

THE CONSTRUCTION OF HEALTHIER EUROPE: LESSONS FROM THE FIGHT AGAINST CANCER

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ABSTRACT:

The increasing involvement of European-level institutions in public health is often told as a story of bureaucratic, neo-liberal expansion. According to this history, the European Commission, backed by a like-minded European Court of Justice, has sought to expand its powers against the wishes of the Member States and their citizens, who see European Union (EU) involvement as a threat to the “European Social Model.” Drawing on a case study of the EU’s involvement in fighting cancer through the “Europe Against Cancer” program, this article offers an alternative explanatory account for the emergence of EU health policy. This article demonstrates how networks of experts and activists have driven the EU’s involvement. In addition, this article also shows how the EU’s activities have not been solely in the form of top-down directives, but rather in the form of networked governance based on knowledge, creation, and policy learning. This approach requires minimal EU involvement or funding to achieve significant advances in cooperative health system reform based heavily on policy entrepreneurs. This paper draws lessons from the history of Europe Against Cancer for the future development of EU health policy.

I. INTRODUCTION

Health systems are a fundamental part of Europe’s social infrastructure. Until relatively recently, however, health care was seen as a matter for national, and, in many cases, regional govern-

ment, not as a European Union (EU) concern. Health *services*, on the other hand, increasingly have been made subject to the binding rules that guarantee the free movement of goods, capital, services, and people. This has occurred largely through a series of high profile court cases brought before the European Court of Justice (ECJ) involving cross-border health care services. As a result, many accounts of the EU's recent involvement in health systems take what is essentially a legal doctrinal approach, giving significant explanatory significance to these cases. The European Commission, according to these accounts, then follows the European Court of Justice's lead, by responding to the undesirable consequences of this litigation.

While not denying the relevance of the European Court of Justice's actions in the health field and recognizing the centrality of the Commission in the EU law and policy making process,¹ a different narrative account of the EU's involvement in health systems governance is related in this article. Policy making in *governance* systems such as the EU, as opposed to the *governments* of the Member States, is often based on networks of actors, both governmental and non-governmental, that are instrumental in facilitating communication and the exchange of new information and ideas regarding the problem at hand. As work on policy networks would suggest, neither formal procedural accounts nor rational-economic market based accounts fully capture governance processes.² Rather, through forging alliances among overlapping interests, various actors, especially non-state actors, can have important influences on both the policy making process and policy outputs.

In this article, an alternative narrative is put forward to the Court and the Commission focused accounts found elsewhere in the literature on EU health governance. This account suggests that

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¹ See Susana Borrás, *The European Commission as a Network Broker*, 11 EUR. INTEGRATION ONLINE PAPERS 1 (2007), <http://eiop.or.at/eiop/texte/2007-001a.htm>.

² John Peterson, *Policy Networks*, in EUROPEAN INTEGRATION THEORY, 117 (Antje Wiener & Thomas Diez eds., 2004).

a policy community emerged in the 1980s coalescing around the EU's involvement in the fight against cancer. The policy processes and outcomes from the activities of that policy community provide a story of one way in which the EU can provide a governance space that successfully influences change in health care settings. The story also provides lessons about the potential of new governance, broadly understood, in the European Union and the ways in which this alternative to more traditional "command-and-control" regulation can take advantage of the diversity and decentralized nature of the European Union. The broader lessons to be learned from the fight against cancer are that a governance system based on policy communities offers one among a number of possible routes forward for the EU's emergent health governance agenda.

Part II of this article discusses the standard history of EU involvement in health and the ways in which the standpoint presented in this article differs. Stressed in this article is the importance of bottom-up dynamics and the creation and activism of patient and expert networks that see EU involvement as a potential method to make health care systems more efficient and effective. Part III discusses in greater detail the case presented in this paper: the EU's "Europe Against Cancer" and the undulating history of the EU's involvement in fighting cancer. Beginning in 1986, at the urging of various Member States and expert groups, the EU began funding a program aimed at facilitating information and experience exchange among policy makers and practitioners regarding the reduction of the incidence and mortality of cancer across the EU. The Program received continued support in five-year increments until 2002, when cancer was given a lower priority vis-à-vis other health initiatives. More recently, however, the fight against cancer has been given a higher priority due to the actions of those same networks. Part IV draws lessons from this case for the current debate over the way forward for EU health policy. Part V of this article concludes by suggesting that the development of the European cancer network may provide a model for future health policy development within the European Union. And while it is only one model among many, as will be shown, the model holds a great deal of potential for improving policy and outcomes at all levels.

II. CROSSROADS IN EU HEALTH POLICY? THE CREATION, TOOLS, AND IMPACT OF NETWORKS

Recently there has been a surge in efforts to develop a comprehensive and coherent health policy in the European Union. Scott Greer argues that we have now come to a critical juncture.³ A number of developments seem to support his argument. In October 2007, the European Commission issued “Together for Health,” a discussion paper designed to generate debate on both the substantive and procedural questions of EU health policy.⁴ Its contents suggest that the EU is moving beyond traditional public health to become involved in health care systems design as well. This paper also indicates that the EU is focused on developing new cooperation mechanisms that would involve the Member States and stakeholders more closely in the decision making process.⁵ At the same time, the significance of a series of much discussed European Court of Justice cases regarding the funding of and access to cross-border health services has resulted in a focused interest in shaping the direction of EU health policy.⁶ Furthermore, in response to those cases and based on its competence to complete the

³ Scott L. Greer, *Choosing Paths in European Union Health Services Policy: A Political Analysis of a Critical Juncture*, 18 J. EUR. SOC. POL'Y 219, 221 (2008).

⁴ *Commission White Paper on Together for Health: A Strategic Approach for the EU 2008-2013*, COM (2007) 630 final (Oct. 10, 2007).

⁵ *Commission Staff Working Document, Document Accompanying the White Paper on Together for Health: A Strategic Approach for the EU 2008-2013*, COM (2007) 630 final (Oct. 10, 2007).

⁶ Case C-158/96, Kohll v. Union des Caisses de Maladie, 1998 E.C.R. I-1931; Case C-368/86, Vanbraekel v. Alliance Nationale des Mutualités Chrétiennes, 2001 E.C.R. I-5363; Case C-157/99, Geraets-Smits v. Stichting Ziekenfonds VGZ (*Geraets-Smits and Peerbooms*), 2001 E.C.R. I-5473; Case C-326/00, Idryma Koinonikon Asfaliseon v. Ioannidis (*IKA*), 2003 E.C.R. I-1703; Case C-56/01, Inizan v. Caisse Primaire D'assurance Maladie des Hauts-de-Seine, 2003 E.C.R. I-12403; Case C-385/99, Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA, 2003 E.C.R. I-4509; Case C-156/01, van der Duin v. Onderlinge Waarborgmaatschappij ANOZ Zorgverzekeringen UA (*ANOZ*), 2003 E.C.R. I-7045; Case C-8/02, Leichtle v. Bundesanstalt für Arbeit, 2004 E.C.R. I-2641; Case C-145/03, Heirs of Keller v. Instituto Nacional de la Seguridad Social (*Keller*), 2005 E.C.R. I-2529; Case C-372/04, Watts v. Bedford Primary Care Trust, 2006 E.C.R. I-4235; Case C-466/04, Herrera v. Servicio Cántabro de Salud, 2006 E.C.R. I-5341; Case C-444/05, Stamatelaki v. NPDD Organismos Asfaliseos Eleftheron Epangelmaton, 2007 E.C.R. I-3185.

internal market (Article 95 of the Treaty of Rome⁷ establishes the European Community, which is the forerunner to the EU) after a long period of public comment and political debate, the Commission on July 2, 2008, made public its proposed directive to lay out patients' rights in cross-border health care.⁸

This directive builds upon the momentum established in part by the "High Level Group on Health Services and Medical Care," which pushed for legislation establishing the basic rights of patients receiving cross-border health services, clarifying the recent ECJ rulings, and also embedding the "core values" of EU health care systems in EU level legislation.⁹ Of particular relevance to the argument presented in this paper, Chapter IV of that directive lays out a series of initiatives designed to "unlock the huge potential for European cooperation to help improve the efficiency and effectiveness of all EU health systems."¹⁰ Beyond establishing a common legal framework for the reimbursement of cross-border health care, the directive seeks to establish improved European cooperation on health care by establishing European Reference Networks,¹¹ increasing the interoperability of information technology

⁷ Treaty Establishing the European Economic Community, Mar. 25, 1957, http://eur-lex.europa.eu/en/treaties/dat/11957E/tif/TRAITES_1957_CEE_1_EN_0001.tif.

⁸ *Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross-Border Healthcare*, COM (2008) 414 final (July 2, 2008). In the Communication from the Commission accompanying the proposed directive, the Commission notes that this most recent proposal is based on the current Treaty, not on revisions expected from the revised Treaty, which still faces many obstacles in its ratification process. *European Commission Staff Working Paper: Towards a Renewed Social Agenda for Europe-Citizens Well-being in the Information Society*, SEC (2008) 2183 (July 2, 2008), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2183:FIN:EN:PDF> (last visited Feb. 27, 2009).

⁹ For instance, "the High Level Group on Health Services and Medical Care" —made up of senior Member State representatives (with other stakeholders contributing on relevant subjects)—prepared a statement on the core values and shared principles of health systems. The statement was adopted by the Council in June 2006. Council Directive 146/01, 2006 O.J. (C 146) 1.

¹⁰ Press Release, European Union, Commission Adopts Proposal for Directive on Patients' Rights in Cross-Border Healthcare, IP/08/1080 (July 2, 2008) available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1080>.

¹¹ *Id.* Already being piloted for rare diseases, a 'European Reference Network' is a group of health care experts in a particular field who share knowledge and expertise in state of the art medical practice. Council Directive 1295/1999, art. 1, 1999 O.J. (L155) 2, 3 (EC). The proposal thus intends to roll out the idea of European level efficiency in health care practice, beyond those rare diseases where the added value of tackling something at EU level is obvious (it is not financially viable to make provision at national level, especially in small Member States), to a more general

used in health systems, and creating Europe-wide networks for the assessment of new medical technology. Most importantly, perhaps, the debate surrounding this directive is often couched not in narrow, technical, or legal terms, but rather in much broader terms of the reshaping Member State health systems through the activity of European institutions.

Standard explanations of the EU's role in health paint a picture in which the Commission and the ECJ play definitive roles.¹²

sharing of knowledge, training, development of best practice benchmarks, and assessment of innovation.

¹² The seminal account of this process (although of course not in the health context) is J.H.H. Weiler, *The Transformation of Europe*, 100 YALE L.J. 2403 (1991). For a recent critical account, suggesting the Court no longer operates in the manner it may have done in earlier periods of its history, see Jo Hunt, *The End of Judicial Constitutionalisation?*, 3 CROATIAN Y.B. EUR. LAW & POL'Y 135 (2007). In the health care context, for instance, see Pedro Cabral, *Cross-Border Medical Care in the European Union – Bringing Down a First Wall*, 24 EUR. L. REV. 387 (1999); WILLY PALM ET AL., ASSOCIATION DE INTERNATIONALE DE LA MUTUALITE, IMPLICATIONS OF RECENT JURISPRUDENCE ON THE CO-ORDINATION OF HEALTH CARE PROTECTION SYSTEMS (2000); Vassilis G. Hatzopoulos, *Killing National Health and Insurance Systems but Healing Patients? The European Market for Health Care Services After the Judgments of the ECJ in Vanbraekel and Peerbooms*, 39 COMMON MKT. L. REV. 683 (2002); Elies Steyger, Case Note, *National Health Care Systems Under Fire (But Not Too Heavily)*, 29 LEGAL ISSUES ECON. INTEGRATION 97 (2002); ANNE PIETER VAN DER MEI, FREE MOVEMENT OF PERSONS WITHIN THE EUROPEAN COMMUNITY: CROSS-BORDER ACCESS TO PUBLIC BENEFITS (2003); Yves Jorens, *The Right to Health Care Across Borders*, in THE IMPACT OF EU LAW ON HEALTH CARE SYSTEMS (Martin McKee et al. eds., Bruxelles: P.I.E. Peter Lang 2002); Jonathan Montgomery, *Impact of EU Law on English Healthcare Law*, in SOCIAL WELFARE AND EU LAW (Eleanor Spaventa & Michael Dougan eds., Oxford: Hart Publishing 2005); TAMARA K. HERVEY & JEAN V. MCHALE, HEALTH LAW AND THE EUROPEAN UNION, 109 (Cambridge Univ. Press 2004); Magdalene Rosenmöller et al., *Patient Mobility: The Context and Issues*, in PATIENT MOBILITY IN THE EUROPEAN UNION: LEARNING FROM EXPERIENCE 1 (Magdalene Rosenmöller, Martin McKee, & Rita Baeten eds., World Health Organization 2006); see IRENE A. GLINOS & RITA BAETEN, OBSERVATOIRE SOCIALE EUROPÉEN, A LITERATURE REVIEW OF CROSS-BORDER PATIENT MOBILITY IN THE EUROPEAN UNION (2006); see SCOTT L. GREER, RESPONDING TO EUROPE: GOVERNMENT, NHS AND STAKEHOLDER RESPONSES TO THE EU HEALTH POLICY CHALLENGE (The Nuffield Trust 2006) available at <http://www.nuffieldtrust.org.uk/ecomms/files/RespondingtoEurope.pdf>; see SCOTT L. GREER, THE NEW EU POLICY AND THE NHS SYSTEMS (Nuffield Trust 2005) available at <http://www.nuffieldtrust.org.uk/ecomms/files/090205EUhealthsystem.pdf>; see Christopher Newdick, *Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity*, 43 COMMON MKT. L. REV. 1645 (2006); Rita Baeten, *Health Care: After the Court, the Policy-Makers Get Down to Work*, in SOCIAL DEVELOPMENTS IN THE EUROPEAN UNION 2004 79 (Eur. Trade Union Inst. ed., 2005); Gareth Davies, *The Process and Side-Effects of the Harmonisation of European Welfare States* (NYU Sch. of Law The Jean Monnet Program, Working Paper 02/06, 2006); see Tamara K. Hervey, *The Current Legal Framework on the Right to Seek Health Care Abroad in the European Union*, CAMBRIDGE Y.B. EUR. LEGAL STUD., 2006-2007, at 261; Willy Palm and Irene Glinos, *Enabling Patient Mobility in the European Union: Between Free Movement and Coordination*, in HEALTH SYSTEMS GOVERNANCE IN EUROPE: THE ROLE OF EU LAW AND POLICY (forthcoming 2009).

According to this institutional expansionism interpretation, in seeking to expand their own power or pursue a neo-liberal agenda, these bodies have forced their way into the previously closed world of Member State health care. While the role of the Commission and the ECJ should not be underplayed, three arguments are presented contrary to this understanding.

First, more generally, many Member State representatives, doctors, and EU officials see real benefits to increased cooperation at the EU level. Clinical practice and scientific research increasingly demonstrate that knowledge obtained from diverse health care systems can yield new information about how best to prevent and treat disease and improve well-being and that this new knowledge can be effectively embedded into local systems. Few would argue, however, that the supra-nationalization of health policy is the best means toward that end. Thus, one challenge of EU health policy is to find a multi-level way to help patients, practitioners, and policy makers learn from the diversity of Europe's political systems.

Second, Europe and the EU are engaged in a delicate balancing act in health policy, attempting to reconcile patients' freedom of movement with the Member States' need and authority to fund, organize, and plan their health care delivery systems. This balancing act, arguably, has been the primary task facing the European Union since its founding. Health policy, then, fits snugly into this "continuity thesis," which argues that EU law, since its founding, has been engaged in an ongoing effort to balance the establishment of a common market with the maintenance of social solidarity.¹³ Recent ECJ cases such as *Kohll v. Union des Caisse de Maladie des Employés Privés* and *Decker v. Caisse de Maladie des Employés Privés* have focused public attention on the need to find this balance in health policy.¹⁴ These cases permitted individual patients to challenge Member States' health care delivery procedures

¹³ Mark Dawson, *The Ambiguity of Social Europe in the Open Method of Coordination*, EUR. L. REV. (forthcoming 2009).

¹⁴ Case C-158/96, *Kohll v. Union des Caisses de Maladie*, 1998 E.C.R. I-1931; Case C-120/95, *Decker v. Caissede Maladie des Employés Privés*, 1998 E.C.R. I-1831.

in the ECJ.¹⁵ The Court found that the Member States' need to plan and organize their health delivery systems did not *automatically* trump a patient's freedom of movement or a provider's freedom to provide services.¹⁶ While the decision was met with trepidation by the Member States, the Court also found that Member States' need to plan and organize their health delivery systems *could* justify a restriction of freedom of movement or freedom to provide services.¹⁷ In other words, a simple Court/Commission expansion account fails to capture the balancing elements of the Court's jurisprudence adequately.¹⁸

Third, again, as is common in many fields of EU policy, this article asserts that networked governance has been and will be important in determining the EU's role in health policy. In the field of health, Europe-wide networks of policy entrepreneurs have long been engaged in generating new ideas about best practices by comparing the performance of each Member State's national health (insurance) system and by embedding that knowledge at the local and national level. In fact, one of the most successful examples of the EU's involvement in health—the fight against cancer—has been the product of such a system. Using funding from the EU's initial foray into health, the Europe Against Cancer (EAC) program, a web of doctors' and patients' organizations has worked to develop a comprehensive program for cancer control. The "Europe Against Cancer" program has been instrumental in the production and dissemination of information about and the implementation of cancer control systems that best reduce the incidence and mortality rates of cancer.

The actors involved in EAC achieved this through the creation of an iterative and reflexive system of networked governance that has been instrumental in guiding the EU's activity in cancer. The creation of this multi-level network has opened up a space in which policy learning can take place, which, in turn, becomes a more effective mechanism for balancing a freer market with con-

¹⁵ See Kohll, 1998 E.C.R. I-1931; Decker, 1998 E.C.R. I-1831.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Dawson, *supra* note 13.

tinued social solidarity. These activities, in the case of cancer, may be contributing to a slight move towards what Maurizio Ferrera describes as “open social citizenship.”¹⁹ His description of one possible route toward that citizenship aptly describes the EAC as the “emergence of inter-regional associations (also promoted and encouraged by specific EU policies), which often include among their objectives the strengthening of cooperation and exchanges in the field of social policy.”²⁰ As such, this article’s portrayal of the EU’s involvement in health policy not only provides a more accurate account, but also suggests a potentially more productive way to move the debate over EU health policy forward.

This new understanding of EU involvement in health highlights important lessons. The EU’s involvement in health is not simply another example of institutional expansionism or a reaction to ECJ decisions. Rather, there were important bottom-up dynamics that shaped EU and Member States’ actions. It is this multi-level network that became the policy community that exists today and that aims to be a central player in guiding and carrying out EU cancer initiatives. Furthermore, networked governance can be quite effective in ensuring real improvements in health care. By modeling future EU health initiatives on this networked governance approach, policy makers could build a decision-making system that incorporates the experience and insight of actors positioned all along the chains of health policy—from doctors and patients in local hospitals to EU-level policy making and regulatory bodies.

The interpretation of the EU’s role in health found in this article shows strong parallels with what has come to be known elsewhere as “new governance:” a means of policy making that stresses flexible and revisable standards, broad participation from all interested parties, the generation of experience-based know-

¹⁹ Maurizio Ferrera, *Towards an ‘Open’ Social Citizenship? The New Boundaries of Welfare in the European Union*, in *EU LAW AND THE WELFARE STATE: IN SEARCH OF SOLIDARITY* 11 (Gráinne de Búrca, ed. 2005); MAURIZIO FERRERA, *THE BOUNDARIES OF WELFARE: EUROPEAN INTEGRATION AND THE NEW SPATIAL POLITICS OF SOCIAL PROTECTION*, ch. 5 (2005).

²⁰ Ferrera, *supra* note 19, at 36; *see also*, Ferrera, *supra* note 19, at 183.

ledge, and the use of social pressure to affect policy change.²¹ While much of the literature on new governance in the EU has come to focus solely upon one specific iteration of new governance, the Open Method of Coordination (OMC),²² this article stresses a broader application. Using the strategic application of relatively modest sums of money, the EU was successful in supporting the establishment of networks that were very effective in generating and disseminating new knowledge about cancer control. A quotation from Dr. Michel Coleman, a key actor in this process, is illustrative:

There is increasing evidence that international survival differences are at least partly attributable to factors that are susceptible to intervention, such as differences in stage at diagnosis, access to optimal treatment, and investment in health care . . . [T]he observation of such differences in cancer survival should stimulate efforts to explain and reduce them.²³

These networks not only create various “soft law” measures, such as codes or guidelines, but also provide advocates with necessary leverage in their efforts to make changes to “hard law.”²⁴

More generally, this multi-level, reflexive system of coordination presents a model of governance that may be best suited to address the gap in governance created recently by the need to respond to the ECJ cases. The solution to that gap, however, must fall within the confines of the boundaries set by the constrained competence of the EU in health policy and the political agreement that supra-nationalized health care is neither a desirable nor feasible solution. Its experimental and pragmatic nature allows for the possibility that the EU and the Member States together can balance economic integration that is an inevitable part of the future of

²¹ Joanne Scott & David M. Trubek, *Mind the Gap: Law and New Approaches to Governance in the European Union*, 8 Eur. L.J. 1, 5-6 (2002).

²² See, e.g., PHILIPPE POCHE ET AL., *THE OPEN METHOD OF CO-ORDINATION IN ACTION: THE EUROPEAN EMPLOYMENT AND SOCIAL INCLUSION STRATEGIES* (Jonathan Zeitlin & Phillippe Pochet eds., 2005).

²³ Michel P. Coleman et al., *EUROCARE-3 Summary: Cancer Survival in Europe at the End of the 20th Century*, 14 (supp. 5) ANNALS OF ONCOLOGY v128, v147 (2003), available at http://annonc.oxfordjournals.org/cgi/reprint/14/suppl_5/v128.

²⁴ The interactions between soft and hard processes raise questions of hybridity. See David M. Trubek & Louise G. Trubek, *New Governance & Legal Regulation: Complementarity, Rivalry, and Transformation*, 13 COLUM. J. EUR. L. 539, 543 (2007).

health care with the long-standing and effective solidarity that is at the core of the “European Social Model.”

III. THE EU AND THE FIGHT AGAINST CANCER

A. THE GENESIS: 1986-2002

One of the most successful ventures by the European Union into public health was the Europe Against Cancer program.²⁵ In 1986, following the explosion at Chernobyl power station, political pressure from influential cancer experts on at least two Heads of State of the larger Member States,²⁶ and the recommendations of an expert committee,²⁷ the Council resolved to establish the EAC.²⁸ The program contained three main elements (1) cancer prevention, (2) information and public awareness, and (3) training.²⁹ This first direct involvement with public health came a full decade before the *Kohll* and *Decker* rulings of the ECJ.³⁰

The first action plan under EAC (1987-1989) was a Commission led and EU-wide information campaign covering: prevention, early screening, and treatment of cancer.³¹ The Commission, in the form of a relatively independent unit headed by Michel Richonnier, a French civil servant,³² coordinated exchanges of information and experience between cancer specialist health professionals

²⁵ The EAC always included a substantial commitment to the anti-smoking campaign. HERVEY & MCHALE, *supra* note 12, at 368-84.

²⁶ Professor Maurice Tubiana persuaded his close friend, President Francois Mitterand of France, and Professor Umberto Varonese influenced Prime Minister Bettino Craxi of Italy. Anna Gilmore & Martin McKee, *Tobacco Control Policy in the European Union*, in UNFILTERED: CONFLICTS OVER TOBACCO POLICY AND PUBLIC HEALTH 219, 224 (Eric A. Feldman & Ronald Bayer eds., 2004).

²⁷ *Id.*

²⁸ Resolution of the Council and the Representatives of the Governments of the Member States, Meeting within the Council of 7 July 1986, on a Programme of Action of the European Communities Against Cancer, 1986 O.J. (C 184) 19, 20.

²⁹ *Id.* HERVEY & MCHALE, *supra* note 12, at 369.

³⁰ Case C-120/95, *Decker v. Caissede Maladie des Employés Privés*, 1998 E.C.R. I-1831; Case C-158/96, *Kohll v. Union des Caisses de Maladie*, 1998 E.C.R. I-1931.

³¹ Council Decision 88/351/EEC, 1988 O.J. (L 160) 52 (EC). The budget for this campaign was a mere 10 million Euros. *Id.*

³² Gilmore & McKee, *supra* note 26, at 225.

across the EU. A high-level expert committee, chaired by Professor Maurice Tubiana, a distinguished French oncologist and friend of President Mitterand (the former President of France), was largely responsible for setting its agenda.³³

The governments of the Member States, acting within the EU's Council of Ministers, then gave a further mandate to EAC to continue its work from 1990-1994.³⁴ This time, the action plan had a much stronger emphasis on the public health dimensions of the fight against cancer, particularly on prevention.³⁵ The Commission funded projects on: the prevention of tobacco consumption (such as prevention strategies targeted at particularly vulnerable groups, e.g., young women); studies into the relationships between diet (including alcohol) and cancer; comparative work on cancer screening programs; developing quality assurance guidelines by European networks on breast, cervical, and colorectal cancer screening; and the continued expansion of a European Network of Cancer Registries.³⁶ In 1992, the cancer unit's relative independence was constrained by its move to within the Commission's Public Health Unit (within Social Affairs Directorate General). The advisory committee's role altered dramatically and its influential chair resigned.³⁷ Scholars have argued persuasively that these changes were a result of pressures from the powerful tobacco industry.³⁸

The EU's third action plan to combat cancer (1996-2000) was established in 1996.³⁹ Its objectives were more ambitious than the first two plans, although its budget was still extremely mod-

³³ *Id.* at 224-26.

³⁴ Council Decision, 90/238/EEC, 1989 O.J. (L 137) 31 (EC).

³⁵ *Id.*

³⁶ Council Decision 90/238, Annex, I (A)-(E). 1989 O.J. (L 346) 1 (EEC), The European Network of Cancer Registries was funded by the European Commission until 2004. *See* Council Decision 646/96, O.J. 1996 (L95) 9 (EC), extended to 31 December 2003 by Council Decision 521/2001, O.J. 2001 (L79) 1 (EC). It is now sponsored by the International Agency for Research on Cancer; Canceropole Lyon Auverge Rhones-Alpes; and the International Association of Cancer Registries. Its secretariat is hosted at the WHO's International Agency for Research on Cancer, Lyon, France. International Agency for Research on Cancer, European Network of Cancer Registries, <http://www.enrc.com.fr/> (last visited Feb. 27, 2009).

³⁷ Gilmore and McKee, *supra* note 26, at 227-228.

³⁸ *Id.* at 229-31.

³⁹ Council Decision 646/96, 1996 O.J. (L 95) 9 (EC).

est.⁴⁰ The aims of the EU were to reduce European mortality and morbidity due to cancer and to promote quality of life, in particular by minimizing the economic and social consequences of cancer.⁴¹ The action plan included: data collection and research, information and health education, early detection and screening, and training and quality control.⁴² Again the public health focus of the plan is evident.

The development of the EAC strategies themselves, at least in the first instance, and, crucially, the strategic use of the funding made available by EAC, was carried out in large part by networks of doctors, not solely by technocrat driven Commission decisions. Coming from the public health/epidemiology tradition, several high profile cancer experts (doctors), such as Professor Peter Boyle, along with others, were interested in gathering and analyzing epidemiological data on cancer rates and treatment success across Europe. Existing networks of oncology specialists, such as the World Health Organization's (WHO) International Agency for Research on Cancer, took advantage of the availability of new sources of funding, albeit modest, to support EU-wide research into the public health dimensions of cancer, along with a supranational platform for its dissemination. Toward that end, the doctors—who seem to be the key drivers of these governance processes—performed four important tasks.

First, they worked hard to gather data about cancer rates and treatment by expanding and improving existing cancer registries, forming the European Network of Cancer Registries (ENCR).⁴³ These registries contained information on cancer incidence, mortality, and prevalence from across Europe and integrated data from countries either not previously included or that theretofore did not have any registries at all.⁴⁴ Just as important, these registries also harmonized the data collected through requirements of form and

⁴⁰ Euro 64 mill, to cover 5 years. *Id.* at 11.

⁴¹ *Id.*

⁴² *Id.*

⁴³ The European Network of Cancer Registries, <http://www.enrc.com.fr/> (last visited July 21, 2008).

⁴⁴ F. Bray et al., *Comprehensive Cancer Monitoring Programme in Europe*, 13 EUR. J. PUB. HEALTH 61, 61 (2003).

type of data collection, producing a body of knowledge that was much more complete and that made cross-national and cross-regional comparisons much easier.⁴⁵

Second, doctors were critical in disseminating the new knowledge that the gathered data produced. Once the information was gathered, the EURO CARE project was set up in 1989 to measure and explain international differences in cancer survival in Europe.⁴⁶ The group then disseminated that information in the form of league tables, which clearly identified substantial international inequities⁴⁷ for the first time.⁴⁸ These league tables, through demonstrating substantial international variation, profoundly affected policymaking in some countries.⁴⁹ In addition, the CaMon Program was established to operate a cancer surveillance system that also disseminates data on cancer incidence and mortality throughout Europe and the world,⁵⁰ which eventually fed into the health monitoring system of the EU's public health program. Dr. Michel Coleman, a key actor in the EAC, wrote:

⁴⁵ Cancer Research UK, *European Cancer Survival-Is Britain the 'Sick Man of Europe'?*, <http://info.cancerresearchuk.org/news/behindtheheadlines/europeancancersurvival/> (last visited Sept. 18, 2008) ("Before the EURO CARE project, people suspected that there were variations between European countries' survival rates, but no one could actually prove it. The published survival statistics among European countries obviously weren't the same, but no one could say for sure whether the differences were because of the quality of treatment or the way the statistics were collected and analyzed.").

⁴⁶ Coleman et al., *supra* note 23, at v128.

⁴⁷ The EU now defines "health inequities" as inequalities in health that are avoidable and unfair. In the United States this is often termed "health disparities." There is a big debate in the EU about the methodology for measuring this, and the EU has funded various projects on the subject, e.g., the European Health Expectancy Monitoring Unit (EHEMU) project, which has developed the "Healthy Life Years indicator" to measure health as a productivity/economic factor; and the European Community Health Indicators (ECHI) project, which provides comparable reports on European health status. See Europa-Public Health, *Health Information-Analysing and Reporting on Health*, http://ec.europa.eu/health/ph_information/reporting/community_en.htm (last visited Sept. 18, 2008).

⁴⁸ Coleman et al., *supra* note 23, at v129.

⁴⁹ See, e.g., UK introduced NHS Cancer Plan in 2000, the first comprehensive national cancer plan in England, which sets out a 10 year strategy to reorganize, standardize and rejuvenate cancer services so that by 2010, the five-year survival rates for cancer would "compare with the best in Europe," DEPARTMENT OF HEALTH, THE NHS CANCER PLAN (2000).

⁵⁰ Bray et al., *supra* note 44, at 61. See also The European Commission Health Monitoring Programme, *CAMON-Comprehensive Cancer Monitoring Programme*, <http://www-dep.iarc.fr/hmp/camon.htm> (last visited Sept. 18, 2008).

The aim of exploring geographic differences in cancer survival is not to establish international league tables, or to excite national rivalries, but to estimate the range of survival rates, and to identify regions or countries in which survival could be improved.⁵¹

Thus while league tables were not seen as the end, those tables and the transparency of the comparative data seem to have been key means to promoting practice and policy changes. As Hildrun Sundseth, head of the EU Policy for the European Cancer Patient Coalition, wrote: “This exposes Member States to naming and shaming. European patient groups such as ours have ensured that our member organizations in the countries can use the data as tools to urge their ministry of health into action.”⁵²

Third, doctors applied the knowledge gained and disseminated above to establish new and higher standards for cancer control. Perhaps the single most important tool was the development of the “European Code Against Cancer,” a collection of recommended protocols on cancer screening, as well as best practices for the prevention and treatment of all cancers.⁵³ Much of the information included in the protocols was obtained directly from the improved cancer registries.⁵⁴ These protocols have become the industry standard in cancer treatment in Europe and are continually updated to reflect new information on cancer control.⁵⁵ As well as

⁵¹ Coleman et al., *supra* note 23, at v146.

⁵² Letter from Hildrun Sundseth, Head of the EU Policy for the European Cancer Patient Coalition, (Feb. 19, 2008) (on file with author).

⁵³ Europe Against Cancer, *European Code Against Cancer and Scientific Justification: Third Version* (2003), <http://www.cancercode.org/code.htm> (last visited Sept. 18, 2008). The Council set out guidelines for best practice in early detection of breast, cervical and colorectal cancers. Various networks then worked on the production of detailed guidelines. For instance, the European guidelines for quality assurance in breast cancer screening and diagnosis are now in their fourth edition. EUROPEAN GUIDELINES FOR QUALITY ASSURANCE IN BREAST CANCER SCREENING AND DIAGNOSIS (N Perry et al. eds., 4th ed. 2006). European Guidelines on Cervical Cancer Screening were supposed to be developed by the European Cervical Cancer Screening Network, but the current diversity between national approaches made it unrealistic to produce a single set of quality assurance standards. See A. Linos et al., *Introduction: cervical cancer screening*, 36 EUR. J. CANCER 2175, 2175-6 (2000). See Fighting Against Cancer Today (FACT) Project, Policy Dialogue 2, *Policy and Programmes for Cancer Screening: Discussion Paper*, Nov. 12-13, 2007, <http://www.projectfact.eu/policy-dialogues/2nd-policy-dialogue/media/pd2.screening.pdf> (last visited Sept. 18, 2008).

⁵⁴ Risto Sankila & J.W. Coebergh, *Cancer Registries Contribute to Quality Improvements in Clinical Care for All European Cancer Patients*, 40 EUR. J. CANCER 635, 635 (2004).

⁵⁵ *Id.*

being used by medical professionals, advocacy groups also rely on the Cancer Code to press national and regional governments to improve standards.⁵⁶ Based on the Code, the networks pushed to establish a benchmark for cancer reduction. Those efforts resulted in the high-level European Committee of Cancer Experts' decision to set a target to reduce cancer mortality by 15 percent by the year 2000.⁵⁷ The benchmark was widely publicized.⁵⁸ One ongoing example is the 2003 Council Recommendation on Cancer Screening, which made recommendations for population based screening for colon, breast, and cervical cancer.⁵⁹ A report on the Member States' implementation is carried out after five years. Again, Sundseth writes: "One of the drivers for action in cancer is that we have Europe-wide data and we can therefore compare."⁶⁰

Finally, these information systems, including the EURO CARE and CaMon Programs, are used to monitor the implementation and effectiveness of cancer control programs in the Member States. Taken together, these three roles played by the networks—standard setting, benchmarking, and monitoring—serve to create an iterative information process whereby the knowledge on effectiveness gained through monitoring via EURO CARE and CaMon is fed back into new iterations of the Cancer Codes and benchmarks, as well as proposals for more traditional regulatory measures, such as EU-level legislation.

⁵⁶ For instance, German women's groups have used the breast cancer screening code to argue for changes in national practices in Germany. Interview with Directorate General of Health and Consumer Affairs cited in Tamara Hervey & Bart Vanhercke, *Healthcare and the EU: The Law and Policy Patchwork*, in HEALTH SYSTEMS GOVERNANCE IN EUROPE: THE ROLE OF EU LAW AND POLICY (Rita Baeten et al. eds., forthcoming). The Board of the Czech Oncological Society has protested that the official figures provided to EURO CARE-4 were seriously deficient, and called for urgent remedial action. See Press Release, Czech Oncological Society, The Board of the Czech Oncological Society Strongly Protests Against the Outcomes of the EURO CARE-4 Study (Aug. 24, 2007), available at <http://www.onconet.cz/obr/File/press-release-2007-08-24.pdf> (last visited Sept. 18, 2008).

⁵⁷ Peter Boyle et al., *Measuring Progress Against Cancer in Europe: Has the 15% Decline Targeted for 2000 Come About?*, 14 ANNALS ONCOLOGY 1312, 1321 (2003). See also European Public Health Alliance, *Europe Against Cancer Programme Saves Lives*, <http://www.eph.org/a/591> (last visited Oct. 1, 2008).

⁵⁸ See Boyle et al., *supra* note 57.

⁵⁹ Council Recommendation No. 878/2003 of 2 Dec. 2003, 2003 O.J. (L 327) 34 (EC).

⁶⁰ Sundseth, *supra* note 52.

The effective building of this cancer network provides an important lesson about networked governance more generally. Cooperation towards achieving shared interests is at the core of effective networked governance. In this instance, cooperation between the Commission and Member States was not only critical, but also enhanced by the impetus for better cancer control policy created by the EAC and doctors networks. The valuable comparative data gained through the European Cancer Registries Network, for example, relied on registries that in some cases already existed at the national level. In others, the EAC helped create those registries, as we have noted. In all cases, however, the national registries were improved by placing them within a more comparative context. Importantly, relevant national actors accepted the sometimes embarrassing results generated by the league tables, which was essential to the effectiveness of the information. They seemed aware of the potential gain that such information represented. In other governance networks in the EU, there has been more resistance within Member States to such “naming and shaming.”⁶¹

This acceptance of potentially negative publicity likely stemmed from the fact that the EU has made it clear that its role is not to supplant Member States’ initiatives, but to contribute to an EU-level value added: by facilitating cooperation and information exchange, the EU can raise the aspiration and hopefully the performance of Member States’ cancer control initiatives.⁶² This is particularly the case for the preventative, public health elements of the EAC policy outcomes, where national policy changes do not

⁶¹ David M. Trubek & James S. Mosher, *New Governance, Employment Policy, and the European Social Model*, in *GOVERNING WORK AND WELFARE IN A NEW ECONOMY* 33, 39 (Jonathan Zeitlin & David M. Trubek eds., 2003).

⁶² This might be considered a prime example of the EU’s system of multi-level governance. See Liesbet Hooge & Gary Marks, *Types of Multi-Level Governance*, 5 *EUR. INTEGRATION ONLINE PAPERS* 1, 5 (2001), <http://www.eiop.or.at/eiop/texte/2001-011.pdf>. See Mike Richards, *Does the UK Really Have an Effective Cancer Plan?*, 8 *LANCET ONCOLOGY* 747, 747 (2007) (displaying the example of the response from the UK professional and patient communities to the publication of EURO-CARE-4). See Cancer Research UK, *European Cancer Survival- Is Britain the ‘Sick Man of Europe’?*, *supra* note 42. See also *5 Year Survival. What EURO-CARE-4 Really Tells Us. A Tug in the Right Direction.*, <http://www.canceractive.com/page.php?n=1845> (last visited Oct. 1, 2008) (drawing attention to the similarity between cancer survival in the UK as a whole and in some Eastern European countries that spend less than one third of the UK’s per capita health budget).

have a direct impact on individual cancer patients, as they aim to reduce the incidence of cancer in the first place. From a governance perspective, however, it is important to note that there is a less cooperative side. The wider access to more comparative data regarding cancer rates has provided individual patients additional leverage vis-à-vis Member States' health systems, making them "increasingly likely to demand, and pay for, cutting edge drugs that the health service considers too expensive to be cost-effective."⁶³ Counterfactually, with those political and budgetary costs in mind, it seems likely that Member States would have been unwilling to shoulder the costs of these initiatives had they not been incorporated in a cooperative manner into the process.

Furthermore, as a result of this cooperative system, significant impact could be achieved without funding expensive, invasive, and unwanted monitoring mechanisms and without extended legal and political battles about competence. As a result, the funding necessary to make the above gains in the fight against cancer were minimal. From 1987-2002, the EU contributed roughly €150 million in total through the "Europe Against Cancer" initiative. In addition, the network that was built with this funding was successful in obtaining additional funding through the EU's competitive Framework Programs for Research (FPs).⁶⁴ The EU's FP funds aim to support cross-EU networks of expertise, so the availability of FP funding itself encouraged the formation of new cross-national networks. Some of the projects specifically aimed to coordinate national activities.⁶⁵ All of these funds, of course, were

⁶³ Sarah Lyall, *Those Who Pay for Private Healthcare Are Testing Britain's Public Health System*, N.Y. TIMES, Feb. 21, 2008, at A12.

⁶⁴ For example, under FP5's (1998-2002) 'Thematic Programme' on 'Quality of Life and Management of Living Resources', cancer-related projects on diet and breast cancer in young women; on alcohol and cancer; on prostate cancer (two) and on ultrasound in cancer treatment were funded. FP6's (2002-2006) 'Thematic area' on Life sciences, genomics and biotechnology for health' funded some 65 cancer research projects, *see generally* CORDIS: FP6: Life Sciences, Genomics and Biotechnology for Health: Combating Cancer, <http://cordis.europa.eu/lifescihealth/cancer/cancer-pro-calls.htm> (last visited Sept. 16, 2008).

⁶⁵ For instance, the 'EUROCAN+PLUS' project, project no LSCC-CT-2005-015197, which aimed to identify areas where cancer research across the EU is wasteful and duplicative, and where therefore economies of scale could be exploited by a more cost-efficient closer cooperation between national cancer research activities. EUROCAN+PLUS, FEASIBILITY STUDY FOR COORDINATION OF NATIONAL CANCER RESEARCH ACTIVITIES: SUMMARY REPORT OF THE EUROCAN+PLUS PROJECT iii (2008).

above and beyond the continuing funding that Member States contributed to their own national initiatives, as well as private/charitable funding available for cancer research. The EU funding was insignificant when compared to Member State funding. A survey of non-commercial sources of cancer research found the following:

In our survey, we identified 139 noncommercial funding organizations that collectively spent €1.43 billion on cancer research for the year spanning 2002–2003. Absolute spending in 2002–2003 on cancer research varied widely across the EU, ranging from €388 million in the United Kingdom to €0 in Malta, with three countries spending greater than €100 million, nine greater than €10 million, and ten less than €1 million. Of all the countries in the survey, only Bulgaria failed to report their spending, and only Malta spent nothing on cancer research in 2002–2003.⁶⁶

Even though the funds made available by the EU were relatively insignificant, they may have played an important role in determining the parameters of the EAC network. Because most of the funding was directed towards cross-border collaborative activities, and because the chances of successfully attracting funds were increased by having greater numbers of partners in a particular project, the EU funding may, to some extent, have smoothed out disparities in resources between the different actors within the network. In particular, doctors in Central and Eastern European states⁶⁷ may have been enabled to act within the network on a greater level of parity with those from Member States whose health care systems enjoyed more resources than would otherwise have been the case. So, while participatory forms of governance, whether new governance or democratic decision making more generally, can often be critiqued for the inequities in participation of less powerful groups, the funding of the EAC had the effect of bringing to the table groups that theretofore had been outweighed

⁶⁶ Seth Eckhouse & Richard Sullivan, *A Survey of Public Funding of Cancer Research in the European Union*, 3(7) PUB. LIBR. SCI. MED. 994, 995 (2006), http://medicine.plosjournals.org/archive/1549-1676/3/7/pdf/10.1371_journal.pmed.0030267-L.pdf.

⁶⁷ These countries include, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia. At the time these countries were still candidate member states.

politically. More entrenched interests have often been a drag on the use of the classic community method in the fight against cancer.⁶⁸

The programs funded by the EU have the potential to raise the costs of health care that must be paid by the Member States. The activity of both the ECJ, in demanding, for example, justification of lengthy wait times, and the Commission, in encouraging the EU-wide reproduction of best practices, may lead to higher costs of Member State health systems.⁶⁹ However, in assessing costs, we must also take into account the lowered long-term costs associated with more comprehensive preventive health care and the public health/prevention focus of EAC. For example, the EU's efforts to improve screening for colorectal cancer have been shown to reduce not only illness and mortality, but also the costs associated with the treatment of that illness.⁷⁰

The EAC was, by most accounts, successful. Most importantly, analysts have noted that the number of cancer deaths in Europe, compared to the number expected, was reduced by 10 percent by 2000.⁷¹ As Peter Boyle wrote: "Although the target of a 15 percent reduction was not met, the effects of the program should by no means be viewed as a failure."⁷² He attributed the success of the program to EACs' emphasis on prevention in all cancer control activities and creating "an environment within the member states . . . where cancer control activities could flourish."⁷³ Other research has also noted that, in addition to reducing the rate of cancer deaths, EAC has also made improvement in areas such as developing standardized protocols for the treatment of certain cancers.⁷⁴

⁶⁸ See HERVEY & MCHALE, *supra* note 12, at 384.

⁶⁹ We thank Rita Baeten for pointing out this important consideration.

⁷⁰ German E. U. Presidency and the Union Internationale Contre le Cancer (UICC), Conference Power Point at European Conference on Colon Cancer Prevention in Europe-Status Quo and Perspectives (May 9, 2007) (on file with author).

⁷¹ Boyle et al., *supra* note 57 at 1322.

⁷² *Id.*

⁷³ *Id.* See also "Europe Winning Cancer Battle", BBC NEWS, July 28, 2003, <http://news.bbc.co.uk/2/hi/health/3104103.stm> (last visited Sept. 16, 2008).

⁷⁴ *Leukemia Diagnostics: Standardized Protocols for RQ-PCR Residual Disease Analysis Developed*, MED. DEVICES & SURGICAL TECH. WEEK, Apr. 25, 2004, at 108.

Second, the knowledge about cancer control gained from these networks has allowed the networks to advocate successfully for policy change. For example, the proposal for a European Directive on Tobacco Advertising⁷⁵ emerged from the European Experts Cancer Committee, established by the EAC, and it was the Committee's report that led to the broader ranging Tobacco Directive adopted by the European Parliament and Council in 2001.⁷⁶ Additionally, based on the inequities highlighted by the more comparable cancer registries, the Commission called on the Advisory Committees on Medical Training, Training in Nursing, and Training of Dental Practitioners⁷⁷ to review the ways in which the subject of cancer was being taught to their respective professions and to make recommendations for improvements in such training. As a result, all three Committees found continuing education, based on current scientific knowledge, to be lacking and changes were made to national training practices.⁷⁸

Third, this new cancer data highlighted the link between tobacco and cancer and in so doing generated new political will to mount a concerted campaign against tobacco. The EU's anti-tobacco stance has formed an explicit part of its cancer programs. For example, according to the preamble of Decision 88/351/EEC,⁷⁹ which established the cancer information campaign, the "fight against cancer," includes "the fight against tobacco."⁸⁰ The EU has been hampered in its ability to adopt tobacco control regulations by its limited competence in the sphere of health and by powerful ac-

⁷⁵ Council Directive 2003/33, 2003 O.J. (L 152) 16 (EC). The original Directive, Council Directive 98/43 1998 OJ (L 213) 9 (EC), was annulled by the European Court of Justice in litigation brought by the German Government. *See* Case C-376/98, Federal Republic of Germany v. Council, 2000 E.C.R. I-8419. Grüning, Gilmore and McKee have argued that the influence of the tobacco industry on scientists and thus on policy advisors and public opinion in Germany is much greater than in other EU MS, T. Grüning, A. Gilmore & M. McKee, *Tobacco Industry Influence on Science and Scientists in Germany*, 96 AMERICAN JOURNAL OF PUBLIC HEALTH 20, 20 (January 2006).

⁷⁶ Council Directive 2001/37, 2001 O.J. (L 194) 26 (EC); Boyle et. al, *supra* 57, at 1321.

⁷⁷ An EU committee consisting of experts from the Member States, which advised on the standards of medical training in the Member States. It was disbanded in 1999. *See* HERVEY AND MCHALE, *supra* note 12, at 208-209.

⁷⁸ *Id.* at 370.

⁷⁹ Council Directive 88/351, 1988 O.J. (L 160) 52 (EEC).

⁸⁰ HERVEY & MCHALE, *supra* note 12, at 369.

tors such as national governments and the tobacco industry, which often use litigation before the ECJ to challenge measures that are adopted. Gilmore and McKee have argued that lobbying from the tobacco industry, via national administrations, has also impeded the promotion of anti-tobacco legislation at EU level.⁸¹ However, in spite of this, between 1989 and 1992, seven directives and one non-binding resolution on tobacco were adopted.⁸² These measures represented a considerable improvement compared to what had existed in some countries, such as the Netherlands and Greece, where there had been almost no tobacco-control legislation.⁸³ Elsewhere, as in the United Kingdom (UK), legislation supplanted ineffective voluntary agreements.⁸⁴ These examples demonstrate that the knowledge and information about cancer control that these networks yielded were important in shaping the “hard law” promulgated by the EU.

Fourth, the knowledge produced by the European cancer network shifted the focus of the fight against cancer. Previously, most work had focused on treatment, particularly on the research and development of new treatment drugs. This new body of knowledge, in contrast, stressed the need for greater efforts regarding prevention and the need for a public health based program, in addition to drug research and development.⁸⁵

⁸¹ Gilmore & McKee, *supra* note 24, at 230.

⁸² On the Tobacco regulation, *see*: Tobacco Labelling Directives (& Smokeless tobacco) Council Directive 89/662, 1989 O.J. (L 359) 1 (EEC) and 92/41, 1992 O.J. (L 158) 30 (EEC); the Tar Yield Directive, Council Directive 90/239, 1990 O.J. (L 137) 36 (EEC); the Tobacco Products Directive, Council Directive 2001/37, 2001 O.J. (L 194) 26 (EC), which replaces Council Directive 89/622, 1989 O.J. (L 395) (EEC), Council Directive 92/41, 1992 O.J. (L 158) 30 (EEC) and Council Directive 90/239, 1990 O.J. (L 137) 36 (EEC); the Tobacco Tax Directives, Council Directive 92/78, 1992 O.J. (L 136) 5 (EEC); Council Directive 92/79, 1992 O.J. (L 136) (EEC); Council Directive 92/80, 1992 O.J. (L136) (EEC); Council Directive 95/59, 1995 O.J. (L 291) 40 (EC); Council Directive 99/81, 1999 O.J. (L 211) 47 (EC); Council Directive 2002/12, 2002 O.J. (L 46) 26 (EC); the Television Broadcasting Directive, Council Directive 89/552, 1989 O.J. (L 298) 23 (EEC) (Amendments made by Council Directive 97/36, 1997 O.J. (L 202) 60 (EC) and Council Directive 2007/65, 2002 O.J. (L 332) 27 (EC) in response to new technology); and the Tobacco advertising and sponsorship Directive, Council Directive 98/43, 1998 O.J. (L 213) 9 (EC), annulled October 2000, and replaced by Council Directive 2003/33, 2003 O.J. (L 152) 16 (2003). *See* GILMORE & MCKEE, *supra* note 24, at 227.

⁸³ GILMORE & MCKEE, *supra* note 26, at 227.

⁸⁴ *Id.*

⁸⁵ Boyle et al., *supra* note 53. Examples of EU-wide data being used to call for public health approaches to cancer (prevention rather than cure-focused) include F. Bray et al., *Estimates of can-*

Fifth, EAC brought together the various actors involved in cancer policy, including patients, doctors, and politicians, among others, to form a network that would include experts on the myriad aspects of cancer control: prevention, screening, treatment, and education of providers and patients. Across Europe, national patient groups formed which focused on specific cancers and provided a basis upon which a Europe-wide cancer patient network would later be built.

B. A LOSS OF MOMENTUM: 2002-2007

Beginning in 2002, despite the progress made in the fight against cancer since the late 1980s, cancer's relatively high priority began to wane. In 2002, EU funding specifically for the EAC ended.⁸⁶ Instead, the EAC was subsumed, along with seven other health programs, into a broader public health initiative as part of the EU's 2003-2008 public health program.⁸⁷ As further evidence of its low priority, EU funding for many of the cancer related programs discussed above was also cut off. In 2004, the European Commission Public Health Directorate did not renew funding for the European Prospective Investigation into Cancer and Nutrition (EPIC), the European Network of Cancer Registries (ENCR), the European Breast Cancer Network (EBCN), and the European Concerted Action on Survival and Care of Cancer Patients (EUROCARE) study.⁸⁸ The Directorate stated that its hands were

cer incidence and mortality in Europe in 1995, 38 EUR. J. OF CANCER 99 (2002); PETER BOYLE ET AL., *Tobacco: Public Health Disaster of the Twentieth Century* (Oxford University Press 2002); M. Quinn et al., *Cancer Mortality Trends in EU and Acceding Countries*, 14 ANNALS OF ONCOLOGY 1148 (2003); F. Levi et al., *Monitoring Falls in Gastric Cancer Mortality in Europe*, 15 ANNALS OF ONCOLOGY 338 (2004); P. Boyle, *Cancer of the Skin: A Forgotten Problem in Europe*, 15 ANNALS OF ONCOLOGY 5 (2004); P. Boyle et al., *Cancer Incidence and Mortality in Europe, 2004*, 16 ANNALS OF ONCOLOGY 481 (2005); J. Ferlay et al., *Estimates of the Cancer Incidence and Mortality in Europe in 2006*, 18 ANNALS OF ONCOLOGY 581, 581 (2007); Fabio Levi et al., *Urological Oncology: The Changing Pattern of Kidney Cancer Incidence and Mortality in Europe*, 101 BRITISH J. OF UROLOGY 949, 949 (2008).

⁸⁶ Council Decision 96/646, 1996 O.J. (L 95) 9 (EC).

⁸⁷ Council Decision 2002/1786, 2002 O.J. (L 271) 1 (EC).

⁸⁸ John Illman, *Funding Cuts for Public Health Projects in Europe May Affect International Cancer Effort*, 96 J. OF THE NAT'L CANCER INST. 428, 428 (2004).

somewhat tied by legislation authorizing the distribution of funding; other issues were given higher priority.⁸⁹

Somewhat counter intuitively, this diminished role was, in part, the result of an expanded role for the EU in health. In 1999, the Treaty of Amsterdam came into force, which included a larger, although still very vague, role for the EU in promoting health.⁹⁰ The biggest decisions that were taken were to “mainstream” health into all issue areas and to give the EU competence for health promotion as well as protection.⁹¹ Then EU Health Commissioner David Byrne argued that cancer had been given massive support over the previous fifteen years and that it was now able to continue on its own.⁹² By shifting funding priorities to other diseases, the Commission sought to apply the model of cancer to “areas where the situation was at a critical embryonic stage, like cardiovascular disease, diabetes, and mental health.”⁹³ Furthermore, the Commission felt that Member States could underwrite these EU-wide organizations and networks.⁹⁴

Interestingly, this argument was rejected by the Member States as well as by the networks and agencies. Since the EAC network was so strong and Europe-wide and (most likely because) the data collection for the cancer registries had been standardized,⁹⁵ the fight against cancer had been effectively Europeanized and individual states no longer felt it imperative to control the parameters of nor take responsibility for the maintenance of registries and research. It appears certain that one critical factor in Member States’ failure to take up the slack was funding. Member States likely preferred the EU to continue to fund network activities. As discussed above, however, the funding required for the maintenance of the

⁸⁹ *Id.*

⁹⁰ Treaty of Amsterdam Amending the Treaty on European Union, Oct. 2, 2007, www.europarl.europa.eu/topics/treaty/pdf/amst-en.pdf (reproduction of original text).

⁹¹ Tamara K. Hervey, *Community and National Competence in Health after Tobacco Advertising*, 38 COMMON MKT. L. REV. 1421, 1423-27 (2001); HERVEY AND MCHALE, *supra* note 12, at 76-81.

⁹² See Illman, *supra* note 88, at 428.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Tamara K. Hervey, *The European Union and the Governance of Health Care*, in LAW AND NEW GOVERNANCE IN THE EU AND THE U.S. (Gráinne de Búrca and Joanna Scott eds., 2006).

network was minimal, especially when compared to the benefits gained.⁹⁶ Thus, it seems that Member States were unwilling to provide the necessary funding because the European aspect, which had proven to be so valuable, would be diminished by a return to Member State level funding and organization. This understanding highlights, in particular, the multi-level nature of the networks surrounding cancer.

C. A REGENESIS: 2007 TO THE PRESENT

One of the most interesting points in the history of the EU's fight against cancer is its revival. A number of reinforcing factors have recently come together to push cancer back to a higher political priority.

Not to be underestimated is the considerably higher priority currently being granted to health policy within EU circles. As the authors of this paper, along with other scholars have pointed out, this rise in interest is due in no small part to decisions by the ECJ that some see as threatening to Member States' health systems.⁹⁷ The controversy surrounding cases such as *Kohll* and *Decker* have served to highlight the impact that EU laws inevitably have on Member States' health systems. While these cases are often interpreted as ECJ activism, it should not be forgotten that these cases were brought originally by patients seeking redress for what they considered to be insufficient health care.⁹⁸ Mark Flear refers to the resulting body of rights that these cases have developed as "Euro-

⁹⁶ See generally BOYLE, *supra* note 57 (article describes the positive outcomes associated with the Europe Against Cancer program, an example of a network). See generally European Public Health Alliance, *supra* note 57.

⁹⁷ Hervey, *supra* note 95.; See, e.g., HERVEY AND MCHALE, *supra* note 12, at 379.; See Tamara Hervey and Louise Trubek, *Freedom to Provide Health Care Services within the EU: An Opportunity for Hybrid Governance*, 13 (3) COLUM. J. EUR. L. 623 (2007); See generally IRÈNE GLINOS & RITA BAETEN, A LITERATURE REVIEW OF CROSS-BORDER PATIENT MOBILITY IN THE EUROPEAN UNION (2006) (significant literature regarding cross-border patient mobility, an issue addressed by the European Court of Justice), http://www.ose.be/files/health/WP12_lit_review_final.pdf.

⁹⁸ Case C-158/96, *Kohll v. Union des Caisses de Maladie*, 1998 E.C.R. I-1931 at ¶¶2-3; Case C-120/95, *Decker v. Caissede Maladie des Employés Privés*, 1998 E.C.R. I-1831.

pean biocitizenship.”⁹⁹ Furthermore, this EU-level activity dovetails with a broader “patients’ rights movement” found in various EU Member States.¹⁰⁰ Some Member States have adopted patients’ rights legislation; others have patients’ rights embedded in constitutional documents.¹⁰¹ The EU’s own fundamental rights document, the EU Charter of Fundamental Rights, which will become a binding part of EU law if the Lisbon Treaty is ratified, includes a number of provisions relevant to patients’ rights, such as human dignity, the right to life, integrity of the person, privacy rights, and the right to health care.¹⁰² The EU health policy space, it seems, is being pried open from all angles.

Regarding the fight against cancer in particular, perhaps the single most important factor was the accession of new Member States and the enlargement of the European Union in 2005. This was important in several ways. The crumbling condition of new Central and Eastern European Member States’ health care systems required immediate attention and funding from the EU¹⁰³ and other funding sources.¹⁰⁴ The EU contributed funding and expertise, as well as the legal context provided by the *aquis communautaire*, the body of EU law with which new Member States must comply before accession. As a result, EU programs are now seen as essential parts of national health systems.¹⁰⁵ The ECJ, or perhaps the threat

⁹⁹ Mark Flear, *Together for Health? How EU Governance of Health Undermines Active Biological Citizenship*, (forthcoming 2008).

¹⁰⁰ See, e.g., Herman Nys et al., Patient Rights in EU Member States after the Ratification of the Convention on Human Rights and Biomedicine, 83 (2-3) HEALTH POL’Y 223 (2007).

¹⁰¹ Such as Belgium, Finland, Hungary, Italy, Luxembourg, the Netherlands, Portugal, and Spain. Tamara K. Hervey, *The ‘Right to Health’ in European Union Law*, ECONOMIC AND SOCIAL RIGHTS UNDER THE EU CHARTER OF FUNDAMENTAL RIGHTS 193, 198 (Tamara K. Hervey and Jeff Kenner eds., 2003).

¹⁰² See J McHale, *Fundamental Rights and Health Care*, in HEALTH SYSTEMS GOVERNANCE IN EUROPE: THE ROLE OF EU LAW AND POLICY ((E. Mossialos, R. Baeten, G. Permanand, and T. Hervey, eds., forthcoming 2009); HERVEY, *supra* note 101, at 193-97, 200.

¹⁰³ In addition to the public health programme funding, and FP6/7 funding, the European Union’s Structural Funds, the European Regional Development Fund and European Social Fund, have been used in the healthcare sector. See Hervey and Vanhercke, *supra* note 52.

¹⁰⁴ The World Bank and the World Health Organization were very active in the reform of healthcare in the accession countries.

¹⁰⁵ This network building made the transition for accession easier. Note that this is one of the claimed advantages of networked governance—ability to adapt to change. See Jonathan Zeitlin & Charles Sabel, *Learning from Difference: The New Architecture of Experimentalist Governance in the European Union*, 14 (3) EUR. L.J. 271, 272-76 (2008).

of the ECJ, also played a very important role. Old Member States were concerned that the ECJ, based on the basic freedom of movement guaranteed in the Treaties, would give citizens from the accession countries access to the old Member States' health care systems.¹⁰⁶ The old Member States feared this influx would swamp their already overstretched health care systems.¹⁰⁷

Additionally, early on, the EAC provided extensive data on the comparatively low quality of the accession countries' health care systems through the league tables. All five Central and Eastern European countries included in the 2004 enlargement were already participating in EURO CARE.¹⁰⁸ The league table on "all-cancers survival index" indicated that the all-cancers survival rates in 1999 were lowest in the enlargement states of Slovenia, the Czech Republic, Slovakia, Estonia, and Poland.¹⁰⁹ The documented differences, both at the stage of diagnosis and the availability of and access to resources to fight cancer, represented a benchmark for reduction in inequalities in cancer survival.¹¹⁰ Cancer survivor trends reflect a substantial and increasing gap in the overall prognosis of cancer between Eastern and Western Europe. Thirdly, experience from previous enlargements, in particular the 1995 accessions of Finland and Sweden, showed that accession to the EU, and in particular the impact of internal market law, is not neutral in public health terms.¹¹¹ Shifts in the EU's external bor-

¹⁰⁶ HERVEY AND MCHALE, *supra* note 12, at 417-18.

¹⁰⁷ *Id.* at 418.

¹⁰⁸ Dr. Michel Coleman, Professor of Epidemiology and Vital Statistics, Non-communicable Disease Epidemiology Unit, London School of Hygiene and Tropical Medicine, Differences in Survival Between Rich and Poor: Can the "War on Cancer" be Won?, Address at Workshop on Public Health in the European Union: "'War on Cancer' and Accountability for Outcomes: A Transatlantic Dialogue on How and Why of Success" (Apr. 16, 2007), <http://eucenter.wisc.edu/Conferences/HealthApr07.htm> (last visited Sept. 25, 2008).

¹⁰⁹ *Id.* See also M. Sant et al., *Cancer Survival increases in Europe, but international differences remain wide*, 37 EUROPEAN JOURNAL OF CANCER (ISSUE 13) 1659 (2001), available at www.sciencedirect.com (search "journal/book title" for "European Journal of Cancer"; then follow top result hyperlink; then follow Volume 37 (2001) hyperlink; then follow Volume 37, Issue 13 pp. 1581-1727 (September 2001) hyperlink; then open PDF from result 14) (last visited Sept. 25, 2008). They conclude that "inequality of access to adequate healthcare facilities is likely to be a major cause of the wide differences in cancer survival in Europe." *Id.* at 1665.

¹¹⁰ Coleman, *supra* note 23.

¹¹¹ Anna Gilmore et al., *Free Trade Versus the Protection of Health: the Examples of Alcohol and Tobacco*, in HEALTH POLICY AND EUROPEAN UNION ENLARGEMENT 198, 212-18 (Martin McKee, Laura MacLehose, & Ellen Nolte eds., 2004), available at

ders, the widening of price differentials within the EU, and increased competition within the internal market tend to stimulate bootlegging and smuggling of products such as alcohol, and more importantly for our purposes here, tobacco, which is of course largely treated as a product like any other within the EU's legal regime, rather than as a major threat to public health. New Member States with more comprehensive tobacco control legislation (such as Poland) faced the difficulty of defending higher national standards than the existing EU norms, in the context of internal market law.¹¹² This increased the political impetus for ratcheting up of norms at the EU level—particularly where national policies have been shown to be effective by the comparative data provided by the networks, such as in the case of Poland's tobacco advertising laws.¹¹³

The second crucial factor in the resurgence of the fight against cancer was the political activism of some Members of Parliament. In March 2006, forty-four Members of the European Parliament announced the formation of the "MEPs against Cancer" (MAC).¹¹⁴ The mission of the group was to "promote action on cancer as an EU priority and harnessing European health policy to

<http://www.euro.who.int/document/e82999.pdf>; Anna Gilmore & Witold Zatonski, *Free Trade v. the Protection of Health: How Will EU Accession Influence Tobacco Control in Poland?*, 8 EUROHEALTH (4) (SPECIAL ISSUE) 31, 31 (2002), available at <http://www.lse.ac.uk/collections/LSEHealth/pdf/eurohealth/vol8no4.pdf>.

¹¹² Internal market law is the provision of the Treaty of Rome on free movement of the factors of production and the body of secondary legislation supporting those provisions. Treaty Establishing the European Community E/52, art. 28, 2006 O.J. (C321), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:321E:0001:0331:EN:PDF>.

¹¹³ Polish laws adopted in 1995 and 1999 involve a comprehensive ban on tobacco advertising, including through radio, TV, cinema, and print, indirect advertising, and sponsorship. They also outlawed the production and sale of smokeless tobacco, sales to minors, vending machines, and prohibited smoking in schools, health care facilities and enclosed workplaces. Health warnings were required to cover 30% of the packaging, which was the largest proportion required anywhere in the world at the time. Through the 1990s, male smoking rates in Poland fell from around 60% to around 40% and female smoking rates fell from 30% to 20%. Life expectancy rose by about four years in men and three years in women after a 30-year period of stagnation. The steady increase in lung cancer mortality since the 1940s ceased. See Gilmore et al., *supra* note 107.

¹¹⁴ The group now has over sixty members, see http://www.mepsagaincancer.org/index.php?option=com_frontpage&Itemid=1 (last visited Sept. 26, 2008).

that end.”¹¹⁵ The press release went on to state “the present health inequalities across the EU twenty-five are unacceptable.” One of the founding members was an MEP from Slovenia, Alojz Peterle.¹¹⁶ In addition, the fact that the league tables had shown significant variation among the original members of the EU, including very low rates for England, Scotland, and Wales, served as the an impetus for a large number of MEPs from those regions to join MAC.¹¹⁷ This Parliamentary support represented a substantial increase in the political resources available to the cancer network. Interestingly, the MAC pointed to a singular success in EU health policy: “Europe Against Cancer,” initiated in 1986.¹¹⁸

The third factor in the resurgence of the EU fight against cancer was the involvement of the activist patient in the European sphere. Within the Member States, patients became important players in cancer control, both in managing individual delivery and in shaping public debates about cancer policy. A recent dramatic example is the debate in the United Kingdom over disparities in payment and, therefore, treatment systems within the UK.¹¹⁹ Patients, activated by information gained from activist networks and the internet, are working the system in order to obtain the most advanced treatment that they may be denied by the National Institute of Health. Doctors also play a major role in battles over access to and payment for cancer treatment. This, of course, is a microcosm of the larger debate now being played out at the European level regarding access to and payment for cross-border health services.

¹¹⁵ Press Release, MEPs Against Cancer, All Europeans are equal, until they have cancer (March 22, 2006) (on file with authors).

¹¹⁶ MEPs Against Cancer, Alojz Peterle, http://www.mepsagaincancer.org/index.php?option=com_content&task=view&id=35&Itemid=1 (last visited Sept. 19, 2008).

¹¹⁷ Around one third of the members of the caucus as at September 2008 are from the UK. MEPs Against Cancer, http://www.mepsagaincancer.org/index.php?option=com_content&task=view&id=14&Itemid=30 (last visited Sept. 19, 2008).

¹¹⁸ MEPs Against Cancer, MEPs Against Cancer – Statement, http://www.mepsagaincancer.org/index.php?option=com_content&task=view&id=18&Itemid=32.

¹¹⁹ See, e.g., Jonathan Waxman, *We Need Cancer Drugs. NICE Must Go*, THE TIMES ONLINE, August 8, 2008, available at http://www.timesonline.co.uk/tol/comment/columnists/guest_contributors/article4481345.ece (last visited Sept. 26, 2008).

Taken together, these two examples show how activist patients at the local level have been successful in tying domestic health care debates to larger worlds of health policy and treatment.

The activist patient in the cancer sphere took on a truly European dimension with the founding of the European Cancer Patients Coalition (ECPC), which aims to be the voice for all cancer patient groups in Europe.¹²⁰ Founded in 2003, the ECPC was organized in direct response to the cutting of funds discussed above and now plays a number of important roles in the EU fight against cancer. ECPC is a partner in projects producing some of the guidelines discussed above, such as the quality assurance guidelines for colorectal screening, to be developed by 2009.¹²¹ It has campaigned for the revision of EU-level legislation on pharmaceuticals.¹²² Most importantly, the ECPC has worked closely with the 2008 Slovenian presidency of the EU to put cancer back on the list of EU priorities.¹²³ It also serves as the secretariat for the MEPs Against Cancer caucus. The result, according to those involved, has been a “win-win situation.”¹²⁴ When ECPC was founded, cancer had become a low priority in Europe. In fact, it was in response to this low priority that ECPC was founded.¹²⁵ But because “no policy maker wanted to hear about cancer,” ECPC turned to the European Parliament, whose members in turn saw this as an opportunity to

¹²⁰ European Cancer Patient Coalition, About ECPC, <http://www.cancerworld.org> (follow “European Cancer Patient Coalition–ECPC” hyperlink; then follow “About ECPC” hyperlink). President is Lynn Faulds Wood, broadcaster and bowel cancer campaigner.

¹²¹ Press Release, Europa, Commission publishes new EU Guidelines on Breast Cancer Screening and Diagnosis (April 7, 2006) (on file with authors).

¹²² For instance, the recent Regulation on advanced therapy medicinal products applying EU level safety standards to products and treatments from new technologies such as gene-therapy, cell-therapy and tissue engineering. See generally Council Regulation 1394/2007, 2007 O.J. (L324) 121 (EC).

¹²³ E-mail from Hildrun Sundseth, Head of EU Policy, European Cancer Patients Coalition, to Louise G. Trubek, Clinical Professor of Law Emerita: Faculty Affiliate LaFollette School of Public Affairs, University of Wisconsin Law School (Feb. 9, 2008, 03:57 CST) (on file with authors).

¹²⁴ E-mail from Hildrun Sundseth, Head of EU Policy, European Cancer Patients Coalition, to Louise G. Trubek, Clinical Professor of Law Emerita: Faculty Affiliate LaFollette School of Public Affairs, University of Wisconsin Law School (Feb. 19, 2008, 12:26 CST) (on file with authors).

¹²⁵ *Id.*

make a much needed connection with their constituents.¹²⁶ The result of these efforts has been an ongoing cooperation, where the ECPC serves as an informational router between the EU and Member States' citizens, while MAC is able to ensure necessary funding from the research budget. Together they are arguably the driving force in health policy and budget allocation.

Fourth, using their new, if temporary, power as agenda setter, the Slovenian delegation to the EU used its presidency in the first half of 2008 to place cancer high on the EU priority list once again.¹²⁷ Additionally, they worked hard to reinvigorate and refocus the network so that it could remain a primary player in the development of cancer control policy in the EU. For example, the Slovenian delegation organized numerous meetings and conferences that brought together the myriad of actors that have been identified in this article to plan the way forward on the issue of cancer in the EU. The Slovenian presidency also established a secretariat to coordinate the activity. The Fight Against Cancer Today (FACT) project is being run jointly by Slovenia's Institute of Public Health, the London School of Hygiene and Tropical Medicine, the Institute of Oncology in Slovenia, and the European Observatory on Health Systems and Policies.¹²⁸ The presidency also sponsored a high-level conference, bringing together over two hundred senior decision makers representing the twenty-seven Member States, the European Commission, European Parliament, and cancer experts from the EU and non-governmental organizations.¹²⁹ The conference discussion was supported by the latest EURO CARE report,¹³⁰ which, among other things, calls for a Eu-

¹²⁶ *Id.*

¹²⁷ See Slovenian Presidency Programme, SI.nergy for Europe, January-June 2008, available at http://www.eu2008.si/includes/Downloads/misc/program/Programme_en.pdf.

¹²⁸ Fighting Against Cancer Today, <http://www.projectfact.eu> (last visited Feb. 13, 2008).

¹²⁹ Slovenian Ministry of Health Conference, *The Burden of Cancer – How can it be Reduced?*, 7-8 February 2008, Brdo pri Kranju, Slovenia. See http://www.mz.gov.si/predsedovanje_eu_in_evropske_zadeve/konference/conference_the_burden_of_cancer_how_can_it_be_reduced_7_8_februar_2008_brdo_pri_kranju. See also *EU-Wide Cancer Approach Needed*, BBC NEWS, Feb. 5, 2008, <http://news.bbc.co.uk/2/hi/health/7228402.stm> (last visited Sept. 15, 2008).

¹³⁰ Franco Berrino et al., *Survival for eight major cancers and all cancers combined for European adults diagnosed in 1995-1999: results of the EURO CARE-4 study*, 8 LANCET ONCOLOGY 773 (2007).

ropean cancer taskforce to oversee prevention, diagnosis, treatment and care for cancer patients. The report proposes cross-EU learning on screening, use of drugs, palliative care, and cancer research.¹³¹ It also suggests establishing European centers of reference for rare cancers.¹³² Above all, the authors of the EURO CARE report stress the need to take public health measures, such as tobacco control, as the “number one priority in Europe.”¹³³ The Slovenian presidency seems keen to concentrate EU-level efforts on prevention through public health measures such as lifestyle changes rather than developing expensive new pharmaceuticals.

It seems, therefore, that after some years of relative demotion, the fight against cancer is becoming an issue for the EU once more. Increased interest in the governance network that emerged from EAC may be expected to lead to increased funding for its activities, and consequent increase in its influence on EU and national policy making stages. Now the question presented is, “how does this relate to the bigger picture of EU health care governance”?

III. NETWORKED GOVERNANCE AS THE WAY FORWARD: THE EMERGING EU HEALTH CARE GOVERNANCE FRAMEWORK

Scott Greer’s contention that EU health policy is at a critical juncture¹³⁴ may be true. There is a widespread perception that the ECJ has destabilized, at least in part, the status quo.¹³⁵ This article argues against that historiography by illustrating that EU involvement in health has been driven in important areas by multi-level, transnational networks of epidemiologists, patients, activists, and policy makers. What is clear, however, is that the ECJ’s decisions have focused the efforts of actors at all levels on solving the problem of (and/or gaining the benefits from) cross-border health care.

¹³¹ See *id.* at 781.

¹³² Health Policy Monitor, Institute of Public Health Slovenia, <http://www.hpm.org/survey/si/a11/5>.

¹³³ See *id.* Other public health/lifestyle measures are also stressed, such as dietary modifications, increasing physical activity and avoiding or reducing obesity. *Id.*

¹³⁴ Greer, *supra* note 3, at 219.

¹³⁵ See GLINOS & BAETEN, *supra* note 97.

Furthermore, the debate has widened from being about (the relatively minor issue of) cross-border movement of individual patients.¹³⁶ The debate now includes interactions between the EU's existing public health policy, the competitive internal market in health care services, and consumer/patient protection in the internal market. Health policy has also been framed as a key factor in Europe's productive workforce.¹³⁷ A more European perspective on health might further economic development by capitalizing on potential efficiency gains arising from economies of scale and cross-EU sharing of best practice while also preserving and enhancing "European" models of welfare through EU social policy. Some observers have also begun tying debates over health and social policy to broader discussions about the meaning and sources of citizenship within the EU.¹³⁸ Finally, it is clear that the debate over health policy is feeding into and shaping a much broader movement underway in the EU—in which actors and institutions are attempting to strike a delicate balance between the potential that further economic integration would offer and the social solidarity that is such an important part of the collective European identity. It is also being linked to the dominant discourse of the Lisbon strategy and its aim to make the EU the most competitive information society in the world. From being a "non-topic" for the EU, health care clearly is emerging as one of the EU's major policy fields.¹³⁹

It therefore should come as no surprise that there is a competitive race to define the future of EU health policy. Four major constellations of actors—"social," "enterprise," "economic," and "public health"—are influencing the debate on the future of EU

¹³⁶ The vast majority of patients are either unable to unwilling to seek healthcare in another state. Data on cross-border movements of patients in the EU is limited, but what data is available suggest that expenditure on cross-border health care represents between 0.1% and 0.2% of overall public spending on health care in the EU. See Hervey, *supra* note 12, at 261 n.1.

¹³⁷ See *Commission White Paper on Together for Health: A Strategic Approach for the EU 2008-2013*, at 5, COM (2007) 630 final (Oct. 23, 2007), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0630:FIN:EN:PDF> (last visited?) ("Principle 2: Health is the Greatest Wealth").

¹³⁸ Flear, *supra* note 98. FERRERA, *supra* note 19.

¹³⁹ Wolfram Lamping, *European Integration and Health Policy*, in *HEALTH GOVERNANCE IN EUROPE: ISSUES, CHALLENGES, AND THEORIES* 18, 20-21 (Monika Steffen ed., 2005).

health care governance.¹⁴⁰ For the “social” actors, health care is seen as part of the EU’s strategic modernization of social welfare,¹⁴¹ now being taken forward through the Open Method of Coordination for social protection and social inclusion.¹⁴² The “enterprise” actors are interested in improving competitiveness in Europe while at the same time encouraging high levels of health care protection. This focus reflects a number of matters of key relevance to the pharmaceutical industry operating in Europe, such as providing medicines to patients, opening up the single market in pharmaceuticals, developing global competitiveness of the European pharmaceutical industry, and supporting research and development into innovative medicinal products.¹⁴³ Some “enterprise” actors, such as the tobacco industry, have little interest in increasing levels of health care protection. The interactions between the mandates of economic and monetary union and welfare policies,

¹⁴⁰ Hervey & Vanhercke, *supra* note 56.

¹⁴¹ This may be traced back to 1992. *See id.*; Counsel Recommendation 92/442/EEC of 27 July 1992, 1992 O.J. (L 245) 49 (EC); *Commission Report on Social protection in Europe*, COM (93) 531; *Commission Green Paper on European Social Policy: Options for the Union*, COM (1993) 551 (Nov. 17, 1993) (*communicated by* Pdraig Flynn); *Commission White Paper on European Social Policy: A Way Forward for the Union*, COM (1994) 333 (July 27, 1994); *Commission Communication on Modernising and Improving Social Protection in the European Union*, COM (97) 102 (Mar. 12, 1997); *Commission Communication on a Concerted Strategy for Modernising Social Protection*, COM (99) 347 final (July 14, 1999) (the ‘Social Affairs’ Council of the European Union, launched a ‘Concerted Strategy’ on social protection in 1999, which became the ‘OMC’ a few years later).

¹⁴² “On the basis of the Commission Communication, [*Commission Communication on Working Together, Working Better: A New Framework for the Open Coordination of Social Protection and Inclusion Policies in the European Union*, COM (2005) 706 final (Dec. 22, 2005),] the European Council adopted a new framework for the social protection and social inclusion process in March 2006. The existing open methods of coordination in the fields of social inclusion and pensions, and the current process of cooperation in the field of health and long-term care, are brought together under common objectives and simplified reporting procedures.” The EU Social Protection and Social Inclusion Process, http://ec.europa.eu/employment_social/spsi/common_objectives_en.htm (last visited Sept. 17, 2008). This OMC is overseen by DG Social Affairs.

¹⁴³ A ‘High Level Group on Innovation and Provision of Medicines in the EU’ (known as the ‘G10’ Medicines Group), set up by Enterprise Commissioner Liikanen and Health Commissioner Byrne, consisted of Health and Industry ministers from five member states, representation from different sectors of industry, mutual health funds and a specialist in patient issues. It heard evidence from a wide variety of actors through a public consultation and reported to Commission President Prodi in 2002. *See Commission G10 Medicines Report* (May 7, 2002), available at <http://ec.europa.eu/enterprise/phabiocom/docs/g10-medicines.pdf> (last visited Sept. 17, 2008).

including health care,¹⁴⁴ which have been noted by the European Council since at least 2001,¹⁴⁵ bring into the picture “economic” players such as the Economic and Financial Affairs Council (ECOFIN) and its main advisory body the Economic Policy Committee. Finally, the Directorate General for Health and Consumer Affairs (DG SANCO) has been particularly effective in using wide public participation to ground and legitimize its activities and proposals.¹⁴⁶ DG SANCO’s involvement in public health was in large part due to the leadership of Commissioner David Byrne. This competition among actors has a further dimension of conflict in that various modes of governance available in the EU likely would give an advantage to one group over the others.¹⁴⁷

The debate among these groups of actors is framed in large part by two ongoing initiatives of the Commission, both of which create a strong role for the kind of networked governance exemplified by the Europe Against Cancer program. The first is a direct response to *Kohll* and *Decker* and attempts to establish a framework for the application of patients’ rights regarding cross-border health care. The Commission on July 2, 2008, issued a proposal for a directive on the application of patients’ rights in cross-border health care.¹⁴⁸ While most of the press comment on the proposal

¹⁴⁴ In particular the need to reduce national spending so as to meet EMU’s stringent budgetary requirements.

¹⁴⁵ The Gothenburg European Council in June 2001 stipulated that further reflections should deal with “healthcare and care for the elderly,” which is now considered, together with pensions, as part of the “meeting the challenge of an ageing population” agenda. Göteborg European Council, *Presidency Conclusions*, §43 (June 15-16, 2001).

¹⁴⁶ See generally Europa, The Health Policy Forum, http://ec.europa.eu/health/ph_overview/health_forum/policy_forum_en.htm (last visited Sept. 23, 2008) (the EU Health Policy Forum is a platform of almost 50 umbrella organizations in the health sector) and The European Patients’ Forum, About Us, http://www.eu-patient.eu/about_us/what_is_epf.php (last visited Sept. 23, 2008) (the European Patients Forum is the umbrella group of pan-European patient groups active in the field of European public health and health advocacy, through which DG SANCO can test new ideas and gather stakeholder support).

¹⁴⁷ For an example of the complexity of this debate, see the work on the intra-Commission debate. HERVEY & VANHERCKE, *supra* note 54. “DG Social Affairs has the legal instruments (legal base), but it does not have the legitimate constituency at national level. DG SANCO has privileged relationships with national actors, but it does not have the legal instruments. Result: we have to find a compromise, but for the moment it is a real conflict, a battle for power. Of which we do not see the end yet.” Interview with DG Social Affairs (July 2007).

¹⁴⁸ *Proposal for a Directive of the European Parliament and of the Council on the Application of Patients’ Rights in Cross-Border Healthcare*, COM (2008) 414 final (July 2, 2008).

concerns Chapters II and III of the proposal, concerning the rights and responsibilities of patients and Member States where patients receive cross-border health care services,¹⁴⁹ Chapter IV on cooperation in health may prove to be more significant in the longer term.

In laying out the way forward for cooperation in health, the Commission writes that their aim is to encourage cooperation in areas where “European cooperation can add value to the actions of the Member States because of the scale or nature of the health care concerned.”¹⁵⁰ They propose three basic initiatives, which reflect a model of governance that is network based and multi-level. The key mechanisms are information exchange, policy learning, and decentralized development of Europe-wide standards. This model of governance is very similar to that established in the Europe Against Cancer program. Article 15 proposes the creation of European reference networks, which would specialize in specific illnesses and specific treatments.¹⁵¹ Article 16 calls on the Commission to develop specific guidelines ensuring the interoperability of E-health, particularly regarding patient privacy and medical information exchange.¹⁵² Article 17 calls on the Member States to “facilitate the development and functioning of a network connecting the national authorities or bodies responsible for health technology assessment.”¹⁵³ Both the Commission and the Member States are given the responsibility to develop and implement these networks. The network established through the Europe Against Cancer program is a long-standing example and might serve as a roadmap for

¹⁴⁹ See *EU Plans Cross Border Healthcare*, BBC NEWS, July 2, 2008, <http://news.bbc.co.uk/go/pr/fr/-/1/hi/world/europe/7484198.stm>; See *Public Health: Health Care Directive Comes out of Black Hole*, EUROPOLITICS ENVIRONMENT, June 26, 2008, Factiva, Inc., Document ENVE000020080626e46q0001k; available at <http://www.encyclopedia.com/doc/1G1-180604169.html>; See Geoff Mead, *Hopes calmed over European Health Deal*, THE INDEPENDENT, July 2, 2008, <http://www.independent.co.uk/life-style/health-and-wellbeing/health-news/hopes-calmed-over-european-health-deal-858866.html>; See Andrew Bounds, *Health Tourism Plan Put Forward*, THE FINANCIAL TIMES, July 2, 2008, http://www.ft.com/cms/s/0/45b87528-485b-11dd-a851-000077b07658.html?nclick_check=1; David Charter *Brussels Offers NHS Patients Europe-wide Treatment*, TIMES ONLINE, July 3, 2008, <http://www.timesonline.co.uk/tol/news/uk/health/article4255880.ece>.

¹⁵⁰ *Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross-Border Healthcare*, at 6, COM (2008) 414 final (July 2, 2008).

¹⁵¹ *Id.* at Art. 15.

¹⁵² *Id.* at Art. 16.

¹⁵³ *Id.* at Art. 17.

the way forward as these networks develop. The result would be the creation of a more iterative and reflexive policy making procedure.

The second framing document for the debate over EU health policy is "Together for Health," mentioned in a number of the articles in this issue.¹⁵⁴ Designed to spur public debate about the best role for the EU in health policy, the White Paper puts forward a number of proposals. Most directly applicable is the Commission's call for "structured cooperation," which seems to envisage interactions between the Commission and various (unspecified) national actors.¹⁵⁵ It seems that the model of networked governance put forth by the networks of policy makers, patients, and practitioners as described in this article, that the "European cancer network" could serve as a positive model for this new push for cooperation from the Commission.

There are a number of important questions that remain regarding key issues in both of these documents. There are a number of ways these issues could be furthered along. Regarding the cross-border directive, for example, Pascal Garel, Chief Executive of the European Hospital and Healthcare Federation, has argued that litigation will continue to play a major role, although the cases may be of a different nature than those that led to the directive in the first place.¹⁵⁶ As has been seen in the story of cancer, litigation can be fundamental in shaping the debate and it has its place in prying open regulatory opportunities and shaking up established patterns that may in fact be sub-optimal in terms of allocation of resources.¹⁵⁷ The use of litigation as the primary means of developing policy is an extremely unpredictable basis for the development of a policy field.

Moreover, as other contributions to this issue point out, the use of the courts as the primary tool for advancing patients' rights

¹⁵⁴ European Commission, *supra* note 4.

¹⁵⁵ *Id.* at 10.

¹⁵⁶ European Aids Treatment Group, *EU Tables Weakened Cross-Border Directive*, <http://www.eatg.org/news/newsitem.php?id=15268> (last visited July 13, 2008).

¹⁵⁷ Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 Harv. L. Rev. 1016 (2004).

is a double-edged sword.¹⁵⁸ While it can force Member States and the EU to respond to the needs of their citizens, it may also serve to undermine the financial stability of Member States' health systems. It is important to note that the plaintiffs in these lawsuits are individuals who are apparently not linked to any broader strategy put forth by advocacy groups. The network that has been described in this article has not sought to use any formal legal resources, such as litigation, in its attempts to set policy agendas and influence policy outcomes.¹⁵⁹ By contrast, various individual patients have used EU law to influence their health care entitlements. In addition, actors with interests quite different to those in the EAC network, such as the tobacco industry, have also used EU constitutional litigation to challenge attempts to change the regulatory landscape concerning cancer. The outcomes of such individual litigation, as a result, may conflict with the efforts of organized patients' groups or other reform efforts aimed at improving quality and access or public health and preventative measures. Moreover, the individual rights based approach of the plaintiffs does not necessarily advance the ability of patients or patients groups to participate in the consequences of the lawsuits. Thus, for instance, Christopher Newdick argues that these cases undercut the elaborate participatory systems currently in place in the United Kingdom's health system.¹⁶⁰ Nonetheless, it seems possible that patient driven litigation will play a larger role in the debate over European health policy in the future.¹⁶¹

Thus, while this article does not deny the likely role of litigation in the creation of a Europe-wide health arena, this article ar-

¹⁵⁸ See Scott Greer, *Migration of Patients and Migration of Power: Politics and Policy Consequences of Patient Mobility in Europe*, (forthcoming 2008). Christopher Newdick, *The European Court of Justice, Trans-National Health Care, and Social Citizenship—Accidental Death of a Concept?* (forthcoming 2008) and Johan van de Gronden, *Cross-Border Health Care in the EU and the Organization of the National Health Care Systems of the Member States: The Dynamics Resulting from the European Court of Justice's Decisions on Free Movement and Competition Law*, (forthcoming 2008).

¹⁵⁹ Hervey and Trubek, *supra* note 97.

¹⁶⁰ Christopher Newdick, *The ECJ, Trans-National Health Care and Social Citizenship—Accidental Death of a Concept?*, (forthcoming 2008).

¹⁶¹ For a discussion of the relevance of "adversarial legalism" to the acceptance of new governance in the US and the EU, see Jason M. Solomon, *Law and Governance in the 21st Century Regulatory State*, 86 TEX. L. REV. 819, 847 (2008).

gues that a more reflexive, iterative, and participatory model of governance such as the one seen in EAC would likely produce policies that would maintain a solidarity model, encourage innovation, improve cost-effectiveness, and enhance well being. Put simply, this paper asserts that the networked governance systems that have been discussed here must be considered to understand not only how this debate came about in the first place, but also to understand where it might be headed. The network that has been described played an important role in the shaping of EU health policy well before ECJ decisions grabbed headlines, or the legislature responded with the proposed Directive. It stands to reason that, given its renewed engagement, this network, in addition to others, may well be influential in setting the way forward for EU health policy. The performance of the cancer network also suggests that, at least if the circumstances are right, the influence of such networks in policy making should be welcomed.

IV. CONCLUSION

The networked governance processes that this article describes offers an alternative explanatory account for the emergence of EU health policy to those that focus solely or mainly on the Court and the Commission as the key agents for change in EU policy making processes. The activities of the EAC network began to influence the shape of EU health policy long before the Court's rulings in *Kohll* and *Decker*, and much longer ago than the Commission's proposals on health care services in the internal market were developed. What remains unclear is the ways in which networked governance processes, such as that described here, interact with "classical" Community law, such as regulations and directives, and in particular the use of litigation, through the "direct effect" of EU internal market and competition law. Exploration of this will have to wait for a future research agenda.

The argument found here is not that this is the way EU health policy will develop in the future. Rather, it is one possibility among many. The analysis provided in this article, however, suggests that this network model of governance holds real potential

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for creating a positive system of policy making within the complex environment of EU politics.