

The Emergent Logic of Health LawM. Gregg Bloche^{*}

With a vengeance, health reform has returned to the top of the national agenda. Fourteen years after the collapse of President Clinton's health reform plan, Americans are again clamoring for relief from soaring costs and telling pollsters and politicians that they want medical care for all. The main difference, this time, is that the problems are much worse. The ranks of the uninsured have risen by about a million a year, to 47 million in 2007.¹ Employment-based coverage is unraveling, and costs continue to climb at more than double the rate of inflation. Most of the care that patients receive is of unproven value, and up to 100,000 Americans die prematurely each year from medical mistakes.²

Are law and lawyers part of the cure? The prevailing view among health care reformers today is that lawyers have little to offer. Sure, statutes need to be drafted, laws must be enforced, and clients need to be told how to comply, but these are technical tasks, requiring little insight or imagination. Lawyers should follow the dots that policymakers draw.³ Within legal academia as well, there is much skepticism about

^{*} Professor of Law, Georgetown University; Non-Resident Senior Fellow, The Brookings Institution; and Adjunct Professor, Bloomberg School of Public Health, Johns Hopkins University. This work was supported in part by a Guggenheim Fellowship and by the Engelberg Center for Health Care Reform at The Brookings Institution. Parts of this paper have been presented at symposia and workshops sponsored by The Brookings Institution, the O'Neill Institute for Health Law at Georgetown University Law Center, the Harvard University Program on Medical Ethics, the Wake Forest University School of Law, and the UCLA School of Law. I thank Henry Aaron, Martha Blaxall, Mark Duggan, Einer Elhauge, Richard Epstein, Michael Gottlieb, Robin Hacke, Mark Hall, Russell Korobkin, William Sage, Ellen Waldman, and Daniel Wikler for their challenges, quibbles, and suggestions.

¹ U.S. Census Bureau, *Income, Poverty, and Health Insurance in the United States: 2006*, Aug. 2007, available at <http://www.census.gov/prod/2007pubs/p60-233.pdf> (accessed Sept. 4, 2007).

² INSTITUTE OF MEDICINE COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 26 (L. Kohn, J. Corrigan, M. Donaldson eds. 2000) (estimating, based on extrapolations from New York, Colorado, and Utah data, that between 44,000 and 98,000 Americans die prematurely from medical errors each year).

³ Christopher Jennings, President Clinton's lead health policy advisor from 1994 through 2000 (and chief health policy advisor to Sen. Hillary Rodham Clinton's 2008 presidential campaign) holds that health care

health law. Such skepticism might seem anomalous, since America is awash in health law. Terabytes of legal text address the provision and financing of medical care, mandating and constraining all manner of activities. But does this vast body of law have a distinctive purpose or mission, or is it merely the sum total of diverse doctrines that happen to apply in the health sphere? To borrow from Frank Easterbrook, who chided “cyberlaw” on these grounds, does it make as little sense to study health care law as it does “the law of the horse?”⁴ Laws govern the sale, theft, and racing of horses, but they don’t thereby constitute a field of inquiry,⁵ let alone reform-minded action. Scholars who devote much of their energy to health law⁶ are made uncomfortable by this question⁷ --

policy is the province of people with expertise in politics, economics, and medicine and public health, not law. Lawyers, he argues, should limit themselves to advising and advocating for their clients – and to implementing and enforcing policies formulated by others with relevant expertise. Interview with Christopher Jennings, March 2007. Lawyers played peripheral roles in developing President Clinton’s health reform plan, numerous participants in that process have told me, and President George W. Bush’s health reform proposals (emphasizing high-deductible health plans and medical savings accounts) were developed by economist Katherine Baicker (a member of the Council of Economic Advisors) and her staff. Interview with Katherine Baicker, July 2006. To be sure, lawyers drafted the legislation that Presidents Clinton and Bush submitted to Congress, but they had minimal roles in formulating the concepts behind it.

⁴ Frank Easterbrook, *Cyberspace and the Law of the Horse*, 1996 UNIV. CHIC. L. FORUM 207.

⁵ This isn’t to say that laws pertaining to horses don’t matter, but it is to suggest that “the law of the horse” isn’t usefully analyzed as a discrete field: “Far better for most students -- better, even, for those who plan to go into the horse trade -- to take courses in property, torts, commercial transactions, and the like Only by putting the law of the horse in the context of broader rules about commercial endeavors could one really understand the law about horses.” *Id.*

⁶ The number of these is difficult to estimate, but a fair measure may be the more than 100 attendees that are typical at the annual “Health Law Professors’ Conference,” sponsored by the American Society of Law, Medicine, & Ethics. See https://www.aslme.org/aslmesecure/info/description.php?conf_id=67 [accessed May 8, 2007] Most of these hold faculty positions at law schools; others teach in schools of medicine and public health.

⁷ The “law of the horse” put-down has provoked a series of responses from leading health law scholars. These include: Mark A. Hall, *The History & Future of Health Care Law: An Essentialist View*, 41 WAKE FOREST L. REV. 347 (2006); Henry T. Greely, *Some Thoughts on Academic Health Law*, 41 WAKE FOREST L. REV. 391 (2006); & Einer R. Elhauge, *Can Health Law Become a Coherent Field of Law?*, 41 WAKE FOREST L. REV. 365 (2006). Earlier, George Annas wondered whether health law could be distinguished from “law and a banana,” George A. Annas, *Health Law at the Turn of the Century: From White Dwarf to Red Giant*, 21 CONN. L. REV. 551, 553 (1989), and Hall -- along with Mary Ann Bobinsky and David Orentlicher -- fretted that health law’s topics were connected by “happenstance,” like “the law of green things or the law of Tuesdays.” MARK A. HALL, MARY ANN BOBINSKY, & DAVID ORENTLICHER, *HEALTH CARE LAW & ETHICS* (6th ed. 2003).

and by the status anxiety it invites.⁸ The question is, of course, rhetorical: the point meant by those who pose it is that the “best” legal thinking stays within bounds -- bounds drawn by established doctrinal category (tort, contract, etc.) or disciplinary method (philosophy, history, or law-and-economics).

The unspoken corollary is that the “best” scholars and practitioners, even on health law topics, are those who combine elite credentials of the classic sort with professional commitment to a legal category or analytic method. Thus, for example, medical malpractice law’s conundrums are best explored by scholars with a rich understanding of tort law theory, or by economists using sophisticated mathematical models and statistical methods. And the legal governance of competition between health care providers is best understood by antitrust lawyers with command of relevant market analysis, rule-of-reason doctrine, and the economics of collusion. A sophisticated grasp of health care systems and medical decision-making is of secondary import, in this view.

⁸ This anxiety is justified by the peculiarities of legal academia’s pecking order. As Henry Greely has pointed out, publications in elite medical and health policy venues like the *New Eng. J. of Med.* and *Health Affairs* don’t count for much when a candidate is being considered for a law faculty position or for tenure. And elite law reviews -- those at schools near the top of the *U.S. News* rankings -- rarely publish articles on health law topics. Since publication in these venues is the principal metric of scholarly accomplishment when hiring and tenure are at issue, would-be health law scholars face a competitive disadvantage. Greely, *supra* note 7. A glimpse at legal academia’s skepticism about health law as a field was recently afforded by litigation (and discovery) that followed the University of Michigan Law School’s denial of tenure to Peter Hammer in 2002. Hammer sued the school (alleging discrimination based on sexual orientation), obtained his tenure file, and posted its contents on a website. A law school committee voted to grant him tenure, but at least one panel member, James J. White, dissented. White won a sufficient percentage of “no” votes from the full faculty to turn down the committee’s recommendation (The faculty voted 18-12 to tenure Hammer; he thus fell two votes short of the two thirds majority that Michigan requires. http://wayneoutlaws.org/hammer_v_umich/background/). In a memo explaining his views, White acknowledged that Hammer “has been recognized by many in the health law field as one of the most prominent students of antitrust law’s application to the health care industry.” But White said this merited “less weight” than the views of antitrust law scholars. Criticizing Hammer (who is both a lawyer and an economist) for having “little contact with law and economic scholars outside of the health care field,” White concluded: “I do not believe that we can rely on the judgment of those in health care about the tenure standards that an elite law school should use....” James J. White, Memo: Separate Views (2002) (Plaintiff’s Exhibit 6 available at http://wayneoutlaws.org/hammer_v_umich/plaintiffs-opposition-to-defendants-motion-for-reconsideration/).

Lawyers can do more for the regulatory governance of medicine, and for law's coherence, by not treating health care as different from other endeavors that law governs.

Health law scholars and practitioners have responded to the "law of the horse" challenge in two ways. Some have argued that medical care provision and financing is indeed different -- so unique and complicated that it calls for an integrated regulatory governance strategy, cutting across doctrinal boundaries.⁹ Others, especially practitioners, have more or less accepted the "law of the horse" problem as an endemic feature of the field. They have eschewed grand theory in favor of practical questions within one or another policy sphere.¹⁰ Health care law matters greatly (and merits respect as a field), they hold, because the subjects it addresses are socially important, and close attention to health care's complexities yields more pertinent insights than does preoccupation with doctrinal categories or disciplinary methods.

⁹ See CLARK HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* (1994) and James Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459 (1994) (calling for reinterpretation of health law's diverse doctrines to support market competition among health plans); Elhauge, *supra* note 7 (urging harmonization of health law doctrines to support a health reform strategy that incorporates market competition, universal coverage, the setting of spending limits via political means, and some deference to physician judgment); William Sage, *Managed Care's Crimea: Medical Necessity, Therapeutic Benefit and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597 (2003) (proposing that health care law be formulated based on "therapeutic jurisprudence" principles); M. Gregg Bloche, *The Invention of Health Law*, 91 CAL. L. REV. 247 (2003) (urging that the task of health law be reconceived as mediation among medical care's competing therapeutic, caring, and other purposes).

¹⁰ See Greely, *supra* note 7 (advising health law scholars not to fret about the absence of an agreed-upon organizing paradigm and to instead get on with the work of analyzing health care law's diverse problems). It is my impression (for which I don't claim proof) that health law scholars with left-of-center politics have been less inclined than have those toward the right to press for recognition of one or another overarching theory -- and more inclined to press for particular legal changes without giving great weight to theory. Sara Rosenbaum, for example, has focused on expanding health care access and bringing civil rights law to bear on racial disparities in care. Sara Rosenbaum & Joel Teitelbaum, *Racial Inequality in Health Care*, in POLICY CHALLENGES IN MODERN HEALTHCARE (D. Mechanic ed. 2005). George Annas has emphasized the safeguarding of patient autonomy and, more recently, the protection of professional discretion from encroachment by powerful, market-driven institutions. E.g. George J. Annas & Frances H. Miller, *The Empire of Death: How Culture and Economics Affect Informed Consent in the U.S., U.K., and Japan*, 20 Am. J.L. & Med. 357, 367-68 (1994). And Alex Capron and Rand Rosenblatt have, in different ways, focused on insulating the physician-patient relationship from market pressures and on resisting the stratification of health care quality based on ability to pay.

There are thus, broadly speaking, three “takes” among lawyers on the field’s prospects and problems. One is rejectionist: “the law of the horse” doesn’t merit separate study. Get the doctrine right, within each *legal* category, and the results will be good, or at least legitimate, for health care and all other endeavors. The second calls upon lawyers to agree on a unifying account of what diverse legal and regulatory schemes should accomplish in the health care sphere. The third tells health lawyers not to fret about theory: get the policy right, case-by-case, by paying heed to law’s practical impact, and don’t worry about coherence in the abstract, either within or across doctrinal realms.

I shall argue herein that health law has enormous potential to ameliorate our nation’s worsening crises of medical care access, cost, and quality, but that none of these approaches can fulfill this promise. Health law rejectionists, I will contend, ignore the urgency of legal coordination. Pursuit of rigor within doctrinal categories and regulatory regimes can create incoherence in the governance of health care provision. Legal tools that are well-designed for some purposes yield dysfunctional results when they work poorly in concert. Proponents of grand theory promise to solve this coordination problem, but basing all of health care law on a single paradigm isn’t possible. The law of health care provision, like medicine itself, pursues diverse and conflicting aims. Organizing the legal governance of medicine around any one theory is bound to neglect some of these aims. Such neglect, I will contend, is incompatible with stable governance. Theory, nevertheless, is indispensable. Too often, health lawyers ignore the big picture, urging solutions to practical problems without heeding the connections between moving parts. Coherence matters, even if it can never be complete, owing to health law’s competing goals.

This will lead me to a sharply different conception of health care law. My central contention is that the law of health care provision, and the health care system itself, are best understood and acted upon as emergent systems.¹¹ This understanding comes to terms with health law's seeming chaos – its emanation from disconnected regulatory and judicial decision-makers, and from myriad, separate doctrinal spheres. As with all emergent systems,¹² these many inputs interact in unpredictable ways, clashing with, reinforcing, and reacting to each other. No one actor is in position to sort out these influences. No one actor takes a grand overview. There is no center of command-and-control. The health care policy this system produces is the sum total of these inputs and of mutual adjustments by stakeholders and decision-makers.

What legal scholars and practitioners who specialize in health care have to offer thus falls short of an ability to influence the law in top-down fashion. Yet their contributions can make a critical difference. By virtue of their disinterestedness,¹³ understanding of clinical practice and health systems, and grasp of relevant fields of law, they are best situated to see how the moving parts fit together. They can glimpse, albeit imperfectly,¹⁴ beyond contiguous interactions between colliding doctrines, rival stakeholders, and decision-makers with overlapping authority. They are thereby able to counsel changes of course that take account of effects throughout the health care system,

¹¹ See *infra* notes 123-126, 129, 131.

¹² See *infra* TAN 128-131.

¹³ They are, of course, not literally disinterested -- they have preferences and passions (and perhaps even clients and consulting arrangements in the health care industry) -- but they are not wholly committed to serving stakeholders' interests, as are legal practitioners, legislative advocates, and hospital and health plan officials.

¹⁴ Scholars of health care law cannot be expected to have fine-grain knowledge of medical practice, the organization and financing of care, or the myriad legal doctrines and regulatory frameworks that govern medical care provision and financing. Competent specialists in each of these areas will have richer "local" knowledge. Health law scholars are akin to general contractors: they should be sufficiently informed to see the connections -- and to tap specialized expertise when it can add substantial value.

while giving weight to legal values such as due process and doctrinal coherence. They can amplify, dampen, or redirect the flow of policy influence through networks of legal and regulatory decision-makers, as well as health care industry actors. Health lawyers, in short, can shape the dynamics of emergence, guiding the law toward accommodations among its many aims.

I shall proceed as follows. Part I will weigh the three, above-described stances toward health care law: rejectionism, the quest for a unifying analytic framework, and pursuit of solutions to practical problems with little regard for either legal coherence or connections between the health system's moving parts. Using examples from diverse doctrinal realms, I will argue that each of these stances ignores critical aspects of health law's role, and that none offer an adequate account of what health law's decision-makers should try to achieve. In Part II, I will make the case for understanding health care law as an emergent system, unguided by any one actor and thus not susceptible to any centrally-imposed paradigm. Health care law's contradictions, I will contend, make sense in bottom-up terms, as the product of competing perspectives and concerns that the law must accommodate. These contradictions give rise to feedback among legal decision-makers, feedback that sculpts health law in self-organizing fashion as these decision-makers react to each other.

In Part III, I will show how an emergent systems perspective can empower health lawyers to play a transformative role. I will argue for a re-imagining of the role of law as an instrument of health reform – a shift from detailed specification and linear pursuit of desired goals to a quest for evolutionary pathways toward greater efficiency, equity, and autonomy. Competing values and stakeholders, not grand designs, drive health law's

evolution. Reform-minded actors must, therefore, become opportunists. They should look for launching points for evolutionary processes – process that leverage current institutions and incentives. Ultimate goals are important, but so are ways of getting there. This article will lay out a strategy for doing so, by harnessing the forces of emergence on behalf of value, fairness, and freedom in the health sphere. To illustrate this strategy, I will offer specific approaches to some of the most urgent questions in health care law.

I. THREE “TAKES” ON HEALTH CARE LAW

There is wide agreement that the law of health care provision, like our medical care delivery system, is in disarray. Commentators who attempt overviews of the field reach this conclusion unflinchingly,¹⁵ each discovering anew that chaos reigns and that the law sends incompatible, often incomprehensible messages to health care payers, providers, and consumers. Astonishingly complicated regulations cover such matters as Medicare “fraud and abuse”¹⁶ and the tax treatment of non-profit hospitals and health plans.¹⁷ Frustratingly convoluted caselaw governs Employee Retirement Income Security Act (ERISA) preemption¹⁸ of state efforts to regulate health plans¹⁹ and expand

¹⁵ E.g. Hall, *supra* note 7; Elhauge, *supra* note 7; Bloche, *Invention, supra* note 9.

¹⁶ Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, (effective Jan. 1992)(Stark I), [60 Fed. Reg. 41,914, \(1995\)](#) (codified at 42 C.F.R. pt. 411); Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, (effective 1995)(Stark II), (66 Fed. Reg. 856) (2001) (“Phase I”), (69 Fed. Reg. 16054) (2004) (“Phase II”), [72 Fed. Reg. 51012-51099 \(2007\)](#). (“Phase III”).

¹⁷ 26 U.S.C.A. § 501. 26 C.F.R. §1.509(a)-3

¹⁸ 29 U.S.C.A. § 1132(a), 29 U.S.C.A. §1144 (2007). Even the U.S. Supreme Court has commented unfavorably on the vagueness and confusion of ERISA preemption law. *See* Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 365 (2002) (“congressional language seems simultaneously to preempt everything and hardly anything”).

¹⁹ Russell Korobkin, *The Failed Jurisprudence of Managed Care, and How to Fix It: Reinterpreting ERISA Preemption*, 51 UCLA L. REV. 457 (2003); Russell Korobkin, *The Battle over Self-Insured Health Plans, or “One Good Loophole Deserves Another”*, 5 YALE J. HEALTH POL’Y L. & ETHICS 89 (2005); *Aetna v. Davila* put the question of employer-sponsored health plans’ liability for coverage denials to rest by holding that ERISA preempts state tort liability. *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004).

medical coverage.²⁰ Further confusion besets health care antitrust law,²¹ medical liability, and other regulatory realms.

Legal scholars bemoan this, since they are lovers of coherence. They ascribe it variously to ignorant legislators, inept agency bureaucrats, clueless judges, and the power of interest groups to shape the law to their liking. Academics who write about health law also get some of the blame. It's become conventional wisdom within hiring and tenure committees at elite law schools that scholarship in this field is poor and that the supply of exciting prospects is thin, by comparison with corporate law, antitrust, and other established subjects.²² Both health law rejectionism and advocacy of a cross-cutting paradigm are responses to the field's disarray. Proponents of case-by-case pragmatism treat this disarray as beside-the-point -- irrelevant to the work of making health care more available, effective, efficient, and fair.

A. Rejectionism: The Case Against Health Law

Easterbrook's "law of the horse" put-down is disingenuous in an obvious way: it works by connotation, not crystalline logic. The problem with horses is that they are

²⁰ Several states, including Massachusetts, California, Connecticut, and Maryland, are considering (or, in Massachusetts' case, implementing) plans that would expand coverage in part by requiring employers to choose between providing it themselves and paying taxes or fees to support state-sponsored coverage. ERISA preemption jeopardizes these efforts. *See Retail Indus. Leaders Ass'n v. Fielder*, 475 F.3d 180 (4th Cir. 2007); *Retail Indus. Leaders Ass'n v. Suffolk County*, 497 F.Supp.2d 403 (E.D.N.Y. 2007) (holding that ERISA pre-empts Maryland's so-called "Walmart" law, requiring firms with 10,000 or more employees to spend 8% or more of their payrolls on medical coverage for their workers). *But see Golden Gate Restaurant Ass'n v. City & Co. of San Francisco*, No. 07-17370 (9th Cir. Jan. 9, 2008) (concluding that such a mandate, imposed by the City of San Francisco's requirement that employers either provide medical coverage or pay into a city-administered fund for this purpose is likely to survive preemption).

²¹ Peter J. Hammer & William H. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 COLUM. L. REV. 545 (2002).

²² The Peter Hammer affair became the occasion for rare public expression of this sentiment (due to the discovery process that followed Hammer's lawsuit against the University of Michigan for denial of tenure). *See supra* note 8. But I have heard it expressed frequently, in private, in conversations about faculty hiring with legal academics ensconced in schools at the north end of the *U.S. News* pecking order.

passé.²³ Other areas of law are no less of a doctrinal and statutory jumble, yet they are widely taught, and some have considerable scholarly cachet. Environmental law is an example.²⁴ It wouldn't have worked as witticism for Easterbrook. It has become a fixture of curricula at almost all law schools -- including the *U.S. News* elite. Articles on environmental matters appear often in the toniest student-edited law reviews (health law articles don't²⁵), and the U.S. Supreme Court regularly hears high-profile environmental cases. As Einer Elhauge points out, even some of the classics of the law school curriculum began as hodgepodes. Torts dates back many centuries, but contract law (as an integrated field) doesn't: it is a *mélange* of once-separate subjects, such as suretyship, admiralty, and the law of sales.²⁶ So a field's being a doctrinal admixture is no bar to its becoming an important focus for scholars and an established part of the curriculum.

Another factor, not the hodgepodge problem, drives health law rejectionism. Legal categories are malleable over time, as the case of contract law illustrates, but the categories that govern at any given moment carry great weight. In all human endeavors, categories frame perceptions and thereby shape decisions. But law's categories are special. Young lawyers are taught to venerate them and to make arguments that treat them as givens. The practice of law is, in large measure, the translation of real-world occurrences into narratives that fit into particular legal categories -- say, elements of a

²³ The "law of the horse" itself isn't quite passé, as my colleague, Michael Seidman, couldn't resist pointing out. Books on the subject include: BRENDA GILLIGAN, *PRACTICAL HORSE LAW: A GUIDE FOR OWNERS AND RIDERS* (2002); JULIE MACKENZIE, *HORSE LAW* (2001); JULIE I. FERSHTMAN, *EQUINE LAW & HORSE SENSE* (1996); DONALD CASSELL AND R. J. F. GORDON, *HORSE AND THE LAW* (1987); C. L. PANNAM, *THE HORSE AND THE LAW* (1986); EDWARD H. GREENE, *LAW AND YOUR HORSE* (1983); JOHN WEATHERILL, *HORSES AND THE LAW* (1979); MURRAY LORING, *YOUR HORSE AND THE LAW* (1975); THEODORE JOHN SOPHIAN, *HORSES AND THE LAW* (1972).

²⁴ One could say equally of environmental law and "the law of the horse" that "property, torts, commercial transactions, and the like," Easterbrook, *supra* note 4, constitute it. Indeed, environmental law is much more of a hodgepodge than is "the law of the horse," since myriad state and federal regulatory regimes contribute to it.

²⁵ See *supra* note 8.

²⁶ Elhauge, *supra* note 7, at 366-367.

cause of action, prerequisites for a binding agreement, or triggers for regulatory intervention. Students, especially in their first year, are assessed and ranked based on their ability to perform these acts of translation with aplomb, on behalf of hypothetical clients or causes. Law's categories anchor this enterprise, and disregard for them won't do.

This conservatism about categories is at the heart of law's morality. It constrains legal decisionmakers' discretion²⁷ and thus limits what lawyers can plausibly argue on their clients' behalf. It is central to what we mean by due process. And its powerful corollary is the importance of interpretive consistency and coherence both within and between legal categories.²⁸ These aren't merely ideals of craft, or further safeguards against arbitrariness; they are answers to a bounded rationality problem. Legal categories invite endless bids for special exceptions, based on claims of unique circumstance. But lawyerly cognition isn't up to the task of fully appreciating the fractal geometry of special circumstances. Legal decision-makers who craft exceptions to rules and categories, especially those that govern complex fields of endeavor, are at high risk for getting things wrong.²⁹ They also risk producing inconsistent results and thereby undermining confidence in rule-of-law values.

Skepticism toward health law reflects this conservatism about categories -- and associated concerns about consistency and coherence. Claims that one or another aspect

²⁷ The extent to which law's categories and procedures constrain discretion is, of course, much disputed -- this large question has been one of the central foci of legal scholarship for the past century.

²⁸ RONALD DWORKIN, *LAW'S EMPIRE* (1986), 219-224

²⁹ The U.S. Supreme Court cited this concern in *Pegram v. Herdrich*, 530 U.S. 211 (2000), as a reason for rejecting a health plan subscriber's bid to construe ERISA to bar some, but not all, financial rewards to physicians for withholding costly treatments. Holding that ERISA's fiduciary duty provisions didn't apply to a health plan's attending physicians, the Court said it lacked the health policy expertise necessary to distinguish between acceptable and troublesome incentives to clinical caregivers to practice frugally and thus would not apply ERISA fiduciary duty principles to the practice of medicine. *Id.* at 213.

of medical care merits distinctive treatment under tort, contract, or antitrust law invite allegations of special pleading and anxiety about departure from the rule of law. The proposition that a unifying paradigm for the legal governance of health care ought to trump interpretive consistency within doctrinal spheres raises an even greater spectre of lawlessness. Health law's low standing among academics is a byproduct of these misgivings.

As environmental law illustrates, such misgivings needn't be decisive: a subject's public import and social cachet can inspire legal decision-makers (and scholars) to shift their professional focus, toward policy coherence across doctrinal categories.³⁰ But health law hasn't yet won such recognition. Courts and regulators have been reluctant to sculpt legal doctrines to accommodate health care's peculiarities. To be sure, there are exceptions. In the late 1990s and early 2000s, judges bent the law of ERISA preemption to permit patients to sue health plans for medical negligence.³¹ Likewise, courts have from time to time applied antitrust law with a wink to let doctors and hospitals collaborate, purportedly on patients' behalf.³² But judges have eschewed explicit

³⁰ This isn't to say that environmental law (or any other "hodgepodge" field) achieves such coherence -- sharp differences over such matters as the role of cost-benefit analysis stand in the way. It is merely to say that pursuit of such coherence across diverse doctrinal spheres and regulatory schemes is a widely-recognized environmental law goal.

³¹ To allow patients to sue HMOs for negligent care by staff physicians, courts characterized HMOs as medical care providers rather than components of employers' fringe benefit plans (ERISA Section 514 preempts state laws that "relate to" fringe benefit plans). Korobkin, *Reinterpreting ERISA Preemption*, *supra* note 19; Bloche, *Invention*, *supra* note 9, at 301. And to circumvent ERISA preemption of actions against employer-provided health plans for negligent refusal to authorize services, some courts characterized health plans' utilization management decisions as medical rather than administrative. *Id.* at 522_. The former characterization has, thus far, survived; the latter was rejected by the U.S. Supreme Court in 2004. *See Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) (holding that ERISA preempts state actions against health plans for negligent denial of medical coverage).

³² *E.g.* California Dental Ass'n v. FTC, 526 U.S. 756 (1999) (upholding professional society's restraints on advertising as procompetitive on the ground that they protected patients against misleading claims). Some market-oriented health law scholars have been sharply critical of courts' willingness to soften their application of antitrust principles when confronted with professional claims that unmitigated competition might harm patients. *E.g.* Clark Havighurst, *Health Care as a (Big) Business: The Antitrust Response*, 26 J. HEALTH POL. POL'Y & L. 939, 949-953 (2001)

reliance on any overarching governance model for health care. Instead, they have typically pursued doctrinal coherence in disparate realms of law, with little regard for the health policy consequences. They have, for example, sustained medical malpractice law's deference to extant clinical practice patterns, impeding efforts to make medical care more evidence-based³³ and cost-sensitive.³⁴ And they have, for the most part, enforced antitrust principles with vigor, in pursuit of a free-market vision for medicine that strains against tort law's more egalitarian approach to specifying the range of allowable clinical alternatives.³⁵

Congress and the federal agencies with authority over medical care financing and provision have shown, if anything, less regard than the courts for the health policy impact of their decisions. The convolutions of Medicare fraud and abuse law, Medicare payment to hospitals and health plans, tax treatment of nonprofit hospitals, and rules governing health information privacy reflect the triumph of interest group power and compromises among competing stakeholders. Additional regulatory convolutions play out at the state level. Constraints on potentially duplicative capital investment by hospitals dampen

³³ A much-publicized RAND Corporation study of clinical decision-making found that just over half of the care Americans receive is "appropriate," when measured against a set of more than 400 evidence-based best-practice standards. Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, NEW ENG. J. MED. 348(26):2635-45(2003). This is hardly a vote of confidence in extant practice patterns -- or in the longstanding medical tort law policy of deference to these patterns whether or not scientific evidence supports them.

³⁴ Extant practice patterns have been forged largely by fee-for-service incentives (which discourage economizing) and by accompanying patient expectations of all possibly beneficial care.

³⁵ The free-market vision allows for multiple levels and standards of care, tied to patients' ability and willingness to pay. HAVIGHURST, HEALTH CARE CHOICES, *supra* note 9. Tort law, by contrast, presumes a unitary standard of care, with only slight downward flexibility when health care providers can show they were operating under resource constraints. Since clinical practice patterns vary widely, John E. Wennberg & Philip G. Peters, Jr., *Unwarranted Variations in the Quality of Health Care: Can The Law Help Medicine Provide A Remedy/Remedies?* 37 Wake Forest L. Rev. 925 (2002); Ctr. for the Evaluative Clinical Sci., *The Dartmouth Atlas of Health Care 1999, The Quality of Medical Care in the United States: A Report on the Medicare Program (1999)*, 9-97, available at <http://www.dartmouthatlas.org/atlas/99Atlas.pdf>, the idea of a unitary standard of care is mythic, but it is an obstacle to formal legal recognition of multiple tiers of care.

competition that antitrust law aims to encourage.³⁶ Statutes requiring health insurers to cover particular services or provider types are products of interest group competition,³⁷ rather than a comprehensive understanding of what medical coverage should include. A comprehensive survey of health care law's crosscurrents and eddies (and contradictory policy messages) is beyond my scope here. But one isn't needed to underscore the point that pursuit of policy coherence across disconnected doctrinal categories and regulatory regimes has not yet become a driving force for health law decision-makers.

Legal academia's rejectionist stance toward health law both reflects and reinforces courts' and regulators' desultory approach to health care policy coherence. An entry-level scholar would be ill-advised, from a careerist point of view, to plunge deeply into health care's institutional and clinical peculiarities.³⁸ Better, or at least safer, to offer a new take on an oft-pondered doctrinal question or to develop an elegant economic model, whether or not its assumptions come close to capturing health care's realities. Even if the model's premises are profoundly mistaken, the professional risks to the modeler are low. That is because only a few scattered scholars of health law and policy are sufficiently knowledgeable and well-positioned to assess the fit between the model's premises and health care's peculiarities and to gain an audience for their criticisms.³⁹ An

³⁶ 36 states require that a hospital obtain a Certificate of Need (CON) in order to commence some capital projects, e.g. construction of a new wing or acquisition of new equipment with costs above some statutory threshold level. [41CJS Hospitals §8 \(2008\)](#). The premise behind CON regulation -- that rivalries among hospitals tend to generate wasteful overcapacity, is at war with the antitrust law premise that competition hones efficiency. Though health law commentators have been making this point for a generation, robust CON regulation and antitrust enforcement persist, side by side.

³⁷ Interest groups at play in this arena, in statehouses across the country, include providers' trade associations and patient advocacy groups (which tend to push for expansion of coverage for particular services) and insurers and employers (which resist new coverage mandates in order to control costs and maintain market flexibility).

³⁸ Such an intellectual immersion is at high risk of yielding work that strikes legal scholars as parochial in its focus and therefore uninteresting.

³⁹ See White, *Separate Views*, *supra* note 8 (asserting that an elite law school should give little weight to the opinions of health law scholars when assessing tenure candidates' work).

early-career scholar can get things fundamentally wrong, from a health policy perspective, while making a stunningly positive impression on leading figures in legal academia who are unfamiliar with health care.

These perverse professional incentives lock in health law rejectionism and reduce legal academia's ability to contribute to the rationalization of health care's regulatory governance. In view of the enormity of our health system's problems, this desultory approach to its governance is a costly indulgence. Mark Hall and Einer Elhauge have argued that health law deserves recognition as a "field" because medical care and its financing are distinctive, even unique, in ways that matter for the application of law.⁴⁰ I would press this further. Fixing America's health care mess is a matter of national urgency, and an integrated approach to the development of health law will be essential to any solution.

The high stakes are familiar but worth underscoring. Continuation of the growth in medical spending that has prevailed over the past several decades⁴¹ will ensure federal

⁴⁰ Both hold that health care's distinctive features are so important to the analysis of legal issues that an industry-wide focus is preferable to treatment of health care as just another application of generic legal doctrines. Hall, *supra* note 7, at 361; Elhauge, *supra* note 7, at 380. Elhauge seeks to differentiate his argument from Hall's by chiding Hall for failing to say *why* medicine's unique features merit treatment of health law as a separate field. *Id.* at 380-381. But Hall does point to particular features that he says *might* merit separate legal treatment: these include the vulnerability of patients, the professional ideals of health care providers, the role of trust and dependency in relations between the two, and medicine's existential stakes. Hall, *supra* note 7, at 358. These features, he says, deserve separate treatment, including departure from generic legal doctrine, to the extent that they matter when law is applied. *Id.* at 361. This is circular reasoning, one might say, but, for Hall, it frames the question of what health law is about: "[I]t [isn't] necessary to agree on what are all the special features of medicine, much less how and why they should matter in particular areas of law. Debating, disagreeing, and figuring this out is what health law scholarship does." *Id.* Elhauge's approach fits within Hall's framework. Elhauge suggests that medical care deserves distinctive legal treatment because it encompasses a unique set of relationships -- among patients, doctors, hospitals, insurers, employers, and the state. Elhauge, *supra* note 7, at 369-370. He notes that other fields, including property and family law, are defined in terms of their governance over distinct sets of relations, *id.* and he proposes to apply a mix of market theory, political authority, professional judgment, and moral thinking about autonomy and equity to the problems that these relations pose. *Id.* at 381-389.

⁴¹ Since 1960, American health care spending has outpaced income growth by an average of 2.7 percentage points per year. Henry J. Aaron, *Budget Prospects and Health Policy*, in BEYOND LEARNED

fiscal catastrophe. To support Medicare and Medicaid at this rate of growth, the percentage of GDP that goes to taxes would need to rise by nearly a third by 2030 and more than half by 2040. By 2050, it would need to nearly double. Failure to keep pace with this schedule of shockingly large tax increases would lock in unsustainable budget deficits.⁴² Absent this Medicare and Medicaid growth, we would face no such nightmare scenario: tax revenues could remain stable, at 18.3 percent of GDP (the average rate in recent decades), without a long-term federal deficit.⁴³ The sustained gap between rates of medical spending increase and growth throughout the rest of the economy also threatens the ability of businesses to compete in world markets while employing Americans. Germany and Canada, our closest health spending rivals, consume little more than half of what we do, per capita, on medical care, and no other country so burdens its business sector with health care costs.⁴⁴ Finally, our national failure to provide medical coverage

HELPLESSNESS: SOLVING AMERICA'S MEDICAL COST CONUNDRUM (G. Bloche & L. Meltzer eds., forthcoming). See also CONGRESSIONAL BUDGET OFFICE, THE LONG-TERM OUTLOOK FOR HEALTH CARE SPENDING (2007) (projecting unsustainable increases in both public and private sector medical spending absent dramatic policy changes).

⁴² Assuming no increase in the percentage of GDP going to taxes, the federal deficit would rise from just over one percent of GDP in 2005 to almost eight percent of GDP in 2030, nearly 12 percent in 2040, and a mind-numbing 16 percent in 2050. *Id.* (citing Congressional Budget Office projections).

⁴³ *Id.* As Aaron notes, neither long-term Social Security obligations nor growth in other entitlement programs are projected to make substantial contributions to the long-term federal deficit. Assuming no cuts in Social Security benefits or increases in Social Security taxes, the projected Social Security shortfall over the next 30 to 40 years is about 2.5 percent of GDP -- hardly trivial, but small compared to the federal government's health care burden. Projected *decreases* (measured in terms of percentage points of GDP) in other parts of the budget will fully compensate for this Social Security shortfall. *Id.* (relying on CBO projections).

⁴⁴ The U.S. is alone in relying so heavily on employers to provide coverage to its non-elderly. Other industrialized countries (except for China, which does not provide universal coverage) spread this expense more broadly, through various public financing schemes. Germany, with its system of employer-supported "Sick Funds," comes the closest to our workplace-based system. See Stephanie Stock et al., *The Influence Of The Labor Market On German Health Care Reforms*, 25 HEALTH AFF. 1143 (2006) (discussing German employers' evolving role in financing that country's "Social Health Insurance" system). But German employers' contributions to "Sick Funds" cover only 46 percent of the cost of care for workers and their families. *Id.* at 1144. Employees pay an additional 54 percent; public funding picks up the rest of the tab. *Id.* By comparison, American employers pay, on average 83 percent of premiums for employee-only coverage and 74 percent of premiums for family coverage. Henry J. Kaiser Family Foundation, *Employer Health Benefits 2006 Annual Survey* at §6 (2006), available at <http://www.kff.org/insurance/7527/sections/ehbs06-sec6-1.cfm>. Employees and their families pay the rest;

to 47 million Americans⁴⁵ isn't merely cruel and indecent; it is a threat to social stability. In the two other industrialized nations that have eschewed universal coverage, the resulting suffering and indignity have fed large-scale civic unrest.⁴⁶ We are hardly at the point of riots in the streets over health care; to the contrary, most Americans report satisfaction with their medical coverage. So far, this has been an obstacle to health care reform: voters are disinclined to give up what they have in order to improve the lot of others. But the growing number of uninsured Americans⁴⁷ could tip the balance suddenly, from complacency toward popular ire.

Should this happen, law will be critical to the crafting of an affordable and effective approach to Americans' health-related hopes and fears. Statutory drafters will

public funding plays no role (unless one counts the tax expenditure represented by the deductibility of employer and employee contributions toward health insurance premiums). In the U.S., employment-based insurance covers 59 percent individuals (workers and their dependents), The Henry J. Kaiser Family Foundation. Employee Health Benefits: 2007 Annual Survey. 11 September 2006. <http://www.kff.org/insurance/7672/index.cfm>; Center on Budget and Policy Priorities. The Number of Uninsured Americans is at an All-Time High. 29 August 2006 <http://www.cbpp.org/8-29-06health.pdf>. 37.7 million workers were uninsured in 2006 because not all businesses offer health benefits, not all workers qualify for coverage and many employees cannot afford their share of the health insurance premium even when coverage is at their fingertips. DeNavas-Walt, C.B. Proctor, and J. Smith. Income, Poverty, and Health Insurance Coverage in the United States: 2006. U.S. Census Bureau., August 2007. <http://www.census.gov/prod/2007pubs/p60-233.pdf>

⁴⁵ See *supra* note 1. Over the past two decades, the ranks of the uninsured have risen by about one million per year.

⁴⁶ The shredding of China's social safety net, including universal access to basic health care regardless of ability to pay, has contributed to widespread disturbances and outbreaks of violence in poor, rural areas. Hannah Beech, *Seeds of Fury*, TIME ASIA, Mar. 13, 2006, at 20; Elaine Kurtenbach, *Health Crisis Plagues Rural Areas of China*, THE SEATTLE TIMES, Mar. 5, 2006, at A16. China is now urgently pursuing strategies for making medical care available to all. William C. Hsiao, *The Political Economy of Chinese Health Reform*, 2 HEALTH ECONOMICS, POLICY & LAW 241, 244-45 (2007). And in apartheid-era South Africa, poor Blacks' lack of access to basic care fueled anger over the indignities and deprivation associated with all-White rule. The American Association for the Advancement of Science and Physicians for Human Rights in Conjunction With The American Nurses Association and the Committee for Health in Southern Africa, *Human Rights and Health: The Legacy of Apartheid* (1998), available at <http://shr.aaas.org/loa/index.htm>. One of Nelson Mandela's highest priorities after becoming president of South Africa in 1994 was the availability of basic medical services to all.

⁴⁷ See *supra* note 45. Rising co-payments, deductibles, and employee contributions toward premiums for employment-based coverage are likely to feed dissatisfaction even among the insured. These costs have not increased substantially as a proportion of total medical spending, but they have risen in relation to employee compensation. Henry J. Kaiser Family Foundation, *Employer Health Benefits 2006 Annual Survey*, *supra* note 44, at §1 & ex. 6.1-6.2.

need to consider how disconnected regulatory schemes work together – and against each other – to frame choices for the health system’s many actors. And the bounded rationality inherent in these drafting efforts will require courts and agencies to fill in the statutory interstices as unanticipated situations arise. To do so without a strategic eye toward the governance of our health system as a whole would be to sow chaos.

The same is true of efforts to gain control of medical costs. Neither public nor private health care spending can be contained in isolation: each influences the other by shaping research investment, product development, standards of care, and patients’ expectations. Cost-control that persists will require trade-offs that Americans can tolerate. This will call for management of tensions between medicine’s therapeutic, caring, and other purposes, as well as mediation of conflicts among health care industry stakeholders.⁴⁸ Striking balances between benefits, risks, and costs in the abstract will not do. As questions arise within the doctrinal and regulatory realms that bear on medical spending, legal decision-makers will need to assess the impact of proposed answers on industry actors’ behavior. They will also need to think strategically about synergies and conflicts between disconnected legal frameworks. Fixation on doctrine and disregard for the health care context will lock in health policy disarray.

This is not to say that health care lawyers and health law decision-makers should eschew doctrinal consistency or other rule-of-law values. To the contrary, these values are a vital part of the health law mix: the health sphere shouldn’t become lawless in pursuit of even the most urgent policy objectives. But it is to say that where plausible interpretations of the law can accommodate important health care policy concerns, legal decision-makers shouldn’t shy away from adopting such interpretations. And it is to say

⁴⁸ Bloche, *Invention*, *supra* note 9, at 302.

that coordination among the doctrinal and regulatory schemes that shape health care policy should be a high priority when legal decision-makers are called upon to make interpretive judgments in the health sphere.

These are hardly radical propositions. Eight years ago, the U.S. Supreme Court did both of these things when it ruled that health plans' financial rewards to physicians for practicing frugally don't violate ERISA's fiduciary duty provision.⁴⁹ Writing for a unanimous Court, Justice Souter acknowledged ERISA's ambiguities, pointed to health plans' need to limit services to stay within budget, and concluded accordingly that the fiduciary requirement should not be read to bar rewards to doctors for rationing care.⁵⁰ Rationing, he wrote, was necessary to control medical spending.⁵¹ Souter also underscored the need to resolve ERISA's ambiguities in a manner consistent with the surrounding health law context.⁵² Construing ERISA to prohibit health plans from rewarding their doctors for saving money would have put ERISA at odds with the *HMO Act of 1973*,⁵³ he said, since such incentives are essential to HMOs' efforts to keep within their budgets. The 1973 Act awarded federal subsidies to HMOs and required

⁴⁹ Pegram v. Herdrich, *supra* note 29. *But see infra* TAN 95-98 (pointing to contradictions between the Court's understanding of health care law in Pegram and in subsequent caselaw).

⁵⁰ *Id.* at 220-21. My own view is that Pegram was unwisely decided: the Justices took no account of the corrosive effect of payments to physicians for withholding care on professional trustworthiness and the doctor-patient relationship. It is indisputable that rationing is inevitable when a health plan undertakes to provide care within a limited budget, but it is hardly the case that *physicians* must play the lead role in doing the necessary rationing. M. Gregg Bloche & Peter D. Jacobson, The Supreme Court and Bedside Rationing, 284 JAMA 2776 (2000). Pegram nevertheless represents an effort to accommodate vital health policy concerns (in this case, the importance of cost containment) and to harmonize the operation of uncoordinated legal and regulatory schemes within the constraints of existing doctrine.

⁵¹ Pegram, *supra* note 29, at 221.

⁵² Two articles by Russell Korobkin, on ERISA's treatment of employment-based health plans' coverage determinations, *The Failed Jurisprudence of Managed Care*, *supra* note 19, and states' efforts to extend coverage to the uninsured, *The Battle over Self-Insured Health Plans*, *supra* note 19, represent, in my view, the finest effort by a legal scholar to resolve ERISA's vagaries in a manner sensitive to both health policy concerns and surrounding legal and regulatory context.

⁵³ Health Maintenance Organization Act of 1973, Pub. L. No. 93-222 (1973) (codified as amended at 42 U.S.C.A. § 300e (2008)).

employment-based health plans to offer an HMO option; this, Souter said, constituted congressional endorsement of HMOs' rewards to doctors for practicing frugally. Souter also cited state law remedies for medical malpractice as reason not to create an ERISA cause of action for improper physician incentives. Such a cause of action, he wrote, would duplicate malpractice law, since proof of substandard care would be necessary to show that improper incentives resulted in harm.

Integration of rule-of-law values with sensitivity to law's impact in the health care sphere is central to the work of health lawyers. So is acceptance that their working conditions are hazardous. Health law practitioners, scholars, and decisionmakers stand on seismically active ground, cleaved by regulatory and common law schemes that strain against each other. Policymakers who are in a position to draft new statutes and regulations would seem to have it better. They can, in theory, formulate rules that take account of both the health system's realities and the surrounding legal environment. But in practice, interest group power and unintended consequences often foil the best of intentions. Later in this article, I will set out a strategy for legal practitioners, scholars, and decisionmakers that takes account of these distinctive challenges.⁵⁴ That the challenges are sufficiently distinctive and urgent to treat health law as both a separate field and a high professional priority cannot, in my view, be seriously contested.

B. "Big Theory": Pursuit of a Unifying Paradigm

If the health law rejectionists are wrong – if the governance of our health care system is in dire need of integrated treatment, as I contend – where should we begin? The way forward, say some, is more and better "big theory" – greater effort by the

⁵⁴ See *infra*, TAN 276 – 281.

brightest minds to develop a unified understanding of what the law of health care provision ought to accomplish. Several unifying models have been urged. One – health law as a scaffold for market competition – ranks well ahead of others in its hold on scholars who aspire toward coherence in health care law. Another, protection for professional authority, often plays the role of straw man in legal scholarship; yet it enjoys considerable support. A third is defense of patient autonomy, and a fourth is public determination (through politically accountable mechanisms) of medical spending priorities. These models are not mutually exclusive; indeed some commentators on health law call for a unified understanding that taps different models for varying governance purposes.⁵⁵ For example, the law could support political (or market) determination of a health plan’s overall budget while deferring to doctors’ clinical judgments within this budget. Such a composite approach could also preserve some space for individual patient choice.

Proponents of each of these several models – and advocates of composite approaches – hold that an overarching conception of health care’s governance should guide the law’s treatment of medicine. They make their cases for why one or another model is best, or why one or another composite is best matched to health law’s variegated governance tasks. But they do not say how we should choose from among them. Hall and Elhauge contend that argument about which is best is an endeavor that health law scholars should undertake with zeal.⁵⁶ But neither they nor others answer the question of how the *makers* of health law – the myriad courts, regulators, and legislators who shape it in piecemeal fashion – ought to settle this argument.

⁵⁵ Hall, *supra* note 7; Elhauge, *supra* note 7.

⁵⁶ *Id.*

To give effect to a unified conception of health care governance, these disconnected decision-makers would have to resolve such arguments in a tightly-coordinated way, within disparate doctrinal and regulatory contexts. Coordination of this sort is unachievable. No single decision-maker has the power to pull all (or even most) of the others into line. No networks, positive feedback loops, or mechanisms of viral spread are capable of the horizontal dissemination necessary to give effect to a single way of doing things. To the contrary, the clashing perspectives of multiple interest groups and levels and branches of government pose an insurmountable obstacle to broad agreement on a single understanding of health care governance.⁵⁷

An even larger obstacle is our irresolution, as individuals and as a society, over the purposes of medicine and, thus, the aims of health policy. It is often said that *the* purpose of medicine is the promotion and restoration of health, yet we could promote health in much more cost-effective fashion by doing more to create educational and economic opportunity. A large body of evidence supports the conclusion that income and wealth,⁵⁸ education, social connectedness,⁵⁹ and the quality of the built environment⁶⁰ are more important than medical care as determinants of health.⁶¹ Some medical services

⁵⁷ See HAYNES JOHNSON & DAVID S. BRODER, *THE SYSTEM: THE AMERICAN WAY OF POLITICS AT THE BREAKING POINT* (1996) (analyzing the collapse of President Clinton's health reform plan as the product of paralytic conflict between interest groups). Conceivably, a crisis of transcendent magnitude – say, an economic cataclysm equal to or worse than the Great Depression of the 1930s – could mobilize Congress and the President to act in the face of interest group power to implement a unified understanding of health care governance as part of a plan for universal coverage and comprehensive health system reform. But the failure of President Franklin Roosevelt's Depression-era plan for universal coverage (a plan opposed by the American Medical Ass'n and other interest groups) underscores the difficulty of doing so.

⁵⁸ Michael G. Marmot, *Understanding Social Inequalities in Health*, 46 PERSPECTIVES IN BIOL. & MED. S9 (2003).

⁵⁹ John T. Cacioppo & Louise C. Hawkley, *Social Isolation & Health, with an Emphasis on Underlying Mechanisms*, 46 PERSPECTIVES IN BIOL. & MED. S39 (2003); Robert J. Sampson, *The Neighborhood Context of Well-Being*, 46 PERSPECTIVES IN BIOL. & MED. S53 (2003).

⁶⁰ *Id.*

⁶¹ Woodrow Wilson International Center for Scholars, *Health Status Disparities in the United States* (April, 2007),

make measurable contributions toward improving health, at reasonable cost,⁶² but many others don't.⁶³ It is easy to read this as proof that we are grossly overspending on medical care,⁶⁴ but this begs the question of why. Self-serving, free-spending doctors may be part of the problem, but why are we so willing to go along? The answer is that we want something else beside utilitarian maximization of health (otherwise we'd bring the wrecking ball to our intensive care units and reallocate this spending to pay for prenatal care or preschool).⁶⁵ We want intangibles like hope (even when it's illusory) and comfort and reassurance. We're willing to pay for plausible explanations of our ailments: some tests that are pure waste from a treatment perspective allay anxiety by helping patients to better understand their circumstances. We want our doctors' uncompromising loyalty at times of need – we appreciate the importance of cost control, but we'd rather that they economize on the other guy. And we cling to the “Saving Private Ryan” perspective on rescue, whatever the cost, as affirmation of every person's moral import and community membership: at dire moments, we believe, doctors should do all they can to save their patients.⁶⁶

http://www.wilsoncenter.org/index.cfm?topic_id=116811&fuseaction=topics.documents&group_id=347153]; see generally RICHARD G WILKINSON, UNHEALTHY SOCIETIES: THE AFFLICTIONS OF INEQUALITY (1996).

⁶² DAVID M. CUTLER, YOUR MONEY OR YOUR LIFE: STRONG MEDICINE FOR AMERICA'S HEALTH CARE SYSTEM (2005) (finding that advances in therapy for heart attacks, depression, and low birth weight have yielded substantial health benefits at reasonable cost).

⁶³ HENRY J. AARON & WILLIAM B. SCHWARTZ, CAN WE SAY NO? THE CHALLENGE OF RATIONING HEALTH CARE (2005) (with Melissa Cox).

⁶⁴ We most certainly are, if health is our sole objective. Research by John Wennberg and his colleagues at Dartmouth Medical School's Center for Evaluative Clinical Sciences strongly suggests that approximately 30 % of American medical spending yields no net health benefits. See, e.g., John E. Wennberg, Elliot S. Fisher, & Jonathan S. Skinner, *Geography & the Debate over Medicare Reform*, HEALTH AFFAIRS, Feb. 13, 2002 (web exclusive) (estimating that 30 % of Medicare spending yields no clinical benefits) [<http://content.healthaffairs.org/cgi/content/full/hlthaff.w2.96v1.pdf>] Accessed July 29, 2007.

⁶⁵ Bloche, *Invention*, *supra* note 9, at 270-282, 299-309.

⁶⁶ *Id.*

We want all these things, but we'd prefer not to pay. We elect politicians who promise tax cuts, and our shopping and dining choices keep the pressure on businesses to skimp on workers' health care. We put the pressure on ourselves (and our doctors) as well, by choosing health plans with an eye toward price, then demanding tests, treatments, and referrals without regard for cost when we are ill and afraid. Some argue that there are right and wrong resolutions to our contradictory expectations of medicine – and of health law and policy.⁶⁷ But even if this is so in the abstract, it is of little help in gaining agreement on the purposes to be served by health law and policy. As a practical matter, our irresolution is sure to persist, abetted by our resistance (as individuals and as a society) to acknowledging the contradictions within ourselves. Ongoing conflict over the aims of health law is therefore inevitable. Agreement on a unitary conception of health care governance – even one composed of a composite of the above-discussed models – is unachievable. The work of health care law, as I will argue later,⁶⁸ must include management of fundamental differences⁶⁹ tied to interest group viewpoints, politics and ideology, and our many cultural and psychological contradictions.

The impossibility of settling on a single conception of health care law is illustrated by the most prominent scholarly effort to purvey one. More than 35 years ago, Clark Havighurst began to challenge the once-prevailing assumption of deference to

⁶⁷ Norman Daniels, for example, holds that the moral purpose of health care is restoration and maintenance of health. NORMAN DANIELS, *JUST HEALTH CARE* (1985). If so, hope, explanation, and affirmation of community solidarity are not grounds for additional medical spending. And Clark Havighurst asserts that once a consumer signs up for a health plan, he or she should be bound by that plan's economizing policies – and that courts have been too willing to defer to sick patients' after-the-fact preferences for pricey care by forcing health plans to pay for services beyond the scope of plans' contractual commitments.

HAVIGHURST, *supra* note 9.

⁶⁸ See *infra*, TAN 240 - 251.

⁶⁹ The fundamental nature of these differences distinguishes health care law from numerous other fields, especially those (antitrust, torts, and contracts, for example) that have become organized, more or less, around the paradigm of economic efficiency.

medical authority over health care resource allocation.⁷⁰ Havighurst urged reliance on markets and criticized laws that allowed physicians to act collectively to fix prices and set standards of care.⁷¹ As the health planning paradigm gained influence in the early 1970s (culminating in legislation creating a national network of politically accountable planning bodies⁷²) he responded with a scathing critique of this strategy’s coercive feature – its requirement that hospitals seeking to offer new services or to make major capital investments obtain a “Certificate of Need” from state regulatory authorities.⁷³

Havighurst also rejected bioethics approaches that emphasized patient autonomy without regard for the need to set limits and to make cost-quality trade-offs. He thought of himself as a “radical,”⁷⁴ and in the early 1970s he was, but he made shrewd use of prestigious and powerful institutions, including the Institute of Medicine and the American Enterprise Institute, to push his views into the mainstream.⁷⁵ Over time, in conjunction with others,⁷⁶ he formulated a comprehensive model of competition in markets for medical care and coverage.⁷⁷ In the tradition of Milton Freedman, he emphasized personal freedom as much as efficiency. Today, his vision of health law as a catalyst for market allocation of clinical resources – driven by consumer preferences and

⁷⁰ Clark Havighurst, *Health Maintenance Organizations and the Market for Health Services*, 35 LAW & CONTEMPORARY PROBLEMS 716 (1971).

⁷¹ See Clark C. Havighurst, amicus brief in *Goldfarb v. Va. State Bar*, 497 F.2d 1 (4th Cir. 1974), *rev’d*, 421 U.S. 773 (1975).

⁷² National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225.

⁷³ Clark C. Havighurst, *Regulation of Health Facilities and Services by “Certificate of Need,”* 59 Virginia Law Review 1143 (1973).

⁷⁴ Clark C. Havighurst, *I’ve Seen Enough: My Life and Times in Health Care Law and Policy*, 14 HEALTH MATRIX 107, 129 (2004).

⁷⁵ Havighurst was also a chief health policy advisor to Ronald Reagan during the 1980 presidential campaign and the early months of Reagan’s presidency.

⁷⁶ Others who played leading roles in development of the market paradigm – and who at times collaborated with Havighurst – include Paul Ellwood (widely-viewed as the father of the HMO concept), Alain Enthoven (who coined the term “Managed Competition”), James Blumstein (an early critic of deference to professional judgment and reliance on political mechanisms to allocate clinical resources), and Richard Epstein (an early advocate of contractual variation in clinical standards of care).

⁷⁷ For his most comprehensive account of this model, see generally Havighurst, *supra* note 9.

specified through contracts among patients, doctors and hospitals, and health care payers – has come close to prevailing among legal scholars who focus on health care organization and financing. Within the upper echelons of the legal academy, it is the main alternative to health law rejectionism.⁷⁸

It has also had enormous real-world impact.⁷⁹ In 1975, the U.S. Supreme Court discarded the “learned professions” exemption from application of the antitrust laws,⁸⁰ opening the way for federal and private actions against anti-competitive practices in health care. Collective price-setting and prohibitions against advertising – once praised by scholars, including a Nobel prize-winning economist, as essential to an anti-commercial ethos that sustained patients’ trust in their doctors⁸¹ – were suddenly illegal. By the end of the 1970s, the health planning paradigm had fallen into wide disfavor, and conservatives were gaining ground in their opposition to regulatory methods of cost-containment.⁸² In 1980, Alain Enthoven’s call for cost control through competition between vertically integrated health systems⁸³ seized policy-makers’ attention. President Reagan’s budget director, David Stockman, lauded the proposal as a “counterrevolution in health care policy.”⁸⁴ Insurers that once passively paid claims for whatever the doctor ordered began to say “no” to pricey, unproven treatments – and to create integrated

⁷⁸ See *supra* note 8 (discussing elite legal academia’s skepticism toward health law).

⁷⁹ What follows is a brief summary of the competition model’s transformative impact on health care law. I am not going so far as to assert that Havighurst’s work alone brought about this impact (the decisiveness of its influence would be exceedingly difficult to assess), but it is beyond question that Havighurst has been the pre-eminent voice for this model among health law scholars.

⁸⁰ *Goldfarb v. Va. State Bar*, 421 U.S. 773 (1975).

⁸¹ Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963).

⁸² In 1979, a Democratic Congress rejected President Jimmy Carter’s proposed national scheme of hospital price controls. Despite considerable evidence that hospital rate regulation constrains private sector health spending, it never again received serious federal consideration.

⁸³ ALAIN ENTHOVEN, *HEALTH PLAN, THE ONLY PRACTICAL SOLUTION TO THE SOARING COST OF MEDICAL CARE* (1980).

⁸⁴ *Id.* (book jacket quotation)

systems like those that Enthoven (and Havighurst) envisioned. Courts empowered insurers to depart from doctors' determinations of "medical necessity" (the almost-universal contractual standard for coverage, then and now) and to decline claims.⁸⁵ Influenced by scholars sharply critical of laws protecting professional prerogative,⁸⁶ judges whittled away at such doctrines as the ban on so-called "corporate practice of medicine," which limited health plans' and hospitals' ability to exercise managerial control over physicians' clinical judgment.

Most importantly, federal courts construed ERISA to pre-empt a wide range of state laws that would otherwise govern employer-sponsored health plans.⁸⁷ This largely deregulated employment-based coverage, since ERISA neither mandates nor restricts employee benefits. Employer-sponsored plans were free to fashion packages of covered services without regard for professional beliefs about appropriate care – or for political action at the state level to set health care priorities.⁸⁸ Plans were, moreover, immune from state medical malpractice suits for denial of coverage. This insulated them further from professional authority, since physician-set standards of care were (and still are) the touchstone of malpractice liability.

A measure of the market model's real-world success is the fact that by 1992, cost-containment through competition between health plans had become the centerpiece of the

⁸⁵ *E.g.* Sarchett v. Blue Shield of California, 43 Cal.3d 1 (1987). To be sure, in Sarchett and other cases courts imposed stringent requirements of good faith and fair dealing. Judges also invoked the standard insurance law principle that ambiguity in coverage contracts must be construed against the insurer and in line with "the reasonable expectations of the insured." But even with these reservations, permitting insurers to say "no" represented a radical step away from blind deference to doctors' determinations of medical necessity.

⁸⁶ Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PENN L. REV. 431 (1988).

⁸⁷ See notes 15-17.

⁸⁸ See *Metropolitan Life Ins. Co. v. Mass.*, 471 U.S. 724 (1985) (construing ERISA's pre-emption provisions to immunize self-insured employer-sponsored plans from state mandatory benefits laws).

Democratic presidential nominee’s proposal for health reform.⁸⁹ Since then, no serious candidate for the presidency has proposed health reform that didn’t rely mainly on markets to cover the uninsured and limit spending.

Yet the market-oriented “counterrevolution” in health care law and policy never fully supplanted competing models. Efforts to shift medical malpractice liability from tort to contract⁹⁰ – and to thereby permit health care payers and providers to offer levels of care that diverged from professional standards – were almost uniformly rejected by the courts. Medical tort litigation remains a contest over whether defendants’ actions measure up to clinical practice norms set by physicians. Even in the antitrust setting, courts have displayed ambivalence about no-holds-barred medical markets. Most notably, a 1999 Supreme Court holding allowed California dentists to band together to set ethical limits on price advertising.⁹¹ The Justices said such limits were “pro-competitive,” and thus permissible under the antitrust laws, because they helped to clarify consumers’ understanding of dentists’ price discounting practices. Market-oriented critics of the professional paradigm chided the Court for turning antitrust principles on their head by characterizing restraints on competition as “pro-competitive.”⁹² The Justices, said Havighurst, had reverted to older thinking about the virtues of professional benevolence as a corrective for flawed markets.

⁸⁹ To be sure, the Clinton plan (both during the 1992 campaign and through the 1993-94 legislative over health reform) also incorporated regulatory measures – *e.g.* national budget ceilings for insured health spending – that the competition strategy’s proponents didn’t like. Enthoven participated in formulating the Clinton plan, then dropped out of the process, disillusioned. Havighurst contributed his views but sharply criticized the Administration’s plan for being too regulatory. Havighurst, *I’ve Seen Enough*, *supra* note 74.

⁹⁰ *E.g.* Richard A. Epstein, *Medical Malpractice: The Case for Contract*, 1976 AM BAR FOUND. RES. J. 87.

⁹¹ *California Dental Ass’n v. FTC*, 526 U.S. 756 (1999). The advertising restrictions at issue required dentists to reveal their standard, pre-discount prices and to otherwise be transparent about the size of claimed discounts.

⁹² Once again, Havighurst led the charge (among scholars, at least). Clark C. Havighurst, *Health Care as a (Big) Business: The Antitrust Response*, 26 J. HEALTH POLITICS, POLICY, & L. 939, 949-953 (2001).

In two, more recent health care opinions, both authored by Justice David Souter (who also wrote the opinion allowing dentists to restrict advertising), the Court showed its ambivalence about markets in a different doctrinal context – ERISA. Both cases involved the balancing of clinical benefits and costs when a physician provides care within a health plan’s budgetary constraints. In *Pegram*,⁹³ decided unanimously in 2000, the Justices embraced the market model wholeheartedly. The Court characterized clinical standards of care in economic terms, as judgments about “acceptable ... risk” and “optimum treatment levels,” to be made by health plans and their physicians in response to market forces.⁹⁴ But two years later, in *Rush Prudential HMO v. Moran*,⁹⁵ the Court opted for the paradigm of deference to medical professionalism. Holding that ERISA does *not* preempt state laws requiring independent physician review of refusals by health plans to pay for tests, treatments, and referrals, a five to four majority characterized such review as akin to a doctor’s “second opinion,” not a legal remedy for contractual breach by a health plan.⁹⁶ This maneuver enabled the majority to rescue state-mandated independent review from the black hole of ERISA preemption (since established jurisprudence holds that ERISA preempts state remedies for coverage denial), but it divorced independent review from health insurance contracts, and thus from the market. Under *Rush Prudential*, medical reviewers are free to make their own clinical judgments – and to thereby require health plans to pay⁹⁷ – without regard for the terms of the deal

⁹³ 530 U.S. at 218-20, 234.

⁹⁴ *Id.* at 221-22. The Court treated ERISA as a statutory framework for such a market, but it allowed that Congress could intervene, if it chose, to set limits on these market-driven “judgments of social value.” *Id.* at 221-22.

⁹⁵ 536 U.S. 355 (2002).

⁹⁶ *See id.* at 381-82 (rejecting characterization of independent medical review as an arbitral remedy for contractual breach).

⁹⁷ Patient who prevail in medical review proceedings can then obtain judicial enforcement of the favorable result by pursuing their federal remedy under ERISA, §1132(a)(1)(B). *Id.* at 385.

struck among employers, health plans, and subscribers. That Justice David Souter wrote both of these opinions, as well as the Court’s 1999 opinion on dentists’ advertising restrictions, underscores the Court’s irresolution when it comes to the market model.

For Havighurst and other market purists, irresolution is probably too polite a term. Havighurst condemns departures from the market paradigm as the product of “authoritarian/collectivist ... leanings,”⁹⁸ and he saves his special ire for those who would allow professional judgment to trump contractual limits on health spending.⁹⁹ But Souter’s irresolution reflects our own, as a nation, about the purposes of health policy and thus the premises of medicine’s legal governance. No legal system can render clarity – certainly not clarity that lasts – out of pervasive conflict over core premises. Full commitment to any one paradigm requires sustained public disregard for passionately-felt concerns that are embodied in others. We are nowhere near to a settled view of the place of market mechanisms, public allocation, and professional judgment in the governance of medicine. We differ sharply – both between and within ourselves – over the relative import of equity, solidarity, rescue, relief of suffering, and the restoration and promotion of health. We differ, also, over the comparative weight we should accord to these purposes and to society’s other concerns – from education and the environment to

⁹⁸ Havighurst, *I’ve Seen Enough*, *supra* note 74, at 110. Havighurst makes me into his example of “persons with authoritarian/collectivist, rather than pluralist, leanings” who oppose allowing “people [to] make consequential choices for themselves.” *Id.* He mischaracterizes my *empirical* account of the limitations of welfare economics as a tool for analyzing choice between health care’s competing purposes: “Bloche,” he says, can’t “imagine ... allow[ing] individuals ... to make the consequential choices” and “is quite comfortable with having non-accountable judges serve as the ultimate arbiters” of health care choice. *Id.* at 110, n. 5 (citing Bloche, *Invention*, *supra* note 9). And he misrepresents my acknowledgement that legal interpretation in the health care context requires normative judgment as a rejection of personal choice in medical matters. *Id.*

⁹⁹ That the “medical necessity” standard for coverage (a staple of almost all health insurance contracts) constitutes *contractual* deference to professional judgment is a possibility Havighurst doesn’t acknowledge.

criminal justice and national security. These differences make agreement on a unifying paradigm for health care law unattainable.

C. Case-by-Case Pragmatism

Proponents of case-by-case pragmatism in health care law treat the quest for a unifying theory of legal governance as beside the point – a distraction from the work of making medical care more efficient, effective, equitable, and otherwise expressive of our values. As Henry Greely puts the point, “the existence or absence of a dominant paradigm has nothing to do with the value of academic health law”¹⁰⁰ or with the quality of health care lawyers’ contributions. Whether one prefers a single paradigm or “a messy, sprawling, and loosely connected field” is a matter of personal style; neither “is right or wrong in the abstract.”¹⁰¹ Rather than fretting about the matter, health lawyers should just get on with it. “There is work to be done.”¹⁰² Most law review articles on health care topics take this tack, as do lawyers’ contributions to the medical and health policy literature. Without reference to overarching theory, or lack thereof, this work addresses particular legal and policy problems, such as medical malpractice, racial disparities in care, and hospitals’ obligations to provide free care to the poor.¹⁰³ It is influenced (overtly or otherwise) by underlying values, but its aim is practical guidance

¹⁰⁰ Greely, *Some Thoughts*, *supra* note 7, at 408.

¹⁰¹ *Id.*

¹⁰² *Id.* at 409.

¹⁰³ Other topics that health law scholarship frequently addresses, in disconnected fashion, include tax treatment of non-profit hospitals, Medicare fraud and abuse, regulation bearing on clinical quality and hospital rates, and myriad bioethics matters.

for courts and regulators,¹⁰⁴ grounded in cross-disciplinary appreciation of the workings of health care and law.¹⁰⁵

This work has made important contributions to the solution of problems in health law. Sara Rosenbaum's quest to bring civil rights law to bear on racial disparities has produced a blueprint for doing so,¹⁰⁶ and put pressure on providers and health plans to take equity more seriously.¹⁰⁷ Jay Katz's call for greater focus on sick people's varying beliefs and fears¹⁰⁸ has sensitized legal commentators, clinical caregivers, and some judges to the pitfalls of allowing informed consent to become a routinized, pro forma process. But these and many other efforts to address particular problems in health law pay too little attention to interactions among the medical care system's moving parts – and to the contradictions and confusion embedded in the messages that health law sends.

¹⁰⁴ They do so at some professional cost (at least for those who sit on law faculties), since editors at elite law journals tend to prefer large, unifying theories and are disinclined toward publishing articles on specialized health law and policy problems.

¹⁰⁵ Outstanding (and diverse) examples of such work include Sara Rosenbaum's vigorous advocacy for use of federal civil rights law as a tool against racial disparities in care (e.g., Sara Rosenbaum & Joel Teitelbaum, *Civil Rights Enforcement in the Modern Health Care System: Reinvigorating the Role of the Federal Government in the Aftermath of Alexander v. Sandoval*, 3 YALE J. HEALTH POL'Y L. & ETHICS 215 (2003)); David Studdert's and Michelle Mello's recommendations for medical malpractice reform (e.g. Michelle Mello et al., *Deterrence of Medical Errors: Theory and Evidence from Malpractice Reform*, 80 Tex. L. Rev. 1595 (2002); David M. Studdert et al., *Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States*, 27 Am. J.L. & Med. 255 (2001)); and Jay Katz's eloquent plea for more emphasis on dialogue between doctor and patient and greater deference to sick people's varying, idiosyncratic preferences (e.g. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* (1984)).

¹⁰⁶ Rosenbaum *supra* note 105. Stepped-up enforcement efforts (by the Department of Health and Human Services Office of Civil Rights) and statutory reform (to establish a private right of action against health care providers based on disparate racial impact, in the wake of *Alexander v. Sandoval*, 532 U.S. 275 (2001), which held that Title VI of the Civil Rights Act provides no such right of action) would be needed to pursue Rosenbaum's blueprint. *But see* Richard Epstein, *Disparities and Discrimination in Health Care Coverage: A Critique of the Institute of Medicine Study*, 48 PERSPECTIVES IN BIOL & MED. S26 (2005) (criticizing covert, mandatory cross-subsidies inherent in civil rights law remedies for racial disparities in medical care).

¹⁰⁷ Hospitals and health plans have been critical of the civil rights approach, preferring to treat racial disparity in care as a quality issue, better addressed by managerial methods that promote best practice for all. Nicole Lurie & Tamara Dubowitz, *Health Disparities and Access to Health*, 297 JAMA 1118, 1121 (2007). But the possibility of civil rights litigation has pushed them to address the disparities question.

¹⁰⁸ Katz, *supra* note 105.

For example, Rosenbaum’s advocacy for robust use of civil rights litigation to combat racial disparities in care disregards the potential impact of such litigation on efforts to improve the quality of medical care. Racial disparity is, at bottom, a quality-of-care matter. At issue are disparities in standards of care and in the compassion and respectfulness with which care is provided.¹⁰⁹ Strategies that bring quality of care (in these several senses) into line with agreed-upon best practice will, in course, ameliorate racial (and other) disparities. Litigation is of doubtful value as a tool for achieving this, as abundant evidence from study of the medical malpractice system shows.¹¹⁰ Litigation prioritizes individual accountability over pursuit of systemic changes that have been shown to promote clinical excellence. These include promulgation of evidence-based practice protocols, candid discussion of clinical errors (with an eye toward “lessons learned”), collection of data on doctors’ and hospitals’ performance, and coordination of care in complex cases (involving multiple specialists).¹¹¹ Malpractice cases commonly turn on the opinions of partisan “experts” rather than science-based standards of practice, putting reduction of legal risk in conflict with pursuit of health care quality.¹¹² Individual

¹⁰⁹ Not all *differences* in care constitute *disparities*. The Institute of Medicine has proposed a useful distinction, between appropriate differences in the care patients receive (arising from differences in clinical circumstances and patient preferences) and inappropriate disparities (tied to race and ethnicity, absent clinical justification). INSTITUTE OF MEDICINE, *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* 125-159 (2003).

¹¹⁰ See INSTITUTE OF MEDICINE, *TO ERR IS HUMAN*, *supra* note 5 (reviewing the large literature on mismatches between the messages sent by the medical tort system and the causes of medical errors).

¹¹¹ See INSTITUTE OF MEDICINE COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* (2001) (urging team-oriented managerial strategies, borrowed from aviation and other industries, for health care quality improvement).

¹¹² The medical tort system, for the most part, continues to labor under the fiction that there is a single standard of appropriate care in each case, to be determined by the trier of fact based on testimony from plaintiffs’ and defendants’ experts. Malpractice law typically accords partisan experts trump status over standards of care developed by academic and clinical leaders, based on scientific evidence. This makes malpractice litigation into something of a roulette wheel, since, doctors’ practice styles vary greatly and often depart from evidence-based standards. See generally DARTMOUTH MEDICAL SCHOOL CENTER FOR THE EVALUATIVE CLINICAL SCIENCES, *THE DARTMOUTH ATLAS OF HEALTH CARE 1998* (1998) (reviewing and analyzing local variations in medical and surgical responses to a broad range of illustrative clinical problems). Thus, at best, the malpractice system offers minimal reward for best, evidence-based practice.

blame, moreover, discourages open discussion of mistakes and of management strategies that might prevent them,¹¹³ since admission of errors can increase liability risk.¹¹⁴ Fear of liability, moreover, discourages collection of data on doctors' and hospitals' performance – data essential to ongoing quality improvement. And pursuit of culpable individuals diverts attention from opportunities to improve quality by better coordinating care and otherwise promoting team effort.

This is hardly to say that civil rights law has no place in efforts to reduce health care disparities. Nor is it to deny the moral force of the argument that racial injustice must be named and blamed,¹¹⁵ even when it results from institutional insensitivities, rather than intentional design.¹¹⁶ But it is to caution that individual culpability operates upon health care systems in paradoxical fashion, creating incentives that put quality improvement – and thus amelioration of racial disparity – at risk. Management of this risk requires attention to medical care's moving parts – and to the mix of messages that the prospect of liability sends.

At worst, the system encourages doctors to depart from best practice when doing so might protect them from plaintiffs' experts. See, e.g., Kirwood K. Shy, et al., *Effects of electronic fetal-heart-rate monitoring, as compared with periodic auscultation, on the neurologic development of premature infants*. 322 NEW ENG. J. MED. 229 (1990) (noting that scientific evidence does not support routine electronic perinatal fetal monitoring, although medical malpractice verdicts have often penalized its non-use).

¹¹³ A substantial literature documents the risk-reducing value of open discussion and rigorous analysis of the causes of error. See, e.g., Ellison C. Pierce, *The 34th Rovenstine Lecture: 40 years behind the mask: Safety Revised*. 84 ANESTHIOLOGY 965-75 (1996) (discussing anesthesiologists' success at reducing risk by identifying mistake-prone parts of the anesthesia process).

¹¹⁴ Immunizing discussion of possible errors from discovery – or from admissibility – in litigation does not fully address this problem, since potential plaintiffs can use information from such discussion to pursue other evidence of alleged clinical errors (e.g. by deposing participants in such discussions).

¹¹⁵ See RICHARD DELGADO & JEAN STEFANCIC, *CRITICAL RACE THEORY* 16-22 (NYU Press 2001) (arguing for the importance of identifying and addressing the racism deeply embedded in our institutions, social structures, and thought processes).

¹¹⁶ See M. Gregg Bloche, *Race and Discretion in American Medicine*, 1 YALE J. HEALTH POL., L., & ETHICS 95 (2001) (analyzing racial disparities in health care as the product of interaction between clinical uncertainty, institutional and economic incentives, bias and stereotypes, and historical discrimination).

Similarly, calls by Jay Katz and others for informed consent law to take richer account of individuals' beliefs, hopes, and fears¹¹⁷ disregard competing health law and policy goals, including cost control and distributive fairness. Empowering patients to assert their subjective preferences puts pressure on doctors to accommodate them – this, of course, is the point of such empowerment. But to the degree that doctors accommodate by prescribing pricier, more intensive treatments to some, medical spending will rise, and health insurance will spread this burden to all of us.

To be sure, “medical necessity” clauses in insurance contracts constrain physicians' ability to accommodate patients subjective preferences. Care that lies at the margins of accepted clinical practice risks going uncovered. On the other hand, health insurance law (which itself embodies tension between support for cost control and for patients' and doctors' clinical freedom) makes it risky for insurers to say “no” to such care.¹¹⁸ Insurance law allows ample room for patients and their doctors to demand such care, pushing costs upward, if they are encouraged to do so by changes to informed consent law.

The changes that Katz and others urge would, moreover, turn informed consent law into an instrument of inequity – and of racial, ethnic, and gender disparity, to the extent that patients' preferences (and willingness to pursue them) vary with group

¹¹⁷ Current informed consent doctrine, as Katz points out, *supra* note 105, makes little space for individual patients' varying preferences. In most states, physicians need only tell patients about risks and benefits that a “reasonable physician” would deem material to a patient's decision (the “reasonable physician” standard, moreover, is typically applied by reference to prevailing professional approaches to disclosure). In other jurisdictions, doctors must disclose those risks and benefits that a “reasonable patient” would deem material; this rule is no more friendly to individual differences in patients' beliefs, hopes, and fears.

¹¹⁸ Constraints on nay-saying by insurers include the availability of independent medical review, in cases of coverage denial, in at least 40 states, *see* *Rush Prudential HMO v. Moran*, *supra* note 95, and rules of insurance contract interpretation (*e.g.* the principle that ambiguous contract language must be construed based on “the reasonable expectations of the insured”) that favor insureds.

membership.¹¹⁹ Tying clinical practice more closely to sick people's subjective preferences would empower the self-assertive to obtain costly, "boutique" care at the insurance pool's expense – care not typically provided to the more retiring among us.¹²⁰ Not only could this widen disparities in care; it would make health insurance into a mechanism for cross-subsidies from the diffident to the demanding.¹²¹

Neither Katz nor other proponents of greater legal deference to patients' individualized preferences acknowledge, let alone address these conflicts among autonomy, control of costs, and distributive fairness. Empowering patients to express their hopes and fears is a deeply appealing idea. But health care law serves other purposes, at odds with maximum responsiveness to sick people's personalized preferences. Focus on informed consent – without regard for these other purposes or for the legal doctrines that pursue them – contributes to health law's confusion.

"There is work to be done," as Greely says, and health care law is indeed a "messy, sprawling" field.¹²² But this work includes the accommodation of health law's cacophony of aims, and the management of conflict among its myriad legal doctrines and regulatory regimes. No single paradigm can neatly accomplish this. Yet disregarding this challenge would guarantee chaos in the governance of our medical system. Law's

¹¹⁹ There is some evidence that male patients are more assertive than women in their care-seeking behavior and that Whites, as a group, are similarly more assertive than African-Americans. INSTITUTE OF MEDICINE COMMITTEE ON UNDERSTANDING AND ELIMINATING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE, UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE, 131-135 (2003),.

¹²⁰ Magnetic resonance imaging (MRI), which typically costs in excess of \$800, is an illustration. Should savvy and assertive patients be referred for MRIs to rule out exceedingly unlikely illnesses, simply because these patients verbalize their anxieties (and make demands of their doctors) with less reserve than do others? Turning informed consent law into a cudgel against doctors who resist such entreaties would further empower the most privileged patients and thus widen socio-economic and racial disparities in medical care.

¹²¹ Since, within any given insurance plan, all pay the same premium, more demanding patients would enjoy subsidies from those in the same clinical circumstances who ask for less.

¹²² Greely, TAN 98-99.

contribution to creating a more cost-effective, caring, and just health system will turn in large measure on how courts, regulators, and other legal decision-makers pursue this task.

II. HEALTH CARE LAW AS AN EMERGENT SYSTEM

Can health care law rise to this challenge? No single legal actor can answer this question. No homunculus can command health law's fragmented decision-makers to adopt one or another way of doing things. The law of medical care provision and financing functions as an emergent system. It arises from myriad "deciders" – and from the interactions between them and the health care system's disconnected participants. Like other emergent systems, biological¹²³ and social,¹²⁴ the legal governance of health care exhibits an intelligence (often perverse¹²⁵) that materializes from below.¹²⁶ Efforts to influence this intelligence for the better must take account of its emergence from interactions among innumerable actors, each with different, "local"¹²⁷ perceptions and motives. In this section and the next, I shall propose a strategy for doing so – a strategy that breaks sharply with the counsel that commentators on health law have, so far, offered legal decision-makers.

¹²³ See, e.g., GERALD R. EDELMAN, *BRIGHT AIR, BRILLIANT FIRE: ON THE MATTER OF MIND* (1992) (analyzing intelligence and consciousness as the emergent product of neural networks); EDWARD O. WILSON & BERT HOLDOBLER, *THE ANTS* (1990) (analyzing the complex social organization of ants (and other insects) as the emergent product of simple biochemical signals exchanged among individual ants).

¹²⁴ See, e.g., THOMAS SCHELLING, *MICROMOTIVES AND MACROBEHAVIOR* (1998) (considering the connections between individual incentives and patterns of social behavior).

¹²⁵ The logic of emergent systems is often perverse (from the perspective of the aims we seek): common examples include the development and spread of cancer, epidemics, war, and economic bubbles and busts. E.g. ROBERT J. SHILLER, *IRRATIONAL EXUBERANCE* (2001) (tracing breakdowns in market valuation that arise from interactions among individuals' self-deceptions and mis-perceptions).

¹²⁶ See generally JOHN HENRY HOLLAND, *FROM CHAOS TO ORDER* (1998); STUART KAUFFMAN, *AT HOME IN THE UNIVERSE: THE SEARCH FOR THE LAWS OF SELF-ORGANIZATION AND COMPLEXITY* (1995) (offering accounts of how order in complex systems emerges from innumerable interactions among simpler elements).

¹²⁷ By "local" here, I refer not to geography (although physical location is a factor in shaping perceptions and motives), but to the different roles and place of each actor in the functioning of the overall system.

A. Beyond the Myth of the “Decider”

Commentary on health care law (and other legal fields) typically presumes the existence of key decision-makers – and their top-down authority over the law within their domains. More often than not, in most fields of law, this presumption is a close-enough approximation to reality. The U.S. Supreme Court holds sway over federal constitutional law, and a variety of federal agencies set the rules within their regulatory realms,¹²⁸ subject to judicial review and Congressional oversight. Health care law doesn’t function this way. No single authority sets the rules, or is in position to implement the proposals and paradigms urged by commentators. Health law is the product of many, scattered deciders who act not in concert but in interdependent fashion. It exhibits the properties of an emergent system – a system with a design that arises from ongoing feedback among these scattered deciders. Its design – its intelligence – transcends these deciders. Indeed, it is a common feature of emergent systems that their component elements do their part absent awareness of their places in the larger scheme.

Ants, for example, “decide” to forage or to fight, or to follow paths and to ferry food from distant places, based on pheromone levels they detect. They neither take orders from superiors nor grasp their larger mission on the colony’s behalf.¹²⁹ Researchers have shown this, by exposing individual ants to different mixes of pheromones in laboratory settings. The ants then forage or follow as they would in the wild, behavior that seems perversely out of context beneath the laboratory’s bright lights.

¹²⁸ Standard examples (of agencies that function as the principal authorities within their realms of law and policy) include the Securities and Exchange Commission, the Internal Revenue Service, and the Environmental Protection Agency.

¹²⁹ Eric Bonabeau and Guy Thiraulaz, *Swarm Smarts*, SCIENTIFIC AMERICAN, March 2000, p. 73.

Our neurons, similarly, sum up the electric signals they receive, then fire to activate or suppress follow-on cells that participate in networks tied to perceiving, understanding, and acting upon the world.¹³⁰ Neurons have no “sense” of their larger, networking mission. They simply follow the laws of chemistry and physics; the logic of our thoughts and behavior emerges from this.

The designs of cities, societies and economies likewise emerge from the motives and actions of individuals who think they know what they are doing, but who are mostly unaware of their roles in fashioning and sustaining neighborhoods, subcultures, industries, or the other social forms that organize our collective lives.¹³¹ We are, of course, different from ants and neurons – we’re more flexible (since our neural networks evolve in response to events), hierarchical, and, up to a point, self-aware. But what we have in common with our remote, six-legged relatives is that the intelligence of our social forms transcends our sense, while in the fray, of our motives, judgments, and actions.

B. The Emergent Logic of Health Care Law

The logic of health law is similarly emergent, for better and worse. Take, for example, the tension between malpractice law’s reliance upon professional standards of care and the proposition that markets should permit consumers to pick from among different levels of care, an idea embedded in antitrust doctrine and, to some degree, judicial interpretation of health insurance contracts. Commentators on health law treat this tension as a failure of coherence. Market-oriented commentators complain that liability for breach of professional standards prevents health plans and providers from

¹³⁰ EDELMAN, *supra* note 123.

¹³¹ PAUL KRUGMAN, *THE SELF-ORGANIZING ECONOMY* (1996).

offering lower-cost care and coverage options.¹³² Liberals who object to tying medical care to ability to pay defend professional standards as a floor below which levels of care should not fall.¹³³

Looking at health law as an emergent system yields a different understanding – one that treats this apparent incoherence as a channel for feedback among scattered deciders with differing perspectives. A deeply-felt commitment to health equity, and to the ideal of life’s pricelessness,¹³⁴ animates tort law’s deference to professional standards of care, as does sick people’s yearning to trust their doctors.¹³⁵ Were the law to utterly abandon its reliance on professional standards, it would detach itself from these concerns. This would undermine people’s confidence in law’s responsiveness to their hopes and fears. Yet life is not priceless, resources are scarce, and Americans revere the market as the most efficient, least authoritarian way to manage scarcity. Antitrust and other doctrines that promote consumer choice in health care express this. The legal regimes that govern medical malpractice and restraints on competition thus embody different suites of concerns,¹³⁶ to which Americans are inextricably committed. From an emergent systems perspective, this isn’t a contradiction; it’s an opportunity for mutual feedback among component systems that constitute health law. Antitrust lawyers who take

¹³² E.g. HAVIGHURST, HEALTH CARE CHOICES, *supra* note 9.

¹³³ See, e.g., Sara Rosenbaum, David M. Frankford, et al., *Who Should Determine When Health Care is Medically Necessary?*, 340 NEW ENG. J. MED. 229 (1999) (urging reliance on professional standards to determine levels of care and health insurance coverage).

¹³⁴ See GUIDO CALABRESI & PHILLIP BOBBITT, TRAGIC CHOICES 135 (1978) (reflecting on tension between the ideal that life is priceless and the reality that we put lives at risk for economic gain).

¹³⁵ Mark Hall has perceptively observed that people’s trust for their doctors increases with severity of illness – and accompanying anxiety and fear. Trust deepens out of proportion to trustworthiness as patients become more needy, Hall cautions. Mark Hall, *Law, Medicine, and Trust*, 55 STANFORD L. REV. 463, 507 (2002).

¹³⁶ I have oversimplified my depictions of these sets of concerns – the thinking behind both (that is, consumer choice approaches and policies that put greater emphasis on equity and/or reliance on professional norms) is more nuanced and variegated. But my oversimplification will serve to support the larger point I am making here, about the role of these suites of concern in health law’s emergence.

Havighurst's combative stance toward professional standards can stay true to their convictions, as can egalitarians who see health care allocation based on ability to pay as anathema. Both sides think they know what they're doing – campaigning to make health law more consistent (and to get it “right”) by cleansing it of the pernicious influence of the opposing view. Both sides, meanwhile, participate in a larger process of which they may be only dimly aware – a process of feedback between legal schemes that sometimes sustains existing arrangements and that at other times pushes health care governance hard in one direction or another,¹³⁷ as scattered deciders take account of developments in neighboring suites of law.

There are many other examples of such feedback schemes in health care law. Some involve classic tensions in American public life, between national and local governance (the struggle over ERISA pre-emption of state efforts to expand coverage is a case in point¹³⁸), equity and autonomy (the debate over the extent to which informed consent law should accommodate individuals' varied preferences¹³⁹ is illustrative), and public versus personal responsibility for finding shelter against life's vicissitudes (the central theme of recurring battles over the scope of Medicaid, SCHIP, and other health insurance initiatives for the disadvantaged). Others are more specific to medicine – e.g.

¹³⁷ Since the late 1970s, health care law has shifted dramatically toward the market model, albeit not as wholeheartedly as some market enthusiasts would have preferred. *See* TAN 76-96.

¹³⁸ *See, e.g.,* Retail Industry Leaders Ass'n v. Fielder, 475 F3d 180 (4th Cir. 2007) (holding that ERISA pre-empts Maryland's so-called “Walmart” law, requiring firms with 10,000 or more employees to spend 8 % or more of their payrolls on medical coverage for their workers). Efforts by multiple states, most notably Massachusetts and California, to expand coverage by requiring employers to contribute more toward medical costs, will likely lead to reprises of this struggle in the months and years ahead.

¹³⁹ TAN 114-117.

different views on the role of science versus clinical intuition in shaping medical practice.¹⁴⁰

Some feedback mechanisms drive health systems change through public impression as much as law. During the late 1990s and early 2000s, the managed care industry successfully fought off class action suits and Congressional proposals (so-called “Patients’ Bills of Rights”) to hold it accountable for refusing to cover physician-prescribed care.¹⁴¹ But press coverage of lawsuits and legislative hearings made managed care horror stories into the stuff of kitchen-table conversation. Consumers left highly-restrictive health plans, or pressed their employers to do so, and investors turned bearish toward the industry, motivated by consumer backlash and perceived legal risk. Health plans responded by abandoning the very practices (such as frequent coverage denials and monetary rewards to doctors for withholding care) they had fought in Congress and the courts to defend.¹⁴² The industry prevailed in the legal arena, but the struggle carried a cost, imposed upon health plans by unhappy customers and investors.

Such feedback schemes enable the expression of values and concerns that are at odds with each other but deeply-felt, to the point that health law cannot realistically discard them. Legal and regulatory actions that offend these values inspire responses – from the losing parties and from legal decision-makers with different perspectives. Decision-makers charged with implementing different legal regimes – tort and contract,

¹⁴⁰ Although the Daubert principle, requiring that expert testimony on scientific and technical matters have a scientific basis (*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)), has been applied by state as well as federal courts in many legal contexts, it has not generally been applied to *medical* testimony concerning appropriate treatment in malpractice and insurance coverage cases. Courts’ peculiar reluctance to extend Daubert to these contexts probably reflects their regard for physicians’ clinical judgment – the proverbial “art of medicine” – when supporting scientific evidence is lacking.

¹⁴¹ M. Gregg Bloche and David M. Studdert, *A Quiet Revolution: Law as an Agent of Health Systems Change*, 23(2) HEALTH AFFAIRS 29 (2004).

¹⁴² *Id.*

ERISA, antitrust, and many others – send negative or positive feedback signals through their responses. Refusal by state judges, for example, to endorse contractual departure from professional standards of care in medical malpractice cases sends a dampening message to antitrust and other decision-makers eager to advance the market model in the medical realm. On the other hand, state courts’ growing willingness since the 1970s to permit insurers to deny coverage for physician-prescribed services on contractual grounds¹⁴³ signals that their support for professional authority has diminished.

The Supreme Court’s refusal to give full effect to the market model even in the antitrust context – e.g. the Justices’ acceptance of professional restrictions on price advertising¹⁴⁴ – may reflect its summing of these and other mixed signals, from many decision-makers, about the comparative desirability of untrammelled competition and deference to professional norms. Justice Souter’s confusion about the sweep of markets – his characterization of clinical standards of care as the product of market-driven cost-benefit trade-offs in *Pegram*, followed by his portrayal of medical standards as a matter of professional opinion, not contract, in *Rush Prudential*¹⁴⁵ – may merit scorn as lawyerly craftsmanship. But it is a sign of the Court’s role as a processor of mixed messages about the role of markets and professionalism in health care governance. The Justices participate in overlapping networks of feedback involving health law’s myriad decision-makers.¹⁴⁶ In response to the varied signals the Justices receive, they invoke competing models of medical governance, all of which have some legal force. So it is hardly

¹⁴³ See TAN 82.

¹⁴⁴ See TAN 88-89.

¹⁴⁵ See TAN 90-95.

¹⁴⁶ The Court is, to be sure, an outsized participant: its “signal” to these networks is decisive on federal law matters plainly covered by its precedents, and it is “loud,” due to its audibility, even on matters outside this scope. Yet the network metaphor still holds: by analogy to strategically-placed cells in neural networks, the Justices have much influence, but they exercise it through constrained channels, in response to other decision-makers.

surprising that the Court sends messages that don't cohere: consistency would require the Justices to discard large parts of health law, embodying values and concerns Americans are unwilling to abandon.

Within the networks of decision-making that constitute health care law, negative feedback tends to support the status quo, and positive feedback tends to promote change. Novel judicial, regulatory, and legislative gambits typically provoke suppressive responses,¹⁴⁷ but they sometimes catch fire, propagating to broader networks of decision-makers. The law's embrace of the market paradigm is the highest-profile case. Isolated initiatives in the 1970s – the Supreme Court's abandonment of the “learned professions” exemption from antitrust law¹⁴⁸ and Congressional passage of a law promoting HMOs¹⁴⁹ – triggered positive responses, probably potentiated by rising skepticism toward professional authority. Other decision-makers picked up, then amplified the signal. The Federal Trade Commission began antitrust enforcement against health care providers, state regulators backed away from limitations on hospitals' capital investment, and courts, as mentioned earlier, allowed insurers to decline coverage for physician-prescribed care.

Preceding and parallel developments in “neighboring” legal spaces widened the possibilities for propagation. Those who urged more robust informed consent

¹⁴⁷ An example is the effort by some state and federal judges, beginning in the late 1990s, to chart a path around ERISA pre-emption of managed care liability for negligent coverage denial. Bloche, *Invention*, *supra* note 9, at 301. To avert ERISA Section 514's pre-emption of state laws that “relate to” employment-based health plans, they sought to characterize health plans' coverage determinations as *medical* judgments (beyond Section 514's pre-emptive reach, based on established precedent) rather than plan administration (clearly within ERISA's pre-emptive shield). *Id.* Variants of this approach caught on in some jurisdictions, including several federal circuits, but the Supreme Court squelched the strategy in 2004, in *Aetna v. Davila*, *supra* note 19, holding broadly that ERISA's pre-emption provisions preclude such liability.

¹⁴⁸ *Goldfarb v. Virginia State Bar*, *supra* note 80.

¹⁴⁹ HMO Act of 1973, 42 U.S.C. § 300e (offering grants and loans to qualifying HMOs, exempting qualified HMOs from restrictive state regulation, and requiring employers with 25 or more employees to offer their workers an HMO alternative to conventional fee-for-service insurance).

requirements during the 1960s and 1970s didn't mean to promote medical markets,¹⁵⁰ but by winning broader legal recognition for patient autonomy, they primed courts', regulators', and the public's receptivity to the competition paradigm. And for the Congress that enacted ERISA in 1974, in response to pension fund scandals that shattered American workers' confidence, the potential implications for health insurance were an afterthought. But by pre-empting most state regulation of fringe benefits (and substituting no minimum requirements of its own), ERISA largely deregulated the market for medical coverage.

Out of many interwoven networks of deciders, health care law emerges. This self-organizing process hardly guarantees a governance system that serves us well; by way of analogy, emergence in biological systems generates tumors, seizures, and other phenomena that careen out of control when the feedback mechanisms that maintain homeostasis fail. America's worsening crises of cost and access, clinical mistakes that kill tens of thousands of patients per year, and the proliferation of treatments absent proof of their value strongly suggest that, in health care law, much has gone awry. How to intervene to make health law part of the solution is a question that calls for attention to the logic of emergence.

III. TOWARD AN EMERGENT AGENDA FOR HEALTH CARE LAW

Commentators on health care law and policy urge courts, legislators, and sundry regulators to pursue elegantly-designed approaches, rooted in one or another governance paradigm. Rarely does this advice get taken. Instead, health law decision-makers

¹⁵⁰ See M. Gregg Bloche, *Medical Ethics in the Courts*, in *ETHICAL DIMENSIONS OF HEALTH POLICY* 133, 135-140 (M Danis, C. Clancy, & L. Churchill eds. 2002) (considering the emergence of patient autonomy as a value in bioethics commentary and legal doctrine during the 1960s and 1970s).

continue to churn out a hodgepodge of disconnected doctrines and policies. Academic disdain for this incoherence makes for edgy teaching and witty commentary,¹⁵¹ but it has done little to change health law. If the health law commentariat is to become more than marginally relevant, it will need to radically shift its focus, toward opportunities for shaping the dynamics of emergence. From an emergent systems perspective, health law's contradictions express competing, deeply-felt values and concerns that feed back upon each other. If health law is to maintain its democratic legitimacy, these discordant values and concerns cannot be abandoned. Thus the challenge for health lawyers is not to efface the field's contradictions. It is to glimpse or intuit the flow of influence through networks of scattered deciders, with an eye toward chances to amplify, dampen, or redirect the flow – and with a readiness to seize moments as they arise.

The most effective democratic leaders – and the greatest lawyers – have preternatural understandings of their potential avenues of influence.¹⁵² In the field of health care reform, such understanding has been in short supply. With disastrous results, the Clinton Administration crafted an unwieldy reform scheme that took little account of likely sources of resistance.¹⁵³ After the Clinton plan's collapse, many observers wrote off the possibility of substantial reform, concluding that interest group opposition stands immovably in the way. This pessimism is misplaced. Opportunities for transformation

¹⁵¹ David Hyman is, by far, the most engaging – and entertaining – on this theme (in my view). *See, e.g.,* DAVID HYMAN, *MEDICARE MEETS MEPHISTOPHELES* (2006).

¹⁵² President Franklin Roosevelt, a law school drop-out, intuited open and closed pathways with famous aplomb as he maneuvered through political and legal obstacles to his economic reform strategies, then to the waging of war. *See generally* DAVID M KENNEDY, *FREEDOM FROM FEAR: THE AMERICAN PEOPLE IN DEPRESSION AND WAR, 1929-1945* (2005). Legendary examples of lawyers with this gift include Thurman Arnold (SPENCER WEBER WALLER, *THURMAN ARNOLD: A BIOGRAPHY* (2005)), Thurgood Marshall (JUAN WILLIAMS, *THURGOOD MARSHALL: AMERICAN REVOLUTIONARY* (2000)), and Clark Clifford (DOUGLAS FRANTZ & DAVID MCKEAN, *FRIENDS IN HIGH PLACES: THE RISE AND FALL OF CLARK CLIFFORD* (1995)).

¹⁵³ THEDA SKOCPOL, *BOOMERANG: HEALTH CARE REFORM AND THE TURN AGAINST GOVERNMENT* 48-73 (1996).

abound. But they require attention to the dynamics of health law's emergence. They also require reformers to acknowledge a corollary of the logic of emergence – that they can jumpstart change but cannot order up precise results, since exact outcomes cannot be known in advance.¹⁵⁴ I shall devote the rest of this article to these opportunities for transformation. Though the obstacles are formidable, possibilities are plentiful on the health care policy fronts that are of most urgent concern – access to care, cost, and value.

A. Expanding Access to Care

Although a large majority of Americans support universal health insurance coverage,¹⁵⁵ political and legal obstacles have repeatedly stymied efforts to achieve it.¹⁵⁶ Contemporary barriers include ERISA pre-emption of state initiatives to expand coverage (many of these initiatives require employers to cover their workers or pay into public funds set up to subsidize insurance), ideological resistance to publicly-supported coverage as incompatible with personal responsibility, and health care stakeholders' concerns about disruptions in cash flows upon which they have come to rely. Foremost

¹⁵⁴ Emergent systems are self-organizing – that is, their order arises from the incalculable (quite literally) combination of simpler interactions at lower levels (*e.g.* neurons that constitute a nervous system; businesses and individuals who comprise an economy). Because these countless, simpler interactions cannot be exhaustively predicted, their emergent results cannot be specified in advance. *See* notes 120-123, 126, 128. Emergent software is illustrative: its repeat “plays” of a given, complex scenario (*e.g.* a model for the spread of an epidemic, the propagation of a financial panic, or the evolution of traits by natural selection) yield different results. The predictive power of such software comes not from individual runs, or “plays,” but from large numbers of “plays” (made possible by enormous computing power) that, together, suggest the range of possible outcomes.

¹⁵⁵ Robin Toner & Janet Elder, *Most Support U.S. Guarantee of Health Care*, N.Y. Times, Mar. 2, 2007, at A1. Survey Data available at http://graphics8.nytimes.com/packages/pdf/national/03022007_poll.pdf

¹⁵⁶ These failures date back to the administration of President Woodrow Wilson, whose nascent proposal for publicly-sponsored coverage was undercut by wartime portrayals of public coverage as a German concept (German Chancellor Otto von Bismarck had pioneered the idea of universal publicly-provided health insurance in the 1870s), incompatible with Americanism. In the 1930s, President Franklin Roosevelt's administration developed a plan for public coverage (as a companion to Social Security), but Roosevelt backed off in the face of fierce resistance from the American Medical Ass'n and others. Other presidents who proposed universal coverage, unsuccessfully, included Harry Truman, Richard Nixon, and, of course, Bill Clinton. RICK MAYES, *UNIVERSAL COVERAGE: THE ELUSIVE QUEST FOR NATIONAL HEALTH INSURANCE* (2005).

among the likely disruptions is the shift from veiled cross-subsidies to visible means of financing care for the less well-off. Americans subsidize care for the medically indigent through a variety of mechanisms that few understand. These include extra payments from the Medicare trust fund to hospitals with large numbers of uninsured patients, as well as private insurance premiums set high enough to contribute to the costs of indigent care.¹⁵⁷ Publicly-sponsored coverage for the less well-off would supplant these covert cross-subsidies with a high-profile tax,¹⁵⁸ an inviting political target. The prospect of these cross-subsidies' disappearance, moreover, alarms hospitals and clinics, who fear that public funding for broader coverage won't suffice to replace this "bird in hand."¹⁵⁹

1. State Solutions?

States have seized the initiative on the health reform front, and creative, bipartisan ideas about how they might expand coverage have spread virally.¹⁶⁰ From a conventional health reform perspective, the prospect of 50 different insurance schemes is anathema: a single, national system (whether market-oriented or government-

¹⁵⁷ M. Gregg Bloche & Robert Carolina, Paying for Undercompensated Hospital Care: The Regressive Profile of a "Hidden Tax," 2 HEALTH MATRIX 141 (1992).

¹⁵⁸ A tax with a distributive profile akin to that of the federal income tax would be more progressive than the current system of veiled cross-subsidies (from private insurance premiums and the Medicare trust fund) for uncompensated hospital care. *Id.* On the other hand, public coverage sufficient to provide access to comprehensive, mainstream care would cost more than the current, incomplete web of cross-subsidies for care in hospitals and community clinics.

¹⁵⁹ Resistance to California Governor Arnold Schwarzenegger's failed health reform plan was illustrative. Schwarzenegger proposed in 2007 to pay for expanded medical coverage in part by pooling current cross-subsidy streams and rechanneling them from hospitals and clinics to support insurance premiums for the less well-off. *Governor's Health Care Proposal*, Jan. 2007, available at http://gov.ca.gov/pdf/press/Governors_HC_Proposal.pdf (accessed Sept. 3, 2007). Health care providers (the recipients of these cross-subsidies) have fretted about the prospect that they could lose these cross-subsidies and still face a substantial uncompensated care burden, absent the achievement of universal coverage.

¹⁶⁰ Stuart Butler & Henry Aaron, *A Bipartisan Push on Healthcare*, WASHINGTONPOST.COM, May 13, 2007, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/05/11/AR2007051101784.html> (accessed Sept. 3, 2007).

administered) is essential to avoid Byzantine bureaucratic and legal complexity.¹⁶¹ But from an emergent systems vantage point, the state-by-state route is worth encouraging. Ongoing ideological and interest group gridlock at the federal level makes national reform improbable in the near term. State-by-state progress, meanwhile, could build momentum toward nationwide insistence on universal coverage, so long as high-visibility state initiatives are seen as successes worth propagating.¹⁶² Similarities in design are likely to result from the propagation of successful state models along informal networks of influence,¹⁶³ this would ease administrative burdens. And, should large employers or health plans become sufficiently concerned about the balkanization of legal and regulatory requirements, they could press Congress and the White House for federalization of the emerging universal coverage scheme. They might well succeed, demonstrating the power of feedback mechanisms to transform health policy and law in circuitous fashion¹⁶⁴ – and locking in a national commitment to medical coverage for all. But if state-level reforms build up a critical mass of momentum (powered by popular expectations) for universal coverage, a subsequent move toward federalization will preserve the principle of health care for all.

Thus support for state initiatives constitutes a wise gamble, from an emergent systems perspective. It carries no guarantee that the country will embrace any particular

¹⁶¹ Multi-state employers, especially, dread the prospect of myriad state regimes, each with its own minimum coverage requirements and revenue-raising scheme.

¹⁶² There is no small risk here. The success or failure of Massachusetts' pioneering plan for universal coverage will have a large impact on the future of state reform. The financial difficulties that endanger Maine's "Dirigo" program (Pam Belluck, *As Health Plan Falters, Maine Explores Change*, N.Y. TIMES, April 23, 2007, Section A, p. 1) and that led to the collapse of Tennessee's "TennCare" scheme (Gordon Bonnyman, *TennCare – A Failure of Politics, Not Policy: A Conversation with Gordon Bonnyman*, 25 HEALTH AFFAIRS w217-w225 (2006)) underscore the uncertain fate of state initiatives.

¹⁶³ Such networks include the National Governors' Ass'n, the National Conference of State Legislatures, the Council of State Governments, and numerous think tanks that function as forums for the sharing of state health reform experiences and ideas.

¹⁶⁴ See TAN 148-149.

model for expanding coverage¹⁶⁵; states will decide, case by case, and, more likely than not, one or a few prevailing models will emerge. Nor must it lead, in the end, to state governance of health insurance coverage. Congress and the White House could respond to state initiatives by imposing an overarching federal scheme. Were this to happen, state reforms would still have served a vital purpose, as part of the larger process of universal coverage's emergence.

This rationale favors legislative revision of ERISA to clear the way for state experimentation¹⁶⁶ – and, meanwhile, judicial construction of ERISA to minimize pre-emption of state initiatives.¹⁶⁷ There is ample doctrinal space for such a judicial reading. The Supreme Court has said, in a case involving state regulation of hospital charges for the purpose of expanding coverage, that ERISA's pre-emptive provisions are to be read narrowly when they infringe upon traditional state power over health matters.¹⁶⁸ To be sure, there is lower court precedent to the contrary,¹⁶⁹ but the accretion of state reform initiatives would put pressure on judges not to stymie legislators' will when neither Supreme Court precedent nor the plain language of ERISA requires it.

¹⁶⁵ States are now weighing a variety of models, alone and in combination; these include expansions of Medicaid, employer obligations to provide coverage or contribute toward its cost, consumer-directed health care, premium support, and insurance market reforms. National Governors' Ass'n Center for Best Practices, *Issue Brief – Leading the Way: State Health Reform Initiatives*, July 11, 2007.

¹⁶⁶ Bipartisan support for revising ERISA will become increasingly likely as states enact coverage expansion initiatives and look to their Congressional representatives for support. Former Massachusetts Governor Michael Dukakis argues that California and other states considering such initiatives should ignore the ERISA pre-emption issue as they draft legislation, then ask Congress to either exempt them or to trim back the pre-emption for everyone. Personal Communication from Michael Dukakis, Feb. 2007.

¹⁶⁷ The extent to which ERISA pre-empts state laws requiring employers to either provide coverage for their employees (up to some state-defined minimum level of benefits) or to contribute funds in some other fashion, toward coverage of the uninsured, will be the principal focus of such pre-emption litigation as state reform gathers steam. *See supra* note 20. State insurance market reforms, including new mechanisms for pooling risk among small employers, could also face pre-emption challenges under ERISA.

¹⁶⁸ *See* New York State Conference of Blue Cross & Blue Shield Plans v. Travelers, 514 U.S. 645 (1995) (holding that state law requiring hospitals to collect higher payments from commercial insurers than from non-profit Blue Cross & Blue Shield Plans survives ERISA Section 514 pre-emption).

¹⁶⁹ *E.g.* Retail Industry Leaders Ass'n v. Fielder, *supra* note 20.

2. Personal Responsibility

Objections to publicly-supported coverage on the ground that it is incompatible with personal responsibility¹⁷⁰ pose a larger challenge for efforts to expand health care access. Commentators, advocacy organizations, public officials, and others who favor government action to increase access have offered many countervailing arguments.¹⁷¹ This battle has been joined in American politics since Theodore Roosevelt urged national health insurance during his Bull-Moose run for the Presidency in 1912.¹⁷² There have been incremental steps forward – Medicare and Medicaid in 1965, Medicaid expansion during the 1980s, and SCHIP in 1997. Yet portrayals of public coverage as a handout – a step toward socialism¹⁷³ and away from self-reliance – have retained their resonance.

Universal coverage proponents have struggled to rebut this portrayal with more and better arguments. But the logic of emergence suggests another approach – one that takes advantage of the tension between people’s contradictory commitments to universal coverage and to self-reliance. Rather than ruing this contradiction, health policy progressives should harness its political energy, by weaving individual responsibility and

¹⁷⁰ The leading proponent of this view among legal scholars is Richard Epstein. *See generally* RICHARD EPSTEIN, *MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE?* (1997).

¹⁷¹ There are innumerable examples; leading scholarly efforts to make the case for government action to achieve universal coverage include NORMAN DANIELS, *JUST HEALTH CARE* (1985) (making a Rawlsian case for universal coverage); MICHAEL WALZER, *SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY* 64-94 (1983) (offering communitarian arguments); EZEKIEL J. EMANUEL, *THE ENDS OF HUMAN LIFE: MEDICAL ETHICS IN A LIBERAL POLITY* 97-244 (1991) (criticizing Rawlsian arguments and making a communitarian case). *See also* INSTITUTE OF MEDICINE COMMITTEE ON THE CONSEQUENCES OF UNINSURANCE, *INSURING AMERICA’S HEALTH: PRINCIPLES AND RECOMMENDATIONS* (2004) (reviewing clinical, economic, and philosophical arguments for universal coverage).

¹⁷² MAYES, *UNIVERSAL COVERAGE*, *supra* note 156.

¹⁷³ The American Medical Association deployed the “socialism” canard with much effect in the 1930s to derail President Franklin Roosevelt’s national health insurance proposal. *See supra* note 156. In muted form, it persists to the present day: 2008 Republican presidential candidate Rudolph Giuliani has characterized Democratic candidates’ universal coverage proposals as “socialized medicine.” *Election 2008: Republican Presidential Candidate Giuliani Discusses Health Care at Events in N.H., S.C.*, KAISER DAILY HEALTH REPORT, Aug 17, 2007, available at http://www.kaisernetwork.org/daily_reports/health2008dr.cfm?DR_ID=46953 (accessed Sept. 3, 2007).

mutual obligation together into a new reciprocity of personal and public commitment to health. This new reciprocity might start with an enhanced sense of individual obligation – to eat sensibly, exercise regularly, avoid smoking, and otherwise care for ourselves.¹⁷⁴ It could include an obligation to buy insurance. Our failure to do these things should carry consequences, such as premium surcharges and a measure of embarrassment over personal behavior that adds health risk without corresponding social benefit.¹⁷⁵ The state, in exchange, should offer some protection when self-reliance falters. Americans who cannot afford coverage should be able to turn to their government for help in acquiring it. If the United States is to come close to universal coverage, personal responsibility will probably need to play a larger role than it did in the mid-20th-century welfare state.¹⁷⁶ But in return, we should be able to count on each other, through our government, to shield us from the degrading, life-endangering consequences of going without basic care because we cannot pay.

3. Taxes, Subsidies, and Settled Expectations

Health care stakeholders' concerns about disruption of their revenue streams as a result of movement toward universal coverage need to be taken seriously. From a conventional "policy wonk" perspective, this disruption shouldn't count. It is a mere

¹⁷⁴ M. Gregg Bloche, *Health Care for All?*, NEW ENG. J. MED. (forthcoming).

¹⁷⁵ Such behaviors include substance abuse, reckless sex, and overeating. Here, conservatives have a point (in my view) when they chide some liberals for characterizing these behaviors as wholly the products of illness, compulsion, corporate marketing, or social injustice, rather than personal choice. Social norms that reward self-control, and punish lapses, have a role. See M. Gregg Bloche, *Obesity and the Struggle Within Ourselves*, 93 GEO. L. J. 1335 (2005). This is hardly to say that social conditions have no causal role in behaviors that put health at risk; to the contrary, poverty (and its tendency to keep people focused on their immediate needs), environmental disadvantages, the media's messages, and other social circumstances are important factors. But it is to say that a sense of individual responsibility can make a positive health difference, even when social unfairness renders the playing field uneven.

¹⁷⁶ The health care reform ideas being taken seriously in state capitals and in the 2008 presidential campaign are notable for their emphasis on personal responsibility. Bloche, *Health Care for All?*, *supra* note 174. Some (including the Massachusetts plan) include an individual mandate to buy insurance, and most make some reference to people's responsibility to keep fit, stop smoking, and otherwise care for themselves.

transition problem. If one or another universal coverage scheme constitutes an improvement over today's tangled web of cross-subsidies, it ought to be enacted – unless a competing scheme would improve things even more. But from an emergent systems perspective, transitions are crucial. They are not details to be worked out, bureaucratically and legally, after new policies are chosen: they are the terrain that must be negotiated to achieve policy ends. Obstacles must be anticipated – obstacles thrown up by stakeholders, bureaucratic structures, and legal regimes. And public perceptions are crucial, as is illustrated by voters' resistance to new taxes, even when these would supplant payroll deductions that cross-subsidize care for the poor.

Presidents Franklin Roosevelt and Lyndon Johnson understood this last point when they insisted on characterizing working Americans' contributions toward Social Security and Medicare as insurance premiums, not taxes. Aspiring architects of expanded medical coverage today would do well to fashion schemes that separate collection of general tax revenues from public financing of care for people unable to meet their own needs. This is more than just rhetoric: Both promising political pathways and insurmountable obstacles to reform emerge from the structure of people's perceptions about the options they confront.¹⁷⁷

Aspiring architects of reform should also avoid large, immediate disruption of current financial arrangements, even when the policy case for disruption is powerful. Sudden disruption of settled expectations invites fierce political and legal resistance from

¹⁷⁷ See DREW WESTON, *THE POLITICAL BRAIN: THE ROLE OF EMOTION IN DECIDING THE FATE OF THE NATION* (2007) (drawing upon neuroscience evidence to argue that people form policy positions by (unconsciously) organizing their perceptions of new circumstances into pre-conceived patterns, then reacting emotionally to these patterns).

stakeholders – resistance that can put reform at risk.¹⁷⁸ From an emergent systems perspective, getting reform “right” is more than a matter of preparing a blueprint for the “best” policy in the abstract; it requires charting a path through networks of political and legal influence. Policies that postpone the prospect of disruption – leaving open multiple, more gradual evolutionary possibilities – will tend to arouse less resistance.

There is, for example, a strong public policy case for ending tax exemption of non-profit hospitals upon the advent of comprehensive, universal coverage.¹⁷⁹ The prevailing rationale for property and income tax exemption of hospitals has long been their provision of care to people unable to pay.¹⁸⁰ Adoption of universal coverage would render this rationale obsolete. Elimination of these tax subsidies would make additional state and federal dollars available to support insurance for those unable to afford it. Redirecting public funds from subsidies for hospitals to coverage for the uninsured would both empower patients¹⁸¹ and better match public spending with clinical need.¹⁸² Yet the non-profit hospital sector’s resistance to loss of its tax exemptions weighs heavily against trying to do so as part of a health reform plan. Exemption, even for hospitals that provide minimal “charity” care, has become a settled expectation, and enactment of universal coverage – at either the state or the federal level – without the non-profit sector’s support

¹⁷⁸ M. Gregg Bloche, *A Graveyard for Grand Theory*, 26 HEALTH AFFAIRS 1534 (2007).

¹⁷⁹ M. Gregg Bloche, *Health Policy Below the Waterline: Medical Care and the Charitable Exemption*, 80 MINN. L. REV. 299 (1995).

¹⁸⁰ This “quid pro quo” rationale is well-established in state property tax law, and until 1969 it was explicitly part of the IRS rationale for federal income tax exemption. *Id.* at 382-83. Other proposed justifications for tax exemption include Henry Hansmann’s argument that it compensates for non-profit firms’ disadvantage in raising capital, owing to their inability to distribute profits to owners, and the non-profit hospital sector’s claim that non-profit status yields community benefits, beyond free care, deserving of public subsidy. *Id.* at 320.

¹⁸¹ Instead of being beneficiaries of hospital charity, the (formerly) uninsured would become consumers with purchasing power and choice of providers. *Id.* at 334.

¹⁸² Tax subsidies for hospitals support hospital-based care, rather than the full range of clinical services (including outpatient screening, chronic disease management, and preventive care) available to patients with adequate insurance. Tax subsidies are thus a poor substitute for insurance. *Id.* at 357.

is difficult to imagine. Thus the demise of this otherwise unjustifiable¹⁸³ subsidy is not worth demanding.¹⁸⁴

The same is the case for other cross-subsidy schemes entangled within the disordered web of American health care financing. Extra Medicare payments to teaching hospitals for the training of residents, so-called “disproportionate share” subsidies from Medicare to hospitals that admit large numbers of poor patients, and myriad other flows of cash have their dug-in defenders. For some observers, such seepages of public funds constitute arguments against government action to expand coverage.¹⁸⁵ But for those who hold that failure to extend coverage to the nearly 50 million Americans without it is indecent, this leakiness is an acceptable cost. The emergent systems perspective counsels patience. Perhaps, once universal coverage becomes America’s baseline expectation, these embedded subsidies will be seen as give-aways, and courts and regulators will no longer countenance them. On the other hand, they could survive, like farm subsidies, despite popular scorn – protected by politically-leveraged advocates.¹⁸⁶

¹⁸³ *But see* Jill R. Horwitz, Why we need the Independent Sector: The Behavior, Law and Ethics of Not-for-Profit Hospitals, 50 UCLA L. Rev. 1345 (2003) (arguing that non-profit hospitals supply community benefits that merit tax exemption).

¹⁸⁴ Although tax exemption is unjustifiable, in my view (*supra* note 178), from a policy analytic perspective, its persistence presents an opportunity. Rather than insisting on its elimination, one might (from an emergent systems perspective) seize upon it opportunistically, as a fulcrum for policy leverage. This might be accomplished by taking nonprofit hospitals’ claims of community benefit, *see* Horowitz, *supra* note 181, very seriously, to the point of conditioning tax exemption upon hospitals’ achievement of benchmarks for health promotion, clinical quality, and as care for the needy. Transforming tax exemption into a type of pay-for-performance, in this fashion, is politically and legally more plausible than eliminating it altogether. M. Gregg Bloche, *Tax Preferences for Nonprofits: From Per Se Exemption to Pay-for-Performance*, 25 HEALTH AFFAIRS W304 (2006).

¹⁸⁵ *E.g.* HYMAN, *supra* note 151.

¹⁸⁶ This points to another role for health law and policy scholars – as participants in the process of emergence. Scholars of health care governance are uniquely positioned to detect embedded interest group influence, to expose it, and to speak to public audiences about its pernicious policy and legal impact. They are especially well-situated to identify cases of government responsiveness to this influence and to call public officials to account when they service parochial interests. This has traditionally been the role of investigative journalists, but deeply-probing reporting on public affairs is in decline. National news organizations are budgeting less for investigative reporting and in-depth analysis, and recent changes in the ownership and business objectives of leading newspapers (most visibly the sale of the LOS ANGELES TIMES

4. The Politics of Emergence: The Demise and Re-Birth of Health Care Reform

Thus far, opponents of publicly-sponsored universal coverage have displayed a deeper intuitive awareness of the power of emergence than have advocates of health insurance for all. A stunning example played out in 1993, as Congressional Republicans scrambled to prepare for President Clinton's anticipated health care reform juggernaut. The party's Senate and House leaders eyed plausible compromises that might have achieved near-universal coverage with a reduced role for government.¹⁸⁷ These compromises hewed to traditional Republican principles. They would have left open a wide playing field for competition between health plans, minimally restricted by federal regulators. But conservative strategist William Kristol looked beyond the policy logic of the possible deals, toward the longer-term implications of government-guaranteed coverage. For Republicans, he intuited, the implications were disastrous. Enactment of *any* publicly-financed scheme to cover all would rekindle Roosevelt-era confidence in government as guarantor of personal security, undermining the broader Republican case for lower taxes and less government.¹⁸⁸ Conversely, utter defeat for health care reform

and the WALL STREET JOURNAL by founding families deeply committed to these publications' journalistic mission) could lead to further declines in penetrating reporting and analysis. The expertise necessary to track and interpret government action in such complicated realms as health makes it unlikely that the blogosphere will fill this gap. By incorporating this work into their professional role, and by seeking visible platforms for their findings and analyses, scholars of health law and policy can diminish the ability of embedded interests to shape health law and policy, unrestrained by the prospect of public revelation. A potent array of public platforms is available to scholars and researchers: these include op-ed pages, medical and health policy journals covered by national media (principally the NEW ENGLAND JOURNAL OF MEDICINE, JAMA, and HEALTH AFFAIRS), symposia and briefings sponsored by high-profile think tanks, and blogs sponsored by some of these venues.

¹⁸⁷ Options included R.I. Sen. John Chafee's proposal, the Health Equity and Access Reform Today Act of 1993, H.R. 3704, 103d Cong. (1993); S. 1770, 103d Cong. (1993). (proposing mandatory private insurance with a scheme of public subsidies for low-income subscribers; co-sponsored by 23 Republican Senators, including Minority Leader Robert Dole) and the Heritage Foundation's "Consumer Choice Plan" (Stuart M. Butler, *Have it Your Way: What the Heritage Foundation Health Care Plan Means for You*, POLICY REV., Fall 1993, pp. 54-59.).

¹⁸⁸ William Kristol, *Memorandum to Republican Leaders: Defeating President Clinton's Health Care Proposal*, Dec. 2, 1993 (Project for the Republican Future, Washington, D.C.), *quoted in* SKOCPOL, BOOMERANG, *supra* note 153, at 145-146. Calling the Clinton plan "a serious political threat to the

on President Clinton's watch would deliver a lasting blow to Americans' belief in government's ability to solve complex social problems – and to confidence in the Democrats' ability to deliver on their promises.¹⁸⁹

In a memo that quickly achieved iconic status among conservatives, Kristol urged Republicans to go all-out to kill health care reform.¹⁹⁰ There should be no deals, no carefully-nuanced compromises, Kristol argued. The Clinton plan should come to nothing, except disillusionment.¹⁹¹ Swayed by Kristol's analysis, House and Senate Republican leaders abandoned compromise alternatives in favor of a scorched-earth stance toward health care reform. By fall, 1994, the Clinton plan had succumbed.¹⁹² A few months later, disillusioned voters delivered both houses of Congress to the Republicans for the first time in 40 years. Universal coverage disappeared from the national agenda for a decade, despite the ongoing increase in the numbers of the uninsured. More than that, Americans maintained their skepticism toward government's ability to transform their lives for the better through grand social policy schemes. Kristol had gotten it right. By focusing his party on the emergent consequences of the success or

Republican Party,” Kristol warned that passage of comprehensive reform would “revive the reputation” of Democrats as “the generous protector of middle-class interests” and “relegitimize middle-class dependence for ‘security’ on government spending and regulation.” *Id.*

¹⁸⁹ Kristol wrote that “rejection” of the Clinton plan “by Congress and the public would be a monumental setback for the president and an uncontestable piece of evidence that Democratic welfare-state liberalism remains firmly in retreat.” *Id.*

¹⁹⁰ *Id.*

¹⁹¹ “The goal over the next several months,” Kristol urged, at the height of the battle over the Clinton plan, “should not be simply to wound the proposal, to nitpick the numbers or criticize some of the most onerous provisions, but to defeat the Clinton plan root and branch. ... We ... want to use the health care debate as a model for routing contemporary liberalism and advancing an aggressive conservative activist agenda.” *Kristol Ball: William Kristol Looks at the Future of the GOP*, POLICY REV., Winter 1993, p. 15.

¹⁹² Neither Kristol nor Congressional Republicans can claim full credit for defeating health reform. Potent opposition from health insurers and other interest groups had a large impact, as did the Clinton Administration's tactical missteps. JOHNSON & BRODER, *THE SYSTEM*, *supra* note 57, at - .

failure of health care reform,¹⁹³ rather than on the policy pluses and minuses of particular compromises, he positioned Republicans to achieve their larger, longer-term objectives.

Proponents of robust government action to achieve universal coverage have been slower to seize upon the promise of emergence. The architects of the Clinton plan intended for it to take effect as a finished product. To be sure, they envisioned a phase-in period, and they deferred to competition among health insurers to fill in the plan's fine details. But they fashioned a detailed, top-down regulatory scheme to define the parameters of this competition,¹⁹⁴ and they envisioned little change in the plan's basic structure once it went into effect. Advocates of Canadian-style "single payer" coverage likewise urge top-down imposition of their approach, with little regard for the enormous disruption it would entail.¹⁹⁵ This disruption is the driving force behind opposition to the "single payer" model. A sudden switch to "single payer" would push the American health economy toward chaos by shattering current financial arrangements and dislocating millions of workers.¹⁹⁶ Political resistance by those potentially affected makes this approach a non-starter.¹⁹⁷

¹⁹³ Kristol didn't explicitly invoke emergent systems thinking, but he *thought* emergently. He strategized to create conditions more likely to give rise to feelings and beliefs conducive to longer-term Republican political and policy success.

¹⁹⁴ The Clinton plan's regulatory mechanisms addressed myriad matters in top-down fashion, including specification of minimum benefits to be provided by competing health plans, establishment of cross-subsidies among insurers to compensate for risk selection and adverse selection, and requirements that employers assume financial and administrative responsibility for employee coverage.

¹⁹⁵ See, e.g., The Physicians' Working Group for Single-Payer National Health Insurance, *Proposal of the Physicians' Working Group for Single-Payer National Health Insurance*, 290 JAMA 798 (2003) (urging complete replacement of private insurance by public, "single payer" coverage without discussion of transition issues, aside from brief mention of job retraining programs for insurance company employees).

¹⁹⁶ Adoption of "single payer" would put an end to cash flows in the hundreds of billions of dollars per year, from private health care payers to hospitals, doctors, drug and device makers, and others. Cash flows from the public payer (or payers, if a system of regional payers were adopted) would commence, in lieu of private payments, but there would surely be substantial changes in coverage policies and amounts paid, with profound financial implications for health care providers. Moreover, many of the millions of Americans who administer our decentralized system of private coverage and payment could find themselves out of work. There would be ripple effects as well, on labor markets (as millions, or at least hundreds of thousands, found themselves out of work), businesses that look to insurance companies for

There is, nevertheless, cause for optimism about health care reform. A new generation of proposals harnesses the power of emergence in ways that enhance the likelihood of extending coverage to all, or at least to many. Leading 2008 presidential candidates from both parties urged legal changes that would free states to pursue promising initiatives – initiatives now jeopardized by ERISA pre-emption¹⁹⁸ and by limits on states’ ability to make creative use of their Medicaid and SCHIP funds to expand coverage.¹⁹⁹ Some supporters of universal coverage dismiss state initiatives as mere incrementalism – a diversion from the quest for universal coverage. This criticism ignores the emergent possibilities of state-by-state action – its potential to propagate “me-too” optimism (and feasible compromises), as well as the prospect that state-by-state success (and ensuing worries about regulatory balkanization) could prompt Congress to enact nationwide reform.²⁰⁰

Likewise, proposals advanced by both Republicans and Democrats would leave private, employment-based coverage intact while opening up evolutionary pathways

investment capital, and economic sectors that depend, in turn, on these businesses’ buying power and on the purchasing power of insurance company employees.

¹⁹⁷ I take no position here on the *policy* question of whether “single payer” would be better as an end state, in the abstract, than other universal coverage schemes. For a powerful argument that the “single payer” model is superior, see THEODORE R. MARMOR, UNDERSTANDING HEALTH CARE REFORM (1994). My limited point is that top-down imposition of “single payer” by legislative enactment would be so disruptive as to preclude its happening.

¹⁹⁸ See TAN 166-169 (discussing possible ERISA pre-emption of state laws requiring employers to contribute toward their workers’ health benefits or toward funds established to subsidize coverage for the uninsured).

¹⁹⁹ Mitt Romney, Rudolph Giuliani, and Barack Obama are among the candidates who made greater deference to state initiatives part of their campaign messages on health care. However, they did not specify the legal changes they would pursue in order to accomplish this. See Robin Toner, *2008 Candidates Vow to Overhaul U.S. Health Care*, N.Y. TIMES, July 6, 2007, at A1; *Transform Bureaucracies and Change Health Care Delivery*, available at <http://www.joinrudy2008.com/commitment/indepth/8> (accessed Sept. 17, 2007) (summarizing Giuliani’s positions on health care); and *Barack Obama’s Plan for a Healthy America*, available at <http://www.barackobama.com/pdf/HealthPlanFull.pdf> (accessed Sept. 17, 2007) (setting out Obama’s proposal for health care reform).

²⁰⁰ See TAN 160-169 (discussing pathways by which state-level reform could expand coverage).

toward large-scale change. President Bush²⁰¹ and the principal Republican contenders to succeed him have urged an end to tax preferences for employer-provided health plans²⁰²: Americans, they argue, should be able to spend pre-tax dollars on care and coverage, up to a limit, whether or not they acquire or tap workplace-based insurance.²⁰³ By leaving employment-based coverage in place, this approach averts the sudden, large-scale disruption of settled arrangements and expectations. But by removing a powerful disincentive to the purchase of care and coverage outside the employment relationship, this strategy opens the way to the emergence of new ways of pooling risk – and to new health plan designs. Over time, as innovative pooling mechanisms appear, workers with employment-based coverage could migrate to them. Meanwhile, Americans without workplace-based insurance options could pay for care and coverage on their own, using pre-tax dollars. This “level playing field” could reduce the ranks of the uninsured, especially if combined with public subsidies for the least well-off.²⁰⁴ On the other hand, this new generation of Republican proposals calls for greater out-of-pocket (albeit tax-subsidized) spending on care²⁰⁵ and a reduced role for insurance, relative to traditional

²⁰¹ 2007 ECONOMIC REPORT OF THE PRESIDENT, available at <http://www.gpoaccess.gov/eop/index.html>.

²⁰² Under current law, employees’ and employers’ contributions toward workplace-based medical coverage are not treated as taxable income. Likewise, employee contributions toward health savings accounts are non-taxable (up to an annual limit). Employers can also make non-taxable contributions to workers’ health savings accounts (up to an annual limit) when employers offer, and workers choose, high-deductible insurance plans. By contrast, Americans who do not subscribe to employment-based health plans must spend post-tax dollars on care and coverage (up to very high annual limits, above which medical expenses become deductible).

²⁰³ See Katherine Baicker, William H. Dow, & Jonathan Wolfson, *Lowering the Barriers to Consumer-Directed Health Care: Responding to Concerns*, 26 HEALTH AFFAIRS 1328 (2007) (article by former Bush Administration Council of Economic Advisors member and staffers, making the case for treating employment-based and independently-purchased health plans in tax-neutral fashion).

²⁰⁴ *Id.*

²⁰⁵ President Bush has called for tax-deductibility of contributions to health savings accounts (his principal proposed vehicle for out-of-pocket medical spending) – a regressive tax subsidy since those most in need pay the lowest marginal tax rates. Other proponents of this approach (so-called “consumer-directed health care,” accompanied by high-deductible insurance) urge that the least well-off be given tax credits toward their contributions to health savings accounts – a more progressive approach. *Id.*

health plans (including HMOs and PPOs). Over time, this approach would probably lead to steeper tiering of levels of care, based on wealth.²⁰⁶

Democratic proposals hold out a different range of emergent possibilities. The leading Democratic Presidential candidates' prioritized universal coverage (their Republican rivals did not), but sought to minimize disruption of established arrangements and settled expectations.²⁰⁷ To this end, the Democrats' proposals leave employment-based coverage in place. They pursue universal coverage by expanding Medicaid and SCHIP to reach lower-income Americans not now eligible for these programs and by subsidizing middle-income Americans' purchase of private insurance. They avoid extending Medicaid and SCHIP to people at income levels that are within the marketing sights of private insurers (doing so would arouse strong insurance industry opposition²⁰⁸). And the subsidies they promise for the purchase of private coverage are a multibillion

²⁰⁶ M. Gregg Bloche, *Consumer-Directed Health Care and the Disadvantaged*, 26 HEALTH AFFAIRS 1315 (2007). By "levels of care," here, I refer to levels of personal attention, convenience, and technological intensity – aspects of health care that are attractive to many patients but that do not necessarily correlate with clinical outcomes.

²⁰⁷ The plans proposed by the three principal Democratic candidates – Hillary Clinton, John Edwards, and Barack Obama – were remarkably similar. Aside from the question of an "individual mandate" – Clinton and Edwards proposed that all Americans be required to sign up for insurance; Obama urged such a mandate only for children) the differences were little more than cosmetic. See generally *American Health Choices Plan*, available at <http://www.hillaryclinton.com/feature/healthcareplan/summary.aspx> (accessed Sept. 18, 2007) (Clinton's proposal); *Universal Health Care Through Shared Responsibility*, available at <http://johnedwards.com/issues/health-care/health-care-fact-sheet/> (accessed Sept. 18, 2007) (Edwards's proposal); *Barack Obama's Plan for a Healthy America*, *supra* note 199. See also Henry J. Aaron, *Take a Chill Pill* THE NEW REPUBLIC, Dec. 14, 2007 (characterizing the campaign vitriol between Senators Clinton and Obama over individual mandates as overdone and contending that the three candidates' health reform proposals did not differ substantially).

²⁰⁸ The gathering conflict over state and federal efforts to expand SCHIP to cover children from families with higher incomes illustrates the likelihood of such opposition. New York, for example, is attempting to make SCHIP available to children in families with annual incomes as high as \$80,000. After the Bush Administration announced it that it was construing the SCHIP statutory scheme to disallow this, the state indicated it would challenge the Administration in court. Sarah Kershaw, *Eight States to Press Bush on Insurance Coverage of Children*, N.Y. Times, Oct. 2, 2007, at B1. Meanwhile, in the last months of 2007, President Bush vetoed two Congressional efforts to expand SCHIP funding and eligibility to income levels unacceptable to the Administration. Robert Pear & Carl Hulse, *Congress Set for Veto Fight on Child Health Measure*, N.Y. Times, Sept. 25, at A28.

dollar benefit for insurers.²⁰⁹ The only likely, near-term “losers” are employers who do not now provide coverage: they would have to choose between offering insurance and paying a tax (or “fee”) to support the public subsidies.²¹⁰ Thus the leading Democratic candidates’ plans build momentum for universal coverage by leveraging some existing arrangements and minimizing disruption to others.

On the other hand, they open pathways toward long-term, fundamental change. By establishing insurance exchanges to pool risk (and thereby reduce premiums) for individual insurance purchasers and small employer groups,²¹¹ they create an economically viable alternative to workplace-based coverage. Over time, this alternative purchasing mechanism could eclipse the workplace as America’s main source for private insurance. The ability of insurance exchanges to attract large numbers of purchasers²¹² and to offer many coverage choices will give them formidable advantages over employment-based plans. Vast purchasing pools could turn these exchanges into the “Amazon.com’s” of medical coverage, able to out-perform all but the largest employers on price. Things *could* play out this way, but, then again, they may not. The Democratic candidates’ plans leave this question open. They are *emergent* in their approach to employment-based coverage. Its persistence, or demise, will be determined by millions

²⁰⁹ Employers that provide insurance to low-wage workers will also benefit from these subsidies (and, possibly, from expansion of Medicaid and SCHIP).

²¹⁰ They would be losers to a lesser degree than they would have been under the 1993 Clinton plan, since the leading 2008 Democratic presidential candidates’ plans contemplate raising most of the revenues needed to support the public subsidies by allowing President Bush’s term-limited income tax cuts to expire at the end of 2010 for the wealthiest Americans.

²¹¹ The large risk premiums that insurers charge for individuals and small groups mean that the prices they pay for a given level of coverage are much higher than the prices for larger groups (which incur more predictable aggregate medical costs).

²¹² Larger numbers of purchasers translate into lower premiums for health plans listed on an exchange, thanks to larger risk pools and higher numbers of “covered lives.”

of Americans, acting as best they can to protect their families and themselves, with minimal attention to the policy impact of their choices.

A more provocative possibility is the emergence of “single payer” coverage from these plans. Each proposal calls for creation of a public plan,²¹³ to be listed on health insurance exchanges as an alternative to the private options. If the public plan fares better than its rivals in the competition for subscribers – whether because of lower administrative costs,²¹⁴ better deals with doctors and hospitals, or other reasons – it could eventually come to overshadow them. This growth could feed back upon itself in positive fashion, by empowering the plan to obtain lower prices from providers,²¹⁵ thereby crowding out private competitors. Absent Congressional intervention to limit the public plan’s monopsony power over providers or to otherwise restrain its growth, it could evolve into “single payer” coverage.²¹⁶ This long-run outcome – ideal in the eyes of some and nightmarish to others – is hardly foreordained. American antipathy toward government bureaucrats and one-size-fits-all solutions could limit the public plan’s appeal. But the major Democratic candidates’ plans leave this possibility open, to be decided upon *emergently* by future health plan subscribers.

²¹³ Hillary Clinton’s proposal calls for “a public plan option similar to Medicare,” *American Health Choices*, *supra* note 207; the Barack Obama and John Edwards proposals contain similar language.

²¹⁴ “Single payer” advocates point to dramatically lower administrative costs for public, “single-payer” plans, by comparison with private plans. *E.g.* Steffie Woolhandler, Terry Campbell, & David U. Himmelstein, *Costs of Health Care Administration in the United States and Canada*, 349 *NEW ENG. J. MED.* 768 (2003). But see Henry J. Aaron, *The Costs of Health Care Administration in the United States and Canada — Questionable Answers to a Questionable Question*, 349 *NEW ENG. J. MED.* 801 (2003) (arguing that projections of administrative savings achievable by implementing the “single-payer” model in the U.S. have been exaggerated).

²¹⁵ See Gerard F. Anderson, Uwe E. Reinhardt, Peter S. Hussey and Varduhi Petrosyan, *It’s The Prices, Stupid: Why The United States Is So Different From Other Countries*, 22(3) *HEALTH AFFAIRS* 89 (2003) (reporting that prices for health services are lower in nations with monopsonistic public plans (or multiple plans that bargain collectively) than they are in the U.S. (where health care purchasing power is fragmented), and explaining these price differences as a function of international differences in payers’ ability to exercise monopsony power).

²¹⁶ Private plans might remain in the market, offering high-end, “boutique” coverage options for wealthy subscribers.

B. Controlling Costs and Pursuing Value

We know, in general terms, what needs to be done to control health care spending. In theory, we need simply say no to care that exceeds budget limits we set, whether for individuals, institutions, or society. But this, of course, begs many questions. Who should set these limits, and at what level of governance – from the individual patient to hospitals, health plans, or the nation as a whole? And how should resources be dispensed within these limits? We could, in theory, just say no, once annual budgets are exceeded (or on a random basis), without regard for the comparative value of different kinds of care. Virtually all agree that this would be a preposterous approach: limit-setting should be tied, somehow, to the expected value of diagnostic and therapeutic measures. But how do we figure these expected values, trade them off against each other (and against the expected value of non-medical spending options),²¹⁷ and decide what health plans should pay for²¹⁸ within their economic constraints?

1. Obstacles to Progress

Despite countless, carefully-thought-out efforts by scholars to resolve these questions, we have not progressed as a society toward answers. America has been loath

²¹⁷ Were it possible to achieve consensus on how to figure the expected values of diagnostic and therapeutic measures – say, in quality-adjusted life years or some other metric that achieves commensurability – trading them off against each other (and against the expected values of alternative, non-medical use of the resources at issue) would be a matter of simple arithmetic. But we are far from agreement on a commensurable measure – or on how to cope with the incommensurability of expected results from different clinical interventions for different illnesses. Bloche, *Invention*, *supra* note 9, at 275 - 277. Einer Elhauge, *Allocating Health Care Morally*, 82 CAL. L. REV. 1449, 1493-1524 (1994).

²¹⁸ People able and willing to pay will have access to extant treatments regardless of the limit-setting treatments that health plans make, but “thumbs-down” judgments by health plans could reduce wealthy people’s demand for some treatments by stamping them as low-value.

to embrace total health care spending limits at the national or regional levels,²¹⁹ and consumers have proven hostile to tight constraints on health plan budgets.²²⁰ They have also been reluctant to appoint themselves as limit-setters by signing up for lower-cost coverage that kicks in only after they and their families spend thousands of dollars on care.²²¹ Moreover, we are nowhere near to agreement on an approach to working out the expected value of clinical interventions, then making the requisite trade-offs, within whatever budget limits are established.

a. Assessing the Benefits and Hazards of Medical Interventions

There are myriad obstacles to the making of these trade-offs – obstacles that pose large challenges for health law. We lack data concerning the effectiveness of most

²¹⁹ Early versions of President Clinton’s health plan included global budgets – national and regional – to be implemented as a back-up cost-control strategy if managed competition failed. In the face of strong resistance from health care interest groups (and charges from Republicans that the Clinton plan would ration care), the Clinton plan’s drafters transfigured their global budgets into a comprehensive scheme of caps on health plan rates (and, therefore, health plan spending). Continued characterizations of this aspect of the plan as health care rationing played a substantial role in the Clinton plan’s declining popularity and eventual defeat. JOHNSON & BRODER, *THE SYSTEM*, *supra* note 57, at [redacted]; SKOCPOL, *BOOMERANG*, *supra* note 154, at [redacted].

²²⁰ *See supra* note 219. Americans’ resistance to health plan budget limits played out in different form during the several years after the Clinton plan’s collapse, as employers shifted vast numbers of workers into HMOs and other restrictive health plans. Restrictions on choice of provider and access to costly treatments triggered intense popular backlash (expressed through political, legal, and market mechanisms; *see* TAN 141-142), forcing health plans to abandon these restrictions and allow costs to float upward, beginning in the late 1990s. More worrisome is our country’s resistance to limits on Medicare spending, though Medicare’s long-term threat to American fiscal stability dwarfs that posed by Social Security, military spending, or any other federal program. Aaron, *Budget Prospects and Health Policy*, *supra* note 41. On the other hand, Americans have proven quite tolerant of budget limits on health plans for the poor and near-poor. Under the pressure of competing priorities and frugal taxpayers, states have capped their Medicaid benefits at levels unthinkable for Medicare and private health plans, to the consternation of advocates for the disadvantaged. *E.g.* Bonnyman, *TennCare – A Failure of Politics, Not Policy*, *supra* note 162.

²²¹ So-called “consumer-directed” health plans, which combine very high deductible insurance with cash contributions to health spending accounts (vehicles for pre-tax, out-of-pocket medical spending), enrolled only five percent of the 158 million Americans who received medical coverage through the workplace in 2007 (up one percentage point from 2006). Only 10 percent of employers offered such plans in 2007. Gary Claxton, Jon Gabel, et. al, *Health Benefits in 2007: Premium Increases Fall to an Eight-Year Low, While Other Rates and Enrollment Remain Stable*, 26 *HEALTH AFFAIRS* 1407, 1411-1413 (2007). The economist Rashi Fein has argued that people choose more comprehensive medical coverage (when they can afford it) in part because they dislike the experience of having to trade off money against health when they or their loved ones are ill: low deductibles that don’t otherwise make economic sense (since they raise premiums substantially) are attractive to health plan subscribers as a safeguard against this unpleasant, sometimes anguishing experience. RASHI FEIN, *MEDICAL CARE, MEDICAL COSTS: THE SEARCH FOR A HEALTH INSURANCE POLICY* [redacted] (1999).

medical interventions,²²² and political resistance from doctors, hospitals, and drug and device makers has blocked large-scale, publicly-funded research to fill this void.²²³

Private insurers lack the requisite incentives to step into the breach. Research into the comparative efficacy of tests and treatments is a classic “public good,” supplied at socially sub-optimal levels by private health plans because they cannot capture all of its social benefits. Savings from published research that results in the demise of low-value therapies redound to the benefit of all health plans, not just those that pay for the research.²²⁴ Likewise, benefits from treatments found to be of high value accrue across the medical marketplace, not just to the plans (and subscribers) that fund the studies. To be sure, pharmaceutical firms and medical device makers finance a great deal of research,²²⁵ but these studies are fashioned with regulatory hurdles in mind. They are aimed at identifying chemical candidates for intellectual property protection and Food and Drug Administration (FDA) approval, neither of which require showings of

²²² Bloche, *Invention*, *supra* note 9, at 18-21.

²²³ See Shannon Brownlee, *Newtered*, WASHINGTON MONTHLY, Oct. 2007, at 27; Bradford H. Gray, Michael K. Gusmano, and Sara R. Collins, *AHCP and the Changing Politics of Health Services Research*, HEALTH AFFAIRS, June 25, 2003, p. W3-283, available at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.283v1.pdf> (accessed Sept. 23, 2007) (identifying interest group hostility as a major factor in the demise of the federal agency devoted to research on the effectiveness of clinical interventions).

²²⁴ In theory, a health plan could conduct clinical effectiveness research on a proprietary basis, then use the research results to formulate coverage policies that yield competitive benefits through cost savings that accrue *uniquely* to the plan. In practice, this scenario is implausible, since coverage policies that deviate from industry practice would spark hostile reactions (including appeals to state-mandated independent reviewers and to the courts) from doctors and patients. To defend these policies, the plan would have to explain them, by going public with its research design and results – and thereby transforming its proprietary information into a public good.

²²⁵ The Pharmaceutical Research and Manufacturers of America (PhRMA) reports that its members spent \$43 billion on drug research and development in 2006, and that 2006 R & D spending for the pharmaceutical industry as a whole was \$55.2 billion. *About PhRMA: Who We Are*, available at http://www.phrma.org/about_phrma/ (accessed Sept. 24, 2007). Skeptics contend that a great deal of this purported investment in research is, in fact, disguised advertising and other promotional spending. E.g. JERRY AVORN, *POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS* 198-216 (2004).

comparative therapeutic value. “Safety” and “efficacy,” not cost-effectiveness (by any measure) are all that the FDA regulatory scheme requires for approval.²²⁶

Even if the federal government (or the private sector) were to commit to a large-scale program of comparative research into the outcomes of diagnostic and therapeutic interventions, serious obstacles to evidence-based, cost-sensitive practice (and payment policies) would remain. Selection of outcome measures for such studies is fraught with normative questions that lack agreed-upon answers.²²⁷ A classic example is comparison of coronary revascularization (angioplasty and coronary artery bypass surgery) and drug therapy for atherosclerotic heart disease. What roles should prolongation of life, reduction of pain, and improvement of physical endurance have in assessment of these therapies? Such measures sometimes correlate, but often, they diverge. Preferences will vary from patient to patient, and for some patients, they will fluctuate over time. Variation of this sort opens the way for competing interest groups – say, heart surgeons, invasive cardiologists,²²⁸ medication-prescribing internists, and cost-conscious insurers – to reject research results (by criticizing the outcome measures chosen) when studies don’t go their way.

The design of comparative clinical trials is bedeviled by another problem that constrains their real-world applicability. Participants in clinical trials typically represent a homogeneous subset of the population with the disease or symptoms being studied.

This reduces the risk that confounding influences – such as age, genetic and lifestyle

²²⁶ The FDA has taken the position that its enabling statute doesn’t permit it to consider a candidate drug’s cost-effectiveness or comparative value. The relevant statutory language strongly supports this position. JOHN R. THOMAS, *PHARMACEUTICAL PATENT LAW* (2005). The pharmaceutical industry opposes Congressional revision of the FDA’s enabling statute to empower the agency to consider comparative efficacy, value, or cost.

²²⁷ Elhauge, *Allocating Health Care Morally*, *supra* note 218, at 1496.

²²⁸ Heart surgeons perform bypass surgery; angioplasty is typically performed by cardiologists (internists who have done fellowships in cardiology).

factors, and the co-existence of other illnesses – will interfere with comparison of the tests or treatments being studied. But this prerequisite for good science means that a study’s findings often apply to a small fraction of the patient population for which the tests or treatments are potentially relevant.²²⁹ That is, most real-world patients would not have qualified for inclusion in the study, rendering application of its findings a dubious proposition for them.²³⁰ The enormous cost of large-scale clinical trials, which can run to the tens of millions of dollars, makes this a large obstacle to construction of an evidence base for most of medical practice, even if outcome measures can be agreed upon.

There is, moreover, a fractal geometry of medical decision-making that complicates the fashioning of clinical practice protocols even when their drafters have abundant data at their disposal. Any protocol applied to a group of patients is open to the criticism that it constitutes a one-size-fits-all approach to sick people who vary in relevant ways – genetically, behaviorally, or otherwise. The astonishing complexity of human biology virtually guarantees the plausibility of this criticism. The more we discover about our biology, the richer the diversity that we can envision. We have, for example, just begun to explore human genomic variation, its implications for the individualized expression of disease, and the resulting possibilities for personalized treatment.²³¹ It will be increasingly possible to object to practice or payment protocols

²²⁹ Bloche, *Invention*, *supra* note 9, at 276 (discussing this problem as an instance of bounded rationality in health care policy).

²³⁰ For example, anticipated differences in the effectiveness of coronary angioplasty – depending on the anatomy of patients’ coronary vasculature, the extent and distribution of atherosclerotic disease across this vasculature, differences in lipid chemistry (e.g. levels of high and low density lipoproteins, known to be mediators of cardiovascular risk), behavioral and lifestyle factors, genetic markers, and age – might lead clinical investigators to narrow the inclusion criteria for an angioplasty trial on such grounds. But by so doing, the investigators narrow the real-world clinical relevance of their findings, to the subset of cardiovascular disease patients who meet these inclusion criteria.

²³¹ See, e.g. Thomas J. Lynch, Daphne W. Bell, et. al, *Activating Mutations in the Epidermal Growth Factor Receptor Underlying Responsiveness of Non–Small-Cell Lung Cancer to Gefitinib* 350 *NEW ENG. J.*

by claiming that some patients to whom a protocol applies will benefit greatly from a disallowed treatment – or visa versa. In practice, the former claim will be more frequent. Doctors, drug makers, and others who stand to gain from a disallowed treatment will have strong incentives to stake this claim – and to seek evidence to support it, by reanalyzing data and performing new studies.²³² Clinical protocols that group patients for the purpose of guiding practice are a probabilistic exercise. They reflect average, expected outcomes, when, in fact, outcomes vary, depending on characteristics that group members don't share. Research that elucidates such characteristics, thereby opening the way to more precise predictions for subgroups, will lead clinical protocols to unravel.

b. Balancing Benefits and Costs: Preferences, Principles, and Political Taboo

A further obstacle to use of clinical protocols, once cost concerns are allowed to count,²³³ is our inability, as a society, to come close to agreement on how to value the benefits of care, even when we have good enough data to quantitate these benefits.²³⁴

MED. 2129 (2004) (reporting on genetic variations that dramatically increase one particular type of tumor's responsiveness to a chemotherapy agent previous found to be only minimally effective for patients, in general, with this tumor type).

²³² Patients who vest hope in the disallowed therapy represent additional leverage for health care providers and drug and device makers intent on challenging clinical protocols. The lobbying efforts of the so-called "Center for Patient Advocacy" are a high-profile example. The Center was founded by a back surgeon opposed to a federal agency's 1993 practice protocol that came out against spinal fusion and discectomy surgery for low back pain. Brownlee, *supra* note 224. Not only did it advocate successfully against broad adoption of this protocol by health care payers; it lobbied successfully (in conjunction with other provider groups, as well as drug and medical device manufacturers) for federal legislation that downsized the offending agency and forbade it from issuing additional practice protocols. *Id.* On this and other issues, it has leveraged people's trust in their doctors, as well as their worries about insurers' skimping on care. Links (accompanied by favorable references to the Center as a resource for patients) from such websites as those of the Kaiser Family Foundation and the Public Broadcasting System program, *Frontline* today bring people to the Center's website without informing them about the Center's origins and ongoing advocacy role for health care providers. *E.g.* http://www.kaisernetwork.org/ref_links/reflinks_advocacy.cfm (accessed Sept. 24, 2007); <http://www.pbs.org/wgbh/pages/frontline/shows/doctor/etc/links.html> (accessed Sept. 24, 2007).

²³³ Explicit cost-consciousness has not, thus far, been incorporated into protocols developed by federal agencies, professional societies, or medical academics. Cost sensitivity has played a role in proprietary payment protocols employed by health plans, but there have been no reports of plans weighing costs against benefits in systematic fashion; rather, consideration of costs has been ad hoc.

²³⁴ Bloche, *Invention*, *supra* note 9, at 271.

Scholars and researchers have proposed myriad formulations, aimed at making assessments of benefits commensurable for the purpose of weighing them against each other and against costs. These approaches range from lives or life years saved to all manner of methods for calculating quality-adjusted life years.²³⁵ But none has caught on, and none seems about to; it is thus implausible that any of these formulations could become a stable solution, in the foreseeable future, to the problem of valuing medical care's benefits.

For this reason, some argue, individuals should decide for themselves, by choosing from among explicitly-stated clinical rationing policies when they subscribe to health plans.²³⁶ This solution is morally appealing²³⁷ but unlikely to work well in practice. As I have argued elsewhere,²³⁸ co-existence of multiple clinical allocation policies would impose too great an information-processing demand on doctors called

²³⁵ For an excellent review of these formulations and their shortcomings, see Elhauge, *Allocating Health Care Morally*, *supra* note 218, at 1493-1526.

²³⁶ Havighurst envisions a medical marketplace made up of differently-priced private health plans, offering multiple tiers of quality and different cost-benefit trade-off policies. Consumers would choose from among these plans based on both their *ex ante* preferences concerning cost-benefit trade-off policies and their willingness and ability to pay. HAVIGHURST, *HEALTH CARE CHOICES*, *supra* note 9, at 22- 24. Elhauge, by contrast, envisions a marketplace of *equally* priced private health plans, offering benefits of equivalent actuarial value. Public financing (constrained by a politically-determined global health care budget) would cover the cost of enrollment. The plans would offer a variety of clinical resource allocation policies readily comprehensible to consumers, who could then choose from among competing plans based on their *ex ante* resource allocation preferences. Patients could purchase additional care out-of-pocket (if able to afford it), but there would be no Havighurst-style tiering of health plans by ability and willingness to pay. Elhauge, *Allocating Health Care Morally*, *supra* note 218, at 1524-1526, 1529-1530, 1538-1544.

As Elhauge points out, the *ex ante* perspective is essential here. *Id.* at 1507. Allowing patients to choose cost-benefit trade-off policies (at the insurance pool's expense) *ex post* the onset of illness reintroduces the moral hazard problem that choice between allocation policies from behind the "veil of ignorance" (about future medical problems) is meant to avoid. Also, as Elhauge notes, the validity of *ex ante* consent to an allocation policy is contingent upon the judgment that the conditions under which consent was given are morally acceptable. *Id.* at 1536. The public subsidies that Elhauge envisions, which would ensure universal coverage sufficient to purchase health care at levels now affordable to the middle class, suffice (in my view) to render the conditions of *ex ante* consent morally acceptable under Elhauge's scheme.

²³⁷ The principal moral concern that many share – that this approach legitimizes multiple tiers of coverage and care, tied to ability to pay (an objectionable development if one view health care as a "merit good") – dissolves if the less well off are given public subsidies sufficient to enable them to afford the levels of coverage and care that middle-class Americans now receive. *Id.*

²³⁸ Bloche, *Invention*, *supra* note 9, at 277.

upon to implement them at the bedside. An engineer can adjust a levee's design to withstand a 10-year flood, or a 100-year or 1000-year tempest, but a doctor cannot adhere, simultaneously, to multiple cost-benefit trade-off schemes for differently-insured patients. Physicians, like soldiers, learn to react, as much as to reason, as clinical circumstances unfold. Medical training entails perception and recognition of patterns – patterns that prompt doctors to make clinical decisions in rapid sequence, typically without engaging in conscious, probabilistic reasoning.²³⁹ Human cognitive capacity is limited to a degree that precludes application of such reasoning to more than a small fraction of the decisions doctors make each day.²⁴⁰ It is beyond this cognitive capacity for a physician to adopt multiple clinical practice styles, each tied to different resource allocation principles.²⁴¹

One might finesse this problem by placing each physician within only one health plan; then each physician could follow his or her plan's allocative principles and policies,

²³⁹ This is an instance of the more general truth – increasingly recognized by cognitive scientists – that people engage in conscious reasoning for only a small fraction of the many, quick-fire judgments they make each day. See GERD GIGERENZER, PETER M. TODD, & THE ABC RESEARCH GROUP, *SIMPLE HEURISTICS THAT MAKE US SMART* (2000) (employing medical and other examples to argue that people make most decisions by employing “fast and frugal” heuristics, not conscious, systematic reasoning).

²⁴⁰ See generally *BOUNDED RATIONALITY: THE ADAPTIVE TOOLBOX* (G. Gigerenzer & R. Selten eds. 2002) (reviewing a variety of psychological adaptations to human cognitive limitations: these include cultural norms, imitation, and emotional responses, as well as unconscious heuristics).

²⁴¹ Physicians' past responses to heterogeneous incentives from different payers reflect this limitation. When, in 1983, Medicare radically changed the way it paid for acute inpatient care – shifting from fee-for-service to lump-sum payment based on diagnosis – hospitals reduced their average lengths of stay for *all* populations of insured patients – private, fee-for-service as well as Medicare. Judith Feder et al., *How Did Medicare's Prospective Payment System Affect Hospitals?*, 317 *New Eng. J. Med.* 867, 870 (1987). This reduction was an expected response to the new Medicare reimbursement scheme, which rewarded frugality through the lump-sum method. But its spillover into the fee-for-service market was surprising, since this spillover *reduced* hospitals' revenues from private, fee-for-service patients. It is difficult to explain this spillover except as an expression of physicians' bounded rationality – their inability to change their approach to Medicare patients without also changing their approach to fee-for-service inpatients. More recently, studies of physicians who see patients covered under multiple private plans with differing incentives (e.g. fee-for-service, capitation, and other schemes that reward doctors for doing less) have found that doctors don't vary their practice styles for patients in differing plans. See, e.g., Laurence C. Baker, *Association of Managed Care Market Share and Health Expenditures for Fee for Service Medicare Patients* 281 *JAMA*. 432 (1999). Uwe Reinhardt, *The Economist's Model of Physician Behavior*. 281 *JAMA* 462 (1999).

without fretting about multiple resource allocation schemes and practice styles.²⁴² This might work, in theory, in heavily-populated areas, with health care markets big enough to support multiple plans, each with their own, in-house specialty services.²⁴³ Market forces, though, have not played out this way. Most medical specialists and virtually all elite tertiary care centers have maintained their independence from health plans.²⁴⁴ They treat patients from many plans, and they possess the bargaining power to resist plans' efforts to influence their practice styles. Restructuring specialty care as an in-house component of private health plans would require aggressive government intervention, at odds with the prevailing preference for market-driven organization of medical care.

In addition to these obstacles to assessing the benefits of care, efforts to limit medical spending must confront a larger challenge. Americans remain, for the most part, unwilling to acknowledge that long-term cost-containment will require the withholding of beneficial care.²⁴⁵ The "R-Word" – rationing – remains taboo in public discussion of policy responses to rising costs,²⁴⁶ except as an epithet employed by politicians to cast

²⁴² The Kaiser-Permanente system (comprised of an HMO and a set of medical practice groups that treat only subscribers to the Kaiser HMO) is the most prominent example of a plan organized in this fashion.

²⁴³ Outside of such areas, there probably isn't sufficient demand to support multiple lineups of specialty care providers, each dedicated to a single health plan. See, e.g., Rebecca T. Slifkin, Thomas C. Ricketts, III, Hilda A. Howard, *Potential Effects of Managed Competition in Rural Areas – Service Delivery in an Evolving Managed Care Environment*, HEALTH CARE FINANCING REVIEW, Summer 1996, at 143 (discussing difficulties that confront efforts to engender competition between multiple health plans, with their own doctors and hospitals, in rural environments).

²⁴⁴ One can interpret this in Coasean, "theory-of-the-firm" terms. R.H. Coase, *The Nature of the Firm*, 4 *Economica* 386 (1937). The higher transaction costs associated with the independence of specialty physicians (and tertiary care hospitals) are counterbalanced by the benefits (for both health plans and providers of specialized services) of the flexibility that comes from annual contracting in a quickly-changing marketplace, as compared with the rigidities and sunk costs of vertical integration. James C. Robinson, *Future of Managed Care Organization*, HEALTH AFFAIRS, March/April 1999, at 7.

²⁴⁵ For a blunt discussion of the need to ration beneficial care in order to hold medical spending to manageable levels, see generally AARON & SCHWARTZ, *CAN WE SAY NO?*, *supra* note 63.

²⁴⁶ Robert Pear, *The "R" Word: Justice Souter Takes on a Health Care Taboo*, NEW YORK TIMES, June 18, 2000, at 43.

aspersions on health reform proposals they oppose.²⁴⁷ We aren't absolutists in practice: unarticulated trade-offs between benefits and costs are embedded in clinical judgment.²⁴⁸ But our public morality permits no discussion of this,²⁴⁹ at least by elected officials, health plan marketers, and others concerned about popular opinion.²⁵⁰ Health plans don't promote competing rationing formulae on their websites, television ads, or billboards on the sides of buses. And insurance contracts persist in promising all "medically necessary" care, without any reference to the weighing of benefits against costs²⁵¹ for the purpose of determining what is "necessary."²⁵² Likewise, medical malpractice law continues to defer to extant professional standards of care, which are, for the most part, only minimally sensitive to cost.²⁵³ For now, at least, efforts to control medical spending

²⁴⁷ The charge that President Clinton's health reform plan (which envisioned competition among HMOs and other prepaid managed health plans) countenanced the rationing of care was one of the missives hurled by the plan's Republican critics in 1993-94. A few years later, when House Republicans proposed that Medicare beneficiaries be enrolled in HMOs, Democrats returned the favor, claiming that Republicans were planning to ration senior citizens' care. Robert Pear, Familiar Ring to the G.O.P Medicare Plan? It's What Clinton Talked About, N.Y. TIMES, Sept. 26, 1995. Both accusations were accurate. A unanimous Supreme Court said as much in *Pegram v. Herdrich* when it noted that "inducement to ration care goes to the very point of any HMO scheme." *Pegram*, *supra* note 29, at 221.

²⁴⁸ JOHN EISENBERG, DOCTORS' DECISIONS AND THE COST OF MEDICAL CARE (1986).

²⁴⁹ The Hippocratic ethic of undivided loyalty to patients, operating in conjunction with insurance coverage for most medical expenditures, obliges treating physicians to take little or no account of costs, reinforcing the taboo against rationing. Some contend that the necessity of rationing justifies permitting doctors to depart from this ethic by withholding care with comparatively low expected benefits even though insurance contracts don't explicitly countenance this and patients expect their doctors to do all they can (so long as expected benefits outweigh expected harm). *E.g.* Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463 (2002). I have cautioned that this puts patient trust at too great a risk, with worrisome implications for medicine's effectiveness and ability to contribute to people's sense of security and solidarity. M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 STAN. L. REV. 919 (2002).

²⁵⁰ As Elhauge points out, many academics, as well, take the absolutist view, refusing to countenance either health-health trade-offs or the weighing of clinical benefits against costs on the ground that we should shift public resources from other programs (e.g. the military) to medicine and health. Elhauge, *Allocating Health Care Morally*, *supra* note 216, at 1461.

²⁵¹ This reference to the balancing of benefits against costs is meant to include health-health trade-offs (that is, choices from among alternative uses of health care resources) within a limited budget, as well as decisions as to whether the expected benefits of a test or treatment justify spending additional dollars to cover it.

²⁵² The Supreme Court's conceptualization of independent review of coverage denials as akin to a second medical opinion, not a matter of contract interpretation (*see* *tan* 95-97), is an additional bulwark against efforts to construe the "medically necessary" standard to permit cost-conscious coverage decision-making.

²⁵³ *See supra* *tan* 34, 89, 132-134.

will have to proceed within the confines of our country's refusal to openly countenance the calculus of cost and benefit.

c. Putting Policy into Practice: Our Fragmented Health Care System

A final difficulty needs to be faced. Were it possible to surmount all of the obstacles just discussed, the fragmentation of our health care system would still present a formidable barrier to implementation of more evidence-based, cost-sensitive practice protocols. In the 1980s, many commentators on health policy predicted that consumers' concerns about value would drive the consolidation of hospitals, doctors, and insurers into vertically-integrated health plans with internal systems of cost and quality control. This vision has not panned out. Medical care remains a radically decentralized endeavor.²⁵⁴ Private physicians, for the most part, continue to practice alone or in small groups,²⁵⁵ organizationally separate from hospitals and health plans. Hospitals have consolidated horizontally, to some degree,²⁵⁶ but they exercise minimal managerial control over medical practice, and they remain institutionally independent from health plans.²⁵⁷ Health plans bargain with doctors and hospitals for discounted rates, but they don't actually manage care.²⁵⁸ Physicians make clinical decisions on their own,

²⁵⁴ See JAMES C. ROBINSON, *THE CORPORATE PRACTICE OF MEDICINE: COMPETITION AND INNOVATION IN HEALTH CARE* 35-62 (1999) (discussing the reasons why a system of competing, vertically-integrated health plans did not arise, and describing the decentralized, rapidly-shifting contractual relationships among hospitals, doctors, and plans that developed in its stead).

²⁵⁵ There are exceptions – large multi-specialty group practices have gained substantial market shares in California, Minnesota, and elsewhere, *id* at 8 – but medical practice remains a “cottage industry” in most locales.

²⁵⁶ Barak D. Richman, *Antitrust and Nonprofit Hospital Mergers: A Return to Basics*, 156 U. PA. L. REV. 121 (2007); Kristin Madison, *Hospital Mergers in an Era of Quality Management*, 7 HOUS. J. HEALTH L. & POL'Y 265 (2007).

²⁵⁷ There are exceptions to this institutional independence: the Kaiser-Permanente HMO in California is the outstanding example (The Kaiser HMO owns its hospitals, which treat only Kaiser-Permanente subscribers).

²⁵⁸ “Managed care” has always been a misnomer. Even during the height of the managed care era, through the mid-1990s, health plans didn't “manage” doctors, if by “manage,” one means rigorous oversight and direction of their performance with an eye toward standardizing their approaches to diagnosis and

influenced by personal values,²⁵⁹ peers and mentors,²⁶⁰ financial incentives,²⁶¹ drug company marketing,²⁶² and myriad other factors that contribute to wide variation in practice styles. Coordination of care, moreover, often gets short shrift, since this fragmented system doesn't support team approaches to patients with multiple medical problems.²⁶³

Alternative models of medical care exist. Leading hospitals and multi-specialty group practices have adopted quality-improvement programs that promote evidence-based practice and collaborative decision-making.²⁶⁴ Medicine's academic leaders have coalesced around an agenda for transformation that stresses the building of systems – systems that share information, reward cooperation, apply state-of-the-art clinical science, discover and learn from mistakes, and adjust to individual patients' varying needs.²⁶⁵ But neither market forces nor health law have nudged a critical mass of doctors and hospitals toward realization of this agenda.²⁶⁶

treatment. At most, health plans declined to cover some tests and treatments, refused to authorize some referrals, and profiled doctors' clinical spending patterns with an eye toward selecting more frugal providers for their networks. Plans made minimal proactive efforts: they neither promulgated their own comprehensive, evidence-based clinical practice guidelines nor pressed their participating physicians to follow guidelines developed by academic or professional leaders.

²⁵⁹ See, e.g., Mary Crossely, *Infected Judgment: Legal Responses to Physician Bias*, 48 VILL. L. REV. 195 (2003).

²⁶⁰ See, e.g., Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373 (2002).]

²⁶¹ Michael F. Cannon, *Pay-for-Performance: Is Medicare a Good Candidate?* 7 YALE J. HEALTH POL'Y L. & ETHICS 1, 3, 18, 27 (2007).

²⁶² AVORN, *supra* note 225, at 292-312.

²⁶³ Failures of coordination can have both life-threatening and wasteful consequences: examples include prescribing of medicines without regard for dangerous drug interactions, duplication of risky and costly tests, and incomplete diagnostic assessment of clinical signs and symptoms that "fall between the cracks" of multiple specialties.

²⁶⁴ James J. Mongan, Robert E. Mechanic & Thomas H. Lee, *Transforming U.S. Health Care: Policy Challenges Affecting the Integration and Improvement of Care*, THE BROOKINGS INSTITUTION: HEALTH POLICY: ISSUES AND OPTIONS, Dec. 2006, available at http://www.brookings.edu/~media/Files/rc/papers/2006/1215healthcare_mongan/20061215_mongan.pdf.

²⁶⁵ See generally INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM*, *supra* note 111.

²⁶⁶ See Barry R. Greene, *Tracking the Six Aims of the IOM Report: Crossing the Quality Chasm*, 30 J. AMBULATORY CARE MANAGEMENT 283 (2007); Thomas H. Lee, *Can We Cross the Quality Chasm?: The*

Our system's poor performance, measured by current understandings of best practice, reflects these failings. A much-publicized study of how American medicine fares nationwide on more than 400 broadly-accepted, evidence-based measures of appropriate care found that doctors make the "right" decisions only 50 to 60 percent of the time.²⁶⁷ There are stunning geographical variations in the care Americans receive and in the costs they incur²⁶⁸ – variations that lack scientific or other justification.²⁶⁹ Indeed, studies of state-by-state variation in Medicare costs have found correlations between *higher*-than-average per capita spending and *lower*-than-average performance on quality-of-care measures.²⁷⁰ These quality measures reflect standards of care supported by current financial incentives. They thus do not incorporate cost sensitivity to the degree necessary for long-term control of medical spending. But our health system's weak performance on these measures bodes poorly for our future ability to put agreed-upon standards of quality and value into effect.

B. Emergent Possibilities

These daunting obstacles to control of costs and pursuit of value in health care cannot be overcome by some grand stroke of legal design. No policy-wonk "D-Day" assault on the problem of medical spending can prevail over health care's entrenched

Case for Realistic Optimism, 4 AM. HEART HOSPITAL J. 16 (2006); Keith D. Moore, & Dean C. Coddington, *Models of Care That Meet the Standards of Crossing the Quality Chasm: A New Health System for the 21st Century*, 25 J. AMBULATORY CARE MANAGEMENT 12 (2002).

²⁶⁷ Elizabeth A. McGlynn, et. al., *The Quality of Health Care Delivered to Adults in the United States*, 348 New Eng. J. Med. 2635 (2003).

²⁶⁸ Katherine Baicker, Amitabh Chandra, Jonathan S. Skinner, and Jon E. Wennberg, *Who You Are and Where You Live: How Race and Geography Affect the Treatment of Medicare Beneficiaries*, HEALTH AFFAIRS, VAR-33. 7 October 2004

²⁶⁹ See THE DARTMOUTH ATLAS OF HEALTH CARE 1998, available at <http://www.dartmouthatlas.org/atlas/98Atlas.pdf>. (reviewing geographical variations in care).

²⁷⁰ Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending. Part 2: Health Outcomes and Satisfaction with Care*, 138 ANNALS OF INTERNAL MEDICINE 288, 297 (2003).

complexities, interest groups, and conflicts of value. Emergent systems thinking counsels a more modest approach. It channels our attention toward opportunities to set change in motion – to navigate around some of the obstacles and to allow others to become less formidable as time passes. It emphasizes opportunism over elegant, system-wide solutions that have minimal chance of being fully implemented.

1. Toward Evidence-Based Practice and Value-Based Protocols

What might an emergent strategy for reform look like in the cost control realm? I shall point to some possibilities. For starters, such a strategy should aim to finesse: (1) interest group resistance to comparative evaluation of both current and proposed therapies, and (2) Americans' aversion to the balancing of health benefits against economic costs. An encouraging sign is the recent surge in of bipartisan support for a ramped-up program of clinical outcomes research.²⁷¹ Large federal deficits and ominous warnings about the consequences of failure to contain Medicare and other entitlement spending²⁷² are pushing Congress toward action despite antipathy from those who profit from tests and treatments that might not pan out. Bills now seriously pending would

²⁷¹ Gail R. Wilensky, *Developing a Center for Comparative Effectiveness Information*, 25 HEALTH AFFAIRS w572 (2006) (published online 7 November 2006; 10.1377/ hlthaff.25.w572). A promising program already up and running is Medicare's "Coverage with Evidence Development" (CED) initiative, announced in 2006 by the Centers for Medicare and Medicaid Services (CMS). See generally *Guidance for the Public, Industry, and CMS Staff: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development*, July 12, 2006, available at http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8#P39_3944 (accessed Oct. 3, 2007). Under the CED program, CMS conditions Medicare coverage of some tests and treatments on the collection of research data (information beyond what is necessary for Medicare billing) that enables CMS to assemble evidence bearing on their risks and benefits. The CED program, initiated under the authority of Social Security Act, Title 18, §1862(a)(1)(E), empowers CMS to modify its coverage rules on an ongoing basis as the agency gathers and assesses data on the tests and treatments at issue. By issuing favorable "National Coverage Determinations" (NCDs) under the CED program, CMS can speed the adoption of new technologies (mollifying patients, providers, and pharmaceutical and medical equipment firms) while making a substantial contribution to clinical outcomes research.

²⁷² Aaron, *Budget Prospects and Health Policy*, *supra* note 41.

dramatically increase federal support for outcomes research.²⁷³ Some proposals would insulate funding for this research from attack by health care providers, pharmaceutical firms, and medical device-makers.²⁷⁴ Possible strategies include allocation of a fixed fraction of annual Medicare spending (to shield outcomes research funding from the politics of the annual appropriations process²⁷⁵) and creation of an autonomous, Federal Reserve-style agency²⁷⁶ to perform this research (or to award research grants on a competitive basis, like the National Institutes of Health). Research partnerships between the federal government and private insurers have also been urged²⁷⁷ to broaden both political and financial support for outcomes research.²⁷⁸

Ideally, this agency or program should do more than just research: it should employ available data to assess and compare the value of clinical interventions,²⁷⁹ so as to guide doctors, hospitals, and health care payers.²⁸⁰ But doctors, drug makers, and

²⁷³ E.g. S. 898, 110th Cong. §445C (bipartisan bill promoting Alzheimer's clinical research co-sponsored by 16 Democrats, six Republicans, and one Independent); S.1708, 110th Cong. §4 (bipartisan bill promoting Lyme disease clinical research co-sponsored by 12 Democrats, two Republicans, and two Independents); S. 1183, 110th Cong. §201 (bipartisan bill promoting paralysis clinical research co-sponsored by 23 Democrats, six Republicans, and one Independent).

²⁷⁴ Such attacks crippled earlier federal efforts to conduct medical outcomes research and develop evidence-based clinical practice protocols. See *supra* note 223.

²⁷⁵ Committing a fixed proportion of Medicare spending – say one or two percentage points – to outcomes research would give it status as an entitlement program, immunizing it from efforts by affected interest groups to cut it during the course of the annual budgetary appropriations process.

²⁷⁶ Possible mechanisms for maintaining the agency's independence include keeping it entirely separate from the Department of Health and Human Services (and thus from the direct influence of the President and his or her appointees), governance by a bipartisan commission appointed to staggered terms, and delegation of the task of appointing commission members to a non-political entity (perhaps the Institute of Medicine of the National Academies of Sciences).

²⁷⁷ Wilensky, *Developing a Center for Comparative Effectiveness*, *supra* note 271.

²⁷⁸ Such partnerships could help to protect an outcomes research program from political attack by positioning insurers as a counterweight to interests that profit from treatments of uncertain value.

²⁷⁹ A possible model for such a program is Great Britain's National Institute for Health and Clinical Excellence (NICE), which performs and publishes assessments of tests and treatments, then issues recommended guidelines for clinical care. See generally <http://www.nice.org.uk/> (accessed Oct. 2, 2007).

²⁸⁰ It would also be helpful for this agency or program to develop alternative analytic frameworks, or models, for: (1) the balancing of benefits against costs, and, (2) the weighing of health benefits against each other (more relevant for to health plans and providers that must make do within fixed budgets). Private and public insurers (and providers) could then try out these models as tools for making allocative decisions in candid, accountable fashion. M. Gregg Bloche, *Beyond Learned Helplessness: America's Health Care*

others dependent on revenues from tests and treatments that could fare poorly in such evaluations have the legislative clout to defeat proposals to empower government to perform them.²⁸¹ From a traditional policy design perspective,²⁸² creation of an agency that sponsors clinical outcomes research but doesn't assess the results – or offer guidance to providers and payers – is problematic. Why do this research without using it to improve health care quality and value? However, from an emergent systems perspective, even this limited mandate holds great promise. Such a program would generate a flood of outcomes data, enabling others to compare therapies and develop evidence-based practice protocols.²⁸³ To be sure, these protocols would be quicker in coming were a federal agency to sponsor them on a large scale. But a series of high-profile studies that found oft-used therapies to be harmful or ineffective²⁸⁴ could inspire doctors and patients to demand more vigorous efforts to compare treatments and to develop evidence-based

Cost Conundrum (forthcoming).. Insurers and providers might or might not experiment along these lines, and such experiments might or might not catch on. Whether or not medical resource allocation evolves to embrace such models would be decided in emergent fashion. But development and dissemination of these models would widen this potential evolutionary pathway.

²⁸¹ Physicians, pharmaceutical firms, and medical device manufacturers have done so in the past. *See supra* note 223. Those involved in current Congressional efforts to ramp up federal support for clinical outcomes research tend toward the view that including statutory language empowering government to perform comparative evaluations of medical interventions and to develop clinical practice protocols would doom legislation to increase funding for outcomes research. Interviews, on condition of anonymity, with Congressional staff involved in developing outcomes research legislation, Dec. 2006.

²⁸² By “traditional policy design perspective,” I refer here to approaches that envision a desired end state and call for reforms meant to bring about this state, rather than to create conditions for the future evolution of policy solutions. *See supra* TAN 294-295.

²⁸³ Among the actors that might make use of a surge in outcomes data to compare treatments and craft protocols are medical academics, health plans, and insurers. The risk of bias in the development of protocols is omnipresent (as it would be were these same actors to participate in the formulation of government-sponsored protocols). The important subject of management of conflicts of interest (e.g. medical academics' relationships with drug companies, as well as their income from providing questionable treatments) is beyond my scope here.

²⁸⁴ Within the last few years, clinical outcomes studies have made headlines by finding that commonly-prescribed treatments increase risks to life. Examples include estrogen replacement therapy for menopausal women (e.g., Garnet L. Anderson et al., *Effects Of Estrogen Plus Progestin On Gynecologic Cancers And Associated Diagnostic Procedures: The Women's Health Initiative Randomized Trial*, 290 JAMA 1739 (2003).) and Vioxx and other new-generation non-steroidal anti-inflammatory medications (e.g. Claire Bombardier et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 NEW ENG. J. MED. 1520 (2000).).

guidelines. Rising medical spending, moreover, will put growing pressure on guideline authors to take costs into account. From an expanding base of data on therapeutic outcomes, evidence-based, cost-conscious protocols for payment and practice could emerge despite strong resistance from affected stakeholders.

Winning widespread compliance with such protocols will require an approach to our health care system's fragmentation.²⁸⁵ Here also, there are emergent possibilities. Medicare is in position to lead, by adopting evidence-based performance standards and rewarding doctors and hospitals that comply. Congress recently authorized Medicare to make extra payments to hospitals that meet Medicare's performance standards²⁸⁶ and to initiate small-scale trials of "pay-for-performance" incentives for physicians.²⁸⁷ Medicare's ___ percent share of hospital spending and ___ percent share of payments to physicians give it enormous influence: past changes in Medicare's financial incentives to providers have produced large changes in their treatment of both privately-insured and Medicare patients.²⁸⁸ Thus far, Medicare has declined to explicitly count cost when issuing coverage rules²⁸⁹ or adopting performance standards. Its enabling statute

²⁸⁵ See *supra* TAN 254-263.

²⁸⁶ The Medicare Modernization Act, § 501(b) (2003), and the Deficit Reduction Act, § 5001(a) (2005), establish hospital payment differentials to reward facilities that report how they fare on Medicare's performance measures. Beginning in fiscal year 2009, Medicare will pay hospitals differentially based on their performance on a variety of measures of quality, as well as their investment in medical information systems. Deficit Reduction Act, § 5001(b) (2005).

²⁸⁷ In 2005, Medicare initiated a pay-for-performance experiment (based on measures of quality in preventive care and management of chronic disease) involving 10 large group practices. Centers for Medicare and Medicaid Services, Medicare Begins Performance-Based Payments for Physician Groups: New Demonstration Program Tests Financial Incentives for Improved Quality and Coordination in Large Group Practices, Jan. 31, 2005, available at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1341> (accessed Oct. 4, 2007).

²⁸⁸ See *supra* note 241.

²⁸⁹ The most recent guidance document on coverage policy from the Centers for Medicare and Medicaid Services (CMS), the agency that administers Medicare, states: "Cost effectiveness is not a factor CMS considers in making NCDs [National Coverage Decisions]. In other words, the cost of a particular technology is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population through an NCD." Centers for Medicare & Medicaid Services, Guidance for the Public, Industry, and CMS Staff: Factors CMS Considers in Opening a National

arguably allows it to do so,²⁹⁰ but the usual alliance of doctors, hospitals, and drug and device companies has been firmly opposed. Still, there is reason for optimism. For the first time, Medicare is linking payment to compliance with clinical standards, thereby creating an incentive scheme that might someday be used to encourage cost-awareness across our fragmented system. Private payers are following suit, joining with each other – and with hospitals and medical groups – to seek common ground on quality measures and practice protocols.²⁹¹ So far, they have been no more willing than Medicare to openly count costs,²⁹² but they are forging collaborative arrangements²⁹³ that could someday be employed to give effect to cost-conscious protocols.²⁹⁴

Coverage Determination, Apr. 11, 2006; available at www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=6.

For an excellent review of the controversy over the potential role of cost in Medicare coverage decision-making, see generally Jacqueline Fox, *Medicare Should, but Cannot, Consider Cost: Legal Impediments to Sound Policy*, 53 BUFFALO L. REV. 577 (2005).

²⁹⁰ The Social Security Act, Title 18, § 1862 (a)(1)(A), states: “Notwithstanding any other provisions of law ... no payment may be made ... for items or services ... not reasonable and necessary for the diagnosis or treatment of illness or injury.” The term “reasonable” has been construed by some commentators to permit consideration of cost; others have read this provision more restrictively. Fox, *Medicare Should, but Cannot, Consider Cost*, *supra* note 291. Because Medicare has never explicitly balanced costs against benefits when promulgating national coverage rules, its authority to do so has not been litigated.

²⁹¹ “America’s Health Insurance Plans” (AHIP), the principal trade association representing private health plans, is combining clinical data from multiple plans – and from Medicare – to make it possible to assess the performance of hospitals and physicians nationwide on agreed-upon measures of health care quality. This aggregation of data will surmount a major obstacle to measurement of provider performance – the fact that providers report clinical data (for billing purposes) to multiple health plans, none of which, therefore, can assemble a complete picture of how well providers fare on quality measures. A consortium of health care industry stakeholders (including insurers, hospitals, group medical practices, and professional and trade associations) known as the “National Quality Forum” (NQF) will formulate quality measures, including standards of care for common medical problems, that will then be applied to the aggregated data to assess health care providers’ performance. The results of these assessments will be widely disseminated with three related purposes in mind: encouraging doctors and hospitals to do better, enabling health plans to reward providers based on performance, and allowing consumers to select providers based on quality. Robert Wood Johnson Foundation, *National Effort to Measure and Report on Quality and Cost-Effectiveness of Health Care Unveiled*, Oct. 3, 2007, available at <http://www.rwjf.org/newsroom/newsreleasesdetail.jsp?productid=22371&typeid=160> (accessed Oct. 4, 2007).

²⁹² Private health plans are beginning to collaborate with doctors and hospitals to develop standardized methods for tracking and comparing different providers’ costs for tests and treatments. *Id.* The avowed aim of this collaboration among stakeholders is to support patients’ (and payers’) efforts to shop for the least expensive (that is, most cost-effective) way to achieve a given therapeutic result. *Id.* But the collaborators in this endeavor have, so far, refrained from balancing benefits against costs when formulating quality-of-care benchmarks.

2. The Emergent Potential of Current Law

Awareness of these emergent possibilities can and should play a role in development of several areas of law that bear on cost and quality: these include antitrust and privacy doctrine, medical malpractice, and the law governing disputes over insurance coverage. Comprehensive discussion of the cost and quality implications of each of these areas of law is beyond my scope here, but I will offer a brief roadmap of potential problems and opportunities, from an emergent systems perspective.

a. Antitrust and Privacy Law Barriers to Information-Sharing?

Antitrust law barriers to clinical data-sharing among doctors, hospitals, and health plans for outcomes research purposes should be minimized, if indeed there are any.²⁹⁵

²⁹³ Interlocking consortia of private health plans, hospitals, medical specialty societies, and other health care industry stakeholders have formed over the past several years for the avowed purpose of reaching industry-wide agreement on the adoption and uses of quality-of-care benchmarks. These include the “AQA Alliance” (focusing on physician care), the “Hospital Quality Alliance” (HQA) (focusing on hospital care), and the “Quality Alliance Steering Committee” (meant to coordinate the efforts of the AQA Alliance and HQA). *See generally* AQA-HQA Collaboration – Quality Alliance Steering Committee, available at <http://www.aqaalliance.org/aqahqacollaboration.htm> (accessed Oct. 4, 2007). The Department of Health and Human Services (HHS) has participated in these consortia and indicated its intention to coordinate Medicare and private sector quality improvement efforts.

²⁹⁴ Health care reform proposals urged by President Bush and by Republican and Democratic candidates for the presidency in 2008 present additional emergent possibilities. The “consumer-directed” model (*see supra* notes 205, 206, 221), advanced by the Bush Administration and by Republican presidential candidates Rudolph Giuliani and Mitt Romney, would make insured patients more sensitive both to cost in general and to insurance contract provisions designed to encourage patients to seek care from providers who score high on performance measures. For example, a “consumer-directed” health plan might require a patient to pay much more out-of-pocket for diabetes or heart disease care from a doctor who scores below some threshold on relevant quality-of-care measures. If and when quality measures come to incorporate cost-benefit trade-offs, this tiering of insurance coverage, tied to provider performance, would strengthen doctors’ and patients’ incentives to accept these trade-offs.

Analogously, the insurance exchanges proposed by Democratic presidential candidates Hillary Clinton, Barack Obama, and John Edwards, *see* TAN 211-214, would require health plans to report their performance on quality-of-care benchmarks in order to sell coverage on these exchanges. If and when cost-benefit trade-offs are built into these quality measures, this prerequisite for market access would become a powerful lever for adoption of cost-conscious treatment protocols.

²⁹⁵ Whether such barriers are real or merely perceived is unclear. Leaders in academic medicine’s efforts to improve health care quality believe that antitrust law stands in the way. James J. Mongan, Robert E. Mechanic & Thomas H. Lee, *Transforming U.S. Health Care: Policy Challenges Affecting the Integration and Improvement of Care*, THE BROOKINGS INSTITUTION: HEALTH POLICY: ISSUES AND OPTIONS, Dec. 2006, available at http://www.brookings.edu/~media/Files/rc/papers/2006/1215healthcare_mongan/20061215_mongan.pdf. Collaborative setting of standards for purposes of collecting and sharing data has raised antitrust issues in

Privacy law protections should be construed with an eye toward the social importance of this research.²⁹⁶ The question of antitrust obstacles to collaboration for the purpose of *agreeing* on quality measures and clinical practice protocols is more complex. There is an obvious tension between antitrust principles, which promote competition on quality as well as price, and collaborative setting of quality benchmarks. Yet current antitrust doctrine leaves room for the argument that collaborative standard-setting can facilitate competition on quality by making it easier for consumers to comparison-shop.²⁹⁷ A comprehensive set of quality benchmarks, accompanied by comparative performance data, would empower patients to choose wisely from among competing doctors, hospitals, and health plans. This, in turn, would put market pressure on plans and providers to deliver greater value to consumers – the end result sought by antitrust law. There is a snarl of doctrinal and economic issues here, in need of disentangling by

other industries, but antitrust law has been open to arguments about the procompetitive impact of network economics. Medical antitrust law scholars who have considered this question tend toward the view that current antitrust doctrine poses no obstacles to industry collaboration on outcomes research. David A. Hyman, *Five Reasons Why Health Care Quality Research Hasn't Affected Competition Law and Policy*, 4 INT'L J. HEALTH CARE FINANCE ECON. 159 (2004). (Part of a special issue devoted to competition and health care quality); William Sage et al., *Why Competition Law Matters To Health Care Quality*, 22 HEALTH AFFAIRS 31 (2003).

²⁹⁶See Lawrence O. Gostin & James G. Hodge, Jr., *Personal Privacy and Common Goods: A Framework for Balancing Under the National Health Information Privacy Rule*, 86 MINN. L. REV. 1439, 1440 (2002) (arguing that “sharing data may be necessary to achieve important health purposes,” such as health research and public health, and urging that “health information privacy laws ... carefully balance the need for individual privacy with the benefits of using health data for the common good” State-of-the-art electronic security technologies, along with entry of clinical data in de-identified form (that is, without information that could be used to trace the data back to individual patients) prior to its aggregation, should provide high levels of privacy protection. But elimination of all risks to privacy is not a realistic goal, particularly in view of the proliferation of high-powered data-mining methods and the possibilities for illicit use of these and other techniques. Sharona Hoffman and Andy Podgurski, *In Sickness, Health, and Cyberspace: Protecting the Security of Electronic Private Health Information*, 48 B. C. LAW. REV. 331, 366 (2007).

²⁹⁷ See generally, “Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition,” U. S. Department of Justice and the Federal Trade Commission, April 17, 2007 and Business Review Letter from Thomas O. Barnett, Assistant Attorney General, U.S. Department of Justice, to Robert A. Skitol (Oct. 30, 2006), available at <http://www.usdoj.gov/atr/public/busreview/219380.pdf>.

antitrust scholars familiar with health care.²⁹⁸ But antitrust law can play a constructive role in the development of national standards of quality and value.²⁹⁹ Antitrust law should aim to distinguish between collaborative standard-setting that spurs competition to deliver clinical value and collusive efforts that exclude rivals and suppress evidence-based therapeutic innovation.³⁰⁰ By so doing, it can promote the emergence of cost-sensitive clinical practice norms and their dissemination through our fragmented health care system.

b. Tort Liability

²⁹⁸ Among the entangled issues are how to keep collaborative standard-setting from slowing the pace of therapeutic innovation, how to prevent anti-competitive abuse of standard-setting mechanisms (to exclude competing treatments and providers without scientific grounds for so doing), and the extent to which antitrust enforcement agencies and the courts should delve into the details of medical science and economics in order to make such judgments (alternative legal approaches include looking to procedural fairness as a surrogate for inquiry into whether standard-setting is anti-competitive as a substantive matter, and, in the extreme, outright rejection of industry-wide clinical practice protocols and other quality standards as anti-competitive).

²⁹⁹ Some market-oriented commentators hold a sharply different view. They question such standard-setting, arguing that industry-wide adoption of medical practice protocols and other quality norms is contrary to the letter and spirit of antitrust law because it prevents competing providers and health plans from marketing multiple tiers of quality. See Clark C. Havighurst, *Applying Antitrust Law to Collaboration in the Production of Information: The Case of Medical Technology Assessment*. L. & CONTEMP. PROBS., Spring, 1988, p. 341 (arguing that agreements among professional bodies to develop consistent positions on the value of tests and treatments deny consumers the welfare-enhancing benefits of competition). Consumer choice is enhanced, in this view, by allowing multiple levels of care, HAVIGHURST, HEALTH CARE CHOICES, *supra* note 9, and in the digital age there is no lack of market-generated information available to consumers to help them to comparison-shop for care. James C. Robinson, *The End of Asymmetric Information*, 26 J. HEALTH POLITICS, POLICY, & L. 1045, 1051 (2001). A rejoinder to this view, grounded in an analysis of antitrust doctrine, is beyond my brief here. But it would likely incorporate the near-impossibility of comparison-shopping (in the face of a cacophony of claims about quality) without broadly-accepted benchmarks, as well as the near-impossibility of maintaining multiple tiers of medical care when the same providers participate in many different health plans (*see supra* tan 238-244). More controversially, it might suggest that enabling providers and plans to offer multiple economic tiers of care should count for less, from an antitrust perspective, than does preservation of most other forms of consumer choice, since medical care is widely seen as a “merit good” – that is, something society distributes (or ought to distribute) based on criteria other than ability or willingness to pay. See Richard A. Musgrave, *Merit Goods*, in 3 THE NEW PALGRAVE: A DICTIONARY OF ECONOMICS 452-453 (J. Eatwell, M. Milgate, & P. Newman eds. 1987) (setting out a definition of “merit good” and including health care as an example). Possible grounds for treating health care as a “merit good,” to be distributed (like education and fire protection) more equitably than most products and services, include: (1) the moral belief that all people should have access to high-quality care as a matter of right or human dignity, and (2) the paternalistic concern that people will undervalue some forms of medical coverage and care – *e.g.* preventive services and long-term management of silent but eventually devastating illnesses like diabetes and hypertension.

³⁰⁰ See *supra* note 298.

Medical tort law's approach to health care quality and value is a relic of past, disproven premises about the practice of medicine. It is thus an obstacle to the emergence of more evidence-based, cost-sensitive clinical care. The malpractice system's greatest failing, from a quality and value perspective, is its reliance on clinical practitioners to specify standards of care.³⁰¹ This deference to doctors is a departure from negligence law's general requirement of "reasonable" conduct, a requirement typically understood in utilitarian terms, as a duty to take precautions so long as benefits outweigh risks and costs.³⁰² Negligence law, to be sure, often looks to common practice within an industry as the measure of reasonableness. But the justification for doing so is that the market works well as a cost-benefit³⁰³ balancing device – well enough to treat industry custom as the standard of care.³⁰⁴

³⁰¹ The medical tort system's many failings have been widely-discussed elsewhere. These include its lack of sensitivity and specificity as a tool for detecting negligence (studies that compared results from medical chart reviews of hospitalizations with the subsequent incidence of malpractice suits, settlements, and judgments arising from these hospitalizations have found little overlap between episodes of negligence discerned by chart reviewers and lawsuits brought, settled, or won), its limited deterrent impact on substandard practitioners, and its failure to compensate the vast majority of victims of negligence. Michelle M. Mello and David M. Studdert, *The Medical Malpractice System: Structure and Performance*, in *MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM* 11-29 (W. Sage & R. Kersh eds. 2006). Moreover, malpractice liability costs, combined with insurance market dysfunctions, have at times pushed liability insurance premiums high enough to measurably reduce patients' access to physicians in high-risk specialties like obstetrics and neurosurgery. OFFICE OF THE ASS'T SECRETARY FOR PLANNING & EVALUATION, U.S. DEPT. OF HEALTH & HUMAN SERVICES, *ADDRESSING THE NEW HEALTH CARE CRISIS: REFORMING THE MEDICAL LITIGATION SYSTEM TO IMPROVE THE QUALITY OF HEALTH CARE* (2003) available at <http://aspe.hhs.gov/daltcp/reports/mediab.htm#sectionI> (accessed April 3, 2008); *But see* U.S. General Accounting Office, *Medical Malpractice: Implications of Rising Premiums on Access to Health Care* [GAO-03-836]. Washington, DC: General Accounting Office, 2003 (finding insufficient evidence to support claims that high malpractice insurance premiums are causing physicians in some specialties to withdraw from practice, reducing patients' access to care).

³⁰² *See, e.g.*, RESTATEMENT (SECOND) OF TORTS §283 (defining negligence law's standard of conduct as "that of a reasonable man under like circumstances") and RESTATEMENT (SECOND) OF TORTS §§ 291-293 (defining reasonableness in terms of the balance between the risk and the utility of an actor's conduct). *But see* Heidi Li Feldman, *Prudence, Benevolence, and Negligence: Virtue Ethics and Tort Law*, 74 *CHI.-KENT L. REV.* 1431 (2000) and Heidi Hurd, *The Deontology of Negligence*, 76 *B.U. L. REV.* 249 (1996) (arguing that negligence law in fact recognizes non-utilitarian concerns such as fairness and respect for persons as ends).

³⁰³ I use "cost" here as shorthand for both risk and cost.

³⁰⁴ *See* James A. Henderson and John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 *CORNELL L. REV.* 1382, 1388 (1994) (arguing that courts

For medical care, this justification has broken down, if indeed it was ever valid.³⁰⁵ It is now widely recognized that physicians know little about the efficacy of most tests and treatments,³⁰⁶ that they often don't follow evidence-based clinical protocols even when such guidance exists,³⁰⁷ and that insurance encourages provision of care with few benefits relative to cost.³⁰⁸ Medical custom is thus a poor guide to socially optimal standards of care.

Malpractice law's reliance on custom locks in extant clinical practice norms that are products of these market failures. This doesn't benefit practitioners, since absent evidence-based answers to most clinical questions, different doctors treat the same medical problems in different ways.³⁰⁹ The result is Russian roulette in the courtroom when things go wrong and patients sue. If there are multiple therapeutic options and the one chosen turns out badly,³¹⁰ the plaintiff can find a physician-expert witness³¹¹ who

should look to industry custom to determine negligence when networks of contractual bargaining suffice take all affected interests into account).

³⁰⁵ It probably never was. Through the mid-20th century, most commentators on health care law and policy believed that doctors' scientific knowledge and patient-centered ethics ensured that (barring negligence) they would exercise medical judgment to which society, including the legal system, should defer. Kenneth Arrow captured this set of assumptions in his oft-cited 1963 article contending that physicians promise patient-centeredness to the public in order to win trust (and business) in the face of patients' inability to evaluate the effectiveness of medical care. Arrow assumed – with undue optimism, it turned out – that physicians *did* know how well their tests and treatments worked, and that they largely delivered on their promise to abjure economic incentives to act contrary to the interests of their patients. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, *supra* note 81.

³⁰⁶ See *supra* TAN [redacted] - [redacted].

³⁰⁷ See *supra* TAN 32 - 34.

³⁰⁸ Commentators have borrowed the term “moral hazard” from the casualty insurance context to convey the impact of insurance on medical spending. I have elsewhere questioned the analogy between increased risk-taking by people with fire or auto insurance and increased health spending by people with medical insurance, Bloche, *Invention*, *supra* note 9, but it is plain that medical insurance promotes overspending on health services, relative to people's other wants and needs.

³⁰⁹ The Dartmouth Atlas of Health Care, *supra* note 35.

³¹⁰ If a treatment yields a bad result because it was administered ineptly – say, the proverbial sponge left in the surgical patient or an overdose of a dangerous drug – negligence is open-and-shut, not a matter of Russian roulette (unless the alleged ineptitude requires a borderline call). Such cases matter because it is important to deter ineptitude and to adequately compensate its victims, but they are not my focus in the above discussion because their health care policy import is comparatively small. They involve errors of execution, not larger conflicts over how health care resources should be spent.

would have opted for one of the others. Malpractice law lets such testimony in, so long as the witness qualifies based on his or her credentials. The law puts testimony about the appropriate standard of care to the test of professional acceptance,³¹² but it does not subject such testimony to *Daubert*-style scrutiny of its scientific foundations.³¹³ And in most jurisdictions, it bars the admission of evidence-based practice protocols (by treating them as hearsay³¹⁴) unless an expert witness testifies as to their content. When evidence-based protocols find their way into court, they are usually given no more weight than other medical testimony,³¹⁵ however flimsy the science base on which this testimony rests.

Thus doctors who follow these protocols are as vulnerable to the liability roulette wheel as are those who adhere to practice norms that lack a scientific basis. The

³¹¹ Expert testimony is required in all jurisdictions to establish elements of the plaintiff's case that are not "a matter of common knowledge" or within the experience of lay people. *See generally*, Michael A. DiSabatino, Annotation, [Admissibility and Necessity of Expert Evidence as to Standards of Practice and Negligence in Malpractice Action Against Attorney](#), 14 A.L.R. 4th 170 (1982).

³¹² Legal tests for professional acceptance vary by jurisdiction: formulations in wide use include the requirement that a standard of care be upheld by a "consensus of opinion" among physicians, that it be adhered to by the "ordinary practitioner," that it be followed by at least a "respectable minority" of physicians, and that it be what a "reasonable and prudent" doctor would undertake under similar circumstances. *See* 61 AM. JUR. 2d *Physicians, Surgeons, Etc.* § 189 (2007); Theresa Porter, *Cause of Action Against Physician or Surgeon for Breach of the Duty of Attention and Care*, 21 CAUSES OF ACTION 1 (2007); *Jackson v. Burnham*, 39 P. 577, 580 (Colo. 1895) ("When a particular mode of treatment is upheld by a consensus of opinion among the members of the profession, it should be followed by the ordinary practitioner; and if a physician sees fit to experiment with some other mode, he should do so at his peril."); *Boyanton v. Reif*, 798 P.2d 603 (Okl. 1990) (The question in professional malpractice suits is not whether a physician has made a mistake, but whether he has used "ordinary care"-that which is ordinarily exercised by his peers.); *Jones v. Chidester*, 610 A.2d 964 (Pa. 1992) (the correct standard for avoiding malpractice liability is that the physician "followed a course of treatment advocated by a considerable number of recognized and respected professionals in his given area of expertise."); *Harris v. Robert C. Groth, M.D., Inc., P.S.*, 663 P.2d 113 (Wash. 1983) ("The plaintiff in an action for professional negligence must show that the defendant health care provider failed to exercise that degree of care, skill, and learning expected of a *reasonably prudent* health care provider in the profession or class to which he belongs.").

³¹³ *See supra* note 140.

³¹⁴ *See* JOHN W. STRONG ET AL, MCCORMICK ON EVIDENCE S321 (4th ed. 1992). In a minority of jurisdictions, practice protocols are admissible under the learned treatise exception to the hearsay rule. Albert Tzeel, *Clinical practice guidelines and medical malpractice: Guidelines gaining credibility in courtrooms, may eliminate expert testimony*, [PHYSICIAN EXECUTIVE](#), [March, 2002](#).

³¹⁵ *See* Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POLITICS, POLICY, & L. 327 (2001) (discussing judicial reluctance to give clinical practice protocols greater weight than expert testimony concerning professional custom).

opposing side need only produce an expert prepared to claim that an alternative therapy is widely-employed and would have yielded a better outcome. Then jurors get to choose one side (unless the judge does so for them³¹⁶), based on professional acceptance, not scientific rigor. The unfortunate consequence for health policy is that early adopters of an evidence-based protocol face enhanced liability risk if the protocol departs from common practice. Prevailing malpractice doctrine is thus at odds with its supposed justification – the utility of medical custom as a measure of reasonable care.

From an emergent systems perspective, there is thus a strong case for privileging evidence-based practice protocols over professional custom. Opportunism knocks: health care providers have taken an interest in practice protocols as a way to ward off lawsuits,³¹⁷ making them potential supporters of greater legal deference to such protocols. This strategy may or may not shield doctors and hospitals from suits,³¹⁸ but provider support for it could leverage reformers' efforts to incorporate science-backed protocols into legal standards of care.

In the near term, doing so is unlikely to restrain rising costs, except insofar as compliance with such protocols averts adverse clinical outcomes that are expensive to treat. Today's practice protocols rarely take cost into account, at least explicitly. But if and when practice protocols evolve toward greater cost-sensitivity, their integration into legal standards of care would ease the way toward wide acceptance of clinical cost-benefit trade-offs – in medical malpractice law and in society more generally. There is

³¹⁶ A trial judge can do so, of course, by determining that one or the other side's expert has stated the correct standard of care as a matter of law (i.e. that no reasonable juror could conclude otherwise).

³¹⁷ Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PENN. L. REV. 645, 666 (2001).

³¹⁸ Although considerable research has addressed the impact of damage caps, shortened statutes of limitations, and other much-debated reforms on the incidence of malpractice suits and the size and frequency of settlements and awards, no study has decisively addressed the influence of clinical practice protocols on these variables.

no guarantee of such acceptance; there could just as well be popular backlash against the courts for countenancing rationing. But incorporating cost-sensitive, science-based protocols into malpractice doctrine will be necessary to keep this body of law from emerging as a formidable obstacle to the balancing of health care's therapeutic benefits and economic burdens.

Detailed consideration of how evidence-based, cost-sensitive protocols might be incorporated into malpractice law is beyond my scope here.³¹⁹ Three principles, though, should guide efforts to nudge malpractice doctrine in this direction – if malpractice law is to abet progress toward cost-benefit trade-offs that Americans can tolerate. First, protocols should be science-based. By this, I don't mean that they should be put to the steep tests required by the research community to treat hypotheses as established.³²⁰ The fractal complexity of clinical outcomes research³²¹ precludes gathering enough data to rest most medical decisions firmly on publishable science. A more realistic requirement is that protocols rest on clinical premises accepted by researchers, based on the best available data, as more probable than not.³²²

Second, the cost-benefit (and health-health) trade-offs embedded in a protocol should be both explicit and broadly-accepted by society. Covert rationing is not

³¹⁹ See Mello, *Of Swords and Shields*, *supra* note 317, for a review of the possibilities.

³²⁰ Strictly speaking, scientists can never say that their hypotheses are *proven* by experiments; they can only judge that a hypothesis has not been *disproven*. KARL POPPER, *THE LOGIC OF SCIENTIFIC DISCOVERY* (Routledge 14th ed. 2002) (1934). In practice, though, researchers treat a hypothesis as *established* when a sufficient number and variety of experiments (sufficiency here is a normative judgment) yield data *consistent with* that hypothesis.

³²¹ See *supra* TAN 229-232.

³²² Use of a "more probably than not" standard here reflects the reality that a clinician must *decide*, one way or the other. Since a decision must be made, any guidance with more than a 50 % prospect of being "right" is useful. Judicial assessment of whether the factual premises undergirding a protocol are "more probable than not" will call for inquiry into both the reasoning behind them and the extent to which they are accepted by the research community. This is a demanding endeavor, but no more so than is the assessment required when courts engage in evidentiary gatekeeping under Daubert. Cassandra H. Welch, Note, *Flexible Standards, Deferential Review: Daubert's Legacy of Confusion*, 29 HARV. J.L. & PUB. POL'Y 1085 (2006).

sustainable. It is inexorably exposed by America's entrepreneurs of revelation – plaintiffs' lawyers, journalists, congressional investigators, and others who reap rewards by minding the gaps between what those in authority say and do.³²³ To win wide-spread, *sustained* acceptance for cost-benefit trade-offs, authors and adopters of practice protocols will need to state their premises about the value of life and various states of disability.³²⁴

Doing so won't guarantee public acceptance. Americans will first have to come to terms with the need to say no to some of medicine's benefits – a need most of us aren't willing to acknowledge.³²⁵ But if and when growing cost pressures bring about broad acknowledgment of the need to set limits, protocol development processes that engage a wide range of participants will stand the best chance of yielding trade-offs that endure. Industry-wide collaboration along these lines – involving doctors, hospitals, and health plans – is already underway. So far, this collaboration has focused on the setting of quality-of-care standards³²⁶ without regard for cost.³²⁷ But, like brain circuits that take on new behavioral tasks as evolution progresses, the organizations that oversee this collaboration could become venues for the weighing of benefits and costs.³²⁸

³²³ Bloche, *Trust and Betrayal*, *supra* note 250, at 947. Popular backlash in the late 1990s against covert rationing by aggressively-managed health plans is illustrative. *Id.*

³²⁴ Government agencies have, on occasion, been forthright about these premises without unleashing popular backlash. The Federal Aviation Administration's basing of its aviation safety rulemaking on dollar values for lives lost and degrees of injury inflicted is illustrative. GRA INC., ECONOMIC VALUES FOR FAA INVESTMENT AND REGULATORY DECISIONS: A GUIDE, §2-2 (2004), available at http://www.faa.gov/regulations_policies/policy_guidance/benefit_cost/media/050404%20Critical%20Values%20Dec%2031%20Report%2007Jan05.pdf (accessed Oct. 12, 2007). Popular backlash, admittedly, will be more likely if such dollar values are built into clinical practice protocols, since medical care (unlike FAA and other health and safety regulation) involves identified lives.

³²⁵ See *supra* TAN 245-253.

³²⁶ See *supra* notes 291, 292, 293.

³²⁷ See *supra* note 292.

³²⁸ See *supra* TAN 293-294.

Still to develop are mechanisms for incorporating the values and preferences of health care consumers.³²⁹ For reasons I set forth earlier, the favored mechanism of most market-oriented health law commentators – consumer choice from among health plans with multiple cost-benefit trade-off tiers – faces formidable cognitive obstacles and moral objections.³³⁰ These cognitive and moral factors favor maintenance of a single cost-benefit trade-off tier for liability purposes. This trade-off policy is likely to be a fuzzy compromise between two starkly-different consumer perspectives – that of health plan purchasers who economize from behind a “veil of ignorance” concerning their future medical needs,³³¹ and that of sick people who want all the beneficial care they can get.³³² Arguably, industry-wide collaboration that balances the perspectives of providers and health plans can serve as a crude stand-in for formalized consumer input. Since health plans profit by paying for less, while doctors and hospitals have incentives to do more, their competing interests approximate the divergent perspectives of consumers before and after the onset of illness.

Third, malpractice law shouldn’t incorporate practice protocols inflexibly, as irrebuttable presumptions. Medicine’s irreducible variability – the fractal complexity of

³²⁹ Many such mechanisms have been proposed, including public opinion surveys, focus groups, presentation of hypothetical decision-making scenarios to research subjects, and elegant formulae that take account of data derived from these sources. So far, none of these approaches has gained institutional purchase, a reality that reflects our national unwillingness to acknowledge cost-benefit and health-health trade-offs in medical care.

³³⁰ See *supra* note 300.

³³¹ This “veil” is, in truth, translucent, not opaque. Chronic disease, genetic and behavioral risk factors, and other health information known to consumers when they purchase medical coverage reduce their inclinations to economize on some kinds of care – the care they anticipate needing.

³³² From an Olympian social welfare perspective, such a fuzzy compromise is unsatisfactory: the perspective of the consumer who economizes from behind the medical “veil of ignorance” is preferable. But as a practical matter, the perspective of the sick person in need will always have countervailing power: our hard-wired empathy (and the politics of social solidarity) will have a great deal of influence on the clinical practice norms adopted by physicians and the law. Cf. Bloche, *Invention*, *supra* note 9, at 272 (discussing compromise between patients’ perspectives on health care resource allocation *ex ante* and *ex post* the onset of illness).

clinical situations – ensures that even protocols with powerful outcomes research behind them will merit exceptions. Outcomes research is necessarily population-based, making it inevitable that some patients will be outliers. Malpractice law can accommodate this by treating protocols as rebuttable presumptions, to be overridden upon an evidence-based showing that a different approach made sense in a particular case.³³³

Tort law can make another contribution to health care quality and value by incorporating state-of-the-art, systems approaches to the management of medical services. This will require moving beyond blame for individuals, toward shared duties to disseminate and adopt evidence-based protocols, coordinate diagnosis and treatment in complex cases, employ information systems that avert mistakes, and report and learn from errors.³³⁴ For example, a doctor's failure to prescribe beta blockers or aspirin to a heart attack patient upon discharge from the hospital should be treated not just as negligence on her part, but as breach of duty by the hospital – if the hospital has not made these medications part of its post-heart-attack protocol and adopted monitoring practices to minimize the risk of their omission. And a nurse's misunderstanding of a doctor's hard-to-read handwritten order, resulting in a fatal overdose, should be understood not merely as the nurse's (or the doctor's) negligence, but as the hospital's breach of its duty to employ reasonably safe information systems.

³³³ By "evidence-based" here, I do not mean scientific proof that measures up to Daubert standards of admissibility (an unrealistically high prerequisite, since comparative effectiveness research cannot anticipate and keep pace with every potential exception to established protocols). A more pragmatic approach would be to require evidence sufficient to show that a prudent physician would, more probably than not, have departed from the protocol under the circumstances. Sharpening this test is a task beyond my scope here. Doing so will be complicated by the tension between aspirations to make medical care more science-based and more responsive to individual differences.

³³⁴ See *supra* TAN 111, 265-266.

Rechanneling medical liability along these lines would help to promote the emergence of a better-coordinated, more efficient health care system.³³⁵ Some have urged enterprise liability as a means of improving health care quality.³³⁶ Were our medical system more vertically-integrated, the case for this approach would be powerful.³³⁷ But our fragmented system presents high barriers to the transmission of enterprise liability's deterrence signals from defendants (health plans or hospitals) to individual care-givers.³³⁸ And, since malpractice settlements and judgments constitute less than one percent of U.S. health care spending,³³⁹ enterprise liability's incentives would not suffice to bring about the vertical integration of American health care.³⁴⁰

³³⁵ There are numerous open questions within the interstices of this proposition: these include whether health plans (which typically contract with many hospitals and physicians but don't exercise managerial control over them) should share in such liability, whether hospitals should ever share responsibility for their staff physicians' negligent treatment of outpatients (courts have thus far said no), and how liability should be distributed among clinical caregivers and institutions (especially hospitals) with system-wide responsibility. Developing rich responses to these questions is beyond my scope here.

³³⁶ E.g. PAUL C. WEILER, *MEDICAL MALPRACTICE ON TRIAL* (1991).

³³⁷ Organizations that integrated health care financing, physician services, and hospital care would be best-situated (and most motivated) to adopt systems approaches to patient safety and medical care quality in response to enterprise liability. For an early, comprehensive argument on behalf of enterprise liability for medical malpractice, see Kenneth S. Abraham and Paul C. Weiler, *Enterprise Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381 (1994) (preferring hospitals to health insurers as objects of enterprise liability).

³³⁸ In theory (from a Coasean perspective), the degree of fragmentation should make no difference: industry actors should bargain toward allocations of liability to the lowest-cost risk-avoiders, regardless of starting-point (or default) liability rules. In practice, this classic story breaks down in the health care industry for many reasons. These include the transaction costs involved in such bargaining (among vast numbers of actors), the difficulty of pinpointing lowest-cost risk avoiders when risk is the product of collective efforts by independent industry actors (e.g. multiple specialists in separate practices who treat the same patient), and cultural factors (e.g. doctors' reluctance to forgo professional autonomy by acceding to hospitals' or health plans' supervisory authority in exchange for avoidance of the threat of liability).

Thus the choice of default liability rules matters greatly in health care. And in our fragmented system, hospitals and health plans generally lack the supervisory authority or bargaining leverage necessary to respond to enterprise liability's incentives by obliging physicians to adopt state-of-the-art, systems approaches to medical care. See *supra* TAN 254-263.

³³⁹ Gerald F. Anderson et al., *Health Spending in the United States and the Rest of the Industrialized World*, 24 Health Aff. 903, 910 (2005) ("The cost of defending U.S. malpractice claims, including awards, legal costs, and underwriting costs, was an estimated \$6.5 billion in 2001 – 0.46 percent of total health spending.").

³⁴⁰ Moreover, as a practical matter, doctors, hospitals, and health plans strongly oppose enterprise liability. Doctors equate giving up the "right to be sued," as one put it, with surrendering their authority and autonomy to insurance or hospital bureaucrats, and hospitals and health plans fear that jurors will see them as "deep pockets." Randall R. Bovbjerg and Robert Berenson, *Enterprise Liability in the Twenty-First*

More realistic – and more doctrinally modest, and thus suitable for judges to do – would be to extend traditional joint-and-several liability to encompass a duty to adopt proven systems approaches to improvement of quality and avoidance of error.³⁴¹ The provider’s personal fault would remain part of the picture, but the failure of health care organizations to adopt information systems, management strategies, and other quality improvement methods that might have averted error³⁴² would subject them to liability. This would complicate litigation and settlement to some degree, but mounting evidence of the risk avoidance achievable through state-of-the-art systems approaches³⁴³ weighs in favor of accepting this cost.³⁴⁴

c. Health Insurance Contracts and “Medical Necessity”

The law governing disputes over medical coverage is more consequence than cause of American society’s reluctance to accept limits on beneficial care.³⁴⁵ Nearly all health insurance contracts employ the term “medical necessity” as their standard for coverage, and Americans continue to see this term as a promise to pay for care whenever

Century, in *MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM* 219, 230-231 (W. Sage & R. Kersh eds. 2006).

³⁴¹ The legal foundations for such a duty are already in place. Since the mid-1960s, courts have held that hospitals have duties to take reasonable care in reviewing the credentials of staff physicians (including those who are independent contractors rather than employees) and monitoring doctors’ and nurses’ ongoing performance. Lee J. Dunn, Jr., *Hospital Corporate Liability: The Trend Continues*, 8 *J. Law, Med. Ethics* 5, 16 (1980) Updating this duty to encompass adoption of systems approaches to quality improvement would be a small doctrinal step.

³⁴² Organizations subject to this duty would include health plans, hospitals, group medical practices, and all others in position to reduce the risk of error by adopting systems approaches.

³⁴³ INSTITUTE OF MEDICINE, *TO ERR IS HUMAN*, *supra* note 2, at 61.

³⁴⁴ Any such extension of institutional liability should be accompanied by empirical study of both its costs and its impact on the incidence of error.

³⁴⁵ Some advocates of minimally regulated medical markets assert otherwise, contending that courts’ lack of deference to insurers’ coverage denials is a large obstacle to health care cost containment. *E.g.* HAVIGHURST, *HEALTH CARE CHOICES*, *supra* note 9, at 115. They are right about judges’ lack of deference, but in my view, judges’ attitudes toward nay-saying by health plans reflect our society’s unwillingness to tolerate the withholding of beneficial care. *See supra* note 300.

its expected benefits outweigh the clinical risks.³⁴⁶ Courts no longer defer blindly to treating doctors' determinations of medical need,³⁴⁷ but the law still looks to professional norms to give content to this formless term. In 40 states, independent medical review schemes rely on physician panels to rule on medical necessity, based on professional practice.³⁴⁸ Extant clinical practice is likewise the touchstone when courts confront medical necessity disputes, whether as breach-of-contract or tort claims.³⁴⁹ As the 1990s backlash against managed care underscores, Americans are not ready to recognize medical necessity as warrant for withholding care, so long as expected benefits outweigh clinical risks. But the law governing coverage disputes could support the emergence of cost-sensitive, evidence-based clinical protocols by permitting insurers to adopt them in lieu of traditional "medical necessity" clauses. A cautious approach is in order: courts should not accede to contractual departures from long-standing consumer expectations³⁵⁰ absent clear explanation of the terms of coverage.³⁵¹ Contract language allowing health

³⁴⁶ To be sure, health insurance contracts also contain a wide array of specific exclusions and limitations – for example, no coverage for cosmetic surgical procedures and limited numbers of psychotherapy sessions per year. Legal disputes over these exclusions and limitations are much less common than are disputes over "medical necessity." One type of exclusion, though, does occasion considerable conflict – non-coverage for "investigational" or "experimental" treatments.

³⁴⁷ See *supra* TAN 85.

³⁴⁸ See *supra* TAN 95-97 and note 118.

³⁴⁹ These disputes present as breach-of-contract cases when patients (or providers) sue insurers to obtain payment after care has been provided or to secure pre-authorization of payment in order to proceed with treatment. They present as tort cases when refusal to pre-authorize care has led to denial of care, resulting (allegedly) in injury. ERISA pre-empts these state law claims when employers provide coverage. But patients with employment-based coverage can obtain payment for care under ERISA after prevailing in state-level independent medical review proceedings. *Rush Prudential HMO*, *supra* note 96, at 359.

³⁵⁰ This deference to long-standing expectations reflects: (1) appreciation of the fact that people buy medical coverage (and other kinds of insurance) in large part for the sense of security that it offers, and (2) acknowledgment that most insurance subscribers have no role in the drafting or negotiation of the specific provisions of insurance policies. This accords with insurance law's special regard for "the reasonable expectations of the insured." See generally Kenneth S. Abraham, *Judge-Made Law and Judge-Made Insurance: Honoring the Reasonable Expectations of the Insured*, 67 VA. L. REV. 1151 (1981).

³⁵¹ Clarity about health plan terms that depart from consumer expectations requires more than the use of language readily accessible to the average person; plan marketing procedures should ensure that such terms are communicated to potential subscribers in vivid, high-visibility fashion. Coverage exclusions, in

plans to weigh therapeutic benefits against costs should explain trade-off principles in plain language.³⁵² Clinical protocols need not be written into the contract³⁵³; it should suffice to incorporate them by reference. But the cost-benefit trade-offs that underlie each protocol should somewhere be made explicit,³⁵⁴ and they should be consistent with the trade-off principles set out in the contract.

One might imagine hybrid contracts, containing traditional “medical necessity” clauses modified by language incorporating some evidence-based protocols – for example, all protocols adopted by one or another of the industry-wide collaborations I discussed earlier.³⁵⁵ Given the incompleteness of the science base for medical practice, total replacement of “medical necessity” (and, thus, deference to customary practice) by clinical protocols is impracticable – and will remain so for the foreseeable future.

Insurers might or might not offer these cost-sensitive contractual formulations, and consumers might or might not accept them in exchange for lower premiums. But if such

particular, should be conveyed in concrete language, perhaps accompanied by examples of tests and treatments covered or excluded under common circumstances. Bloche, *Invention*, *supra* note 9, at 70.
³⁵² *Id.* The FAA’s explicit valuation of life – and of several levels of injury and disability – in dollar terms, GRA INC., ECONOMIC VALUES FOR FAA INVESTMENT AND REGULATORY DECISIONS, *supra* note 324, offers one model for such clarity. As with other limits on medical coverage that depart from consumer expectations, *see supra* note 351, such valuations – and how they are to be incorporated into clinical protocols – should be presented clearly, in vivid, high-visibility fashion, in health plan marketing materials, not merely in the “small print” of insurance contracts.

Health plans should also be clear, in their contracts, about how the protocols they adopt treat scientific uncertainty concerning the efficacy of tests and treatments. Do they, for example, rely on best estimates of efficacy by protocol drafters (including leading researchers in a specialty), or do they reject tests and treatments outright when these have not yet been scientifically shown to work? If plans take the later, more aggressive course, they should advise consumers in plain language that many therapies in wide use lack scientific proof of efficacy and thus will not be covered. Bloche, *Invention*, *supra* note 9, at 70. An in-between course that plans could take is to cover widely-used clinical measures based on best estimates of efficacy by protocol drafters, but to insist on scientific evidence of efficacy for *new* clinical interventions.

³⁵³ To require that they be set out in full in health insurance contracts could turn these contracts into multi-volume medical treatises – hardly a way to make them understandable to subscribers.

³⁵⁴ It should suffice for protocol developers to state the cost-benefit trade-off rules upon which protocols rely. The industry-wide protocol development collaborations now getting underway, *see supra* notes 291 & 293, offer an opportunity in this regard: each collaboration could adopt a common cost-benefit trade-off standard for the protocols it adopts. This would enable health plans to adopt packages of protocols that rest on compatible trade-offs – trade-offs that are also consistent with the resource allocation principles articulated in plans’ contracts with subscribers.

³⁵⁵ *See supra* notes 291 & 293.

plans emerge, the law should enable them, rather than stifling them by subjecting coverage denials to review based on customary practice when denials rest on evidence-based, cost-sensitive protocols.

3. Expectations, Incentives, and the Evolution of Medical Technology

The above-discussed adjustments to current law have large potential to speed the emergence of cost-sensitive clinical practice if and when Americans accept the need to limit beneficial care for the common good. But so long as society rejects such limits, law cannot impose them. Health plans won't set them, and providers won't abide by them.³⁵⁶ Still, there are measures that government can take to slow the escalation of technology-intensive medical spending. Emergent systems thinking suggests an evolutionary strategy, anchored in people's different expectations about treatments that are technically feasible now and those that might arise as medicine advances. Put simply, most of us bristle at the prospect of being denied the benefits of today's health care on account of cost, but we are not made livid by our lack of access to the technologies of the future.³⁵⁷ We *hope* for cures to diseases that terrify us, and some of us feel rage or despair over the blind cruelty of illnesses that wreck the lives of loved ones or end them prematurely. Yet we don't rail against health plans, providers, and public officials because they don't deliver the startlingly-effective care "Dr. McCoy" gives his "Star Trek" shipmates.

This expectations gap constitutes a cost-control opportunity that does not depend on widespread willingness to ration contemporary medicine's benefits. By reining in the

³⁵⁶ Market forces will drive health plans and providers to eschew them, as the late 1990s backlash against managed care organization's rationing methods illustrates. *See supra* TAN 221 - 225.

³⁵⁷ Put differently, our anchoring heuristic for the health care we expect is the medical technology currently available. People alive at the dawn of the 20th century didn't take umbrage at the unavailability of antibiotics (which didn't appear until the 1930s), and we don't bristle today because the gene therapies of the future aren't yet on pharmacists' shelves.

development of ever-more-expensive technologies, we can restrain future spending growth without saying no to beneficial care for identified patients now. An obvious worry about this strategy is the risk of retarding clinical breakthroughs – advances that yield high value, relative to cost, and that are thus worth paying for even if they raise medical spending as a portion of our national wealth.³⁵⁸ But there is a fortuitous answer to this problem. Clinical breakthroughs tend to result from leaps in *biological* understanding of disease – advances in chemistry and physiology that open the way for elegant, decisive interventions. Penicillin, which destroys bacterial cell walls, is perhaps the best-known example. A more recent illustration is the revolution in our understanding of lipid metabolism,³⁵⁹ which opened the way for development of the “statin” drugs that tens of millions of Americans take to slow the growth of artery-clogging atherosclerotic plaque.³⁶⁰ Therapies that target mechanisms of disease in such elegant fashion tend to be relatively inexpensive to provide, once the basic science that supports them has been paid for.

By contrast, our most costly treatments – those that Lewis Thomas famously termed “half-way technologies”³⁶¹ – tend to rest on comparatively crude understandings of the biology of disease. They are, paradoxically, marvels of engineering, electronics,

³⁵⁸ See CUTLER, YOUR MONEY OR YOUR LIFE, *supra* note 62 (reviewing health services research that has identified tests and treatments worth paying for).

³⁵⁹ Nicole Kresge et al., *30 Years of Cholesterol Metabolism: the Work of Michael Brown and Joseph Goldstein*, 281 J. OF BIOLOGICAL CHEMISTRY 25 (2005).

³⁶⁰ The “statin” medications work by inhibiting an enzyme that catalyzes one of the steps in cholesterol synthesis. This reduces the level of low-density lipoproteins (so-called “bad cholesterol”) in the blood, which, in turn, slows, stops, and under some conditions reverses the formation of atherosclerotic plaque. Dominic S. Ng, *The Role of Statins in Oxidative Stress and Cardiovascular Disease*, 5 CURRENT DRUG TARGETS - CARDIOVASCULAR & HAEMATOLOGICAL DISORDERS 165 (2005).

³⁶¹ LEWIS THOMAS, LIVES OF A CELL: NOTES OF A BIOLOGY WATCHER 36 (1974).

and materials science, and of modest, often minimal medical benefit.³⁶² Examples include drug-coated stents designed to keep atherosclerotic arteries open,³⁶³ high-technology life support,³⁶⁴ and last-ditch radiation and chemotherapy regimens meant mainly to sustain hope. Such treatments account for much of the outpouring of medical spending that occurs in the last months of life, in surgical suites, intensive care units, and elsewhere. They are expensive because they are both technology-intensive and clinically indecisive. They employ costly, complex equipment and highly-trained, well-paid personnel. And their inability, in most cases, to make more than a modest therapeutic difference leads, perversely, to their intensive and sustained (rather than one-shot) use. In medicine, as in warfare, decisive victory is cheaper than drawn-out struggle.

A rational incentive scheme for therapeutic advance would reserve its greatest rewards for those technologies most likely to add clinical value. But the American health care system rewards the adoption of new technologies with little regard for value.

Physician time spent performing invasive, technology-intensive procedures is much better compensated than is time spent counseling patients, consulting medical journals, or

³⁶² When I characterize their benefits as modest, I mean modest in the aggregate, relative to cost. Such technologies do, in some cases, add years to people's lives and diminish suffering and disability. Examples include angioplasty during the first 12 hours after a heart attack, Albert Schömig et al., *Mechanical Reperfusion in Patients with Acute Myocardial Infarction Presenting More than 12 Hours from Symptom Onset*, 293 JAMA 2865 (2005) (finding that within the 12-48 hour time angioplasty can positively affect long-term outcomes); Judith S. Hochman et al., *Coronary Intervention for Persistent Occlusion after Myocardial Infarction*, 355 NEW ENG. J. MED. 2395 (2006) (finding that addition of angioplasty to drug intervention after late presentation (three to twenty-eight days) of heart attack did not significantly change long-term outcomes for patients), and replacement of severely arthritic hips and knees with artificial joints. NIH Consensus Development Panel on Total Hip Replacement, *Total Hip Replacement*, 273 JAMA 1950 (1995) ("Total hip replacement is an option for nearly all patients with diseases of the hip that cause chronic discomfort and significant functional impairment. Most patients have an excellent prognosis for long-term improvement in symptoms and physical function.").

³⁶³ See generally, William H. Maisel, *Unanswered Questions — Drug-Eluting Stents and the Risk of Late Thrombosis*, 356 NEW ENG. J. MED. 981 (2007).

³⁶⁴ This can include computer-controlled ventilators and cardiac assist devices, electronic monitoring of intra-cardiac pressures as well as peripheral blood pressure and heart rate, total parenteral nutrition (intravenous feeding), and pressor support for patients unable to sustain viable blood pressure.

ordering and overseeing minimally-invasive measures.³⁶⁵ Doctors thus have powerful incentives to adopt new “half-way technologies,”³⁶⁶ and, in turn, biotechnology firms (and investors) have strong incentives to develop them. By contrast, clinical advances that build on biological breakthroughs to treat disease in decisive fashion typically yield fewer financial rewards for doctors, since these therapies tend to be less invasive and technology-intensive.³⁶⁷ This reward scheme is a recipe for rapid growth of spending on those technologies that are least likely to yield high clinical benefits, relative to cost.

To the extent possible, given market and political constraints, the compensation gap between physician time spent performing technology-intensive procedures and talking with patients (or providing non-invasive care) should be closed. Market pressures rule out an immediate push by private insurers in this direction, since large cuts in a health plan’s payments for such procedures are likely to prompt specialists to drop out of that plan.³⁶⁸ But Medicare’s dominant market share – it accounts for about half of non-pediatric physician payment³⁶⁹ – positions it to lead, by initiating such reductions.

Medicare should go as far as is politically feasible toward closing the chasm between

³⁶⁵ William C. Hsaio et al., *Results and Policy Implications of the Resource-Based Relative-Value Study*, 319 NEW ENG. J. MED. 881 (1988) (finding that, despite the fact that both consume the same resource inputs, invasive procedures tend to be compensated at more than double the rate of evaluation-and-management services).

³⁶⁶ Hospitals can also profit handsomely from these technologies, which, due to economies of scale and close proximity of complementary inpatient services, are often hospital-based. But doctors’ incentives have a much greater influence on their rate of adoption, since doctors are the key decision-makers.

³⁶⁷ An example is prescription of statins (based on advances in our understanding of cholesterol metabolism, *see supra* note 360) to treat or prevent build-up of atherosclerotic plaque in blood vessels. Pharmaceutical firms, of course, can benefit greatly from the sale of drugs, so long as they remain patent-protected, but they cannot ethically or legally share these revenue streams with prescribing doctors. The cardiologist who evaluates a patient, then prescribes a statin, along with, perhaps, a few other medications might be able to bill a few or several hundred dollars. The cardiologist who spends the same time performing an angioplasty with placement of a stent might be able to collect a few or several thousand dollars.

³⁶⁸ In most regions, individual health plans lack sufficient market share to impose such cutbacks without losing large numbers of specialists and thereby diminishing their ability to compete. Antitrust law, of course, keeps plans from colluding to dictate such cuts.

³⁶⁹ [cite (& find Medicare’s exact percentage of non-pediatric physician payment)]

payment for high-tech procedures and other uses of physician time. As evidence accrues concerning the comparative effectiveness of clinical approaches,³⁷⁰ Medicare should adjust its valuations of physician time accordingly.

Stakeholder opposition, mainly from medical specialists,³⁷¹ will limit Medicare's ability to do these things.³⁷² Yet any progress that Medicare can make on these fronts would nudge the future trajectory of health spending downward, especially if (as has happened with past Medicare payment reforms) private health plans follow Medicare's lead. Such progress would diminish doctors' incentives to adopt new "half-way technologies" and thus reduce investment in efforts to develop them. This, in turn, would slow their introduction into clinical practice, moderating their contribution to rising costs. Unidentified future patients would forgo some therapeutic benefits – probably low, in the aggregate, relative to the costs saved. But popular objections to denial of beneficial care wouldn't come into play, since the tests and treatments "withheld" wouldn't be available to anyone in the here-and-now.

This approach can be applied more generally, in ways that differentiate between technologies that are more and less likely to add high value, relative to their costs. Pharmaceutical and medical device firms could be rewarded for new products with

³⁷⁰ See *supra* TAN 271-278.

³⁷¹ Firms that develop and manufacture "half-way technologies" are likely to join in this opposition.

³⁷² New legislation – sure to be resisted by specialty societies – would be necessary to empower the Center for Medicare and Medicaid Services (CMS), the federal agency that runs Medicare, to do so. CMS is currently required by statute to set fees based on the "Resource-Based Relative Value Scale" (RBRVS) methodology, a species of cost-of-service rate-making. RBRVS incorporates physician effort and training costs but disregards therapeutic value. 42 U.S.C. § 1395w-4(a) (2000). RBRVS, enacted in 1989 (Omnibus Budget Reconciliation Act of 1989 § 6102, Pub. L. No. 101-239, 103 Stat. 2111, 2169), was itself an improvement over the physician payment methodology enacted upon Medicare's creation in 1965 – the "reasonable-charge" formula (which set payments to doctors based on the physician charge schedules prevailing in a region, thereby inviting doctors to raise their fees as quickly as the market would bear). RBRVS achieved modest reductions in some specialists' fees (10 to 20 percent in some cases) and correspondingly modest increases in primary care physicians' fees. John K. Iglehart, *Medicare's Declining Payments to Physicians*, 346 NEW ENG. J. MED. 1924, 1925-26 (2002).

intellectual property protection for varying periods, based on how much a product improves therapeutic outcomes.³⁷³ This might nudge R & D decisions, over time, toward larger therapeutic advances, by reducing these firms' opportunities to reap windfalls from exclusive marketing of modest improvements. Alternatively, government could reward firms directly for medical innovation (through prizes or other payments) while requiring all such innovations to pass into the public domain.³⁷⁴ Such rewards could be tied to favorable comparative efficacy research results – or to sales levels,³⁷⁵ if evidence-based clinical practice protocols come to play a large role in adoption of medical innovations.

Potentially intractable complications cast doubt on the viability of these ideas. Settling on metrics of therapeutic improvement would prove difficult at both the statutory and administrative law levels. Political and legal conflict between stakeholders over the selection of benchmarks³⁷⁶ could paralyze implementation of any sliding-scale reward scheme. And firms that benefit from full-fledged intellectual property protection for half-way technologies are likely to oppose enactment of any sliding-scale scheme. I raise these ideas not because I am sure they would work,³⁷⁷ but because they suggest the

³⁷³ [look into whether IP scholars or others have proposed this – talk to John Thomas? Peter Menell] [Haven't found this yet...]

³⁷⁴ See Steven Shavell and Tanguy van Ypersele, *Rewards versus Intellectual Property Rights*, 44 J. L. & ECON. 525 (2001) (arguing that giving innovators a choice between intellectual property rights and a reward system (under which innovations would immediately enter the public domain) is superior to merely conferring intellectual property rights).

³⁷⁵ *Id.* at 526.

³⁷⁶ The possibilities for conflict are much-enhanced by the subjectivity inherent in selection of medical outcome measures. As is the case for selection of outcome measures by comparative effective researchers, see *supra* TAN, and adoption of quality-of-care benchmarks for the purpose of comparing provider performance, see *supra* TAN, different personal preferences and values are best captured by different measures. There will thus always be room to object to designated metrics of therapeutic advance on the ground that they privilege some patients' concerns while giving short shrift to others'.

³⁷⁷ They merit further exploration by scholars of intellectual property who are familiar with the dynamics of technological change in health care. That exploration is beyond my scope here, as is consideration of whether likely opposition from drug and device makers renders these ideas politically implausible.

broader potential of an evolutionary strategy – one that slows spending growth without awakening Americans’ passionate objections to the withholding of beneficial care.

This strategy seizes the opportunity presented by people’s different expectations concerning access to the beneficial care that is technically possible today and that might become feasible in the future. The strategy is emergence-oriented in two ways: it exploits an opening for comparatively modest change in current law, and it anticipates industry actors’ adaptations to changed incentives (and to others’ adaptations). It finesses a premise embedded in our culture and politics – the notion that doctors should provide care, whatever the cost, whenever expected benefits outweigh risks – by slowing the development of high-cost technologies. By itself, however, this finesse could not suffice to keep health care from absorbing an ever-rising share of our national wealth. So long as we continue to reject clinical limit-setting on account of cost, therapies of great technical virtuosity and modest benefit will proliferate at the ragged edges³⁷⁸ of biological understanding, pushing medical spending upward.

CONCLUSION

The American health care system is on a glide path toward ruin. Since the early 1990s, a million people a year have lost or foregone medical coverage, a figure that masks countless stories of anguish – of loved ones dying too soon, life savings lost, and needless suffering and disability. Health spending, meanwhile, has become the fiscal equivalent of global warming. Current rates of increase are unsustainable without federal

³⁷⁸ The term “ragged edges” is Daniel Callahan’s, meant to capture the truth that however far our biological understandings of disease advance, and however quickly we devise effective therapies based on these understandings, there will always be a frontier zone of biological ignorance and minimally-effective tests and treatments. DANIEL CALLAHAN, *WHAT KIND OF LIFE: THE LIMITS OF MEDICAL PROGRESS*, 63-66 (1990).

deficits or tax increases of astonishing size.³⁷⁹ American enterprise faces a parallel threat from the soaring cost of employee coverage.

Can law help to divert our country from this path? I have argued here that the law has enormous potential to do so, but that this potential remains unfulfilled. To take advantage of the possibilities, we must begin to treat health law as more than a jumble of diverse doctrinal parts. Legal schemes that are well-designed for some purposes often work poorly in concert, yielding chaos instead of coherent governance in the health sphere. On the other hand, no single, unifying paradigm can capture all that we expect from the legal governance of health care provision. Like medicine itself, health law pursues diverse and conflicting aims. Organizing the governance of medicine around any one theory is bound to neglect some of these aims. Theory, nevertheless, is indispensable. Too often, health lawyers disregard the big picture, urging answers to discrete questions without heeding the connections between moving parts. Coherence matters, even if it can never be complete, owing to health law's competing goals.

With an eye toward coherence, where possible – and toward opportunities to turn health care policy away from its current path toward ruin – this article offers a new conception of health law. My core proposition is that health law's disconnected doctrinal spheres and myriad decision-makers are best understood as an emergent system. The same is the case for the American way of medical care financing and provision. This understanding comes to terms with health law's contradictions, confusion, and resistance to wholesale change. It also explains our health care system's multiple dysfunctions as regards access, cost, and value. These contradictions and dysfunctions are not the fault of some failed master designer. No one actor has a grand overview – or the power to

³⁷⁹ See *supra* TAN 41-44.

impose a unifying vision. Countless market actors, public planners, and legal and regulatory decision-makers interact in oft-chaotic ways, clashing with, reinforcing, and adjusting to each other. Out of these interactions, a larger system emerges – one that incorporates the health sphere’s competing interests and values. Change in this system, for worse and for better, arises from the interplay between its myriad actors.

By quitting the quest for a single, master design, we can better focus our efforts on emergent possibilities for legal and policy change. We can and should continuously survey the landscape of stakeholders and expectations with an eye toward potential launching points for evolutionary processes – processes that leverage current institutions and incentives. What we cannot do is to plan or predict these evolutionary pathways in precise detail: the complexity of interactions among market and government actors precludes fine-grained foresight of this sort. But we can determine the general direction of needed change, identify seemingly intractable obstacles, and envision ways to diminish or finesse them over time. Dysfunctional legal doctrines, interest group expectations, consumers’ anxieties, and embedded institutional and cultural barriers can all be dealt with in this way, in iterative fashion.

In this article, I have set out a strategy for doing so. To illustrate this strategy, I have proposed specific approaches to the most urgent questions we face in health care policy and law. I have urged approaches to universal coverage that build on possibilities immanent in existing legal and institutional arrangements, draw energy from cultural currents (for example, rising emphasis on personal responsibility), and minimize disruption of settled expectations. And I have counseled cost control stratagems that work around obstacles to scientific assessment of tests and treatments, resistance from

purveyors of profitable care, and the popular belief that we are entitled to all beneficial care, regardless of cost. The indirectness and incompleteness of these approaches is bound to dismay scholars and activists who prefer one or another elegant, sweeping solution to our crises of health care access, cost, and value. But we're not about to adopt any single, all-encompassing answer. The clashing values and perspectives of the health sphere's disconnected legal and regulatory decision-makers make doing so impossible.

There are early signs that an emergence-oriented approach to health reform is catching on. Pending state-level reform plans, as well as proposals from presidential candidates in both parties, are open-ended in their approach to the health system's future design. In contrast to President Clinton's failed plan, which scripted the workings of the system it envisioned in great detail, this new generation of reform ideas leaves central questions unresolved. The principal Democratic candidates' plans build upon employment-based coverage, but they open multiple evolutionary possibilities; these range from purchase of private insurance by individuals to single-payer coverage. Republican proposals foreclose the single-payer option but, like Democrats', defer to markets to decide between employment-based and individually-acquired insurance. Both Democrats and Republicans also leave space for states to seize the initiative by enacting their own reform schemes.

The emergent systems perspective makes sense of the seeming chaos that besets American health law and policy. It empowers health reformers to develop pragmatic agendas for change by looking for evolutionary possibilities immanent in current law, institutions, politics, and culture. I have pointed to some of these possibilities and proposed legal and policy changes to exploit them. It is my hope that this article will

inspire other efforts to do so. Health law's fragmentation and incoherence are large obstacles to urgently-needed change. But they reflect the ongoing collision of values and interests that shape the health sphere's legal governance. Whether we can avert health care's threat to our nation's solvency while extending 21st century medicine's benefits equitably, to all, will turn on our ability to seize the opportunities this collision engenders.

The potential of emergent systems thinking as a way to understand fragmented schemes of legal governance is relevant beyond the health realm. Increasingly, governance problems – within and beyond America's borders – cut across many areas of legal and regulatory authority. Disconnected decision-makers in both the public and private domains shape policy concerning cyberspace, capital flows, and the built and natural environment. Prescriptions for new, hierarchical institutions to meet policy challenges in these areas are, more often than not, political nonstarters. They threaten powerful interests, and they infringe upon fiercely-guarded realms of authority. Proliferation of hierarchical mechanisms, moreover, would create new coordination problems, since inevitably, large issues will arise that cut across *their* domains. Efforts to understand fragmented governance in terms of self-organizing networks of decision-makers have potential to guide law and policy in diverse fields. Adept use of emergent strategies to cope with our worsening crises of health care access and cost could become a model for the governance of other endeavors that sprawl across doctrinal and jurisdictional realms.