Policy as a Process: The Pedagogical Role of the EU in Health Care

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I. Introduction

Health care is a rapidly developing issue of central and compelling importance within the European Union. Global epidemics and emergencies such as the SARS crisis of 2003 and the Avian Flu threat demonstrate both the reality of a new disease spreading throughout a “highly mobile, closely interconnected and interdependent world” as well as the limitations of national governments in responding to such challenges independently. Since its first confirmed identification in November 2002, over four thousand people contracted SARS throughout the world. This experience forcefully demonstrates the truth that national health protection relies on global health detection and prevention. At the same time, EU Member States face perhaps an even more serious fiscal health care crisis domestically. An aging population and advances in treatment and technology are causing national health care expenditures to continue growing throughout Europe, outpacing the ability of national governments to finance their

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4 See WHO Issues Paper, supra note 2. The World Health Organization attributes successful containment of the 2003 SARS outbreak to international detection and response systems, including the Global Public Health Intelligence Network and the Global Outbreak Alert and Response Network. See id. at 1. These international organizations enabled identification and containment of SARS within four months of the first reported outbreak. See id. While the SARS crisis provided an opportunity to observe the coordination of international organizations in an emergency situation, it also threw into vivid relief the failures in the system. See id. at 1, 2. Following the crisis the World Health Organization and other international players called for greater national investments in global health mechanisms. See id. at 2. The crisis also precipitated “sweeping” revisions to International Health Regulations. See id.
provision.\textsuperscript{5} In 2003 the thirty Organization for Economic Cooperation and Development (OECD) Countries, who represent the wealthiest nations in the world, spent an average of 8.8\% Gross Domestic Product (GDP) on health care.\textsuperscript{6} That number continues to grow and national investment in quality continues to disappoint policymakers and populace with its diminishing returns.\textsuperscript{7} The most recent survey of public opinion conducted by the European Commission indicates that health care is one of the greatest challenges facing individual nations, trailing behind only unemployment, the economy, and crime.\textsuperscript{8} Rising health care costs is an issue of such importance and magnitude that nations must utilize every resource available to address the challenge.\textsuperscript{9} This effort includes utilizing resources at a "federal" and intra-national level within the EU.\textsuperscript{10} As a result, health care, originally accepted


\textsuperscript{7} See Health Care Crisis Continues for Most European Countries, supra note 5; see also Wendt, et. al., supra note 5, at 21.


\textsuperscript{9} See David Trubek & Louise G. Trubek, New Governance and Legal Regulation: Complementary, Rivalry and Transformation, 13 COLUM. J. EUR. L. 539, 546 (2007) [hereinafter New Governance and Legal Regulation].

\textsuperscript{10} Throughout this paper, the term "federal" is used as an analogy to the US System, and refers to collective EU action pursuant to organizing treaties.
as a purely domestic policy prerogative, is increasingly associated with the EU's active sphere of competence. “Federal” participation in the governance of health care thus reflects the concerns of European citizens and the realities of a universal global health crisis.

The European Community has taken advantage of Union authority and intra-national resources to address unemployment, the economy and crime, but has historically been hesitant to mobilize an intra-national health policy strategy. Health is different, both in its specific organization and its importance to society generally. As such it should be governed and regulated

11 See generally HERVEY & MCHALE, supra note 1, at 110.


13 See, e.g., HERVEY & MCHALE, supra note 1, at 110. Examples include Europole, the European Union’s criminal investigatory force founded in the Maastricht Treaty in 1992, the European Central Bank (currently adopted by half of all Member States), the Common Foreign and Security Policy established by the Maastricht treaty and the Customs Union and single currency.


according to a different methodology.\textsuperscript{16} Traditionally that methodology has been to leave well enough alone.\textsuperscript{17} Recently, however, politicians and populace alike recognize not only the benefits and practical necessity of health policy convergence, but identify the development of an EU Health Strategy as integral to the legitimacy of the European Union.\textsuperscript{18} Thus, policymakers have slowly restructured the popular understanding of not only federal spheres of action, but also the nature and function of governance and regulation.\textsuperscript{19} Regulation and governance is no longer limited to a command-and-control mentality; instead, policymakers are making a conscientious effort to integrate broader participation in developing performance standards and indicators through soft law mechanisms.\textsuperscript{20} Governance is now understood to refer to "steering the flow of events, rather than...enforced compliance with rules."\textsuperscript{21}

Central to the debated health strategy is whether there is an

\begin{itemize}
\item \textsuperscript{16} Id.
\item \textsuperscript{17} See, e.g., de Búrca, \textit{supra} note 14. This approach is based on the principle that the coordination of social welfare services is a national responsibility and the fear that any interference or regulation of national distribution of services would lead to unanticipated and critical social effects. The latter reasoning is based on a recognition that the importance and impact of health care on society is both pervasive and (presumably) unpredictable.
\item \textsuperscript{18} See Byrne, Future Priorities, \textit{supra} note 12 (arguing that "Health is a preoccupation of Europeans . . . [and] that there can be no Europe without a Europe of Health"); see also Memorandum from Markos Kyprianou, Commissioner of Health and Consumer Protection, on the Orientation Debate on Health Services to the Commission, SEC(2006) 1095/2 (Sept. 4, 2006) available at http://www.csed.eu/csesite/accueil.nsf/url/attachment/$file/Note%20Kyprianou.pdf, [hereinafter Kyprianou].
\item \textsuperscript{19} See Judith Healy & John Braithwaite, \textit{Designing Safer Health Care Through Responsive Regulation}, 184 MED. J. AUSTL. S56, S59 (2006) ("[T]he crucial difference from the old 'command and control' view is that governments increasingly 'steer not row' and are seeking flexible, participatory and devolved forms of regulation."); see also Maurizio Ferrera, \textit{Towards an 'Open' Social Citizenship?: The Boundaries of Welfare in the European Union, in EU LAW AND THE WELFARE STATE, supra note 12, at 11 (positing that European integration has slowly but fundamentally altered popular conception of the function of governance and the relationships between governing institutions); see also White Paper, \textit{supra} note 12, at 3.
\item \textsuperscript{20} White Paper, \textit{supra} note 12, at 3 (asserting that the EU must develop a "policy-making process to get more people and organizations involved in shaping and delivering EU policy . . . [while] promoting greater openness, accountability and responsibility for all those involved").
\item \textsuperscript{21} Healy & Braithwaite, \textit{supra} note 19, at 56.
\end{itemize}
enforceable minimum standard of care in Europe. In this context minimum standard of care refers to the baseline quality of practice and quantity of services received. Member States typically define national standards of health care access through the services included in national insurance systems and enforce these standards through traditional mechanisms of regulation and litigation. However, these instruments are not available at a federal level within the EU. If European citizens are entitled to “high quality protection” of health care, as asserted in the EU Charter of Fundamental Rights, how is this standard to be identified and enforced? The answer, provided through ten years of collaborative and consensus-building relationships, is through information management and new governance techniques.

Today Europe has reached a political and philosophical consensus on the existence of a pan-European right to care. Despite this philosophical consensus, very real obstacles still prevent the identification, implementation, and enforcement of a hard law standard in health care throughout Europe. These obstacles include philosophical tensions between competing principles of “federal” authority versus state sovereignty, as well

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22 See Panos Kanavos, Martin McKee, & Tessa Richards, Cross Border Health Care in Europe: European Court Rulings Have Made Governments Worried, 318 BRIT. MED. J., 1157, 1158 (1999) (outlining the importance of the ECJ’s decisions in Kohll and Decker by asserting that they raise the question of whether there should be a standard of “package of care” available throughout the EU).


24 See HERVEY & MCHALE, supra note 1, at 110; see generally Vassilis Hatzopoulos, Health Law and Policy: The Impact of the EU, in EU LAW AND THE WELFARE STATE: IN SEARCH OF SOLIDARITY, supra note 12, at 111.

25 White Paper, supra note 12, at 32 (noting that “people have similar expectations for the Union as they have for domestic politics and political institutions. But the Union cannot develop and deliver policy in the same way as a national government; it must build partnerships and rely on a wide variety of actors. Expectation must be met in different ways.”).


27 Kyprianou, supra note 18.

28 Id.
as more practical concerns, such as the fear of undermining the financial integrity of individual national health programs. As noted in the ECJ’s decision in *Geraets-Smits Peerbooms v. Stichting Groeup Zorg*, if the EU were to articulate a specific “federal” right of care, “all the planning which goes into a contractual system in an effort to guarantee rationalized, stable, balanced and accessible supply of [health] services would be jeopardised at a stroke.” Addressing the challenge of modern public health policy while simultaneously respecting national sovereignty and national social service infrastructure therefore requires compromise and coordinated collaboration. Such cooperation also requires rethinking and restructuring of governance paradigms and expectations.

During the last ten years, as the European Union has engaged in an aggressive (albeit fractured) effort to centralize health care within EU policy and its sphere of competence, the Commission has utilized various techniques, including traditional regulatory models. However, efforts to integrate and collaborate have been

29 National Health plans rely on prospective budgeting to finance services. In budgeting for the upcoming fiscal year (and in an effort to control costs) states must be able to (1) roughly predict populations (the number of people covered) and (2) restrict utilization by restricting services covered. See Colleen Flood, Mark Stabile, & Carolyn Hughes, *The Borders of Solidarity: How Countries Determine the Public/Private Mix in Spending and the Impact on Health Care*, 12 HEALTH MATRIx 297, 334 (2002) (asserting that UK health systems specifically have implicitly relied on physicians and health authorities to anticipate and ration publicly-funded health care services.); see also *Hervey & McHale, supra* note 1, at 139.


31 *Ferrera, supra* note 19, at 16.

32 *See generally* Julia Black, *Decentering Regulation: Understanding the Role of Regulation and Self-Regulation in a “Post Regulatory” World*, 54 CURRENT LEGAL PROBS. 103 (2001) (positing that regulation is increasingly separated from state police action and that the nature of modern regulation is increasingly characterized by a more cooperative and dynamic model); see also Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342, 343 (2004) (suggesting that deregulation in environmental law indicates a larger collective shift in governance models and expectations).

most successful through soft law measures, which may be characterized as convergence through persuasion.\textsuperscript{34} Throughout the development of the EU Health Strategy, the EU has conscientiously exhibited a consistent preference for non-binding soft-law regulations.\textsuperscript{35} This preference is reflective of both the political and constitutional limitations of the Union, as well as the dynamic nature of modern medicine.\textsuperscript{36} This policy preference was demonstrated most visibly in the recent removal of Health Services from the controversial Service Directive by parliament in February of 2006.\textsuperscript{37} By removing health care services from the Directive, policymakers responded to the popular cry that "health is different" from other services and that consequently the EU role in governing health services requires a non-traditional approach.\textsuperscript{38}

Examination of the continuing evolution of EU health policy serves as a case study of the larger convergence of economic and social policies within the EU and the development of an international forum on health care reform.\textsuperscript{39} Convergence presents

\textsuperscript{34} See Tamara K. Hervey, The European Union and Governance of Health Care, in LAW AND NEW GOVERNANCE IN THE EU AND THE US, 179, 184 (Graînne de Bûrca & Joanne Scotts eds., 2006); but see Alexander Somek, Exploring the Context of European Antidiscrimination Law and Policy, 14 TRANSNAT'L L. & CONTEMP. PROBS, 959, 997 (suggesting that in the absence of traditional enforcement procedures there is inadequate incentive for the dissemination of "best practices" to have lasting effects in social policy).

\textsuperscript{35} See Hervey, supra note 34, at 180; see also Antonio S. Serrano, Improvements in Cross-Border Access to Health Care within the European Union, 43 HARV. INT’L L.J. 553, 563 (2002).

\textsuperscript{36} See Rand E. Rosenblatt, The Four Ages of Health Law, 14 HEALTH MATRIX 155, 161 (2004) (positing that globalization, a global health crisis, and the “biotechnology revolution” necessitate a “fourth age” in health care regulation; one that is characterized by de-regulation and increased attention to and participation of stakeholders); see also Louise G. Trubek, New Governance and Soft Law in Health Care Reform, 3 IND. HEALTH L. REV. 137, 147 (2006) [hereinafter New Governance and Soft Law]; see also Healy & Braithwaite, supra note 19, at S56..

\textsuperscript{37} See Dan Bilefsky, EU Legislators Pass Law to Increase Cooperation in Services, INT’L HERALD TRIB., Nov. 16, 2006, at F11.

\textsuperscript{38} “It was felt that specificities of health services were not sufficiently taken into account, in particular their technical complexities, sensitivity for public opinion and major support from public funds.” Memorandum on Health Services, supra note 15.

\textsuperscript{39} Convergence may be characterized as the “search for an optimum set of social arrangement” across industrialized societies. Through social and economic exchanges societies adapt to one another and adopt similar governance structures and governing infrastructures. Colin J. Bennett, What is Policy Convergence and What Causes It?, 21
both practical and political obstacles, such as the competition between the socio-political independence of the Member States and the Union. This tension is best illustrated in the health policy debate.

II. Policy as a Process – Not a Product: Defining New Governance and Soft Law

At the beginning of the twenty-first century, against the backdrop of global competition, [and] changing patterns in market organization...contemporary legal thought and practice...[pointed]...to the emergence of a new paradigm – [new] governance...[which] supports...a more participatory and collaborative model, in which government, industry, and society share responsibility for achieving policy goals. The adoption of governance-based policies redefines state-society interactions and encourages multiple stakeholders to share traditional roles of governance...Lawmaking shifts from a top-down, command-and-control framework to a reflexive approach, which is process oriented and tailored to local circumstances. 40

New governance 41 is a complex, evolving and increasingly wide-spread governance mechanism which synthesizes a number of modern legal policy theories, including “democratic experimentalism,” “new regionalism,” and “communicative governance.” 42 It may be briefly (and broadly) described as a


40 Lobel, supra note 32, at 344-45.

41 New governance refers to the “range of activities, functions and exercise of control by both public and private actors in the promotion of social, political, and economic ends.” Id.

42 New Governance and Soft Law, supra note 36, at 147; see, Graínne de Búrca & Joanne Scott, New Governance, Law and Constitutionalism, in LAW AND NEW GOVERNANCE IN THE EU AND THE US 1, 2 (de Burca & Scott, eds., 2006), [hereinafter Law and Constitutionalism]; see also Lobel supra note 32, at 344; see also Michael C. Dorf & Charles F. Sabel, A Constitution of Democratic Experimentalism, 98 COLUM. L. REV. 267 (1998); see also Michael C. Dorf, Legal Indeterminacy and Institutional Design, 78 N.Y.U. L. REV. 875, 876 (2003); see also Jan Kooiman, Findings, Speculations and Recommendations, in MODERN GOVERNANCE: NEW GOVERNMENT - SOCIETY INTERACTIONS 249 (Jan Kooiman ed., 1993) (democratic experimentalism refers to a “new” form of governance in which relaxed regulatory standards and decentralization allows local flexibility in responding to local manifestations of national issues. The collaborative and pedagogic “national” infrastructure under democratic experimentalism then provides for information and gain-sharing on a larger level.
construct designed to address traditional policy needs but operating outside the traditional, formal legal infrastructure. Instead, it is characterized by the greater participation and collaboration of non-traditional players, the use of consensus building mechanisms, reliance on peer review and collaboration, and the integration of public-private partnerships and research experiments into the formal policy-making process. As such, new governance constitutes a departure from traditional “command-and-control” models, providing a new framework for policy-development: one in which the State’s responsibility is navigational, leaving responsibility for policy outcomes distributed across society.

A. "The Center Will Not Hold": The Need for Communicative Governance in the Administrative State

Traditional governance, or hard law, is characterized by inflexible centralized decision-making, uniform regulations, and court-enforced compliance. These rigid governance mechanisms prove increasingly inadequate in the face of modern policy challenges, such as: a larger, global playing field; expanded parties

Cooperative governance focuses on the institutionalized relationship between private stakeholders, citizens, and public governing offices).

43 Law and Constitutionalism, supra note 42, at 2. “Hard law” refers to the traditional regulatory enforcement model which relied on litigation to ensure compliance with policy objectives. See, e.g., New Governance and Soft Law, supra note 36, at 149.

44 These players include stakeholders instead of mere representatives in the decision-making process. See, e.g., Law and Constitutionalism, supra note 42, at 3.

45 See Hervey, supra note 34, at 180.

46 Id.

47 Id. (as such it indicates a “shift away from the [traditional institutional] control and monopoly over political and social issues and implicates a greater, concerted incorporation of ‘stakeholders’ within a non-traditional ‘framework.’); see also Wendy Netter Epstein, Bottoms Up: A Toast to the Success of Health Care Collaboratives, 56 ADMIN L. REV 739, 741 (2004); see also Lobel, supra note 32, at 344.

48 Epstein, supra note 47, at 741.

49 “Turning and turning in the widening gyre / The falcon cannot hear the falconer / Things fall apart; the centre cannot hold / Mere anarchy is loosed upon the world.” William Butler Yeats, The Second Coming, in THE NORTON ANTHOLOGY OF ENGLISH LITERATURE 2106, 2106 (M.H. Abrams & Stephen Greenblatt eds., 2000).

50 New Governance and Soft Law, supra note 36, at 149; see also New Governance and Legal Regulation, supra note 9, at 542.
of competing stakeholders; political fragmentation between administrative and governing agencies; and increasingly complex policy issues. These challenges are compounded in health policy, a field that relies on experimentation, interaction and adaptation, something the older, formal system can no longer provide.

The older system, without some changes cannot deal with diversity, the development of new technologies, the increasing flow of new knowledge, and the eroding faith in professionalism...[It] cannot deal with the increased information available through the combination of evidence-based medicine and electronic records. This increased information has created an explosion of new knowledge which depends on feedback and iteration...[which] requires interaction between domains.

As the above observation illustrates, the traditional, regulatory model of health law fails in its inability to both adapt to a dynamic global information market and to adopt an infrastructure for the interaction between both policymakers and practitioners. This deficit in traditional regulation is illustrated most clearly in the area of medical malpractice in the United States. New governance accommodates the modern need for flexibility and

51 New Governance and Soft Law, supra note 36, at 149; see also Dorf & Sabel, supra note 42, at 267.

52 The failure of the old regulatory system is manifest from the most cursory glance and the current medical malpractice system. See New Governance and Soft Law, supra note 36, at 142.

53 Id. at 150-51.

54 See generally Frances Lee Ansley, Rethinking Law in Globalization Labor Markets, 1 U. PA. J. LAB. & EMP. L. 369, 369 (outlining how the global market challenges traditional regulatory models); see also Joel R. Reidenberg, Governing Networks and Rule-Making in Cyberspace, 45 EMORY L.J. 911, 926 (1996) (examining the development of the internet and its impact on the State’s traditional nexus of control and regulation).

55 David Blumenthal, Making Medical Errors into “Medical Treasures”, 272 JAMA 1867, 1867 (1994). Litigation as a primary instrument of quality enforcement is increasingly discredited from a public, and quality standpoint. The threat of malpractice discourages practitioners from acknowledging past medical errors and using them as a larger teaching opportunity among colleagues. The traditional governance model not only fails to encourage needed interaction but restricts or “chills” such communications. See ROBERT KAGAN, ADVERSARIAL LEGALISM: THE AMERICAN WAY OF LAW 14 (Harvard University Press 2001).
interoperability through its reliance on soft law instruments, such as consensus building, peer performance review, and benchmarking. These methods encourage experimentation, accommodate diversity, provide for feedback, and incorporate greater stakeholder participation. Thus new governance may be characterized as a mechanism for communicating and mediating interactions between policymakers.

Greater participation and collaboration are necessary, or rather, inevitable in a modern global market. In the modern information age the State no longer has a monopoly on economic or political power. Instead, power "flows through networks that are more fluid and complex than older structures of governance." As the policy playing field expands to incorporate new players, new mechanisms are needed to accommodate and respond to extended

56 "Soft law" indicates that there is no binding force to enforce provisions, which distinguishes it from traditional, regulatory "hard law." In a recent research paper commissioned by the European Commission, scholars Anne Peters and Isabella Pagotto capture the ambiguous and broad nature of non-traditional soft law by defining it as quasi-legal constructs that are "on the one hand not legally binding in an ordinary sense, but are on the other hand not completely devoid of legal effects either." Anne Peters & Isabella Pagotto, Soft Law as a New Mode of Governance: A Legal Perspective; NEWGOV: NEW MODES OF GOVERNANCE PROJECT, Sept. 28, 2006, http://www.eu-newgov.org/database/DELIV/D04D11_Soft_Law_as_a_NMG-Legal_Perspective.pdf.

57 New Governance and Soft Law, supra note 36, at 148; see also New Governance and Legal Regulations, supra note 9, at 540; see Lobel, supra note 32, at 345 (explaining that new governance models are characterized by "new" strategies such as "negotiated rulemaking, audited self-regulation, performance-based rules, decentralized dynamic problem solving, disclosure regimes, and coordinated information collection").


59 See Alfred C. Aman, Jr., Globalization, Democracy, and the Need for a New Administrative Law, 49 UCLA L. REV. 1687. 1693-94 (2002). Globalization refers to the "complex social, economic, and political processes that in effect denationalize and deterritorialize states." Through globalization the stream of commerce and communication occurs largely outside the management of the state. In order to respond to the effects of international commerce (most notably in environmental protections) state must cooperate, creating international authority and collaborations. This process of intra-national collaboration is referred to as "deterritorialization." Id.

60 Law and Constitutionalism, supra note 42, at 2.

61 Healy & Braithwaite, supra note 19, at S56.
participation and interests. New governance and soft law provide this mechanism. By acceding to and accommodating greater stakeholder participation, new governance distributes power in policy decisions. Similarly, the collaborative paradigm of the new governance model enables policymakers to balance between commitments and competing interests in a global economy and among various stakeholders. New governance, a fundamentally informal system of governance and cooperation, therefore presents a formal and reliable methodology for resolving competing principles and interests presented in the modern global market.

As illustrated above, new governance provides an infrastructure that mediates relationships and interactions between stakeholders and policymakers. This interactive model is of critical importance in adapting existing governance structures and expectations to the demands of a dynamic global economy.

Because soft law has no binding power to enforce compliance, it depends on voluntary collaboration and competition to encourage compliance with policy goals. Soft law derives its persuasive power through information management, namely data collection and comparison of peer institutions. This accomplishes two targeted goals in health policy. First, by providing a forum for information exchange, governments can

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63 Id.; see also Jody Freeman, Collaborative Governance in the Administrative State, 45 UCLA L. REV. 1, 1 (1997) (suggesting that formalized collaborations between public and private actors create new opportunities in governance and require greater agency flexibility).

64 Healy & Braithwaite, supra note 19, at 556, (noting that new governance incorporates alternative, soft law mechanisms to address a balance between competing stakeholders).

65 Id.

66 Id; see also Dorf & Sabel, supra note 42, at 268.

67 See generally Alexander Somek, supra note 34, at 995 (identifying discourse as the "chief instrument of governance" within a soft law framework); see also Hervey, supra note 34, at 191.
accelerate the creation and dissemination of evidence-based "best practices." "Best practices" refers to a method of scientific management and quality assurance that assumes that there is a technique or process which will yield optimal results. The modern practice of "evidence-based medicine" relies on the incorporation of best practices into routine care and medical decisions. Second, by publishing peer reviews and comparative quality assessments of peer institutions, soft law encourages or "shames" individual institutions into complying with evidence-based practices and improving the standard quality of practice. New governance may therefore be characterized as a "carrot and stick" mechanism of quality convergence and improvement. It thus indicates a departure from the centralized command-and-control regulatory approach characterized by traditional lawmaking, focusing instead on data collection, information exchange, and the development and dissemination of "best

68 See Hervey, supra note 34, at 191 (recognizing that state cooperation in collecting and distributing data on best practices "by reference to common challenges to national health care systems from technological development").


70 David L. Sackatt, et al., Evidence Based Medicine: What It Is and What It Isn't, 312 BRIT. MED. J. 71, 72 (1996). Evidence-based medicine is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." Id.; see also Evidence-Based Medicine Working Group, Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine, 268 JAMA 2420, 2420 (Nov. 14, 1992) (introduces the practice of evidence-based medicine and its emphasis on research and information sharing as the new paradigm for modern medical practice).


72 New Governance and Soft Law, supra note 36, at 149-50 ("It can encourage mutual cooperation and exchanges of knowledge and experience through collection, systematization, and diffusion of knowledge. Soft law can be seen as fostering consensus making and incentives to voluntary learning, as much as by shaming."); see also Marshall Ruffin, New Governance for a New Era: Issues and challenges for integrating systems, 9 PHYSICIAN EXEC. 42, 44 (Sept. 21, 1995) (contending that the role of a governing structure is to "force independent operating units to adhere to standards. . . [which] will allow the entire system to operate more effectively and efficiently" and to encourage systemic quality improvement through the dissemination of information).

73 Law and Constitutionalism, supra note 42, at 2.
creating a governance mechanism that is "less rigid, less prescriptive, less committed to uniform outcomes, and less hierarchical in nature." This flexible and evolving governing structure better accommodates the dynamic nature of health care.

The EU acknowledged the emergence and the importance of new governance and soft law as a governance strategy in a Commission sponsored White Paper published in 2001. In the White Paper the Commission outlined five pillars of good governance: (1) openness; (2) participation; (3) accountability; (4) effectiveness; and (5) coherence—all principles central to the new governance paradigm. New governance, broadly identified in the Communication as the future direction of "European" governance, has the potential to not only address these essential principles of representative governance, but also to adapt to the demands of a changing world and an evolving, dynamic industry. As noted in the White Paper, the structure, challenges and expectations confronting the Union are changing. The Union's legitimacy depends on responding to these new challenges by incorporating broader participation and involvement. The White Paper concludes that this involves restructuring the larger framework of governance: "The Union is changing... its legitimacy today depends on involvement and participation. This means that the linear model of dispensing policies from above must be replaced by a virtuous circle, based on feedback, networks and involvement from policy creation to implementation at all levels."

This shift in governance structure also indicates a shift in the

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74 New Governance and Soft Law, supra note 36, at 149 (positing that "there is an emphasis on monitoring results through the collection and public dissemination of data that can lead to revisions and create financial incentives.").

75 Id.

76 Id. at 140.

77 See generally White Paper, supra note 12 (outlining the challenges facing the EU in the upcoming decade, the White Paper explains the need for a more communicative and inclusionary governance model).

78 Id. at 10.

79 Id. at 11.

80 Id.

81 Id.
way we think about law and the function of the policy process. Under such an information-based governing structure, the “center” (in this case the EU) fulfills a pedagogical role. The center is a facilitator, providing a forum for exchange, identifying disparities, and allowing disparate stakeholders to interact more easily. As international law scholars and new governance experts Grainne de Búrca and Joanne Scott assert, the federal state’s core function is no longer to be the sole purveyor of policy; instead, its purpose is to facilitate the development of governing infrastructure and oversee the interaction between stakeholders within the governance framework.

III. Defining EU Jurisdiction

The story of the European Union has been one of steadily expanding powers, of an incremental extension of policy capacity across many aspects of economic, political and social life. And yet there are areas...a nucleus of (national) sovereignty...in which the states retain primary competence and the EU’s influence is indirect or relatively minor... [Thus] even though the EC for many years has had legal power to regulate... the remit of the EU’s social policy remains closely tied to labour-market participation, leaving the broader fields of welfare provision and regulation essentially to the states.

European Union preference for new governance in social policy is a natural selection – a process tailored to the international nature of the emerging economic (and later socio-political) community. As scholars Anne Peters and Isabella Pagotto note, the European Union initially lacked the authority to enforce hard law measures. Collaboration through soft-law mechanisms enabled the EU to take action (if indirectly) where its legal

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82 New Governance and Soft Law, supra note 36, at 139 (explaining that the emergence of new governance alongside traditional approaches creates a new dynamic interaction affecting our conception of health policy and regulatory authority); see also, Healy & Braithwaite, supra note 19, at 10.

83 Law and Constitutionalism, supra note 42, at 3.

84 Id. (asserting that under a new governance model the “center’s” primary role is in “facilitating the emergence of governance infrastructure, and with ensuring co-ordination or exchange as between constituent parts”).

85 de Búrca, supra note 14, at 1.

86 See Peters & Pagotto, supra note 56, at 5.
authority and legitimacy was not yet developed or accepted. Use of less controversial soft law measures to supplement Member States' public health initiatives initially allowed the EU to act in a sphere where its legal jurisdiction was questionable and provided the opportunity for high level deliberation on the future role of EU governance in health policy.

A. The Expanding Orbit of Federal Authority in Social Policy

To appreciate the importance and necessity of soft law in the context of European social policy, it is necessary to understand the political infrastructure and mandate of the European Union. The European Union is a government of limited or derived powers. The European Union began as an extended economic trade agreement; as a result, those powers did not originally extend to social policy. While Member States, in forming the original European Union, were motivated by social objectives, particularly establishing "an ever closer union among European peoples," and improving their respective national standard of living, community action was limited to enforcing the elimination of trade barriers. The Treaty of Rome identifies economic integration as the best assurance of such national social benefits, and makes no provision for direct Community action. Jurisdiction was therefore limited to harmonization of trade

87 Id.
88 See id. at 25-26.
89 Treaty Establishing the European Economic Community, art. 308, March 25, 1957, 340 O.J.C. [hereinafter Treaty of Rome]. The EU can only act where it is "necessary to attain, in the course of the operation of the common market, one of the objectives of the Community and . . . [the] Treaty has not provided the necessary powers."
90 Id. at art. 2.
91 Id.
92 Id.
93 Id. at art. 3(a).
94 Id. at art. 2. These economic priorities (and the social principles motivating them) are spelled out carefully in the original treaty: "It shall be the aim of the Community, by establishing a Common Market and progressively approximating the economic policies of Members States to promote . . . a harmonious development of economic activities . . . an increased stability, an accelerated raising of the standard of living and closer relations between its Member States." Id.
policies and tariffs and there was no formal or informal mechanism for developing Union social policy, which remained entirely the purview of national governments.95

Today, the European Union's authority over social policy has expanded dramatically.96 This expansion of power is a product of a closer, more integrated Union, and is legally justified through the "necessary and proper" clause of the original Treaty.97 This clause, and Europe's use of it to expand policy powers, suggests that there are "few [legal] limits upon which the region can legislate... once a political consensus has been reached."98 The problem arises out of developing that consensus in an environment of competing Member States, all of whom are naturally careful to preserve their national autonomy. The history of European formal involvement in intra-national social policy is therefore a series of compromises, marked by both recognition of the benefits of centralized oversight and the imposition of restrictions to protect against undue encroachment.

95 Treaty of Rome, supra note 89, at art. 2. In the neo-liberal economic world following the Second World War, European governments accepted the elimination of international trade barriers as the best assurance of national social benefits. Id. at art. 3(a). The treaty acknowledges that the development of the Common Market will benefit convergence of social systems, but aside from assuming an aspiration for close collaboration between the Commission and Member State Governments in the field of social policy, the administration of social policy (with the exception of a few soft law reporting measures) remained the responsibility and prerogative of Member States. Id. at art. 2.

96 This expansion has been encouraged by an active (and some argue activist) Judicial Branch. This expansion in the sphere of "federal" or supranational authority is illustrated in the Treaty of Amsterdam, amending the earlier Treaty of Rome: "The Community shall have as its task, by establishing a common market and an economic and monetary union and by implementing common policies or activities . . . to promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of employment and of social protection, equality between men and women, sustainable and non-inflationary growth, a high degree of competitiveness and convergence of economic performance, a high level of protection and improvement of the quality of the environment, the raising of the standard of living and quality of life, and economic and social cohesion and solidarity among Member States." Treaty of Amsterdam Amending the Treaties Establishing the European Communities, art. 2, Nov. 10, 1997, 340 O.J.C.

97 Treaty of Rome, supra note 89, at art. 235 (allows the EU to act where it is "necessary to attain, in the course of the operation of the common market, one of the objectives of the Community").

98 RALPH FOLSOM, EUROPEAN LAW IN A NUTSHELL 33 (2005).
The organization and delivery of health care services remains the express responsibility of individual Member States.\textsuperscript{99} Member States have the exclusive authority to organize and administer health services. Despite this express reservation of power, the EU as a "federal" body increasingly involves itself in the governance of health care,\textsuperscript{100} thus gradually but fundamentally altering the institutional relationships and governance expectations.\textsuperscript{101} This explosion in EU participation in health care services was sparked by the European Court of Justice (ECJ) 1997 decision in \textit{Kohll v. Union des Caisses de Maladie} challenging the legality of barriers to patient and practitioner mobility within the Union.\textsuperscript{102} \textit{Kohll} has since been dubbed the hard law catalyst for soft law reform.\textsuperscript{103} In \textit{Kohll}, a Luxembourg native was refused prior authorization and reimbursement for dental services sought in Germany. The Court held that national rules restricting reimbursement of the costs of services available through a State’s health care system but provided in other Member States is illegal because these rules infringed on freedom of services principles by discouraging publicly insured patients from contracting with medical service providers in other Member States.\textsuperscript{104}

\textbf{B. Free Mobility Principles: Between a Rock and a Hard Place}

Article 49 EC prohibits restrictions on freedom of mobility of services within the EU.\textsuperscript{105} “Services” were originally understood to encompass commercial transactions for “remuneration,” thereby

\begin{itemize}
\item \textsuperscript{99} EU Constitution Treaty, Article III-278 (7) CT; see generally Kyprianou, supra note 18.
\item \textsuperscript{100} Hervey, supra note 34, at 179. Scholar Tamara Hervey goes so far as to classify EU attention and action as an “explosion” in EU government involvement over recent years. \textit{Id.} at 180.
\item \textsuperscript{101} Ferrara, supra note 19, at 11.
\item \textsuperscript{102} Hervey, supra note 34, at 183-84. Article 49 EC prohibits restrictions on service mobility within the EU. In \textit{Kohll} the scope of “service” was applied to publicly financed national health care services for the first time. \textit{Id.}
\item \textsuperscript{103} \textit{Id.} at 185.
\item \textsuperscript{104} Case C-158/96 Kohll v. Union des Caisses de Maladie, 1998 E.C.R. I-1931, at para 1.
\item \textsuperscript{105} Hervey, supra note 34, at 182.
\end{itemize}
excluding publicly-financed health care systems. However, in Kohll, the ECJ departed from conventional wisdom and held that the "special" and social welfare nature of health care services does not exempt it from the "ambit of the fundamental principles of freedom of movement." 

Although in the absence of harmonization at Community level Member States were free to determine conditions concerning the right to be insured with a social security scheme or for entitlement to benefits, they were in so doing, nonetheless, required to comply with Community law, including Articles 59 and 60 EC.

By redefining the scope of services covered by the treaty to encompass publicly financed health services, the Court established the foundation and authority (indeed the necessity) for EU action in monitoring health quality and developing a federal policy on health care; however, it did not clarify the scope of that authority. One of the most fundamental questions presented by Kohll is whether it creates an enforceable European standard of care, and if so, how to determine and fairly evaluate its application given disparities in access and quality practices across the Union.

Conversely, the ECJ's decision in Kohll did not further articulate on the restrictions imposed on Member State actions. While the Court aggressively asserts that the Member States have broad discretion in the operation and administration of their social security systems, it also stresses that national health services are still subject to the principles of free movement of services. In

106 See Treaty of Rome, supra note 89; see also Hervey, supra note 344, at 182.

107 Kohll, supra note 104, at para. 1.

108 Id.

109 Mike Sedgley, Smits/Peerbooms: A clarification of confusion? 7 EUROHEALTH 1,1 (2001). "In attempting some sort of balance between a right to receive and an obligation to provide, the judgments seem to grant to citizens the right to cross border care, as long as the operational integrity of national systems is not undermined by large numbers of people acting on their right." Id.

110 Memorandum on Health Services, supra note 15.

111 See Case C-372/04, Yvonne Watts v. Bedford Primary Care Trust, Secretary of State for Health, 2006 E.C.R. I-04325 at sec. 3, para. 37, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62004J0372:EN:HTML (holding that a Member State may not restrict access to health care services except where such restrictions are necessary in order to maintain the financial integrity of the facilities administration, where such restrictions impose undue delay in the treatment of a patient
Kohll, the Court reasoned that restrictive policies, such as prior authorization for services contracted abroad could be "justified," namely if there is a "genuine and actual risk" of undermining the financial integrity of national health systems. This decision acknowledges the complex and potentially fragile economic balance in budgeting for health care services and demonstrates a determination not to interfere unduly, opening a "Pandora's box" of health care management. National health plans rely on prospective budgeting to finance services. In budgeting for the upcoming fiscal year, states must be able to roughly predict populations (the number of people covered) and restrict utilization by restricting services covered. Kohl indicated that trade barriers to patient and practitioner mobility could be justified. A string of patient mobility cases following Kohl further elaborated on this theme, as articulated in the later Smits-Peerbom v. Stichtig Ziekenfonds case. In Geraets-Smits/Peerbooms, the Court broadly summarized justified public interest as ensuring universal access and quality of care for citizens by maintaining the financial and administrative infrastructure of national health plans; by providing non-discriminatory coverage; and by preserving resources to

they are no longer justified); see also Geraets-Smits/Peerbooms, supra note 30 (where the court accepted a restrictive national policy as justified but formally reaffirmed a European citizen's right to the best medical treatment available throughout the Union).

112 Kohl, supra note 104, at para. 5.


114 See Colleen M. Flood, Mark Stabile, & Carolyn Hughes Tuohy, The Borders of Solidarity: How Countries Determine the Public/Private Mix in Spending and the Impact on Health Care, 12 HEALTH MATRIX 297, 334 (2002) (explaining that UK health systems have implicitly relied on physicians and health authorities to anticipate and ration publicly-funded health services); see also HERVEY & MCHALE, supra note 1, at 139 (noting that "States calculate their health care needs by reference to their populations ... too much movement of patients might result in overburdening ... thus jeopardizing] the national health ... systems of all Member States"); see generally PABLO GOTTRET & GEORGE SHIEBER, HEALTH FINANCING REVISITED: A PRACTITIONER'S GUIDE, 2006 (The International Bank for Reconstruction and Development/ The World Bank eds., 2006).
address national needs. In implementing these standards, the courts took a permissive approach. For example, in Vanbrackel v. Alliance Nationale des Mutualités Chrétiennes, to assert a Belgian patient’s right to have services in France, the Court calculated a Belgian schema. In Geraets-Smits/Peerbooms the Court accepted a restrictive national policy as justified but formally reaffirmed a European citizen’s right to the best medical treatment available throughout the Union. Most recently in Watts v. Bedford Primary Trust, the Court asserted the primacy of European Community law over national regulations, but held that a one-year waiting period for certain medical procedures was not an unreasonable obstacle to heath service. These European Court of Justice decisions outline broad principles and apply them to specific fact scenarios but are inadequate to independently provide the legal clarity needed for national policy.

Kohll and the string of decisions that followed not only carved out a federal role in the sphere of health care but also presented a politically charged confrontation between nationalist and federalist principles. The creeping expansion of EU social policy mandated by the ECJ and affirmed in following treaties necessitates a changing dynamic between national governments and the Community. Under this changing relationship, social power and benefit allocation have become “less comprehensive and ‘ultimate.’”

115 Geraets-Smits/Peerbooms, supra note 30.
117 Geraets-Smits/Peerbooms, supra note 30.
118 Watts, sec. 3, para 37.
119 See Elias Mossialos & Martin McKee, Health Care and the European Union: Profound but Uncertain Consequences for National Health Systems 324 BRIT. MED. J. 991, 991 (2002) (“A failure to address health care explicitly at a European level means that the evolving legal situation is based largely on policies designed to address broad principles... but leaving uncertainty as to how they should be interpreted in similar but slightly different circumstances.”).
120 Ferrara, supra note 19, at 1 (“[T]he integration process has been gradually weakening two essential traits of social sovereignty in its traditional meaning: 1) the capacity of a state to ‘lock in’ and exert coercive rule on actors and resources which are crucial to the stability of redistributive institutions within the national territory and 2) the capacity of a state to bar external authority structures from interfering into their own...”)
IV. Health is Special: State Sovereignty and National Identification

The success or failure of any government in the final analysis must be measured by the well-being of its citizens. Nothing can be more important to a state than its public health; the state’s paramount concerns should be the health of its people.121

Health occupies a special place in the national consciousness (and as a reflection of the national conscience) of the modern state.122 A government’s legitimacy depends on its ability to provide for and protect the health of its citizenry.123 Health security and promotion are therefore both necessary responsibilities of any formal State structure and useful tools in defining and strengthening broader governance.

A. State Sovereignty and National Identification

Health care is of particular symbolic importance in Europe.124 Following the devastation of World War II, health services developed as a very nationalist statement of social values,125 and even today allotted expenditures continue to assert and to identify

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122 Gostin, supra note 121.

123 Randy Cheek, Focus on Medical Diplomacy: Public Health as a Global Security Issue, 81 F.S.J. 22, 23 (Dec. 2004) (“Public health is the basic tenet upon which all other forms of security rest . . . Thus a government that cannot secure the health of its people has failed in its most fundamental responsibility, [and will lack] legitimacy.”).

124 See Ferrera, supra note 19, at 11.

125 The Beveridge Report, an expansive social insurance proposal presented to British Parliament in 1942, is the paradigm example of a shift in governing paradigms and national identification. The Beveridge Report, passed in 1946, established the British National Health Service and created a right of care for all British citizens. Similar social insurance initiatives developed in France. See Daniel T. Rogers, Borrowing Policy, 21 COMP. LAB. L. & POL’Y J. 431, 437 (2000) (explaining the evolution of the “European Social Contract” following the Second World War and the development of national identification through shared social values); see also Ruth Ben-Israel, Social Security in the Year 2000: Potentialities and Problems, 16 COMP. LAB. L.J. 139, 143 (1995) (outlining the development and progression of liberal social security systems throughout the world).
with these values. The European countries are predominantly welfare states. As such, the social benefits of citizenship hold an important place in defining governments and the legitimacy of governance: "[T]he right to decide about the forms and substance of social citizenship has always been considered in its turn a crucial aspect of national sovereignty." Social policy, therefore, is "closely related to the idea of the nation state," which exercises the traditional prerogative of determining the nature and extent of social benefits provided within its territory.

France, for example, has long prided itself on its comprehensive health system. In 2000 the World Health Organization named France the best public health system among the 191 developed nations surveyed. This social and political prioritization of health care is reflected in the nation’s budget allocations. The organization of a national health plan also functions as a very specific statement of national values.

The nature of health care services provided in a national plan also indicates national priorities and values. For example, the Swedish care system incorporates a strong emphasis on family medicine and home care. As such, it may be distinguished from

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127 Ferrera, supra note 19, at 11.
128 Id. (asserting that “social components of citizenship are no less important than its civil and political components”).
129 Martinsen, supra note 12, at 98.
131 Lenain, supra note 130 (“Health spending in France as a percentage of GDP far outstrips the average for OECD countries”); ‘see Kinney & Clark, supra note 126, at 294 (health expenditures provide a “crude indicator” of national commitment to health as a social value).
Austrian health services, which are notable for the absence of a model of integrated care.134

Similarly, organization of health care services is indigenous to and reflective of national governance structures.135 This organization is illustrated in the Finnish health system, which is constructed around local, municipal governance.136 This focus on local governance means that the Finnish system lacks the “second tier” of state oversight built into neighboring Sweden’s governing structure.137 This structure impacts both the delivery and the design of health care service.

B. Health as a European Value and a European Right

Health care is fundamental to the development of a supranational “European” identity and has been used rigorously in the “Europeanization” campaign.138 EU activity in health care is increasingly identified as a linchpin in developing such an inclusive social and political consciousness.

In December 2000 the European Parliament passed The Charter of Fundamental Rights.139 The Charter was designed to create “an ever closer union... based on common values”140 and incorporated a universal right of access to health care “under the conditions established by national laws and practices.”141 It also articulated a federal role in ensuring health protection by

134 See Paolo Rondo Brovetto & Eva Krczal, Situation in Austria, in INTEGRATED CARE IN EUROPE, supra note 133, at 73.

135 See Sirkka Sinkkonen & Pekka Jaatinen, Situation in Finland, in INTEGRATED CARE IN EUROPE, supra note 133, at 15, 15; see also, Jaane Martikainen & Hannu Valtonen, Rationing Health Care in Europe – Finland, in RATIONING OF MEDICAL SERVICES IN EUROPE, supra note 130, at 3.

136 Sinkkonen & Jaatinen, supra note 135.

137 Id.; see Martikainen & Valtonen, supra note 135, at 8.

138 “Europeanization” refers to the development of a continental European identity. See Martinsen, supra note 12, at 89.


140 The Charter of Fundamental Rights, supra note 26, at Preamble.

141 Id. at art. 35.
'centralizing' health policy within "all Union policies and activities."142

The Charter thus lays the groundwork for former Commissioner Byrnes' aggressive EU public health campaign and for the later EU Health Strategy framework.143 As Commissioner of Health and Consumer Protection, Commissioner Byrne recognized the practical exigency and symbolic importance in developing a cohesive and responsive federal health policy and advocated for centralizing public health concerns in all EU policy decisions.144

Health is a preoccupation of Europeans. We need to get it right on health, if we are going to get it right on a new Europe that means something to our citizens ... [O]ur citizens are telling us... that there can be no Europe without a Europe of Health... And they expect their Europe to put their health at the centre of its agenda.145

Attention to and action in health care is necessary for EU legitimacy.146 Congruently, adoption of a European health policy serves as an important tool in defining federal, European values and developing a European consciousness.147

C. Health Security: A Global Concern

[P]ublic health is the basic tenet upon which all other forms of security rest ... Since security must now be addressed globally, so must its basic foundations – including health. It is no longer enough to concern ourselves with national health, for threats to security in any region, however remote, can have serious implications for all regions. Global threats require global solutions, and the threat to public health is no exception...148

142 Id.
144 Byrne, Future Priorities, supra note 12.
145 Id. (emphasis in original)
146 See White Paper, supra note 12, at 11.
147 Byrne, Future Priorities, supra note 12 ("We are at a crossroads in Europe today . . . Perhaps all this would be clearer to our citizens -- if we obsessed a little less about 'Europe', and a little more about 'Europeans.'").
148 Cheek, supra note 123, at 22-23 (arguing that the United States must coordinate
In addition to health care as a tool in developing a federal consciousness and as a necessary mechanism in the global market, the communicable nature of disease and of health security risks necessitate supra-national surveillance and protection.\footnote{149} This lesson was forcibly brought home to the United States following the September 11th attacks and the anthrax scares,\footnote{150} and repeatedly impressed upon the European Community with the naturally-occurring SARS and Avian Flu epidemics.\footnote{151} The threat presented by communicable disease is global in nature, so preventive and responsive management models must be global in kind.\footnote{152} The 2003 SARS scare and the 2005 Avian Flu crisis present the most dramatic examples of the need for supra-national preventive oversight and response systems. It should be noted that the Community Action Programme for Health was launched in 2003, following the SARS crisis.\footnote{153} As Commissioner Byrne stated in his address at the European Health Forum, “[t]here must be a role for the Community.”\footnote{154}

D. EU Health Strategy

The ECJ’s decision in Kohll, Decker, and subsequent cases preventive and supervisory health initiatives internationally in order to protect US health security).

\footnote{149} Id. at 29 (“The commitment of global resources is the only answer to the challenge of infectious disease. The threat to human security is not restricted to individual nations or regions, so the response must be on a similar scale.”); see generally, Patrick Wallis, Book Review, 18 SOC. HIST. MED. 496 (2005) (reviewing DAVID P. FIDLER, SARS, GOVERNANCE AND THE GLOBALIZATION OF DISEASE (2004)).


\footnote{151} See Kristin Choo, The Avian Flu Time Bomb: The Legal System Will Play a Key Role in Planning the Response to a Possible Onslaught of the Virus, 91 A.B.A. J. 36, 38 (Nov. 2005)

\footnote{152} Cheek, supra note 123, at 23; see also William Onzivu, Globalism, Regionalism or Both: Health Policy and Regional Economic Integration in Developing Countries, an Evolution of a Legal Regime? 15 MINN. J. INT’L L. 111, 115 (2006).


\footnote{154} Byrne, Future Priorities, supra note 12.
constituted a radical reinterpretation of EU’s role in social policy and governance. While the shared sphere of competence is now generally accepted, developing political and social consensus of federal authority was not an immediate or organic process, but rather the product of a continuous debate and an aggressive political and social campaign to “sell” Europeanization. The concept of shared competence is now formalized in the Treaty of Nice. 155 In the midst of all of this conflict was the growing need for legal clarity, not only in regards to what the EU as a federal body could do, but also articulating what Member States could not do. In other words, what constitutes an unjustifiable barrier to the free movement of health care services needed defining.

V. The Service Directive

Today, political leaders throughout Europe... [face] a real paradox. On the one hand, Europeans want them to find solutions to the major problems confronting our societies. On the other hand, people increasingly distrust institutions and politics or are simply not interested in them... [This problem] is particularly acute at the level of the European Union... The Union is often seen as remote and at the same time too intrusive. 156

Sponsored by Fritz Bolkestein, Director of the Internal Market, the original Directive on Services in the Internal Market proposed the creation of a single, integrated service market. 157 Keeping with ECJ interpretation of publicly financed health cares services as within the scope of community action, the original proposal

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155 Treaty of Nice: Amending the Treaty of European Union, The Treaties Establishing the European Communities and certain Related Acts, March 10, 2001 O.J. (C. 80/16), available at http://eur-lex.europa.eu/lex/en/treaties/dat/12001C/pdf/12001C_EN.pdf. Signed in 2001, the Treaty of Nice was designed to address the challenges presented by the enlargement of the EU. In order to adapt to the changing circumstances of the Union and the socio-economic disparities between the older, established member states and the new members, the Treaty provided for a great expansion of centralized power generally. While the Treaty (the most recent reforms to the founding mandate) buttressed expansions made in earlier agreements regarding governing authority it also built upon those agreements to establish a “shared competence” between Member States and the federal State in the realm of policy action. Id.

156 White Paper, supra note 12, at 3.

157 Freedom Fried, supra note 33.
included provisions on health care systems. The Service Directive was widely unpopular and generally acknowledged as the second most controversial proposal sponsored by the EU. Following popular protests and years of political debate, an amended version of the Service Directive passed Parliament in February 2006, and excluded all references to publicly financed health services.

Incorporation of health care services within the Directive on Services in the Internal Market (Service Directive) was one effort by the European Community to provide legal clarity on patient and practitioner mobility. Like the US, the EU is a service-oriented economy. Services account for seventy percent of all economic activity within the EU. The Directive formally applies free mobility principles to the service market, thereby creating a single service market in the EU. A unified service market is acknowledged as necessary to reach the Lisbon Agenda pledge of making the EU "the world's most dynamic and competitive economy."

158 Id.

159 See id. The most controversial EU proposal remains the passage of the EU Constitution. Concerns about the constitution and the Service Directive mirror each other in their fear of "social dumping" and defense of more protective social and labor policies.


163 "Bolkestein Directive" to Stay, But Will Be Watered Down, supra note 160.

164 See Kyprianou, supra note 18. The Service Directive was seen as an implementation of the Lisbon Agenda goals, where the EU pledged to make the EU "the world's most dynamic and competitive economy" by 2010. Q&A: EU's Lisbon Agenda, BBC News, March 22, 2005, available at http://news.bbc.co.uk/2/hi/business/4373485.stm. Organization of a single market system through a service directive was identified as essential to fulfilling this objective, since 70% of Europe's GDP comes from the service industry. Id.

165 Kyprianou, supra note 18.
Originally dubbed "the Bolkestein Directive,"166 the Directive was a controversial initiative to abolish service industry regulations infringing on free mobility unless the state showed that such regulations (1) were non-discriminatory, (2) served the public interest, and (3) were proportionate to the public good protected.167 These regulations or restrictions were not, in principle, "revolutionary" in the context of health care, but were a reaffirmation of the Court’s decision in Kohll that “unjustified” barriers to service mobility are “unconstitutional.”168 The Service Directive’s function is therefore projected as a primarily formal ratification of existing policy intended to encourage national political deliberation.169 Commissioner Bolkestein addressed this very point in a response to a letter from British public health officials expressing concern of the supposed “harmonisation” of health policy and practice through the Directive, asserting:

It is already the case that Member States may not discriminate against service providers from other Members States... unless such restrictions can be justified by reasons of overriding general interest as recognized by the ECJ, and are proportionate. The Directive would ensure that Member States examine their legislation systematically to ensure that remaining discriminatory provisions are removed.170

Despite such assurances, the proposal elicited a virulent and hostile public response.171 Nearly a hundred thousand people congregated in Brussels in March of 2005 to protest the proposed Service Directive.172

The Service Directive and the "country of origin principle" created controversy generally; however, inclusion of health care
services elicited controversy and criticism specifically. Opponents consistently assert that treating health as any other commercial activity lends itself to unscrupulous practice of medicine and a serious risk to health care quality.

The Directive is controversial because it applies the same rules to healthcare and social services as it does to estate agents, fairground providers...and private security firms. The commission no longer sees the services provided... as a special public good to be enjoyed by all citizens, but as an "economic activity," a commodity to be traded across the EU much like any other.

Opponents consistently assert that health is different. As one vocal British politician stated: "For my part, I believe that health is not a commercial service to be traded across borders like kitchen sinks."

Consequently, health services were eventually removed from the amended version of the Service Directive, which passed Parliament in February 2006. Removal of public health services from the Service Directive was important because it was based on the opinion that "health is different" from other commercial and social service activities, and because the formalized structure of health policy within the service market was an anathema to the existing structure organized through soft law mechanisms.

Central to this exclusion of health care services is the concept that such formal (or laissez faire) procedures are incongruous with health practices and that in addition to misrepresenting the role

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173 Freedom Fried, supra note 33. The biggest problem with the Bolkestein Directive is with "the country of origin principle," which allows service providers to practice in Member States under that labor laws and regulations of their home states. More developed and liberal states, such as France (particularly France) and the UK protested that this would lead to unfair employment practices, competition and social dumping. Id.


175 Id.


177 Memorandum on Health Services, supra note 15 ("It was felt that specificities of health services were not sufficiently taken into account, in particular their technical complexities, sensitivity for public opinion and major support from public funds").

178 Kyprianou, supra note 18.
and nature of health care, the role of the federal government in regulating health care is misrepresented. The Service Directive was, therefore, a break from the model of managing public health adopted by the European Community following the Kohll decisions. Upon its removal, the Commission and Commissioner Kyprianou reasserted earlier soft law approaches.

VI. Persuasive Convergence: The Pedagogical Role of the EU

Governments exist for, and should use their vast powers for the betterment of the people. Aside, therefore, from its essential governing powers, it is the peculiar province of a government, especially of a national government, to exercise a supervisory, investigating and, as it were, pedagogic attitude toward the material welfare of its people. Under this head are embraced those administrative functions that are of an investigating statistical nature, that consist not in the exercise of any new powers, not in the interference with or control of any of the social activities of the people, but solely in the study of conditions and of methods, and the diffusion of the information thus obtained.179

From the very beginning the EU has accepted a limited role in the development of social policy, acknowledging that there is a restricted and specific area where federal action and authority is appropriate.180 That means adapting to a governing structure that accommodates the social service nature of health care (as illustrated in the rejection of the Service Directive) as well as respecting the proper scope of “federal” authority. Health care is a sphere of “shared competence;” the Union should only act where something cannot be accomplished at a national level181 and where, consequently, supranational action would give added value to national action. The EU’s role is as a supporter and facilitator.

179 W.W. Willoughby, A National Department of Health, 4 ANNALS AM. ACAD. POL. & SOC. SCI. 292, 297 (1893) (arguing for the establishment of a national health department that fulfills a specific supervisory and “pedagogical” role).


While this role is limited, it is also unique and necessary; "federal" oversight provides opportunities not previously available to national governments acting separately.\footnote{182} These principles directed the EU to carefully target its area of focus and authority. In 2000, the European Commission issued a communication outlining a broad framework for the future health strategy of the EU.\footnote{183} Publication of this document was the first step in a larger process of identifying and responding to the need for a health care strategy.\footnote{184} In addition to outlining a broad statement of need, it submitted a proposal for a Community Action Programme, which would become the focal point of all EU Public Health policy initiatives. Building upon the initial communication following the ECJ's decision in \textit{Kohll}, the strategy focuses on "improving health information; establishing a rapid response mechanism; and tackling health determinants."\footnote{185} These three areas of action constituted then, and continue now, to be the focus of EU action in public health.\footnote{186}

Parliament and the Council eventually accepted the program proposal outlined in the Communication establishing the Community Action Programme for Public Health in September 2002. Earlier that year the Commission issued an invitation to health ministers to participate in a \textit{High Level Reflection Process}, or working group, on the very issue of health care services in the

\footnote{182} Council Decision 1786/2002, Adopting a Programme of Community Action in the Field of Public Health, 2002 O.J. (L 271) 1, 3 (EC), available at http://eur-lex.europa.eu/eli/leg/en/oj/dat/2002/l_271/l_27120021009en00010011.pdf. ("The Community and its Member States have at their disposal certain means and mechanisms in relation to information and monitoring in the field of public health. It is therefore necessary to ensure a high level of coordination between actions and initiative taken by the Community and the Member States to implement the programme, to promote cooperation between Member States and to enhance the effectiveness of existing and future networks in the field of public health."); \textit{Id.} ("It is essential that the Commission ensure the effectiveness . . . cohesion . . . [and] cooperation between Member States.").\footnote{183}

\footnote{184} Communication from the Commission to the Council, supra note 12.\footnote{184}

\footnote{185} Paul J. Belcher and Phillip C. Bernan, \textit{Health in Other EU Policies or an EU Health Policy?}, 7 \textit{EUROHEALTH} 1, 1 (Autumn 2001), available at http://www.euro.who.int/Document/Obs/Eurohealth7_4.pdf.\footnote{185}

Union. The Working Group and their report issued the following year are identified as the first and most visible “institutional and governmental response at EU level to the Kohll litigation”\textsuperscript{187} and demonstrate the first serious effort at managing health policy on a “federal” level.\textsuperscript{188}

The High Level Reflection Report outlined nineteen recommendations under five directing principles.\textsuperscript{189} The fourth of these overarching themes directly addressed policy harmonization and legal clarity under the title of “reconciling national health policy with European obligations.”\textsuperscript{190} The Working Group’s response focused on soft law measures and cooperative forums to resolve conflict between national health policies and the emerging federal model, but also included hard law recommendations of treaty reform and secondary legislation.\textsuperscript{191} With the passage of time this developed into a conscientious policy choice: soft law measures would be used to develop standards and hard law to enforce them.\textsuperscript{192}

The Community Action Programme for Public Health proposed in 2001 has been refined over the years, but the principle objectives remain the same: “To lay the foundation for a comprehensive and coherent [EU] approach [to health policy] by concentrating on three key priorities: health information, health threats, and health determinants.”\textsuperscript{193} The Programme is modeled on the \textit{Open Method of Coordination} (OMC). The OMC, originally developed to address social inclusion disparities, is well suited to confront the particular challenges presented in health care. “In this context, the ‘open method of coordination’ will be a flexible tool, respecting the diversity of the national situations and competences and therefore particularly well adapted to the specific

\textsuperscript{187} Hervey, \textit{supra} note 34, at 185.

\textsuperscript{188} \textit{See id.}

\textsuperscript{189} \textit{Id.}

\textsuperscript{190} \textit{Id.} at 185-86.

\textsuperscript{191} \textit{Id.} at 186 (In addition to the hard law measures outlined above, the Report focused on “Commission communications; Member State initiatives and bilateral cooperation; and a permanent cooperation mechanism at EU level.”).

\textsuperscript{192} \textit{See id.}

\textsuperscript{193} Council Decision 1786/2002, \textit{supra} note 183, at 3; \textit{see also} Community Action Website, \textit{supra} note 186.
features of health care systems in all the branches of social protection.194

Just as there are national public goods, so there are international ones, and many types of knowledge fall into this category. No single country will invest enough in the creation of such goods, because the benefits would accrue to all countries without the creating country receiving full compensation. But international institutions, acting on behalf of everyone, can fill this gap.195

VII. Health Information and Indicators: Managing the Exchange of Information

Following the OMC model outlined above, the Community Action Programme focuses on the creation and maintenance of networks and forums for the exchange and dissemination of information.196 It is an information-centered network.197 This focus on information-based governance can be organized into three primary functions: (1) providing a forum for political and policy deliberation; (2) creating a forum for scientific exchange; and (3) collecting and disseminating health quality statistics and determinants. These three pedagogic roles all contribute to clarifying and raising the general standard of care.

A. Political and Policy Deliberation

As noted in the above discussion, the EU’s first formal action in addressing the questions raised by Kohll was to organize a high

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196 Community Action Website, supra note 186.

197 See id. ("As part of this integrated approach, particular attention is paid to the creation of links with other Community programmes and actions. Health impact assessment of proposals under other Community policies and activities, such as research, internal market, agriculture or environment will be used as a tool to ensure the consistency of the Community health strategy."). Id.
level working group to reflect on the problem presented.\(^{198}\)

Between the HLRP, the Working Group, Commissioner Byrne's Reflection Process, and the current working group developing the health-specific Service Directive, the history of health policy in the EU is a string of policy forums and deliberation. However, the EU's contribution to the health policy debate is not restricted to formal political deliberation; instead the EU, through the Community Action Programme has established a series of forums for both policymakers and industry leaders to collaborate and exchange information: the European Health Forum Gastein (EHFG).

The EU relies on the power of the purse to establish and encourage participation in scientific forums.\(^{199}\) The most notable and successful example of such a platform is the European Health Forum Gastein (EHFG). Established in 1998, the EHFG incorporates stakeholders from government, industry and academia in an annual conference on common challenges in health care.\(^{200}\) The Forum offers a "well-established platform which is necessary as a think tank to health policy... and administration in Europe."\(^{201}\) The EHFG is not only a think tank or a forum for deliberation; it has also served as a launching pad for various EU health projects and initiatives. The EHFG was fundamental in advocating for including health care in the Charter of Fundamental Rights in 2000.\(^{202}\) Commissioner Byrne used the conference as a platform to introduce his "Europe of Health" coalition in 2002.\(^{203}\) Most recently the conference was recognized as central to the development and the direction of the future EU Health Services

\(^{198}\) Hervey, supra note 34.

\(^{199}\) Id.


\(^{203}\) Byrne, Future Priorities, supra note 12 (This initiative has since been accepted as the philosophical foundation of the EU's developing Health Strategy).
Directive. Andrzej Rys, Director of Public Health on the Commission, reiterated this very point in his address to the Health Forum: "Gastein is a set point on the agenda for the commission's work and is the best opportunity to present the work of previous years and plans for next year to experts."  

The EHFG's value and contribution to the health care debate is its ability to bridge the gap between policymakers and the experts. Failure to take advantage of the opportunity for deliberation and cooperation presented by the conference and other forums means failure in broader public health initiative and public relations efforts, as EHFG President Leiner emphasized in his opening address at 2006 Health Forum: "Experts have to develop solutions, but politicians also have to adequately communicate this to the public." Failure to cooperate between these two sometimes disparate camps means failure in implementing viable and responsive policy, and "no one should be surprised that... the EU fails to enjoy the credit it actually deserves."  

In addition to establishing a forum for deliberation and a route of access for policymakers and stakeholders, the EU is committed to developing regular, interoperable information systems between Member States. The proposed "European Centres of Reference" is one example of such a program. These Centres of Reference are federally-sponsored "poster" facilities, offering highly-specialized treatments and providing a focal point for research and information dissemination. Although not yet implemented, the proposal has received warm popular political support. They were most recently identified as a primary

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205 Id.

206 Id.

207 Versweyveld, supra note 201.

208 EHFH Congress, supra note 205.

209 Hervey, supra note 34, at 189 (citing "health technology" as the greatest "contributor to escalating costs of the European Health care systems" and recommending collaboration between the fragmented national systems trying to compare and evaluate the relative value of new technologies compared to existing, less expensive tools).

210 Id.
objective of the 2007 Health Plan.

B. Encouraging Interoperability

To take advantage of EU sponsored forums, Member States must be able to compare systems and output. National Health services vary greatly in terms of organization, services included, and population served. What works best in one forum may not translate to another. By encouraging systems interoperability, the EU can accelerate the dissemination of best practices in administration and treatment. Therefore developing quality indicators is a focal point of the Community Action Programme.

Quality review and coordination relies on quality measures and indicators. This presents two challenges. First, the variance in health care systems and populations within Member States make quantifying health outcomes difficult and contentious. Second, quality of care is a difficult concept to quantify. Health care outcomes are not determinatively dependent on quality of care. Quality care encompasses more than mere science and adherence to “best practices;” quality care is patient-centered care. Patient-centered, quality care involves honoring subjective patient

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212 European Commission Health and Consumer Protection Directorate-General, Strategy on European Community Health Indicators: The “Short List” (July 5-6, 2004), available at http://ec.europa.eu/health/ph_information/documents/ev20040705_rd09_en.pdf (“Most of the actions supported by the former programme of Community action . . . were in relation to the development of indicators and the improvement of the methodology of collection of statistics and preparation of reports”).

213 Hervey, supra note 34, at 192 (“‘hard’ quantitative objectives and indicators . . . [are the] basis for evaluation and benchmarking”).

214 Harvey Jolt & Martin Leibovici, America’s Health in Transition: Reforming America’s Health System, IOM White Paper 7 (1994), available at http://books.nap.edu/openbook.php?record_id=9147&page=R1 (outlining that while certain areas of care have scientifically accepted methodologies, other areas are behind).


216 Jolt & Leibovici, supra note 214.
decisions — sometimes against objective medical advice.\textsuperscript{217} The question then is how to quantify and measure quality practices in a field characterized by uncertainty and where no outcomes (save eventual death) are guaranteed.

To address this challenge, the Community Action Programme organized and financed research into developing quality health indicators throughout Europe in 2003. By June of 2006 the European Community Health Indicator Project developed a list of over 400 quality indicators.

\textbf{C. Consumer Education: "Europe of Health"}

In addition to providing forums for policymakers and practitioners, by managing health information the Action Programme has also committed resources to expanding the quantity and quality of information available to consumers. This enables consumers to make more informed decisions in selecting care. Improving care therefore is not just a question of investing more, but ensuring that "money is well spent."\textsuperscript{218} Recent studies conducted in the United States demonstrate that billions of dollars are wasted on unnecessary, and even harmful, care because patients, lacking basic information and the confidence to exercise discretion in the care of their conditions, are unable to participate in critical decisions.\textsuperscript{219} The result is the practice of defensive medicine and over-utilization of services.\textsuperscript{220} Wasted resources are not the only victims; approximately 1.5 million people suffer from medication errors.\textsuperscript{221} The Institute of Medicine estimates that over


\textsuperscript{218} David Byrne, European Comm’r for Health and Consumer Protection, Address at the EPC Conference: Enabling Good Health for All: The Future of Health in Europe (July 15, 2004); see also Andrew Ruskin, Empowering Patients to Act Like Consumers: A Proposal Creating Price and Policy Choice within Health Care, 73 ST. JOHN’S L. REV. 651, 661-662 (1994).

\textsuperscript{219} Blumenthal, supra note 55.

\textsuperscript{220} See generally Barry R. Furrow, Regulating for Patient Safety: Toward a Federal Model of Medical Error Reduction, 12 WIDENER L. REV. 1, 2 (2005).

\textsuperscript{221} See COMMITTEE ON IDENTIFYING AND PREVENTING MEDICATION ERRORS, PREVENTING MEDICATION ERRORS: QUALITY CHASM SERIES 105-107 (Phillip Aspden, Julie Wolcott, J. L. Bootman, & Linda R. Cronenwett eds., 2007).
3.5 billion dollars are spent annually in responsive treatment to medication errors in the United States alone.\textsuperscript{222}

Correcting this system failure involves incorporating "not just health care organizations and federal agencies, but... consumers... [and] ensuring that consumers are fully informed."\textsuperscript{223} The concept of integrated, cooperative care does not only apply to pharmaceutical decisions, but instead indicates a larger failing in coordinated health systems.

The greater incorporation and education of patients as consumers was central to Commissioner Byrne's proposed health strategy.\textsuperscript{224} In his address to the European Health Forum, Commissioner Byrne emphasized health information and dissemination to citizens as a primary objective of EU action.

[T]he Community has an important role to play in the dissemination of information and the empowerment of citizens... One key action is to improve health information and make it more widely available. By ensuring easy access to timely, accurate, and authoritative information we can minimize the risk of people relying on partial, biased or misleading information or advice.\textsuperscript{225}

To this end, Commissioner Byrne proposed the creation of an internet health portal for consumers. Establishing easily accessible and reputable information on health care services available, he argued, will enable patients "to become active partners in managing their own health."\textsuperscript{226} The EU launched the proposed internet Health Portal and an E-Health Report Cards for consumers in 2006.\textsuperscript{227}

Once again the Community role focuses not only on the

\textsuperscript{222} Id. (It should be noted that this is a conservative estimate taking into account only the direct medical costs incurred in correcting medication errors. It does not take into account victims lost wages or productivity or overhead hospitalization costs.)


\textsuperscript{225} Byrne, Future Priorities, supra note 12.

\textsuperscript{226} Id.

\textsuperscript{227} Id.
dissemination of information but its general management. Under the earlier e-Europe 2002 Action Plan, the Commission developed a core set of quality criteria to measure health related websites.\textsuperscript{228} As reiterated in the European e-Health Action Plan adopted in 2004, Community action takes a twin-track approach: maximizing the quantity of information integration and exchange and the quality of such communications.\textsuperscript{229}

\textbf{D. Legal Clarity: A “Framework Right” to Health Care}

[The EU should] enable those responsible for health services to have a clear framework of Community law within which they can fulfill their responsibility and take advantage of cooperation between health systems where this can help in providing safe, high quality and efficient health services. In so doing this initiative can also contribute to helping Member States in achieving a better use of resources... through more efficient planning and allocation.\textsuperscript{230}

EU action is focused on the management and control of health care information.\textsuperscript{231} This includes the establishment of policy forums, systems for scientific reference and the education of health care consumers. The latter element (consumer education) should not be underestimated in its importance to the overall federal strategy; indeed the Union mandates certain standards in communicating benefits to citizen-beneficiaries.\textsuperscript{232} This is designed as a means of instituting or encouraging national policy improvements and raising the general standard of care throughout the EU.\textsuperscript{233} ECJ decisions not only provide directing principles to a developing European Health strategy – it complements and reinforces independent European action by requiring member

\begin{footnotesize}
\textsuperscript{228} Information Can Save Your Life, Europa Website, http://europa.eu.int/information_society/qualif/health/index_en.htm (last visited Sept. 20, 2007)
\textsuperscript{229} Id.
\textsuperscript{230} Id.
\textsuperscript{231} See Kyprianou, supra note 18.
\textsuperscript{233} See Mike Sedgley, Smits/Peerbooms: A Clarification of Confusion?, 7 EUROHEALTH 1, 1, available at http://www.euro.who.int/Document/Obs/Eurohealth7_4.pdf (asserting that EJC decisions are designed to “move Member States to clarify the entitlements to healthcare that they give to their national citizens”).
\end{footnotesize}
states to clearly articulate social security benefits available to citizens. While assiduously asserting national right to determine the nature and extent of citizen’s health care rights, once the state provides a right to a specific health care service it cannot prevent or inhibit access to those same services in other Member States. A Member State must now clearly articulate the nature and extent of services available to its citizens.”

A clear national statement of the health rights and services thus enables citizens to take advantage of intra-national care and enables the federal EU system to take advantage of market forces to encourage policy promotion and potentially natural convergence. The idea is to harness economic power and encourage policy convergence and quality control by mandating clear statements of national policy.

VIII. Conclusion: Evolving Dynamics in Governance

Finally, this brings us to an examination of the evolving nature of governance and its impact on institutional dynamics and general expectations of governance. As scholar Louise Trubeck summarized, “New governance is transformative of law in that it challenges what we think of as law.” New governance’s emphasis on flexible and persuasive mechanisms such as consensus building, general guidelines, best practices and peer review envision policy-making and attendant regulations as a cooperative and evolving process; a process which involves many players across many forums. As such it may be distinguished from the command-and-control old governance model. Under the traditional regulatory model the state enforced compliance with bright line rules. While such a structure provides clarity and strong police power, it does not accommodate the demands of a modern administrative state. New governance corrects this market failure and enables the adaption of existing governing systems to the changing economy. As the Commission concluded

234 Id.
235 Id.
236 Id.
237 Id.
238 Trubeck, New Governance and Soft Law, supra note 36, at 149.
239 Id.
240 See id. at 147.
in its 2000 White Paper on European Governance: "The Union cannot develop and deliver policy in the same way as a national government; it must build partnerships and rely on a wide variety of actors. Expectations must be met in different ways."\textsuperscript{241}

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\textsuperscript{241} \textit{White Paper, supra} note 12, at 32.