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Relational Duties, Regulatory Duties, and the Widening Gap Between Individual Health Law and Collective Health Policy

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WILLIAM M. SAGE*

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INTRODUCTION

In an editorial dated May 24, 2007, titled *Government in Medicine*, Jeffrey M. Drazen, M.D., editor-in-chief of the *New England Journal of Medicine*, writes as follows: "It is not that physicians do not want oversight and open discussion of delicate matters but, rather, that we want these discussions to occur among informed and knowledgeable people who are acting in the best interests of a specific patient. Government regulation has no place in this process."¹

As a response to specific events, Dr. Drazen has a legitimate gripe. His

* Vice Provost for Health Affairs and James R. Dougherty Chair for Faculty Excellence, The University of Texas at Austin. © 2008, William M. Sage. Helpful comments were received from Professors Jeanne Lambrew, Einer Elhauge, Russell Korobkin, and participants in the Petrie-Flom workshop series at Harvard Law School.

1. Jeffrey M. Drazen, *Government in Medicine*, 356 NEW ENG. J. MED. 2195, 2195 (2007).

complaint was provoked by two highly political government decisions: federal legislation banning “partial birth” abortion, and Congress’s attempt, at the eleventh hour, to prevent life support from being withdrawn from Terri Schiavo. Dr. Drazen was also carrying the torch for editors past in defense of medical professionalism. A similar piece by his predecessor at the helm of America’s most prestigious medical journal, Dr. Jerome Kassirer, berated Congress for enacting the “partial birth” abortion ban in the first place, as well as for mandating forty-eight hours of post-partum insurance coverage and for publicly endorsing mammography for all women in their forties.² To Dr. Drazen, the Supreme Court’s decision to uphold the Congressional ban shows that “the judicial branch has regrettably joined the legislative branch in practicing medicine without a license.”³

As a blanket statement, however, Dr. Drazen’s objection to government regulation is (to put it mildly) problematic. The United States spends roughly \$2 trillion annually on health care.⁴ Health care comprises 16% of gross domestic product,⁵ and provides approximately one in ten jobs, more than any other industry. Along with education, health is a building block of community and a primary determinant of both personal liberty and economic productivity. Yet some 16% of Americans lack health insurance (25% in Texas, where I live), and with it access to basic medical care.⁶ If regulation has no place in medicine, how can a modern health care system function? Without government, as less patrician New Englanders have been reputed to say, “You can’t get there from here.”

Dr. Drazen’s standard for ethically acceptable health policy has two prongs, one relating to expertise and the other to orientation. Through most of its history, health care regulation has contended with some version of Dr. Drazen’s preference for oversight and discussion (he does not say “decision”) by “informed and knowledgeable people.” As Jay Gold wrote twenty-five years ago, a major challenge in health law is how to hold experts accountable to non-experts.⁷ The complexity of health care puts it beyond the ken of most mortals, and ignorance is a bad basis for government. Because of its informational advantages (leaving aside for the moment any moral ones it may also possess), the medical profession claims it should retain primary responsibility for the public policy of health care.

This is nothing new. Professional (that is, physician) control over health care

2. Jerome P. Kassirer, *Practicing Medicine Without a License—The New Intrusions by Congress*, 336 *NEW ENG. J. MED.* 1747, 1747 (1997).

3. Drazen, *supra* note 1, at 2195.

4. Nat’l Coal. on Health Care, *Health Insurance Cost: Facts on the Cost of Health Care* (2007), <http://www.nchc.org/facts/cost.pdf>.

5. *Id.*

6. Nat’l Coal. on Health Care, *Health Insurance Coverage: Facts on Health Insurance Coverage* (2007), http://www.nchc.org/facts/coverage_fact_sheet_2007.pdf.

7. Jay A. Gold, *Wiser than the Laws?: The Legal Accountability of the Medical Profession*, 7 *AM. J.L. & MED.* 145, 146–47 (1981).

has a long, checkered history of both public-mindedness and protectionism. As Ron Gilson has noted, “a necessary condition for professionalism is market power.”⁸ Unsurprisingly, the public message of organized medicine has been more than *noblesse oblige*. *Après moi le deluge* better captures the disaster that looms, the American Medical Association (AMA) often has argued, should society stray far from physician authority.⁹

There are alternative defenses against ignorance. What generalist legislators and courts lack in knowledge, for example, expert administrative agencies can readily supply. Though Dr. Drazen does not inveigh directly against the executive branch, bureaucratic control seldom appeals to the medical profession, which prefers that government delegate authority to self-regulatory bodies such as the Joint Commission on Accreditation of Healthcare Organizations. As a matter of information policy, of course, we could also leave as many “discussions” as possible to the market, which has well-established advantages over central planning in its ability to communicate signals that coordinate complex activity through the “marvel” of competitive pricing.¹⁰

Rather than rehashing arguments over expertise, this Essay concerns itself with the second of Dr. Drazen’s criteria: the “best interests of a specific patient.” In the political din over who controls what, this subtle but important point is often overlooked. In my view, however, it drives a wedge between health law and health policy that constitutes a major obstacle to productive health care regulation.

A “specific patient” refers to more than a specific diagnosis or treatment. Part of the charge against policymakers for “practicing medicine” indeed involves substitution of political for clinical judgment in technical areas. Narrowly tailored legislation—such as mandated health insurance coverage for hospitalization following childbirth (“drive-through delivery” laws) and breast cancer surgery (“drive-through mastectomy” laws), and explicit informed consent requirements for patients undergoing mastectomy, sterilization, abortion, or other surgical intervention—can be criticized for kowtowing to interest groups, resisting modification in light of new evidence, and abdicating responsibility for dealing with larger issues. But the problem of patient specificity, although present in these laws, is not just a matter of keeping medical textbooks out of politicians’ hands.

A “specific patient” is an identifiable person, often someone afflicted with a serious disease that we can imagine ourselves suffering from but are grateful we

8. Ronald J. Gilson, *The Devolution of the Legal Profession: A Demand Side Perspective*, 49 MD. L. REV. 869, 916 (1990).

9. See generally PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 3–9 (1982) (casting the history of American medicine in terms of physicians’ successful collective opposition to both corporate and governmental control).

10. See generally F.A. Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 519, 526–28 (1945) (arguing that free markets are informationally superior to central planning, in large part because of price signaling).

do not actually have to endure.¹¹ Occasionally, as with Terri Schiavo, the political process intrudes on the private medical decisions of named individuals.¹² Usually, however, politicians and policymakers apply the mental construct of the specific patient, and that patient's therapeutic relationship with a specific physician, to problems of collective costs and benefits for which such a starting point, I will argue, is not appropriate. In other words, I come not to praise Dr. Drazen's second criterion for health care regulation, but to bury it.

The distinction I want to draw is between legal obligations to discrete parties and legal regimes that serve abstract goals or broad collectives. What I call a "relational duty" is generally owed to an individual, one on one, though it may be owed to a legal entity other than a person, or to a well-defined group of persons or entities. In health care, the obligation of physician to patient constitutes the paradigm case of relational duty. Law often approaches relational duties as problems of legal agency: the agent (the physician) serves the principal party (the patient).¹³ The dichotomy I present generally distinguishes between legal duties rooted in concern for particular individuals and duties rooted in concern for society as a whole. An important disclaimer is that my intent is to spotlight and scrutinize sources of path determinism in health law and policy, not to offer a deontological argument for choosing among welfarist, distributional, libertarian, or communitarian conceptions of the good.

Not all laws, of course, address relational duties. Many laws are primarily intended to advance collective goals such as public safety, economic growth, and the general welfare, and affect individuals only insofar as they may have contact with prohibited or regulated activities. An obligation to further the interest of a something rather than a someone—perhaps an aggregate of persons, perhaps, an ideal—I call a "regulatory duty." The thesis of this Essay is that far more legal issues in health care are approached as relational than as regulatory problems, making it very difficult for law to serve truly "public" policy. The Essay begins by speculating about sources of health law's relational bias, and ends by discussing four areas of contemporary health policy that, in my view, require a more regulatory approach.

11. Mental imagery plays an important role in health law by establishing archetypes against which legal rules and ethical precepts are evaluated. For example, David Orentlicher argues that social acceptance of the right to refuse medical resuscitation and social resistance to the right to assisted suicide derive in large part from images associating the former with elderly patients suffering from terminal cancer and the latter with young adults suffering from depression. David Orentlicher, *The Legalization of Physician-Assisted Suicide*, 335 NEW ENG. J. MED. 663, 665–66 (1996).

12. See generally *The Schiavo Case: A Symposium*, 22 CONST. COMMENT. 383 (2005) (collecting articles about the case).

13. For purposes of this Essay, the legal term of art that attaches to the physician-patient relationship is not important. Strict definitions of agency may not capture all of what physicians do for patients. And commentators differ on whether the physician-patient relationship should be considered "fiduciary" or merely "confidential." Compare Tamar Frankel, *Fiduciary Law*, 71 CAL. L. REV. 795, 796 & n.6 (1983) ("[P]hysicians and psychiatrists have recently become members of the fiduciary group."), with RESTATEMENT (SECOND) OF TRUSTS § 2 cmt. B (1959) (defining the relationship between physician and patient as confidential, but not fiduciary).

It is an apt time to consider these issues. Key constituencies are clamoring for comprehensive national health reform in the lead-up to the 2008 presidential election, much as they did before President Bill Clinton was elected in 1992, and health care has again moved to the front of the domestic policy agenda in public opinion polls. Many of the same arguments² are being made today as fifteen years ago. But many of the same obstacles exist as well, including the relational orientation of prevailing law. This Essay therefore uses experiences from that earlier, unsuccessful effort to illustrate current tensions in public policy and to draw lessons for the future.

I. SOURCES OF HEALTH LAW'S RELATIONAL BIAS

A relational perspective, particularly where the delivery of medical services is concerned, is a defining characteristic of American health law. This is inescapable and to a considerable degree desirable, because the product of health care, as Kenneth Arrow once wrote, is inseparable from the process of providing it.¹⁴ The healing professions are based on intimacy, with good care requiring a combination of compassion, competence, and confidentiality.¹⁵ The U.S. health care system has retained this flavor despite its massive scope and scale. As a result, over a period of decades, sometimes because of direct pressure and sometimes because of lack of countervailing force, most health regulatory problems have been framed in relational terms. The following merit brief discussion as continuing sources of relational bias: lack of distinction between private law and public law; professional ethics and bioethics; budgetary and general politics; and health care consumerism.

A. PRIVATE LAW AND PUBLIC LAW

Common law jurisdictions such as the United States, where courts engage in lawmaking as well as legal interpretation, draw much less distinction between private law and public law than do civil law jurisdictions. Federalism and separation of powers further blur the line between the two types of law because jurisdictional overlap and inter-branch competition (with their attendant politics) are inherent aspects of our constitutional system. American lawyers therefore tend to regard government regulation as a complement to private legal claims, not a substitute.¹⁶

14. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 949 (1963). For a comprehensive updating and analysis of Arrow's seminal article, see *UNCERTAIN TIMES: KENNETH ARROW AND THE CHANGING ECONOMICS OF HEALTH CARE* (Peter J. Hammer et al. eds., 2003).

15. CLARENCE WILBUR TABER, *TABER'S CYCLOPEDIA MEDICAL DICTIONARY* 662 (14th ed. 1981) (reproducing the Hippocratic Oath).

16. See generally William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387 (2003) (attributing health care litigation to incomplete industrialization, incomplete consumerism, and incomplete social solidarity in the U.S. health care system).

In the early nineteenth century, a serious attempt in American medical schools to create a public-minded field of “medical jurisprudence” similar to that thriving in the centralized bureaucracies of Western Europe was thwarted in the United States by local politics and courtroom processes.¹⁷ Instead, much of what we now call “health law” developed around discrete interactions between one patient and one physician, such as medical malpractice, in which private legal accountability both drew from and criticized the established ethics of personal medical care. Subsequent legislation and administrative law, whether associated with government health insurance programs such as Medicare, with private health care financing, or with assuring the safety and quality of medical care, layered atop this foundation of private legal governance. Considerable attention has been paid to whether contract principles or tort principles should guide legal judgments about medical care and health insurance coverage,¹⁸ but the decision to frame the choice as being between these two private law regimes and not a public law regime is rarely questioned. Attempts to reform the law of medical malpractice to improve collective safety and provide equitable compensation for injury, for example, are still criticized for ignoring fundamental values of individual justice.¹⁹ “Public” health law evolved separately as “public health law,” but—as discussed below—has had little connection to the medical profession or to the large and expensive institutions that supply and fund it.

The decision whether or not to include a private right of action in a regulatory regime gives some indication—although one cannot control for partisan politics—of the priority given to enforcing relational claims. Notably, several major federal health initiatives have limited the individual relief available. These include health coverage disputes governed by the Employee Retirement Income Security Act (ERISA) (contractual damages only),²⁰ claims of inadequate emergency screening and stabilization under the Emergency Medical Treatment and Active Labor Act (EMTALA) (private right of action against hospitals but not physicians),²¹ violations of the rights of human subjects under the “Common

17. See JAMES C. MOHR, *DOCTORS AND THE LAW: MEDICAL JURISPRUDENCE IN NINETEENTH-CENTURY AMERICA* 94–108 (1993) (describing how the legal and medical professions grew apart in small towns with locally appointed coroners and high-profile lawsuits in which physicians lost face as witnesses and defendants).

18. Wendy K. Mariner, *Slouching Toward Managed Care Liability: Reflections on Doctrinal Boundaries, Paradigm Shifts, and Incremental Reform*, 29 J.L. MED. & ETHICS 253, 254–60 (2001) (surveying the debate between tort law and contract law proponents).

19. See, e.g., John C.P. Goldberg, *The Constitutional Status of Tort Law: Due Process and the Right to a Law for the Redress of Wrongs*, 115 YALE L.J. 524, 528–29 (2005); John C.P. Goldberg, *Tort Law for Federalists (and the Rest of Us): Private Law in Disguise*, 28 HARV. J.L. & PUB. POL'Y 3, 3–4, 7 (2004). But see Samuel Issacharoff & John Fabian Witt, *The Inevitability of Aggregate Settlement: An Institutional Account of American Tort Law*, 57 VAND. L. REV. 1571, 1573–78 (2004) (arguing that aggregate resolution of tort claims, albeit through private institutions, has served as a pragmatic counterpoint to the notion of “individualized justice” throughout modern American history).

20. 29 U.S.C. § 1132(a)(1)(B) (2000); see also *Aetna Health Inc. v. Davila*, 542 U.S. 200, 222–24 (2004) (Ginsburg, J., concurring) (questioning prior rulings on available damages under ERISA).

21. 42 U.S.C. § 1395dd(d)(2)(A) (2000 & Supp. IV 2004).

Rule" (no private right),²² and violations of medical privacy under Health Insurance Portability and Accountability Act (HIPAA) (no private right).²³ On the other hand, federal health law tends to assume a vigorous baseline of state personal injury litigation best kept in state court,²⁴ which not infrequently piggybacks state claims on factual violations of federal law.²⁵

B. PROFESSIONAL ETHICS AND BIOETHICS

The relationship between a single patient and a single physician is at the heart of medical ethics. When physicians provided mainly comfort and solace to families, plus guidance regarding *materia medica* that could be both used and misused, not causing harm and valuing the patient's interest above all else were sufficient, and sensible, ethical precepts. As the ability of physicians to diagnose and treat improved, and the revenues associated with doing so grew, the medical profession reconstituted its authority under formal codes of ethics that also conveyed the profession's collective importance to society.²⁶ As Paul Starr and others have explained, these increasingly political documents invoked relational values—such as free choice of physician by patient and of patient by physician, direct payment for services rendered, unfettered clinical decisionmaking, and secrecy regarding the details of care—in order to protect the medical profession's economic position and forestall both government and corporate control.²⁷

The bioethics revolution of the late twentieth century helped the medical profession understand the ethical implications of changing technology, but did not alter its relational orientation. Anglo-American bioethics expresses itself in individualistic terms that reflect its classical liberal heritage, emphasizing personal liberty and freedom of choice more than collective obligation or community cohesiveness. Since the 1950s, for example, the principal project of bioethics has been to convert the tradition of professional beneficence into a commitment to patient autonomy,²⁸ ethical impulses that could nearly as easily have been channeled into social responsibility. Bioethicists' regulatory mission—mediating the mutual obligations of individuals and society—has remained inchoate,

22. 45 C.F.R. § 46.123 (2006).

23. Pub. L. No. 104-191, 110 Stat. 1936 (1996); *see also* 42 U.S.C. § 1320d-5, d-6 (2000) (civil administrative and criminal enforcement provisions).

24. *See, e.g.*, *Pegram v. Herdrich*, 530 U.S. 211, 236 (2000) ("ERISA was not enacted . . . in order to federalize malpractice litigation.").

25. *See, e.g.*, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (denying summary judgment under state tort law in a case involving alleged violations of federal research regulations).

26. *See* STARR, *supra* note 9, at 79–144 (discussing physicians' "consolidation of authority" between 1850 and 1920). Starr describes the AMA's initial code of ethics at mid-century as an attempt by mainstream physicians to exclude unconventional practitioners, *id.* at 90–91, and notes that professional self-regulation was ineffective until decades later when, because of medical advances, "[t]he public granted the legitimate complexity of medicine and the need for institutionalized professional authority." *Id.* at 141.

27. *See id.* 299–301 (describing physician resistance to health insurance innovations).

28. *See, e.g.*, RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 88–101 (1986).

subsumed (and often invisible) within the relational mission of mediating interactions between health professionals and specific patients.

This emphasis reflects in part an inversion of the original relationship between bioethics and government. The founding document of modern bioethics is the Nuremberg Code, which was a response to Nazi wartime atrocities masquerading as scientific experimentation.²⁹ Its basic purpose was to remind individual scientists that they were both professionals and human beings with moral obligations to other human beings, regardless of government direction to the contrary. The Belmont Report issued in reaction to the U.S. government's notorious Tuskegee Syphilis Study had a similar character.³⁰ By contrast, research ethics today consists of dense regulations issued by government that are enforced against individual researchers on pain of withholding their funding. The historical threat to research subjects, state power, has become their chief protector.

Also supporting the relational emphasis of bioethics is that, notwithstanding the Bush administration's aggressive national security agenda, money rather than renewed government power is the *bête noire* of today's medical ethicists. The commercialization of medicine involves private conduct, not state action, and therefore tends to be perceived as a threat to individual patients and corresponding professional values rather than as a perversion of collective interest.³¹ This places bioethics in a difficult position because it must reconcile resistance to commercial exploitation of patients by profit-seeking corporations with overall support for patient autonomy, including freedom to participate in the marketplace. The result has been an ethics of consumer protection, with various precepts adopted to provide patients and research subjects with complete information and prevent fraud, coercion, or duress.³² Consumer protection, however, focuses on individual decisionmaking and therefore gives bioethics few opportunities to articulate collective, social goals.

A retreat to relational bioethics is also pragmatic. Although ethicists have long believed that the proper allocation of society's scarce resources is a key question solidly within their purview, their opinions about social responsibility

29. *Nuremberg Code*, in 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW, No. 10, at 182 (1949), available at http://www.ushmm.org/research/doctors/Nuremberg_Code.htm.

30. The Belmont Report emphasizes beneficence, and prohibits "brutal or inhumane treatment" regardless of consent. THE NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, U.S. DEP'T OF HEALTH, EDUC. & WELFARE, THE BELMONT REPORT: ETHICAL PRINCIPLES & GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 17 (1978). This is similar to the Nuremberg Code's ban on experimentation where possible death or disabling injury can be expected.

31. See, e.g., MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST*, at xiii-xvii (1993) (describing the dangers to patients of marketizing medicine and changing the financial incentives of physicians).

32. See, e.g., E. HAAVI MORREIM, *HOLDING HEALTH CARE ACCOUNTABLE: LAW AND THE NEW MEDICAL MARKETPLACE* 80-91 (2001) (dividing quality problems in medical markets into expertise issues and resource issues, and proposing corresponding duties involving tort, agency, and contract).

and redistribution tend not to be as well received by the political process as their opinions about individual liberty. The bioethicists who were invited to the White House to work on health reform in 1993, for example, expected rationing to be their most important agenda item. To their surprise, they were explicitly forbidden from mentioning the word by the administration's reform czar, Ira Magaziner, and were instructed instead to craft a lofty preamble for the Clinton administration's universal coverage legislation and then to work on familiar relational issues such as advance directives.³³

C. POLITICS, ESPECIALLY BUDGETARY POLITICS

Political dynamics reinforce relational governance. Although some commentators criticize the notion of a "statistical" life,³⁴ regulatory policies that increase the risk of physical injury or death in tangential ways for faceless persons (for example, raising speed limits or relaxing environmental controls) are easier for politicians to adopt and maintain than policies that cost more immediate lives (for example, not paying for organ transplantation). Health care regulation is uniquely amenable to portrayal in terms of identified lives. For example, Jacobs and colleagues credit Oregon's controversial Medicaid rationing plan with increasing public budgeting for health care by forcing state legislators to cast votes on coverage of specific treatments that have direct implications for identifiable people.³⁵

Anecdotes have power in all politics, but especially so in health care.³⁶ Pressure for cost containment, both public and private, has been resisted most successfully when vivid narratives—albeit often exaggerated or misused—can be offered to the public. Examples at the federal level include EMTALA³⁷ and the Newborns' and Mothers' Health Protection Act of 1996.³⁸ On the other hand, preventive care is not as compelling politically as treatment of manifest disease because its effects are less salient—a reason why successful prevention campaigns, such as for a polio vaccine, often use "poster children."³⁹

33. These pressures have been bipartisan. It has been suggested, for example, that the first President Bush rejected the state of Oregon's Medicaid waiver application because he did not want to be known as the "rationing president." See Thomas Bodenheimer, *The Oregon Health Plan—Lessons for the Nation (First of Two Parts)*, 337 *NEW ENG. J. MED.* 651, 652 (1997).

34. See, e.g., Lisa Heinzerling, *The Rights of Statistical People*, 24 *HARV. ENVTL. L. REV.* 189, 189–92 (2000).

35. Lawrence Jacobs et al., *The Oregon Health Plan and the Political Paradox of Rationing: What Advocates and Critics Have Claimed and What Oregon Did*, 24 *J. HEALTH POL. POL'Y & L.* 161, 174 (1999).

36. See David A. Hyman, *Do Good Stories Make for Good Policy?*, 25 *J. HEALTH POL. POL'Y & L.* 1149, 1149–50 (2000) (arguing that when atypical or incomplete stories motivate health care "reform," unsound policies may result).

37. 42 U.S.C. § 1395dd (2000 & Supp. IV 2004); see also David A. Hyman, *Patient Dumping and EMTALA: Past Imperfect/Future Shock*, 8 *HEALTH MATRIX* 29, 32–34 (1998).

38. Pub. L. No. 104-204, 110 Stat. 2874 (1996); see also David A. Hyman, *What Lessons Should We Learn From Drive-Through Deliveries?*, 107 *PEDIATRICS* 406, 407 (2001).

39. See DAVID M. OSHINSKY, *POLIO: AN AMERICAN STORY* 79–91 (2005).

Even comprehensive health reforms must withstand scrutiny one patient at a time. When I worked in the Clinton White House in 1993, I asked the experts whose work I was coordinating to construct fictitious profiles of ordinary Americans on whom the effects of their proposed policies could be assessed and described. A few months later, in his first public appearance promoting the newly released Health Security Act,⁴⁰ President Clinton stumbled (uncharacteristically) over the initial question, which was from a mother who wanted to know if his plan would have covered experimental treatment for her son, who had died of leukemia.⁴¹ The Health Insurance Association of America (HIAA) exploited this relational bias to help defeat the Clinton proposal using the "Harry and Louise" ads, which portrayed an ordinary couple complaining about the government limiting their individual choices.⁴²

To avoid the trap of the identified life, politicians usually constrain health care through aggregate financing decisions (which savvy opponents now assiduously convert to children's lives lost, cancer patients left untreated, et cetera), and scrupulously avoid reforms that alter health care delivery even though it is health care delivery that ultimately determines cost, access, and quality. It is ironic that an analysis credited with helping kill the Health Security Act, Betsy McCaughey's essay *No Exit*,⁴³ was primarily about how private managed care might compromise health care delivery, an issue with no direct connection to the Clinton proposal that came to the fore more quickly after the Act's defeat than had the proposal passed.⁴⁴ Financing decisions also fall squarely within Washington's comfort zone. To tax or not to tax is the critical vote that public officials must defend in re-election campaigns, and handing out money is how politicians win friends and influence people.

The health care delivery system remains politically untouchable. Lawrence Jacobs distinguishes America's politics of health care supply from Europe's politics of health care access, noting how this makes U.S. health policy vulnerable to interest group pressure in support of narrowly defined services and providers.⁴⁵ Because innovators tend not to lobby, and because regulatory

40. Health Security Act, H.R. 3600, 103d Cong. (1993).

41. *Remarks by Pres. Clinton During A California Town Hall Meeting*, U.S. NEWSWIRE, Oct. 4, 1993.

42. See THEDA SKOCPOL, *BOOMERANG* 137-38 (1996) (discussing HIAA's advertising campaign); Raymond L. Goldstein et al., *Harry and Louise and Health Care Reform: Romancing Public Opinion*, 26 J. HEALTH POL. POL'Y & L. 1325, 1345-47 (2001) (suggesting that advertising of this sort can demobilize public support for health policy initiatives that are unfavorable to special interests). When I returned to California the following year, I learned that a local Democratic operative supporting health reform had contacted the actress who played "Louise," hoping to persuade her to go public with the fact that she herself lacked health insurance and might well benefit from government-sponsored universal coverage. The actress arrived at the meeting wearing a hidden recording device provided by the Republican opposition. Welcome to politics.

43. Elizabeth McCaughey, *No Exit: What the Clinton Plan Will Do for You*, NEW REPUBLIC, Feb. 7, 1994, at 21.

44. *Id.*

45. Lawrence R. Jacobs, *Politics of America's Supply State: Health Reform and Technology*, HEALTH AFF., Mar.-Apr. 1995, at 143.

changes to existing ways of receiving services could be seen as threatening identified lives, government policymakers have been largely powerless to improve the system's collective efficiency, and, therefore, to make it affordable for more of the population. As Jacobs observes, access to health care for economically disadvantaged groups has been "fiscalized" as a problem of allocating scarce tax dollars rather than as a source of social solidarity and future stability.⁴⁶

Budgetary considerations had a far greater impact on health reform in the early 1990s than is often appreciated (after the Republicans gained control of Congress in 1994, by contrast, reining in Medicare and Medicaid spending became an ideological as well as a fiscal priority). Because the third-party candidacy of Ross Perot in 1992 had made deficit reduction an independent political priority, the Clinton administration upon taking office felt obligated to generate "scoreable savings" from universal health coverage—no matter how implausible this might seem from a back-of-the-envelope calculation of the cost of adding 15% of the American population to a health care system already experiencing persistent double-digit annual increases.

Consequently, the collective meaning of the Clinton health reform plan was budgetary, not service-oriented. Two major design features of the Health Security Act had as their principal purpose to persuade the Congressional Budget Office (CBO) that universal coverage could be achieved without massive tax increases and that spending would not exceed predetermined limits. Nominally private "health alliances" (the forerunner of the "connector" in the recently enacted Massachusetts Health Plan) were created to collect premium dollars and broker health plan enrollment, and "global budgets" were written into law to backstop market competition if aggregate spending continued to rise.⁴⁷ CBO bought the this-will-keep-spending-down argument but rejected the this-is-not-a-tax argument, killing health reform as a political matter.⁴⁸

46. *Id.* at 149–52.

47. "Health alliances" (previously called "health insurance purchasing cooperatives") were non-profit bodies that would have structured regional health insurance markets, receiving contributions from employers and paying risk-adjusted premiums to the health plans in which beneficiaries had enrolled. "Global budgets" would have limited, as a matter of law, the aggregate amount that could be paid for the statutory package of health benefits, imposing various correctives that (if not revised by a subsequent Congress) would be triggered should the limits be exceeded. For a policy-minded explanation of these and other features of the Clinton Health Plan, see Paul Starr & Walter A. Zelman, *Bridge to Compromise: Competition Under a Budget*, HEALTH AFF. (Supp.) 18–21 (1993). For insight into the role of the CBO, as well as its struggle to maintain impartiality, see Viveca Novak, *By the Numbers*, NAT'L JOURNAL, Feb. 12, 1994, at 348.

48. See *Health Care Reform (Part 10): Joint Hearing Before the Subcomm. on Health and the Env't and the Subcomm. on Commerce, Consumer Prot. and Competitiveness of the H. Comm. on Energy and Commerce*, 103d Cong. 10 (1994) (testimony of Robert D. Reischauer, Director, CBO) (citing data that the limits placed on premiums and Medicare savings are sufficient to reduce national health expenditures by some \$30 billion below baseline levels by 2000 and \$150 billion below baseline levels by 2004, but also concluding that mandatory payments from private employers to health alliances constitute "an exercise of sovereign power").

D. HEALTH CONSUMERISM

A major change in the language used to describe recipients of medical care—from dependent “patients” to demanding “consumers”—has reinforced the non-collective, relational nature of most health care regulation. Consumerism, like feminism and environmentalism, is often described as a product of the 1960s rebellion against establishment values. Because consumerism is associated with individual market transactions, however, its impact on collective priorities is scattershot almost by definition. In health care, consumerism (assisted by the Internet) has substantially overcome physicians’ monopoly on medical information, but has made insured patients even more insistent in their pursuit of seemingly beneficial treatment. Consumerism (assisted by bioethics) has oriented physicians to goals defined by patients, but has largely freed the medical profession from ethical responsibilities beyond the satisfaction of individual demand.⁴⁹ Consumerism (assisted by persistent cost inflation) may finally open medical pricing to public scrutiny, but it frames financial commitments as decentralized decisions rather than the product of collective deliberation and negotiation.⁵⁰

Consumerism also assigns government a facilitative rather than constitutive role in health care. President Clinton endorsed this individualistic approach in his Second Inaugural Address, proposing that “a new government for a new century . . . [would be] humble enough not to try to solve all our problems for us but strong enough to give us the tools to solve our problems for ourselves”⁵¹ Largely for this reason, information disclosure has been a mainstay of health care regulation for the last decade.⁵²

This approach has visceral appeal to “third-way” politicians. During the frenetic months in early 1993 when the Clinton health plan was being formulated, task force director Magaziner repeatedly rejected calls by medical quality experts for mandatory data gathering from health plans and providers, calling it wasteful bureaucracy, but unhesitatingly embraced the same measures when presented (several years prematurely) as a functional “report card” for use by individual health care consumers. The fact that information-based regulation is essentially off-budget enhances its political attractiveness.

Consumerism has begun to exert pressure on established forms of collective regulation. Consider the Food and Drug Administration (FDA), which in the 1990s turned to industry-paid user fees to help it keep up with increasingly

49. See David A. Hyman, *How Law Killed Ethics*, 34 PERSP. BIOLOGY & MED. 134, 146–47 (1990); William M. Sage, *The Lawyerization of Medicine*, 26 J. HEALTH POL. POL’Y & L. 1179, 1184–87 (2001).

50. Monetizing medical practice also breeds suspicion of group purchasing because of concern about economic self-interest on the part of employers, health insurers, or other purchasing intermediaries. See *infra* text accompanying notes 69–80.

51. *The Inauguration: Transcript of President Clinton’s Second Inaugural Address to the Nation*, N.Y. TIMES, Jan. 21, 1997, at A14.

52. See generally William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999); see also *infra* text accompanying notes 82–88.

vocal demand for breakthrough drugs while still protecting the public.⁵³ High-profile failures of oversight, such as occurred with Vioxx, sensitized consumerist voters to the financial self-interest of the pharmaceutical industry, but have not led them to recognize that, in collective terms, medical innovation can never be both quickly available and assuredly safe and effective. Before being overruled by the entire court, a panel of the United States Court of Appeals for the District of Columbia Circuit went so far as to hold that patients with life-threatening conditions had a constitutionally protected liberty interest in accessing drugs not approved by the FDA if basic safety testing had been completed and a physician was willing to administer them.⁵⁴

One of the striking differences between national health reform rhetoric following the 1992 presidential elections and candidates' campaign statements in connection with the 2008 race is the emergence of "value for money" as a reform objective.⁵⁵ This trend reflects growing public recognition that the quality and safety of American medicine are questionable, as well as its cost being extremely high. By contrast, when I volunteered in 1994 as health policy advisor to California Democratic gubernatorial candidate Kathleen Brown, the proposal my colleague (a partner in a major global health consulting firm) and I presented to her campaign team was dismissed out of hand as inconsistent with voter priorities. Its theme? Value for money. Still unstated in current campaign literature, however, is whether the now-familiar consumer mantra of "value" should be measured in individual or collective terms where health care is concerned.

Medical consumerism continues to express itself in new ways. Collectivist viewpoints currently underlie both sides of the debate over stem cell research: a strongly held belief among conservative Christians that the destruction of human embryos is immoral, and a pragmatic opinion among innovators (and some state governments) that the economic benefits of biomedical science will bypass communities that limit research. It seems likely, however, that stem cell research rules will be liberalized because of heightened individual demand among the consuming public for the medical innovations that unfettered science seems poised to produce, not because the balance of power between the existing socially oriented constituencies will shift fundamentally. If this occurs, my enthusiasm for the substantive outcome will be tempered by the recognition that

53. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1840–44 (1996) (analyzing the adoption of drug user fees).

54. *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 469 F.3d 129 (D.C. Cir. 2006), *vacated and rev'd*, 495 F.3d 695 (D.C. Cir. 2007) (en banc); see also John A. Robertson, *Controversial Medical Treatment and the Right to Health Care*, 36 HASTINGS CTR. REP. 15 (2006); Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007).

55. Sen. Clinton's official website, for example, describes her newly released reform plan as "[b]uilding on her proposals to rein in costs and to insist on value and quality." Hillary for President, American Health Choices Plan, <http://www.hillaryclinton.com/feature/healthcareplan/summary.aspx> (last visited Oct. 22, 2007).

an individual, relational orientation will once again have eclipsed a collective approach to public debate over health policy.

II. CURRENT NEEDS FOR COLLECTIVE GOALS AND REGULATORY GOVERNANCE

Relational bias resulting from the factors identified above might simply be an uncomfortable fact of life for health care policymakers were it not for the crushingly high costs that health care imposes on American society and the suboptimal benefits it provides. Far more than social security, Medicare and Medicaid entitlements dominate government budgets and squeeze out discretionary spending on education, infrastructure, and economic development. At the same time, millions of “one patient-one physician” encounters do not really sum to a system, but remain a fragmented collection of inaccessible services with uneven quality, questionable safety, and insufficient impact on the health of the nation.⁵⁶

Between the debate over national health reform in 1993–94 and today, new challenges for health law and health policy have arisen, and new approaches have been offered. Unfortunately, little explicit attention is being paid to the tension between individual and collective goals that these trends and ideas present. Without attempting to cover the landscape of policy innovation, this Essay will offer observations about relational and regulatory governance in four areas: conflicts of interest in biomedical research, managed care and pay-for-performance, health care transparency and education, and the “new” public health.

A. RESEARCH “CONFLICTS OF INTEREST”

The modern biomedical research enterprise offers an instructive example of how relational governance can confuse and mislead health policy. The medical marketplace encompasses research as well as clinical care, and money changing hands in unaccustomed ways has provoked criticism in both domains.⁵⁷ Critics of commercialized research have labeled as “conflicts of interest” many payments by industry to academic researchers that perturb the critics’ moral compass.⁵⁸ Ethically, a conflict of interest suggests corruption. Legally, it triggers a limited menu of responses: disclosure and consent, partitioning of functions, or

56. See KAREN DAVIS ET AL., MIRROR, MIRROR ON THE WALL: AN INTERNATIONAL UPDATE ON THE COMPARATIVE PERFORMANCE OF AMERICAN HEALTH CARE (2007); Editorial, *World’s Best Medical Care?*, N.Y. TIMES, Aug. 12, 2007, at WK9 (describing the American health system’s shortcomings compared with other nations).

57. Dr. Bud Relman, a highly influential prior editor of *The New England Journal of Medicine* and a vigorous defender of traditional ethics and practices, cautioned physicians in 1991 about medicine’s transition from profession to industry, warning that “our profession faces an ethical and economic crisis of unprecedented proportions, as it struggles to find its bearings in a health care system that has become a vast and highly lucrative marketplace.” Arnold S. Relman, *Shattuck Lecture—The Health Care Industry: Where Is It Taking Us?*, 325 NEW ENG. J. MED. 854, 854 (1991).

58. See, e.g., Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest*, 295 JAMA 429, 430 (2006). See generally SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE

outright prohibition.

Money might compromise fundamental values among scientists, particularly those who work in universities. It might change the direction of scientific agendas. It might threaten the integrity of research. It might harm research subjects. It might delay the dissemination of research results to the scientific community and the public. Finally, it might reduce public trust in biomedical science, and therefore also reduce support for government research funding and willingness to participate in clinical trials.

All of these are real risks, with real scandals to illustrate them.⁵⁹ But are they conflicts of interest? When lawyers guard against their own conflicts of interest, as required by the rules of professional responsibility, they define them in relational terms. As legal ethicist Brad Wendel explains: "A conflict of interest arises when a person (the agent) [that is, the lawyer] stands in a relationship of trust with another person (the principal) [that is, the client] that requires the agent to exercise judgment on behalf of the principal, and where the agent's judgment is impaired because of another interest of the agent."⁶⁰

Critics of new biomedical funding models, by contrast, typically justify their concern by invoking something like the following definition of conflict of interest: "a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)."⁶¹ The problem with this definition is that only the first example is individual and relational; a physician who is legally and ethically obligated to be loyal to a specific patient might well be conflicted if paid by another. The second example, the validity of research, is an abstraction with collective, regulatory significance but no relational meaning. One cannot be loyal to research integrity, or to the common welfare, or to motherhood and apple pie (though one

LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? (2003) (criticizing university-industry relationships, often involving patented technologies).

59. At the University of Pennsylvania, Jesse Gelsinger died after physicians with a commercial stake in a novel gene therapy ignored warning signs when enrolling research subjects to test the procedure. Sheryl Gay Stolberg, *F.D.A. Officials Fault Penn Team in Gene Therapy Death*, N.Y. TIMES, Dec. 9, 1999, at A22. In another case, a pharmaceutical company, Apotex, pressured the University of Toronto, to which it had promised a multimillion dollar gift, to demote a hematologist who had published negative findings about its new iron-binding drug. Krista Foss, *Grievance Filed in Drug-Research Controversy at U of T: Doctor in Lengthy Battle with Company over Freedom To Publish Her Negative Findings*, GLOBE & MAIL (Toronto), Dec. 18, 1998, at A11. The maker of Synthroid, Boots Pharmaceutical, attempted to suppress the publication of research that it sponsored at the University of California, San Francisco, which failed to show its product to be advantageous. See Drummond Rennie, *Thyroid Storm*, 277 JAMA 1238, 1238-39 (1997); see also *In re Synthroid Mktg. Litig.*, 264 F.3d 712, 714 (7th Cir. 2001) (discussing the published study).

60. W. Bradley Wendel, *The Deep Structure of Conflicts of Interest*, 16 GEO. J. LEGAL ETHICS 473, 477 (2003). A general economic definition of an agent is anyone who makes a decision on behalf of another. The law of agency sets its scope more narrowly, defining an agent as a fiduciary subject to the principal's right of control. RESTATEMENT (THIRD) OF AGENCY § 1 (2006).

61. Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 573 (1993).

certainly can be loyal to one's mom).

Unlike lawyers and clients, there is no identifiable party to whom biomedical researchers owe exclusive loyalty, unless it is merely those researchers' academic or corporate employers. The most intuitive relational accusation against researchers who receive outside funding is disloyalty to people who participate in human subjects research. If the researcher-subject relationship, like the physician-patient relationship, demanded such loyalty, conflict of interest discourse would be appropriate. But, as Coleman has explained, no such dominant relational duty exists.⁶²

One of the principal insights of modern bioethics is that the proper measure of research is its value to society.⁶³ Scientists are ethically and legally obligated to minimize risk of harm to participants, and can never conduct experiments that are likely to cause serious injury. But subjects participate in research, and sometimes even suffer harm, to further a social mission rather than in expectation of personal medical benefit. For this reason, ethicists often worry about the "therapeutic misconception": research subjects' incorrect belief that the white-coated researcher who supervises the experiment has their cure or physical improvement as her primary concern.⁶⁴

Financial flows in biomedical research therefore are less about conflicts of interest—unless a researcher is also a patient's treating physician—and more about getting the regulatory incentives right for productive, ethical experimentation. Moral purity is not the issue; professional effectiveness is. To appreciate this, one need only think beyond money (which seems "conflicting" because it has an identifiable source) to what has been called "nonfinancial conflicts of interest."⁶⁵ Human motivation is complex, and indeed biomedical researchers may do what they do for many reasons in addition to payment: publication, promotion, peer recognition, et cetera. Selecting skilled researchers and giving them the proper incentives to produce useful knowledge is an important social project, but one cannot coherently argue that intellectual curiosity or altruism is always a better motivator than monetary gain or desire for fame.

This is particularly so given the incentive-rich environment the federal

62. Coleman identifies recent litigation against clinical researchers as a pressing reason to define clearly the obligations owed by researchers to subjects because the template for such litigation is the obligation of physician to patient under established laws of medical malpractice and informed consent. Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 388–91 (2005).

63. See, e.g., Franklin G. Miller, *Research Ethics and Misguided Moral Intuition*, 32 J.L. MED. & ETHICS 111, 114 (2004). Miller notes the curiosity that founding documents in bioethics assume that researchers must act with "therapeutic beneficence" toward human subjects, *id.* at 111, but that recent conceptions of research ethics minimize direct benefit to the subject as the basis for participation, stressing instead altruistic desire to help future sufferers among the general public, or within susceptible subgroups in whose wellbeing the participant has at most an indirect interest. *Id.* at 114.

64. See Paul S. Appelbaum, *Clarifying the Ethics of Clinical Research: A Path Toward Avoiding the Therapeutic Misconception*, 2 AM. J. BIOETHICS 22, 23 (2002) (discussing the substantial prevalence of "therapeutic misconception").

65. See Norman Levinsky, *Nonfinancial Conflicts of Interest in Research*, 347 NEW ENG. J. MED. 759, 760 (2002).

government deliberately created for biomedical researchers. The watershed event in this respect was the passage in 1980 of the Bayh-Dole Act, which responded to American industry's seeming inability to commercialize technologies whose prototypes were funded by public research dollars (compared, at the time, to the Japanese).⁶⁶ The Bayh-Dole Act encouraged universities to patent inventions derived from NIH, NSF, or similar funding streams, and then license those patents to private industry for commercial development (at the same time producing a politically attractive off-budget subsidy for universities through licensing fees and royalties). The generation of research scientists that followed the Bayh-Dole Act looks and acts unlike its predecessors.⁶⁷ Earlier university researchers were from relatively homogeneous backgrounds, accepted modest pay, and sought little publicity, but enjoyed prestige and security within their academic communities. For the more diverse generation that followed, achieving success requires entrepreneurship, monetary rewards matter, and it is important to be in the public eye.

There may be good reason to refine research incentives as a matter of collective public policy, much as incentive compensation for corporate managers has been recalibrated to better align their interests with those of shareholders without tempting them to commit fraud. However, labeling those incentives "conflicts of interest"—whether from honest concern, misplaced nostalgia, or inability to compete—merely provokes public disapproval and legal scrutiny without solving the problem. In particular, only when one gets past conflict-of-interest rhetoric do the empirics matter. Instead of leveling moral accusations, society can ask—and determine as a regulatory matter—what incentive structures, informational requirements, and legal remedies produce new, useful knowledge at reasonable cost without unacceptably endangering research subjects.⁶⁸

B. THE MANAGED CARE BACKLASH AND PAY FOR PERFORMANCE

Another illustration of misguided relational emphasis comes from the country's first widespread experiment with payer involvement in health care delivery: the managed care expansion of the 1980s and 1990s. Health insurers may not be saints, but the managed care experience primarily spotlights America's inability to engage affordable access to basic medical care as a collective issue.

66. 35 U.S.C. §§ 200–12 (2000). See generally Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, VA. L. REV. 1663, 1691–95 (1996) (tracing the history of the Bayh-Dole Act and its attempts to "facilitate [universities'] efforts to transfer technology to industry").

67. To illustrate, I recently learned from the chair of biomedical engineering at the University of Texas that most junior faculty joining his department list "starting a company" as one of their five-year career goals. It is hard to imagine that ambition being either offered or accepted as a path to academic success a generation ago.

68. For a more detailed argument, see William M. Sage, *Some Principles Require Principals: Why Banning "Conflicts of Interest" Won't Solve Incentive Problems in Biomedical Research*, 85 TEX. L. REV. 1413 (2007).

As Havighurst and Richman observe, American law turns out to be no friend to the have-nots where health coverage is concerned.⁶⁹

Managed care regulation began as a common project to loosen the organized medical profession's economic grip on the health care system by clearing away self-protective laws, such as prohibitions on selective contracting with hospitals or physicians, thereby freeing up resources for both public and private expansions of access. It ended in a legislative frenzy to keep things exactly as they had been for well-insured individuals with political power.⁷⁰ The language of the backlash legislation, "patient protection," perfectly captured the (successful) political strategy of managed care's opponents: frame the debate in relational terms using the image of someone ill facing restrictions on desired treatment. A collective voice—including potential patients for whom the current system is unaffordable—was never heard.

Reactionary legislation was bolstered by the medical profession and the courts. Health insurance is constructed around pre-existing risk pools such as workplaces; physicians, however, fiercely resisted assuming ethical responsibility for "populations" and reasserted the primacy of "advocacy" for individual patients.⁷¹ The courts, drawn into managed care because health plans are governed by an uneasy mix of state insurance law and ERISA, never got beyond the relational perspective. Cases involving patient injury plausibly attributable to managed care restrictions were finessed by most judges to allow equitable results without setting lasting precedents, at least until the Supreme Court articulated a bright-line rule in favor of defendant health plans.⁷² Non-ERISA coverage cases decided under state insurance law have consistently looked to plaintiffs' treating physicians for the best evidence of medical necessity, downplaying the significance of expertise regarding collective cost-

69. Clark C. Havighurst & Barak D. Richman, *Distributive Injustice(s) in American Health Care*, 69 LAW & CONTEMP. PROBS. 7, 8–9 (2006).

70. See David A. Hyman, *Managed Care at the Millennium: Scenes From a Maul*, 24 J. HEALTH POL. POL'Y & L. 1061, 1061 (1999).

71. See Jerome P. Kassirer, Editorial, *Managing Care—Should We Adopt a New Ethic?*, 339 NEW ENG. J. MED. 397, 397 (1998) (arguing that a population-based ethic for the provision of health care—"intentionally providing minimally acceptable care to some for the benefit of others"—is wrong). But see William M. Sage, *Physicians as Advocates*, 35 HOUS. L. REV. 1529, 1558, 1581 (1999) (arguing that a strict duty of physician advocacy on behalf of individual patients would be counterproductive). Among medical practice settings, only a few well-established HMOs seem to have developed cultures that make physicians feel responsible for their colleagues' patients as well as their own, promoting cost-consciousness without obligating them to "ration at the bedside." For a revealing portrait of the tension between individual and group health management, see David M. Eddy, *Broadening the Responsibilities of Practitioners: The Team Approach*, 269 JAMA 1849 (1993) (discussing the proper use of expensive radiographic contrast agents).

72. Compare *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 356 (3d Cir. 1995) (holding that lawsuits alleging problems with the "quality" of employer benefits are not completely preempted by ERISA), with *Aetna Health Inc. v. Davila*, 542 U.S. 200, 221 (2004) (holding that ERISA completely preempts claims alleging patient injury by insurers under employee benefit plans). By the time *Davila* was decided, however, aggressive managed care was already dead as a practical matter.

effectiveness or even clinical benefit.⁷³ The best judicial opportunity for giving legal meaning to collective obligations in managed care was *Pegram v. Herdrich*,⁷⁴ which asked the federal courts to consider how an ERISA plan's fiduciary duty to groups of beneficiaries might affect the delivery of services to individuals. Unfortunately, the Supreme Court found a way to dispose of the case without resolving, or even discussing, that critical question.⁷⁵

To be fair, courts are constituted to hear specific controversies presented by plaintiffs with standing to sue, and only make general law when necessary to the resolution of an individual dispute. Other than *Pegram*, which was not litigated expertly by the plaintiff, there were few vehicles for articulating regulatory duties using judicial processes. As managed care developed, some judicial outcomes were frankly ironic. By the time researchers established that high-dose chemotherapy with autologous bone marrow transplantation for advanced breast cancer was medically harmful, dozens of courts deciding individual claims had pilloried health insurers for ruling the treatment "experimental" and hence not covered.⁷⁶ In *Aetna Health Inc. v. Davila*, a contrary ruling by the Supreme Court would have had the effect of vindicating a managed care enrollee's allegation of injury because he had been denied Vioxx, an expensive medication whose reputation had slipped from "wonder drug" to "safety hazard" between the case's filing and its resolution.⁷⁷ Collective litigation over managed care—several class action suits were filed—dealt either with pedestrian matters, such as delays in physician payment, or with highly speculative ones, such as whether all purchasers of managed health coverage had been simultaneously "defrauded" because of the limited nature of their coverage, even if they had never been denied appropriate medical treatment.⁷⁸

73. See, e.g., *Florence Nightingale Nursing Serv., Inc. v. Blue Cross & Blue Shield of Ala.*, 832 F. Supp. 1456, 1461 (N.D. Ala. 1993) (ridiculing the defendant health plan's medical director for being trained "not only in medicine but in 'cost containment'"), *aff'd*, 41 F.3d 1476 (11th Cir. 1995).

74. 530 U.S. 211 (2000).

75. *Id.* at 231–34, 237 (holding that a mixed eligibility-treatment decision made by an HMO through its employed physicians is not a fiduciary act under ERISA); see also William M. Sage, *UR Here: The Supreme Court's Guide for Managed Care*, HEALTH AFF., Sept.–Oct. 2000, at 219 (discussing *Pegram*).

76. See Michelle M. Mello & Troyen A. Brennan, *The Controversy over High-Dose Chemotherapy with Autologous Bone Marrow Transplantation for Breast Cancer*, HEALTH AFF., Sept.–Oct. 2001, at 101. For insight into judicial reasoning in these cases, see Mark A. Hall et al., *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L. REV. 1055 (1996); William M. Sage, *Judicial Opinions Involving Health Insurance Coverage: Trompe L'oeil or Window on the World?*, 31 IND. L. REV. 49 (1998).

77. See David J. Graham, *COX-2 Inhibitors, Other NSAIDs, and Cardiovascular Risk: The Seduction of Common Sense*, 296 JAMA 1653 (2006) (summarizing science and regulation of Vioxx); Henry A. Waxman, *The Lessons of Vioxx—Drug Safety and Sales*, 352 NEW ENG. J. MED. 2576 (2005) (describing overzealous marketing efforts).

78. See, e.g., *Maio v. Aetna*, 221 F.3d 472 (3d Cir. 2000); *In re Managed Care Litigation*, 209 F.R.D. 678 (S.D. Fla. 2002); see also Clark C. Havighurst, *Consumers Versus Managed Care: The New Class Actions*, HEALTH AFF., July–Aug. 2001, at 8. Beyond the health care context, "fraud on the market" similarly reflects the legal system trying to address systemic harms by extrapolating from individual ones. See Sage, *supra* note 68, at 1461–62; see also *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336 (2005); John C. Coffee, Jr., *Causation by Presumption? Why the Supreme Court Should Reject Phantom Losses*

Although 1990s-style managed care ultimately achieved a draw in the courts, it lost the battle for public acceptance. The war against health care costs continues, of course, because affordability remains a major concern of the Medicare and Medicaid programs, of most employers, and of nearly all individuals who purchase or want to purchase health insurance. But there is still no indication that policymakers have solved, or even that they recognize, the problem of building collective benefits using relational tools.

Today's care management is kinder and gentler (or, if you prefer, sadder yet wiser) than its prior incarnation. Having endured a cycle of both consumer rejection (admittedly during an economic boom) and legal restriction for seeming to interfere with relational obligations to patients, health plans no longer offload capitated risk on financially unsophisticated physicians, rarely limit enrollees to narrow physician panels selected for unrevealed but presumably economic reasons, and seldom exercise unilateral corporate authority to rule physician-recommended treatment "not medically necessary." Instead, managed care (and Medicare as well) has reinvented its objective as value-based purchasing, is beginning to measure and publicize provider quality, and is attempting to pay physicians and hospitals more for better performance.⁷⁹

What is nobody explaining? Whether "value," "quality," and "performance" are to be judged by individual or by collective criteria.⁸⁰ The first generation of pay-for-performance is merely pay-for-measurement, creating the public good of baseline and trend information that can be justified as pro-consumer but that has primarily collective benefit. Government standards and Medicare-based subsidies for electronic recordkeeping in essence reflect this fact. What will the next generation of pay-for-performance represent? Pay for physician loyalty to individual patients, based on subjective satisfaction, accessibility of desired treatment, and individual health outcomes? Or pay for compliance with cost-effective best practices and population-based disease prevention and lifestyle modification that improves society's productivity and reduces its disease burden? If the latter, how will these practices be selected and how will the results be measured? This choice is more than a technical one. It goes to the heart of assessing health care in individual relational versus collective regulatory terms.

C. HEALTH CARE TRANSPARENCY AND EDUCATION

Similar problems regarding overemphasis on relational obligations and failure to define collective goals afflict the legion of regulatory mandates that

and Reverse Broudo, 60 BUS. LAW. 533, 543 (2005); Merritt B. Fox, *Demystifying Causation in Fraud-on-the-Market Actions*, 60 BUS. LAW. 507 (2005).

79. See, e.g., Michael E. Chernew, Allison B. Rosen & A. Mark Fendrick, *Value-Based Insurance Design*, 26 HEALTH AFF. (WEB EXCLUSIVE) w195 (2007), available at <http://content.healthaffairs.org/cgi/content/full/26/2/w195>; Meredith B. Rosenthal et al., *Paying for Quality: Providers' Incentives for Quality Improvement*, HEALTH AFF., Mar.-Apr. 2004, at 127-28.

80. See William M. Sage, *Pay-for-Performance: Will It Work in Theory?*, 3 IND. HEALTH L. REV. 305, 314-22 (2006).

comprise the “health care transparency” movement. Informational asymmetries between physicians and patients have been cited since the 1960s as the principal reason why efficient markets seldom emerge in health care.⁸¹ These insights have been used to explain the continued importance of professional ethics and to promote broad government involvement in funding and overseeing medical care.⁸²

During the 1980s, coinciding with the general consumerist movement discussed above, information came to be seen as a method by which government could enable citizens to become smarter health care purchasers and patients. Many factors account for this shift, including decreased faith in direct government control, budgetary pressures limiting extensive public involvement, distrust of traditional medical paternalism given the profit potential of overusing new technologies, employers’ attempts to compensate for “moral hazard” among insured but passive patients, and—with changing provider payment methods and the rise of managed care—desire to help patients navigate new and potentially unreliable access points for treatment.

Virtually all information-based regulation enacted during this period was cast in relational terms, from informed consent laws and patients’ “bills of rights” to *Consumer Reports*-style shopping guides to health plans and providers. These developments coincided with a general turn in American politics toward free-market governance and a greater commitment among health care payers to cost containment through competition, ending the Carter Administration’s flirtation with national health planning and rendering suspect many state certificate-of-need programs. In response, states with strong health planning traditions, such as New York and Pennsylvania, reinvented significant parts of their regulatory programs as consumer-oriented “report card” initiatives.

Although bringing patients’ knowledge closer to physicians’ would seem to benefit both autonomy and competition, the relational dangers of asymmetric information were already old news when these programs were instituted. The real action has involved collective information acquisition and processing, addressing problems revealed by Wennberg’s small-area variation studies and the Institute of Medicine’s subsequent exposés of quality and safety lapses in hospitals.⁸³ The hope of wringing substantial cost savings out of this disorganized and wasteful system, while actually enhancing quality of care through

81. Arrow, *supra* note 14, at 946–47.

82. See generally *id.* (discussing professional ethics as a non-market social institution that reduces uncertainty in medical markets); Peter J. Hammer, *Arrow’s Analysis of Social Institutions: Entering the Marketplace with Giving Hands*, in *UNCERTAIN TIMES: KENNETH ARROW AND THE CHANGING ECONOMICS OF HEALTH CARE* 216–26 (Peter J. Hammer et al. eds., 2003) (analyzing Arrow’s thesis regarding social institutions); James C. Robinson, *The End of Asymmetric Information*, in *UNCERTAIN TIMES: KENNETH ARROW AND THE CHANGING ECONOMICS OF HEALTH CARE* 181 (Peter J. Hammer et al. eds., 2003) (criticizing the political use of information asymmetry to justify heavy-handed regulation).

83. See INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 23–28 (2001); INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000); JOHN E. WENNBURG, *THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES* 2 (1996).

incentives and subsidies for data gathering and communication among health care providers, is what motivates interest in electronic health records, decision support software, and other information technology. Transparency intended to support another current marketplace trend, “consumer-directed care,”⁸⁴ similarly combines individual transactional utility with collective benefit. The pragmatic purpose of consumer-directed care among employers and government payers is to reduce third-party financing of health insurance from a comprehensive commitment to a defined contribution in the face of continued medical inflation. But proponents of health savings accounts and similar insurance products also believe that large aggregate savings will be realized once consumers, pursuing financial self-interest, use information about price and quality to make prudent choices.⁸⁵

Transparency is to a large extent a public good, and should be structured and regulated accordingly. Ideally, demand-side and supply-side effects of transparency could combine to free health care delivery from its historical tethers and enable it to achieve efficiencies typical of most other modern economic sectors. The “retail medical clinic” movement, for example, associates basic medical care with familiar pharmacy and supermarket brands that offer assurances of price competition and customer service, but are spared the presumption of an adversarial financial relationship that made brand-name managed care organizations unattractive to consumers in the 1990s.⁸⁶

Transparency also has collective meaning in health care through its reinforcement of democratic governance. Near the end of his career, Thomas Jefferson wrote: “I know no safe depository of the ultimate powers of the society but the people themselves; and if we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion”⁸⁷ Among other things, the public deserves information to help it approve or reject the massive redistributions of wealth that the health care system facilitates: generational and income-based

84. See James C. Robinson, *Consumer-Directed Health Insurance: The Next Generation*, 24 HEALTH AFF. (WEB EXCLUSIVE) w583 (2005), available at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.583/DC1>.

85. See Phil Gramm, *Why We Need Medical Savings Accounts*, 330 NEW ENG. J. MED. 1752, 1752–53 (1994) (claiming that waste in health care is primarily attributable to the moral hazard of costlessness at the point of service); Gerald L. Musgrave et al., *Lunch Insurance*, 15 REGULATION 257 (1992) (making the same point by postulating a “lunch system” with subsidies similar to the current health care system). Whether or not one agrees with this assessment of moral hazard, see John A. Nyman, *Is “Moral Hazard” Inefficient?: The Policy Implications of a New Theory*, HEALTH AFF., Sept.–Oct. 2004, at 194 (arguing that health insurance shifts dollars to more highly valued future uses), the consumer-directed care movement deserves respect in political terms for having both an innovation and a theory to support it, something little seen in health care since the Nixon administration’s flirtation with health maintenance organizations.

86. For a discussion of the public policy implications of retail clinics, see William M. Sage, *The Wal-Martization of Health Care*, 28 J. LEGAL MED. 503 (2007).

87. Letter from Thomas Jefferson to William Charles Jarvis (Sept. 28, 1820), in X THE WRITINGS OF THOMAS JEFFERSON, 1816–1826, at 161 (Paul Leicester Ford ed., 1899).

transfers through Medicare and Medicaid, tax expenditures arising from non-taxability of employer-sponsored coverage, and tax exemptions for hospitals and other non-profit providers. Even information about medical error and compensation for avoidable patient injury has a social dimension—involving collective insurance against misfortune and the value received for public investment in the health care and legal systems—that complements new (and praiseworthy) relational commitments of physicians to reveal and discuss with patients any unanticipated outcomes of medical care.⁸⁸

D. PUBLIC HEALTH

Public health is a fourth area of current interest in which relational-regulatory balance is important. Traditional public health law focused on protecting society from negative externalities of individual behavior such as transmission of disease through contagion or contamination. As noted previously, public health law represents the paradigm case for a regulatory, collective approach to health policy, but has been marginalized both legally and financially compared with the diagnosis and treatment of individual patients.⁸⁹ From roughly 1950 to 2000, in particular, public health not only was substantially less lucrative for physicians than acute-care medicine, but seemed to have outlived its usefulness (at least domestically) as the great plagues were conquered in rapid succession by sanitary infrastructure, vaccines, and antimicrobial drugs.

This complacency has ended, with globalization, terrorism, and natural disaster resurrecting traditional public health as “biopreparedness” and “biosecurity.”⁹⁰ At the same time, chronic disease has come to dominate our national medical record, imposing huge social costs in dollars and in reduced quality of life.⁹¹ In response, advocates have articulated a “new” public health agenda that attempts to reduce demand for health care services by instilling individual habits of healthy living, disease prevention, and emotional well-being.⁹²

88. See Carol B. Liebman & Chris Stern Hyman, *A Mediation Skills Model To Manage Disclosure of Errors and Adverse Events to Patients*, HEALTH AFF., July–Aug. 2004, at 22; William M. Sage et al., *Bridging the Private-Public Divide: A Pragmatic Information Policy for Medical Malpractice and Patient Safety*, 59 VAND. L. REV. 1263, 1283–84, 1308 (2006).

89. See Arrow, *supra* note 14, at 941 (clarifying immediately for readers that the subject of his economic analysis was medical care and not health).

90. See LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT, at xix (2000) (analyzing legal and ethical tradeoffs between public goods and private rights). These threats, and the AIDS pandemic that preceded them, have also reinvigorated and reshaped public health efforts in the international arena. See Jon Cohen, *The New World of Global Health*, SCIENCE, Jan. 13, 2006, at 162–63 (2006).

91. See Steven A. Schroeder, *We Can Do Better—Improving the Health of the American People*, 357 NEW ENG. J. MED. 1221 (2007) (reviewing the public health crisis in the United States, with an emphasis on risk factors for chronic disease and premature death).

92. See generally LAWRENCE O. GOSTIN & PETER D. JACOBSON, LAW AND THE HEALTH SYSTEM 41–76 (2006) (considering whether public health law should concern itself with issues such as socioeconomic status and the built environment, and whether state intervention can be justified in the absence of market externalities).

These challenges, and the resource needs that accompany them, can best be met by remarrying the public health and health care systems, both in substance and in legal governance. Doing so requires providing a regulatory rationale for issues that are currently seen through a relational lens.⁹³ With respect to controlling obesity, for example, a recent article by Alderman and colleagues laments that “[c]urrent policy and legal analysis are singularly focused on individuals as rational choice makers or on breaking the chain of causation close to the individual and rarely takes [sic] a larger view. Environmental factors and the individual’s social context are not considered.”⁹⁴ Another article in the same symposium identifies five promising areas for collective intervention to reduce individual obesity: the school environment, the built environment, community facilities, the point-of-sale environment, and earmarked taxes and fees.⁹⁵ However, the relational underpinnings of health law do not currently provide a normative roadmap for entering this territory, although some ethicists and legal philosophers have attempted to supply one based on theories of justice and interconnectedness.⁹⁶

Transparency initiatives offer another illustration of how relational approaches tend to crowd out regulatory ones in contemporary public health policy. As noted, the appropriate scope of public health remains a subject for debate. Defenders of the “old” public health argue on ideological grounds that individual liberty should trump paternalism, and emphasize the close historical connection between the narrow role of public health law in fighting communicable disease and essential constitutional limitations on the state’s coercive powers.⁹⁷ Advocates for the “new” public health argue on pragmatic grounds that chronic disease has become a greater risk to individuals than infection, and emphasize that most modern public health measures are noncoercive, with

93. It is worth acknowledging that utopian visions of managed care also included bringing public health together with clinical medicine based on the assumption that population-based “health maintenance” by prepaid health plans serving broad segments of their communities required such an approach. A detailed ethical framework for governing these organizations based on political rather than market or professional accountability was even proposed. See Ezekiel J. Emanuel & Linda L. Emanuel, *Preserving Community in Health Care*, 22 J. HEALTH POL. POL’Y & L. 147, 158–64 (1997).

94. Jess Alderman et al., *Application of Law to the Childhood Obesity Epidemic*, 35 J.L. MED. & ETHICS 90, 91 (2007) (symposium issue on childhood obesity).

95. Marice Ashe et al., *Local Venues for Change: Legal Strategies for Healthy Environments*, 35 J.L. MED. & ETHICS 138, 139 (2007).

96. See, e.g., Leslie P. Francis et al., *How Infectious Disease Got Left Out—And What This Omission Might Have Meant for Bioethics*, 19 BIOETHICS 307, 308 (2005) (speculating on how the historical coincidence of liberal bioethics taking shape at the nadir of concern over infectious disease might have drained bioethics of collective content); Lawrence O. Gostin & Madison Powers, *What Does Social Justice Require for the Public’s Health? Public Health Ethics and Policy Imperatives*, HEALTH AFF., July–Aug. 2006, at 1053, 1059–60 (2006) (urging an interventionist approach to the multiple causes of systematic disadvantage in health).

97. See Richard A. Epstein, *Let the Shoemaker Stick to His Last: A Defense of the “Old” Public Health*, 46 PERSP. BIOLOGY & MED. (SUPP.) S138, S139, S148 (2003).

information their principal example.⁹⁸

An unrecognized problem with this response is its retreat from a regulatory to a relational justification. The fact that a public health intervention—even an individually oriented one such as information provision—physically protects an individual from her own diseases rather than someone else’s does not drain the intervention of collective importance. Transparency and education geared to wellness and prevention of noncommunicable disease honor “public” health in several ways: by promoting community cohesiveness, by boosting economic productivity and increasing aggregate prosperity, by conserving public funds for non-health-care purposes, and by creating a critical mass of voter and consumer demand that can force changes to the built and purchased environment through democratic and market processes. Although these points are sometimes made, public health advocates would do well to stress such collective benefits even for informational and educational programs. Because budgetary politics often dominate health policy, as discussed above, an important specific reform would be to revise government accounting rules and practices to take account of savings outside the health care system generated by investments in the health care system, and to accommodate (with appropriate discount rates and sensitivity analyses) the longer time horizons necessary to realize returns on those investments.

CONCLUSION

It is sometimes said that the plural of anecdote is not data. One might add that the plural of health law seems not to be health policy. This Essay argues that the modern American health care system cannot be governed effectively using legal standards and methods suited to individual physician-patient encounters, regardless of whether those encounters reflect mainly professional or mainly market-place behavior. Instead, health law must develop collective meaning that supports health policymakers’ efforts to expand access, improve quality, and maintain affordability.⁹⁹

As industry and society change, it is not unusual for relational duties that frame individual transactions to be adapted into regulatory duties with collective social importance. One can observe the phenomenon not only in health care, but in corporate governance, environmental regulation, and other areas.¹⁰⁰ But it represents a particular challenge for professions such as medicine that, because of their overall success, have become regulated industries. In these

98. Lawrence O. Gostin & M. Gregg Bloche, *The Politics of Public Health: A Response to Epstein*, 46 *PERSP. BIOLOGY & MED.* (SUPP) S160, S164–65, S172–73 (2003).

99. Collective meaning implies shared sacrifice as well as shared benefit, not merely a right to health care—as the “social paradigm” is often portrayed in contrast to professional or market dominance. See, e.g., Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 *HEALTH MATRIX* 155, 166–75 (2004) (describing a version of health law based on an egalitarian social contract).

100. See, e.g., Donald C. Langevoort, *The Social Construction of Sarbanes-Oxley*, 105 *MICH. L. REV.* 1817 (2007) (explaining the Sarbanes-Oxley Act as mediating between individual investor and collective social risks associated with large public corporations).

settings, it is worth reminding ourselves that collective goals matter, and that a profession can still be valued for its social contribution as well as its technical skill.¹⁰¹

With the future promising far greater technical advances for medicine, but without a way either to temper demand for those resources or to finance them for ordinary citizens, even the United States must eventually transform its individually oriented health care system into a collective one. Gregg Bloche describes the desired process as “a new reciprocity of personal and public commitment.”¹⁰² Physicians can be a positive force in helping to define and achieve these collective goals, but only if they can carry both their scientific skills and their humanitarian commitments beyond the best interests of a specific patient. Faced with evidence of declining physician influence,¹⁰³ commentators are beginning to turn in this direction. Cassel and Brennan call a physician-led regulatory approach managing the commons;¹⁰⁴ Stevens calls it a “new public service ethos.”¹⁰⁵

It may indeed take a public health crisis—pandemic influenza, natural disaster, or bioterrorism—to dislodge health law from its relational roots, but progress without panic is preferable. The health reform debate of 2008 is an opportune moment to frame the legal aspects of health policy in regulatory and not merely relational terms.¹⁰⁶

101. Steven Brint distinguishes “social trustee” professionals from “expert knowledge” professionals, and asserts a historical trend in favor of the latter group, who tend to provide sophisticated services to paying clients. STEVEN BRINT, IN AN AGE OF EXPERTS: THE CHANGING ROLE OF PROFESSIONALS IN POLITICS AND PUBLIC LIFE 7–8 (1994); see also WILLIAM F. MAY, BELEAGUERED RULERS: THE PUBLIC OBLIGATION OF THE PROFESSIONAL 6, 67 (2001) (arguing that all professions have social as well as technical duties, including to teach virtue to their clients within their fields of expertise).

102. M. Gregg Bloche, *Health Care for All?*, 357 NEW ENG. J. MED. 1173, 1175 (2007).

103. See Mark Schlesinger, *A Loss of Faith: The Sources of Reduced Political Legitimacy for the American Medical Profession*, 80 MILBANK Q. 185, 189–90 (2002).

104. Christine K. Cassel & Troyen E. Brennan, *Managing Medical Resources: Return to the Commons?*, 297 JAMA 2518 (2007) (articulating physicians’ duty to attend to collective costs).

105. Rosemary A. Stevens, *Public Roles for the Medical Profession in the United States: Beyond Theories of Decline and Fall*, 79 MILBANK Q. 327, 344–47 (2001) (urging the profession to redefine patients as groups, physicians as teams and organizations, and science as a “positive joint effort of numerous organizations and interests”).

106. See William M. Sage, *Legislating Delivery System Reform: A 30,000-Foot View of the 800-Pound Gorilla*, 26 HEALTH AFF. 1553 (2007) (arguing that health care delivery system reform requires a theory for success, collective meaning, and political champions).