



Legal Studies Research Paper Series Paper No. 1128

14 Journal of Health Care Law & Policy
(forthcoming)

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Two Examples from the United States
and the European Union**

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How Regulatory Frameworks Fight Cancer: Two Examples from the United States and the European Union

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Abstract

Integrated networks of doctors, patients, and hospitals are a major technique of cancer governance. They enable stakeholders to pool information and resources and achieve systematic learning. Two groups, the childhood cancer group in the US and the Europe Against Cancer initiative, are examples of network governance. Both demonstrate learning processes, production of new data and dissemination, 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 networks work properly. Integrated networks are vulnerable when the frameworks fail to provide the necessary accountability, fairness and participation.

Introduction:

The fight against cancer is now a timely topic. President Obama in his State of the Union address endorsed a renewed fight.^a Elizabeth Edwards listed it as the next big item for the Obama administration in the second half of his term.^b In part the political proposals for a renewed fight are based on the fact that the results of the first war have been disappointing. Cancer is now the number one cause of death in the United States. The response to the political attention from

^a President Barack Obama, State of the Union Address (Jan. 27, 2010).

^b Elizabeth Edwards, *Fight Cancers, Win Elections*, *N.Y. Times*, July 16, 2010, available at <http://www.nytimes.com/2010/07/18/opinion/18obama.html?pagewanted=all> (last visited on July 22, 2010).

many in the cancer establishment has been two fold. First there is a group that says that the results have been better than reported and that the criticisms are not entirely fair.^c A second group agrees that more could be done but points to the answer as individual therapies based on genetic factors or more money for research.^d In this current debate there has been little attention to the role of inadequate governance and ineffective use of regulatory tools as a contributing cause to the disappointing results.

This paper is an interdisciplinary and international comparative study. The authors include a political scientist, a law professor and medical oncologist. The team included experts on the organization of cancer and health care in European Union and the United States. The authors researched the two fights against cancer that have been in process over the past several decades. The authors used archival research of governmental reports, analyzed medical studies, looked at the regulation and legal literature and conducted in face interviews.

The paper is based on an analysis of two successful projects to improve cancer care outcomes. The first project is the childhood cancer group based in the United States. The second is the European Union fight against cancer. The paper documents how well-organized networks of experts using data and coordinating research and clinical care can obtain good results. It also demonstrates that when the broader institutional support for these networks is weakened, the ability to continue to produce good results declines. It is a counter-intuitive result for many who do not see how governmental action and structures can produce better results for cancer patients. In recent months an important study just was issued by the prestigious Institute of Medicine on cancer trials that pinpointed poor results in cancer trials to the ill-coordinated and organized system currently functioning.^e The fact that this report has been widely reported and discussed in both the popular and medical media indicates that there may be emerging a broader understanding that legal and policy tools are important aspects in achieving better care and outcomes.^f

^c See generally Susan M. Gapstur & Michael J. Thun, *Progress in the War on Cancer*, 303 J. AM. MED. ASS'N 1084 (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 it actually is).

^d See generally Alan G. Thorson, *Progress in Cancer Care: A Rational Call To Do Better*, 60 CAL. CANCER J. CLINICIANS 7 (2010) (indicating that a lot of progress has been made in the war on cancer, but continuous time and resource investment in cancer research is crucial to accelerate the slow pace of progress).

^e See generally SHARYL J. NASS, HAROLD L. MOSES & JOHN MENDELSON, A NATIONAL CANCER CLINICAL TRIALS SYSTEM FOR THE 21ST CENTURY: REINVIGORATING THE NCI COOPERATIVE GROUP PROGRAM (Institute of Medicine ed., 2010) (reviewed the cancer trial system in the US and concluded that the process is inefficient and counterproductive, and often leads to unacceptable delays).

^f See generally Robert C. Young, *Cancer Clinical Trials – A Chronic but Curable Disease*, 363 NEW ENG. J. MED.

The paper is organized in four sections. The first section discusses the history of the institutional fights against cancer in the United States and the European Union. The second section describes two integrated networks that are linked to the governmental fights against cancer. The childhood cancer group is the US based example and the Europe Against Cancer is the EU example. The section describes how these networks shared three aspects that contribute to their effectiveness: production of data and dissemination of data, financial support for research and treatment and engagement of stakeholders. Section three describes how regulatory frameworks in which networks are embedded are necessary for continued improvement and learning. The section shows how regulatory frameworks can provide accountability for performance, coordinate stakeholder participation, support physician decision-making and guarantee fairness of data. However, if the regulatory frameworks failed to adequately accomplish the tasks and utilize the available governance tools, the networks, will not achieve their potential. The final section 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. The frameworks must be strengthened. In both regions, medical and political leaders are initiating legislative and regulatory initiatives.

I The Early United States and European Union Context

The history of United States and the European Union cancer programs demonstrate how governance can affect cancer outcomes. In both regions, there has been a vision of regulatory frameworks that would enable the production of new knowledge, transference of that knowledge, and utilization in patient care. The motivating force behind this vision was networks of medical experts and important political leaders.

In his State of the Union address 1971, President Richard Nixon asked the Congress for appropriations “to launch an intensive campaign to find a cure for cancer . . .”^g The commitment took form of the National Cancer Act of 1971,^h which led to increased funding for cancer research. The original vision of the National Cancer Act (NCA) was that the National Cancer Institute (NCI) would be given both the responsibility and authority to coordinate all cancer-

306 (2010) (pointing out that the recommendations in the new IOM report are similar to those made in the past, which, if implemented, will greatly improve the clinical trials program and align it with the needs of 21st-century cancer medicine); Editorial, *Faltering Cancer Trials*, *N.Y. Times*, April 24, 2010, available at <http://www.nytimes.com/2010/04/25/opinion/25sun1.html> (last visited on July 22, 2010) (warning that the deficiency of the current cancer trial system will jeopardize President Obama’s ambitious health care reforms and “his audacious goal of finding ‘a cure for cancer in our time’ will have almost no chance at all”).

^g President Richard Nixon, State of the Union Address (Jan. 25, 1971).

^h Pub. Law No. 92-218, 85 Stat. 778.

related activities. The NCI was expected not only to support basic research but also to provide leadership in translating scientific findings to actual improvement in bedside cancer care.ⁱ By the 1980s, the NCI began to provide financial support to institutions that perform basic, clinical and epidemiological research. Institutions that received these grants were designated Comprehensive Cancer Centers. These centers were expected to boost translational research and help disseminate newly developed treatments and interventions to community physicians. Before and after the 1971 legislation, NCI also established grant-supported cooperative research groups to bolster translational research.^j A typical cooperative research group includes members such as comprehensive cancer centers and non-NCI-designated academic cancer centers around the country. It was hoped that through cancer centers and cooperative research groups, researchers and clinicians would collaborate to ensure wide adoption of new standards of practice, and to bridge the critical gap between science and treatment and bring real improvement to the cancer care system.

The efforts of the European Union (EU) against cancer are based on a different set of circumstances than the United States. The authority to provide health care is based almost entirely in the member states, but the performance of the member states was uneven by geography and types of cancer. Starting in 1985 the EU launched an initiative against cancer, entitled Europe Against Cancer (EAC). The EAC was an elaborate plan developed by epidemiologists from across the EU with the assistance of the political leaders, accompanied by modest funding to support the development of new agencies and research.^k The goal was to improve the cancer care outcomes in each member state through linking the member state networks and institutions and creating European wide data information. The Europe Against Cancer (EAC) is considered to be the pioneering program to use the European Union as a platform to coordinate healthcare across the member states.^l

II. Integrated Networks

This section discusses two integrated networks: the childhood cancer groups and the

ⁱ MARIA E. HEWITT & JOSEPH V. SIMONE, ENSURING QUALITY CANCER CARE 19 (Nat'l Cancer Pol'y Board ed., 1999).

^j National Cancer Institute (NCI) Website, <http://www.cancer.gov> (follow "Cancer Topics" hyperlink; follow "NCI Fact Sheets" hyperlink; follow "About NCI" hyperlink; then follow "NCI's Clinical Trials Cooperative Group Program" hyperlink) (last visited on July 22, 2010).

^k Louise Trubek, Mark Nance & Tamara Hervey, *The Construction of Healthier Europe: Lessons from the Fight Against Cancer*, 26 WIS. INT'L L. J. 804, 814-6 (2008).

^l See François Briatte, *The Europeanization of Health System Performance: The EURO CARE Study and Cancer Control in England 4-6* (2010) (unpublished manuscript, on file with authors, presented in "Council for European Studies (CES) Seventeenth International Conference, Montreal: Canada (2010)").

European-wide cancer programs. These two networks have been successful in integrating learning and practice.

Through the childhood cancer group, significant improvement in survival for acute lymphoblastic leukemia (ALL) has been achieved. The 5-year survival for ALL jumped from nearly 15 percent to over 60 percent between 1969 and 1975, and has now reached about 80 percent.^m Some researchers argue that the biological and genetic differences between childhood and adult cancers make childhood cancer easier to treat. However, others point to the unique network among childhood cancer researchers, clinicians, and patients as the key. The network was created with the NCI's financial support. In 2000, four pediatric cancer groups merged together to form the Children's Oncology Group (COG), one of the 12 cooperative research groups currently funded by NCI to conduct clinical research. Unlike other cooperative groups, the childhood cancer group achieved substantially higher participation rates in clinical trials and methodical comparative effectiveness studies than other groups. These high participation rates enabled researchers to improve clinical treatments without a major breakthrough in drug development.ⁿ 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.^o

The EAC is another well-known example of such a network. From 1986 to 2002, three action plans, funded by the European Commission, were established to combat cancer. The development of these action plans, as well as the use of funding provided by the EAC program, was driven by a network of high profile epidemiologists, oncologists, activist patients, and policy-makers. The EAC is an example of a network utilizing a multilevel monitoring system. This system uses tools of public reporting, league tables, cancer registries, and practice guidelines. This multilevel EU system by producing comparative data has enabled the member states to analyze their performance on cancer outcomes using the comparative statistics.^p This information enabled, for example, the United Kingdom to substantially revise their cancer

^m Maura O'Leary et al., *Progress in Childhood Cancer: 50 Years of Research Collaboration: a Report from the Children's Oncology Group*, 35 SEMINARS IN ONCOLOGY 484, 485 (2008).

ⁿ Cf. Joseph V. Simone, *History of the treatment of childhood ALL: A paradigm for cancer cure*, 19 BEST PRACTICE & RES. CLINICAL HAEMATOLOGY 353, 357 (2006) (mentioning in passing that "no new major therapeutic agent has been developed in the last 30 years in part because drug companies are not interested in childhood cancer because the sales market is too small").

^o 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, 1661-2 (2003).

^p Trubek, Nance & Hervey, *supra* note 11, at 814-26.

treatment and allocate substantially more funding to cancer treatment.^q The information on the prevalence of lung cancer assisted in the passage of E.U. law controlling tobacco usage.^r

Successful integrated networks not only facilitate opportunities for collaboration, but also change the ways that research is done, patients are treated, and public health interventions are implemented. Examination of the stories of the childhood cancer group and the Europe Against Cancer 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, in particular phase III trials.^s The clinical trials conducted at the childhood cancer group worked extremely well for childhood cancer. Very high rates of patient participation in clinical trials allow the network to compare the outcome of different interventions and improve the overall effectiveness of cancer care. “[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.”^t The childhood cancer group also uses epidemiological studies to identify disparities in outcomes based on race, ethnicity, and social economic background.^u

The use of clinical guidelines is essential to the dissemination of knowledge produced in clinical trials. The childhood cancer group, along with several other cooperative groups, publishes trial results and preferred treatment protocols to their members. The childhood cancer group routinely produces, revises and distributes clinical guidelines to ensure that most children

^q See Briatte, *supra* note 12, at 16-19 (discussing that the poor health performance of the UK, illustrated by the EURO CARE-2 study, pushes the UK government to spend more attention and money toward the NHS, cancer services in particular, in an attempt to avoid political blame).

^r HEALTH SYSTEMS GOVERNANCE IN EUROPE: THE ROLE OF EUROPEAN UNION LAW AND POLICY 269-72 (Elias Mossialos et al. eds., 2010).

^s See SUZANNE H. REUBEN, THE PRESIDENT’S CANCER PANEL, TRANSLATING RESEARCH INTO CANCER CARE: DELIVERING ON THE PROMISE, 2004-2005 4 (2005) (discussing the importance of translational research, to which clinical trials are basic element, in the fight against cancer).

^t CureSearch Website, <http://www.curesearch.org/> (follow “Newsletter” hyperlink under “News and Media”; then follow “View the CureSearch E-newsletter archives” hyperlink; then follow “August 2006” hyperlink) (last visited on July 22, 2010).

^u Interview with Paul M. Sondel, Professor of Pediatrics, Human Oncology and Medical Genetics, University of Wisconsin School of Medicine and Public Health, in Madison, WI (July 27, 2009).

diagnosed with cancer are treated with the best interventions available. 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.^v

Similarly, members of the EAC network worked hard to expand and improve existing cancer registries by forming the European Network of Cancer Registries (ENCR). “These registries contained information on cancer incidence, mortality, and prevalence from across Europe.”^w The ENCR serves as a cancer surveillance system and the information obtained is used to develop the European Code Against Cancer. The Code is “a collection of recommended protocols on cancer screening, as well as best practices for the prevention and treatment of all cancers.”^x These protocols “have become the industry standard in cancer treatment in Europe and are continually updated to reflect new information on cancer control,” and were also used by advocacy groups to push national governments to reduce the overall cancer burden.^y

B. Financial Support for Research and Treatment.

Financial support is crucial in achieving sustainable network integration. In the United States, the lack of universal coverage for health care is acknowledged as a deterrent to system improvement. Inconsistent methods of determining payment for treatments also add to difficulties in making cancer care affordable. Enrollment in cancer trials is one of the treatment options often rejected by the payer, and such payment obstacles often discourage trial participation.^z An Institute of Medicine 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.”^{aa}

However, the childhood cancer group has been successful in overcoming the financial barrier. The childhood cancer group locates financial resources from disparate insurance payors. The childhood cancer group, through its CureSearch website, provides substantial information on accessing and advocating for payment. Private insurance companies, influenced by consistent patient advocacy, have cooperated by approving coverage for participation in clinical trials. Their rapid approval recognizes clinical trials are accepted standard of care for treatment.^{bb} The

^v *Id.*

^w Trubek, Nance & Hervey, *supra* note 11, at 816.

^x Trubek, Nance & Hervey, *supra* note 11, at 818.

^y Trubek, Nance & Hervey, *supra* note 11, at 818-9.

^z INSTITUTE OF MEDICINE, MULTI-CENTER PHASE III CLINICAL TRIALS AND NCI COOPERATIVE GROUPS: WORKSHOP SUMMARY 47-50 (2009).

^{aa} *Id.*, at 44.

^{bb} Gina Kolata & Kurt Eichenwald, *In Pediatrics, a Lesson in Making Use of Experimental Procedures*, *N.Y. Times*,

childhood cancer group also organized families, including cancer survivors, to raise funding for care and to support specific federal legislation for research. The Caroline Pryce Walker Conquer Childhood Cancer Act of 2008 is one example.^{cc} Financial support from the EU was crucial to the EAC's research and information gathering function. The league tables produced by that information demonstrated for example that the UK had poor results in cancer outcome. These EAC league tables convinced the UK in the Blair era to fund more cancer treatment.^{dd} Since the introduction of increased funding, there has been an improvement in UK cancer outcome.^{ee}

C. Engagement of All Stakeholders

Engaging network members is critical for the learning process. The engagement of patients is especially crucial. In the childhood cancer group, patient interest in clinical trials is an essential part of information gathering. The childhood cancer group was able to help patients through careful support by the oncologists and other medical personnel at the cancer centers.^{ff} The childhood cancer group provided patients with trustworthy doctors and hospital centers, long-term commitment to them and their families, and financial support. They also quickly informed patients about available trials and facilitated consent. Many parents were willing to travel far distances to obtain the best care. As a result, there were higher rates of clinical trial participation and a higher capacity to conduct comparative effectiveness studies in the childhood cancer group than in other cancer networks.^{gg}

The EAC 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). The ECPC is now active in Europe, but it also distributes comparative information on outcomes on the national and local level. The ECPC works closely with the researchers funded through the EU and advocates for continued funding. In addition, they helped develop the Members of Parliament Against Cancer caucus at the European

October 3, 1999, available at <http://www.nytimes.com/1999/10/03/us/in-pediatrics-a-lesson-in-making-use-of-experimental-procedures.html> (last visited on July 22, 2010).

^{cc} Public Law 110-285, 122 Stat. 2628-2631.

^{dd} Briatte, *supra* note 12, at 16-19.

^{ee} Yvette Cooper, Cancer. London: Her Majesty's Stationery Office. Commons Hansard [Parliamentary Record] 372 (20 July 2001)(372): c718W-c719W, 2001.

http://www.publications.parliament.uk/pa/cm200102/cmhansrd/vo010720/text/10720w66.htm#10720w66.html_sbhd1

^{ff} *Supra* note 21.

^{gg} See O'Leary et al., *supra* note 13, at 485; Harris Interactive, *Misconceptions and Lack of Awareness Greatly Reduce Recruitment for Cancer Clinical Trials* (2001),

<http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=222> (last visited on July 22, 2010).

Parliament.^{hh}

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 allow integrating learning and standardization. The regulatory frameworks, the National Cancer Act and the EAC, were crucial in the early development of two integrated networks: the childhood cancer group and European-wide cancer programs. However, in recent years, there is a reduction in the effectiveness of the US and the EU cancer programs. The ineffectiveness is based in part on the weakening of the regulatory framework. In recent decades, the U.S. regulatory framework created in the 1970s shifted away from translational research and from systematic coordination. NCI delegated the goal of connecting research and clinical care to institutions like comprehensive cancer centers and cooperative research groups. The collaboration between researchers and clinicians proved spotty and difficult to maintain.ⁱⁱ Moreover the record of achievement is not impressive. The reductions in cancer mortality have been relatively weak compared to more rapid progress in heart disease and other major health threats. 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. After almost 40 years and \$200 billion spent on cancer research, there have been disappointing returns on the nation's investment. In 2010, it is estimated that 1,529,560 new cancer cases are expected to be diagnosed and 569,490 Americans are expected to die of it in the U.S.^{jj} Globally, cancer is poised to become the leading cause of death.^{kk}

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.^{ll} Analysts often attribute the unsatisfactory outcome of the first war on cancer to an overwhelming focus on basic research and dominance of a “cell-kill paradigm.”^{mmm} A recent highly critical Institute of Medicine(IOM)report on cancer clinical trials system for example highlights that the “complex trials system has become inefficient and cumbersome” and that “a robust, standing cancer clinical trials network is essential to effectively

^{hh} Trubek, Nance & Hervey, *supra* note 11, at 833-4.

ⁱⁱ See President's Cancer Panel, *The National Cancer Program: Assessing the Past, Charting the Future: 1999 Annual Report* (1999), <http://deainfo.nci.nih.gov/advisory/pcp/pcp99rpt/99report.htm> (“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.”) (last visited on July 22, 2010).

^{jj} AMERICAN CANCER SOCIETY, *CANCER FACTS & FIGURES 2010 1-2* (2010).

^{kk} *Id.*, at 52.

^{ll} Reuben, *supra* note 19.

^{mmm} GUY B. FAGUET, *THE WAR ON CANCER: AN ANATOMY OF FAILURE, A BLUEPRINT FOR THE FUTURE* 61-90 (2008).

translate discoveries into clinical benefits for patients.”ⁿⁿ So even though the children cancer 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.

In the European story, despite the initial success, the EAC was not refunded in 2002 and the program languished. The EU health programs grew in the first decade of the 21st century but the cancer control process was put on hold. EAC functioned under a EU commission planning document that integrated member-state programs with EU funding and institutions. After its early success, EU funding and Commission commitment were reduced in 2002. The EU commission thought that the member states would take over the funding and planning. The member states however, saw the EAC as a permanent element in a multilevel project. Without the EU resources, the network was in danger of collapsing. The multilevel, monitoring function that had been provided by the EU commission plan and personnel plus the funding for the research function proved essential for the EAC to thrive.^{oo}

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 continued existence and integration. Once these frameworks fail to function effectively, the networks become isolated and fragile. In the case the childhood cancer group, the fragmentation of the cancer institutions originally coordinated by the National Cancer Institute left the childhood cancer group isolated. In the EAC, the cut-off of minimum resources from EU research funds and shift in priorities from cancer to other health issues left the network under resourced.

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 well 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. Secondly, they monitor the openness and accessibility of the stakeholder participation. Thirdly, they remove the economic and others barriers that discourage physicians from participating the learning process. Finally, they guarantee fairness in the process in the creation

ⁿⁿ Nass, Moses & Mendelsohn, *supra* note 5, at 2. Also *see generally* Young, *supra* note 6.

^{oo} Trubek, Nance & Hervey, *supra* note 11, at 811-4.

and provision of the data.

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 childhood cancer group and the EAC, the networks themselves worked to expand the availability of data, convert it into knowledge, and disseminate that knowledge. 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 of the US public health agencies, including the NCI, Centers for Disease Control, Food and Drug Administration, Department of Veterans Affairs, and even the Department of Defense have jurisdiction over parts of the cancer care system. In addition, a number of voluntary organizations such as the American Cancer Society and 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. This impressive roster of participants is a badge of both honor and failure in the US's effort to combat cancer. The scope of participation is impressive, but none of the participating individuals or institutions is accountable for the full scope of the problem or 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. In 1993, the National Cancer Advisory Board conducted an evaluation of the National Cancer Program.^{pp} In its report, the NCAB identified six problems hindering progress against cancer. The first and main problem was the lack of national coordination of public, private and voluntary stakeholders. One decade later, coordination remains a fundamental barrier to improving cancer outcomes.^{qq} In the EU, the

^{pp} See generally NATIONAL CANCER ADVISORY BOARD, *CANCER AT A CROSSROADS: A REPORT TO CONGRESS FOR THE NATION* (1994).

^{qq} See President's Cancer Panel, *supra* note 35 (“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.”) (last visited on July 22, 2010); Clifton Leaf, *The War on Cancer: Why We're Losing the War on Cancer (and How to Win It)*, *FORTUNE*, Mar. 9, 2004, at 77, 81-2 (indicating 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”).

reduction in funding for the EAC weakened coordination. Since 2002 the regulatory framework at the EU level has been struggling.

2. Performance assessment

Coordination is particularly important for a framework 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. 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. Public reporting and pay-for-performance are two relatively “soft” regulatory initiatives emerging in some healthcare networks 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. “The doctrine of performance 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.”⁷⁷ 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. 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. 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 (WCHQ), it is technically feasible to measure values such as 5-year survival, and to track how well physicians adhere to recommended treatment protocols. However, he notes that financial, organizational and philosophical barriers will have to be addressed before these initiatives are systematically incorporated into specialty services like oncology.⁷⁸

⁷⁷ Donald Moynihan, *Through a Glass, Darkly: Understanding the Effects of Performance Regimes* 1 (University of Wisconsin-Madison La Follette Sch. Working Paper No. 2009-020, 2009), available at <http://www.lafollette.wisc.edu/publications/workingpapers> (last visited on July 22, 2010).

⁷⁸ Interview with Chris Queram, President and Chief Executive Officer, the Wisconsin Collaborative for Healthcare Quality, in Madison, WI (July 24, 2009).

The public dissemination of performance indicators is meant to encourage individual clinicians and institutional providers to deliver quality care by introducing reputational incentives.^{tt} An example of success is the relationship between the EAC and the European Network of Cancer Registries (ENCR) allowed the creation of data and subsequent use in public reporting in league tables.^{uu} The ENCR system allows the EAC network to publicly monitor the performance of member states. The EAC initiative measured international differences in survival rates and disseminated that information in league tables, which clearly identified substantial international inequities for the first time. The public dissemination of performance data also provided reputational incentives for member states to improve their own performance. For example, the league table showed the British had long lagged behind other member states in treating lung cancer, even though the National Health Institute provides free services for all. The data motivated further studies which later discovered the fact that many patients do not receive treatment not because of lack of payment but due to the distance from treatment location.^{vv}

As shown in the case of 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. 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.^{ww} Gwyn Bevan underscored the importance of reputational incentives.^{xx} In the United Kingdom, “Those who ran hospitals 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.”^{yy} 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, robust to criticism from the organizations being assessed, understood in broad terms by the public, and published and widely disseminated. The regulatory framework, be it NCI or a private groups in the US or a relaunched EU wide fight against cancer 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

^{tt} See 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. THE ROYAL STAT. SOC’Y 161, 181, 184 (2009).

^{uu} Trubek, Nance & Hervey, *supra* note 11, at 816-19.

^{vv} Cooper, *supra* note 41.

^{ww} WILLIAM T. GORMLEY & DAVID LEO WEIMER, ORGANIZATIONAL REPORT CARDS 123-7 (1999)

^{xx} Bevan & Hamblin, *supra* note 46.

^{yy} 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).

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. However, cancer centers never had an integrated system to incorporate information gained through basic and translational research into community oncology practices until the establishment of the National Comprehensive Cancer Network (NCCN) in 1995. The NCCN is an alliance of 21 of the nation's leading cancer centers, which collaborated independent of NCI funding to develop and disseminate clinical practice guidelines in oncology. "We decided a long 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."^{zz} 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. The majority of cancer centers do not formally participate in this development effort because they are not NCCN members, most commonly because NCCN membership is expensive.

Creating clinical practice guidelines in oncology is a critical early step in linking the research institutions and the community clinical establishments who care for the majority of patients. 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, either 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..."^{aaa}

The national model for cancer collaboration through the comprehensive cancer centers and cooperative research groups have only a recent history of disseminating clinical guidelines to community oncologists through a distinct body, NCCN, and there has been no effort to monitor the impact of these guidelines. Furthermore, there is no effort to monitor major cancer outcomes,

^{zz} Ellen Okin Powers, *An interview with William T. McGivney, PhD, CEO of the National Comprehensive Cancer Network (NCCN): The NCCN guidelines: how do they relate to community oncology practice?*, 1 COMMUNITY ONCOLOGY 98, 98 (2004).

^{aaa} *Id.*, at 99-100.

such as 5-year survival or quality of life, at the level of community oncologists, clinical sites, or institutional providers. 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.^{bbb} 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 childhood cancer group and Europe against cancer networks is based in part on the 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 participation is notable. 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. Almost spontaneously, in different parts of the country, organizations emerged from support groups where women met and discussed their experiences with breast cancer. Their shared frustration with the cancer network led to the formation of the National Breast Cancer Coalition (NBCC) in 1991. After formation of the NBCC, funding increased \$11.7 million in 1991, \$77.3 million in 1992, and \$252 million in 1993. These funding increases were almost entirely attributable to the advocacy influence.^{ccc} Similarly, the patient advocacy associated with the EAC strengthened the political and policy power of the EAC programs both at the EU level and within the member states. The ability of the EAC to interest patients in participating in their work was motivated by the strong commitment of the EU commission to the cancer program. The patient groups in the EU and the member states recognized that their work was encouraged by the EU and often funded by the EU. When the EU funding lapsed in 2002, the patient groups organized to refund the efforts and elevate cancer control again as a major issue on the EU agenda. They realized that without that framework, their influence would wither.

Yet, traditional justification for cancer patient involvement continues to be categorized as patient representation or raising funding for medical cancer establishment.^{ddd} There is a tendency

^{bbb} *Id.*, at 100.

^{ccc} 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).

^{ddd} There are also some scholars believing that patient influence over the healthcare system can be strengthened

to see the patients and their advocates as allies in fund raising and recruitment for research but not as full participants in system learning and improvement. For example, the NCI has the Office of the Advocacy Relations but its role seems to be in locating people to serve on the plethora of NCI program and advisory committees.^{eee} Meg Gaines, the director of the Center for Patient Participation at the University of Wisconsin-Madison, indicates that there is not a clear understanding of the role of patient representation on the committees. The lack of clarity is found on all sides: among patient advocates, researchers, and clinicians.^{fff} The approach to engage patients through government advisory committees is also inadequate. Advisory committees are unsuccessful in providing meaningful patient input because there is a separation between the scientific expertise and the policy development.^{ggg} The learning from the advisory committee is not easily shared with policy initiatives and the learning process does not function.

The involvement achieved by integrated networks however, goes much deeper than fundraising or serving on advisory committees. The networks demonstrates 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 can lead to improving outcomes. Although the traditional patient advocacy performs the needed functions of fundraising and legislation, the learning process itself can function 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 childhood cancer group was formed initially because there were not enough patients for individual investigators to conduct meaningful research. Such an intolerable status quo motivated entrepreneurial pediatric oncologists to pool resources and share information with each other. They also developed a system to engage patients and achieve impressive level of clinical trial participation. Similar conditions do not exist in other cancer networks, 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, others

through consumerism and mechanism 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, 19-20 (2010).

^{eee} Interview with Martha E. Gaines, Director, Center for Patient Partnerships, University of Wisconsin Law School, in Madison, WI (July 8, 2009).

^{fff} *Id.*

^{ggg} See David L. Weimer, *The puzzle of private rulemaking: Expertise, flexibility, and blame avoidance in US regulation*, 66 PUB. ADMIN. REV. 569, 571-2 (2006) (pointing out that for advisory committees to integrate expertise into policy involves value trade-offs that might jeopardize such committees’ credibility in making impartial judgment based on committee members’ expertise).

have something to lose. Coordination of all of these stakeholders and steps to reduce or compensate potential costs is 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.^{hhh}

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, the 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 the clinical physicians. The EAC success in the early period is related to the codes and protocols that it produced and were disseminated. The creation of cancer registries throughout the EU also provided information that could be utilized by the physicians. In the COG the clinical physicians are the essential leaders assisting each other through their well-functioning, coordinated system.

However, there is substantial evidence that the physicians do not receive this support in other areas of diseases. A survey conducted by the American Society of Clinical Oncology found that physicians face significant barriers with respect to time, staff, and resources that hinder patient referrals to clinical trials. Physicians must keep track of complicated entry criteria for many trials to determine which patients are eligible for which trials, identifying appropriate patients and then introducing the concept of clinical trials to unfamiliar patients or providers, dealing with insurance company pre-approval prior to patient participation, and all of these must be done amidst a busy clinic with patients waiting.ⁱⁱⁱ This process is time intensive and poorly reimbursed, if at all. Physicians also lack support from the academic environment. A recent Institute of Medicine report quoted a cancer researcher: "...working in oncology clinical cooperative groups is frequently not well rewarded with academic recognition and advancement...this 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

^{hhh} David L. Weimer, *Governance of Organ Transplantation: A Desirable Model for Inducing Evidence-Based Medicine?* 13-7 (2010) (unpublished manuscript, on file with authors, Presented in the symposium "Smart Regulation: Can New Types of Governance Improve Health?" held in Madison, Wisconsin, 9 October 2009).

ⁱⁱⁱ See Ezekiel J. Emanuel et al., *The costs of conducting clinical research*, 290 J. CLINICAL ONCOLOGY 4145, 4149-50 (2003) (discussing challenges and obstacles discouraging physicians from enrolling patients into clinical trials).

research; and the under-funding of much of this effort.”^{jjj} The knowledge that physicians need a variety of support in order to provide the best care has been demonstrated and documented. Yet, the regulatory frameworks that could mandate and fund such supports is 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. As a result, apparent and potential conflicts of interest affect all phases of the clinical trials from design to data collection to reporting of the results. The dependence on the industry for financial support of the trials is due to the inadequate insurance reimbursement for participants. Companies often pay for the drugs and medical devices used in the trials and the doctors involved in the trials do not always reveal their connection to those commercial interests. Another potential ethical concern is the current practices employing “ghost writers” to generate the protocols and manuscripts that are then reviewed and approved by scientists and clinicians.^{kkk}

A recent report outlines an oversight system for conflicts in clinical trials. The report suggests expanding the purview of the institution based regulatory system (IRB) to include analyzing potential conflicts of interest. This local review would be framed by federal mandates that outline acceptable parameters. This proposal is an example of how multilevel frameworks can provide coordinated oversight without limiting local variation and experimentation.^{lll} A revised IRB system could also encourage physician willingness to engage in advance treatment. The outdated and cumbersome institutional review board (IRB) is highlighted as contributing to physicians’ unwillingness to engage in research/clinical process.^{mmm}

IV. Reconstituting the Regulatory Framework

There is an effort underway to reconstitute the frameworks. In the US the attention to the recent Institute on Medicine report on the failures of cancer trials indicates that the inadequacy of

^{jjj} Institute of Medicine, *supra* note 26, at 50.

^{kkk} Duff Wilson & Natasha Singer, *Ghostwriting Is Called Rife in Medical Journals*, *N.Y. Times*, September 11, 2009, available at <http://www.nytimes.com/2009/09/11/business/11ghost.html> (last visited on July 22, 2010).

^{lll} See Kathleen M. Boozang et al., *Conflicts of Interest in Clinical Trial Recruitment & Enrollment: A Call for Increased Oversight* 25-33 (Seton Hall Law School, White Paper for the Center for Health & Pharmaceutical L. & Pol’y, 2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1515762 (last visited on July 22, 2010).

^{mmm} See Scott Burris, *Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals*, 2 REG. & GOV’CE 65, 66-70 (2008) (indicating that “with no check...the IRB has acted very much like a traditional bureaucracy).

the framework in the US is evident.ⁿⁿⁿ 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.^{ooo} 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 EU funding dried out in 2002, the EAC left in place key constituencies 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 EU Research Frameworks Program, and the pharmaceutical industry have now rallied and are pursuing the reinvigoration of a regulatory framework. The launching of the European Partnership Action Against Cancer (EPAC) in 2009 provides a planning process and perhaps new waves of funding.^{ppp} 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 percent by 2020, and coordinating one-third of cancer research from all funding resources across EU by 2013.^{qqq} 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).”^{rrr} The objective is for all Member States to have integrated cancer plans. The long-term aim set out by the Commission is to reduce cancer by 15% by 2020.^{sss}

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, intensify the production and utilization of comparative information, and encourage accountability through benchmarks and

ⁿⁿⁿ Nass, Moses & Mendelsohn, *supra* note 5, at 2-4.

^{ooo} Legislations introduced in 2009 include the Comprehensive Cancer Care Improvement Act of 2009, H.R. 1844, 111th Cong.; the Access to Cancer Clinical Trials Act of 2009, H.R.716, 111th Cong.; the Access to Cancer Clinical Trials Act of 2009, S.488, 111th Cong.; and the Oncology Care Quality Improvement Act of 2009, H.R. 2939, 111th Cong.

^{ppp} *Communication on Action Against Cancer: European Partnership*, at 3-8, COM (2009) 291 final (Jun. 24, 2009), available at http://ec.europa.eu/health/ph_information/dissemination/diseases/docs/com_2009_291_en.pdf (last visited on July 22, 2010).

^{qqq} *Id.*

^{rrr} Press Release, European Partnership Action Against Cancer: Contribution of EU-funded research (Jun. 8, 2009), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/294&format=HTML&aged=0&language=EN>

^{sss} *Id.*

standardization. Both initiatives also emphasize dissemination of knowledge throughout their region to achieve equitable care for all cancer patients. These two initiatives promise a better fight against cancer.

Conclusion

This paper argues that regulatory frameworks are necessary for networks to work properly. Integrated networks are vulnerable when the frameworks fail to provide the necessary accountability, fairness and participation. This research coincides with the emergence of a substantial literature on how checklists, evidence-based medicine and performance-incentives play a role in improving medical care.^{ttt} This literature has raised awareness that regulatory institutions affect the quality of medical care. The authors of this paper believe that interdisciplinary research can provide useful information and lead us to suggestions on how to improve the current cancer governance system. This research attempts to illuminate specific instances where disease treatment intersects with legal institutions, legislative enactments, government regulation and public-private organizations. Understanding the importance of governance in health outcomes is a needed and crucial enterprise.

^{ttt} *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).