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IN U.S. HEALTH CARE

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I. INTRODUCTION*

Eighty-two per cent of Americans rank health care among their top issues.¹ People are satisfied with health care when they can get it but are afraid they will not be able to secure it. Over 45 million people were without health insurance during 2003.² Inadequate health care quality has been well documented. Compounding the problems is an extremely complicated health care scheme. Health care coverage is provided through a mixed public, private, and non-profit system. It delivers services through local provision with federally controlled programs such as Medicare. This complicated framework for providing health care has thwarted the use of technology, which has been so crucial to modernizing other industries. Despite the development of evidence-based information and new technology, the problems of the uninsured, cost escalation, and improving quality are still threatening the viability of the health care system.

There is a sense that these problems can be resolved. This belief is related to the realization that the old system of governance can't solve these problems, but there are new techniques and theories that can help resolve problems. The old tools include centralized government entitlement programs with primary authority at the Washington level; inflexible rules; self-regulation; and heavy reliance on

* Thanks to Jessica Levie and Tom O'Day for their excellent research and editing help. I would also like to thank the students in my 2002, 2003, and 2004 health law courses.

¹ Paul Krugman, 'The Health of Nations', *New York Times*, Feb. 17, 2004, at A23.

²U.S. Census Bureau, *Income, Poverty, and Health Insurance Coverage in the United States: 2003* (August 2004) 14.

litigation.³ However, since the 1970s, critics from the left and right of government regulation and the administrative state have called for alternatives to this vision. Out of this critique has emerged new approaches to governance that are not simply deregulation.

The inability of the old set of tools, legal theories, and institutions to resolve the problems was highlighted in the failure of the Clinton health plan and the partial failure of managed care in the 1990s. These failures set the stage for a series of collaborations of people searching for new ways of resolving these ongoing problems. This new approach is called ‘new governance’ and consists of devolution, public-private partnerships, stakeholder collaboratives, new types of regulation, network creation, coordinated data collection, benchmarking, and monitoring. This type of ‘new governance’ changes the way law is created and administered. It restructures relationships among markets, government, and the professions and re-opens the age-old issue of how best to maintain social and environmental values in a market economy. New governance is a third way between traditional administrative law and total deregulation. It recognizes that, while privatization can bring important new tools to help solve problems (like market-based approaches), ‘private markets cannot be relied on to give appropriate weight to public interests over private ones without active public involvement.’⁴

In health care, there has always been a mix of self-regulation, market forces, and government regulation.⁵ As one observer asked, ‘How can professionalism be balanced with corporate or government

³ For an extensive discussion of these issues see, William H. Simon, ‘Solving Problems v. Claiming Rights: The Pragmatist Challenge to Liberal Legalism’ (2004) 46 *William and Mary Law Review*.

⁴ Lester M. Salamon, ‘The New Governance and the Tools of Public Action: An Introduction’ (2001) 28 *Fordham Urban Law Journal* 1635.

⁵ Troyen A. Brennan, ‘The Role of Regulation in Quality Improvement’ (1998) 76 *Milbank Quarterly* 709.

oversight and measurement of the quality and costs of care provided by physicians?’⁶ The problem has been understanding how to balance these, in the context of the problems that have to be resolved. The context includes gridlock in Washington, the political interest in shifting power to local levels, the potential of technology, the skepticism about professional expertise, and the desire for more individual responsibility and involvement.

As these new governance practices take hold, they become a challenge to the way in which we view government and the way law works. The New Deal/Great Society model seems out of touch and disfavored. The new governance practices are a way of seeking new methods to resolve real social problems. Skeptics of new governance, such as Mark Tushnet, believe that the issues of transparency, fragmentation, unproven success of new tools, and imbalance of power are major obstacles to the promise of new governance.⁷ On the other hand, Tushnet has characterized the conservatives as having a vision and agenda that is persuasive and may be implemented and sees new governance as one of the few efforts to create a liberal counterpoint.⁸ Other scholars have more confidence that new governance alliances and tools can win favor and move beyond the unpersuasive, New Deal bureaucratic model to achieve a more just society.⁹

This paper examines the way new governance tools are being incorporated in resolving health care problems. The first section discusses stakeholder collaborations. These collaborations are the arenas in which the leading actors are developing ways of dealing with three health care conundrums: how to

⁶ Lawrence P. Casalino, ‘Physicians and Corporations: A Corporate Transformation of American Medicine?’ (2004) 29 *Journal of Health Politics, Policy and Law* 869.

⁷ Mark Tushnet, *The New Constitutional Order* (Princeton, 2003).

⁸ *Ibid.*

⁹ Michael C. Dorf, ‘After Bureaucracy’ (2004) 71 *University of Chicago Law Review* 1245.

embed technology, how to eliminate racial and ethnic disparities, and how to achieve universal coverage. These alliances are not one format; the format will depend on the nature of the problem and the actors involved. The second section describes new governance techniques in these three problem areas. The description documents how effort to resolve these three problem areas moves from traditional regulation to a different set of strategies. The final section takes a broad view of these new practices and shows that legal theories and concepts must be rethought in order to have the practices successfully resolve the health care conundrums.

II. STAKEHOLDER COLLABORATIONS

There is an underlying energy among many actors who sense an opportunity to drastically revise and improve the way health care is delivered in the United States, despite its overwhelming problems. This optimism stems from two sources: a shared understanding among the stakeholders that change is essential for the economic and personal health of the nation and a confidence that they can figure out how to do it. The stakeholders realize the limitations of the health care system must be overcome in order for the U.S. to continue to have a strong, growing economy and provide excellent high-quality health care for all people. One physician reformer has noted that we have the most expensive health care system in the world and fail to be number one on all other worldwide indicators.¹⁰ A new set of actors in healthcare have the confidence that they can solve the problems. These reformers are revising existing institutions, creating new arenas, and founding monitoring organizations. The new actors are participating in this series of collaborations and dialogues in all types of governance. Local, state, and federal governments

¹⁰ Dr. Jeff Grossman, Address at The Digital Healthcare Conference (June 23, 2004) (presentation on file with author).

are working at the policy level with health care institutions, as well as business and consumer groups. Health care institutions are working together to make changes, such as developing standardized data collection tools that will work within and across institutions. At the patient-provider level, the interaction is changing from a hierarchical relationship to that of a more sharing of expertises.¹¹ Within these institutions and arenas, the actors are able to interact, carry out, and initiate the reforms necessary to improve health care. These approaches can be referred to as new governance practices.

Under traditional regulation, stakeholders did not interact with each other, either because there was no need or because of long-time adversarial positions. The realization that collaboration between actors was necessary developed out of challenges in the late 1980s and 1990s. The first challenge was the move to managed care, developed and led by employer purchasers. These employers believed that they were paying too much money for low-quality services. Many of these leading employers were devotees of quality management in their own businesses. The move to managed care was unsuccessful partially due to resistance by consumers and physicians. The second event was the Clinton health plan debacle. This major effort at the federal level to produce universal coverage failed and was a tremendous blow to the proponents of a centralized single system to deliver health care. The final event was the potential for massive development of information technology that had been transforming other industries such as banking and securities. Despite the tremendous importance of technology to the economic welfare and individual health, the move to technology is moving slower than in other industries for two reasons. First, there has been tremendous resistance to creating the standards necessary to exchange and protect the information. Second, there is reluctance by medical providers to invest in technology because of costs, perceived loss of autonomy, and the fear of a centralized data set.

¹¹ Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington D.C., 2001).

These three experiences emboldened key stakeholders to overcome traditional animosities and self-interests in order to achieve health care reform. The actors are creating new arenas that encourage the collaboration that had been previously difficult to achieve. They realize that bringing varied expertise and broad experiences to the collective governance structure is essential.¹² Active participation of health care actors—providers, consumers, government, and employers—is necessary to solve the persistent conundrums. Each entity has important information that, when shared with all stakeholders, improves the understanding of and the ability to address a problem. Sometimes this process is called ‘bootstrapping’ where separate organizations come to a unified vision for future goals.¹³ These new collaborations may decide to bring in more organizations or have local pilot projects to see what works. This exploration leads to something different and perhaps more ambitious than what they started out with.

Four sets of actors are now emerging as proponents and leaders of alternative approaches to solve the health care conundrums through these new collaborations: the pioneering physician, the concerned payor, the active consumer, and the facilitating government leader. These actors have the characteristics of the ‘policy entrepreneur,’ crucial to the implementation of these new routes.¹⁴ These policy entrepreneurs participate together in various networks, alliances, and forums in order to solve health policy problems. Each policy entrepreneur brings to the alliance a constituency that eventually must

¹² Orly Lobel, ‘The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought’ (2004) 2004 *Minnesota Law Review* 342.

¹³ Wendy Netter Epstein, ‘Bottoms Up: A Toast to the Success of Health Care Collaboratives, What Can We Learn?’ (2004) 56 *Administrative Law Review* 3.

¹⁴ Thomas R. Oliver, ‘Policy Entrepreneurship in the Social Transformation of American Medicine: The Rise of Managed Care and Managed Competition’ (2004) 29 *Journal of Health Politics, Policy and Law* 701.

accept working with the new alliances. This requires the entrepreneur to work well with the disparate stakeholders and simultaneously assure that their constituency accepts the collaboration and sees it as a way to achieve the constituency's goals.

The role of physicians is crucial in order for new governance in health care to be successful. Historically, professionalism was a way for physicians to mediate between the tensions of a market-driven approach to health care and the alternative of government regulation. Professional values and institutions have been viewed as necessary in order for physicians to maintain an independent role between the market and regulation. This worked successfully for physicians for a period of time. However, business and consumer advocates complained that physician control was resulting in higher costs, lack of access, and inconsistent quality of care. The managed care revolution in the 1980s—businesses' attempt to create a competitive market—drastically undermined these traditional professional institutions and controls and damaged the overall leadership of physicians. The recent backlash against managed care, created in part by the actions of health care providers, has emboldened them to once again assert their leadership role. The managed care backlash came about in part by an alliance between physicians and consumers to fight the intrusion of the '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.'¹⁵ In attempting to reassert their leadership role, physicians noted the effectiveness of business leaders in advancing quality in health care through the use

¹⁵ Jill Quadagno, 'Physician Sovereignty and the Purchasers' Revolt' (2004) 29 *Journal of Health Politics, Policy and Law* 815.

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-payor, who emerged in the 1980s to control health care costs, is still active and prominent. Employers wanted to control health care costs because they are a major factor in their profitability and sustainability, since health care coverage in the United States is largely provided through the workplace. Since the 1980s, employers have expanded their activities to improving quality and have even become active in solving the problem of the uninsured.¹⁶ The leading voice of business in health care is the Leapfrog Group, a consortium of more than 100 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.

The rise of consumers as key players in health care is related to both the use of markets in health care as one tool of controlling costs and the rise in chronic diseases that must be controlled by the patient's own involvement. Therefore, two consumer roles are important in health care: the role of the purchaser of healthcare services and the patient active in their own health care. After managed care, employer purchasers now 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 changes 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.

¹⁶ Milt Freudenheim, '60 Companies to Sponsor Health Care for Insured' *New York Times*, January 27, 2005, C1.

Patients are also being called upon to take more active control over managing their personal health care and in designing their health care benefits.¹⁷ A major model for quality improvement, for example, is planned care based on the successful disease management model. It relies on a bottom up, patient empowerment, community-linked approach.¹⁸ The role of the consumer as a co-producer of good health, as well as a consumer choosing appropriate and quality services, is now a major theme in health care reform. Some advocate for the development of intermediary organizations to assist consumers in participating in their own care both through selection of benefit packages, taking on responsibility for following protocols, and for disputing when their care is inadequate.

Government is still a crucial actor in these new arenas. While it may no longer be the authoritative directing agency, as envisioned in the traditional command and control model, government actors are needed for ultimate sanctioning, as sources of funding, and accountability for fair and equitable processes. They are also major payors for health care directly for many groups and therefore, share some of the roles discussed for private employers. Their participation in the collaboratives is essential to assuring that health care services, even if devolved, are fair, equitable, and effective.

There are internal and external mechanisms that affect the potential success of these collaboratives.¹⁹ The first is the internal interests of the stakeholder. For instance, physicians are not a monolithic group. Surgeons, for example, may be threatened by some quality standards in different ways

¹⁷ Christopher Querem, 'Aligning Health Care Incentives' (2003) (unpublished MS on file with author); **see also** Institute of Medicine, *Health Literacy: A Prescription to End Confusion* (Washington D.C., 2004).

¹⁸ Institute for Health Improvement, *The Business Case for Planned Care* (2003).

¹⁹ John Braithwaite, et al., (2004) 'The Governance of Health Safety and Quality' 27, fig.3 (unpublished MS on file with author).

that pediatricians are affected. Small businesses have different interests and power than the Fortune 500 companies. And the success of the collaborative may depend on who within the organization is participating and their relationship to 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 can't sell the collaboration to the rest of the organization, the goals of the collaborative may be undermined.

The external mechanisms that affect the success of the collaboration are the transparency of collaborative, dampening of innovation due to fears of liability and regulations, and the absence of difficult to organize 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. In addition, fears of litigation based on malpractice may also be an obstacle to development and implementation of innovative techniques. Substantive government regulations that do not allow innovative systems, such as payment for quality, are also external checks on the effectiveness of collaborations. A third external barrier is the absence of participation by patients and consumers who have traditionally had difficulty organizing due to their diverse income, race, ethnicity, gender, and geography.²⁰

Various models of collaboratives are negotiating how to solve three of the health care problems confronting the U.S. health care system. The way to address each problem will depend on the nature of the problem and may involve different stakeholders and different tools. One example is the rapidly developing collaboratives that seek to reduce the uneven quality of health care services. These collaboratives are addressing the problem through developing data collection, agreeing on standard

²⁰ John Harley Warner, 'Grand Narrative and its Discontents: Medical History and the Social Transformation of American Medicine' (2004) 29 *Journal of Health Politics, Policy and Law* 769.

benchmarks, and disseminating this information to the public. Businesses' development and use of standards and guidelines to improve quality and encourage the adoption of technology initially threatened the leadership of physicians.²¹ Physicians and other health care institutions are now both cooperating with these business-led collaborations and leading the development of alternative collaborations. These networks can restore the weakened professional influence and leadership of physicians through these newer networks of professionals.²² These networks, however, include not only physicians, as in the older model, but others who share values and interests, such as consumer groups, business groups, and government groups. The consumers are necessary to provide and utilize the information system in order to choose the best providers and also in managing their own care. Business is essential because they pay for health care for a substantial percentage of the population and possess expertise on how to produce business quality. The government is essential to assure that all the relevant stakeholders are part of the quality system and that they themselves as payors will pay for quality. These emerging collaborations for quality are the places where practices are developed and monitored; ideally, each stakeholder returns to his or her organization to implement the best practices and systems reforms advocated by the collaboration.

²¹ 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 MS on file with author).

²² Deborah A. Savage, 'Professional Sovereignty Revisited: The Network Transformation of American Medicine?' (2004) 29 *Journal of Health Politics, Policy and Law* 661; William D. White, 'The Physician "Surplus" and the Decline of Professional Dominance' (2004) 29 *Journal of Health Politics, Policy and Law* 853.

III. NEW GOVERNANCE PRACTICES

Converting the U.S. health care system to an excellent producer of high-quality care for a reasonable price is a daunting task. Health care reformers are concentrating now on three specific issues: implementing technology, reducing racial and ethnic disparities, and expanding coverage. In each area, there is a new set of tools and institutions being deployed to solve these problems and solving each problem will require a tailored approach using the panoply of potential tools, such as devolution, public-private partnerships, new types of regulation, network creation, coordinated data collection, benchmarking, and monitoring. The stakeholders involved will change, depending on the problem being addressed. Similarly, the levels at which the intervention occurs will depend on which is the most effective to solve the problem.

A. Embedding Technology: From Command and Control to Standards and Local Collaborations

An electronic-based system may improve health care quality by giving providers and consumers access to information necessary to make health care decisions, as well as improve communication between provider and patient and among providers.²³ Improving health care technology could cut administrative costs, reduce health care inefficiency, and improve health care quality by creating new high-technology medical records that provide better data. Further, an electronic system could be used to rapidly detect and respond to bioterrorism attacks, as well other population health issues, such as SARS.²⁴ However, there has been tremendous resistance to creating the standards necessary to exchange and protect the information and there is reluctance by medical providers to invest in technology because of high costs, perceived loss of autonomy, and fear of a centralized data set.

²³ Above note 3, at 58-9.

²⁴ Newt Gingrich and Patrick Kennedy, 'Operating in a Vacuum' *New York Times*, May 3, 2004, at A25.

The first effort to encourage the health care system to move to adopt technology was the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA delegates 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 the rules relied on the traditional federal Administrative Procedure Act rule-making process and took many years and many hearings to finally produce pages of pages of rules. The proponents of HIPAA relied on the command and control model.

However, the rules-based system seemingly proposed in HIPAA was never quite the old model. First, the concept underlying the need for a standardized system across competing providers and insurers was initiated by a series of public-private collaborations, known as HIPAA Collaboratives. State-based and local collaboratives consist of all the stakeholders including business, government, technology experts, and providers from all types of backgrounds. Prior to the creation of HIPAA, these groups were already in existence, trying to create local technology standards. In fact, their work was one of the impetuses behind the enactment of HIPAA. Since HIPAA has been enacted, these groups have been helping their members comply with HIPAA by providing information and sharing techniques.²⁵ While there is no formal relationship between the Collaboratives and HHS, they have a mutual dependence. HHS provides the ‘stick’ of the rules while the Collaboratives provide best practices and local implementation so that the vision can be achieved. These Collaboratives continue to provide information back to HHS to improve implementation. These groups also linked with each other and created websites to share information within their own regions.²⁶ Further, HHS, in charge of enforcement, has

²⁵ Above note 13.

²⁶ *Ibid.*

emphasized that they have little interest in conventional enforcement; indeed, there is no budget for enforcement.

In the last several months, there has been a major initiative to further embed technology led by a bi-partisan alliance between former Republican Speaker Newt Gingrich and Representative Patrick Kennedy.²⁷ This reflects the continued reports that describe how advanced technology could radically transform the quality and reduce the cost of healthcare.²⁸ The Bush Administration has proposed a national healthcare regional infrastructure, which will be responsible for coordinating all private sector initiatives into the National Health Information Infrastructure.²⁹ 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 funds demonstration projects at the local because local governance facilitates a high level of trust and it is easier to align incentives that have local appeal. The proposal is for ‘regional’ systems that could be smaller or larger than states. These local health systems seem to build on the success of the HIPAA Collaboratives and move beyond the centralized, rule-based HIPAA system.

This proposal tracks new governance in that it suggests the devolution of governance from the federal government to local and state entities.³⁰ Devolution recognizes that idea of ‘subsidiary’: that ‘all

²⁷ Above note 24.

²⁸ Above note 11.

²⁹ Dr. William A. Yasnoff, Address at The Digital Healthcare Conference (June 23, 2004) (presentation on file with author).

³⁰ Above note 12.

government tasks are best carried out at the level closest to those affected by them.’³¹ This reordering involves more than shifting power from the federal government to more local entities. The technology proposals recognize that the federal government may not be the best entity to completely solve social problems, but it retains a strong role for the federal government in setting standards, monitoring compliance, and providing incentives through funding.³² It allows local public and private groups to respond to local conditions and reduce fears of excessive data collection in Washington.

Devolution does not mean there is no role for coordinating institutions and systems. The local groups, each of which has its own method of addressing technology, also share their knowledge, successes and failures with other groups by way of a nation group that facilitates the exchanges. This requires some form of orchestration, either through horizontal sharing or through multi-level feedback, where a larger entity takes the information and experience and distributes it to other like programs. Orchestration is also necessary to ensure that the quality of the services provided at the local level is adequate and to prevent the race to the bottom, which can occur with isolated and fragmented local projects.

The idea of experimentation is closely linked to devolution, since the more local an entity is, the easier experimentation becomes. Often, experimentation occurs outside the realm of regulation or parallel to it.³³ Experimentation can also be seen as similar to continuous quality improvement because organizations should be constantly experimenting with what works and what does not.³⁴

³¹ *Ibid.*

³² See Louise G. Trubek and Maya Das, ‘Achieving Equality: Health Care Governance in Transition’ (2003) 29 *American Journal of Law and Medicine* 411.

³³ Louise G. Trubek, ‘Lawyering for a New Democracy: Public Interest Lawyers and New Governance: Advocating for Health Care’ (2002) 2002 *Wisconsin Law Review* 594.

It is also closely linked to networking, through the process of finding out from organizations in the field what already works or does not work and adapting to this. The use of networks also changes the role of government because it no longer regulates or commands organizations to achieve desired outcomes. While negotiation through networks may be difficult, rules and standards that have been negotiated by the networks may be better complied with because of the negotiation process.³⁵

Traditional governance has been skeptical of collaboration between private and public. The positive relationship between the HIPAA Collaboratives, which consist of public and private groups including providers and insurers, and the national standard development has been mutually supportive. New governance embraces such networks,³⁶ recognizing that public and private entities have different strengths that can be used in concert to solve public problems.³⁷ The local HIPAA Collaboratives implement the national standards in different ways, creating diverse systems of compliance while still producing an ability to communicate nationally and meet federal standards.

B. Eliminating Racial and Ethnic Disparities:

From Anti- Discrimination Litigation to Quality Assurance Tools³⁸

There is revived interest in eliminating racial and ethnic disparities in health care treatment. Studies have shown that minority Americans receive less health care and what they do receive tends to be lower quality

³⁴ *Ibid.* at 587.

³⁵ Above note 13.

³⁶ Above note 4, at 1634.

³⁷ *Ibid.* at 1633-34.

³⁸ Above note 21.

care.³⁹ These differences remain even when alternative explanations, for example, insurance status and income, are controlled for.⁴⁰ There are substantial new reports emerging that document the issue. These reports are implicitly critical of the old approaches to overcoming disparities.⁴¹

The traditional approaches to eliminating disparities in health care were based on the civil rights litigation approach dating from the 1960s and the passage of the Civil Rights Act of 1964. Title VI litigation was considered a major tool to eliminate racial and ethnic disparities. Lawsuits were brought against hospitals and communities where discriminatory practices were alleged. In addition, command and control enforceable rules were issued by the Department of Health, Education and Welfare and successor agencies, accompanied by an enforcement unit.⁴² Since the 1960s substantial credence and energy were devoted to this approach. Federal agencies were responsible for enforcement of this law and there was also private litigation. Over the past 20 years, however, the civil rights litigation approach has been unable to eliminate health disparities due to a lack of success in the courts, a dearth of lawyers willing to take the cases to court and weak outcomes even when litigation has been successful. At the federal agency level the enforcement has been unsuccessful. Further, what action has been taken has been

³⁹ Sidney D. Watson, 'Race, Ethnicity and Quality of Care: Inequalities and Incentives' (2001) 27 *American Journal of Law and Medicine* 208-9.

⁴⁰ *Ibid.* at 208.

⁴¹ Institute of Medicine, *Unequal Treatment* (Washington D.C., 2003); **See also** Healthy People 2010 at <http://www.healthypeople.gov/About/goals.htm>.

⁴² Title VI of the Civil Rights Act of 1964, 42 United States Code § 2000d (2000).

reactive not proactive. There were never sufficient lawyers, persuasive fact situations, or effective remedies to make the federal enforcement approach work.⁴³

In response to the documentation of the persistence of health disparities, there is a major initiative led by reformist health care leaders to adopt a quality-based approach to the provision of health care as an indirect route to achieving equality. A recent report called 'Within Our Reach' indicated that 'leveraging existing quality assurance systems to monitor and address disparities could substantially reduce the disparities in healthcare treatment.'⁴⁴ The confidence in the ability to reduce disparities is based in the confidence in new quality strategies. But there are two problems with implementing quality: the complex regulatory structure of health care and the existing malpractice framework.

The first problem is the complex regulatory structure in health care. 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.⁴⁵ Although the U.S. has one of the most expensive health care systems in the world, the quality of care that health care consumers receive is mixed. The Agency for Healthcare Research and Quality's *National Healthcare Quality Report* indicates that the U.S. system currently does not do enough to prevent diseases, diagnose them early to improve treatment outcomes, or provide coordinated care to patients with chronic diseases.⁴⁶ Since health care is

⁴³ Above note 39; Marianne Engelman Lado, 'Unfinished Agenda, The Need for Civil Rights Litigation to Address Racial Discrimination and Inequalities in Health Care Delivery' (2001) 6 *Texas Forum on Civil Liberties and Civil Rights* 16.

⁴⁴ Above note 21.

⁴⁵ See Leapfrog, <http://www.leapfroggroup.org/>.

⁴⁶ Agency for Healthcare Research and Quality, *National Healthcare Quality Report* (2003) (available at http://qualitytools.ahrq.gov/qualityreport/download_report.aspx).

a combination of self-regulation and professional values and institutions, the effort to embed quality involves increasing regulatory governance while including the traditional self-regulation and professional roles. This is an explanation for the complexity of merging quality improvement with a traditional government regulatory framework.⁴⁷ Any framework for implementing quality must integrate the physician voice into the mechanism.

The second problem with implementing quality is the existing malpractice framework. There is widespread agreement that the malpractice litigation system is failing in compensating injured parties and to deter future negligence. The proponents of the quality assurance system assert that it will do a better job of deterring negligent behavior as well as preventing unnecessary errors. However, there is no consensus as to how to compensate patients who are injured through negligent or non-negligent behaviors. Many alternatives have been proffered such as no-fault, enterprise liability or new types of redress such as medical courts or arbitration.⁴⁸ One reason for the lack of action is the uncertainty as to how to tie in the compensation system with the quality assurance system. They must be in tandem; otherwise, there will be no buy in to the new quality systems and the substantial reform of the existing malpractice framework. The new compensation system must demonstrate that it will advance quality care and fairly compensate injured patients. This new quality system has to create a culture of safety within the health care system. For example, it is likely that the standards for care that are being produced by the new stakeholder quality alliance groups will be used to establish the standard for competency and health

⁴⁷ Above note 5.

⁴⁸ Paul C. Weiler, 'Fixing the Tail: The Place of Malpractice in Health Care Reform' (1995) 47 *Rutgers Law Review* 1157.

care providers will be held to that standard.⁴⁹ In order for this to be successful, physicians must accept that the new standards are fair to them and consumers must believe that the new system will fairly reward injured patients. These new systems must proceed together.

If the problems with quality can be resolved, it will open the way not only to a high-quality health care system, but also to reduce health disparities. It is by making reduction of health disparities a core value of providing quality health care that the system can deal effectively with this controversial subject. By recognizing health care disparities as a quality problem, it forces the organizations that are subject to and participate in the quality initiatives to deal with racial and ethnic disparities. Once they are committed to the assessment and measuring of quality, they then must also examine these issues for racial and ethnic minorities who are part of their delivery system. It puts particular pressure on public purchasers, such as Medicaid and Medicare, who provide health care for a substantial number of minority Americans. Thus, since we have seen quality initiatives that started in private, employer-based plans spread to Medicaid and Medicare, the same could happen for initiatives on racial and ethnic disparities.

There are still, however, important methodological challenges to using this quality approach to monitoring and addressing racial/ethnic disparities. The key issue is data collection. There has been substantial controversy over the collection of racial and ethnic indicators in the United States. Many believe that the information can be used for racial profiling and other discriminatory purposes. In addition, there are controversies over the definition of ethnic groups, such as what it means to be Hispanic/Latino and the confusion over multiple ethnicities. Nonetheless, there appears to be a consensus across the stakeholders that the collection of this data is essential in order to eliminate racial and ethnic disparities.

⁴⁹ Michelle M. Mello, et al., ‘The Leapfrog Standards: Ready to Jump from Marketplace to Courtroom’ (2003) 22 *Health Affairs* 46.

The quality approach to reducing disparities results in a different role for lawyers than the civil rights litigation approach embodied in the Title VI and HHS enforcement model. The lawyer's role would no longer be as an advocate for the individual and institutions that alleged discrimination by the health care provider or the health care system generally. It would therefore decenter the court as the main arena for redressing the harm that came from discriminatory conduct. The major emphasis would be placed on reforming internal health care systems through a combination of creating incentives for positive outcomes and evidence-based medicine. Employees and government payors would tie payment to quality outcomes that would include 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. The civil rights model, therefore, 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.

It is clear that many of the new chronic care models rely on physician leadership in implementing and controlling the system. The quality purchasers are leading in the push for aligning the incentives to encourage the use of these techniques but the physicians are participating in a clear effort to make sure that they are part of the process. For example, in a recent policy statement issued by the AMA endorsing chronic care management as a way to achieve quality, they stressed that the physician who was the primary doctor for the patient be incorporated into the patient management system and not be bypassed.⁵⁰ They want to maintain control and avoid a system like managed care that will diminish their expertise.

⁵⁰ American Medical Association, Report of the Council of Scientific Affairs (2004).

C. Vision of Universal Coverage:

From a Centralized Single System to Linked State Experimentation

The lack of universal coverage has long been the most noted deficiency in U.S. health care. The effects of uninsurance are notable in personal health, additional costs, and on the economic health of the nation. The lack of insurance in the U.S. results in poor health for those residents who are uninsured. In addition, it results in the shifting of the costs for providing care of the uninsured onto two sets of payors: the employers pay more than their share because of the shifting of uncompensated care costs by the medical establishment; and the government payors who are forced to raise taxes in order to cover their share of uncompensated care. It 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.

The Clinton health plan was an effort to achieve a seamless universal system through an elaborate, federally controlled, all-embracing system. The Clinton health 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. The failure is viewed as a vote against centralized, government dominated, bureaucratically controlled governance.⁵¹

At the same time as the failure of the Clinton health plan, there was a concerted attack on entitlement programs. 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

⁵¹ Louise G. Trubek, 'Health Care and Low-Wage Work in the United States: Linking Local Action for Expanded Coverage' in Jonathan Zeitlin and David M. Trubek (eds.), *Governing Work and Welfare in the New Economy* (Oxford, 2003).

the New Deal, had dreamed the adoption of the European ‘social citizenship’ model.⁵² 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.

A new incremental approach, based on new programs and proposals, was generated in the wake of the Clinton plan’s failure.⁵³ States have addressed the issue of coverage by expanding eligibility for Medicaid to more low-income children and parents⁵⁴ as well as accessing the federal State Children’s Health Insurance Program (SCHIP) funds.⁵⁵ SCHIP is an expansion of health care coverage targeting uninsured children. The federal government, in enacting SCHIP, encouraged states to experiment with various approaches to insuring children and families with the additional funding. States seized on an approach of increasing health care coverage to low-income Americans state by state via government programs. There is now a rich array of state approaches to providing coverage for the uninsured. Networks of state government officials, legislators, and governors across states spread ‘best practices’ and encouraged united action to support the programs.⁵⁶ Combining public programs with employer-based coverage is also being proposed through further expansion of Medicaid and encouraging small business to

⁵² Joel F. Handler, *Social Citizenship and Workfare in the United States and Western Europe: The Paradox of Inclusion* (Cambridge, 2004).

⁵³ Symposium, *Facing Health Care Tradeoffs: Costs, Risks and the Uninsured*, La Follette Policy Report (Robert M. La Follette School of Public Affairs, University of Wisconsin-Madison), Winter 2003-04.

⁵⁴ Above note 51.

⁵⁵ Above note 11.

⁵⁶ Above note 51.

offer health care coverage through a combination of tax credits and subsidies from government programs.⁵⁷

There is now an acknowledged consensus that some form of universal coverage for residents is essential for the economic and personal health of the U.S.⁵⁸ In part the consensus is based on the incremental approach, which is state-based, public and private coverage mix. In the recent presidential election both major presidential candidates endorsed the incremental route to expanding coverage. However, the move to the state-based experiments in health care coverage can be seen as resulting in an even more fragmented, differential package benefits. The proponents of the incremental system are demonstrating that the expansion will include quality coverage and promotion of healthy life styles and cost-effective treatment. This approach emphasizes the individual's participation as a consumer and a self-managing patient. It also includes methods insure that the benefits paid are guided by medical science. It deemphasizes the bureaucratic, single set of universal benefits and administration. It also aims to assure that the relationship between the physician and patient is a core element.⁵⁹

However, there are problems with a state-based system. First, the states are struggling to maintain their commitment to health care due to the current fiscal crisis at the state level. It is striking how the

⁵⁷ Above note 53; Barbara Zabawa, 'Breaking Through the ERISA Blockade: The Ability of States to Access Employer Health Plan Information in Medicaid Expansion Initiatives' (2001) 5 *Quinnipiac Health Law Journal* 1.

⁵⁸ **See, eg,** Paul Fronstin, 'The "Business Case" for Investing in Employee Health: A Review of the Literature and Employer Self-Assessments' (March 2004) 267 *Employee Benefit Research Institute*.

⁵⁹ Mark Schlesinger, 'Reprivatizing the Public Household? Medical Care in the Context of Public Values' (2004) 29 *Journal of Health Politics, Policy and Law* 969.

governors have rallied around their newly ambitious health care coverage programs and have, to a great extent, resisted cutbacks. One observer noted:

State officials explained why SCHIP seemed largely immune to significant cuts, citing its strong popularity among consumers, providers, and politicians; the fact that it was small and inexpensive (relative to Medicaid) and not an entitlement (making it a program that policymakers felt they could ‘control’); its high federal matching rate (making it a less attractive target for cuts); and its success at its critical objective—insuring low-income children. But these same officials hinted that continued fiscal pressures could result in future cuts to SCHIP.⁶⁰

This statement highlights the crucial importance of increasing federal funding and supporting states in their innovation.⁶¹ This might include new types of flexible standards and requirements that both encourage innovation but also guarantee financial integrity and coverage for the most vulnerable and high-cost groups.⁶² New technology can encourage movement between public and private plans (so called seamless enrollment) by simplifying even complex eligibility requirements. Information technology enables people to move from public plans to private coverage and vice versa with no loss of coverage when their job and income situation requires.⁶³ The seamless system requires horizontal networks within the states and communities to allow public programs and private employers to communicate and share information on eligibility.

⁶⁰ Ian Hill et al, The Urban Institute, *Squeezing SCHIP: States Use Flexibility to Respond to the Ongoing Budget Crisis, New Federalism: Issues and Options for States* (Washington D.C., 2004).

⁶¹ The Kaiser Commission on Medicaid and the Uninsured, *Medicaid’s Federal-State Partnership: Alternatives for Improving Financial Integrity* (California, 2002) (available at www.kff.org/medicaid/4068-index.cfm).

⁶² *Ibid.*

⁶³ Above note 53.

The critics of the incremental approach assert that the abandonment of the rights/entitlement model guarantees that the universality, essential for an effective and efficient healthcare system, will never be achieved. They argue that the fiscal constraints of state government and the elimination of judicially reviewable entitlements will undercut coverage and low-income people will once again lose coverage.⁶⁴ However, they admit that the political will for the single-payer, rights/entitlement route is gone. In order to be persuasive, the groups promoting the incremental approach must demonstrate their ability to work together and resist retrenchment.⁶⁵

IV. LAW, GOVERNANCE AND HEALTH CARE

While solving the three health care problems requires different tools, all share some of the same new governance practices. In understanding how these new governance practices challenge the New Deal/Great Society administrative state, four shifts are highlighted: new types of participation; multilevel public and private networks; different roles for government; and an understanding of law as ‘soft’—flexible rules with informal sanctions. Each of these shifts presents serious challenges to the conventional understanding of how law and governance should work and can be effective. In order for these new practices to be viewed as significant alternatives to the traditional, command and control/rights-based conventional governance, a convincing case must be made that these new mechanisms can be effective in delivering large-scale, accountable, and legitimate resolutions to health care problems.

⁶⁴ David A. Super, ‘The Political Economy of Entitlement’ (2004) 104 *Columbia Law Review* 633. **See also** Timothy S. Jost, *Disentitlement?* (Oxford, 2003).

⁶⁵ **See** Steve Lohr, ‘The Disparate Consensus on Health Care for All’ *New York Times*, December 6, 2004, at C16.

A. New Types of Participation

The new governance practices in the three problem areas demonstrate a shift to new ways in which decisions are made and participation occurs in health care. Traditionally, disadvantaged groups were able to participate through public interest lawyer advocacy at the administrative agency, social movements at the legislative level, and litigation against discrimination and malpractice.⁶⁶ In recent years, the old system often did not achieve the desired result of making health care more equitable and efficient. Health care failures, like the centralized Clinton health plan and the civil rights litigation strategy⁶⁷, are examples of the inadequacy of the older model. However, in the struggle to make the older models of participation work, some techniques emerged that can be identified as part of the new system. These include state-based expansion of access, consumer-physician alliances, the patient empowerment movement, and the acknowledgement of racial and gender biases in health care.

The positive insight from the Clinton health plan demise was that, after that failure, states were able to expand coverage for the uninsured through a combination of new federal funding and encouragement of flexibility in the states. The flexibility allowed at the state level resulted in a wide group of actors participating in the development of each state's own strategies. The coverage that resulted from that process has proved popular and increased the funding and influence of local providers and institutions, such as community health centers and free clinics.

The second insight was the ability of consumers and physicians to work together to challenge the negative aspects of managed care. This alliance achieved a reduction in the rigidity of managed care procedures. Consumers and physicians realized from this success that the quality indicators that business developed as part of managed care could be a tool for improving the quality of care for even

⁶⁶ Above note 33.

⁶⁷ Above note 32.

disadvantaged patients. Consumers in particular are beginning to see that alliances with unlikely allies can improve their ability to obtain the type of programs that they advocate.

The patient empowerment movement was based initially on dissatisfaction with the quality of health care delivery. It arose from the alternative treatment movement, as well as a desire for patients to control their own treatment. This created the concept of the consumer as an independent actor in the health care arena. The activated consumer, making health care decisions based on quality and cost information, is a continuation of that movement. 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 decisionmaking.⁶⁸

An understanding of how race, gender, and ethnic aspects impact health care outcomes developed out of the discrimination/civil rights approach to reducing disparities. The civil rights critique of the existing health care system had a powerful effect on the conventional belief that the health care system was unbiased. However, the failure to reduce disparities by the civil right approach led concerned people to seek to move beyond gridlock and be open to new approaches to solving racial and ethnic disparities.

There is energy now to creating more equitable participation in health care through the stakeholder collaborations based on these insights within the current political climate. There remain barriers to fully implementing the new practices. The first barrier is the lack of explicit measurement of the participation of disadvantaged groups in any of these new practices.⁶⁹ There needs to be an explicit focus on participation in these new practices. This requires a guideline on the importance of such participation and

⁶⁸ Sydney Halpern, 'Medical Authority and the Culture of Rights' (2004) 29 *Journal of Health Politics, Policy and Law* 835.

⁶⁹ Brandon L. Garrett & James S. Liebman, 'Experimentalist Equal Protection' (2004) 22 *Yale Law and Policy Review* 321.

a method of monitoring that the guidelines were actually being met. The second barrier is that these practices are being conducted in a variety of sites with a variety of actors. They are difficult to locate and view for purposes of monitoring and evaluating effectiveness. The old entitlement programs were much easier to track through the public availability of documents and required, though limited, methods of participation.⁷⁰ These new practices do not have procedural requirements, like the Administrative Procedure Act, and are not easily judicially reviewable. A third barrier is uncertainty about who will be the advocates for disadvantaged groups. While individual 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. Advocates for disadvantaged group participation can be lawyers or reformist physicians and others committed to an all-inclusive health care system. These advocates play the role of assuring that the barriers to participation are removed; for example, ensuring collection of data on the number and characteristics of the uninsured that is reliable for program and policy development.⁷¹ 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 monitoring institutions that assure abusive and negligent behavior is prevented and sanctioned.⁷² The traditional public interest lawyers had systems for funding and legitimacy that were developed in the 1960s and 1970s. These new advocacy roles in the new governance practices are more fluid and less subject to external requirements than the traditional, public interest advocacy of the earlier period. For example, a consumer group that wanted to participate

⁷⁰ Above note 64, at 726.

⁷¹ Wisconsin Public Health and Health Policy Institute, *Issue Brief, No. 5* (Madison, October 2002).

⁷² William M. Sage, 'Unfinished Business: How Litigation Relates to Health Care Regulation' (2003) 28 *Journal of Health Politics, Policy and Law* 387.

in one of the collaboratives could be excluded and there would no administrative or judicial review required because these collaboratives are organized as private groups.

B. Multilevel Public and Private Networks

Health care in the U.S. has always been a messy mix of private market, self-regulation, and state and federal programs. Nonetheless, there is a decided shift in the relationship between these four elements in the new governance practices. Most commentators agree the momentum has decidedly shifted to the states and public-private partnerships.⁷³ This was a surprise to most longstanding health care reformers who always assumed that any universal coverage and improved quality had to be based on a national, uniform program like Medicare.

The success of state experimentation leading to positive change can be seen in both the expansion of coverage and in curbing the abuses of managed care. The demise of the Clinton health care plan, changes in federal regulations, and the passage of SCHIP allowed the states to experiment. The ability of individual states to be leaders resulted in a diffusion of good practices. A second example is the enactment of legislation in the states to protect patients, challenging the nascent managed care movement. The state enactments catalyzed sweeping changes in the way health care was delivered by the managed care companies all over the country. This story delivered the message that action by individual states could be diffused through the national market without the necessity of uniform, national legislation.⁷⁴

In President Bush's proposals for disseminating new technology in health care and in the Medicare Modernization Act, there is both a commitment to regionalism, described as below the

⁷³ See generally John Holahan (ed.), *Federalism & Health Policy* (Washington D.C., 2003).

⁷⁴ Mark A. Hall, 'The 'Death' of Managed Care: A Regulatory Autopsy' (unpublished MS, on file with author).

Washington level but not necessarily at the state level, and also incentives for providing the infrastructure through public-private networks.⁷⁵ This is consistent with the academic discussion about ‘new regionalism’ and ‘new localism.’⁷⁶ 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. However, regional units have been difficult to achieve. The challenge, therefore, of proposing regional structures in the U.S. is daunting. Nonetheless, many of the hospital/health care systems, as they become large and integrated, including several million users, may be a base for public-private structures that might provide a framework for successful health care delivery at a devolved level.⁷⁷

C. Different Roles for Government

The New Deal view of government as the controlling, commanding presence is no longer accurate. A role for government does continue, but new governance practices can result in confusion about what that role is.⁷⁸ Government remains an important stakeholder in the evolving collaborations. It assumes a coordinating role in implementation of health care services and organizes activities so that each actor can do whatever it does best. With entitlements on the decline, government has a crucial role in orchestrating and justifying programs.⁷⁹ The various ways in which government can be involved include facilitating

⁷⁵ Above note 29.

⁷⁶ David J. Barron, ‘A Localist Critique of the New Federalism’ (2001) 51 *Duke Law Journal* 377.

⁷⁷ Above note 32.

⁷⁸ Mark Schlesinger, ‘On Government’s Role in the Crossing of Chasms’ (2004) 29 *Journal of Health Politics, Policy and Law* 1.

⁷⁹ Above note 64.

collaboration; monitoring programs for effectiveness; collecting data; using regulation and funding to assure quality; correcting imbalances in participation, as when low-income patients and small businesses find it difficult to participate; and through sanctioning in order to prevent privatization failure and to assure that actors participate fairly.

The need for monitoring is particularly evident in assuring participation of all the stakeholders, transparency of the information that is generated, and holding the health care system accountable for achieving its benchmarks.⁸⁰ Government can monitor through public law litigation,⁸¹ enactment of statutory requirements for information availability and dissemination,⁸² and requiring self-regulatory systems.⁸³

One recent example shows the challenge for the state in effectively transitioning from a command and control, central authority to a more flexible manager. This challenge emerged from the privatization of traditionally government-provided health care prevention and outreach services to low-income people. The state now contracts with health care organizations to provide these services. Increasingly, the contracting organizations are using small, community-based organizations to reach minority patients.

⁸⁰ Sidney D. Watson, 'REL Reform: Mandating Systems Reform to Reduce Racial, Ethnic and Language Disparities in Health Care' *Symposium, Racial and Ethnic Disparities in Health Care Treatment*, The Harvard Civil Rights Project (May 18, 2004)(unpublished MS, on file with author).

⁸¹ Charles F. Sabel and William H. Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2004) 117 *Harvard Law Review* 1016.

⁸² Vernellia R. Randall, 'Eliminating Racial Discrimination in Health Care: A Call for State Health Care Anti-Discrimination Law' *Symposium, Racial and Ethnic Disparities in Health Care Treatment*, The Harvard Civil Rights Project (May 18, 2004)(unpublished MS, on file with author).

⁸³ Above note 69.

These nonprofits are undertaking a substantial responsibility for raising funds and providing services for the underserved and underrepresented. This privatization has risks for low-income people who rely on these services, as well as for the credibility of the entire health care system. In order for this approach to succeed, the state has to maintain its financial commitment, monitor the quality of the care, and share information on the quality of services. The danger is that if the state does not assume these responsibilities, the privatized system will collapse with serious consequences for patients and the system as a whole.⁸⁴

D. Soft Law

Guidelines, benchmarks, and standards that have no formal sanctions are referred to as soft law. Soft law is an important component of new governance practices. Traditional regulation relies on uniform rules, sanctions if the rules are not followed, and court challenges for noncompliance.⁸⁵ This hard law approach has proved inadequate in many cases in regulating health. First, the use of court challenges to enforce regulations has been ineffective, due to the complexity of the problems seeking to be solved, the lack of fit between the institutional structures that are causing the failures with the remedies provided by courts, and the recent unwillingness of judges to undertake massive reforms through court systems. The failure of the anti-discrimination paradigm in racial and ethnic disparities is an example.⁸⁶ Secondly, there is the famed gap between law on the books and law in action. Uniform rules are not automatically enforced by

⁸⁴ Rick Lyman, 'Once a Model, A Health Plan is Endangered' *New York Times*, November 20, 2004, A1, A11.

⁸⁵ David M. Trubek and Louise G. Trubek, 'Hard and Soft Law in the Construction of Social Europe: The Role of the Open Method of Coordination' (forthcoming 2004) *European Law Journal*.

⁸⁶ Above note 80.

the agencies, nor does enforcement necessarily lead to the desired outcome.⁸⁷ 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 in the books and effective achievement of the goal. Another failure of traditional regulation is the use of malpractice litigation as the major to prevent errors and improve quality. The randomness of the cases, the high costs of litigation, including lawyers' fees, and the resistance of health care institutions to utilize the information of failures in a self-regulatory way, are all problems with the hard law approach.

A choice may not be required between hard and soft law. Different modes may be required for different issues and combining them may be useful when they are complimentary. An example is found in reducing the racial and ethnic disparities in health care treatment. The move to using the 'law of quality compliance' includes soft law instruments such as benchmarking, data collection, and reporting.⁸⁸ There is, however, still a role for court and legislative requirements to compel the collection and format for the data collection. 'This classic legal construct, which grounds the problem of disparities in the law of civil rights, may now be giving way to shared ownership with the law of health care quality.'⁸⁹ The discussion of the ability of the discrimination model to effectively co-exist with the quality-assurance model is just beginning.

There is also a continued role for new types of regulation, particularly those that combine hard law and soft law. The standard setting technology regulations are an example of regulation that is necessary. A second example is the use of action-forcing regulations where health care institutions must put in place

⁸⁷ Above note 85.

⁸⁸ Sara Rosenbaum and Joel Teitelbaum, 'Addressing Racial Inequality in Health Care' *Symposium, Racial and Ethnic Disparities in Health Care Treatment*, The Harvard Civil Rights Project (May 18, 2004)(unpublished MS, on file with author).

⁸⁹ *Ibid.*

quality assurance and compliance programs in order to get continued accreditation and funding. A third example is regulations that foster discussions among patients, field-level workers, and family.⁹⁰

V. CONCLUSION-PUTTING THE PIECES TOGETHER

Rand Rosenblatt⁹¹ in a recent article posits that we are entering into a fourth age of health law. He describes the first three ages as the authority of the medical profession, modestly egalitarian social contract, and market competition. This fourth age, in his opinion, is linked to a more general shift to new governance. This paper supports that view and shows that this fourth age is developing rapidly.

The larger issue is whether this evolving system can be both popular and effective. The partial failure of managed care and the Clinton health plan was due in part to the inability of the reformers to demonstrate that people would be better off and fairly treated under that governance system. In envisioning this fourth age, it will be important to maintain the positive aspects of the earlier ages, such as social contract, physician trust, and innovation that market forces bring. Hybrid solutions would be a way of reforming while reassuring everybody that, despite the changes, the essential stability of the system is in place.⁹² Despite the seemingly overwhelming problems of reforming health care provided in the U.S., it remains one of the top concerns among residents. Health care actors sense this opportunity and are working to develop new practices. These new practices, in turn, challenge conventional institutions and processes.

⁹⁰ Above note 19.

⁹¹ Rand Rosenblatt, 'The Four Ages of Health Law' (2004) 14 *Health Matrix* 155.

⁹² Clark C. Havighurst, 'Starr on the Corporatization and Commodification of Health Care: The Sequel' (2004) 29 *Journal of Health Politics, Policy and Law* 947.