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NEW GOVERNANCE AND SOFT LAW IN HEALTH CARE REFORM

Louise G. Trubek*

INTRODUCTION

Health care reform is underway. To resolve longstanding health care problems, reformers are using new technologies, revising the role of public agencies, expanding the use of information, and creating flexible and participatory tools. These processes are different from previous understandings of health care governance. They are based on an emerging set of practices that can be called “new governance,” “post-regulatory,” or “new proceduralism.” New governance includes devolution, public-private partnerships, new types of regulations and incentives, network creation, coordinated data collection and dissemination, benchmarking, monitoring, and active patient participation. One aspect of new governance is a transformation of how we think of law; it includes guidelines and benchmarks that have no formal sanctions.

These techniques are intertwined with the reenvisioning of how to improve health care. Reformers are using these new processes to tackle three health care conundrums: universal access, reducing racial and ethnic disparities, and embedding information technology. These new processes consist of six innovative mechanisms that are utilized to resolve the health care conundrums: 1) alternative sites; 2) consumer and patient participation; 3) different roles for government; 4) redesigned organizational forms; 5) alternative methods for dispute resolution; and 6) new regulatory tools. These innovations can be understood in the framework of new governance practices and soft law regulatory reforms.

The new governance mechanisms are interacting with the older governance systems. The coexistence of the two systems creates different types of interactions. One interaction is a dynamic rivalry between the old and new, a second is orchestrating a multipronged strategy that incorporates new governance techniques with more traditional incentives, and a third is integrating traditional legal values into the new processes.

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The article begins with a discussion of contemporary health care reform and describes the three health care conundrums that frame the reform efforts. The first conundrum is creating universal coverage. The article describes how the reform effort is using incremental approaches that include experimentation at the state level. The second conundrum is how to embed new technology into the currently fragmented system. The reform effort is using national standards implemented through diverse regional collaboratives. The third conundrum is how to eliminate racial and ethnic disparities. The reform efforts are proposing to utilize newly developing quality indicators. The article then places these health care reform stories in the context of a broad regulatory reform. The article describes the particular new governance mechanisms that can be observed in these health care reform stories. The article concludes with a discussion of the variety of interactions between new governance and the older systems and proposes that the values of participation, transparency, and equity can be maintained within the new regulatory reforms.

I. HEALTH CARE REFORM: THREE STORIES

Eighty-two percent of Americans rank health care among their top concerns.¹ People are satisfied with health care when they can get it but are afraid they will not be able to secure it. Over forty-five million people were without health insurance during 2003.² The poor quality of health care has been well documented, but an extremely complicated health care scheme makes the problem seem unsolvable. Health care coverage is provided through a mixture of public, private, and nonprofit systems. It delivers local services through federally controlled programs such as Medicare, and through varied benefits provided by employer-based plans. The competitive world economy is straining the employer-based health care system because, unlike many nations, a large portion of health care costs is paid by employers.³ Rising health care costs are also a major issue straining the fiscal budgets at the state level due to Medicaid, and at the federal level due to Medicare. Another driver for reform is the medical malpractice system that is no longer efficient or equitable in deterring negligence and redressing patient harms. Systems such as evidence-based medicine combined with the collection and

1. Paul Krugman, *The Health of Nations*, N.Y. TIMES, Feb. 17, 2004, at A23.

2. U.S. Census Bureau, *Current Population Reports, P60-226 Income, Poverty, and Health Insurance Coverage in the United States: 2003*, 14 (2004).

3. Daniel Akst, *The Hidden Price Tag For Health Care*, N.Y. TIMES, Dec. 12, 2004, at BU6.

dissemination of data are being proposed as alternatives methods to reduce errors and compensate patients.⁴

Another aspect of the contemporary context is the failure of ambitious proposals to improve the health care system, such as the Clinton Administration health plan and the managed care movement of the 1980s. The Clinton health plan was an effort to achieve universal health coverage through an elaborate, federally controlled system. That plan was defeated, in part, because it was viewed as an attempt to replace the existing diverse and complex health care system with a mammoth bureaucracy.⁵ The failure is viewed as a blow against centralized, government dominated, bureaucratically controlled governance.⁶ The experiment with managed care, represented as a managed competition approach to solving health care problems, has also reached a plateau due to a perceived consumer desire for choice and the limits of its initial cost savings.⁷

Stakeholders realize that these problems can and must be tackled, even in this complex environment. Stakeholder groups include physicians, health care providers, business, government, consumers/patients, and technology experts and entrepreneurs. A set of reformers is emerging from the stakeholders.⁸ These reformers are leaders in creating new techniques and theories that challenge the older systems. There is an understanding among the reformer stakeholders that change is essential for the economic and personal health of the nation, and that their actions are creating the basis for that change. There are three specific conundrums where the reform efforts are directed: 1) achieving universal coverage; 2) embedding technology into health care delivery; and 3) attaining high quality care for all.

4. William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387, 399 (2003). Medical disciplinary boards have also proved to be of limited use as a way of preventing medical errors and of providing redress for patients. See also Ruth Horowitz, *Medical Licensing and Discipline in the United States: Medical, Legal and Public Discursive Domains* (June 2005) (unpublished manuscript, on file with author) (discussing the effect on medical disciplinary boards).

5. Louise G. Trubek, *Health Care and Low-Wage Work in the United States: Linking Local Action for Expanded Coverage*, in GOVERNING WORK AND WELFARE IN THE NEW ECONOMY 292 (Jonathan Zeitlin & David M. Trubek eds., 2003).

6. *Id.*

7. See Mark Hall, *The "Death" of Managed Care: A Regulatory Autopsy*, 30 J. HEALTH POL. POL'Y & L. 427 (2005).

8. See, e.g., Tommy G. Thompson, *Foreword: The State of America's Health Care System*, 31 WM. MITCHELL L. REV. 805 (2005); Donald M. Berwick & Thomas W. Nolan, *Physicians as Leaders in Imposing Health Care: A New Series in Annals of Internal Medicine*, 128 ANN. INT. MED. 289 (1998); Troyen Brennan, see links to his homepage, research affiliations and articles at http://www.researchmatters.harvard.edu/people.php?people_id=459 (last visited June 5, 2006); Ron Pollack, *Families USA: The Voice for Health Care Consumers*, at <http://www.familiesusa.org> (last visited June 5, 2006).

A. Universal Coverage: From a Centralized, Single System to Incrementalism

The lack of universal coverage has long been the most noted deficiency in U.S. health care. The importance of insurance in the United States results in poor health care for those who are uninsured.⁹ In addition, lack of coverage results in the shifting of the costs for providing care of the uninsured onto two sets of payers: the employers, who pay more because the medical establishment shifts added costs, and the government payers, who are forced to raise taxes in order to cover their share of uncompensated care. Lack of coverage also affects the economy by encouraging job lock where employees cannot move to the position that matches their talents because of their fear of losing health care coverage.¹⁰

There is now an acknowledged consensus that some form of universal coverage for residents is essential for the economic and personal health of the United States.¹¹ This consensus has developed for two reasons: the acknowledgment by business groups that universal coverage is crucial for its success and a shift in vision to one based on an incremental approach rather than a radical restructuring. The incremental approach grew in popularity in the wake of the Clinton plan's failure.¹² The incremental approach reassures business and providers who fear a government controlled, one-size-fits-all model for health care. It de-emphasizes the bureaucratic, single set of universal benefits and administration. Business groups are getting involved because they see that solving the uninsured problem is necessary for their own economic health and the competitive situation of the United States in the world economy. Business groups understand, to the extent they can no longer afford their own health care programs, other programs to cover their workers will have to be designed and funded.¹³

The incremental approach to universal coverage is proceeding on four tracks: 1) experimenting at the state level; 2) integrating networks with federal funding; 3) linking public and private coverage; and 4) incorporating coverage

9. See Karen Davis, *The Costs and Consequences of Being Uninsured*, 60 MED. CARE RES. & REV. 2 (2003).

10. Kevin T. Stroup et. al., *Chronic Illness and Insurance-Related Job Lock* (March 2000), available at <http://www-cpr.maxwell.syr.edu/cprwps/wps19abs.htm> (last visited June 4, 2006).

11. The business case for universal coverage is increasingly documented. See, e.g., Paul Fronstin, *The "Business Case" for Investing in Employee Health: A Review of the Literature and Employer Self-Assessments*, EBRI Issue Brief No. 267 (March 2004).

12. Thomas R. Hefty, *Facing Health Care Tradeoffs: Costs, Risks, and the Uninsured*, 14 LA FOLLETTE POL'Y REPORT (Robert M. La Follette Sch. of Pub. Aff., Univ. of Wis.-Madison), Winter 2003-04 at 19.

13. In cases like General Motors profits are falling. See Matt Miller, *CEOs Should Force Health Care Issue*, WIS. STATE J., May 22, 2005, at B2. For Wal-Mart the issue is covering low wage workers. See Stacy Forster, *Big Companies Fill BadgerCare Rolls*, MILWAUKEE J. SENTINEL, May 24, 2005, at A1.

for the uninsured through pooling and incentives. There is now a rich array of state approaches to providing coverage. In the 2005 budget debate, the National Governors Association united across bi-partisan lines to oppose massive cuts in Medicaid and to develop a system for reforming Medicaid that cut costs while maintaining coverage levels and improving quality. The Medicaid cuts were reduced and a high-level Medicaid commission is being appointed.¹⁴ This commission's goal is to work with a variety of stakeholders, including state and federal leaders, to figure out ways that Medicaid funding can be used more efficiently to expand access and improve quality.¹⁵ The Governors Association's effectiveness in the recent Medicaid debate is based on its state-by-state incremental approach.

State governments are experimenting with various methods trying to figure out ways of putting the pieces together to achieve greater coverage.¹⁶ Combining public programs with employer-based coverage is being proposed through further expansion of Medicaid. Small businesses are encouraged to offer health care coverage through a combination of tax credits and subsidies from government programs.¹⁷ Private businesses can be integrated into state employee coverage pools to reduce businesses' health care costs.¹⁸ Information technology enables people to move from public plans to private coverage and vice versa with no loss of coverage when their jobs and income situations change.¹⁹ States are emphasizing quality techniques, patient involvement, and community participation to improve care.²⁰ Networks of state government

14. *Lawmakers Express Anger Over Leavitt Medicaid Commission*, WASH. HEALTH POL'Y WEEK IN R. (The Commonwealth Fund), May 23, 2005, available at <http://www.cmwf.org> (last visited June 4, 2006).

15. *Id.*

16. A recent study indicated that the quality of care received through Medicaid is equivalent to the care received by low income privately insured adults. This information supports the usefulness of considering options for expanding Medicaid or expanding coverage for low income people through private plans, perhaps with a government subsidy. See Teresa A. Coughlin et al., *Assessing Access to Care Under Medicaid: Evidence for the Nation and Thirteen States*, 24 HEALTH AFF. 1073, 1077 (2005); *State Health Insurance: Making Affordable Coverage Available To All Americans*, in FOSTERING RAPID ADVANCES IN HEALTH CARE 69, 76 (INST. OF MED. 2002).

17. See Democratic Policy Committee, *Senate Democrats Introduce Affordable Health Care Plan for Small Business* (March 7, 2006), available at <http://democrats.senate.gov> (follow "Newsroom" hyperlink) (last visited June 4, 2006).

18. David Callender, *Health Plan Would Cover All in State*, CAPITAL TIMES, June 15, 2005, at A1.

19. Hefty, *supra* note 12, at 19. See also *State Health Insurance: Making Affordable Coverage Available To All Americans*, in FOSTERING RAPID ADVANCES IN HEALTH CARE 69 (INST. OF MED. 2002).

20. *Frist-Bingaman Bill Would Allow Uninsured Children to Enroll in Medicaid, SCHIP*, WASH. HEALTH POL'Y WEEK IN R. (The Commonwealth Fund), May 23, 2005, available at <http://www.cmwf.org>. The incremental approach is based on states combining the resources of the Medicaid program as expanded through the State Children's Health Insurance Program (SCHIP) funds. SCHIP is an expansion of health care coverage targeting uninsured children. The federal government, in enacting SCHIP, encouraged states to experiment with various

officials, legislators, and governors across states are spreading “best practices” and encouraging united action to support the programs.²¹

B. Embedding Technology: From Command and Control to National Standards and Regional Collaboratives

Reformers are pursuing major initiatives to embed technology in the health care system.²² There is a bi-partisan alliance between former Republican Speaker Newt Gingrich, Democratic Representative Patrick Kennedy, and Democratic Senator Hillary Clinton. The alliance is committed to advancing technology that could radically transform the quality and reduce the cost of healthcare.²³ However, there is reluctance in the medical community to invest in technology because of high costs, a perceived loss of autonomy in exercising professional expertise, and fear of a centralized data set.²⁴ There is also difficulty in developing a national system that protects privacy and security.²⁵

The Bush Administration has proposed a national health care regional infrastructure which will be responsible for coordinating all private sector initiatives under the framework of the American Health Information Community (“AHIC”).²⁶ The goal is to create a comprehensive, knowledge-based network of interoperable systems capable of providing information anytime, anywhere. It is, however, not a central database of medical records. The role of the federal government is to ensure that standards are in place to allow the interoperable systems; the model is the banking information infrastructure. The proposal is for “regional” systems that could be smaller or larger than states; it is coordinated through the federally funded Connecting Communities for Better Health program.²⁷ The AHIC is a forum that includes seventeen commissioners representing consumers, privacy interests, states, payers, providers, vendors, and purchasers.²⁸ The group is “chartered for two years, with the option to renew up to five years, to be succeeded by a private-

approaches to insuring children and families with the additional funding.

21. Trubek, *supra* note 5, at 292.

22. *Information and Communications Technology Infrastructure: A “Paperless” Health Care System*, in FOSTERING RAPID ADVANCES IN HEALTH CARE 57 (INST. OF MED. 2002).

23. *Id.*

24. Newt Gingrich & Patrick Kennedy, *Operating in a Vacuum*, N.Y. TIMES, May 3, 2004, at A23.

25. Press Release, Office of the Nat’l Coordinator for Health Info. Tech., Secretary Leavitt Takes New Steps to Advance Health IT (June 6, 2005), available at <http://www.hhs.gov/news/press/2005pres/20050606.html> (last visited June 4, 2006).

26. *Id.*

27. Website funded through an agreement with the Health Resources and Services Admin. Office for the Advancement of Telehealth, available at <http://telehealth.hrsa.gov> (last visited Feb. 23, 2006).

28. New Steps to Advance Health IT, *supra* note 25.

sector health information community initiative.”²⁹ While the federal government is initiating this effort, its investment is relatively modest.

These ongoing efforts build in part on the experience with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). HIPAA delegated power to the Department of Health and Human Services (“HHS”) to promulgate rules to advance health care technology through uniform standards for electronic transactions, privacy protections, and security of data. The production of these rules relied on the traditional rule-making process and took many years and many hearings to finally produce pages of rules. The implementation of HIPAA, however, also included a series of public-private collaborations, known as HIPAA Collaboratives.³⁰ These state-based and local collaboratives consist of all the stakeholders: business, government, technology experts, and providers from all types of backgrounds.³¹ Since HIPAA has been enacted, these groups have been helping their members comply with HIPAA by providing information and sharing techniques.³²

C. *Guaranteeing Quality and Equity: From Anti-Discrimination and Medical Malpractice to Quality Assurance Tools*

The reformers realize that just having health insurance is not enough to guarantee health; the care must be of high quality. Since the late 1990s, reformers from the medical sector and concerned business purchasers have promoted quality as an achievable and necessary goal for the health care system.³³ Although the United States has one of the most expensive health care systems in the world, the quality of care is mixed. The *National Healthcare Quality Report* indicates that the U.S. system currently does not do enough to prevent diseases, diagnose early to improve treatment outcomes, or provide coordinated care to patients with chronic diseases.³⁴ In addition, uneven quality is particularly noticeable in connection to the disparities of health outcomes of racial and ethnic minorities. Studies have shown that minority Americans receive less health care, and what they do receive tends

29. *Id.*

30. See Wendy Netter Epstein, *Bottoms Up: A Toast to the Success of Health Care Collaboratives . . . What Can We Learn?*, 56 ADMIN. L. REV. 739 (2004).

31. *Id.*

32. *Id.*

33. See, e.g., The Leapfrog Group for Patient Safety, available at <http://www.leapfroggroup.org> (last visited Feb. 23, 2006).

34. AGENCY FOR HEALTHCARE RES. AND QUALITY, U.S. DEP’T OF HEALTH & HUMAN SERVS., NATIONAL HEALTHCARE QUALITY REPORT 2-4 (2003), available at <http://qualitytools.ahrq.gov> (follow “National Healthcare Quality Report 2003” hyperlink) (last visited June 4, 2006).

to be lower quality care, even when controlling for insurance status and income.³⁵

In response to the documentation of the persistence of health disparities, there is a major initiative to adopt a quality-based approach to the provision of health care as an indirect route to achieving equality. A recent report indicates “leveraging existing quality assurance systems to monitor and address disparities could substantially reduce the disparities in healthcare treatment.”³⁶ If the quality problems can be resolved, the way is opened to both a high-quality health care system, and to a reduction in health disparities. Once providers and payers are committed to the assessment and measuring of quality, they can use these techniques to access and improve the outcomes for racial and ethnic minorities. There is evidence that publication of quality indicators can be an effective way to improve quality for minority populations. A recent study demonstrated that the quality of care improved for minority populations when public data on the success of physicians were made available and distributed to minorities.³⁷

II. NEW GOVERNANCE AND SOFT LAW

Historically, in health care, there has been a mix of self-regulation, market forces, and government regulation.³⁸ Rand Rosenblatt defines this mix as the remains of the three ages of health law: 1) authority of the medical profession; 2) modestly egalitarian social contract; and 3) market competition.³⁹ The authoritative period of health law was characterized by self-regulation and accreditation as the preferred ways to govern. The second age that Rosenblatt defines as “modest social contract” is sometimes called the “new deal/great society period.”⁴⁰ This age emphasized command and control based in Washington, D.C. The administrative agencies issued periodic rules

35. Sidney D. Watson, *Race, Ethnicity and Quality of Care: Inequalities and Incentives*, 27 AM. J.L. & MED. 203, 208-09 (2001).

36. Kevin Fiscella, *Within Our Reach: Equality in Health Care Quality*, Symposium, Racial and Ethnic Disparities in Health Care Treatment, The Harvard Civil Rights Project (May 18, 2004) (unpublished manuscript, on file with author).

37. Dana B. Mukamel et al., *Quality Report Cards, Selection of Cardiac Surgeons, and Racial Disparities: A Study of the Publication of the New York State Cardiac Surgery Reports*, 4 INQUIRY 435 (2004-05), available at <http://www.inquiryjournalonline.org> (last visited June 4, 2006).

38. Troyen A. Brennan, *The Role of Regulation in Quality Improvement*, 76 MILBANK Q. 709 (1998), available at <http://www.blackwell-synergy.com/doi/abs/10.1111/1468-0009.00111> (last visited June 4, 2006). The argument is that in no substantive area was there ever true self-regulation because there was always some government action in some way, be it administrative, legislative, or judicial.

39. See Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155 (2004).

40. See Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004).

and emphasized professional expertise as the source of information and knowledge. There was an emphasis on entitlement programs and a reliance on individual litigation.⁴¹

Since the 1970s, critics of government regulation have called for alternatives to the New Deal/Great Society model.⁴² Rosenblatt defined the period that comprised privatization, deregulation, and reliance on market competition as the third age.⁴³ Managed care is one manifestation of that age. While managed care succeeded in briefly reducing costs, it engendered a backlash from physicians and consumers. The widely used phrase was that it “managed costs not care.” The inability of these tools and institutions to resolve health care problems is highlighted in the failure of the Clinton health plan. “President Clinton attempted to solve these problems with a national health insurance proposal that ingeniously combined the social contract, market competition, and professional authority models, but was unable to mobilize the political support to overcome intense opposition.”⁴⁴

The health reform stories discussed earlier describe an emerging set of practices that can be called “new governance,” “post-regulatory,” or “new proceduralism.”⁴⁵ In a recent article, Rosenblatt posited that these practices can be called a fourth age of health law.⁴⁶ These new governance techniques are intertwined with the reenvisioning of how to improve health care. This fourth age is linked to a more general shift in the evolution of governance. While this paper describes new governance in health care, other sectors are also affected by these emerging practices. New governance is a broad phenomenon and its tenets are shared in different sectors like work place safety programming and the environment.⁴⁷ The word “new” does not imply that it has been invented recently; rather it is used to refer to the widespread

41. For an extensive discussion of these issues see William H. Simon, *Solving Problems v. Claiming Rights: The Pragmatist Challenge to Legal Liberalism*, 46 WM. & MARY L. REV. 127 (2004). In health care, medical malpractice is used to redress negligent errors and civil rights litigation is used to redress discriminatory behavior.

42. See MARK TUSHNET, *THE NEW CONSTITUTIONAL ORDER* 1-5 (2003).

43. See Rosenblatt, *supra* note 39.

44. Rosenblatt, *supra* note 39, at 175.

45. Scott L. Cummings, *Mobilization Lawyering: Community Economic Development in the Figueroa Corridor*, in CAUSE LAWYERS AND SOCIAL MOVEMENTS (Austin Sarat & Stuart Scheingold eds., Stanford Univ. Press, forthcoming 2006)(post-regulatory); Wolf Heydebrand, *Hard but Soft: Having Law Both Ways?* (March 2005) (unpublished manuscript, on file with author) (new proceduralism); Lester M. Salamon, *The New Governance and the Tools of Public Action: An Introduction*, 28 FORDHAM URB. L. J. 1611, 1635 (2001) (new governance).

46. Rosenblatt, *supra* note 39, at 193.

47. See Orly Lobel, *Interlocking Regulatory and Industrial Relations: The Governance of Workplace Safety*, 57 ADMIN. L. REV. 1071 (2005) (OSHA); Bradley C. Karkkainen, *Environmental Lawyering in the Age of Collaboration*, 2002 WIS. L. REV. 555 (2002) (environmental).

and explicit use of nonconventional forms of governing.⁴⁸ It recognizes that privatization can bring important new tools to help solve problems (like market-based approaches), but “private markets cannot be relied on to give appropriate weight to public interests over private ones without active public involvement.”⁴⁹

New governance includes devolution of government, public-private partnerships, new types of regulations and incentives, network creation, coordinated data collection and dissemination, benchmarking, monitoring, and active individual involvement.⁵⁰ Devolution moves power to lower levels of government, including local and state, and de-emphasizes inflexible nationally administered programs. There is a multilevel interaction in which the national government sets standards, or provides funding with a relationship among the federal, state, and local level. Experimentation is closely linked to devolution, since the more local an entity is, the easier is experimentation. Often, experimentation occurs outside of, or parallel to, regulation.⁵¹ Experimentation can also be seen as continuous quality improvement—organizations should be constantly experimenting to see what works and what does not.⁵² There is experimentation with different models of resolving problems at the state and local levels. It is producing information about what works and does not work, and this information is shared through shareholder networks, such as networks of government officials and business purchasers.

Another element is public-private partnerships. Here, traditionally isolated organizations and programs are brought together to work on shared problems, crossing barriers of diverse corporate forms and competing constituencies. It is also closely linked to networking—a process of learning from the field what works and adapting. The use of networks also changes the government’s role because it no longer regulates organizations to achieve desired outcomes. While negotiation through networks may be difficult, rules and standards that have been negotiated by the networks may be complied with because of the negotiation process.⁵³

Traditional governance has been skeptical of collaborations between private and public entities. New governance recognizes that public/private networks have different strengths that can be used in concert to solve public problems.⁵⁴ The collection of data is emphasized in order to evaluate whether

48. Task Force on Legal Issues II, *New Modes of Governance in Europe* (NEWGO), May 16, 2005 (Grainne De Burca ed.), available at <http://www.eu-newgov.org> (follow “publications” hyperlink) (last visited June 6, 2006).

49. Salamon, *supra* note 45, at 1635.

50. Salamon, *supra* note 45, at 1635.

51. Louise G. Trubek, *Lawyering for a New Democracy: Public Interest Lawyers and New Governance: Advocating for Health Care*, 2002 WIS. L. REV. 575, 594 (2002).

52. *Id.* at 587.

53. Wendy Netter Epstein, *Bottoms Up: A Toast to the Success of Health Care Collaboratives, What Can We Learn?*, 56 ADMIN. L. REV. 739 (2004).

54. *Id.* at 1633-34.

goals that are set and benchmarked are achieved. There is an emphasis on monitoring results through the collection and public dissemination of data that can lead to revisions and create financial incentives.⁵⁵

New governance is transformative of law in that it challenges what we think of as law. Guidelines, benchmarks and standards that have no formal sanctions are important elements in new governance. There is also a development of informal processes to resolve grievances and disputes, including negotiation and multistep procedures.⁵⁶ This can be called "soft law." Soft law is an important component of new governance practices.⁵⁷ "Hard law" can be characterized as command and control, court based dispute resolution, uniform rules, punitive sanctions, and court challenges for noncompliance. This approach has proved inadequate in many cases. First, the use of court challenges to enforce regulations has been ineffective because the problems seeking to be solved are extremely complex. There is a lack of fit between the institutional structures that are causing the failure to solve problems with the traditional court remedies.⁵⁸ Second, the failure of the anti-discrimination paradigm in racial and ethnic disparities is an example of the inadequacy of exclusive reliance on court remedies. Another failure of traditional regulation is the use of malpractice litigation as the major tool to prevent errors and improve quality of care. The random selection of cases, the high cost of litigation, and the resistance of health care institutions to use the information gained in lawsuits are all problems with malpractice litigation.⁵⁹ Finally, there is a famed gap between the law on the books and the law in action. Uniform rules are not enforced by the agencies, nor does enforcement necessarily lead to the desired outcome.⁶⁰ The perceived inability of the HIPAA rules to advance the consumer's interest in health data collection is an example of the gap between law on the books and effective achievement of the goal of assuring privacy and improving care.

Soft law allows for learning and feedback. It allows actors to take on multiple roles, and creates alliances between traditional adversaries. Further, soft law incorporates economic incentives into the governance framework

55. One observer has said health care reform is all about purchasing for value. Dave Riemer, Commentary by Dave Riemer at Univ. of Wis. Med. Sch., April 4, 2005 (comments on file with author).

56. See Alexander J.S. Colvin, *From Supreme Court to Shopfloor: Mandatory Arbitration and the Reconfiguration of Workplace Dispute Resolution*, 13 CORNELL J.L. & PUB. POL'Y 581 (2004). Susan Sturm, *Second Generation Employment Discrimination: A Structural Approach*, 101 COLUM. L. REV. 458 (2001). Nan D. Hunter, *Managed Process, Due Process: Structures of Accountability in Health Care*, at <http://www.ssrn.com> (follow "search" hyperlink, then author's name) (last visited June 6, 2006).

57. See David M. Trubek & Louise G. Trubek, *Hard and Soft Law in the Construction of Social Europe: The Role of the Open Method of Coordination*, 11 EUR. L. J. 343 (2005).

58. Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 HARV. L. REV. 1015, 1070 (2004).

59. Sage, *supra* note 4.

60. *Hard and Soft Law*, *supra* note 57, at 356.

while allowing for diversity and experimentation. It allows public and private domains, and different regulatory clients, to interact more easily. "It can encourage mutual cooperation and exchanges of knowledge and experience through collection, systematization, and diffusion of knowledge. Soft law can be seen as fostering consensus making and incentives to voluntary learning, as much as by shaming."⁶¹

This discussion shows how new governance is transformative of traditional law. However, in assessing new governance it is important to evaluate how these techniques maintain the traditional legal values of inclusion, equity, participation and transparency.⁶² The larger issue is whether this evolving system can be both popular and effective. The partial failure of managed care and the demise of the Clinton health plan were due to the inability of the reformers to demonstrate that people would be better off and treated fairly under that governance system. Skeptics of new governance believe that the issues of transparency, fragmentation, the unproven success of new tools, and the imbalance of power are major obstacles to the promise of new governance.⁶³

The health care stories—creating universal coverage, embedding technology, and reducing disparities—demonstrate that there is an emerging set of soft law elements crucial for new governance. These innovations also include elements of more traditional legal processes and values. Part three describes these innovations. Part four indicates how these innovations demonstrate the coexistence of new governance and soft law with the traditional legal processes and values.

III. INNOVATIONS

The older system, without some changes, cannot deal with diversity, the development of new technologies, the increasing flow of new knowledge, and the eroding faith in professionalism. The old system cannot deal with the increased information available through the combination of evidence-based medicine and electronic records. This increased information has created an explosion of new knowledge which depends on feedback and iteration. This feedback requires interaction between domains; for example, the information obtained from the public and private payer must be integrated at the policy and

61. Kerstin Jacobsson, *Between Deliberation and Discipline: Soft Governance in EU Employment Policy* (unpublished manuscript, on file with author).

62. David M. Trubek & Louise G. Trubek, *The Coexistence of New Governance and Legal Regulation: Complementarity or Rivalry?*, July 2005 (unpublished manuscript, on file with author).

63. TUSHNET, *supra* note 42, at 167-68. Tushnet has characterized the conservatives as having a vision and agenda that is persuasive and may be implemented. He sees the new governance vision as one of the few efforts to create a liberal counterpoint to the conservative vision.

clinical level for the whole picture to emerge. It also allows traditional public health to be merged with health care delivery; a physician with ten diabetic patients using the same treatment protocols can obtain information about diabetes treatments, and share this internally, as well as with other institutions. The use of benchmarking will lead to increased learning. As benchmarking is utilized, new ways to do a better job emerge. The older system must be changed to reorient to a new, more productive system. The combination of linking information technology with evidence-based medicine, new roles for the actors, and aligning incentives can lead to redesign and innovation of health care practices.⁶⁴

These innovations that are being created are the key elements of new governance in health care. The first innovation is alternative sites that create locations for stakeholder interaction and implementation of programs and projects. The second innovation is the enhanced role of consumer/patient participation. Part of the reason older systems cannot adapt is the difficulty of figuring out how to integrate the essential knowledge of patients/consumers into the decision-making. The government's role becomes a set of practices that can be employed differently depending on the specific problem to be resolved. The role of private organizations shifts as well. The traditional distinction between public and private becomes less effective as the government allows more economic and market incentives to play a role and as private corporations take on a more socially-oriented function. While the innovations often result in larger units, such as public/private pooling, they also encourage development of smaller units, such as local clinics that can deliver care specific to the cultural and geographical needs of the community. Furthermore, the traditional court-based dispute resolution system may be ill-suited for some of the new governance focus on continuous learning. However, redress for the individual is essential for the legitimacy of the processes. Dispute resolution systems provide for this redress using "alternative forms of victim compensation through administrative processes similar to workers compensation and conflict avoidance through informal methods to explain and apologize for error."⁶⁵ Finally, the new governance system uses information as a regulatory technique by publishing data on outcomes, offering fiscal incentives for good performance by hospitals and clinics, and issuing rules that allow diverse ways of achieving positive outcomes.

A. Alternative Sites for Deliberation and Implementation

The failures of the late 1980s and the 1990s emboldened key stakeholders to overcome traditional animosities and self-interests to experiment

64. Barry P. Chaiken, Address at the Digital Healthcare Conference (June 9, 2005) (unpublished presentation, on file with author).

65. Coexistence of New Governance, *supra* note 62.

with new ways of providing and paying for health care. The traditional arenas that brought together stakeholders to debate, deliberate, and resolve problems were the administrative agency rulemaking process, courts, markets, and self-regulation. However, none of these arenas worked: stakeholders were missing, locations were inflexible, experimentation and diversity were difficult to achieve, enforcement relied heavily on sanctioning, and the new available technology could not be integrated into the existing systems.

Reformers are creating new sites that encourage collaboration previously difficult to achieve. The most common sites of collaboration consist of stakeholders that convene to solve health care problems or crises. Examples of these new sites are quality collaboratives, local technology groups, and groups planning to pool public and private coverage systems.⁶⁶ These collaboratives exist at the local and state levels. There are national groups, as well, such as the National Committee for Quality Assurance and the National Quality Forum.⁶⁷ The founders of the collaboratives realize that bringing varied expertise and experiences to the collective governance structure is essential to understand the issues and to create solutions.⁶⁸ Participating at these sites are the health care stakeholders: providers, consumers, government, and employers.⁶⁹ Each stakeholder has important information that, when shared with all stakeholders, improves understanding and the ability to address problems.⁷⁰ These new collaboratives may decide to bring in more organizations or develop local pilot projects. This exploration may lead to different analysis of problems and solutions than initially envisioned.

Four sets of reformers are now emerging as proponents and leaders of alternative approaches to solve the health care conundrums through these new collaborations: pioneering physicians, concerned payers, active consumers, and facilitating government leaders.⁷¹ Each reformer group participates in various networks, alliances, and forums to solve health policy problems. Each participant has a constituency that must accept working with the new alliances. These leaders must also change the culture of their constituency so

66. See discussion of proposals of David Cutler. Roger Lowenstein, *The Quality Cure?*, N.Y. TIMES, Mar. 13, 2005, at 46.

67. See Wisconsin Collaborative for Health Care Quality, available at <http://www.wiqualitycollaborative.org> (last visited Feb. 2, 2006).

68. Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342, 343-44 (2004).

69. See Wisconsin Collaborative, *supra* note 67.

70. Wendy Netter Epstein, *Bottoms Up: A Toast to the Success of Health Care Collaboratives . . . What Can We Learn?*, 56 ADMIN. L. REV. 739, 787 (2004).

71. Thomas R. Oliver, *Policy Entrepreneurship in the Social Transformation of American Medicine: The Rise of Managed Care and Managed Competition*, 29 J. HEALTH POL. POL'Y & L. 701, 713 (2004). These actors have the characteristics of the "policy entrepreneur," crucial to the implementation of these new routes.

the entire group accepts the value of collaboration and views it as a way to achieve its own goals.

The role of physicians is crucial in order for new governance to be successful in health care. Historically, professionalism allowed physicians to mediate the tensions of a market-driven approach to health care and government regulation. Professional values and institutions were thought necessary for physicians to maintain an independent role. This worked for a period of time, however, business and consumer advocates complained that physician control resulted in higher costs, lack of access to care, and inconsistent quality of care. The managed care revolution in the 1980s and businesses' attempt to create a competitive market undermined traditionally professional institutions and controls, and physician leadership. The recent backlash against managed care, created in part by the actions of health care providers, has emboldened physicians to re-assert their leadership role. The managed care backlash came about in part by an alliance between physicians and consumers to fight the intrusion of "outsiders" into the physician-patient relationship. Although physicians won this battle, managed care had changed the environment in which they practice through the development of large integrated hospital and clinic systems where most physicians now practice, the creation of evidence-based medicine, and increased reliance on allied health care professionals. As one observer noted, "physicians are weakened but not vanquished."⁷² In attempting to reassert their leadership role, physicians noted the effectiveness of business leaders in advancing quality in health care through the use of networks. They now emulate these network collaborations by working with a wide variety of stakeholders.

Although physicians are asserting a new role, the concerned employer-payer, who emerged in the 1980s to control health care costs, is still active and prominent. Since provision of health care coverage in the United States occurs significantly through the workplace, employers want to control health care costs as they are a major factor in their profitability and sustainability. The pressures of the global economy require businesses to engage in global arenas that are not integrated into traditional sites. National competitiveness is being threatened by health care costs. Some large companies can no longer pay for health care for their workers through their revenues. Entrepreneurial companies cannot pay for health care as they "start up." This is why business leaders have joined the fight for universal coverage. Alternative sites may encourage business reformers to launch the effort for universal coverage. In addition to the access problem, employers have expanded their activities to improving quality and even becoming active in solving the problem of the uninsured.⁷³ The leading voice of business in health care is the Leapfrog

72. Jill Quadagno, *Physician Sovereignty and the Purchasers' Revolt*, 29 J. HEALTH POL. POL'Y & L. 815, 832 (2004).

73. Milt Freudenheim, *Companies Band Together as a Way to Offer Health Care to Part-Time Employees*, N.Y. TIMES, May 13, 2004, at C3.

Group, a consortium of more than one hundred large employers that have mobilized to use their purchasing power to affect the health care system. The Leapfrog Group, while national, has substantial influence on business actions at the state and local level. It exerts a major external force on the internal workings of health care institutions and professional groups through the production and dissemination of benchmarks on the quality and cost of health care procedures.⁷⁴

These evolving collaborations, while often effective, face challenges. First, there are internal and external mechanisms that have to be refined in order for the process to achieve its goal. There is also a reliance on regionalism, a level of government that has been of mixed success in the United States. Finally, the “publicness” of these collaboratives is often insufficient.

There are internal mechanisms that affect the potential success of these collaboratives.⁷⁵ The first is the internal interests of the stakeholder. For instance, physicians are not a monolithic group. Surgeons and pediatricians may be threatened by some quality standards in different ways.⁷⁶ Small businesses have interests and power that differ from than the Fortune 500 companies. Also, the success of the collaborative may depend on who within the organization is participating and their relationship with their constituency. For example, the participation of the head of a stakeholder organization may provide certain kinds of authority, but if the head of the organization cannot sell the collaboration to the rest of the organization, the goals of the collaborative may be undermined. These collaboratives contain internal costs that must be weighed against the benefits. These costs include the time that stakeholders invest in lengthy meetings and interactions. An additional cost is the money required to maintain an ongoing organization and to pay for staff. Finally, the process may be slow, limiting flexibility, which is the *raison d'être* of such collaboratives.⁷⁷

The external mechanisms that affect the success of the collaboration are transparency of collaboratives, dampening of potential innovation caused by fears of liability and existing inflexible regulations, and the absence of unorganized constituencies. State and federal administrative procedure acts and open records and open meetings laws do not apply to many of these collaboratives because they are not organized as public bodies. This makes the availability of information about their activities difficult to find and makes their work seem suspicious. However, the new American Health Information

74. See Leapfrog, *supra* note 33.

75. John Braithwaite et al., *The Governance of Health Safety and Quality*, 27 fig.3 (2004) (unpublished manuscript, on file with author).

76. Rachell Callcut, *The Influence of Private Regulation on the Practice of General Surgery* (Dec. 6, 2004) (unpublished manuscript, on file with author).

77. A. Bryce Hoflund, *An Exploration of the Costs Associated with Consensus Making in Healthcare* (June 2005) (unpublished manuscript, on file with author).

Community (“AHIC”) provides a collaborative to accelerate the application of health information technology. The collaborative developed by the Department of Health and Human Services is specifically organized under the framework of the Federal Advisory Committee Act⁷⁸ in order to allow for open public meetings and “widespread stakeholder participation in which everyone has a voice.”⁷⁹ In addition, fears of malpractice litigation may also be an obstacle to the development and implementation of innovative techniques. Substantive government regulations that do not allow for innovative systems, such as payment for quality, are also external checks on the effectiveness of collaborations. A third external barrier is the difficulty of patient and consumer participation. These groups have traditionally had difficulty organizing due to their diverse income, race, ethnicity, gender, and geography.⁸⁰

Regional groups are also mooted. In President George W. Bush’s proposals for disseminating new technology in health care⁸¹ and in the Medicare Modernization Act,⁸² there is a commitment to regionalism, described as below the federal level but not necessarily at the state level. This is consistent with the academic discussion about “new regionalism” and “new localism.”⁸³ Scholars note that in order to achieve the values of local autonomy there needs to be a legal regime that encourages local participation; limiting centralized power is not enough to create greater diversity and participation. Some of the proposals now available cross states but are not geographically contiguous. For example, prescription drug pools now cross state lines. The I-Save Rx plan allows five non-contiguous states to develop a shared pool to purchase drugs for a lower cost.⁸⁴ The states’ locations range from the Midwest to the East.⁸⁵ The efficiency of this type of pooling comes from the ability to use one purchasing system to buy in bulk internationally and deliver the drugs via mail.

78. Federal Advisory Committee Act, 5 U.S.C.A. app. 2 (1972).

79. Press Release, Office of the Nat’l Coordinator for Health Info. Tech., Questions and Answers: American Health Information Community (June 6, 2005), available at <http://www.hhs.gov/healthit/qa.html> (last visited May 2, 2006)

80. John Harley Warner, *Grand Narrative and its Discontents: Medical History and the Social Transformation of American Medicine*, 29 J. HEALTH POL. POL’Y & L. 757, 769 (2004).

81. Questions and Answers Am. Health Info. Cmty., *supra* note 79.

82. See Medicare Modernization Update, available at http://www.cms.hhs.gov/MMAUpdate/01_Overview.asp#TopOfPage (last visited May 2, 2006)

83. David J. Barron, *A Localist Critique of the New Federalism*, 51 DUKE L.J. 377, 432 (2001).

84. Press Release, Ill. Office of the Governor, Governor Blagojevich & Congressman Emanuel joined by Wis. Governor Doyle in launching I-SaveRx Prescription Drug Imp. Program; Citizens of Ill. & Wis. Now Able to Purchase Rx Drugs from Europe & Canada (Oct. 4, 2004), <http://www.illinois.gov/PressReleases/PressReleasesListShow.cfm?RecNum=3439> (last visited June 6, 2006).

85. *Id.*

One striking aspect of the collaborations is the interaction of public and private arenas that can be seen in the emerging public/private partnerships. These collaboratives have various organizational forms that allow for flexibility. All of these sites need some form of “publicness.” However, getting public and private interaction is not easy because efficiency and legitimacy are both needed. One obstacle to getting the interaction right is the lack of coordination between public law and private law. Public law is embodied in administrative law and procedure whereas private law is contract, tort and property. Each domain has a separate and robust history, expertise, and skill set. However, if these emerging private partnerships are to work they must be composed of both public and private law. One model would be through contracts with public agencies where the services provided are subject to open meetings and open records requirements.⁸⁶ Another technique would be through monitoring standards for these alternative sites by a credible organization.⁸⁷ It would be beneficial to have a period of experimentation for various models of “publicness” accomplished through sharing models designed to exchange experiences and evaluate effectiveness.⁸⁸ Various models are proposed in the debate over the ownership of health data between providers and consumers.⁸⁹

B. Consumer and Patient Participation

One distinctive feature of new governance practices is the increasing and changing role of the patient and consumer. The patient and consumer are envisioned as independent actors who can influence outcomes at the clinical and policy level. The development of economic incentives such as co-pays and positive economic incentives are methods of the individual using his or her market power to improve quality of health care. The use of public information based on data that enable the consumer to make choices will both improve the quality of care and the entire system. These economic and information incentives can be combined with methods of delivery encouraging

86. One example is the contract between the Wisconsin Department of Health and Family Services and the Wisconsin Hospital Association to administer the data collection program for the state.

87. One example of this the work of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). See Blum, *infra* note 117

88. See Cary Coglianese, *The Internet and Citizen Participation in Rulemaking*, 1 INFO. SOC. J.L. & POL'Y 33 (2005) (discussing the tension between regulators and industry and transparency of interactions; pointing out that sometimes the public interest is advanced through informal communications that are not always visible to all).

89. One commentator has noted that if these decisions on ownership and availability are allowed to be, proprietary democratic values will be lost, and our society could be called a “banana republic.” John Chapin, *Health Data in a Banana Republic* (Jan. 2005) (unpublished manuscript, on file with author).

patients to participate in the management of their own care, particularly with connection to chronic illnesses.

There is also an emphasis on consumer participation in the collaborative sites. The consumers are considered essential to the functioning health care improvement processes; the voice of consumers and patients is essential for deliberation. The voices of the consumers and patients can be provided through groups of consumers, such as disease groups, and lawyers who represent disadvantaged groups, including racial and ethnic minorities.

In earlier periods physicians were relied on as the trusted agents for patients because physicians were the sources of knowledge. Physicians were also the major reformers of the health care system during the early Twentieth Century.⁹⁰ During the Great Society period, consumers and patients participated in deliberation through public interest lawyer advocacy at the administrative agency, social movements at the legislative level, collective bargaining with employers, and litigation against discrimination and malpractice.⁹¹ In the market model that emerged in the 1990s, consumers were sometimes viewed as creating costs unrelated to necessary care and were encouraged to join managed care organizations where decisions regarding the type and quantity of care were made by management.

The rise of consumers as key players in health care is related to the use of markets in health care to controlling costs and the increase in patient involvement to control chronic disease. Therefore, two consumer roles are important in health care: the role of the purchaser of healthcare services and that of the patient active in his own health care.⁹² After managed care, employer purchasers realize that more allies are needed to develop and implement any new healthcare system design. They view a strong consumer role as essential to any sustainable change to the system. They also believe that giving consumers a greater voice in the purchase and delivery of health care is essential to creating a cost-effective and high quality system. The interface of the longstanding patient rights vision with the newer patient empowerment movement opened the path to a more active role for patients/consumers in the level of clinical and institutional decision making.⁹³ The initial move toward public disclosure, while led by business groups, now has the strong endorsement of traditional consumer groups such as Consumers Union.⁹⁴ Consumers Union has created a campaign called "Stop Hospital

90. Joe Rees, *The Origins of Self-Regulation in the American Hospital Industry* (June 2003) (unpublished manuscript, on file with the author).

91. *Lawyering for a New Democracy*, *supra* note 51, at 584.

92. Barry Kozak, *New Health Savings Accounts Promote Consumer Driven Health Care*, 18 CBA REC. 58, 59 (2004). Consumer driven health care is advocated as encouraging both aspects of the consumer role.

93. Sydney Halpern, *Medical Authority and the Culture of Rights*, 29 J. HEALTH POL. POL'Y & L. 835, 842 (2004).

94. See Consumers Union, <http://consumersunion.org> (last visited May 2, 2006).

Infection” to “help consumers get the best quality of care by promoting public disclosure of hospital infection rates . . . Consumers and employers can select the safest hospitals and competition among the hospitals will quickly force the worst to improve.”⁹⁵ Consumers Union is endorsing the passage of legislation to require the infection rates be made public.⁹⁶ The emphasis on patient self-management has decentered the physicians and lawyers.

The new governance legal forms also require a revised role for lawyers. The new governance processes incorporate all the stakeholders in order to develop a system that acknowledges and utilizes diverse knowledge. Lawyers therefore can participate by representing their constituency and by developing processes and programs that work to improve the system. One example of a different role for lawyers is the quality approach in reducing disparities. The civil rights litigation approach embodied in Title VI and HHS enforcement model were based on the lawyer as the adversarial advocate for the patient.⁹⁷ In the quality assurance approach, the lawyer’s role would no longer be as an advocate for the individual or institutions alleging discrimination by health care providers and payers. It would decenter the court as the main arena for redressing the harm that came from discriminatory conduct. The major emphasis is placed on reforming internal health care systems through a combination of creating incentives for positive outcomes and evidence-based medicine. Employees and government payers would tie payment to quality outcomes, including compliance with outcomes that have a significant affect on preventing disparities. Examples of such outcomes are good prenatal care, normal birth-weight babies, and proven chronic care management. Therefore, the civil rights model, which is based on an adversarial lawyer and court complex, would no longer be the dominant model. The performance of physicians and the medical institutions, combined with carefully developed guidelines and benchmarks, would be the tools for reducing disparities.

A concern about new lawyer roles is uncertainty about who will be the advocates for disadvantaged groups. While educated patients can be effective at the patient-physician level, representatives of the interests of the disadvantaged groups are essential at the institutional and policy level. The move to consumer-driven health care contains the idea that consumers and patients, if they are provided information or economic incentives, can influence the system as well as obtain better, less expensive care. The advocate’s role in assisting patient participation can tie into the important

95. *Id.*

96. They have a model act “Hospital Infection Disclosure Act” and are encouraging activists to argue for its passage. In some cases, sponsors of the legislation include the hospital associations and patients and families who were infected. Lawyers who brought the lawsuits on behalf of the patients are also involved.

97. Marianne Engelman Lado, *Unfinished Agenda: The Need for Civil Rights Litigation to Address Race Discrimination and Inequalities in Health Care Delivery*, 6 TEX. F. ON C.L. & C.R. 1, 16 (2001).

work done on negotiation and dispute resolution. The personal health record is one tool that is being promoted as a way for consumers to be in control, particularly in relation to their physician and health care institution.⁹⁸ These exercises teach the patient to operate on the patient/client, institutional, and policy levels.⁹⁹

Many people cannot deal with the overwhelming number of choices. One example is the difficulties associated with the Medicare plan for pharmaceuticals which is failing because of excessive information.¹⁰⁰ People often need information tailored to their own health history; people with chronic disease may need assistance in locating information on what programs provide intensive disease management. On the institutional and policy level, the knowledge required for intervention is often sophisticated and requires skills such as accessing institutional policies, locating statutes and court cases, and discovering the places where intervention will be useful. Advocates for disadvantaged groups can be lawyers or reformist physicians committed to an all-inclusive health care system. These advocates play the role of assuring that barriers to access are removed. For example, they could ensure the collection of reliable data on the number and characteristics of the uninsured for program and policy development.¹⁰¹ These advocates may also play an important role in diffusing the liability debate that is a barrier to implementing the new quality tools. They could advocate for the creation of monitoring institutions that assure that abusive and negligent behavior is prevented or sanctioned.¹⁰²

C. Disaggregated but Necessary: The Role of Government

The New Deal view of government as the controlling, commanding presence is no longer accurate.¹⁰³ It is imagined that the social dimension of government should primarily be directed from Washington through national legislation implemented through administrative agencies issuing uniform regulations. State and local governments, while still involved, had a subordinate role. In the 1980s, with the move towards confidence in market

98. Connecting For Health, <http://www.connectingforhealth.org>. (last visited May 2, 2006).

99. David Dominguez, *Getting Beyond Yes to Collaborative Justice: The Role of Negotiation in Community Lawyering*, 12 GEO. J. ON POVERTY L. & POL'Y 55, 59-60 (2005).

100. Jane Zhang, *Seniors Are Slow To Sign Up on Own For Drug Benefit*, WALL ST. J., Dec. 23, 2005, at B3.

101. Donna Friedsam, *Racial and Ethnic Data: Are they Reliable for Program and Policy Development?*, WIS. PUB. HEALTH AND HEALTH POL. INST., ISSUE BRIEF, No. 5 (Oct. 2002) available at <http://www.pophealth.wisc.edu/uwphi/publications/briefs/oct02brief.htm> (last visited June 6, 2006).

102. Sage, *supra* note 4, at 402.

103. See TUSHNET, *supra* note 42; William H. Simon, *Solving Problems v. Claiming Rights: The Pragmatist Challenge to Legal Liberalism*, 46 WM. & MARY L. REV. 127 (2004).

based incentives as the means to provide health care improvement, the confidence in external government regulation declined. However, in the recent discussions about governance, the role of government is seen as necessary, even though it may no longer be the authoritative directing agency as envisioned in the traditional command and control model.¹⁰⁴ Traditionally, the government's primary role has been fiscal through the public budgetary process.¹⁰⁵ Through its fiscal capacity, the State can align various private players with public policy goals. It can use this power to play disaggregated roles: enactor of innovative regulation, crucial funder, active monitor, final sanctioner, orchestrator, and justifier of programs. The States' participation in the collaboratives, for example, is essential to ensure that health care services, even if privatized, are fair, equitable, and effective. The government assumes a coordinating role in the implementation of health care services and organizes activities so that each actor can do whatever it does best. The various ways in which government can be involved include facilitating collaboration, monitoring programs for effectiveness, collecting data, using regulation and funding to assure quality, correcting imbalances in participation, and sanctioning to ensure that actors participate in good faith.

D. New Corporate Forms

There is also a change in the governance of hospitals. The existing governance structures cannot cope with pressures such as pay for performance regulations, benchmarking for quality care, and embedding technology. Hospitals are considering a wide range of redesigns of their systems in order to be able to deal with these external pressures. Hospitals are considering coordinating with other health care organizations, using industry based regulatory systems such as ISO 9000, placing more responsibilities to meet public goals on boards of directors, and creating a systems approach to liability.¹⁰⁶ As hospitals and clinics become larger integrated systems, there is also a move towards standardization of benchmarks and improved internal communication. This requires lawyers and compliance people to agree on systems in order for the information to be produced over the entire range of institutions and people responsible for institutions. Thus, we see a crossing over between all institutions necessary to demonstrate value for the compensation to be paid. Therefore, the governing system requires more

104. See Mark Schlesinger, *On Government's Role in the Crossing of Chasms*, 29 J. HEALTH POL. POL'Y & L. 1 (2004); see also TROYEN A. BRENNAN & DONALD M. BERWICK, *NEW RULES: REGULATION, MARKETS, AND THE QUALITY OF AMERICAN HEALTH CARE* (1996).

105. Carolyn Hughes Tuohy, *Agency, Contract, and Governance: Shifting Shapes of Accountability in the Health Care Arena*, 28 J. HEALTH POL. POL'Y & L. 195, 210 (2003).

106. Sarah Kaput, *Expanding the Scope of Fiduciary Duties to Fill a Gap in the Law: The Role of Nonprofit Hospital Directors to Ensure Patient Safety*, 38 J. HEALTH L. 95, 102-03 (2005).

collaboration and interaction and undercuts the board of directors in a single institution. One way to achieve this goal is for lawyers and compliance professionals to work together to develop standards.¹⁰⁷ What is emerging in new governance is a blurring of the boundaries among for-profit institutions, large health care nonprofit organizations, and community-based agencies. The new collaborative sites include multiple actors from different organizational structures. These collaborations can orchestrate new ways of delivering health services and improve quality of services. Useful tools include learning from each other, sharing of data, and the dissemination of peer benchmarks. Through this process, there can be a reconsideration of the traditional legal forms.

The reassessing of nonprofit hospitals as a source of assistance and funding for expansion of access is one example of what the collaborative action may create. There have been longstanding charity care pools that exist in many states serving as sources of funding to meet the health care costs of uninsured people. These programs have been routinely criticized as being insufficiently integrated with the health care delivery system and with the individual needs of clients.¹⁰⁸ There is also a charitable requirement for nonprofit hospitals. This requirement has been poorly monitored by the government and insufficiently integrated with the health care needs of the uninsured. Recently, class action lawsuits have been filed across the country against hospitals for their failure to provide services to the uninsured. These lawsuits, while largely unsuccessful, have forced hospitals to consider how they link their service for the uninsured to their organizational status and to their community outreach.¹⁰⁹

In Utah, former Governor Leavitt initiated integrating hospital charitable programs into the Medicaid program. This represents an example of public-private integration and orchestration discussed earlier. It is a redesign of the corporate form, where the state's interest is expressed, not only through the corporate non-profit law and the attorney general's authority to intervene in charities, but through the government directly working with the boards of directors in a common mission. The federal government is significantly increasing its funding for community based health centers because of their excellent record for providing equitable, quality care for poor and marginalized groups. Its services can be put together with large for-profit insurers and large nonprofit hospitals and clinics to contribute to a funding

107. Barry P. Chaiken, Address at the Digital Healthcare Conference (June 9, 2005) (transcript on file with author).

108. Elisabeth Benjamin & Kat Gabriesheski, *The Case for Reform: How New York State's Secret Hospital Charity Care Pool Funds Fail to Help Uninsured and Underinsured New Yorkers*, 8 N.Y.U. J. LEGIS. & PUB. POL'Y 5, 8-9 (2004-05).

109. Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 HARV. L. REV. 1015, 1018 (2004); Guy Boulton, *Uninsured Get More Discounts*, MILWAUKEE J. SENTINEL, May 16, 2005, at A1.

package that will be administered by the participating groups. This allows for a variety of groups to do what they do best and also allows for structural monitoring and review of the dollars in the “deal.”¹¹⁰

E. Alternative Dispute Resolution

The disillusion with traditional litigation has been ongoing for several decades. The high costs, unequal access to lawyers, and poor fit between the social problem and the results of litigation has engendered a series of proposed reforms. These proposed reforms move toward new types of redress, reduced use of lawyers, and improved health care outcomes.

Two additional types of dispute resolution are emerging as part of changing governance. The first is independent external review, a dispute resolution system for health care contract claims. This system developed out of dissatisfaction with the managed care system and is a way of reasserting physician peer review and curbing excesses in cost containment. The system, now enacted in almost all states, is primarily a paper review and almost eliminates lawyers from the system. The external review process is created through legislation but it is administered by private organizations certified by the state. These external review organizations use peer reviewers with very specific knowledge about the subject of the complaint. As one scholar notes they have a “structural hybridity, a discursive marbling of demands for democratic control over profit-driven health care services together with calls for responsiveness to medical expertise . . . a renegotiation of the role of government, not a simple contraction or expansion.”¹¹¹ There is also a relationship between the complaints and improvement in the quality of the healthcare plan. The information obtained from the complaints received and the decision of the review body can be accessed by the government agency and the health care plan and this information can be evaluated and utilized in improving the quality of the health services. Public disclosure of the complaints and their resolution is another important component that can encourage systemic changes within the health care plan.¹¹²

A second type of dispute resolution system is a version of restorative justice. The traditional command and control regulatory system relies on inspection, regulation, and sanctions. For many health care facilities that are financed through government payments, there is a narrow range of financial viability. The use of fines as deterrence is not viable since the facilities,

110. See John D. Colombo, *The Failure of Community Benefit*, 15 HEALTH MATRIX 29, 62 (2005) (discussing proposal for an access based test for nonprofit hospitals to justify their tax-exempt status).

111. Nan D. Hunter, *Managed Process, Due Care: Structures of Accountability in Health Care*, 6 YALE J. HEALTH POL'Y L. & ETHICS 93 (2006). See also Rachel Tanner, *Health Insurance Oversight*, HPTS ISSUE BRIEF 015010.3, Oct. 10, 2005.

112. Hunter, *supra* note 111.

particularly nursing homes, are barely making it, and a failure will leave the state with the burden of relocating residents. Thus, as the push for high quality nursing homes continues, there is a need to come up with other means of correcting poor quality that does not involve heavy fines. In the restorative justice model, family members, residents, and if possible community and advocacy groups, meet together to discuss the problem and come up with a plan for improvement. This is a first step prior to the institution of the traditional regulatory sanctions.¹¹³

F. New Regulatory Tools

Another set of tools might be described as hitting the physicians and hospitals in their wallets and their egos. These three regulatory tools can be called: public information, financial incentives tied to efficiency, and regulations that allow the institutions to develop diverse ways of successfully meeting the standards.

There is widespread development of data about outcomes and commitment to protocols. Participation by physicians and other health care professionals is required in the development of standards and benchmarks for credibility. This information is sometimes collected by clinics, hospitals, and physicians and is often posted and accessible to all via the internet. These tools are different than traditional regulation. Instead of rigid requirements issued after great debate, but often not revisited for many years, these systems are designed to be constantly updated and reviewed. This information can affect performance through shaming and motivates the institutions to develop systems that obtain results. By gathering data and updating results on a regular basis, there is a constant reinforcement to improve performance. Another approach to improving performance is to align the incentives by tying financial payments to quality¹¹⁴ One commentator recently noted that “value for dollar” is now the game in health care.¹¹⁵

A third approach may be referred to as management-based regulation.¹¹⁶ Management-based regulation is a mechanism that “directs regulated entities to engage in planning processes, that are self determined, to meet a particular public goal.”¹¹⁷ Unlike technology-based and performance-based regulations,

113. Braithwaite, *supra* note 75.

114. Judith H. Hibbard et al., *Hospital Performance Reports: Impact on Quality, Market Share, and Regulation*, 24 HEALTH AFF. 1150, 1159 (2005).

115. Dave Riemer, Address at Univ. of Wis. Med. Sch., Apr. 4, 2005 (transcript on file with author).

116. Cary Coglianese & David Lazer, *Management Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 L. & SOC'Y REV. 691, 691 (2003).

117. John D. Blum, *Combating Those Ugly Medical Errors-Its Time for a Hospital Regulatory Makeover!* (June 2005) (unpublished manuscript, on file with Widener University Law Review).

management-based regulation is focused on planning.¹¹⁸ Here again Medicare is taking the lead through the implementation of a quality assessment and performance program to reduce medical errors which is part of the broader Medicare conditions of participation. It is a planning model that is designed to allow hospital flexibility in initiating new programs.¹¹⁹

Medicare has recently invested heavily in collecting quality data and publicly disseminating such information. It has also been active in encouraging groups of stakeholders to develop benchmarks and indicators to be used for the comparisons. However, there is still an ongoing debate about how effective economic incentives and public data dissemination are in motivating providers. One issue is whether the data should be used to encourage internal systems reform by sharing the data exclusively within the organization, such as hospitals and physician practices. An alternative approach would be to publicly publish the data by individual hospital or physician to encourage consumer choice. The proponents of public dissemination see that option as "a social movement wrapped in a business model."¹²⁰ There is also an issue of publicness of the process of data collection and dissemination. If the collaborative sites that are producing and disseminating the information are not adequately transparent, the process could become insular and self-protective. One commentator has said that the control of the data and its dissemination requires adequate public oversight; otherwise our democracy has become a "banana republic."¹²¹

IV. COEXISTENCE: DYNAMIC BETWEEN OLD AND NEW, ORCHESTRATING MULTI-PRONGED STRATEGIES, AND INTEGRATING LEGAL VALUES

These three stories about resolving health care problems are descriptions of works in progress. As the reforms proceed, two questions emerge. The first is the question of how and whether new governance and soft law relate to the existing regulatory system. The second question is whether the innovations that are emerging can reform health care while assuring participation, fairness, equity and accountability.

There are three examples of coexistence between old governance/hard law and new governance/soft law in health care stories. The first is dealing with medical error, where old and new models coexist as alternatives and potentially as rivals. The second is where a government agency takes on the whole range of new governance techniques and employs them as part of its regulatory and funding functions. An example of this is the Medicare program of the Centers for Medicare and Medicaid Services. The third route is the

118. Coglianesi & Lazer, *supra* note 116, at 691.

119. See Blum, *supra* note 117.

120. Mark Xistrass, Address at Colloquium on Health Care Data Collection and Reporting (Feb. 7, 2005) (transcript on file with author).

121. Chapin, *supra* note 89.

integration of traditional legal values as part of the new governance approaches: monitoring to ensure participation, assuring commitment to eliminating discrimination through maintenance of equal protection, and linking the right to health care to the achievement of a robust economy.

A. Dynamic Between Old and New

Coexistence between new governance and soft law and the traditional hard law can occur through a dynamic rivalry. One example of the interrelationship between the two is the effort to move from the traditional medical malpractice and administrative sanctioning of physicians to a systemic increase in quality.¹²² The old governance system relied on medical malpractice and administrative physician sanctioning to guarantee quality and compensate injured parties. However, the existing malpractice legal structure is now a barrier to the development of a new framework that gets physician buy-in, adequately compensates patients for poor medical outcomes, and creates systemic processes to avoid medical errors. There is widespread agreement that the malpractice litigation system fails to compensate injured parties and to deter future negligence. Proponents of the quality assurance system assert that it will do a better job of deterring negligent behavior as well as preventing unnecessary errors.¹²³ However, there is not yet a consensus as to how to compensate patients who are injured through negligent or non-negligent behaviors. Many alternatives on how to compensate patients who are injured have been proffered such as no-fault insurance, enterprise liability, or new types of redress such as medical courts or arbitration.¹²⁴

B. Orchestrating Multi-pronged Strategies

In some cases there is coexistence between a traditional government agency and new governance techniques where they are yoked in a multi-pronged strategy that deals with complex problems. Orchestration is one example of a multi-pronged strategy. It uses new governance techniques to integrate new knowledge, encourage innovation, and allow for diversity. The government agency, however, relies on its traditional regulatory and funding

122. See Michelle M. Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375, 411 (2005) (discussing the tension between tort law and other regulatory approaches citing this area as one of the structural issues for what they call rational regulation).

123. See Sage, *supra* note 4.

124. Paul C. Weiler, *Fixing the Tail: The Place of Malpractice in Health Care Reform*, 47 RUTGERS L. REV. 1157, 1185 (1995).

roles to provide baseline incentives for participation in the new governance processes.¹²⁵

The role of the Center for Medicare and Medicaid Services (“CMS”) is a dramatic example. CMS is embarking on a multi-pronged strategy to improve quality and contain costs using new governance techniques for Medicare. It is currently funding pay for performance pilot projects throughout the country that may be the basis for future widespread use.¹²⁶ The pay for performance criteria will be used as a condition of participation for hospitals seeking to receive Medicare reimbursements. It is creating forums for deliberation and action for quality improvement. For example, the Hospital Quality Alliance is a public-private partnership designed to produce published consumer information coupled with health care quality improvement.¹²⁷ CMS recently required the submission of hospital quality data as a condition of compliance in order to receive Medicare funding;¹²⁸ this data is now displayed on a website.¹²⁹ They have initiated other substantial publication of consumer information starting with comparative nursing home quality indicators.¹³⁰ CMS initiated a discussion among many stakeholders on how Medicare information can be used by beneficiaries in medical health records. It is one of several initiatives put forth in response to “President Bush’s call for Americans to access their health records electronically within ten years.”¹³¹

C. *Integrating Legal Values*

The New Deal/Great Society model for governance emphasized the need for universal “rights,” based on constitutional or statutory law. The function of rights can be seen as coexisting with new governance modes. This coexistence can be seen in the way traditional legal values must be maintained in order for new governance to be effective and legitimate. Three approaches to health care reflect the coexistence of these new governance techniques with

125. Mello et al. term this form of coexistence “pluralistic regulatory environment.” Mello et al., *supra* note 122, at 381.

126. Press Release, Center for Medicare and Medicaid Services, Medicare “Pay For Performance (P4P)” Initiates (Jan. 31, 2005), <http://www.cms.hhs.gov> (follow “Newsroom” hyperlink, then “Media Release Search”) (last visited June 6, 2006).

127. Marybeth Farquhar, *New Governance in Hospital Quality Improvement: The Hospital Quality Alliance* (June 2005) (unpublished manuscript, on file with author).

128. *Id.*

129. See Hospital Compare at <http://www.hospitalcompare.hhs.gov> (last visited May 2, 2006).

130. Nursing Home Compare, <http://www.medicare.gov/NHCompare/home.asp> (last visited May 2, 2006).

131. Summary Report, Center for Medicare and Medicaid Services, Summary of Responses to an Industry RFI Regarding a Role for CMS with Personal Health Records, <http://www.cms.hhs.gov/EducationMaterials/Downloads/SummaryofRFI.pdf> (last visited June 6, 2006).

legal values: inclusion in universal access, equity in health care treatment, and participation and transparency in health care decision making.

1. Inclusion

The long-standing battle for a “right to health care” underlies many of the campaigns for universal provision of health care coverage. The failure to achieve a constitutional right for universal coverage was a major disappointment of the 1960s and 1970s “war on poverty.” More recently, the entitlement to Medicaid coverage, a partial type of “right,” was seriously threatened in a congressional battle and many of the new programs do not have entitlements.¹³² The elimination of the entitlement status of the major welfare program for poor people—Aid for Dependent Children (“AFDC”)—was a tremendous blow for the progressives who, since the New Deal, had dreamed of the adoption of the European “social citizenship” model.¹³³ The maintenance of the entitlement to Medicaid is a continual battle. The battle over entitlements, coupled with the Clinton plan failure, undermined the progressive belief that an entitlement/rights approach was a likely route to universal coverage. Constitutional approaches have proved ineffective and recent court decisions have further undermined the court-constitutional approach.

What is needed is a conceptualization of the relationship between hard law entitlements with soft law techniques such as experimental expansions of coverage and linking private employer based programs with public coverage.¹³⁴ The merger of public and private programs is a way of achieving universal coverage where the poor will not be targets of inadequate funding and poor quality.

In the access area, the importance of a commitment to universality continues. Recent proposals have indicated a wider base of support among business and conservative legislators for universal coverage based on the “business case.”¹³⁵ Some type of hard law commitment may be a necessity to keep the attention on the importance of universality. But, a right is not sufficient if there is inadequate care and excessive patient payment contribution.¹³⁶ Recent state battles over maintaining Medicaid expansion programs have demonstrated the conflict between court mandates and the

132. Sara Rosenbaum et al., *Public Health Insurance Design for Children: The Evolution from Medicaid to SCHIP*, 1 J. HEALTH & BIOMEDICAL L. 1, 41 (2004).

133. JOEL F. HANDLER, *SOCIAL CITIZENSHIP AND WORKFARE IN THE UNITED STATES AND WESTERN EUROPE: THE PARADOX OF INCLUSION* 1-19 (Cambridge Univ. Press 2004).

134. See Tamara K. Hervey, *The European Union and the Governance of Health Care*, LAW AND NEW GOVERNANCE IN THE EUROPEAN UNION AND THE UNITED STATES (De Burca & Scott eds., Hart Pub. 2006).

135. Pam Belluck, *Massachusetts Sets Health Plan for Nearly All*, N.Y. TIMES, April 5, 2006, at A1.

136. Rosenbaum, *supra* note 132, at 41. See also, Bill J. Wright et al., *The Impact of Increased Cost Sharing on Medicaid Enrollees*, 24 HEALTH AFF. 1106 (2005).

more flexible non-entitlement approaches.¹³⁷ If the standards are not enforceable, there will be a tendency to cut back when funding is tight. The recent budget battles have demonstrated a strong commitment to expanded health care by Governors on a bi-partisan basis. But the fragility of the expanded programs demonstrates that a combination of diverse state programs, that merge public and private coverage, has to be incorporated into a framework that allows for court and public scrutiny.

2. *Equity*

There are major initiatives underway to reduce disparities in race and ethnicity, but the role of rights is decentered in the new approaches. There is reliance instead on quality tools such as benchmarking, nationally accepted protocols for best practice, and patient self-management to eliminate disparities. Preliminary results show that these processes may be effective in reducing racial disparities. The move to using the law of quality compliance includes soft law instruments such as benchmarking, data collection, and reporting.¹³⁸ However, the law of civil rights can be combined with the law of quality compliance. The quality compliance techniques require collection of data and a commitment by the providers and institutions to collect, examine, and utilize the data. They also require a sharing of information across local groups and at the state and national level. Community and patient participation in the system for quality are required for the protocols to be successful. In order for there to be confidence that the standards and protocols are being followed, there must be an ability to monitor the work of institutions, such as hospitals and clinics. The civil rights community has maintained an interest in health care and the potential for legal remedies remains. Its role can include ensuring that public data dissemination is available and usable by outside groups. Specific monitoring systems can be set up, at the community level, the state level, the self-regulatory body level, or the national level. Without these checks it is difficult to monitor that the techniques are in place and effective. Once new governance techniques show positive results, it will be possible to use litigation to pressure health care providers to adopt the new processes. In that way, the simultaneous presence of anti-discrimination law and new quality improvement processes may make possible progress not previously achievable.

137. See Bureau of TennCare, *available at* <http://www.tennessee.gov/tenncare/news/index.html> (last visited June 6, 2006).

138. Sara Rosenbaum, Symposium, Racial and Ethnic Disparities in Health Care Treatment (May 18, 2004) (unpublished manuscript, on file with author).

3. *Participation and Transparency*

The values of participation and transparency are essential for a democratic system of governance. The process is likely to lose legitimacy if important and affected groups are left out of the process due to exclusion or lack of information. This may mean that special efforts must be made to ensure participation of underorganized and underrepresented groups, as well as organized groups. One approach to ensure participation is providing a system for explicit measurement of the participation of disadvantaged groups in these new sites.¹³⁹ This requires guidelines for participation and monitoring to ensure that the guidelines are being met. Another approach is to provide a process where groups who view themselves as excluded from the process can challenge the transparency and effectiveness of the governance scheme. A final approach would be to develop a process where actors who are refusing to collaborate in these new alliances are sanctioned. Some type of sanctioning might be necessary to provide the incentives for participation.

In order to be legitimate, the processes must be visible and accountable. The sites for deliberation, crucial elements in new governance decision making, should allow their work to be visible to interested parties. The problems involving access to electronic records raise important issues, such as the control of valuable social information. The interest in personal health records raises intriguing questions about the availability of the information and the interaction between the patient and the health care institutions. The coexistence of the need for flexible public private spaces and information must be balanced with the ability to hold the actors accountable for their outcomes.¹⁴⁰

CONCLUSION

This is an interesting time to look at alternative governance in health care. It is an opportunity to explore the implications of these alternatives and evaluate which types of regulation and governance work most effectively to achieve health care goals. Many innovations challenge conventional institutions, roles, and professions. They also challenge the way people participate in society and our view of how government and law can operate. Many questions remain including the relationship of the new techniques to the older system. However, since the health care industry is one of the most significant sectors affecting the lives of every person as well as the productivity and growth of the economy, examining alternatives is a worthwhile endeavor.

139. Brandon L. Garrett & James S. Liebman, *Experimentalist Equal Protection*, 22 YALE L. & POL'Y REV. 261, 321 (2004).

140. Patricia Flatley Brennan, Address at the Digital Healthcare Conference (June 9, 2005) (transcript on file with author).

