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### Recommended Citation

Louise G. Trubek, Thomas R. Oliver, Chih-Ming Liang, & Matt Mokrohisky, *Improving Cancer Outcomes Through Strong Networks and Regulatory Frameworks: Lessons from the United States and the European Union*, 14 J. Health Care L. & Pol'y 119 (2011).  
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# IMPROVING CANCER OUTCOMES THROUGH STRONG NETWORKS AND REGULATORY FRAMEWORKS: LESSONS FROM THE UNITED STATES AND THE EUROPEAN UNION

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## ABSTRACT

Integrated networks of doctors, patients, and hospitals are a major piece of cancer governance. They enable stakeholders to pool information and resources and achieve systematic learning. Two groups, the Children's Oncology Group in the United States and the Europe Against Cancer initiative, are examples of network governance. Both demonstrate learning processes, production and dissemination of new data, financial support, and engagement of all stakeholders. Why have these integrated networks been successful while so many others have failed? Because both are embedded within regulatory frameworks that ensure that the networks work properly. Integrated networks are vulnerable when the frameworks fail to provide the necessary resources, accountability, fairness, and participation.

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## INTRODUCTION

The fight against cancer is now a timely topic. In his first State of the Union address, President Obama endorsed a renewed fight.<sup>1</sup> Elizabeth Edwards listed it as the next big item for the Obama administration in the second half of his term.<sup>2</sup> In part, the political proposals for a renewed fight are based on the disappointing results of the first war against cancer.<sup>3</sup> Cancer is poised to become the leading cause of death in the United States.<sup>4</sup> The response to the political attention from stakeholders in the fight against cancer has been two-fold. Some contend that the results have been better than reported and that the criticisms are not entirely fair.<sup>5</sup> Others argue that more could be done and point to individual therapies based on genetic factors or more money for research as possible answers to the problem.<sup>6</sup> In this current debate, much attention has been paid to medical science and technology, and little attention has been paid to the role of inadequate governance and ineffective use of regulatory tools as a contributing cause of the disappointing progress against this dread disease.

This article is an interdisciplinary and international comparative study. The authors include a law professor, a political scientist, and a medical oncologist. The team examined developments in the organization of cancer and health care in the European Union and the United States over several decades. They used archival research of governmental reports, analyzed medical studies, looked at regulatory and legal literature, and conducted in-person interviews.

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1. See President Barack Obama, Annual Message to the Congress on the State of the Union (Jan. 27, 2010), available at <http://www.whitehouse.gov/the-press-office/remarks-president-state-union-address> (encouraging increased funding for basic research that could lead to innovative cancer treatments).

2. Elizabeth Edwards, Op-Ed., *Fight Cancers, Win Elections*, N.Y. TIMES, July 18, 2010, at WK8. Elizabeth Edwards sadly lost her own battle with cancer on December 7, 2010. See Jan Hoffman, *Elizabeth Edwards Through Many Eyes*, N.Y. TIMES, Dec. 12, 2010, at WK4 (detailing the many facets of Elizabeth Edwards' life).

3. See GUY. B. FAGUET, *THE WAR ON CANCER: AN ANATOMY OF FAILURE, A BLUEPRINT FOR THE FUTURE 1* (2005) (noting that little progress has been made in the "War on Cancer" since it began with the enactment of the National Cancer Act of 1971).

4. *Leading Causes of Death*, CTRES. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/nchs/fastats/lcod.htm> (last visited Jan. 7, 2011).

5. See generally Susan M. Gapstur & Michael J. Thun, *Progress in the War on Cancer*, 303 JAMA 1084, 1084-85 (2010) (arguing that in evaluating the result of the war on cancer, critics should take into consideration the fact that cancer is "a pleomorphic, complex, and highly adaptable disease" and that the aging population makes cancer statistics look worse than they actually are).

6. See generally Alan G. Thorson, *Progress in Cancer Care: A Rational Call To Do Better*, 60 CANCER J. FOR CLINICIANS 7, 10 (2010) (indicating that a lot of progress has been made in the war on cancer, but that consistent investments of time and resources into cancer research are crucial to accelerating the slow pace of progress).

This article is based on an analysis of two successful projects to improve cancer care outcomes. The first project is the Children's Oncology Group based in the United States. The second is the Europe Against Cancer initiative. This article documents how well-organized networks of experts using data, coordinating research, and guiding clinical care can obtain good results.<sup>7</sup> It also demonstrates that when broader institutional support for these networks is weakened, the ability to continue to produce good results declines.<sup>8</sup> It is a counter-intuitive result for many who do not see how governmental action and structures can produce better results for cancer patients. An important study recently issued by the prestigious Institute of Medicine (IOM) on cancer trials linked poor results in cancer trials to the ill-coordinated and disorganized system currently functioning in the United States.<sup>9</sup> The fact that this study has been widely reported and discussed in both the popular and medical media<sup>10</sup> indicates that there may be a broader understanding emerging that legal and policy tools are important in achieving better care and outcomes.<sup>11</sup>

This article is organized into four sections. The first Part discusses the history of the institutional fights against cancer in the United States and the European Union.<sup>12</sup> The second Part describes two integrated networks that are linked to the governmental campaigns against cancer:<sup>13</sup> the Children's Oncology Group in the United States, and the Europe Against Cancer initiative in the European Union. It describes how these networks share

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7. See *infra* Parts II–IV.

8. See *infra* Parts II–III.

9. See generally SHARYL J. NASS ET AL., INST. OF MED., A NATIONAL CANCER CLINICAL TRIALS SYSTEM FOR THE 21ST CENTURY: REINVIGORATING THE NCI COOPERATIVE GROUP PROGRAM 7, 10 (2010) (reviewing the cancer trial system in the United States and concluding that the process is inefficient and counterproductive, and often leads to unacceptable delays, due in part to problems in government oversight).

10. See generally, e.g., Peggy Eastman, *IOM Report: NCI Clinical Trials Cooperative Group Programs Needs Urgent Retooling*, ONCOLOGY TIMES, May 10, 2010, at 13–14 (finding that the IOM report's suggestions for increased funding, reimbursement to clinicians, and consolidation of administrative functions are necessary to address the cooperative group program's defects); Editorial, *Faltering Cancer Trials*, N.Y. TIMES, Apr. 25, 2010, at WK11 (reporting on the IOM study and noting particularly that many government-subsidized trials are not completed, and citing regulatory inefficiency as a major reason so many trials are left incomplete); Robert C. Young, *Cancer Clinical Trials—A Chronic But Curable Crisis*, 363 NEW ENG. J. MED. 306, 307–08 (2010) (noting that the IOM report recommended consolidating administrative and management functions, improving prioritization of trials, and increasing funding to resolve inefficiencies in the clinical trials program).

11. See generally Young, *supra* note 10, at 307–09 (discussing the IOM recommendations to improve cancer trials and noting particularly the legal and policy components of the report); *Faltering Cancer Trials*, *supra* note 10 (highlighting the regulatory and policy components of the IOM recommendations).

12. See *infra* Part I.

13. See *infra* Part II.

three aspects that contribute to their effectiveness: production and dissemination of data, financial support for research and treatment, and engagement of stakeholders.<sup>14</sup> Part three explains why regulatory frameworks in which networks are embedded are necessary for continued improvement and learning.<sup>15</sup> It demonstrates that regulatory frameworks can provide accountability for performance, coordinate stakeholder participation, support physician decision-making, and guarantee fairness of data.<sup>16</sup> It also explains that if the regulatory frameworks fail to adequately accomplish the tasks and utilize the available governance tools, the networks will not achieve their potential. The final Part discusses how, in the United States and the European Union, there is an emerging understanding that, as the fight against cancer is renewed, institutional structures and regulation are key tools.<sup>17</sup> The frameworks must be strengthened. In both regions, medical and political leaders are initiating legislative and regulatory initiatives.<sup>18</sup>

#### I. THE EARLY UNITED STATES AND EUROPEAN UNION CONTEXT

The history of cancer programs in the United States and the European Union demonstrates how governance can affect cancer outcomes. Both regions share a vision of regulatory frameworks that would enable the production of new knowledge, transference of that knowledge, and utilization in patient care.<sup>19</sup> The motivating forces behind this vision were networks of medical experts and important political leaders.

In his 1971 State of the Union address, President Richard Nixon asked Congress for appropriations “to launch an intensive campaign to find a cure for cancer . . . .”<sup>20</sup> The commitment took the form of the National Cancer Act of 1971,<sup>21</sup> which led to increased funding for cancer research.<sup>22</sup> The

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14. See *infra* Part II.

15. See *infra* Part III.

16. See *infra* Part III.

17. See *infra* Part IV.

18. See *infra* Part IV.

19. See generally HELENA LEGIDO-QUIGLEY ET AL., ASSURING THE QUALITY OF HEALTH CARE IN THE EUROPEAN UNION: A CASE FOR ACTION xiv (2008) (describing the connections between public health research and policy decisions); see also NASS, *supra* note 9, at 7–10 (examining the NCI’s clinical trials program and finding that strengthening administrative frameworks and infrastructure would promote the production of new research leading to better patient care).

20. President Richard Nixon, Annual Message to the Congress on the State of the Union (Jan. 22, 1971), available at <http://www.presidency.ucsb.edu/ws/index.php?pid=3110>.

21. National Cancer Act of 1971, Pub. L. No. 92-218, 85 Stat. 778 (1971) (codified in scattered sections of 42 U.S.C.).

22. John T. Kalberer, Jr. & Guy R. Newell, Jr., *Funding Impact of the National Cancer Act and Beyond*, 39 CANCER RES. 4274, 4274–75 (1979).

original vision of the National Cancer Act (NCA) gave the National Cancer Institute (NCI) the responsibility and authority to coordinate all cancer-related activities.<sup>23</sup> The NCI was expected not only to support basic research, but also to provide leadership in translating scientific findings into actual improvement in bedside cancer care.<sup>24</sup> By the 1980s, the NCI began providing financial support to institutions that perform basic, clinical, and epidemiological research.<sup>25</sup> Institutions that received these grants were designated Comprehensive Cancer Centers.<sup>26</sup> These Centers were expected to boost translational research and to help disseminate newly-developed treatments and interventions to community physicians.<sup>27</sup> Before and after the 1971 legislation, NCI also established grant-supported cooperative research groups to bolster translational research.<sup>28</sup> A typical cooperative research group includes members such as Comprehensive Cancer Centers and non-NCI-designated academic cancer centers around the country. The hope was that, through cancer centers and cooperative research groups, researchers and clinicians would collaborate to ensure wide adoption of new standards of practice, thus bridging the critical gap between science and treatment, and bringing real improvement to the cancer care system.<sup>29</sup>

The European Union's anti-cancer efforts are based on a different set of circumstances than those of the United States.<sup>30</sup> The authority to provide

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23. §§ 2(b), 407(a), 85 Stat. at 779.

24. NAT'L CANCER POLICY BD., INST. OF MED. & COMM'N ON LIFE SCI., NAT'L RESEARCH COUNCIL, ENSURING QUALITY CANCER CARE 19 (Maria Hewitt & Joseph V. Simone eds., 1999).

25. See generally NAT'L CANCER INST., U.S. DEP'T HEALTH & HUMAN SERVS., DECADES OF PROGRESS 1983 TO 2003: COMMUNITY CLINICAL ONCOLOGY PROGRAM 7–10 (2004), available at <http://prevention.cancer.gov/files/programs-resources/pubs/ccop20th/book.pdf> (providing a brief history of NCI's Community Clinical Oncology Program, which began in the early 1980s and funds hospitals and medical centers engaged in cancer research and clinical trials).

26. Kalberer & Newell, *supra* note 22, at 4275.

27. *Id.* at 4279.

28. See Y. Nancy You et al., *Operative Trials: The Opportunity Beckons—An Update on the American College of Surgeons Oncology Group*, 139 SURGERY 455, 456 (2006) (providing a list of NCI cooperative group programs founded between 1956 and 1999); see also *NCI's Clinical Trials Cooperative Group Program*, NATIONAL CANCER INSTITUTE (Nov. 23, 2009), [http://www.cancer.gov/images/documents/448c13d2-2b94-452b-8170-44c7a04970e8/Fs1\\_4.pdf](http://www.cancer.gov/images/documents/448c13d2-2b94-452b-8170-44c7a04970e8/Fs1_4.pdf) (detailing the Clinical Trials Cooperative Group Program).

29. See *NCI's Clinical Trials Cooperative Group Program*, *supra* note 28 (noting that cooperative groups comprising researchers, community physicians, and cancer centers are designed to collectively research and promote new cancer treatments and preventions).

30. Compare, e.g., Kevin McCarthy, *Foreword I* of LEGIDO-QUIGLEY ET AL., *supra* note 19, at xiii (noting that the European Union's efforts to provide high quality health care are the result of increased interconnectedness between health care systems and policies), with Karen Davis, *Foreword II* of LEGIDO-QUIGLEY ET AL., *supra* note 19, at xvii (finding that the need for transparency and accountability in the United States' health care system led to its "quality improvement movement").

health care is based almost entirely in the member states,<sup>31</sup> and health care quality performance has varied by geography and types of cancer.<sup>32</sup> Starting in 1985, the European Union launched the Europe Against Cancer initiative (EAC).<sup>33</sup> The EAC was an elaborate plan developed by epidemiologists from across the European Union, who, with the support of key political leaders, secured modest funding for the development of new agencies and research.<sup>34</sup> The goal was to improve the cancer care outcomes in each member state by linking the state-level networks and institutions together and creating a bank of information that included health data from across Europe.<sup>35</sup> The EAC is considered the pioneering program for using the European Union as a platform to coordinate healthcare across the member states.<sup>36</sup>

## II. INTEGRATED NETWORKS

This section discusses the development and achievements of two integrated networks, the Children's Oncology Group in the U.S. and the EAC initiative. These two networks have been successful in integrating learning and practice.<sup>37</sup>

Through the Children's Oncology Group, significant improvement in survival for Acute Lymphoblastic Leukemia (ALL) has been achieved.<sup>38</sup> The five-year survival rate for ALL jumped from nearly 15 percent to over 60 percent between 1969 and 1975, and has now reached about 80

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31. Herbert E. G. M. Hermans, *Cross-Border Health Care in the European Union: Recent Legal Implications of 'Decker and Kohl'*, 6 J. EVALUATION CLINICAL PRAC. 431, 432–33 (2000).

32. See Peter Boyle, Editorial, *Favorable Trends in Cancer Mortality in the European Union But No Room for Complacency*, 19 ANNALS ONCOLOGY 605, 605–06 (2008) (discussing the gap in health quality status between “old” Europe and “new” Europe and noting particularly that lung cancer rates among Polish men are almost four times that of Swedish men); see generally C. Bosetti et al., *Cancer Mortality in the European Union, 1970-2003, With a Joinpoint Analysis*, 19 ANNALS ONCOLOGY 631, 633–39 (2008) (detailing mortality rates in the European Union by type of cancer).

33. Peter Boyle et al., *Measuring Progress Against Cancer in Europe: Has the 15% Decline Targeted for 2000 Come About?*, 14 ANNALS ONCOLOGY 1312, 1312 (2003).

34. Louise Trubek et al., *The Construction of Healthier Europe: Lessons from the Fight Against Cancer*, 26 WIS. INT'L L. J. 804, 816 (2008).

35. *Id.*

36. See François Briatte, *The Europeanization of Health System Performance: The EURO CARE Study and Cancer Control in England 4–5* (Apr. 15–17, 2010) (unpublished manuscript) (on file with authors) (detailing the strong influence of the EAC programs on broader European cancer control and on European health policy generally).

37. See Maura O'Leary et al., *Progress in Childhood Cancer: 50 Years of Research Collaboration: A Report from the Children's Oncology Group*, 35 SEMINARS ONCOLOGY 484, 484 (2008) (describing the development of new treatments for Childhood Cancer Groups); Trubek et al., *supra* note 34, at 814 (recounting the mission of the European-wide cancer programs).

38. O'Leary et al., *supra* note 37, at 484–85.

percent.<sup>39</sup> Some researchers argue that the biological and genetic differences between childhood and adult cancers make childhood cancer easier to treat.<sup>40</sup> However, others point to the unique network among childhood cancer researchers, clinicians and patients as the key.<sup>41</sup> The childhood cancer network was created with the NCI's financial support.<sup>42</sup> In 2000, four pediatric cancer groups merged together to form the Children's Oncology Group (COG), one of the twelve cooperative research groups currently funded by NCI to conduct clinical research.<sup>43</sup> Unlike other cooperative groups, the Children's Oncology Group achieved substantially higher participation rates in clinical trials and methodical comparative effectiveness studies than other groups.<sup>44</sup> These high participation rates enabled researchers to improve clinical treatments without a major breakthrough in drug development.<sup>45</sup> Similar multi-center and collaborative networks can also be observed in most western European countries, where more than 70 percent of children diagnosed with cancer participate in national or international phase III clinical trials.<sup>46</sup>

The EAC is another well-known example of such a network. From 1986 to 2002, three action plans, funded by the European Commission,

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39. *Id.* at 484.

40. See JOSEPH V. SIMONE & JANE LYONS, SUPERIOR CANCER SURVIVAL IN CHILDREN COMPARED TO ADULTS: A SUPERIOR SYSTEM OF CANCER CARE? 3, available at <http://www.iom.edu/~media/Files/ActivityFiles/Disease/NCPF/Manuscript.pdf> (explaining that embryonic sarcomas, which are more common in childhood cancers, are more susceptible to radiotherapy and chemotherapy than mature carcinomas, which are more common in adult cancers).

41. See *id.* at 5–7 (suggesting that pediatric cancer patients' participation in clinical trials—which enable researchers to learn directly from cancer patients—is key to their increased survival rates).

42. *About the Children's Oncology Group (COG)*, CURESEARCH.ORG, [http://www.curesearch.org/about\\_us/index.aspx?id=7840](http://www.curesearch.org/about_us/index.aspx?id=7840) (last visited Jan. 11, 2011).

43. *New Cooperative Group Created to Cure and Prevent Childhood and Adolescent Cancer*, AM. CHILDHOOD CANCER ORG., <http://www.candlelighters.org/Advocacy/COGmerger.aspx> (last visited Jan. 11, 2011). For more information about NCI's twelve cooperative research groups, see Brooke Hardison Wang & Alea Farrakh, *Cooperative Groups Help Advance Cancer Research*, NAT'L CANCER INST. (Feb. 29, 2008), <http://benchmarks.cancer.gov/2008/02/cooperative-groups-help-advance-cancer-research/>.

44. See Stephen J. Shochat et al., *Childhood Cancer: Patterns of Protocol Participation in a National Survey*, 51 CA: CANCER J. FOR CLINICIANS 119, 128–29 (2001) (finding that children with various forms of cancer have significantly improved chances of survival when treated at a pediatric center, and that 94% of young childhood cancer patients are seen at either a Pediatric Oncology Group (POG) or a Children's Cancer Group (CCG) affiliated hospital).

45. See O'Leary et al., *supra* note 37, at 485 (suggesting that clinical research of the type conducted in cancer research groups—more than other factors like drug development—has been primarily responsible for dramatic improvements in childhood cancer survival rates).

46. S. Ablett & C. R. Pinkerton, *Recruiting Children into Cancer Trials—Role of the United Kingdom Children's Cancer Study Group (UKCCSG)*, 88 BRIT. J. CANCER 1661, 1661–62 (2003).



were established to combat cancer.<sup>47</sup> The development of these action plans, as well as the use of funding provided by the EAC, was driven by a network of high profile epidemiologists, oncologists, patient activists, and policy-makers.<sup>48</sup> The EAC is an example of a network utilizing a multilevel monitoring system.<sup>49</sup> This system uses tools of public reporting, league tables, cancer registries, and practice guidelines.<sup>50</sup> By producing comparative data, this multilevel system has enabled the member states to analyze their performance on cancer outcomes.<sup>51</sup> This information enabled the United Kingdom to substantially revise its cancer treatment and allocate more funding to cancer treatment.<sup>52</sup> The information on the prevalence of lung cancer assisted in the passage of a European Union law controlling tobacco usage.<sup>53</sup>

Successfully integrated networks not only facilitate opportunities for collaboration,<sup>54</sup> but also change the ways in which research is conducted,<sup>55</sup> patients are treated,<sup>56</sup> and public health interventions are implemented.<sup>57</sup> Examination of the stories of the Children's Oncology Group and the EAC

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47. Trubek et al., *supra* note 34, at 814–16.

48. *Id.* at 816.

49. See Hadii M. Mamudu & Donley T. Studlar, *Multilevel Governance and Shared Sovereignty: European Union, Member States, and the FCTC*, 22 GOVERNANCE: INT'L J. POL'Y ADMIN. & INSTS. 73, 81 (2009) (describing the nature of multi-level governance as it relates to cancer and tobacco control in Europe and noting that the formation of the EAC played a large role in its development). For a detailed discussion of the notion of multi-level governance as it relates to health care in Europe, see generally Trubek et al., *supra* note 34, at 820–22.

50. Trubek et al., *supra* note 34, at 816–18.

51. See Freddie Bray et al., *The Comprehensive Cancer Monitoring Programme in Europe*, 13 EUR. J. PUB. HEALTH (SUPP. 3), Sept. 2003, at 61, 61–62 (explaining how cancer data has been used to make comparative estimates of cancer incidence, mortality, and survival in Europe).

52. See Briatte, *supra* note 36, at 18–19 (discussing the EURO CARE-2 study that revealed that Britain had one of the worst cancer survival rates as compared to the rest of the developed world and suggesting that the data were key forces driving the United Kingdom's revised cancer policy). For more information about EURO CARE (EUROPEAN CANCER REGISTRY), see *Survival of Cancer Patients in Europe*, EURO CARE, <http://www.eurocare.it/> (last visited on Jan. 11, 2011).

53. Council Decision 04/513, art. 1, 2004 O.J. (L 213) 8 (EC). See generally Ruth Roemer et al., *Origins of the WHO Framework Convention on Tobacco Control*, 95 AM. J. PUB. HEALTH 936, 936 (2005) (discussing the adoption of the Framework Convention on Tobacco Control (FCTC) among WHO member states).

54. See Dennis L. Kodner & Cor Spreuwenberg, *Integrated Care: Meaning, Logic, Applications, and Implications—A Discussion Paper*, 2 INT'L J. INTEGRATED CARE, Nov. 14, 2002, at 1, 2 (explaining that health care integration fosters cooperation and collaboration).

55. See Andrew C. von Eschenbach, *A Vision for the National Cancer Program in the United States*, 4 NATURE REVIEWS CANCER 820, 827 (2004) (discussing the “new cancer-research paradigm” that is developing in part due to the increasing integration of disciplines, technologies, and tactics).

56. ROZ D. LASKER & COMM. ON MED. AND PUB. HEALTH, MEDICINE & PUBLIC HEALTH: THE POWER OF COLLABORATION 55 (1997).

57. See *id.* at 105 (explaining that integrated health networks help foster collaborative efforts that strengthen the essential functions of public health).

demonstrate that these new practices can lead to systematic and sustainable learning, and have large impacts. Three important practices contribute to the success of integrated networks: production of data and dissemination of knowledge; financial support for research; and treatment and engagement of all stakeholders.

#### *A. Production of Data and Dissemination of Knowledge*

An effective system of information gathering and dissemination is essential for systematic learning. In the area of cancer care, this purpose is often achieved through clinical trials, particularly phase III trials.<sup>58</sup> Clinical trials conducted at the Children's Oncology Group provided promising results.<sup>59</sup> Very high rates of patient participation in clinical trials allow the network to compare outcomes of different interventions and improve the overall effectiveness of cancer care.<sup>60</sup> "[D]ata concerning treatment and responsiveness to treatment is gathered on each patient and analyzed by the COG Statistics and Data Center. Research findings are then shared with the entire COG membership and evaluated for developing new therapies."<sup>61</sup> The Children's Oncology Group also uses epidemiological studies to identify disparities in outcomes based on race, ethnicity, and socioeconomic background.<sup>62</sup>

The use of clinical guidelines is essential to the dissemination of knowledge produced in clinical trials. The Children's Oncology Group,

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58. See SUZANNE H. REUBEN, PRESIDENT'S CANCER PANEL, 2004-2005 ANN. REP., TRANSLATING RESEARCH INTO CANCER CARE: DELIVERING ON THE PROMISE 3 (2005) (discussing the importance of translational research, of which clinical trials are a basic element in the fight against cancer).

59. See Shochat et al., *supra* note 44, at 120 (explaining that childhood cancer survival rates are improved by, *inter alia*, participation in controlled clinical trials).

60. See *id.* at 128 (concluding that progress in the cure of childhood cancers is optimized when affected children enter into group clinical trials); *Ten Things to Know About Cancer Treatment Trials*, NAT'L CANCER INST. (Jan. 10, 2000), <http://www.cancer.gov/clinicaltrials/education/things-to-know-treatment-trials> (detailing cancer clinical trials and noting that they provide for comparison of treatment regimens).

61. *COG Update*, CURESEARCH.ORG (Aug. 2006), [http://www.curesearch.org/support\\_curesearch/eblast.aspx?id=3740](http://www.curesearch.org/support_curesearch/eblast.aspx?id=3740) (last visited Jan. 11, 2011).

62. See generally, e.g., Brad H. Pollock et al., *Racial Differences in the Survival of Childhood B-Precursor Acute Lymphoblastic Leukemia: A Pediatric Oncology Group Study*, 18 J. CLINICAL ONCOLOGY 813, 813-20 (2000) (reporting on findings from a study of racial disparities in childhood cancer outcomes conducted with patients in Pediatric Oncology Groups, and noting that socioeconomic factors might also account for disparities); Sharon Worcester, *Childhood Cancer Survival: Racial Disparities Persist*, INTERNAL MED. NEWS (Jan. 15, 2007), [http://findarticles.com/p/articles/mi\\_hb4365/is\\_2\\_40/ai\\_n29392985/](http://findarticles.com/p/articles/mi_hb4365/is_2_40/ai_n29392985/) (reporting on findings from the United States Surveillance, Epidemiology, and End Results (SEER) program that indicate that racial disparities in childhood cancer outcomes are narrowing). See also Interview with Paul M. Sondel, Professor of Pediatrics, Human Oncology & Med. Genetics, Univ. of Wis. Sch. of Med. & Pub. Health, in Madison, Wis. (July 27, 2009).

along with several other cooperative groups, publishes trial results and preferred treatment protocols to their members.<sup>63</sup> The Children's Oncology Group routinely produces, revises, and distributes clinical guidelines to ensure that most children diagnosed are treated with the best interventions available.<sup>64</sup> A pediatric oncologist interviewed by the authors said the use of clinical guidelines could be traced back to the early years of this network, before the Internet, when most communication was conducted by mail.<sup>65</sup>

Similarly, members of the EAC network worked hard to expand and improve existing cancer registries by forming the European Network of Cancer Registries (ENCR).<sup>66</sup> "These registries contained information on cancer incidence, mortality, and prevalence from across Europe[.]"<sup>67</sup> The ENCR serves as a cancer surveillance system and the information obtained is used to develop the European Code Against Cancer.<sup>68</sup> The Code is "a collection of recommended protocols on cancer screening, as well as best practices for the prevention and treatment of all cancers."<sup>69</sup> These protocols "have become the industry standard in cancer treatment in Europe and are continually updated to reflect new information on cancer control[;]"<sup>70</sup> they are also used by advocacy groups to push national governments to reduce the overall cancer burden.<sup>71</sup>

63. *Clinical Trial Results: Summaries of Newsworthy Clinical Trial Results*, NAT'L CANCER INST., <http://www.cancer.gov/clinicaltrials/results/type/childhood> (last visited Jan. 12, 2011).

64. See NURSING DISCIPLINE CLINICAL PRACTICE SUBCOMM. & LATE EFFECTS COMM., CHILDREN'S ONCOLOGY GRP., ESTABLISHING AND EXCHANGING SERVICES FOR CHILDHOOD CANCER SURVIVORS: LONG-TERM FOLLOW-UP PROGRAM RESOURCE GUIDE xii–xiii (Wendy Landier ed., 2007), available at <http://www.survivorshipguidelines.org/pdf/LTFUResourceGuide.pdf> (describing the most recent standards and strategies for caring for childhood cancer survivors); see also *COG and Its Role in Clinical Trials*, CURESEARCH.ORG, [http://www.curesearch.org/our\\_research/index\\_sub.aspx?id=1472](http://www.curesearch.org/our_research/index_sub.aspx?id=1472) (last visited Jan. 12, 2011) (discussing the production of treatment guidelines and protocol); *Progress*, CURESEARCH.ORG, [http://www.curesearch.org/our\\_research/index\\_sub.aspx?id=1527](http://www.curesearch.org/our_research/index_sub.aspx?id=1527) (last visited Jan. 12, 2011) (detailing the most recent treatment successes resulting from COG clinical trials and research).

65. Interview with Paul M. Sondel, *supra* note 62.

66. See Freddie Bray et al., *Estimates of Cancer Incidence and Mortality in Europe in 1995*, 38 EUR. J. CANCER 99, 99–100 (2002) (describing the history and purpose of the ENCR).

67. Trubek et al., *supra* note 34, at 816.

68. See *id.* at 816–18 (explaining that information obtained through the improved registries is used to update the European Code Against Cancer).

69. *Id.* at 818.

70. *Id.*

71. See *id.* at 818–19 (noting that patient advocacy prompted the European Union to set higher standards for cancer mortality reduction).

### *B. Financial Support for Research and Treatment*

Financial support is crucial in achieving sustainable network integration. In the United States, the lack of universal health care coverage is acknowledged as a deterrent to system improvement.<sup>72</sup> Inconsistent methods of determining payment for treatments also add to difficulties in making cancer care affordable.<sup>73</sup> Insurance companies often deny coverage for treatment through cancer trials, an obstacle that discourages many patients from participation in these trials.<sup>74</sup> An IOM workshop describes the payment obstacles to recruitment for trials: “Instead of cooperation there is competition fueled by limited financial resources and a lack of the sort of communication that would foster more efficient alignment.”<sup>75</sup>

In contrast, the Children’s Oncology Group has been able to overcome financial obstacles through public education, advocacy, and fundraising.<sup>76</sup> The Children’s Oncology Group locates financial resources from disparate insurance payors.<sup>77</sup> The Children’s Oncology Group, through its CureSearch website, provides patients and their families with information on how to access and advocate for payment from insurance providers and charity organizations.<sup>78</sup> Private insurance companies, influenced by consistent patient advocacy, have cooperated by approving coverage for

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72. See generally Karen Davis, *Commentary*, 60 MED. CARE RES. & REV. (SUPP.) 89S, 89S–97S (2003) (arguing that the high number of uninsured Americans has resulted in harm to the country and to the health care system).

73. See, e.g., Paula Kim, *Cost of Cancer Care: The Patient Perspective*, 25 J. CLINICAL ONCOLOGY 228, 228–29 (2007) (describing the numerous hidden costs of cancer care and explaining that one payment method is usually insufficient).

74. MARGIE PATLAK ET AL., INST. OF MED., MULTI-CENTER PHASE III CLINICAL TRIALS AND NCI COOPERATIVE GROUPS: WORKSHOP SUMMARY 47–50 (2009), available at [http://books.nap.edu/openbook.php?record\\_id=12535&page=R1](http://books.nap.edu/openbook.php?record_id=12535&page=R1).

75. *Id.* at 44.

76. See *CureSearch Fact Sheet*, CURESEARCH NAT’L CHILDHOOD CANCER FOUND. (Apr. 9, 2008), [http://www.curesearch.org/uploadedFiles/CureSearch\\_Fact\\_Sheet\\_61\\_22\\_07.pdf](http://www.curesearch.org/uploadedFiles/CureSearch_Fact_Sheet_61_22_07.pdf) (stating that the Children’s Oncology Group has been able to conduct clinical trials with the support provided by public education, advocacy, and fundraising).

77. See *Resource Directory, National and International Resources: Financial Assistance*, CURESEARCH.ORG, <http://www.curesearch.org/resources/resourceservice.aspx?ServiceId=1> (last visited Jan. 12, 2011) (providing contact information for and descriptions of diverse sources that offer financial support for cancer therapy).

78. *Insurance Denials*, CURESEARCH.ORG, [http://www.curesearch.org/for\\_parents\\_and\\_families/newlydiagnosed/article.aspx?ArticleId=3182&StageId=1&TopicId=5&Level=1](http://www.curesearch.org/for_parents_and_families/newlydiagnosed/article.aspx?ArticleId=3182&StageId=1&TopicId=5&Level=1) (last visited Jan. 12, 2011); *Insurance Issues*, CURESEARCH.ORG, [http://www.curesearch.org/for\\_parents\\_and\\_families/newlydiagnosed/article.aspx?ArticleId=3118](http://www.curesearch.org/for_parents_and_families/newlydiagnosed/article.aspx?ArticleId=3118) (last visited Jan. 12, 2011); *Tips for Dealing with Insurance*, CURESEARCH.ORG, [http://www.curesearch.org/for\\_parents\\_and\\_families/newlydiagnosed/article.aspx?ArticleId=3181&StageId=1&TopicId=5&Level=1](http://www.curesearch.org/for_parents_and_families/newlydiagnosed/article.aspx?ArticleId=3181&StageId=1&TopicId=5&Level=1) (last visited Jan. 12, 2011) (providing advice and guidance on obtaining payment through insurance providers).

participation in clinical trials.<sup>79</sup> The companies' rapid approval suggests that they recognize that clinical trials are an accepted standard of care for treatment.<sup>80</sup> The Children's Oncology Group also organized families, including cancer survivors, to raise funding for care and to support specific federal legislation for research.<sup>81</sup> The Caroline Pryce Walker Conquer Childhood Cancer Act of 2008 is one example.<sup>82</sup>

In Europe, financial support from the European Union was crucial to the EAC's research and information gathering function.<sup>83</sup> The league tables produced by the information collected by the EAC demonstrated that the United Kingdom had poor results in cancer outcome.<sup>84</sup> These EAC league tables convinced the United Kingdom in the Blair era to fund more cancer treatment.<sup>85</sup> Since the introduction of increased funding, there has been an improvement in United Kingdom cancer outcomes.<sup>86</sup>

### C. Engagement of All Stakeholders

Engaging network members is critical for the learning process. The engagement of patients is especially crucial. In the Children's Oncology Group, patient interest in clinical trials is an essential part of information gathering. Through their careful support, oncologists and other medical personnel at the cancer centers maximized the Children's Oncology Group's capacity to help patients.<sup>87</sup> The Children's Oncology Group provided patients with trustworthy doctors and hospital centers,<sup>88</sup> long-term commitment to them and their families,<sup>89</sup> and financial support.<sup>90</sup> The

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79. Gina Kolata & Kurt Eichenwald, *In Pediatrics, a Lesson in Making Use of Experimental Procedures*, N.Y. TIMES, Oct. 3, 1999, at 40.

80. *See id.* (describing the success of childhood cancer clinical trials in attracting participants and noting that this is due in part to cooperative insurance companies).

81. *CureSearch Fact Sheet*, *supra* note 76.

82. Caroline Pryce Walker Conquer Childhood Cancer Act of 2008, Pub. L. No. 110-285, 122 Stat. 2682.

83. Trubek et al., *supra* note 34, at 811.

84. Briatte, *supra* note 36, at 9.

85. *Id.* at 16-19.

86. *See* 372 PARL. DEB., H.C. (6th ser.) (2001) 718W-720W (U.K.), available at [http://www.publications.parliament.uk/pa/cm200102/cmhansrd/vo010720/text/10720w66.htm#10720w66.html\\_sbhd1](http://www.publications.parliament.uk/pa/cm200102/cmhansrd/vo010720/text/10720w66.htm#10720w66.html_sbhd1) (detailing funding for cancer study and the coincident increase in cancer survival rates). *See also, e.g.*, Boyle et al., *supra* note 33, at 1312-13, 1315, 1317-18, 1321 (providing extensive data indicating that U.K. cancer rates have improved with an increase in funding for research and treatment).

87. *See* O'Leary et al., *supra* note 37, at 484-85 (describing COG's long record of success in providing childhood cancer patients with the best available cancer therapies).

88. *See id.* (discussing physicians' treatment of children with cancer).

89. NURSING DISCIPLINE CLINICAL PRACTICE SUBCOMM. & LATE EFFECTS COMM., *supra* note 64, at xii.

90. *See* sources cited *supra* notes 77-78.

group was also quick to inform patients about available trials and facilitated consent for participation in such trials.<sup>91</sup> Many parents were willing to travel far distances to obtain the best care.<sup>92</sup> As a result, there were higher rates of clinical trial participation and a higher capacity to conduct comparative effectiveness studies in the Children's Oncology Group than in other cancer networks.<sup>93</sup>

The EAC has also benefited from forms of patient activism. Various national cancer advocacy groups, generally organized around specific cancers, came together to form the European Cancer Patients Coalition (ECPC).<sup>94</sup> The ECPC is now active across Europe,<sup>95</sup> and it also distributes comparative information on outcomes on the national and local level.<sup>96</sup> The ECPC works closely with the researchers funded through the European Union and advocates for continued funding.<sup>97</sup> In addition, the organization

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91. See *Resource Directory: Clinical Trials*, CURESEARCH.ORG, [http://www.curesearch.org/our\\_research/clinical\\_trials/](http://www.curesearch.org/our_research/clinical_trials/) (last visited Jan. 12, 2011) (providing general information about clinical trials and links to two databases of clinical trials currently seeking participants); *Informed Consent*, CURESEARCH.ORG, [http://www.curesearch.org/for\\_parents\\_and\\_families/intreatment/medical/articl.aspx?ArticleId=3122&StageId=3&TopicId=76&Level=1](http://www.curesearch.org/for_parents_and_families/intreatment/medical/articl.aspx?ArticleId=3122&StageId=3&TopicId=76&Level=1) (last visited Jan. 12, 2011) (explaining the process involved in consenting to treatment through a clinical trial).

92. See, e.g., Karen H. Albritton et al., *Site of Oncologic Specialty Care for Older Adolescents in Utah*, 25 J. CLINICAL ONCOLOGY 4616, 4618–19 (2007) (providing data to indicate that many families with young children in Utah are willing to travel long distances to receive medical treatment).

93. Compare O'Leary et al., *supra* note 37, at 485 (providing data indicating that higher participation rates in childhood cancer trials has led to higher cure rates), with *Misconceptions and Lack of Awareness Greatly Reduce Recruitment for Cancer Clinical Trials*, HEALTH CARE NEWS (Harris Interactive, Inc., New York, N.Y.), Jan. 22, 2001, at 1, available at [http://www.harrisinteractive.com/news/newsletters/healthnews/HI\\_HealthCareNews2001Vol1\\_iss3.pdf](http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2001Vol1_iss3.pdf) (describing the low rate of clinical trial participation in other cancer networks).

94. *About ECPC*, EUR. CANCER PATIENT COAL. <http://www.ecpc-online.org/about-ecpc.html> (last updated Oct. 6, 2010).

95. See *id.* (explaining ECPC's current and future policy goals in the European Union).

96. See Trubek et al., *supra* note 34, at 833–34 (discussing ECPC's role "as an informational router between the EU and Member States' citizens).

97. See *id.* (discussing ECPC's role in obtaining continued funding through the MEPs Against Cancer (MAC) caucus). See also EUR. CANCER PATIENT COAL., ECPC ANNUAL REPORT 2009, at 15–17 (2009), available at [http://www.ecpc-online.org/component/docman/doc\\_download/161-ecpc-annual-report-2009.html?ItemId=127](http://www.ecpc-online.org/component/docman/doc_download/161-ecpc-annual-report-2009.html?ItemId=127) (discussing ECPC's goal of enlarging its funding base and noting the coalition's EU funding and expenditures on EU related projects); *ECPC Flyer*, EUR. CANCER PATIENT COAL., [http://www.ecpc-online.org/component/docman/doc\\_download/1-ecpc-flyer-english.html](http://www.ecpc-online.org/component/docman/doc_download/1-ecpc-flyer-english.html) (last visited Jan. 12, 2011) (discussing ECPC's role in the Partnership for Action Against Cancer which connects researchers with governments, patient organizations, health professionals, and industry).

helped develop the Members of Parliament Against Cancer (MAC) caucus at the European Parliament.<sup>98</sup>

### III. WHY REGULATORY FRAMEWORKS ARE NECESSARY

The success of the two networks is based both on the early visionary regulatory frameworks and the new practices that integrate learning and standardization. These regulatory frameworks, the NCA and the EAC, were crucial in the early development of the networks. However, in recent years, there has been a reduction in the effectiveness of the United States and the European Union cancer programs.<sup>99</sup> The ineffectiveness is based in part on the fragmentation of the regulatory framework.<sup>100</sup> In recent decades, the United States regulatory framework created in the 1970s shifted away from translational research and systematic coordination.<sup>101</sup> The NCI delegated the goal of connecting research and clinical care to institutions like comprehensive cancer centers and cooperative research groups.<sup>102</sup> The collaboration between researchers and clinicians proved spotty and difficult to maintain.<sup>103</sup>

Moreover, the record of achievement has been unimpressive. The reductions in cancer mortality have been relatively weak compared to more

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98. *About MAC (MEPs Against Cancer)*, MEPS AGAINST CANCER, [http://www.mepsagainstcancer.org/index.php?option=com\\_content&task=view&id=12&Itemid=27](http://www.mepsagainstcancer.org/index.php?option=com_content&task=view&id=12&Itemid=27) (last visited Jan. 12, 2011).

99. See Trubek et al., *supra* note 34, at 826–27 (describing 2002 EAC funding cuts and member nation difficulties); *Faltering Cancer Trials*, *supra* note 10 (describing bureaucratic hurdles facing and the poor coordination of NCI, and how NCI is near a “state of crisis”).

100. See Clifton Leaf, *Why We’re Losing the War on Cancer (And How to Win It)*, FORTUNE, Mar. 22, 2004, at 77, 80–82 (describing the American cancer effort as “utterly fragmented” and “increasingly narrow,” with funding coming from multiple federal agencies, states, and private industry with very little coordination).

101. See PRESIDENT’S CANCER PANEL, THE NATIONAL CANCER PROGRAM: ASSESSING THE PAST, CHARTING THE FUTURE, 1999 ANNUAL REPORT (2000), available at <http://deainfo.nci.nih.gov/advisory/pcp/archive/pcp99rpt/99report.pdf> (recounting five amendments to the National Cancer Act from 1971 to 1993 that increased NCI’s research capacity without improving information delivery systems). For a more detailed understanding of what translational research entails, see generally Steven H. Woolf, *The Meaning of Translational Research and Why It Matters*, 299 JAMA 211, 211–13 (2008). Dr. Woolf points out that there are currently two different areas of research called “translational.” *Id.* at 211. The first “refers to translating research into practice,” and “ensuring that new treatments and research knowledge actually reach the patients[.]” *Id.* The second form of translational research attempts to “reorganiz[e] and coordinat[e] systems of care,” and help “clinicians and patients to change behaviors and make more informed choices.” *Id.*

102. See FAGUET, *supra* note 3, at 99–101 (discussing NCI’s delegation of research tasks to 39 Comprehensive Cancer Centers and noting that it has spent as much as \$252.2 million (5.5% of its total operating budget) in 2003 on cooperative trials).

103. See PRESIDENT’S CANCER PANEL, *supra* note 101 (“Simply put, we are not applying what we know—interventions demonstrated to be efficacious and validated through the clinical trials process—nearly well enough, quickly enough, or widely enough.”).

rapid progress in heart disease and other major health threats.<sup>104</sup> Progress across different types of cancers and across geographic areas has been uneven, with mortality and disability substantially reduced for some but not for others.<sup>105</sup> After almost 40 years<sup>106</sup> and \$200 billion<sup>107</sup> spent on cancer research, the return on the nation's investment is disappointing.<sup>108</sup> In 2010, an estimated 1,529,560 new cancer cases will be diagnosed,<sup>109</sup> and an estimated 569,490 Americans will die from cancer.<sup>110</sup> Globally, cancer is poised to become the leading cause of death.<sup>111</sup>

Today, many cancer experts acknowledge that improved outcomes require a wide spectrum of activities: basic research, translational research, clinical care, and public health-based cancer control programs.<sup>112</sup> Analysts often attribute the unsatisfactory outcome of the first war on cancer to an overwhelming focus on basic research and the dominance of a "cell-kill paradigm."<sup>113</sup> A recent IOM report on cancer clinical trials system argued that the "complex trials system has become inefficient and cumbersome" and that "a robust, standing cancer clinical trials network is essential to effectively translate discoveries into clinical benefits for patients."<sup>114</sup> So

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104. See Gina Kolata, *In Long Drive to Cure Cancer, Advances Have Been Elusive*, N.Y. TIMES, Apr. 24, 2009, at A1 (reporting that the death rate for cancer dropped by 5 percent between 1950 and 2005, while the death rate for heart disease fell by 64 percent and the death rate for flu and pneumonia by 58 percent). COMPARE AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2010, at 2 (2010), available at <http://www.cancer.org/acs/groups/content/@nho/documents/document/acspc-024113.pdf> (charting incidents of cancer-related mortality in the United States), with NAT'L HEART LUNG & BLOOD INST., FACT BOOK FISCAL YEAR 2006, 35–51 (2007), available at <http://www.nhlbi.nih.gov/about/factbook-06/06factbk.pdf> (charting incidents of heart and other major disease-related mortality in the United States).

105. See AM. CANCER SOC'Y, *supra* note 104, at 40–41 (discussing variability in lung cancer rates across the United States); Kolata, *supra* note 104 (discussing variability in life expectancy between colorectal, prostate, and lung cancers).

106. See Sharon Begley with Anne Underwood, Jeneen Interlandi & Mary Carmichael, *We Fought Cancer . . . And Cancer Won*, NEWSWEEK, Sept. 15, 2008, at 42 (noting that President Richard Nixon declared war on cancer in 1971).

107. *Id.*

108. See *id.* ("[T]he scientists and physicians whom Nixon sent into battle have come up short. Rather than being cured, cancer is poised to surpass cardiovascular disease and become America's leading killer . . . . [I]n 2008, cancer will take the lives of 230,000 more Americans—69 percent more—than it did in 1971.")

109. AM. CANCER SOC'Y, *supra* note 104, at 1.

110. *Id.*

111. *Id.* at 52.

112. REUBEN, *supra* note 58, at i–ii, xi–xii, xvi (discussing NCI's recommendations for a more effective national cancer research network, ranging from greater research coordination to information dissemination in local clinics).

113. See FAGUET, *supra* note 3, at 63–64 (discussing at length the "cell-kill paradigm," including its misconceptions and resulting drug inefficacy).

114. NASS ET AL., *supra* note 9, at 2. See generally Young, *supra* note 10, at 307–09 (explaining that NCI's clinical trial program is cumbersome and ineffective, and summarizing



even though the Children's Oncology Group has managed to conduct the trials, its experience cannot be effectively transferred to the broader cancer enterprise. There is no effective, multilevel monitoring structure that can provide that function.

Despite its initial success, the EAC was not completely refunded in 2002, and, as a result, the program languished.<sup>115</sup> The European Union health programs grew in the first decade of the 21<sup>st</sup> century,<sup>116</sup> but the cancer control process was put on hold.<sup>117</sup> The EAC functioned under an European Union Commission planning document that integrated member-state programs with European Union funding and institutions.<sup>118</sup> After the Commission's early success, European Union funding and Commission commitment were reduced in 2002.<sup>119</sup> The Commission thought that the member states would take over the funding and planning.<sup>120</sup> However, the member states saw the EAC as a permanent element in a multilevel project.<sup>121</sup> Without the European Union resources, the network was in danger of collapsing.<sup>122</sup> The multilevel, monitoring function that had been previously provided by the European Union Commission's plan and personnel, plus the funding for the research function, proved essential for the EAC to thrive.<sup>123</sup>

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IOM's recommendations to improve trial efficiency, prioritization, and physician and patient participation).

115. Trubek et al., *supra* note 34, at 826.

116. *See id.* at 827 (describing the growth of EU health programs and the shift to research in emerging areas such as cardiovascular disease, diabetes, and mental health).

117. *See id.* at 826 (noting that EU funding for the EAC ended in 2002).

118. 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. (C184) 19, 20, available at [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:41986X0723\(04\):EN:HTML](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:41986X0723(04):EN:HTML). *See also* Trubek et al., *supra* note 34, at 814–16 (chronicling various EU action plans designed to “coordinate[] exchanges of information and expertise between cancer specialist health professionals across the EU[,]” as well as the strategic use of funding made available to the EAC).

119. Trubek et al., *supra* note 34, at 826.

120. *Id.* at 827.

121. *See id.* at 827–28 (explaining that Member States saw the fight against cancer as Europeanized); *see also* John Illman, *Funding Cuts for Public Health Projects in Europe May Affect International Cancer Effort*, 96 J. NAT'L CANCER INST., 428, 428 (2004), available at <http://jnci.oxfordjournals.org/content/96/6/428.full.pdf+html> (quoting Richard Sullivan, M.D., Ph.D., head of clinical programs at Cancer Research U.K., who explained that “[w]hen EURO CARE was cut off at the knees, it was told to go to member states for money but, in effect, the member states said: ‘Don’t be ridiculous. This is a European issue.’”).

122. *See* Trubek et al., *supra* note 34, at 827–28 (describing Member States' unwillingness to take over funding and coordinating responsibilities from the EU).

123. *See id.* at 811–14 (arguing that the EAC's “iterative and reflexive system of network governance” proved “instrumental in guiding the EU's activity in cancer”).

Why were these outstanding networks unable to stabilize or serve as exemplary projects on their own? The reason is that the regulatory frameworks in which they were embedded proved essential to their continued existence and integration. Once these frameworks fail to function effectively, the networks become isolated and fragile. In the case of the Children's Oncology Group, the fragmentation of the cancer institutions originally coordinated by the NCI left the Children's Oncology Group isolated. In the EAC, the drastic reduction of resources from European Union research funds and the shift in priorities from cancer to other health issues left the network under-resourced.<sup>124</sup>

What are the essential elements that these frameworks provide? The frameworks can include a mix of governmental agencies, health care institutions, non-profit organizations, and private companies. These frameworks can be defined as institutional conditions that create, support, and maintain the proper functioning of an integrated learning process. These frameworks support the web of relationships that make up the networks. They also ensure the viability and trustworthiness of the networks. First, the frameworks provide accountability for performance quality.<sup>125</sup> Second, they monitor the openness and accessibility of the stakeholder participation.<sup>126</sup> Third, they remove the barriers, economic and otherwise, that discourage physicians from participating in the learning process.<sup>127</sup> Finally, they guarantee fairness in the processes that create and provide data.<sup>128</sup>

#### *A. Ensuring Accountability for Performance in Networks*

Networks promote the creation of data to support the production and dissemination of relevant knowledge. In the case of the Children's Oncology Group and the EAC, the networks themselves worked to expand the availability of data,<sup>129</sup> convert it into knowledge,<sup>130</sup> and disseminate

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124. Trubek et al., *supra* note 34, at 826.

125. See *infra* Part III.A (explaining how frameworks ensure accountability by establishing coordination, assessing performance, and disseminating results).

126. See *infra* Part III.B (noting that the Childhood Cancer Group and the EAC networks increased the influence of patients as stakeholders in the collaborative fight against cancer).

127. See *infra* Part III.C (detailing how programs like the EAC provided greater access to a wider array of research and protocol from which clinical care physicians could reference and learn).

128. See *infra* Part III.D (noting that strong oversight can help alleviate the threat of conflicts of interest).

129. See generally O'Leary et al., *supra* note 37, at 484–85 (discussing the purpose and history of the Children's Oncology Group (COG), its antecedent organizations, and the collaborative research conducted by members); Trubek et al., *supra* note 34, at 816–17 (explaining how the EAC expanded the availability of data).

that knowledge.<sup>131</sup> An effective framework can ensure that the networks continually improve data collection and dissemination, and that their learning is shared with other networks. They do this through emphasizing coordination, creating and publishing performance measures, and monitoring the dissemination of positive results and protocols.

### *1. Coordination*

The path to system improvement requires policy and program coordination at multiple levels. Many United States public health agencies, including the NCI, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Veterans Affairs, and even the Department of Defense have jurisdiction over parts of the cancer care system.<sup>132</sup> In addition, a number of voluntary organizations such as the American Cancer Society and the American Lung Association, biotech and pharmaceutical firms and associations, comprehensive cancer centers, community hospitals and oncology clinics, clinical trial cooperative groups, employers, insurers, patient advocacy groups, survivor networks, and patients all play important roles in research and treatment.<sup>133</sup> This impressive roster of participants is both a badge of honor and failure in the United States' effort to combat cancer. The scope of participation is impressive, but none of the participating individuals or institutions are accountable for the full scope of the problem, nor are the participants provided with sufficient authority and resources to be held accountable. The combination of fragmented and overlapping authority is widely noted as a problem in combating cancer.<sup>134</sup> In 1993, the National Cancer Advisory Board (NCAB) conducted an evaluation of the National Cancer Program.<sup>135</sup>

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130. See generally, O'Leary et al., *supra* note 37, at 484–85 (describing the “pooling of scientific ideas, patient data, and other resources” in order to facilitate collaborative research); Trubek et al., *supra* note 34, at 816–17 (explaining the EAC's conversion of data into knowledge).

131. See O'Leary et al., *supra* note 37, at 485 (discussing the public discourse through publications and presentations generated by collaboration in the COG); Trubek et al., *supra* note 34, at 817 (noting the EAC's role in disseminating knowledge from research conducted by participants).

132. SUBCOMM. TO EVALUATE THE NAT'L CANCER PROGRAM, NAT'L CANCER ADVISORY BD., *CANCER AT A CROSSROADS: A REPORT TO CONGRESS FOR THE NATION* 11 (1994).

133. See *id.* at 11–13 (noting the role of comprehensive cancer centers, clinical trial cooperative groups, biotech and pharmaceutical firms, advocates, health care facilities, insurers, assorted foundations, and other voluntary organizations in the National Cancer Program); PRESIDENT'S CANCER PANEL, *supra* note 101 (making note of the role of public and private payers in the process of determining available cancer care); *Finding Cures*, AM. LUNG ASS'N, <http://www.lungusa.org/finding-cures> (last visited Jan. 13, 2011) (describing the American Lung Association's role in the development of research and treatments for lung cancer).

134. PRESIDENT'S CANCER PANEL, *supra* note 101.

135. See generally SUBCOMM. TO EVALUATE THE NAT'L CANCER PROGRAM, *supra* note 132, at 5–7 (summarizing the major findings of the study).

In its report, the NCAB identified six problems hindering progress against cancer.<sup>136</sup> The first and main problem was the lack of national coordination of public, private and voluntary stakeholders.<sup>137</sup> One decade later, coordination remains a fundamental barrier to improving cancer outcomes.<sup>138</sup> In the European Union, the reduction in funding for the EAC weakened coordination.<sup>139</sup> Since 2002, the regulatory framework at the European Union level has been struggling.<sup>140</sup>

## 2. Performance Assessment

Coordination is particularly important if a framework is to provide multi-level monitoring. Many actors in the cancer network believe that measuring the quality of cancer care is an essential first step towards improving the quality of that care.<sup>141</sup> Without performance indicators, it is argued, there is no way to distinguish the difference between excellent, good, adequate, and inadequate care, and, thus, no basis on which to identify strengths and weaknesses in the system to design improvements.<sup>142</sup> Public reporting and pay-for-performance are two relatively “soft” regulatory initiatives emerging in some healthcare networks that are designed to measure the quality of care and provide incentives for quality improvement. It is well established that performance information, like rankings and report cards, can have a “purposeful” use in improving existing programs and service delivery.<sup>143</sup> “The doctrine of performance

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136. *Id.* at 5.

137. *Id.* at 5, 14.

138. See PRESIDENT’S CANCER PANEL, *supra* note 101 (“At this time, however, there is no consensus in either the research or health care delivery communities as to whether, or in what manner, coordination of a total national cancer effort is possible or desirable.”); Leaf, *supra* note 100, at 80–81 (reporting that “[t]oday the cancer effort is utterly fragmented—so much so that it’s nearly impossible to track down where the money to pay for all this research is coming from.”).

139. See Trubek et al., *supra* note 34, at 826–28 (discussing the failure of European states to “take up the slack” of maintaining research registries and similar data sharing initiatives after the EAC funding was not renewed).

140. See *id.* (describing the cuts in funding for a number of cancer-related programs, and the failure of the individual countries to take financial responsibility for funding a similar regulatory framework).

141. See NAT’L CANCER POLICY BD., *supra* note 24, at 80 (providing reasons why different actors in the cancer network should measure the quality of cancer care).

142. See Antonio Giuffrida et al., *Measuring Quality of Care With Routine Data: Avoiding Confusion Between Performance Indicators and Health Outcomes*, 319 BRIT. MED. J. 94, 94–97 (1999) (contending that performance indicators specifically are necessary in assessing care, as basic outcome data is inadequate to accurately evaluate care providers’ records).

143. See Martin N. Marshall et al., *Public Reporting on Quality in the United States and the United Kingdom*, 22 HEALTH AFF., 134, 143 (explaining hospitals’ response to report card data); Donald P. Moynihan, *Through a Glass Darkly: Understanding the Effects of Performance Regimes*, 32 PUB. PERFORMANCE & MGMT. REV. 592, 593 (2009) (explaining the nature of the “purposeful” category of performance information).

management promised a more efficient and accountable public sector. Performance data would be used to better allocate resources, make decisions about strategy, reengineer processes, motivate workers, and usher in a new era of accountability.”<sup>144</sup> The potential impact, however, depends on whether the incentives established by performance measures are properly aligned with the goals—in this case, reducing the incidence of cancer mortality and disability.

Within the cancer network in the U.S., however, utilization of these tools has been limited to measuring how well providers adhere to cancer screening protocols.<sup>145</sup> For example, data is collected to determine whether physicians are performing mammography, PSA, or PAP smear exams at the appropriate time and intervals for individual patients.<sup>146</sup> Experts are optimistic that effective indicators can also be identified to evaluate the quality of cancer care. According to Chris Queram, CEO for the Wisconsin Collaborative for Healthcare Quality, it is technically feasible to measure values such as five-year survival and to track how well physicians adhere to recommended treatment protocols.<sup>147</sup> He notes, however, that financial, organizational, and philosophical barriers will have to be addressed before these initiatives are systematically incorporated into specialty services like oncology.<sup>148</sup>

The public dissemination of performance indicators is meant to encourage individual clinicians and institutional providers to deliver quality care by introducing reputational incentives.<sup>149</sup> An example of success is the relationship between the EAC and the ENCR which facilitated the creation of data and subsequent use in public reporting in league tables.<sup>150</sup> The ENCR system allows the EAC network to publicly monitor the performance of member states.<sup>151</sup> The EAC initiative measured

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144. Moynihan, *supra* note 143, at 592.

145. See, e.g., Robert A. Smith et al., *Cancer Screening in the United States, 2009: A Review of Current American Cancer Society Guidelines and Issues in Cancer Screening*, 59 CA: CANCER J. FOR CLINICIANS 27, 38–39 (2009) (describing the results of an evaluation of cancer screening conducted over the past two decades and needed reforms).

146. *Id.* at 37.

147. Interview with Chris Queram, President and Chief Exec. Officer, Wis. Collaborative for Healthcare Quality, in Madison, Wis. (July 24, 2009).

148. *Id.*

149. See, e.g., Gwyn Bevan & Richard Hamblin, *Hitting and Missing Targets by Ambulance Services for Emergency Calls: Effects of Different Systems of Performance Measurement Within the UK*, 172 J. ROYAL STAT. SOC’Y 161, 181, 184 (2009) (hypothesizing that a requirement to publish comparative data will encourage service providers “to remedy serious underperformance” in order to prevent reputational damage).

150. Trubek et al., *supra* note 34, at 816–19.

151. See *id.* at 816–17 (explaining that the European Network of Cancer Registries (ENCR) system allowed for cross-national comparisons of certain cancer care data).

international differences in survival rates and disseminated that “information in league tables, which clearly identified substantial international inequities for the first time.”<sup>152</sup> The public dissemination of performance data also provided reputational incentives for member states to improve their own performance.<sup>153</sup> For example, the league table showed that the British had long lagged behind other member states in treating lung cancer,<sup>154</sup> even though the National Health Institute provides free services for all.<sup>155</sup> The data motivated further studies that later revealed that many patients do not receive treatment, not because of lack of payment, but due to their distance from treatment locations.<sup>156</sup>

As shown by the EAC, performance assessment can have some positive impact if the results threaten the reputation of organizational and community leaders. “Fear of embarrassment is perhaps the most powerful motivator for organizational leaders.”<sup>157</sup> This is because reputation affects the degree of oversight from government officials and consumer advocates and therefore the degree of managerial discretion for leaders over resources and operations.<sup>158</sup> Gwyn Bevan has underscored the importance of reputational incentives.<sup>159</sup> In the United Kingdom, “those who ran hospitals

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152. *Id.* at 817.

153. *See, e.g.,* Bevan & Hamblin, *supra* note 149, at 184 (discussing the application of the “reputation pathway” as a performance-enhancing measure that successfully increased ambulance response time in the UK).

154. *See* Mike A. Richards, *The Size of the Prize for Earlier Diagnosis of Cancer in England*, 101 BRIT. J. CANCER S125, S127 (2009) (finding that “1-year survival rates in England (26.9%) [were] well below the European average (36.0%) . . .”). *See also* Sarah Boseley, *UK Trails in European Cancer Cure Survey*, GUARDIAN, Mar. 24, 2009, <http://www.guardian.co.uk/society/2009/mar/24/health-cancer> (reporting that cancer cure rates in England and Scotland did “less well than most of the 15 European countries whose performance was analysed.”).

155. *See* 372 PARL. DEB., H.C. (6th ser.) (2001) 719W (U.K.) (statement of Yvette Cooper, Sec. of State for Health), *available at* [http://www.publications.parliament.uk/cm200102/cmhansrd/vo010720/text/1072w66.htm#10720w66.html\\_sbhd1](http://www.publications.parliament.uk/cm200102/cmhansrd/vo010720/text/1072w66.htm#10720w66.html_sbhd1) (referencing NHI standards which ensure that “everyone with suspected cancer will be able to see a specialist . . . These arrangements were guaranteed for everyone . . .”).

156. *Compare* Neil C. Campbell et al., *Rural Factors and Survival from Cancer: Analysis of Scottish Cancer Registrations*, 82 BRIT. J. CANCER 1863, 1866 (2000) (finding a correlation between increased distance from a cancer center and survival as patients were less likely to be diagnosed before death, and noting that the correlation remained, albeit weaker, post-diagnosis), Neil C. Campbell et al., *Impact of Deprivation and Rural Residence on Treatment of Colorectal and Lung Cancer*, 87 BRIT. J. CANCER 585, 590 (2002) (finding distance from treatment facility a factor influencing receipt of treatment, but also noting that the degree of disease advancement at diagnosis is the most important factor for rural patients).

157. Thomas R. Oliver, *Population Health Rankings as Policy Indicators and Performance Measures*, 7 PREV. CHRONIC DIS. 1, 5 (2010), *available at* [http://www.cdc.gov/pcd/issues/2010/sep/pdf/10\\_0040.pdf](http://www.cdc.gov/pcd/issues/2010/sep/pdf/10_0040.pdf).

158. WILLIAM T. GORMLEY & DAVID LEO WEIMER, ORGANIZATIONAL REPORT CARDS 123–27 (1999).

159. Bevan & Hamblin, *supra* note 149, at 181, 184.

were confident that highlighting failure would result, not in reputational damage, but the promise of increased budgets. Such systems encourage underperformance of the public sector.”<sup>160</sup> He concluded that for a system of performance measurement to have an impact, it must be capable of inflicting reputational damage through information that is reliable, responsive to criticism from the organizations being assessed, understood in broad terms by the public, and published and widely disseminated.<sup>161</sup> A strong regulatory framework, be it NCI, private groups in the United States or a relaunched European Union-wide fight against cancer, could provide the infrastructure for producing the measures and the comparisons. The monitoring that is possible requires a strong coordinated framework. Integrated networks alone cannot provide the comparative measures.

### 3. Systems for Disseminating Results Throughout the Region

In the United States, most cancer patients are treated in community oncology clinics and hospitals.<sup>162</sup> However, until the creation of the National Comprehensive Cancer Network (NCCN) in 1995, these cancer centers lacked an integrated system to incorporate information gained through basic and translational research into community oncology practices.<sup>163</sup> The NCCN is an alliance of 21 of the nation’s leading cancer centers<sup>164</sup> which collaborate independently of NCI funding to develop and disseminate clinical practice guidelines in oncology.<sup>165</sup> “We decided a long

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160. Gwyn Bevan, *Performance Measurement of “Knights” and “Knaves”: Differences in Approaches and Impacts in British Countries after Devolution*, 12 J. COMP. POL’Y ANALYSIS 33, 34 (2010).

161. See Bevan & Hamblin, *supra* note 149, at 183–84 (discussing the facets of an effective performance measurement system that utilizes reputational components).

162. According to one source, 84% of US cancer patients are treated at community cancer clinics. *Petition to Stop Cancer Cuts Surpasses 50,000 Signatures: Petition to Be Delivered to Congress June 23*, PR NEWSWIRE, June 2, 2010, <http://www.prnewswire.com/news-releases/petition-to-stop-cancer-care-cuts-surpasses-50000-signatures-95435819.html>.

163. See Ellen Okin Powers, *The NCCN Guidelines: How Do They Relate to Community Oncology Practice?*, 1 COMMUNITY ONCOLOGY 98, 98 (2004) (explaining that the 1995 formation of the NCCN represented the first effort to develop oncology practice guidelines); *NCCN Disclosure Policy*, NAT’L COMPREHENSIVE CANCER NETWORK, <http://www.nccn.org/about/disclosure.asp#Guidelines> (last visited Jan. 22, 2011) (identifying NCCN guidelines as the product of an “evidence-based process integrat[ing] . . . the expert judgment of multidisciplinary panels of expert physicians from NCCN Member Institutions.”).

164. *About NCCN.com*, NAT’L COMPREHENSIVE CANCER NETWORK, <http://www.nccn.com/about-us.html> (last visited Jan. 21, 2011).

165. See *NCCN Disclosure Policy*, *supra* note 163 (stating that the funding for the NCCN guidelines comes from NCCN member institution dues and that the organization accepts no industry support for direct costs of guideline development). See also *Disclosure of NCCN Organizational Relationships*, NAT’L COMPREHENSIVE CANCER NETWORK, [http://www.nccn.org/about/financial\\_support.asp?p=about](http://www.nccn.org/about/financial_support.asp?p=about) (last visited Jan. 22, 2011) (listing NCI

time ago that we would make our guidelines available, not only to our academic centers but also to community oncologists and whoever else might be able to use them in decision-making.”<sup>166</sup> In other words, from the inception of the cancer center model in 1971 until the formation of the NCCN in 1995, there was no formalized effort to influence community oncology practices by the cancer centers themselves. However, the majority of cancer centers do not formally participate in this development effort because NCCN membership is expensive.<sup>167</sup>

Creating clinical practice guidelines in oncology is a critical early step in linking the research institutions and the community clinical establishments responsible for the majority of patient care. Additional measures, however, are also required. Once guidelines have been disseminated to community oncologists, there must be a mechanism to track adherence to the recommended therapies and continued surveillance to determine the impact of adoption of those practices in terms of improved health outcomes. The NCCN has never monitored how well, or to what extent, community oncologists implement their guidelines. In 2004, NCCN CEO William McGivney said, “I don’t know how well the guidelines are adhered to in the community setting . . . . Long term, we’re interested in involving the community in reporting . . . .”<sup>168</sup>

Only recently, the national system for cancer collaboration through the comprehensive cancer centers and cooperative research groups has disseminated clinical guidelines to community oncologists through the NCCN. And this has been done without any effort to monitor the impact of these guidelines.<sup>169</sup> Furthermore, there is no effort to monitor major cancer outcomes, such as five-year survival or quality of life, at the level of

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among the supporting organizations but reiterating that “all NCCN content is produced completely independently.”).

166. Powers, *supra* note 163, at 98.

167. *Compare NCI-designated Comprehensive Cancer Centers*, CANCER CTRS. PROGRAM (Jan. 3, 2011), [http://cancercenters.cancer.gov/documents/ccc\\_list.pdf](http://cancercenters.cancer.gov/documents/ccc_list.pdf) (listing forty NCI-designated comprehensive cancer centers, a figure not inclusive of all existing cancer centers in the United States), *with* Press Release, Nat’l Comprehensive Cancer Network, NCCN Survey Analyzes Clinical Trial Accrual at Academic Cancer Centers (June 4, 2010), *available at* <http://www.nccn.org/about/news/newsinfor.asp?NewsID=252> (listing the twenty-one NCCN members, twenty of which are on the NCI list).

168. Powers, *supra* note 163, at 99–100.

169. *See id.* at 100 (noting a desire to work with community oncologists at some point in the future in order to determine whether the guidelines provide them with valuable information); Caroline McNeil, *Putting NCCN’s Guidelines Into Practice: It All Depends on Data*, 89 J. NAT’L CANCER INST. 468, 469–70 (1997) (indicating that there was a plan to “creat[e] the systems to track practice patterns and outcomes and feed them into the large NCCN database” which met with many difficulties, e.g. system compatibility).



community oncologists, clinical sites, or institutional providers.<sup>170</sup> As a result, comparative analyses of the effectiveness of different community practices are not possible. Groups such as the NCCN appear to recognize the importance of monitoring performance indicators and using them to assess disparities in health outcomes, but funding this type of research is expensive and lacking.<sup>171</sup> A robust regulatory framework would monitor the adoption of the best practices and insist that performance indicators be institutionalized.

### *B. Coordinating Stakeholder Participation*

The success of the Children's Oncology Group and Europe Against Cancer networks is based, in part, on strong stakeholder participation. The stakes for participation are obvious for doctors, hospitals, researchers, and pharmaceutical companies. However, how and why patients can participate is a more controversial topic. Cancer care has been an area where patient and patient advocate participation is notable.<sup>172</sup> The influence of patient advocacy has been most evident in the fight against breast cancer, where a grass-roots mobilization of women demanding representation emerged in the late 1980's.<sup>173</sup> Almost spontaneously, in different parts of the country, organizations emerged from support groups where women met and discussed their experiences with breast cancer.<sup>174</sup> Their shared frustration with the cancer network led to the formation of the National Breast Cancer Coalition (NBCC) in 1991.<sup>175</sup> After the formation of the NBCC, funding

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170. See Sharon Begley, *What You Don't Know Might Kill You*, NEWSWEEK (Oct. 17, 2009), <http://www.newsweek.com/2009/10/16/what-you-don-t-know-might-kill-you.html> (reporting that there is only one community cancer center that makes detailed outcome data publicly available, and that the NCCN compiles data on how well cancer centers follow its guidelines but will not release information relating to specific centers).

171. Powers, *supra* note 163, at 100.

172. See Deborah Collyar, *Science and Society: How Have Patient Advocates in the United States Benefitted Cancer Research?*, 5 NATURE REV. CANCER 73, 73–74 fig. 1 (2005) (indicating the growing presence of cancer patient advocacy in political, fundraising, research, support, and watchdog capacities); Press Release, Am. Cancer Soc'y Cancer Action Network, Hundreds of Cancer Advocates Urge Lawmakers to Make Cancer Research and Prevention Funding a Top National Priority (Sept. 27, 2010), available at <http://www.Acscan.org/mediacenter/view/id/342/> (reporting on the lobbying efforts of cancer patients and survivors).

173. Collyar, *supra* note 172, at 73. But see Vicki Brower, *The Squeaky Wheel Gets the Grease: Research Funding Is Not Necessarily Allocated to Those Who Need It Most*, 6 EMBO REPS. 1014, 1014–16 & tbl.1 (2005) (suggesting that the highly visible and effective patient advocate campaign surrounding breast cancer has led to an imbalance in funding as other diseases with broader and arguably more devastating effects receive less).

174. See Collyar, *supra* note 172, at 74 fig.2 (revealing that cancer patients and advocates from diverse backgrounds formed support groups).

175. *NBCC's History*, NAT'L BREAST CANCER COAL., <http://www.stopbreastcancer.org/about/history/> (last visited Jan. 13, 2011) ("NBCC has been revolutionizing the breast cancer community since its inception in 1991.").

for breast cancer research increased to \$11.7 million in 1991,<sup>176</sup> \$77.3 million in 1992,<sup>177</sup> and \$252 million in 1993.<sup>178</sup> These funding increases were almost entirely attributable to the advocacy influence.<sup>179</sup> Similarly, the patient advocacy associated with the EAC strengthened the political power of the EAC programs, both at the European Union level and within the member states.<sup>180</sup> The ability of the EAC to interest patients in participating in its work was motivated by the strong commitment of the European Union commission to the cancer program.<sup>181</sup> The patient groups in the European Union and the member states recognized that their work was encouraged and often funded by the European Union.<sup>182</sup> When the European Union funding lapsed in 2002, the patient groups organized to refund the efforts and elevate cancer control again as a major issue on the

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176. See Emily S. Kolker, *Framing as a Cultural Resource in Health Social Movements: Funding Activism and the Breast Cancer Movement in the US 1990–1993*, 26 SOC. HEALTH & ILLNESS 820, 829 (2004) (identifying breast cancer spending at approximately \$19 million in 1990 and indicating that the funding increases began when NCCN began lobbying following its formation in 1991).

177. *Id.* at 824 (finding that the efforts of the National Breast Cancer Coalition to increase federal funding in 1991 “led to the appropriation of an additional 43 million for breast cancer research for fiscal year 1992 . . .”).

178. See MAUREEN H. CASAMAYOU, *THE POLITICS OF BREAST CANCER* 103–52 (2001) (describing the strategy and success of the National Breast Cancer Coalition’s lobbying efforts to expand government funding for cancer research) See also, Kolker, *supra* note 176 (“Encouraged by their initial success, activists lobbied Congress for an additional \$300 million in research funds for fiscal year 1993 . . . [increasing from] \$89 million in fiscal year 1991 to \$433 million in fiscal year 1993 . . .”).

179. See MAUREEN H. CASAMAYOU, *supra* note 178. See also Kolker, *supra* note 176, at 824 (identifying the NBCC as “[c]ritical to the efforts of breast cancer funding” as well as the “most forceful [organization] in publicly defining breast cancer as a problem of governmental neglect.”).

180. Hildrun Sundseth & Lynn Faulds Wood, *Cancer Patients – Partners for Change, in RESPONDING TO THE CHALLENGE OF CANCER IN EUROPE* 191, 194–96 (Michel P. Coleman et al. eds., 2008), available at [http://www.epha.org/IMG/pdf/Responding\\_to\\_the\\_challenge\\_of\\_cancer\\_in\\_Europe.pdf](http://www.epha.org/IMG/pdf/Responding_to_the_challenge_of_cancer_in_Europe.pdf) (identifying the primary purpose of advocacy groups like the European Cancer Patient Coalition, a patient-led organization, as “ensur[ing] that policy-makers, politicians, health professionals, the media and the general public recognize the serious burden of cancer and the need for concerted action. . .,” including lobbying the EU on behalf of Europe Against Cancer prior to its demise in 2002).

181. Memorandum, Eur. P’ship Action Against Cancer: Contribution of EU-Funded Research (June 24, 2009), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/294&format=HTML&aged=0&language=EN> (detailing the specifics of how the EU supports cancer research, the coordination of cancer research in Europe, and its commitment to cancer education).

182. See generally Sundseth & Wood, *supra* note 180, at 194–95 (illustrating that patient advocacy groups, as sophisticated politically-minded entities, are very aware of EU organizations’ roles in promoting, and most importantly funding, political action against cancer).

European Union agenda.<sup>183</sup> They realized that without that framework, their influence would wither.<sup>184</sup>

Yet the traditional justification for cancer patient involvement continues to be categorized as patient representation or fundraising for the medical cancer establishment.<sup>185</sup> There is a tendency to see patients and their advocates as allies in fundraising and recruitment for research, but not as full participants in system learning and improvement.<sup>186</sup> For example, the NCI has the Office of the Advocacy Relations, whose role is to locate people to serve on the plethora of NCI program and advisory committees.<sup>187</sup> Martha E. Gaines, the director of the Center for Patient Partnerships at the University of Wisconsin-Madison, indicates that there is not a clear understanding of the role of patient representation on the committees.<sup>188</sup> The lack of clarity exists on all sides: among patient advocates, researchers and clinicians.<sup>189</sup> Engaging patients through government advisory committees is also inadequate. Advisory committees are generally unsuccessful in providing meaningful patient input because there is a separation between the scientific expertise and the policy development.<sup>190</sup> The learning from the advisory committee is not easily shared with policy initiatives and the learning process does not function.

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183. *Id.* at 196 (“Anxious that cancer should remain firmly on the EU’s political agenda despite closure of the Europe Against Cancer programme in 2002, [the European Cancer Patient Coalition] encouraged Members of the European Parliament to set up an informal all-party forum – MEPs Against Cancer, or MAC.”).

184. See Hildrun Sundseth, *Shaping EU Cancer Policy*, 16 PUB. SERVICE REV.: EUR. UNION 282, 282 (2008), available at [http://www.publicservice.co.uk/article.asp?publication=European%20Union&id=353&content\\_name=Oncology%20Developments&article=10407](http://www.publicservice.co.uk/article.asp?publication=European%20Union&id=353&content_name=Oncology%20Developments&article=10407) (discussing that the ECPC necessarily had to engage Parliament in order to tackle the problem of cancer).

185. Deirdre O’Connell & Paola Mosconi, *An Active Role for Patients in Clinical Research?*, 67 DRUG DEV. RES. 188, 188 (2006). There are also some scholars who believe that patient influence over the healthcare system can be strengthened through consumerism and mechanisms like quality report cards. Patients who use report cards “act as consumers, in the sense that they weigh information gathered outside of a pre-existing clinical relationship in selecting a new provider.” Kristin Madison, *Patients as “Regulators”? Patients’ Evolving Influence Over Health Care Delivery*, 31 J. LEGAL MED. 9, 19 (2010).

186. See Madison, *supra* note 185, at 23–24 (highlighting the fact that patients generally are not knowledgeable and may not make the best decisions, and that few tools are available to help inform patients).

187. See *Mission & Vision*, OFFICE OF ADVOCACY RELATIONS, NAT’L CANCER INST., <http://advocacy.cancer.gov/about/mission> (last visited Jan. 13, 2011) (indicating that the Office of Advocacy Relations connects advocacy and National Cancer Institute groups to advance shared goals).

188. Interview with Martha E. Gaines, Dir., Ctr. for Patient P’ships, Univ. of Wis. Law Sch., in Madison, Wis. (July 8, 2009).

189. *Id.*

190. See David L. Weimer, *The Puzzle of Private Rulemaking: Expertise, Flexibility, and Blame Avoidance in U.S. Regulation*, 66 PUB. ADMIN. REV. 569, 571–72 (2006) (pointing out

The involvement achieved by integrated networks, however, goes much deeper than fundraising or serving on advisory committees. The networks demonstrate that when patients are an integral part of the research project as well as collaborate in treatment, the system could deliver a positive learning cycle that could lead to improving outcomes. Although traditional patient advocacy performs the needed functions of fundraising and legislation,<sup>191</sup> the learning process functions best when patients become active partners of the cancer care system.

A robust regulatory framework can motivate broad stakeholder participation and ensure that the participation is continuous and equitable. This is especially true for patient participation. The Children's Oncology Group was formed initially because there were not enough patients for individual investigators to conduct meaningful research.<sup>192</sup> Such an intolerable status quo motivated entrepreneurial pediatric oncologists to pool resources and share information with each other.<sup>193</sup> They also developed a system to engage patients and achieve impressive levels of clinical trial participation.<sup>194</sup> Similar conditions do not exist in other cancer networks,<sup>195</sup> and intentionally designed incentives may be necessary to engage stakeholders. While some of the critical stakeholders in the national cancer effort have something to gain by engaging in the learning process,<sup>196</sup> others have something to lose.<sup>197</sup> Coordinating these stakeholders and

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that, for advisory committees, integrating expertise into policy involves value trade-offs that might jeopardize such committees' credibility in making impartial judgment based on committee members' expertise).

191. Stephanie Cajigal, *The Patient Revolution*, 4 NEUROLOGY NOW 23, 24 (2008).

192. See Steve Benowitz, *Children's Oncology Group Looks to Increase Efficiency, Numbers in Clinical Trials*, 92 J. NAT'L CANCER INST. 1876, 1876 (2000) (noting two organizations were competing for a only small population, perhaps 8,000 to 10,000 children that are diagnosed with cancer each year, thus necessitating the creation of one group).

193. Gregory H. Reaman, *Clinical Advances in Pediatric Hematology & Oncology: Cooperative Group Research*, 3 CLINICAL ADVANCES HEMATOLOGY & ONCOLOGY 133, 135 (2005).

194. See W. Archie Bleyer, *The U.S. Pediatric Cancer Clinical Trials Programmes: International Implications and the Way Forward*, 33 EUR. J. CANCER 1439, 1443 (1997) (stating that the clinical trial participation rate for American children with cancer exceeds 70% compared to a participation rate of only 2% for adult cancer patients).

195. See Primo N. Lara et al., *Prospective Evaluation of Cancer Clinical Trial Accrual Patterns: Identifying Potential Barriers to Enrollment*, 19 J. CLINICAL ONCOLOGY 1728, 1728 (2001) (stating that only 2% to 4% of all newly-diagnosed adult cancer patients participate in clinical trials).

196. See Carol P. Somkin et al., *Organizational Barriers to Physician Participation in Cancer Clinical Trials*, 11 AM. J. MANAGED CARE 413, 414–15 (2005) (discussing the attitude of oncologists regarding clinical trials and finding the majority of oncologists believed such trials are good for both patients and doctors).

197. See *id.* at 415 (highlighting the concern of health plan leaders that the number of poorly-designed clinical trials continues to grow, which is a tremendous waste of resources and can threaten patient safety).

taking steps to reduce or compensate potential costs are necessary to align the incentives of multiple stakeholders. A regulatory framework can use the tools of aligning incentives, overseeing the recruitment of a wide range of stakeholders, and training the stakeholders in collaboration. The alignment of incentives may be delivered through providing additional government funding, changing reimbursement policy, or restricting access of uncooperative members to important resources.<sup>198</sup>

### *C. Supporting Physician Decision-making*

Physicians who provide clinical care require information and assistance to provide the best care for their patients. Their decision-making is improved through the information produced by basic research, experience embodied in protocols, and knowledge of appropriate clinical trials. A substantial aspect of the success of the integrated networks is the support they provide to clinical physicians.<sup>199</sup> The EAC's success in the early period is related to the codes and protocols that it produced and disseminated.<sup>200</sup> The creation of cancer registries throughout the European Union also provided information that could be utilized by the physicians.<sup>201</sup> In the COG, the clinical physicians are the essential leaders assisting each other through their well-functioning, coordinated system.<sup>202</sup>

However, there is substantial evidence that the physicians do not receive this support in other areas of disease.<sup>203</sup> A survey conducted by the American Society of Clinical Oncology found that physicians face

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198. See David L. Weimer, *Stakeholder Governance of Organ Transplantation: A Desirable Model for Inducing Evidence-Based Medicine?* 4 REG. & GOVERNANCE 281, 282–83, 291, 293, 295, 298 (2010) (indicating that in the context of organ transplantation, other sources of government funding, questions about the fairness of access to rulemaking, and reimbursement considerations have influenced incentives).

199. See NAT'L CANCER INST., *supra* note 28 (indicating that researchers, cancer centers, and community physicians work together to support clinical trials).

200. See Peter Boyle et al., *European Code Against Cancer and Scientific Justification: Third Version (2003)*, 14 ANNALS ONCOLOGY 973, 977 (2003) (indicating that, given the rising number of cancer cases in Europe, the European Code Against Cancer was introduced to reduce cancer incidence and improve outcomes).

201. See EUR. COMM'N, EUROPE AGAINST CANCER: OPTIMISATION OF THE USE OF REGISTRIES FOR SCIENTIFIC EXCELLENCE IN RESEARCH 1 (2008), available at [http://cordis.europa.eu/fp7/coordination/pdf/eurocourse\\_en.pdf](http://cordis.europa.eu/fp7/coordination/pdf/eurocourse_en.pdf) (stating that cancer registries have been essential in strengthening the quality and access to cancer occurrence and outcome information).

202. Julie A. Ross & Andrew F. Olshan, *Pediatric Cancer in the United States: The Children's Oncology Group Epidemiology Research Program*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1552, 1552 (2004).

203. See ASCO Clinical Trials Workshop Provides Guidance for Community Practices, 1 J. ONCOLOGY PRAC. 8, 8 (2005) (noting that physician barriers to clinical trial participation are well-known and thoroughly documented).

significant barriers with respect to time, staff, and resources that hinder patient referrals to clinical trials.<sup>204</sup> Physicians must keep track of complicated entry criteria for many trials to determine which patients are eligible for which trials,<sup>205</sup> identify appropriate patients, introduce the concept of clinical trials to unfamiliar patients or providers,<sup>206</sup> and deal with insurance company pre-approval processes prior to patient participation. All of these steps must be done amidst a busy clinic with patients waiting.<sup>207</sup> This process is time intensive and poorly reimbursed, if at all.<sup>208</sup> Physicians also lack support from the academic environment.<sup>209</sup> A recent IOM report quoted a cancer researcher:

[W]orking in oncology clinical cooperative groups is frequently not well rewarded with academic recognition and advancement . . . . [T]his is caused by a number of factors, including: a lack of awareness by promotions committees of what such research entails; the collaborative nature of the research, which makes it difficult to mark individual accomplishments; the time factor involved in clinical research; and the under-funding of much of this effort.<sup>210</sup>

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204. See *id.* (highlighting the financial costs, including staff and office expenses, and time costs of conducting clinical trials).

205. See Philip P. Breitfeld et al., *Web-based Decision Support for Clinical Trial Eligibility Determination in an International Clinical Trials Network*, 24 *CONTROLLED CLINICAL TRIALS* 702, 703 (2003) (noting that the entry criteria for clinical trials is becoming increasingly complex).

206. See Robert L. Comis et al., *Public Attitudes Toward Participation in Cancer Clinical Trials*, 21 *J. CLINICAL ONCOLOGY* 830, 830–31, 834 (2003) (discussing the point that determining eligibility for clinical trials may be burdensome, that physicians often need to explain the particulars of a clinical trial to the patients, and that a high percentage of patients are unfamiliar with many aspects of clinical trials).

207. See Ezekiel J. Emanuel et al., *The Costs of Conducting Clinical Research*, 21 *J. CLINICAL ONCOLOGY* 4145, 4149–50 (2003) (discussing challenges and obstacles discouraging physicians from enrolling patients into clinical trials); Ana S. Iltis, *Costs to Subjects for Research Participation and the Informed Consent Process: Regulatory and Ethical Considerations*, 26 *IRB: ETHICS & HUM. RES.*, Nov.–Dec. 2004, at 9, 11–12 (noting that physicians have very busy schedules and that a discussion of cost and reimbursement with individual patients may not be the best use of a physicians' time).

208. See Iltis, *supra* note 207, at 11 (stating that a discussion of cost and reimbursement with patients may not be ideal when physicians already have such busy schedules and costs vary from patient to patient); *IOM Releases Recommendations for Cancer Clinical Trials*, *HEMONCTODAY.COM* (Apr. 16, 2010), <http://www.hemonctoday.com/article.aspx?rid=63268> (noting that over a ten year period the per-case reimbursement had not increased and reflected, in 2005, only about a third of the actual cost per case).

209. See Lenore M. Buckley et al., *Attitudes of Clinical Faculty About Career Progress, Career Success and Recognition, and Commitment to Academic Medicine*, 160 *ARCHIVES INTERNAL MED.* 2625, 2627–28 (2000) (noting that career development programs are often not in place for clinical researchers).

210. *PATLAK ET AL.*, *supra* note 74, at 50.

The knowledge that physicians need a variety of support in order to provide the best care has been demonstrated and documented.<sup>211</sup> Yet, the regulatory framework that could mandate and fund such supports has not been effectuated or has been partially dismantled.

#### *D. Guaranteeing Fairness of Data*

Strong oversight and monitoring prevents conflicts of interest. Pharmaceutical companies often conduct or sponsor a large proportion of clinical trials.<sup>212</sup> As a result, actual and potential conflicts of interest affect all phases of the clinical trials from design to data collection to reporting of the results.<sup>213</sup> The dependence on the industry for financial support of the trials is due to the inadequate insurance reimbursement for participants.<sup>214</sup> Companies often pay for the drugs and medical devices used in the trials,<sup>215</sup> and the doctors involved in the trials do not always reveal their connection to those commercial interests.<sup>216</sup> Another potential ethical concern is the current practice of employing “ghost writers” to generate the protocols and manuscripts that are then reviewed and approved by scientists and clinicians.<sup>217</sup>

A recent report outlines an oversight system for conflicts in clinical trials.<sup>218</sup> The report suggests expanding the purview of the institution based regulatory system to include analyzing potential conflicts of interest.<sup>219</sup> This local review would be framed by federal mandates that outline

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211. See, e.g., *id.* at 43–44 (highlighting the need for financial support and greater institutional communication and cooperation).

212. Thomas Bodenheimer, *Uneasy Alliance — Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539, 1539 (2000).

213. *Id.* at 1541 (identifying common problems relating to conflicts of interest).

214. See generally Gerardo Colon-Otero et al., *Disparities in Participation in Cancer Clinical Trials in the United States: A Symptom of a Healthcare System in Crisis*, 112 CANCER 447, 450 (2008) (explaining that since NCI-sponsored clinical trials are poorly reimbursed and pharmaceutical clinical trials are often better reimbursed, the industry tends to favor clinical trials conducted by pharmaceutical companies).

215. *Cancer Clinical Trials*, NAT'L CANCER INST. (Apr. 27, 2010), [http://www.cancer.gov/images/documents/87c21e93-ad1e-4bf1-b441-10bc58751060/Fs2\\_11.pdf](http://www.cancer.gov/images/documents/87c21e93-ad1e-4bf1-b441-10bc58751060/Fs2_11.pdf).

216. See KATHLEEN M. BOOZANG ET AL., CTR. FOR HEALTH & PHARM. LAW & POLICY, CONFLICTS OF INTEREST IN CLINICAL TRIAL RECRUITMENT & ENROLLMENT: A CALL FOR INCREASED OVERSIGHT I (2009), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1515762](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1515762) (explaining that the compensation methodologies create potential conflicts of interests and thus would cause a doctor to hesitate in revealing his or her commercial interests).

217. Duff Wilson & Natasha Singer, *Ghostwriting Is Called Rife in Medical Journals*, N.Y. TIMES, Sept. 11, 2009, at B5, [http://www.nytimes.com/2009/09/11/business/11ghost.html?\\_r=2](http://www.nytimes.com/2009/09/11/business/11ghost.html?_r=2).

218. See BOOZANG ET AL., *supra* note 216, at 1–2 (explaining that federal regulations should be amended and new requirements added in order to avoid conflicts in clinical trials).

219. *Id.* at 13.

acceptable parameters.<sup>220</sup> This proposal is an example of how multilevel frameworks can provide coordinated oversight without limiting local variation and experimentation.<sup>221</sup> A revised institutional review board (IRB) system could also encourage physician willingness to engage in advance treatment.<sup>222</sup> The current outdated and cumbersome IRB process is highlighted as contributing to physicians' unwillingness to engage in the research and clinical process.<sup>223</sup>

#### IV. RECONSTITUTING THE REGULATORY FRAMEWORK

There is an effort underway to reconstitute the frameworks.<sup>224</sup> In the United States, the recent IOM report detailing the failures of cancer trials indicates that the inadequacy of the framework in the United States is evident.<sup>225</sup> Leaders from the cancer nonprofits such as the Lance Armstrong Foundation, cancer researchers, and evidence-based reformers have introduced several legislative packages that may coordinate and strengthen the interrelationship between stakeholders and endorse new tools.<sup>226</sup> The organizers of these legislative initiatives envision a formal framework embodied in a coordinated directive. The directive includes a commitment to funding, comparative information, regulatory parameters, and stakeholder engagement.

After the European Union funding dwindled in 2002, the EAC left key constituencies in place around which new initiatives could be developed. The members of the European Parliament, the patient coalition, the network of epidemiologists that were previously funded through the European Union Research Frameworks Program, and the pharmaceutical industry have now rallied and are pursuing the reinvigoration of a regulatory framework.<sup>227</sup>

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220. *See id.* at 8, 13 (explaining that a system of independent IRB's has developed to facilitate compliance with federal review requirements).

221. *See generally id.* at 25–33 (proposing a system of oversight which would integrate national concerns with local practices while not disrupting such).

222. *See* Scott Burris, *Regulatory Innovation in the Governance of Human Subjects Research: A Cautionary Tale and Some Modest Proposals*, 2 REG. & GOVERNANCE 65, 68, 70 (2008) (explaining that the current IRB system is arbitrary, expensive, and unreliable and discourages participation).

223. *See id.* at 70–74 (explaining various problems with the IRB model as it currently exists).

224. *See generally* NASS ET AL., *supra* note 9, at 1 (reviewing cancer trial programs in the U.S.).

225. *Id.* at 2–4.

226. For example, legislation introduced in 2009 included the Oncology Care Quality Improvement Act of 2009, H.R. 2939, 111th Cong. (2009); the Comprehensive Care Improvement Act of 2009, H.R. 1844, 111th Cong. (2009); the Access to Cancer Clinical Trials Act of 2009, S. 488, 111th Cong. (2009); and the Access to Cancer Clinical Trials Act of 2009, H.R. 716, 111th Cong. (2009).

227. *See* COMM'N OF THE EUR. CMTYS., COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE



The launch of the European Partnership Action Against Cancer in 2009 provides a planning process and perhaps new waves of funding.<sup>228</sup> The partnership has laid out several ambitious goals, such as “achieving 100% population coverage of screening for breast, cervical and colorectal cancer” by 2013, reducing inequalities in cancer mortality by 70% by 2020, and coordinating one-third of cancer research from all funding resources across the European Union by 2013.<sup>229</sup> To increase the funding from and collaboration with the private sector, the European Commission and the pharmaceutical industry “set up a joint initiative to support the faster discovery and development of better medicines for patients: the Innovative Medicines Initiative (IMI).”<sup>230</sup> The objective is for all Member States to have integrated cancer plans.<sup>231</sup> The Commission’s long-term goal is to reduce cancer by 15% by 2020.<sup>232</sup>

Initiatives in both regions identify a strengthened regulatory framework as essential for a new period of cancer governance. In reconstituting the frameworks, the reformers are proposing to increase the coordination and engagement of stakeholders,<sup>233</sup> intensify the production and utilization of comparative information,<sup>234</sup> and encourage accountability through benchmarks and standardization.<sup>235</sup> Both initiatives also emphasize dissemination of knowledge throughout their region to achieve equitable

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AND THE COMMITTEE OF THE REGIONS ON ACTION AGAINST CANCER: EUROPEAN PARTNERSHIP 2 (2009), *available at*

[http://ec.europa.eu/health/ph\\_information/dissemination/diseases/docs/com\\_2009\\_291\\_en.pdf](http://ec.europa.eu/health/ph_information/dissemination/diseases/docs/com_2009_291_en.pdf).

(explaining that the European Parliament and Council of the European Union have shown their political commitment and given strategic direction to future European cancer activities and have proposed a European Partnership for Action Against Cancer to pursue the reinvigoration of a regulatory framework).

228. *See id.* (explaining that providing a framework for identifying and sharing information, capacity and expertise in cancer prevention and control, and by engaging relevant stakeholders across the European Union in a collective effort).

229. *Id.* at 5–7.

230. Memorandum, Eur. P’ship Action Against Cancer, *supra* note 181.

231. *Id.* *See also* COMM’N OF THE EUR. CMTYS., *supra* note 227, at 3 (explaining that the objective to more effectively coordinate activities and actions taken within different policy areas by Member States and other stakeholders, with the aim of reducing the increasing and unequal European burden of cancer is to propose a European Partnership for Action Against Cancer).

232. COMM’N OF THE EUR. CMTYS., *supra* note 227, at 3.

233. *Id.* at 2.

234. *Id.*

235. *See id.* at 3, 7–8 (explaining that using a Healthy Life Years indicator and coordinating the European Partnership for Action Against Cancer would help achieve these goals); Memorandum, Eur. P’ship Action Against Cancer, *supra* note 181 (explaining that the European Partnership Action Against Cancer will bring together the EU, national and regional research programs, activities and policies).

care for all cancer patients.<sup>236</sup> These two initiatives promise a better fight against cancer.

#### CONCLUSION

This article argues that supportive regulatory frameworks are necessary for clinical care networks to work properly.<sup>237</sup> Integrated networks are vulnerable when the frameworks fail to provide the necessary resources, accountability, fairness, and participation.<sup>238</sup> This research coincides with the emergence of a substantial literature on how other regulatory tools such as checklists, clinical guidelines, comparative effectiveness research, and performance-incentives can play a role in improving medical care.<sup>239</sup> The authors of this article believe that more interdisciplinary research and analysis is needed to improve the governance and performance of the health care system, including the current approaches to cancer surveillance and treatment. Understanding how governance shapes health outcomes is a crucial enterprise.

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236. COMM'N OF THE EUR. CMTYS., *supra* note 227, at 3.

237. *See supra* Part III.

238. *See supra* text accompanying notes 126–29.

239. *See generally* ATUL GAWANDE, THE CHECKLIST MANIFESTO-HOW TO GET THINGS RIGHT (2010) (making the case that the use of simple checklists before medical procedures can significantly improve outcomes).

