at the EU level would better equip the Court in decision-making, and represent a more balanced framework for policy-makers to employ. Our concern here, therefore, is with the lack of a strong legal basis in the Treaty for health and social protection policies (including health

¹⁸⁰ L. Hantrais, *Social Policy in the European Union* (Basingstoke: Palgrave Macmillan, 2007).

care), and to what extent the resulting patchwork of legal and policy instruments that characterizes the EU health care arena can be better managed.

Balance is thus the challenge for the future. For, while focusing on individual patients is crucial, it should not be at the expense of other important issues, such as population public health policies more generally. The development of an EU agenda thus depends in large part on what the Member States themselves are doing at home, not just what the Commission or the Court may be pursuing. Indeed, the Commission's push for a directive on the application of patients' rights in cross-border health care may reflect a case of doing what it can where it can, and as a means of increasing its own scope of authority, rather than pursuing a more normative and coherent framework for health care and social policy in the EU. For the Member States, this raises a question in respect of protecting the social basis of their health systems and, indeed, social cohesion more generally. For it has been suggested that economic integration in Europe may lead to a 'gradual and indirect process of social policy erosion'.¹⁸¹ Without necessarily endorsing this view – indeed, as Majone already noted some fifteen years ago, 'if there is a crisis of the welfare state ... this is because of factors which have nothing to do with the process of integration: demographic trends, the mounting costs of health care, the world crisis in social security, taxpayers' revolts, excessive bureaucratization and so on'¹⁸² – it is clear that the Member States will have to be careful here. The EU framework is certainly more about trade than reflecting or protecting a social dimension to health policy. But, as this book endeavours to show, the Member States are nonetheless still able to defend the social character of their health systems. Rules on public procurement or services of general economic interest have a special status in respect of national health care systems. And it will be up to the Member States themselves to ensure that moves towards, for example, greater privatization of health services do not undermine the social model and its goals of equity and social cohesion, which otherwise underpin European health care systems.

¹⁸¹ S. Leibfried and P. Pierson, 'Prospects for social Europe', *Politics and Society* 20 (1992), 333–66.

¹⁸² Majone, 'The European Community', above n.40, at 160.