



2003

The Invention of Health Law

Maxwell Gregg Bloche

Georgetown University Law Center, bloche@law.georgetown.edu

<http://www.law.berkeley.edu/students/jrnlorgs/journals/>

This paper can be downloaded free of charge from:

<https://scholarship.law.georgetown.edu/facpub/55>

91 Cal. L. Rev. 247-322 (2003)

This open-access article is brought to you by the Georgetown Law Library. Posted with permission of the author.

Follow this and additional works at: <https://scholarship.law.georgetown.edu/facpub>

 Part of the [Health Law and Policy Commons](#), and the [Judges Commons](#)

GEORGETOWN LAW

Faculty Publications



January 2010

The Invention of Health Law*

91 Cal. L. Rev. 247-322 (2003)

Maxwell Gregg Bloche

Professor of Law

Georgetown University Law Center

bloche@law.georgetown.edu

This paper can be downloaded without charge from:

Scholarly Commons: <http://scholarship.law.georgetown.edu/facpub/55/>

SSRN: <http://ssrn.com/abstract=405801>

Posted with permission of the author

* Copyright 2003 by the California Law Review, Inc. Reprinted from *California Law Review*, Vol. 91, No. 2, by permission of the Regents of the University of California.

California Law Review

VOL. 91

MARCH 2003

No. 2

Copyright © 2003 by California Law Review, Inc.

The Invention of Health Law

M. Gregg Bloche†

TABLE OF CONTENTS

Introduction.....	249
I. Welfare Maximization and the Enigma of Efficiency.....	257
A. The Standard Story of Waste.....	257
B. Moral Hazard.....	260
C. The Problem of Medical Uncertainty.....	266
D. Valuing the Benefits of Medical Care.....	270
1. The Informed-Consent Paradigm.....	271
2. Informed Consent Reconceived: The Ex Ante Approach ...	272
3. The Indeterminacy of the Ex Ante Approach.....	274
4. The Indeterminacy of Efforts to Aggregate Health-Plan Subscribers' Allocative Preferences.....	277
E. Making Systemwide Cost-Benefit Trade-Offs.....	282
II. Legal Conflict and the Quest for Efficiency.....	287
A. Medical Tort Law.....	289
B. Disputes Over Medical Coverage.....	290

Copyright © 2003 California Law Review, Inc. California Law Review, Inc. (CLR) is a California nonprofit corporation. CLR and the authors are solely responsible for the content of their publications.

† Professor of Law, Georgetown University Law Center and Adjunct Professor, Department of Health Policy and Management, Johns Hopkins University. J.D., Yale University, 1987; M.D., Yale University, 1984. My work on this Article was supported by a Robert Wood Johnson Foundation Investigator Award in Health Policy Research. I thank Anita Allen, Jennifer Arlen, Robert Ellickson, Richard Epstein, Lawrence Gostin, Lisa Heinzerling, Avery Katz, Michael Moore, Diane Orentlicher, Sara Rosenbaum, Elyn Saks, Michael Seidman, Michael Shapiro, Lynn Stout, Alan Sykes, Mark Tushnet, Bruce Vladek, and participants in faculty workshops at the University of Chicago, University of Pennsylvania, Georgetown University, and the University of Southern California for their comments and suggestions. I also thank participants in the Robert Wood Johnson Foundation's Cluster Group on Competition and Regulation in Health Care and Johns Hopkins University's Greenwall Fellows program. I am grateful to William Tarantino, Elizabeth Jungman, and Genevieve Grabman for their research assistance.

C. Legal Safeguards for Medical Professionalism	294
D. Health Care Antitrust Law	295
E. Regulation of Capital Investment	297
III. The Law of Health Care Provision, Reconceived	299
A. Citizens' Expectations and the Purposes of Medicine	299
B. The Aims of Health Law	301
IV. Preliminary Applications.....	309
A. Medical Tort Law	310
B. Disputes Over Medical Coverage	315
C. Legal Safeguards for Medical Professionalism	317
D. Health Care Antitrust Law	318
E. Regulation of Capital Investment	320
Conclusion	321

The Invention of Health Law

M. Gregg Bloche

By default, the courts are inventing health law. The law governing the American health system arises from an unruly mix of statutes, regulations, and judge-crafted doctrines conceived, in the main, without medical care in mind. Courts are ill-equipped to put order to this chaos, and until recently they have been disinclined to try. But political gridlock and popular ire over managed care have pushed them into the breach, and the Supreme Court has become a proactive health policy player. How might judges make sense of health law's disparate doctrinal strands? Scholars from diverse ideological starting points have converged toward a single answer: the law should look to deploy medical resources in a systematically rational manner, so as to maximize the benefits that every dollar buys. This answer bases the orderly development of health care law upon our ability to reach stable understandings, in myriad circumstances, of what welfare maximization requires. In this Article, I contend that this goal is not achievable. Scientific ignorance, cognitive limitations, and normative disagreements yield shifting, incomplete, and contradictory understandings of social welfare in the health sphere. The chaotic state of health care law today reflects this unruliness. In making systemic welfare maximization the lodestar for health law, we risk falling so far short of aspirations for reasoned decision making as to invite disillusion about the possibilities for any sort of rationality in this field. Accordingly, I urge that we define health law's aims more modestly, based on acknowledgment that its rationality is discontinuous across substantive contexts and changeable with time. This concession to human limits, I argue, opens the way to health policy that mediates wisely between our desire for public action to maximize the well being of the many and our intimate wishes to be treated non-instrumentally, as separate ends. I conclude with an effort to identify the goals that health law, so constructed, should pursue and to suggest how a strategy of accommodation among these goals might apply to a variety of legal controversies.

INTRODUCTION

By default, the courts are inventing health law. The law governing American health care arises from an unruly mix of state and federal

agencies and from a jumble of statutes and common-law doctrines¹ conceived, in the main, without medical care in mind. Congressional attempts to create a comprehensive regulatory scheme to govern the managed care revolution have fallen victim to political gridlock and interest-group power.² Political paralysis and the proliferation of legal conflict over the rights and responsibilities of patients, managed health plans, and medical-care providers have pushed judges front and center in the health-policy arena. Yet the courts are ill equipped to put order to the health-policy chaos. And, aware of their institutional limitations, they have until recently been disinclined to try. With no comprehensive health policy to guide them, judges tended to pursue doctrinal integrity within disparate areas of law. In so doing, they not only sacrificed the goal of systemwide rationality in the health sphere; they added to the national health-policy disarray.

In the late 1990s, this began to change. Under pressure from a growing caseload spawned by conflict over managed care, courts construed statutes and common-law precepts more creatively to fill health-policy gaps. The most important developments involved ERISA, the 1974 federal law that, by accident, has become the virtual constitution for the health care marketplace.³ Its drafters paid little heed to its implications for medical care. Their aim was a national regulatory scheme for employee fringe

1. State laws regulating the health sector include common-law tort, contract, and trust rules; separate statutory schemes governing licensing, tax exemption, and insurance; and statutes and regulations implementing Medicaid and other collaborative state and federal health programs. Courts, licensing boards, attorneys general, insurance commissions, and other administrative agencies interpret and enforce these laws in disconnected fashion. Federal sources of health care law include the statutes (and an enormous body of regulations) governing Medicare and Medicaid, which together pay for close to half of all health services; statutes, regulations, and other guidelines governing federal income-tax exemption; the Employee Retirement Income Security Act ("ERISA"), which governs employees' fringe benefits (and therefore sets ground rules for most privately purchased medical coverage); and the statutory and regulatory schemes governing approval and marketing of drugs and medical devices. Federal judges, the Treasury Department, the Department of Labor (which has jurisdiction over ERISA), and multiple agencies within the Department of Health and Human Services construe and apply these sources of law in similarly disconnected fashion. See Clark C. Havighurst, *American Health Care and the Law*, in *THE PRIVATIZATION OF HEALTH CARE REFORM: LEGAL AND REGULATORY PERSPECTIVES* (M. Gregg Bloche ed., 2003) (criticizing the lack of common principles in health law and promoting market competition as a unifying paradigm).

2. The collapse of President Clinton's health care reform plan in 1994 is the most dramatic recent example. See generally HAYNES JOHNSON & DAVID S. BRODER, *THE SYSTEM: THE AMERICAN WAY OF POLITICS AT THE BREAKING POINT* (1997) (chronicling the role of interest groups in the failure of the Clinton administration's health reform efforts). The repeated failure of so-called Patients' Bill of Rights legislation since the late 1990s is also illustrative. Such legislation would establish an overarching system of rules for federal and state legal governance of managed health plans and the market for medical insurance coverage.

3. ERISA, 29 U.S.C. §§ 1001-1461 (1994 & Supp. III 1997), governs all health-insurance coverage offered by employers. Since the vast majority of Americans with private medical coverage obtain it through their (or family members') employment, ERISA functions as the main statutory framework for the health-insurance marketplace.

benefits.⁴ To this end, they immunized fringe-benefit plans against state law.⁵ Through the mid-1990s, courts conferred this immunity on managed health care.⁶ In so doing, they held to formal consistency at an embarrassing price—the inability of most Americans to sue their health plans for mishandling care.⁷ By the late 1990s, managed care impunity had become the stuff of political stump speeches and popular ire. Judges looked for ways to cut it back.⁸ With the U.S. Supreme Court's encouragement, courts have remade medical tort law over the past several years, putting troublesome cost-control methods squarely in the sights of state tort lawyers.⁹

4. The Congress that enacted the statute in 1974 focused on nationally uniform disclosure and financial and fiduciary standards as a way both to make it easier for employers to offer fringe benefits (especially pension plans) and to protect pension funds from corrupt and inept management. *See* U.S. SENATE SUBCOMM. ON LABOR OF THE COMM. ON LABOR & PUBLIC WELFARE, 94TH CONG., 2D SESS., LEGISLATIVE HISTORY OF THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974; *see also* *Shaw v. Delta Air Lines*, 463 U.S. 85, 105 n.25 (1983).

5. ERISA section 514(a) calls for preemption of any state laws that "relate to" an employee benefit plan. 29 U.S.C. § 1144(a) (1994 & Supp. III 1997). This so-called conflict preemption must be pleaded as a defense. ERISA section 502(a) confers upon plan beneficiaries a federal cause of action "to recover benefits due" under a plan. *Id.* § 1132(a)(1)(B). This provision results in so-called complete preemption and requires removal of a case to federal court if a would-be beneficiary files an action in state court that constitutes an attempt "to recover benefits due." *See, e.g., Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987); *Jass v. Prudential Health Care Plan, Inc.*, 88 F.3d 1482 (7th Cir. 1996).

6. In the 1980s, the U.S. Supreme Court construed ERISA's preemption clause, section 514(a), broadly, foreclosing state damage suits against fringe-benefit plans. *See, e.g., Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47-48 (1987). In this case, which involved employer-provided disability insurance, the Court held that ERISA preempted all state tort and contract law of general applicability, including actions for negligence. Subsequent lower court decisions extended *Pilot Life* to immunize health plans against state tort actions for improperly withholding or delaying authorization for care. *See, e.g., Kuhl v. Lincoln Nat'l Health Plan of Kansas City, Inc.*, 999 F.2d 298 (8th Cir. 1993); *Corcoran v. United HealthCare, Inc.*, 965 F.2d 1321 (5th Cir. 1992).

7. The managed care industry's immunity from liability for declining to authorize care ensued from ERISA preemption of state tort and contract remedies and ERISA's lack of an alternative, federal-law basis for damages. *Corcoran*, 965 F.2d at 1321.

8. Some took their cue from a 1995 Supreme Court opinion characterizing health as a matter for state regulation and suggesting that ERISA preemption of state law be narrowed accordingly in the health sphere. *See N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995) (holding that state regulations governing employee benefit plans' payments to hospitals were beyond the scope of ERISA preemption); *see also* Karen A. Jordan, *Travelers Insurance: New Support for the Argument to Restrain ERISA Pre-emption*, 13 YALE J. ON REG. 255 (1996).

9. The courts' basic strategy, pursued by various doctrinal means, was to distinguish between health care provision and health-plan administration, apply ERISA preemption only to the latter, and characterize troublesome cost-control methods as fitting within the former. *See generally* Peter D. Jacobson & Scott D. Pomfret, *Form, Function, and Managed Care Torts: Achieving Fairness and Equity in ERISA Jurisprudence*, 35 HOUS. L. REV. 985 (1998). Courts thereby cleared a path to tort liability for managed care frugality that ends badly. Cost-control methods that some courts, since the mid-1990s, have treated as issues of health care provision, not health benefits administration (and therefore beyond ERISA's preemptive reach), include preapproval review of doctors' treatment plans by managed care administrators, for example, *Pappas v. Asbel*, 768 A.2d 1089, 1093-96 (Pa. 2001), and supervisory influence (maintained via financial incentives, administrative oversight, and the power to select and "de-select" participating physicians) over the clinical judgment of managed care organizations' participating physicians. *See, e.g., Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350 (1995)

As judges look to harmonize health law's disparate doctrinal strands, what vision should guide them? Over the past decade, scholars from diverse ideological starting points have converged toward a single answer: the law should seek to deploy resources in a systematic manner, so as to maximize the medical benefits that every dollar buys.¹⁰ This approach rejects physician conceptions of medical need that call for provision of care regardless of cost when expected clinical benefits outweigh potential clinical harms.¹¹ It treats these conceptions as tainted by physicians' financial self-interest and insured patients' "moral hazard," their preference for care that they would not purchase if they had to pay the entire cost. It also envisions a cultural shift that has yet to occur—the advent of widespread public willingness to treat medical resources as scarce and to tolerate the withholding of beneficial care.

The Supreme Court endorsed this economics-oriented approach to the law of health care provision in 2000, in its first-ever opinion on the regulatory governance of managed care.¹² The Justices stunned observers¹³ by declaring that health care rationing is both routine in the United States and a matter of national policy. The Court characterized the work of health policy as the making of judgments about "acceptable medical risk" and "optimum treatment levels," and it sanctioned rewards to doctors for withholding care as an acceptable rationing method.¹⁴

(rejecting ERISA preemption arguments on the ground that plaintiffs' state action against health maintenance organizations ("HMOs"), under theories of ostensible and actual agency, addressed the quality of medical care provided, not plan administration). Two years ago, the Supreme Court invited judges to widen this path. See M. Gregg Bloche & Peter D. Jacobson, *The Supreme Court and Bedside Rationing*, 284 JAMA 2776 (2000); Peter J. Hammer, *Pegram v. Herdrich: On Peritonitis, Preemption and the Elusive Goal of Managed Care Accountability*, 26 J. HEALTH POL., POL'Y & L. 767 (2001). The Justices characterized gatekeeping HMO physicians' cost-control efforts as "mixed" medical and administrative activity, then placed this "mixed" activity beyond ERISA's preemptive reach. *Pegram v. Herdrich*, 530 U.S. 21, 231-32 (2000).

10. See, e.g., Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381 (1994); Einer Elhauge, *The Limited Regulatory Potential of Medical Technology Assessment*, 82 VA. L. REV. 1525 (1996); Einer Elhauge, *Allocating Health Care Morally*, 82 CALIF. L. REV. 1449 (1994) [hereinafter Elhauge, *Allocating Health Care Morally*]; Richard A. Epstein, *Managed Care Under Siege*, 24 J. MED. & PHIL. 434, 438-39 (1999).

11. See, e.g., SHERRY GLIED, CHRONIC CONDITION: WHY HEALTH REFORM FAILS 26-33 (1997) (criticizing this "medicalist" perspective on health care resource allocation).

12. *Pegram*, 530 U.S. at 234.

13. See Robert Pear, *The 'R' Word: Justice Souter Takes On a Health Care Taboo*, N.Y. TIMES, June 18, 2000, § 4, at 3.

14. Writing for a unanimous Court, Justice Souter said that "inducement to ration care goes to the very point of any HMO scheme," *Pegram*, 530 U.S. at 221, and that Congress has for more than twenty-seven years promoted the creation of HMOs and thereby endorsed "the profit incentive to ration care," *id.* at 233. Justice Souter framed the central question in the case—whether ERISA's fiduciary duty provisions limit HMOs' monetary rewards to doctors for withholding care—as one calling for judgment about optimum levels of care and "unacceptably risky HMO structure." *Id.* at 221. The Court declined to read ERISA to set such limits on the asserted ground that Congress is better situated than the Court to make these requisite "judgments of social value." *Id.* at 365.

In its most pointed form, the new, economic paradigm for health care law instructs courts and regulators to value medical services only insofar as they boost biological functioning and to decide controversies so as to maximize collective welfare.¹⁵ Whether this economic reasoning will someday tie together the disconnected strands of American health law is an open question. But, it is making rapid progress. It is encouraging courts to take a more favorable view of managed care organizations' cost-control strategies, including preauthorization review of doctors' treatment plans, financial incentives to physicians to limit care, and termination of contracts with high-spending physicians. It is inclining some judges toward greater deference to limit-setting provisions in health plans' contracts with consumers¹⁶ and reduced deference to sick patients' wishes and expectations. It is pushing decision makers in tort litigation and insurance-coverage disputes to pay less heed to doctors' conceptions of clinical need. It has encouraged the erosion of legal safeguards for physician autonomy, which it treats as a barrier to optimal clinical resource use. And it is the driving force behind antitrust law's expanding application to medical care.¹⁷

This Article challenges the proposition that we can resolve legal controversies in the health care sphere through traditional economic reasoning. I argue that the systematic rationalization of medical and health-policy

The respondent, Cynthia Herdrich, had initially sued her health plan in state court, under Illinois law, for offering financial rewards to physicians to limit care. *Herdrich v. Pegram*, 154 F.3d 362, 365-66 (7th Cir. 1998), *rev'd*, 530 U.S. 211 (2000). The plan persuaded a federal district court to dismiss this claim as preempted by ERISA. *Id.* Herdrich then recast her claim as a federal action, alleging that financial enticements to withhold treatment violate an employee benefit plan's fiduciary duty, under ERISA, to administer benefits "solely in the interest of the participants and beneficiaries." 29 U.S.C. § 1104(a)(1) (2000). She asserted that her health plan's financial incentives for physicians led her doctor to delay an abdominal ultrasound examination. During the alleged delay, her appendix ruptured, resulting in peritonitis, a life-threatening infection of her abdomen. The district court dismissed Herdrich's ERISA fiduciary duty claim. *Herdrich*, 154 F.3d at 365-66. The Seventh Circuit Court of Appeals reinstated the claim, holding that ERISA's fiduciary duty provisions impose limits on physicians' incentives to withhold services and warning that such incentives threaten the quality of medical care. *Id.* at 373. The Supreme Court reversed, holding ERISA's fiduciary duty provisions inapplicable to incentives to physicians to limit care. *Pegram*, 530 U.S. at 237.

15. In Richard Epstein's words:

[I]t is possible for the left and the right to make common cause, and to insist that health care should be regarded as a means and not an end in itself. . . . The end is good health, and . . . the correct normative approach is one that asks whether the next dollar spent on health produces greater benefit than that next dollar spent on any one of a number of other goods in the market basket.

Epstein, *supra* note 10, at 438-39. Unless the answer to this question is yes, social waste is occurring. And, the paradigm's adherents hold third-party payment ensures that the answer is almost always no.

16. Such provisions include exclusions for "investigational" or "experimental" therapies, reliance upon cost-conscious clinical practice protocols, restrictions on access to specialists and out-of-network providers, and cost-sensitive definitions of "medical necessity."

17. See generally Clark C. Havighurst, *Health Care as a (Big) Business: The Antitrust Response*, 26 J. HEALTH POL., POL'Y & L. 939 (2001) (reviewing history of health care antitrust law and defending robust antitrust responses to provider collaboration that reduces options available to consumers).

decision making that classic welfare economics envisions is far beyond our cognitive and moral reach. We know little about the efficacy of most of medicine, and the complexity and variability of patients' illnesses make large advances in this knowledge unlikely for the foreseeable future. We are nowhere near to social consensus on how to value the benefits and harms of therapeutic intervention. We differ profoundly over which benefits and harms ought to "count," how we should measure them, and how we should mediate between our desire for health policy that maximizes the welfare of the many and our intimate wishes to be cared for without compromise. Health economists' frequent simplifying step, their treatment of therapeutic effectiveness as the measure of medicine's social worth, disregards needs that play large roles in how people value health care. The moral and emotional import of rescue, people's fears of abandonment and helplessness, and their yearnings for dignity in time of vulnerability are among the humane concerns health economics typically ignores—and could not reliably tally were it to try.

These failures feed confusion, even chaos, when health law looks to systemwide economic rationality as the lodestar for conflict resolution. Yet we need not abandon the quest for rationality in health law. We can and should retrieve rationality from the province of social welfare maximization and recast it in more pragmatic terms.¹⁸

To this end, I propose an alternative understanding of health law's aims. This understanding concedes that medical uncertainty, people's cognitive constraints and emotional needs, and persisting moral disagreements limit the possibilities for rational health policymaking. Treating health law as a matter of balancing costs and benefits tends to obscure these difficulties. By collapsing competing policy considerations onto a

18. It is not my intention, in so urging, to challenge the normative desirability, in principle, of systemic welfare maximization as a paradigm for the law of health care provision. I leave to others the question of whether this paradigm, in theory, can encompass all that is normatively at stake in health care law. My concern, in this Article, is the real-world manageability of this paradigm. In practice, the "error bands" that ensue from empirical uncertainty, cognitive limitations, and normative disagreement are too wide to enable decision makers to derive reliable answers to legal questions in the health care sphere by reference to what will systematically maximize social welfare. To be sure, empirical doubts, cognitive limitations, and normative disagreement beset legal decision making in many other policy spheres. But in health care, these sources of uncertainty and variance are especially large. The uniqueness and extraordinary complexity of each person's physiology—and, arising from this complexity, the innumerable judgments about resource use that patients, doctors, and institutions must make—distinguish medical care from policy areas, such as environmental protection and public utility regulation, marked by population-wide decisions that are much fewer in number. Medical care, moreover, is unique for the poignancy with which individuals' often desperate claims clash with population-wide priorities. We cannot resolve such clashes simply by according trump value to the population-wide perspective, as welfare economics is wont to do, unless we utterly disregard individuals' yearnings to be seen noninstrumentally as ends in themselves. Economic thinking may well be able to incorporate this individualized, Kantian perspective, but the effort to so adapt the welfare-economics paradigm to incorporate this view, by somehow quantifying these human aspirations, is fraught with fuzziness and indeterminacy of the sort that economists typically eschew.

one-dimensional axis, the cost-benefit balancing model diverts attention from the underlying substance of legal disagreements. The approach I urge encourages judges, litigants, and society to focus on this underlying substance. It reframes health law's disputes to highlight society's disagreements about health care's value and purposes. By so doing, it empowers courts to address these underlying disagreements in more coherent, predictable fashion in disparate doctrinal contexts. Beyond this, the enhanced visibility of core disagreements, and the law's handling of them, promotes public deliberation over the desirability of the answers the law provides. This openness, in turn, expands possibilities for public-regarding political choice in health matters and shrinks the space for special-interest-group influence.

In Part I, I consider the use of welfare economics as a tool for resolving health law's main questions.¹⁹ First, I review the standard story of waste that lies behind most welfare-economics thinking about health care provision. This story's central claim—that excess consumer demand, created by health insurance, results in large-scale social waste—has much support. But without undergirding moral judgments about how to achieve distributive fairness, how to measure people's health preferences, and how to manage medicine's many uncertainties, the standard story of waste cannot yield conclusions about optimal resource use. I argue that disagreement about how to make these moral judgments renders the idea of insurance-induced excess demand too fuzzy or indeterminate to be of much use to legal decision makers.

I then address the related problem of valuing the results of medical care for purposes of using law to maximize social welfare. Economics approaches to this problem have in common the rejection of old-fashioned professional paternalism, the idea that doctors know best, in favor of deference to consumer preferences. But these approaches differ in how they seek to discern consumer preferences, and the different approaches yield sharply conflicting results. Choosing from among these approaches and results is a moral, not a technical, matter. Americans' sharp disagreements about how to make these choices widen the scope for conflict and uncertainty over the social-welfare-maximizing perspective's implications for law. I conclude Part I by contending that even if this conflict and uncertainty could be reduced to manageable levels, citizens' and policymakers' psychological limitations would make the ideal of consistent, systemwide cost-benefit trade-offs impractical in the health sphere.

19. This discussion of welfare economics in the health sphere is restricted to the issues most central to American health care law. For consideration of the application of welfare-economics norms to wider distributive and other health policy questions, see Uwe E. Reinhardt, *Can Efficiency in Health Care Be Left to the Market?*, 26 J. HEALTH POL., POL'Y & L. 967 (2001); see also THOMAS H. RICE, *THE ECONOMICS OF HEALTH RECONSIDERED* (1998).

In Part II, I briefly consider the welfare-maximization model's inroads in five illustrative areas of legal conflict: medical malpractice, health-insurance coverage, protections for professional autonomy, antitrust, and regulation of capital investment. Within each of these areas, I contend, the welfare-maximization model has not only failed to reduce the law's inconsistencies and uncertainties; it has contributed to them, thereby increasing the possibilities for destructive conflict.

In Part III, I present an alternative model for the quest to harmonize health law. This alternative approach takes a pragmatic account of Americans' conflicting expectations of medicine—expectations that often lie unseen behind conflicting claims about what social-welfare maximization requires. In addition to promoting and restoring health, these expectations include protection against abandonment, provision of comfort and support, regard for people's dignity at their most vulnerable moments, and universal access to care as an expression of our common humanity.²⁰ The model for health law that I propose renders these expectations explicit and highlights the tensions between them. It thereby directs legal decision makers' attention to litigants' (and society's) disagreements about how to manage conflict between these expectations. It does not offer single, "right" answers to legal questions. Rather, it channels legal reasoning to take a richer, more open account of health care's conflicting purposes than does the language of welfare economics. By so doing, it enables legal decision makers to achieve greater coherence and predictability across doctrinal settings over time. It also fosters public reconsideration of the judgments that courts and regulators make.

Part IV suggests how this alternative model might guide the development of health law. I briefly explore the model's implications for the five illustrative spheres of legal conflict I consider in Part II. I do not offer a detailed doctrinal roadmap, as such a project is far beyond my scope here.²¹ My limited purpose, in Part IV, is to offer a glimpse of how this approach might work in practice and how it differs from the welfare-economics vision for health law. It pursues coherence and predictability, but it accepts untidy pragmatism as it mediates between Americans' contradictory aspirations and fears about health and disease.

20. Borrowing from Amartya Sen, one can distinguish between "culmination outcomes"—final results disconnected from the processes by which they are achieved—and "comprehensive outcomes," which take account of both final results and the processes by which these results are brought about. AMARTYA KUMAR SEN, *DEVELOPMENT AS FREEDOM* 27 (1999). Standard welfare-economics thinking values health care exclusively in terms of a "culmination outcome," the impact of medical care on health status. This Article looks to "comprehensive outcomes," including feelings of being cared for, respect for personal dignity, and the deepened sense of community that health care can bring about.

21. Other, forthcoming work will flesh out, in different common-law and statutory contexts, the approach to harmonization of health care law that this Article proposes.

I

WELFARE MAXIMIZATION AND THE ENIGMA OF EFFICIENCY

A. *The Standard Story of Waste*

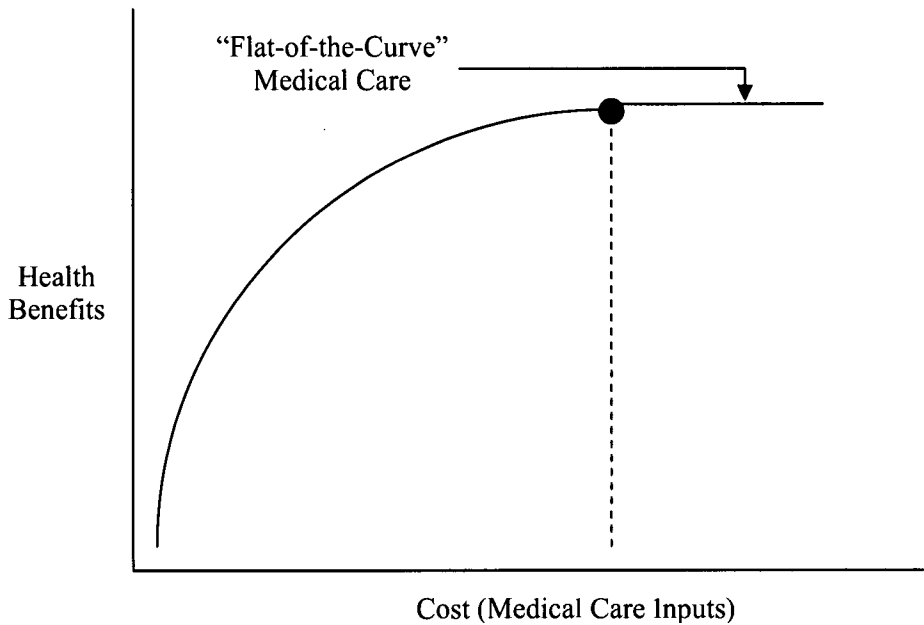
Economics-oriented scholars from a range of ideological vantage points tell a now-standard story about inefficiency in health care. This story is consistent in theory with a variety of positions on the role of government in the health sector, from support for universal, publicly financed and administered medical care²² to reliance on minimally regulated markets. Yet the standard story is most often invoked by supporters of the market-driven restructuring of health care. This restructuring, its proponents argue, promises to rationalize the allocation of medical resources while respecting individuals' preferences to a greater extent than could any publicly administered process.

Adherents to the standard story start with a compelling account of waste within classic, fee-for-service health care. This account begins with well-insured patients who assert their medical preferences without regard for medical costs. Insulated from these costs by insurance and advised by physicians with a financial stake in the provision of more services, patients demand all potentially beneficial care.²³ In economics terms, well-insured patients and their doctors push demand up the slope of the clinical cost-benefit curve to a plateau at which further clinical intervention (and expense) yields no additional health benefits—so-called flat-of-the-curve medicine.

22. Government could attempt to identify and root out inefficiencies in health care by developing systemwide cost-benefit trade-off principles and requiring doctors and patients to abide by them. Indeed, some advocates of publicly funded medical care for all have incorporated cost containment along these lines into their proposals. See, e.g., THEODORE R. MARMOR, UNDERSTANDING HEALTH CARE REFORM 218-21 (1994); Dan E. Beauchamp & Ronald L. Rouse, *Universal New York Health Care—A Single-Payer Strategy Linking Cost Control and Universal Access*, 323 NEW ENG. J. MED. 640 (1990). Proponents of publicly funded and administered health care coverage often argue that political accountability makes government the most legitimate maker of hard decisions concerning the costs and benefits of medical treatments.

23. To be more precise, this account holds that fully insured patients demand all care with expected therapeutic benefits (the sum of the probability multiplied by the magnitude of the benefit, for all possible benefits) that outweigh expected adverse health effects (the sum of the probability multiplied by the magnitude of the adverse effect, for all possible adverse effects). Patients with less-than-complete insurance (that is, those with unmet deductible or copayment requirements) demand all care with expected therapeutic benefits that outweigh expected adverse health effects plus out-of-pocket expenses (that is, copayments). This story assumes the quantifiability and comparability of potential clinical benefits and harms (through Bayesian methods for the valuation of unrealized possibilities), as well as the commensurability of adverse health outcomes and financial expenses.

FIGURE 1



The story allows that the Hippocratic ethic of loyalty to patients may discourage provision of lucrative services that do more medical harm than good. But the story presents this professional ethic, in conjunction with the reduced cost sensitivity (moral hazard) introduced by insurance, as both an instrument of physician financial self-interest and a catalyst of irrationally high health care spending.

This story has inspired some to seek to constrain clinical spending through such regulatory means as global budget ceilings,²⁴ limits on capital investment,²⁵ and promulgation of comprehensive clinical-practice protocols that incorporate systemic cost-benefit trade-offs.²⁶ The former two approaches target the supply side, leaving bedside allocation decisions to clinicians and local administrators, who must cope with supply and demand mismatches and the resulting queuing of well-insured patients.²⁷ The

24. See, e.g., Uwe E. Reinhardt, *Operating Under a Global Budget: Perspectives from the United States and Abroad*, in *CHANGING THE HEALTH CARE SYSTEM: MODELS FROM HERE AND ABROAD* 68, 70 (Institute of Medicine ed., 1994); Richard B. Saltman, *Single-Source Financing Systems: A Solution for the United States?* 268 JAMA 774 (1992).

25. See generally Sallyanne Payton & Rhoda M. Powsner, *Regulation Through the Looking Glass: Hospitals, Blue Cross, and Certificate-of-Need*, 79 MICH. L. REV. 203 (1980) (criticizing regulatory constraints on capital investment through so-called certificate-of-need programs).

26. See Mark V. Pauly, *Practice Guidelines: Can They Save Money? Should They?*, 23 J.L. MED. & ETHICS 65 (1995).

27. See Jeffrey E. Harris, *The Internal Organization of Hospitals: Some Economic Implications*, 8 BELL J. ECON. 467 (1977).

issuance of practice protocols for regulatory purposes is more ambitious. This demand-side approach seeks to centralize clinical allocation decisions, giving doctors detailed rules to apply when using collective resources on their patients' behalf.

More market-oriented adherents to the standard story object that politically accountable decision makers are unable to set the painful limits necessary to prevent irrationally high health care spending,²⁸ that regulatory methods of limit setting deny choice to individuals,²⁹ and that the work of developing and implementing spending ceilings or comprehensive practice protocols is beyond the administrative capabilities of government. They urge instead that the task of limit-setting be left to contractual ordering between medical-care consumers, payers, and providers. In Clark Havighurst's words:

Because the idea of rationing care—depriving people of beneficial services on the ground that they are too costly—is so controversial, it should seem wise to make whatever rationing occurs a matter of contract rather than public compulsion. If health care must be rationed—and, in some sense, it must—it would seem preferable to have it done with the consumer's consent.³⁰

The advent of managed health plans, Havighurst and others argue, makes such limit setting possible. The key to private limit setting, and to preservation of personal choice, is the requirement that health-plan purchasers make medical-spending decisions before the onset of clinical need. Seated in the employee-benefits office or otherwise shopping the medical marketplace, consumers can choose the plan (and budget limits and resource-allocation policies) that best fits their health care "tastes" and their comparative preferences for medical coverage versus other goods.³¹ When employers offer only one or a few health-coverage options, this line of argument discerns de facto consumer choice by treating the employer as a good-enough purchasing agent for its employees. Managed health plans, the argument goes, can implement these ex ante consumer choices—and thereby rationalize medical spending—through clinical practice styles that reflect systemic cost-benefit trade-off policies. Unlike regulatory means of effecting such policies, competition between private health plans permits experimentation with diverse means for doing so—and simultaneous

28. RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE 174 (1997).

29. CLARK HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM 34 (1995) ("[W]ell meaning legislative attempts to fix deficiencies in the de facto regulatory system . . . might complete the regulatory takeover. . . . Few would be aware enough of what was happening even to mourn as another stake was driven into the heart of private contracts as instruments of choice and individual liberty.").

30. *Id.* at 115.

31. See Elhauge, *Allocating Health Care Morally*, *supra* note 10, at 1451.

satisfaction of varying personal preferences as to these means. Among competing plans, cost-benefit trade-off policies may differ, but this variation better serves varying consumer preferences than can any single, state-mandated cost-benefit trade-off scheme.

This market-oriented version of the standard story calls for government to stay out of the fray, except, perhaps, to channel subsidies to the poor (to give them access to a decent range of coverage options)³² and, more controversially, to rectify market failures.³³ This overarching conception of government's role frames debate within the paradigm over what the law and policy of medical-care provision should seek to accomplish. It presents health care law and policy as an adjuvant to the market-driven quest to maximize collective welfare. In so doing, it rests the orderly development of health law and policy upon our ability to reach stable understandings, in myriad circumstances, of what welfare maximization requires.

B. Moral Hazard

The standard story of waste in health care provision presents insurance as the engine of clinical inefficiency. Medical insurance, the story goes, creates "moral hazard" by enabling patients to purchase care for a fraction of its actual price and its true cost to society.³⁴ This fraction, in the form of deductible and copayment requirements, sets the threshold above which the perceived value of a medical service must rise to prompt a decision to purchase it. Patients experience only this fractional cost because they—or employers or government—have already incurred insurance premiums, which collectively cover most medical costs. In turn, the story holds, physicians evolve standards of care that reflect the false cost-benefit balance signal sent by purchase decisions restrained only by this fractional cost. This signal, the product of insurance-augmented buying power, spurs provision of existing medical services at higher-than-optimal levels. More significantly, from a financial perspective, it overstimulates investment in the development of new clinical technologies, reallocating resources

32. HAVIGHURST, *supra* note 29, at 34.

33. See, e.g., Alain Enthoven, *The History and Principles of Managed Competition*, HEALTH AFF., Supp. 1993, at 24; Alain Enthoven & Richard Kronick, *A Consumer-Choice Health Plan for the 1990s: Universal Health Insurance in a System Designed to Promote Quality and Economy*, 320 NEW ENG. J. MED. 94 (1989).

34. See Martin S. Feldstein, *Hospital Cost Inflation: A Study of Nonprofit Price Dynamics*, 61 AM. ECON. REV. 853 (1971); see also Willard G. Manning et al., *Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment*, 77 AM. ECON. REV. 251, 258-59 (1987) (concluding that people are more likely to use medical services when their out-of-pocket costs are lower). But see Cam Donaldson & Karen Gerard, *Countering Moral Hazard in Public and Private Health Care Systems: A Review of Recent Evidence*, 18 J. SOC. POL'Y 235, 248 (1989) (concluding that free care at the point of delivery does not necessarily result in higher health care costs through increased moral hazard).

inefficiently from other sectors of the economy and causing medical costs to rise more quickly than the general rate of inflation.³⁵

This account, embraced by virtually all health economists, employs the notion of “moral hazard” in a way that obscures key normative questions. To see this, consider the difference between this usage of “moral hazard” and classic “moral hazard” in the casualty insurance context. The classic “moral hazard” of insurance is its effect on insureds’ willingness to take risk.³⁶ Homeowners’ insurance, for example, is thought to make the backyard-grill enthusiast marginally less likely to take care, and more willing to risk fiery destruction of her property, than she would be without coverage. In theory, the uninsured patio chef will take the “right” amount of risk, striking a socially optimal balance between the pleasures of care-free cooking and the prospect of harm to her property.³⁷ The chef with fire insurance, however, will take too little care (from a social-welfare-optimizing perspective), since she can rationally disregard or discount the prospect of an insured loss. The key idea here is that insurance changes risk-taking behavior—in a manner that reduces social welfare.³⁸ This is an observable effect, not a counterfactual proposition, though its precise measurement is difficult in practice.

“Moral hazard” is used differently in discussion of medical insurance. To be sure, health insurance does carry a measure of classic “moral hazard”: the well-insured person may be marginally more likely to ski, smoke, bungee jump, or eat Brie. But health care economists invoke the notion of moral hazard to characterize the influence of insurance on consumers’ medical-purchasing decisions, not their risk-taking behavior. By augmenting clinical buying power, medical insurance lifts consumers’ medical demand curves from a starting point of zero when people confront illnesses treatable only at costs exceeding their incomes and life savings. Such costs make purchase of such treatment impossible without insurance. For the vast majority of Americans, hospital stays of several days or more fit into this category.³⁹

35. See Annetine Gelijns & Nathan Rosenberg, *The Dynamics of Technological Change in Medicine*, HEALTH AFF., Summer 1994, at 28.

36. See STEVEN SHAVELL, *ECONOMIC ANALYSIS OF ACCIDENT LAW* 194-97 (1987).

37. This example assumes, of course, that our chef neither underestimates nor overestimates the likelihood or magnitude of the potential harm, is neither risk averse nor risk seeking, and lives in sufficiently isolated splendor that she can create risk only for herself, not her neighbors.

38. This reduction in social welfare is counterbalanced by the social benefits of loss spreading, which derive from the increasing marginal disutility of larger and larger losses suffered by any one person.

39. In 1998, the median income for a family of four was \$56,061. U.S. Census Bureau, *Median Income for Four Person Families by State*, at <http://www.census.gov/hhes/income/4person.html> (last revised Aug. 22 2002). According to an analysis of the benefits paid by Mutual of Omaha, the 1998 cost of one day of inpatient services in an American hospital was \$2,510. MUTUAL OF OMAHA COMPANIES’ GROUP BENEFIT SERVICES ANN. REP., *CURRENT TRENDS IN HEALTH CARE & DENTAL COSTS & UTILIZATION*: 2001 ED. 5 (2001), at <http://www.nichsa.org>.

By contrast, our home-owning backyard chef is able in fact, with or without fire insurance, to take the different levels of care mentioned earlier. It is financially and physically possible for her to take a variety of precautions that reduce her risk of burning her house down. We can thus compare her levels of care, and the resulting fire risks, with and without insurance. This comparison, in turn, enables us to estimate the actual waste from more frequent fiery backyard miscues that the moral hazard of fire insurance introduces.⁴⁰ However, for medical care that is too costly to buy without health insurance, we cannot measure real-world moral hazard—induced waste by comparing patients' purchasing decisions with and without health insurance. We can easily observe that the twenty-seven-year-old schoolteacher with liver failure will not spend \$150,000 on a lifesaving liver transplant unless her health insurance covers it. But unless we treat this intervention's value to the individual as determined by the unsubsidized price she is willing and able to pay for it,⁴¹ we cannot treat this observation as evidence that insurance coverage for this transplant induces waste. To assay moral hazard here, and to discern waste, we must compare her decision about a real-world option (using her insurance to purchase the transplant) against a hypothetical, even imaginary, standard—the choice she would make if she had to pay the full price out of pocket and had \$150,000 or more in the bank or available on credit.

Unless we infuse content into this hypothetical standard of comparison, we cannot determine whether insurance, in this instance, induces wasteful medical spending. The content of this standard, though, comes from our counterfactual judgment—our subjective ideas about what a person in imaginary circumstances would choose to do. These ideas are not the product of empirical observation of actual behavior. It is the possibility of such observation that gives classic moral hazard in the casualty insurance context its analytic power as an objective, market-based measure of economic waste.⁴² Counterfactual thinking about what a patient without insurance would choose lacks this empirical basis. It rests on our value-laden judgments about how to define the counterfactual situation.

For example, almost none of us would favor, as a counterfactual standard, our twenty-seven-year-old schoolteacher's forgoing of the liver transplant, absent insurance or other access to the necessary \$150,000. To accept this standard would be to treat the social value of a person's desire to live (and of the loss to others from a person's avoidable death) as so

40. Any estimation will, in practice, be exceedingly difficult, but the difficulties stem from practical problems of data collection and aggregation. The task is not, in theory, impossible.

41. See, e.g., Richard A. Posner, *Wealth Maximization and Judicial Decision-Making*, 4 INT'L REV. L. & ECON. 131 (1984).

42. Its objectivity as a measure of waste is not complete, since it rests on value-laden assumptions about the translation of different levels of care and different probabilities of different kinds of casualty losses into dollar terms.

linked to one's financial resources that inability to pay for lifesaving treatment proves its social wastefulness. Our rejection of this standard rests on our shared moral conviction that the value of a person's life should not be treated purely as a function of his or her wealth.⁴³

On the other hand, many (including most health economists) would support, as a counterfactual standard, the decision about the transplant that our schoolteacher would make were an insurer to simply issue her a \$150,000 check, on proof of medical need, without conditions on its use. That this is a counterfactual standard is confirmed by the fact that health insurers do not write such policies, presumably because of lack of consumer demand⁴⁴ or the risk of opportunistic claims of medical need.⁴⁵ This standard is similarly laden with moral content: its application calls for speculation that entails normative choices. Its moral content derives from the effect of our schoolteacher's financial and other life circumstances upon her decision. The poorer her economic prospects and the more pressure she might feel to leave the \$150,000 to needy loved ones, the less likely it would seem that she would choose the transplant. This standard thus ties the transplant's social value to the patient's finances and other life pressures. Health economists' acceptance of this tie constitutes a moral decision to accept some linkage between valuation of a person's life and her wealth and other life circumstances.⁴⁶ Moreover, this standard cannot be applied without speculating about what the patient would do in the counterfactual situation. Such speculation is an exercise in imagination, not inference.⁴⁷ We cannot know how her immersion in this extraordinary situation would influence her feelings and preferences.⁴⁸ We can, at best,

43. Put in other terms, life-prolonging health care is a "merit good"—something we (or, at least, most of us) do not believe should be available solely on the basis of people's wealth.

44. Consumer disinterest in such policies could reflect widespread desire to precommit to spending insurance proceeds on health care, rather than keeping them, in the event of illness, so as to avoid agonizing decisions—for example, a choice between life-prolonging intensive care and heroic forgoing of these services so as to leave an insurance-derived financial legacy to one's children.

45. The risk of opportunism would be greater than it is for conventional health-insurance policies, since claimants could obtain large sums of money to keep (without having to endure noxious medical procedures).

46. To be sure, the connection between wealth and the value of life is less direct here than it is for the (almost) universally abhorrent standard discussed previously, since the \$150,000 check renders all recipients financially able to obtain the transplant, while the previous scenario makes it economically impossible for anyone without \$150,000 to choose the transplant.

47. Could we simply ask the patient, at the moment of clinical decision, whether, if she were presented with a choice between the transplant and \$150,000 in cash, she would choose the transplant? We could, but if the purpose of the question is to determine whether the transplant would be wasteful in her case—and thus should be withheld from her in the interest of making medical care more efficient—then she would have a life-and-death incentive not to answer honestly if in fact she thinks she would choose the cash. If she answers this hypothetical question honestly, then in real life she will be denied the transplant.

48. The context dependence of preferences is empirically well established and is a focus of ongoing research. *E.g.*, Douglass H. Wedell & Jonathan C. Pettybone, *Preference and the Contextual Basis of Ideals in Judgment and Choice*, 128 J. EXPERIMENTAL PSYCHOL.: GEN. 346 (1999).

reflect empathically on the trade-offs she might make. But empathy requires that we imagine ourselves in her (counterfactual) place. To do so imports our own feelings, values, and preferences into our speculation about what she would decide. Application of this counterfactual standard thus rests on contestable normative judgment.

One might respond to the need for normative judgment by looking to more objective methods for the social valuation of medical services. Many such approaches are conceivable, and I address only a small sample of them here. To begin with, one could borrow from one of the inventive techniques economists have developed for the empirical valuation of life and health. These methods, often based on statistical measurement of the wage premiums workers receive for incurring on-the-job risks, yield prices on life and on states of well-being.⁴⁹ By adjusting these prices for the incremental life-saving potential of particular clinical interventions (assuming this potential is measurable), one can derive empirically based estimates of the social values of medical services. Analogously, one might extrapolate such estimates from measurements of the cost-benefit trade-offs implicit in consumers' decisions about the purchase of low-cost clinical services (for example, diagnostic screening tests) not covered by insurance. Such methodology takes valuation of medical care and estimation of insurance-induced waste out of the realm of purely subjective speculation. But it does not connect the measurement of insurance-induced waste to observation of actual consumer choices in medical markets. It draws its raw material for valuation—observations of people's risk-dollar trade-offs—from different market settings. This approach runs contrary to evidence that the trade-offs we make between money and health vary greatly depending on the context of the decision.⁵⁰ Our apparent willingness to pay much more, per unit of risk reduction, for medical treatment of life-threatening illness than for equivalent increments of risk reduction when risks are relatively low (as they tend to be in labor markets) suggests that deriving medical risk-dollar trade-offs from labor and other market settings would introduce large errors.

But perhaps error of this sort is in the eye of the beholder. Advocates of this methodology might respond that risk-dollar trade-offs observed in labor and other markets where health risks are relatively low are better indicators of the social value of life and good health than is the willingness of patients with dread disease to pay dearly for a small additional prospect of survival or improved functioning. If so, then they hold promise as baselines for estimation of insurance-generated waste. But preference for these baselines over the more anxious, even desperate, risk-dollar trade-offs of

49. See W. KIP VISCUSI, *FATAL TRADEOFFS: PUBLIC AND PRIVATE RESPONSIBILITIES FOR RISK* 34-41 (1992).

50. See *infra* text accompanying notes 116-31.

sick patients would be an overtly political choice, decoupled from the medical marketplace. There is no nonpolitical, nonmoral reason for choosing this methodology over other techniques that are likewise not based on observed behavior in the medical marketplace, such as public-opinion surveys,⁵¹ focus groups, or rulings by regulatory agencies.⁵² Indeed, there are reasons for preferring openly political methods to extrapolations from market behavior.⁵³

My point is not that we should choose political methods or any particular approach. It is, rather, that the moral-hazard concept as conventionally applied to health care is incapable of generating estimates of waste based solely on empirical observation of consumer behavior in medical markets. We can judge the magnitude of insurance-induced inefficiency only by reference to a standard with moral and political content—a standard that reflects social choices about which benefits and costs to count and how to count them. However we craft such a standard, its use to measure insurance-induced waste departs sharply from the ideal of deference to individuals' expressed preferences. This ideal is central both to free-market economics and to the principle of informed consent. This is not to say that invoking moral hazard in the medical setting makes no sense or that we should always defer to patients' expressed preferences. Insulating patients from most of the costs of medical treatment, and virtually the entire cost of the most expensive care, surely induces some misallocation of social resources. The dilemma for policymakers, including legal decision makers, working within the systemic welfare-maximization paradigm, is that the dimensions of this resource misallocation are indeterminate without normative choices—moral and political judgments—of the kind I have just described. Our underlying disagreements about how to make these choices

51. See OR. HEALTH SERVS. COMM'N, *PRIORITIZATION OF HEALTH SERVICES: A REPORT TO THE GOVERNOR AND LEGISLATURE* (1991); *Oregon Medicaid Rationing Experiment: Hearing Before the Subcomm. on Health and the Env't of the House Comm. on Energy and Commerce*, 102d Cong., 1st Sess. 19 (1991) (testimony of Tina Castanares, Or. Health Servs. Comm.) (describing use of public-opinion polls in designing Medicaid rationing plan).

52. See John Gardner, *HCFA Revives Proposal for Cost-Effectiveness Rule*, 26 MOD. HEALTHCARE 70 (1996). The Health Care Financing Administration ("HCFA") has sought to make cost-effectiveness a component of its definition of "reasonable and necessary," employed to qualify treatments for Medicare reimbursement, but the agency has encountered political resistance.

53. From the communitarian and "civic republican" perspectives, deliberative public decision making may be preferable on the ground that political engagement engenders a less self-centered, more public-regarding outlook, deserving of priority over individuals' private choices. See Cass R. Sunstein, *Legal Interference with Private Preferences*, 53 U. CHI. L. REV. 1129, 1132-33 (1986). A standard rejoinder (from public-choice theorists and their sympathizers) is that idealized public decision making of this sort is either rare or nonexistent and that self-serving interest groups more typically exert such disproportionate influence on political processes that markets do better at approximating the public good. See Henry N. Butler & Jonathan R. Macey, *Health Care Reform: Perspectives from the Economic Theory of Regulation and the Economic Theory of Statutory Interpretation*, 79 CORNELL L. REV. 1434 (1994).

translate into ongoing conflict, inconsistency, and instability in the legal and regulatory governance of health care provision.

C. *The Problem of Medical Uncertainty*

The standard story of waste also accommodates the growing realization that many, even most, medical decisions are not evidence based and that uncertainty about treatment efficacy pervades clinical practice. This realization is not essential to the standard account of wasteful clinical spending. Even if we had scientific evidence as to the efficacy of all medical interventions, the account of insurance-induced waste just discussed would have much force. Uncertainty about the value of medical interventions is an obstacle to the standard story's central policy prescription: systematic allocation of limited clinical resources so as to maximize the aggregate medical benefits our clinical dollars buy. Absent information about the efficacy of clinical measures, neither markets nor government can make the necessary cost-benefit trade-offs. Those committed to some form of this policy prescription must and do urge a comprehensive set of responses to the problem of uncertainty about medical care's effectiveness. Unfortunately, these responses go only a small way toward alleviating this intractable problem. The result is another, irreducible sphere of indeterminacy about what is rational and another nidus of legal and regulatory conflict.

Before the mid-1970s, discussion of the economic implications of uncertainty in medical markets centered on the problem of patients' ignorance and tended to presume knowledgeable physicians.⁵⁴ By the 1980s, however, reports of wide variation in clinical-practice patterns between different geographic areas⁵⁵ began to draw researchers' and commentators' attention to the empirical foundations of medical decision making.⁵⁶ Clinical judgment fared poorly under this scrutiny. Most clinical practice is not evidence based.⁵⁷ To some degree, this reflects practicing physicians'

54. Kenneth Arrow's classic 1963 account of the economics of uncertainty in medicine is perhaps the best example. Arrow sought to explain the medical profession's fiduciary ethic as a market response to the potential for patient mistrust created by the knowledge gap between patient and physician. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963). From a 2003 vantage point, Arrow seems almost quaintly confident that physicians know the efficacy of what they do.

55. See, e.g., Mark R. Chassin et al., *Does Inappropriate Use Explain Geographic Variations in the Use of Health Care Services?*, 258 JAMA 2533 (1987); Leon Eisenberg & Paul H. Wise, *What Do Regional Variations in the Rates of Hospitalization of Children Really Mean?*, 320 NEW ENG. J. MED. 1209 (1989); John E. Wennberg et al., *Small Area Variations in Health Care Delivery*, 182 SCIENCE 1102 (1973).

56. See David L. Sackett & William M.C. Rosenberg, *The Need for Evidence-Based Medicine*, 88 J. ROYAL SOC'Y MED. 620 (1995); John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, HEALTH AFF., Summer 1984, at 6-32.

57. See INST. OF MED., GUIDELINES FOR CLINICAL PRACTICE: FROM DEVELOPMENT TO USE (1992).

failure to take full advantage of available data from clinical trials and other scientific sources.⁵⁸ But scientific research has not, thus far, yielded conclusory information about the efficacy of more than a small portion of physicians' clinical decisions. Although some adherents to the standard story understate the import of this problem, others squarely acknowledge it. They urge, in response, a large-scale program of clinical-outcomes research, funded by public and private sources and conducted by academic institutions, government agencies, and health plans.⁵⁹ They hold to the conviction that such research can, in the foreseeable future, produce a comprehensive empirical basis for medical practice.

This empirical foundation, the argument holds, will make possible the development of comprehensive clinical-practice protocols, incorporating both relevant clinical-outcomes data and agreed-upon cost-benefit trade-off principles. Here, the standard story's central policy prescription separates into many strands, reflecting our society's disparate ideas about distributive justice and deference to individuals' preferences. Some urge a single, society-wide cost-benefit trade-off norm, imposed, perhaps, by a single, public payer, government regulators, or the courts.⁶⁰ Others argue for legal acceptance of multiple tiers of cost-benefit trade-off rules and standards of care, adhered to by different health plans with different market prices and subscribed to by consumers with different levels of wealth and coverage preferences and needs.⁶¹ Proponents of this family of approaches have conceived myriad, ingenious methods for measuring and comparing the benefits of medical interventions by assaying the opinions of relevant consumer groups,⁶² whether subscribers to particular health plans or more

58. See generally John M. Eisenberg & Eric C. Schneider, *Strategies and Methods for Aligning Current and Best Medical Practices: The Role of Information Technologies*, 168 W.J. MED. 311 (1998) (urging educational interventions to increase use of clinical evidence in medical decision making).

59. See, e.g., Carolyn M. Clancy & John M. Eisenberg, *Outcomes Research: Measuring the End Results of Health Care*, 282 SCIENCE 245 (1998); Michele Robinson, *PROs Use Medical Practice Standards to Assess Quality*, HOSPITALS, Oct. 20, 1988, at 19. See generally Wendy K. Mariner, *Outcomes Assessment in Health Care Reform: Promise and Limitations*, 20 AM. J.L. & MED. 37 (1994).

60. See M. Susan Marquis & Stephen H. Long, *Federalism and Health System Reform*, 278 JAMA 514 (1997); Edith Rasell, *An Equitable Way to Pay for Universal Coverage*, 29 INT'L J. HEALTH SERVICES 179 (1999); see also Beauchamp & Rouse, *supra* note 22.

61. See Elhauge, *Allocating Health Care Morally*, *supra* note 10; Clark Havighurst, *Rational Capacity: Right-Sizing Delivery in the Health Systems Era*, 30 HEALTH SYS. REV. 25 (1997); E. Haavi Morreim, *Managed Care, Ethics and Academic Health Centers: Maximizing Potential, Minimizing Drawbacks*, 72 ACAD. MED. 332 (1997); E. Haavi Morreim, *Cost Containment and the Standard of Medical Care*, 75 CALIF. L. REV. 1719 (1987).

62. See, e.g., Peter A. Ubel et al., *Societal Value, the Person Trade-Off, and the Dilemma of Whose Values to Measure for Cost-Effectiveness Analysis*, 9 HEALTH ECON. 127 (2000). These methods typically assay consumers' preferences (ex ante) at the onset of illness or injury (and medical need); thus they typically assume the superiority of the ex ante perspective over the perspectives of sick patients as a vantage point for valuing clinical outcomes.

inclusive populations. Such measurements and comparisons could, in theory, make it possible to fashion comprehensive clinical-practice protocols tailored to fit health plans' resource constraints and the preferences of plan participants.

The enormous appeal of this answer to the problem of medical uncertainty belies its serious shortcomings. To begin with, medical history counsels modesty. At least since the eighteenth century, clinical idealists have aspired to recast medicine as a systematic compilation of evidence-based rules of practice, centrally administered and enforced.⁶³ That this recurring hope remains unfulfilled invites at least the suspicion that intractable problems stand in the way. Indeed, this suspicion preoccupied some eighteenth-century commentators, including a French observer who cautioned:

The science of man is concerned with too complicated an object, it embraces a multitude of too varied facts, it operates on too subtle and too numerous elements always to give to the immense combinations of which it is capable the uniformity, evidence, and certainty that characterize the physical sciences and mathematics.⁶⁴

The link between biomedical complexity and uncertainty is still with us. It vexes contemporary efforts to create a comprehensive science of clinical outcomes. The gold standard for outcomes research is the randomized, prospective, double-blind clinical trial, a scientific experiment elegantly designed to yield useful knowledge in the face of complexity. The prospective clinical trial tests alternative treatments or other interventions by factoring out confounding influences, then observing a small number of outcome indices.⁶⁵ Current ethical norms severely limit the use of such trials: if researchers have good reason to believe that one course of treatment is more efficacious than another, they may not proceed with a comparative trial of the two.⁶⁶ Prospective trials are thus difficult or impossible to

63. See MICHEL FOUCAULT, *THE BIRTH OF THE CLINIC: AN ARCHAEOLOGY OF MEDICAL PERCEPTION* 27-32 (A.M. Sheridan Smith trans., 1973). The idea of clinical practice guidelines dates at least to the Old Testament: Leviticus prescribes detailed rules for the treatment and prevention of a variety of ailments. See, e.g., *Lev.* 13:10-11 ("[A]nd the priest shall make an examination, and if there is a white swelling in the skin, which has turned the hair white, and there is quick raw flesh in the swelling, it is a chronic leprosy in the skin of his body.").

64. FOUCAULT, *supra* note 63, at 97 (quoting C.L. Dumas).

65. See LEON GORDIS, *ASSESSING THE EFFICACY OF PREVENTIVE AND THERAPEUTIC MEASURES: RANDOMIZED TRIALS IN EPIDEMIOLOGY* 89-96 (1996); see also *THE CLINICAL RESEARCH PROCESS IN THE PHARMACEUTICAL INDUSTRY* (Gary M. Matoren ed., 1984).

66. More precisely, it is "generally accepted" that "the investigators [must] be able to state an honest null hypothesis," that is, that "there is no scientifically validated reason to predict" the superiority of one therapy over another. ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 187 (2d ed. 1986). Clinical trials of less expensive HIV antiviral treatment regimens in less developed countries have engendered sharp ethical criticism. See Marcia Angell, *The Ethics of Clinical Research in the Third World*, 337 *NEW ENG. J. MED.* 847 (1997). But see Ruth Faden & Nancy Kass, Editorial, *HIV Research, Ethics, and the Developing World*, 88 *AM. J. PUB. HEALTH* 548 (1998) (arguing that the trials are defensible, on pragmatic grounds, when more expensive treatments would likely be unavailable).

employ, under current rules, to measure the magnitudes of known differences in efficacy—knowledge essential to the making of cost-benefit trade-offs. Clinical trials are also very expensive, since researchers must enroll, treat, and monitor many patients to achieve statistically significant results when small differences in efficacy are at issue.⁶⁷

Moreover, the design of clinical trials is beset by a paradox that constricts their clinical relevance. To be good science—that is, to give “clean” therapeutic answers and to minimize confounding influences on clinical outcomes—their inclusion criteria must be narrow: the experimental and control groups must be relatively homogeneous with respect to multiple demographic and pathophysiological characteristics.⁶⁸ Such factors as age, gender, race and ethnicity, environmental exposure, and personal and family histories of particular illnesses are often grounds for exclusion from prospective trials. In addition, the outcome variables to be monitored and assessed must be susceptible to objective (that is, statistically reliable) measurement and must be few and simple enough to make the research manageable. A well-designed prospective trial is therefore likely to assess only a small number of the many effects of a course of treatment upon a person’s life.

Indeed, there is a roughly inverse relationship between the quality of clinical trials as science and the scope of their real-world relevance. Application of their findings to patients and to situations falling outside their narrow inclusion criteria requires a leap of nonscientific inference. Physiological differences between such patients and a clinical trial’s homogeneous subjects may have large effects on clinical outcomes. And to the extent that outcomes other than those monitored in a clinical trial are deemed important in practice, the relevance of a trial’s findings may be limited even for patients who match the inclusion criteria. For example, a trial that discerns small differences in survival time between two cancer treatments may be of marginal import for a patient who is concerned primarily about her level of functioning or quality of life.

These limitations have inspired enthusiasm for large-scale, retrospective review of clinical data. Data from clinical practice is becoming accessible to researchers on an unprecedented scale, thanks to the enormous electronic databases of managed health plans,⁶⁹ and retrospective study of these databases is a promising avenue. Yet such research presents daunting problems, arising from the complexity and subtlety of clinical observation. The recording of bits and pieces of clinical information by busy

67. See GORDIS, *supra* note 65, at 98-100.

68. *Id.*

69. See David B. Kendall & S. Robert Levine, *Pursuing the Promise of an Information-Age Health Care System*, HEALTH AFF., Nov.-Dec. 1998, at 41; J.D. Kleinke, *Release 0.0: Clinical Information Technology in the Real World*, HEALTH AFF., Nov.-Dec. 1998, at 23.

practitioners, concerned variously about utilization review,⁷⁰ billing, liability risk, and communicating with colleagues about management of cases, produces spotty, inconsistent records. These limitations make identification of groups of similar patients, for the purpose of comparing alternative diagnostic or treatment measures, quite problematic. Case-by-case variations in both record keeping and clinical management make it equally problematic to identify and track, for purposes of comparison, discrete diagnostic and therapeutic approaches, and to systematically study retrospectively chosen outcome measures.

Other outcomes research methods present analogous difficulties, tied to the complexity and subtlety of clinical measurement.⁷¹ Such research promises to improve the scientific quality of clinical decision making and is worthy of public investment.⁷² Yet a comprehensive science of clinical outcomes and a comprehensive empirical basis for medical practice remain far beyond our reach. Absent such an empirical foundation, no agreed-upon set of cost-benefit trade-off principles can yield a comprehensive set of clinical-practice protocols to guide medical spending decisions. The resulting indeterminacy leaves room for wide variation in clinical practice—and thus for ongoing conflict over such legal and regulatory matters as determination of medical necessity by health plans, reasonable care in medical tort law, and the scope of Medicare and Medicaid coverage. Beyond this, it presents a large obstacle to systemically rational, population-wide allocation of limited clinical resources, whether by contractually authorized or regulatory means.

D. *Valuing the Benefits of Medical Care*

Were a comprehensive science of clinical outcomes on the horizon, complete with reliable data on the efficacy of most medical interventions in

70. See M. Gregg Bloche, *Fidelity and Deceit at the Bedside*, 283 JAMA 1881 (2000); Matthew K. Wynia et al., *Physician Manipulation of Reimbursement Rules for Patients: Between a Rock and a Hard Place*, 283 JAMA 1858 (2000) (reporting and analyzing evidence that physicians engage on a large scale in deceptive recording of clinical information for the purpose of qualifying for insurance coverage).

71. Observational case-control studies, for example, have been urged as a cheaper, less ethically problematic approach than the randomized clinical trial for the evaluation of widely used treatments that have never been empirically validated. See Ralph I. Horwitz & Alvan R. Feinstein, *Improved Observational Method for Studying Therapeutic Efficacy: Suggestive Evidence that Lidocaine Prophylaxis Prevents Death in Acute Myocardial Infarction*, 246 JAMA 2455 (1981). This strategy, which, like randomized prospective trials, requires development of inclusion criteria to produce homogeneous patient groups for comparative study, involves systematic monitoring of patients who receive different treatments from their own, nonresearch physicians.

72. Published clinical-outcomes research, like most scientific research, is a classic "public good" in the economic sense. Private actors (for example, managed health plans) that support it cannot capture all its social benefits and can therefore be expected to underinvest in it; thus public support for it (for example, by the Agency for Health Care Research and Quality and the National Institutes of Health) is desirable.

most clinical circumstances, the challenge of valuing actual and expected medical outcomes would still render systemic welfare maximization deeply problematic as a policy and legal goal. This challenge has inspired a range of approaches, virtually all of which look in some manner toward subscriber, patient, or citizen preferences. About all that these approaches have in common is their clear rejection of old-fashioned, 1950s paternalism, the notion that doctors know best about the desirability of particular clinical outcomes. Aside from this, they differ fundamentally in their treatment of questions that underlie much of the current ethical and legal debate over patients' rights and responsibilities.

1. *The Informed-Consent Paradigm*

These differences in approach are tied to the varying ways by which one can assay preferences. The classic informed-consent model largely defers to patients' individual, subjective preferences at the moment of medical decision, after their physicians have advised them about clinical risks, benefits, and alternatives. To be sure, informed-consent law places some limits on patients' subjective judgment. These constraints operate mainly through standards for assessing the sufficiency of physician disclosure. Most U.S. jurisdictions require physicians to reveal what a reasonable practitioner would disclose (that is, to adhere to a professionally defined standard).⁷³ Others mandate disclosure of all that a reasonable patient would find material to her decision.⁷⁴ Some critics dismiss both approaches as insufficiently deferential to individuals' bedside preferences. Instead, they urge a subjective-disclosure standard, tailored to the psychological make up of each patient.⁷⁵ The requirement of competence to give consent also limits the law's deference to individuals' subjective preferences. Patient preferences that health professionals believe are unreasonable can trigger psychological examinations and findings of incompetence when signs of reason-distorting mental illness are present.

The classic informed-consent paradigm presumes the sovereignty of patients' preferences, variously assessed, when clinical needs arise. It disregards the influence of insurance coverage, and of economic incentives and pressures more generally,⁷⁶ on sick patients' choices.⁷⁷ Despite

73. See, e.g., *Riedisser v. Nelson*, 534 P.2d 1052, 1054 (Ariz. 1975); *Gorab v. Zook*, 943 P.2d 423, 427-28 (Colo. 1997); *Natanson v. Kline*, 350 P.2d 1093, 1106 (Kan. 1960); *McPhee v. Bay City Samaritan Hosp.*, 159 N.W.2d 880, 882 (Mich. Ct. App. 1968); *Butler v. Berkeley*, 213 S.E.2d 571, 580, 582 (N.C. Ct. App. 1975).

74. See *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972); *Logan v. Greenwich Hosp. Ass'n*, 465 A.2d 294, 299-301 (Conn. 1983); *Carr v. Strode*, 904 P.2d 489, 500 (Haw. 1995).

75. See Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69 (1994).

76. See M. Gregg Bloche, *Clinical Counseling and the Problem of Autonomy-Negating Influence, in HIV, AIDS & CHILDBEARING: PUBLIC POLICY, PRIVATE LIVES* 257-319 (Ruth R. Faden & Nancy E. Kass eds., 1996).

criticism from adherents to the standard story of waste in health care provision,⁷⁸ the informed-consent paradigm remains governing law throughout the United States. However, the criticism is gaining attention.

2. *Informed Consent Reconceived: The Ex Ante Approach*

The proposition that insurance coverage delegitimizes the sovereignty of sick patients' clinical preferences has taken on the status of assumed wisdom for many health-policy commentators.⁷⁹ The ex ante perspective, the vantage point of consumers visiting the employee-benefits office to select a health plan, is, for these commentators, the preferred locus for binding health care choices. The employee-benefits office has become health care financing's Rawlsian "original position"—a place for subsequently binding choices that draw their moral legitimacy from each chooser's ignorance about what biological time and chance hold in store.

The ex ante approach abates the problem of moral hazard by constraining the chooser after time and chance have dealt their fate. It aspires, instead, toward a new kind of empowerment—the authority to impose future limits on oneself through a binding contract with a health plan that conserves collective resources by limiting sick people's options. Some proponents of universal, government-provided medical coverage urge an analogue to this approach. They suggest that we can give ex ante consent collectively, through political processes, to constraints on sick peoples' choices imposed by statute or by regulation, as part of a public medical-insurance scheme.⁸⁰ Another analogue, in the private sector, applies to consumers whose employers offer only one or a few coverage options, severely limiting the scope of ex ante choice. In this scenario, the employers act as medical purchasing agents for their employees, selecting from a wide range of coverage options and thereby making ex ante commitments on their employees' behalf.⁸¹

Detailed consideration of these ex ante models' problematic treatment of the ideal of personal choice is beyond the scope of this Article. Instead, I

77. See Susan M. Wolf, *Toward a Systemic Theory of Informed Consent in Managed Care*, 35 Hous. L. Rev. 1631 (1999).

78. See EPSTEIN, *supra* note 28, at 300-06, 346 (objecting to allowing sick, insured patients to make unbridled claims on insurance risk pools).

79. E.g., Mark A. Hall & Gerald F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637 (1992); PAUL T. MENZEL, *STRONG MEDICINE: THE ETHICAL RATIONING OF HEALTH CARE* (1990).

80. Michael J. Garland, *Rationing in Public: Oregon's Priority-Setting Methodology*, in *RATIONING AMERICA'S MEDICAL CARE: THE OREGON PLAN AND BEYOND* 37, 37 (Martin A. Strosberg et al. eds., 1992).

81. This analogue finds some support in the limited fiduciary duties ERISA imposes on employee-welfare benefit plans. See, e.g., *Varity Corp. v. Howe*, 516 U.S. 489, 506 (1996). It is plausible in economic terms to the extent that labor-market pressures (and the tax environment) give employers incentives to offer attractive fringe-benefit packages that incorporate balances employees would strike between receipt of wages and benefits.

focus on the uncertainties these models present for welfare-economics approaches to health care decision making. First, the general notion that we should privilege the ex ante perspective has hardly carried the day, legally or culturally, as the current state of informed-consent doctrine illustrates. Legal conflict is likely to arise if health insurers try to hold patients to ex ante commitments to forego therapeutic options arguably preserved by informed-consent law's disclosure requirements or by judicial understandings of "medical necessity."⁸² One might dismiss such conflict as a mere transition problem—a by-product of the long half-life of outmoded thinking about personal choice when others foot the bill. But the law's reluctance to adopt the ex ante perspective may reflect bona fide moral qualms about binding people in medical extremis to precommitments they make casually and unreflectively at best, and unknowingly at worst, when they visit the employee-benefits office, step into the voting booth, or merely accept a job.

Second, there are limits to the assumptions of risk and the precommitments we permit. For example, we spend collectively to rescue kayakers or hikers who venture into harm's way in defiance of law or after signing all manner of waiver. We also provide life-saving surgical care to young accident victims who could have bought health insurance but failed to do so. We provide care for a mix of reasons, difficult to disentangle. These include paternalism; society's squeamishness about the consequences of doing otherwise; and the belief that inadequate information, in the form of ex ante ignorance about our feelings while drowning, starving, or bleeding to death, precludes the treatment of such high-stakes risk taking as binding.

This last belief rests on the premise that our emotional responses enrich our understanding of the choices we face. Our emotional reactions to life's experiences affect our preferences in morally relevant ways, this line of thinking holds. John Stuart Mill took the position that we should not regard a person's assent to something as consent to the consequences that follow from it unless the person has both an emotional and a cognitive appreciation of these consequences.⁸³ Some contemporary utilitarians pay close attention to links between preference changes and life experience, arguing for what Jon Elster has termed "respect for the freedom of choice

82. To the consternation of critics who favor the ex ante perspective (and judicial recognition of multiple market tiers of care), courts have tended to treat "medical necessity" standards in insurance contracts as warrants for professional (physician) judgment about appropriate treatment, irrespective of insurers' ex ante resource constraints. See, e.g., *Rush Prudential HMO, Inc. v. Moran*, 122 S. Ct. 2151, 536 U.S. 355 (2002) (characterizing "medical necessity" standards as matters of professional judgment, not contract interpretation).

83. JOHN STUART MILL, *ON LIBERTY* 172-73 (Gertrude Himmelfarb ed., Penguin Classics 1974) (1859).

of later selves.”⁸⁴ Feminist writers have won growing recognition for the emotional dimension of human understanding and the incompleteness of purely cognitive models of knowledge and information.⁸⁵ Other moral philosophers have recently shown heightened interest in connections between feelings and evaluative judgments.⁸⁶

When we sign up for a health plan, we have at best some vague ideas about acceptable trade-offs among price, quality, and constraints on choice. We may particularly dread some medical risks and discount others. However, we do not and cannot reflect with care about what we would feel and prefer in the event of each of the vast range of tragic medical possibilities.⁸⁷ We are ignorant, both cognitively and affectively, about what biological time and chance hold in store for us and about how we will feel (and what our medical preferences will be) when fate shows its hand.

To the extent that this ignorance matters morally, health care financing’s “original position” is not a morally secure redoubt. And to the extent that we paternalistically question others’ medical precommitments, or become squeamish about the nastier consequences of treating them as binding, our misgivings about this “original position” are magnified. Thus an unresolved, perhaps unresolvable, tension exists between the appeal of the ex ante perspective as an answer to insurance’s distortion of incentives and our reluctance to hold patients to it. We are fundamentally ambivalent over whether it is more “rational” to privilege people’s ex ante decisions or to credit “the freedom of choice of later selves” who possess insurance-augmented buying power. The law of health care provision embodies this ambivalence. Litigation over “medical necessity” and myriad coverage exclusions, as well as legislative and regulatory conflict over patients’ rights vis-à-vis health plans, express it.

3. *The Indeterminacy of the Ex Ante Approach*

Were we to fully embrace the ex ante perspective, in either market-oriented or political (collective-consent) form, the task of assigning values to potential health outcomes so as to maximize welfare through medical (and health-law) decision making would remain problematic because of multiple indeterminacies. In theory, a health plan with a fixed budget set by annual premiums should strive to maximize the aggregate health value

84. See JON ELSTER, *ULYSSES AND THE SIRENS: STUDIES IN RATIONALITY AND IRRATIONALITY* 73 (1979).

85. See generally MARTHA C. NUSSBAUM, *LOVE’S KNOWLEDGE: ESSAYS ON PHILOSOPHY AND LITERATURE* (1990).

86. See generally Justin D’Arms, *Empathy and Evaluative Inquiry*, 74 CHI.-KENT L. REV. 1467 (2000).

87. Our affective capacity to anticipate our future feelings and consequent changes in our preferences is bounded, no less than is our cognitive capacity to anticipate and plan for future contingencies. See James G. March, *Bounded Rationality, Ambiguity, and the Engineering of Choice*, 9 BELL J. ECON. 587 (1978).

its medical spending produces.⁸⁸ To do this in practice, a health plan would need to assign expected values to its universe of clinical interventions, and then set a threshold expected value-to-cost ratio for coverage of clinical interventions. Health-plan managers, inventive researchers, and commentators have proposed many outcome-valuation methods, virtually all tied in some manner to measurement of consumers' or citizens' health-related preferences. Surveys,⁸⁹ structured interviews,⁹⁰ focus groups,⁹¹ and community meetings⁹² are among the techniques that have been tried or urged to assay respondents' ex ante thinking about the values of clinical outcomes. Commentators have also proposed experimental markets—presentation of hypothetical trading options to human subjects to generate comparative valuations of outcomes—and extrapolations from implicit valuations of life and states of health in labor and consumer-products markets.⁹³ Joined to an extensive program of medical-outcomes research, such methods hold out the promise of a comprehensive set of expected values for clinical interventions.

In theory, "quality adjusted life years" and a variety of other common metrics make it possible to test a universe of expected value-to-cost ratios against the plan's threshold for coverage. In practice, multiple difficulties confound this promise, introducing indeterminacies that invite legal conflict. To begin with, although advocates of the ex ante consent paradigm often analogize to the classic informed consent at the bedside,⁹⁴ the outcome valuation approaches just discussed entail a sharp departure from informed-consent doctrine's deference to individuals' idiosyncratic, subjective judgments. To be sure, as I noted earlier, the classic informed-consent doctrine cabins the permissible subjectivity of patients' decisions. But these outcome-valuation approaches allow no individualized variation in health plans' resource-allocation protocols based on subscribers'

88. In practice, plan managers' allocative decisions may be affected by other, conflicting incentives, such as pressures to assuage "squeaky wheel" patients and providers and risk-selection opportunities that inhere in the administration of benefits. The important problems these incentives present are beyond my scope here.

89. See Peter A. Ubel, *How Stable Are People's Preferences for Giving Priority to Severely Ill Patients?*, 49 SOC. SCI. & MED. 895 (1999); Peter A. Ubel et al., *Public Preferences for Prevention Versus Cure: What If an Ounce of Prevention Is Worth Only an Ounce of Cure?*, 18 MED. DECISION MAKING, Apr.-June 1998, at 141.

90. See, e.g., Oregon Health Decisions, Report of the Making Health Policy 2000 project, available at <http://www.ahd.org/states/or/hd2000.html>.

91. See, e.g., Peter A. Ubel, PRICING LIFE: WHY IT'S TIME FOR HEALTH CARE RATIONING 53-54 (1999).

92. See, e.g., Joshua M. Wiener, *Rationing in America: Overt and Covert*, in RATIONING AMERICA'S MEDICAL CARE: THE OREGON PLAN AND BEYOND 12, 13 (Martin A. Strosberg et al. eds., 1992).

93. Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. PA. L. REV. 1553, 1558 (2002).

94. See Mark A. Hall, *The Problems with Rule-Based Rationing*, 19 J. MED. & PHIL. 315 (1994); Mark A. Hall, *Informed Consent to Rationing Decisions*, 71 MILBANK Q. 645 (1993).

idiosyncratic, ex ante health-related anxieties, fears, and wishes.⁹⁵ These approaches rest, instead, on population-wide assessments of ex ante preferences, setting the stage for conflict with the law's traditional deference to personal idiosyncrasy.

Such conflict is unavoidable because bounded rationality problems make it impossible for health plans to offer large menus of alternative protocols, tailored to prospective subscribers' individualized anxieties, fears, and wishes. To construct a menu of such protocols and to make them minimally understandable to consumers, a health plan would need to learn the private, even unconscious anxieties, fears, and wishes of thousands of prospective subscribers, a task posing an insurmountable problem of "information impactedness."⁹⁶ It would then need to translate and categorize this knowledge into alternative sets of allocative principles, general enough to be understandable to prospective subscribers,⁹⁷ yet specific enough to provide meaningful information about alternative sets of detailed allocative rules.⁹⁸

If health plans could accomplish this impossibly complex task, then implementation of the resulting multiple allocative policies would be unachievable. Each health plan would need to develop multiple sets of allocative rules, covering thousands of clinical scenarios; plan physicians would need to remember and apply the different allocative rules to clinically similar patients who made different ex ante allocative commitments. This approach would require physicians to set aside ethical prohibitions against making such bedside distinctions between patients.⁹⁹ Were they willing to

95. At most, health plans may allow subscribers to "buy out" of their allocative protocols—for example, by paying more out of pocket to access out-of-network providers.

96. See Oliver E. Williamson, *Markets and Hierarchies: Some Elementary Considerations*, 63 AM. ECON. REV. 316 (1973) (presenting notion of "information impactedness" as a way to characterize poor accessibility of information to outside observers, including administrators in a bureaucracy); cf. F.A. Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 519 (1945) (contending that decentralization of knowledge increases efficiency of decision making).

97. Cf. Howard Latin, "Good" Warnings, Bad Products, and Cognitive Limitations, 41 UCLA L. REV. 1193, 1211-15 (1994) (discussing limits on consumers' abilities to understand detailed warnings regarding hazards posed by consumer products).

98. Mediating sets of allocative principles, much more general and simple than detailed clinical-practice protocols, would be necessary to achieve consumer comprehension. Asking prospective subscribers to choose ex ante between alternative, complete sets of allocative protocols, covering thousands of clinical scenarios, would present an impossible task.

99. It would be Pollyannaish to portray physicians as other than deeply implicated in past and present discrimination in medical-resource use based on insurance coverage, social class, race and ethnicity, and gender. See generally M. Gregg Bloche, *Race and Discretion in American Medicine*, 1 YALE J. HEALTH POL'Y L. & ETHICS 95 (2001). Yet even in the most dramatic cases, for example, overt racial discrimination in apartheid-era South Africa and the pre-1970s American South, individual practitioners have tended to abide by single standards of care (subject to externally imposed resource constraints) and to resist, on ethical grounds, pressures to practice differently on clinically similar patients. Those who engineered apartheid medicine in South Africa created an administratively fragmented system within which the individual clinician could devote herself to one standard of care (for one segment of society) and thereby feel protected from a sense of personal complicity in the

do so, they would confront insurmountable cognitive limits. The available evidence indicates that getting physicians to comply with even a single, comprehensive set of centrally promulgated clinical-practice protocols is exceedingly difficult.¹⁰⁰ Physicians' practice patterns are matters of personal habit, drawn from mentors' expectations, interactions with peers, and a lifetime of professional experience. Physicians acquire them unreflectively and are resistant to changing them in response to scientific data, let alone the entreaties of health-plan managers. Evidence suggests that when physicians change their practice styles to accommodate pressures to economize on care for only some of their patients, they make similar adjustments in the care they give to their other patients, even when doing so is contrary to their economic interests.¹⁰¹ Although one might explain this by hypothesizing that physicians adhere altruistically to an antidiscrimination principle, it is also consistent with cognitive obstacles to applying different allocative protocols to clinically equivalent patients with differing insurance coverage. Because physicians' practice styles are more matters of personal habit than of self-conscious, rational design, they are peculiarly resistant to managerial reengineering.

4. *The Indeterminacy of Efforts to Aggregate Health-Plan Subscribers' Allocative Preferences*

A health plan, therefore, can aspire, at best, toward a single, comprehensive set of allocative protocols, perhaps informed by population-wide methods of valuing states of health and illness and years of life. Yet, even this more modest goal presents serious obstacles.

The survey, extrapolation, and other techniques discussed earlier promise to supply the population-wide preference data needed to develop expected values for clinical interventions and to test expected value-to-cost ratios against plan thresholds for coverage. However, efforts to aggregate individuals' preferences into population-wide valuations are notoriously path dependent. Even if individuals' expressed preferences were invariant

imposition of apartheid. HUMAN RIGHTS AND HEALTH: THE LEGACY OF APARTHEID (Audrey R. Chapman & Leonard S. Rubenstein eds., 1998) [hereinafter HUMAN RIGHTS AND HEALTH: THE LEGACY OF APARTHEID].

100. See Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement*, 282 JAMA 1458 (1999); see also Eisenberg & Schneider, *supra* note 58.

101. After the Medicare program's shift in 1983 from per diem and fee-for-service payment of hospitals to prospective payment by diagnosis, which gave hospital administrators powerful incentives to press physicians for earlier discharges and lower-cost diagnosis and treatment, average hospital stays (the product of physician decision making) dropped substantially not only for Medicare patients but also for privately insured, fee-for-service patients. See Judith Feder et al., *How Did Medicare's Prospective Payment System Affect Hospitals?*, 317 NEW ENG. J. MED. 867, 870 (1987). This development defied predictions that the advent of Medicare prospective payment would lead providers to compensate for lost Medicare revenues by lengthening privately insured patients' hospital stays so as to collect more from fee-for-service payers.

and easily discernable, efforts to aggregate them would yield different results depending on the sequencing of questions asked.¹⁰² Moreover, multiple, well-studied cognitive predispositions¹⁰³ make individuals' answers to questions about their relative valuation of risks and benefits dependent on the context and framing of the questions. Unconscious rules of thumb¹⁰⁴ incline persons toward evaluative judgments that give special weight to vivid and recent experiences (the "availability" heuristic), initial impressions (the "anchoring" heuristic), and the idiosyncrasies of each person's experience more generally (the "representativeness" heuristic). Starting points (for example, the "endowment effect"¹⁰⁵), framing biases, and other influences produce additional, path-dependent variation in persons' expressed preferences. This variation virtually guarantees that different methods of valuing states of health and illness will yield divergent results and differing resource-allocation protocols. To the extent that patients or providers dissatisfied with allocative results seek administrative or legal relief, these differences make ongoing conflict over health plans' spending decisions predictable.

Such conflict is likely to be especially divisive and morally troublesome when rules of thumb, starting point effects, and other path-dependent biases produce allocative protocols begrudging in their treatment of socially disfavored groups. For example, a survey that asks people to value maintenance treatment for people with chronic schizophrenia might yield ungenerous results due to starting-point effects. The vast majority of people (and those close to them) do not have schizophrenia.¹⁰⁶ Many people view it as a dread, incurable condition,¹⁰⁷ making them likely to see maintenance therapy as a low-benefit endeavor, since it cannot ameliorate the deficits that keep many people with the disease from aspiring to high-functioning occupational and personal lives.¹⁰⁸ Personal experience with

102. See KENNETH J. ARROW, *SOCIAL CHOICE AND INDIVIDUAL VALUES* 2-3 (2d ed. 1970).

103. A well-known, comprehensive review of this work is *JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES* (D. Kahneman et al. eds., 1982).

104. See Herbert A. Simon, *Rational Choice and the Structure of the Environment*, 63 *PSYCHOL. REV.* 129 (1956). Cognitive psychologists interpret such rules of thumb as adaptations to humans' limited information-processing capacities.

105. Jack L. Knetsch, *The Endowment Effect and Evidence of Nonreversible Indifference Curves*, 79 *AM. ECON. REV.* 1277 (1989).

106. Epidemiological surveys have found incidence rates of 1% or less for schizophrenia in many nations and cultures. See *The International Pilot Study of Schizophrenia*, *SCHIZOPHRENIA BULL.*, Winter 1974, at 21.

107. One might conceptualize this perception in terms of the "availability" or "representativeness" heuristics. For those without personal experience with schizophrenia, media and other popular stereotypes of homeless and other profoundly dysfunctional people with this disease probably play a large role in shaping impressions.

108. See D. Dickinson & R.D. Coursey, *Independence and Overlap Among Neurocognitive Correlates of Community Functioning in Schizophrenia*, 56 *SCHIZOPHRENIA REG.* 161 (2002) (examining correlations between cognitive and other deficits and levels of community functioning in patients with schizophrenia).

schizophrenia might lead to higher regard for maintenance therapy, tied to appreciation for well-treated patients' enhanced capacities to care for themselves and socialize with others.¹⁰⁹ Another example is valuation of treatment for diseases widely thought to ensue from reckless or socially scorned voluntary behavior, such as alcoholic liver cirrhosis and HIV infection.¹¹⁰ On the other hand, detailed allocative protocols can protect patients against recently documented sub rosa and unconseious racial and gender discrimination in the provision of costly, high-technology treatments.¹¹¹

Proponents of various methods of assessing population-wide ex ante preferences are developing sophisticated responses to the problem of cognitive predispositions. A new line of research seeks to chart the terrain of cognitive biases and apparent inconsistencies encountered by survey techniques that ask subjects to make hypothetical trade-offs between treatment for different disease states.¹¹² This work is animated by the hope that designers of resource-allocation protocols can correct for these biases and inconsistencies when extrapolating from survey results to derive expected values for medical interventions. But determining which biases and inconsistencies merit correction—and how to make such corrections—is hardly clear cut. Efforts to distinguish between cognitive error and preferences

109. This effect is distinct from adverse selection since it influences ex ante preferences of individuals independently of their likelihood of someday needing treatment for schizophrenia. For example, friendship with an afflicted person (or the person's family) might either sensitize one to the capacity of treatment to enhance well-being and dignity or traumatize one to the point of embittered rejection of the value of maintenance therapy.

110. The social and moral status of disease-causing behavior may have more influence than such behavior's perceived voluntariness upon public beliefs about the value of treatment for ensuing illness. The telephone survey that Oregon employed initially to rank medical conditions and treatments for its Medicaid rationing program is illustrative: it generated low rankings for treatment of schizophrenia and liver cirrhosis. See OREGON HEALTH SERVS. COMM., *supra* note 51. Even after Oregon adjusted its survey-derived rankings through a process of town meetings and deliberations with medical ethicists, the U.S. Department of Health and Human Services ruled that the rankings so prejudiced people with some medical conditions that they violated the Americans with Disabilities Act ("ADA"). The Clinton Administration revised and eventually authorized the Oregon Plan. See Robert Pear, *U.S. Backs Oregon's Health Plan for Covering All Poor People*, N.Y. TIMES, Mar. 20, 1993, § 1, at 8.

Compare attitudes toward cardiac care for Brie-eating, steak-loving, six-figure earners with attitudes toward liver transplantation for alcoholic cirrhosis or costly antiviral regimens for HIV-infected drug users or practitioners of anal sex.

111. See INST. OF MED. COMM. ON UNDERSTANDING AND ELIMINATING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE, *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* (Brian D. Smedley et al. ed., 2002); see also Bloche, *supra* note 99.

112. See, e.g., Peter A. Ubel et al., *Value Measurement in Cost-Utility Analysis: Explaining the Discrepancy Between Rating Scale and Person Trade-Off Elicitations*, 43 HEALTH POL'Y 33 (1998); Peter A. Ubel et al., *Individual Utilities Are Inconsistent with Rationing Choices: A Partial Explanation of Why Oregon's Cost-Effectiveness List Failed*, 16 MED. DECISION MAKING, Apr.-June 1996, at 117.

that might merit deference¹¹³ run afoul of the latent or overt normative content in myriad cognitive predispositions. Low valuation of maintenance therapy for schizophrenia is illustrative: it is cognizable either as a misunderstanding of the disease or as a value judgment about life with schizophrenia, with and without treatment. Cognitive psychology's heuristics based on the availability and representativeness of information, as well as the anchoring effect of first impressions, model the sort of thinking, based on stereotypes, that leads many to place little value on treatment for schizophrenia. But the notion of cognitive heuristics does not distinguish between logical error and normative bias, let alone between bias that does and bias that does not merit legal or social acceptance. Whether maintenance treatment for schizophrenia should be valued less or more highly than, say, clinical management of lupus, asthma, or other chronic illnesses is a moral and political question, beyond the reach of cognitive-psychology research.

Apparent cognitive inconsistencies present similar normative issues. Consider a survey that presents a hypothetical trade-off between equally costly and effective life-saving treatment for people with and without some disabling condition, say quadriplegia. Suppose that survey respondents attach equal value to providing this treatment to able-bodied and quadriplegic patients but that, in answering another survey question, the respondents place a high value on intervention that restores some quadriplegic people to able-bodied status. One might read this as a logical inconsistency. If respondents equally value saving the lives of the able-bodied and the quadriplegic, should they not see restoration of function to quadriplegic people as having no value?¹¹⁴ Or, if respondents highly value restorative therapy, do they not see life with quadriplegia as less desirable than able-bodied life and life-saving treatment as therefore less valuable for those with quadriplegia than for the able-bodied?

Extrapolation from hypothetical trade-offs in pursuit of a comprehensive scheme of expected values requires resolution of such seeming inconsistencies. Identification and correction of cognitive errors promise to accomplish this resolution but require answers to normative questions. What is the error—respondents' attachment of value to restorative therapy for people with quadriplegia or their equal valuation of life-saving treatment for the quadriplegic and the able-bodied? Or is this apparent

113. See Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 61-62 (1995) (arguing for recognition of distinctions between errors in risk perception and different valuations of the same "objective" risk).

114. Indeed, some object to restorative therapies (for example, intervention to enable deaf people to hear) on precisely these grounds, arguing that attaching positive value to such therapies devalues disabled people's lives. Harlan Lane & Michael Grodin, *Ethical Issues in Cochlear Implant Surgery: An Exploration into Disease, Disability, and the Best Interests of the Child*, 7 KENNEDY INST. ETHICS J. 231 (1997).

inconsistency understandable in terms of the respondents' moral commitments? Perhaps respondents who assign equal value to saving the lives of the quadriplegic and able-bodied patients, but who attach a high value to ameliorating quadriplegia, are adhering to a concept of formal equality, regardless of disability, for life-saving purposes. Perhaps they, at the same time, think it is better to be cured of quadriplegia than to be fated to it, but they treat this disability as morally irrelevant to decisions about life saving.¹¹⁵ What seems on the surface like a logical inconsistency may have a deeper philosophic justification.

Attempts to correct for such inconsistencies and for cognitive predispositions thus necessarily entail the substitution of some moral preferences for others. "Prejudice" in the valuation of medical interventions based on population-wide *ex ante* preferences is unavoidable, since people's *ex ante* preferences are almost always prejudgments—beliefs formed without personal experience of the disease states in question. To the extent that the moral preferences at issue are socially controverted, resource-allocation protocols derived from them will be open to political, administrative, or legal challenges by those who lose out. The prolonged controversy in Oregon over Medicaid rationing priorities illustrates the potential for paralytic conflict over moral choices underlying relative valuations of clinical benefits.

To summarize, welfare-maximizing resource use within a health system, through equalization of the marginal benefits of medical spending, requires agreement on how to value the benefits of medical care. Such agreement is not in sight. A broad social and legal consensus supports the general idea that we should value the benefits of health care by looking to consumer preferences. Beyond this, agreement breaks down. The classic informed-consent model, still relied upon by courts and supported in various forms by commentators, defers to patients' health care choices at the moment of medical decision and disregards the influence of insurance coverage. *Ex ante* approaches try to take account of this influence by looking to consumers' expressed or imputed valuations of health care prior to the onset of clinical need. In its different guises, the consent model imputes value to clinical interventions in many ways, with varying results, all linked at least tenuously to expressed preferences. Potent moral arguments can be marshaled for and against these many alternative approaches to valuing medical care's benefits. Because these arguments express contradictory moral commitments deeply rooted in our society and culture, their resolution is not on the horizon. Measurement of medical care's benefits is thus deeply problematic. When valuation issues reach regulators, the

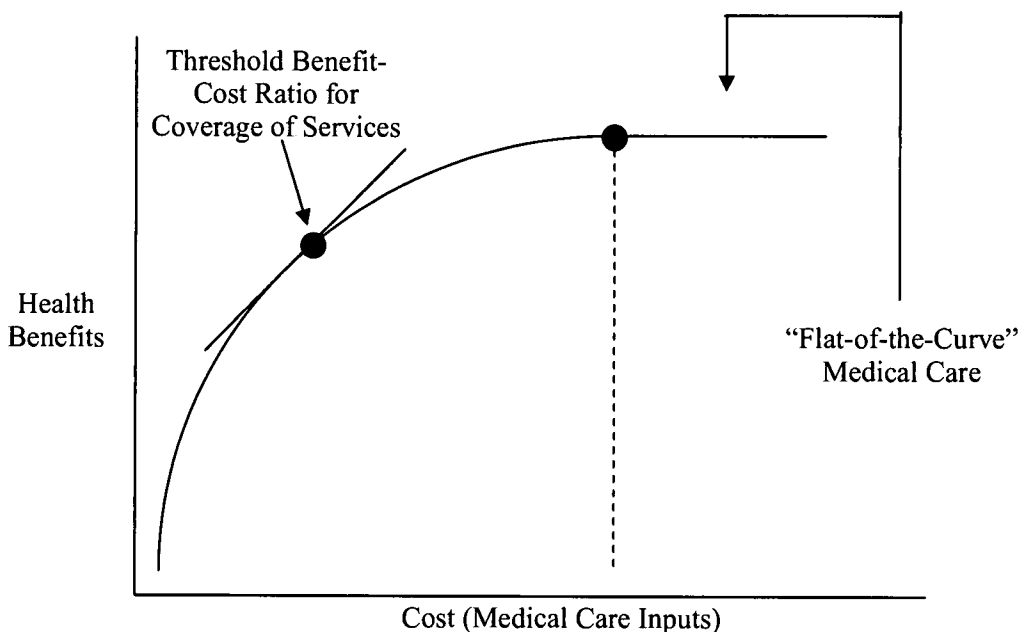
115. Such thinking infuses our everyday morality. For example, we expect firefighters to make equal efforts to rescue rich and poor people from burning buildings, even though we tend to think it is better to be rich than to be poor. The ADA's legal safeguards for the disabled embody such thinking.

courts, or other dispute management institutions, incoherent results are inevitable. The ensuing unpredictability increases the likelihood of frequent, protracted conflict. These valuation problems are additional reason to doubt that the welfare-maximization principle can usefully channel the development of health law.

E. Making Systemwide Cost-Benefit Trade-Offs

The challenge of employing clinical resources in systematic fashion, to maximize the medical benefits that every dollar buys, requires a systemwide, threshold benefit-cost trade-off ratio, set to match the available resources. A health care system, in theory, should supply only services with anticipated benefit-cost ratios above this threshold. This threshold is typically represented visually in the health-care-financing literature as a tangent to a curve drawn concave-downward to express the decreasing marginal benefits of additional medical spending.

FIGURE 2



Some adherents to the welfare-maximization principle envision implementing this threshold through a comprehensive set of allocative protocols, informed by medical outcomes data, clinical costs, and methodologies for valuing years of life and states of health. I have already addressed the difficulties presented by uncertainty and indeterminacy about clinical costs and outcomes, as well as valuation of life and health. I turn now to the

unworkability of the single, programwide benefit-cost trade-off threshold as an allocative precept for health systems and for the law.

This allocative precept for medical care is consistent with larger trends in environmental and other health-related law and regulatory policy. The notion that policymakers should aspire toward systemwide equalization of cost-benefit trade-off triggers for regulatory intervention in health-related matters has become standard wisdom well beyond the health care policy sphere. The last four U.S. presidents issued or abided by executive orders requiring comparative cost-benefit assessments of proposed health and safety regulations with an eye toward developing a coordinated inter-agency approach to cost-benefit trade-offs.¹¹⁶ Regulatory-reform advocates commonly make consistency in the treatment of costs and benefits the touchstone for their policy proposals and their criticisms of current approaches. Gross discrepancies, whether actual or purported,¹¹⁷ in costs per life saved between different federal regulations are often cited to support reform proposals designed to make health and safety regulation more systematically rational.¹¹⁸

This standard wisdom is at odds with how we actually think about risks and costs in different contexts. A dissenting line of commentary on environmental regulation points to cognitive predispositions and inconsistencies of the sort discussed above as proof that people make different choices about hazardous alternatives than conventional risk analysis—grounded in expected-utility theory—would predict or prefer. This commentary interprets discrepancies between people's choices and the results of conventional risk analysis as expressions of people's valuations of risks and benefits. It departs from the standard wisdom principally by contending that these discrepancies should be treated as indicators of legitimate popular preferences and morals, not cognitive errors in need of correction.¹¹⁹

Earlier, I discussed the difficulties that people's cognitive predispositions and inconsistencies pose for health systems' efforts to assign values

116. Exec. Order No. 13,193, 66 Fed. Reg. 7,387 (Jan. 18, 2001); Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993); Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 17, 1981); Exec. Order No. 12,044, 3 C.F.R. 152 (1978).

117. See John F. Morrall III, *A Review of the Record*, REGULATION, Nov.-Dec. 1986, at 25. But see Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981 (1998) (raising doubts about Morrall's costs-per-life-saved estimates).

118. E.g., STEPHEN G. BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* (1993). Such proposals include: a national regulatory "budget" designed to focus political attention on the social costs of regulation and to encourage regulators to economize; reliance on interagency cadres of interdisciplinary experts (skilled at economic reasoning and knowledgeable about health and environmental risk) to make regulatory policy; and congressional rewriting or creative judicial reinterpretation of statutes (for example, the Delaney Clause, requiring zero cancer risk for food additives) that impose prohibitions without regard for countervailing costs.

119. See Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 604-16 (1992).

to the benefits of medical interventions. But the distinction between valuation of benefits and formulation of cost-benefit trade-off rules is largely a matter of labeling. The data that formed the basis for cognitive psychologists' modeling of heuristics, framing biases, and the like were drawn from experimental subjects' choices in trade-off scenarios. We can characterize these choices in either of two ways—as expressions of the weights people ascribe to particular costs and benefits or as applications of people's cost-benefit trade-off rules. The choice between these characterizations has practical importance. The former characterization treats people's cognitive biases and inconsistencies as influences on people's valuations of the costs and benefits at issue. This characterization leaves open the possibility of a single, systemwide cost-benefit trade-off rule. Once we decide whether cognitive biases and inconsistencies represent errors of logic, requiring correction, or people's preferences or moral beliefs, deserving of respect, we can then, in theory, apply a single cost-benefit trade-off principle systemwide.

By contrast, treatment of people's choices—and their cognitive biases and inconsistencies—as irrational cost-benefit trade-off behavior casts doubt on whether systemwide cost-benefit trade-off rules are manageable in practice. It is one thing to specify a cost-benefit trade-off rule in the numerical abstract, in terms of dollar value for a quality-adjusted life-year, or some similar measure, and another thing to gain social and legal acceptance for such a rule. If cognitive biases and inconsistencies incline either lay people or experts toward trade-off judgments inconsistent with each other and at odds with any one across-the-board trade-off rule, then they set the stage for social and legal conflict over the formulation and imposition of such rules.

The wide variety of inconsistent cost-benefit balances struck by current medical practice suggests a high potential for such conflict. As is often noted, the enormous costs, per life-year saved, for some intensive-care-unit services and types of organ transplantation¹²⁰ contrast sharply with low to moderate costs per life-year saved for many primary care and screening services. On a society-wide scale, the marginal benefits, in life-years saved, of money spent on medical care in general are almost surely much less than they are for equivalent spending on effective public health,¹²¹

120. See Meg Durbin, *Bone Marrow Transplantation: Economic, Ethical and Social Issues*, 82 PEDIATRICS 774 (1988); Tammy O. Tengs et al., *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness*, 15 RISK ANALYSIS 369, 371 (1995).

121. See Karla Kerlikowske et al., *Continuing Screening Mammography in Women Aged 70 to 79 Years: Impact on Life Expectancy and Cost-Effectiveness*, 282 JAMA 2156 (1999); Matthias Schrappe & Karl Lauterbach, *Systematic Review on the Cost-Effectiveness of Public Health Interventions for HIV Prevention in Industrialized Countries*, 12 AIDS 231 (Supp. A, 1998); cf. Milton C. Weinstein et al., *Recommendations of the Panel on Cost-Effectiveness in Health and Medicine*, 276 JAMA 1253 (1996).

environmental,¹²² and economic development¹²³ programs. Evidence from comparative studies supports the conclusion that per capita income, education, and other measures of socio-economic well-being influence the health status of populations to a much greater extent than does per capita spending on medical care.¹²⁴

Were we to take seriously the ideal of society-wide rationalization of health-related spending through equalization of cost-benefit triggers for action, we would need to think seriously about shutting down much of what acute-care medical centers do. Were we to take seriously the less-sweeping goal of rationalizing medical spending alone along these lines, we would need to contemplate an enormous shift of resources from high-technology, crisis-oriented care to less-intensive health promotion, disease-prevention, and crisis-avoidance services. Little evidence suggests that any Western, industrialized society is prepared to do these things, through either political or market mechanisms.¹²⁵

Certainly, the wide gap between current health-related spending patterns and the requisites for reallocation of this spending from a welfare-maximization perspective merit deeper scrutiny. Cognitive psychology accounts of bias and inconsistency explain much in retrospect, in seemingly objective fashion, but their ad hoc, after-the-fact use¹²⁶ is undisciplined by the rigor of experimental method. Emotional and interpersonal factors such as differing degrees of dread, family and social ties, perceived voluntariness of risk exposure, and perceived culpability of others for harm¹²⁷ offer enriched understanding of health spending patterns, subject to the same ad hoc problem. Cultural factors may make a difference. For example, the more individualistic a society's values, the less inclined it may be toward systemic approaches to resource allocation. Least studied have been the individualized symbolic meanings, conscious and unconscious, of illness, diagnosis, and therapy.¹²⁸

122. See Kenneth J. Arrow et al., *Is There a Role for Cost-Benefit Analysis in Environmental, Health, and Safety Regulation?*, 272 SCIENCE 221 (1996).

123. See Paul Clements, *A Poverty-Oriented Cost-Benefit Approach to the Analysis of Development Projects*, 23 WORLD DEV. 577 (1995).

124. See RICHARD WILKINSON, *UNHEALTHY SOCIETIES: THE AFFLICTIONS OF INEQUALITY* 66-68 (1996).

125. A dramatic counterexample is postapartheid South Africa, where the health ministry and members of parliament are pushing for wholesale redirection of resources from the nation's elite, publicly funded tertiary-care centers to community health centers and health-promotion programs in impoverished townships and rural areas. HUMAN RIGHTS AND HEALTH: THE LEGACY OF APARTHEID, *supra* note 99.

126. David M. Kreps, *Bounded Rationality*, in *THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND LAW* 168, 170 (P. Newman ed., 1998).

127. M. Gregg Bloche & Carol Eisenberg, *The Psychological Effects of State-Sanctioned Terror*, HARV. MENTAL HEALTH NEWSLETTER, Nov. 1993, at 40.

128. The role of these symbolic meanings in people's medical decisions can be studied in rich detail through psychodynamic exploration of connections between individuals' fears, anxieties, and

An enriched appreciation of what people want (and fear) from the medical system and from health-related public policy more generally would not only contribute to our understanding of the divergence between actual health-related spending and its rationalization from a welfare-maximizing perspective; it could also reduce this gap in two complementary ways. First, it could enable welfare-economics analysis to take better account of what people want from health spending beyond objectively measurable improvement in biological functioning. Such intangibles as fidelity of clinical caretakers,¹²⁹ equity in the distribution of risks and benefits, responsiveness to fears and anxieties evoked by illness and treatment, and symbolic affirmation of the pricelessness of persons through high-cost-low-yield rescue measures for patients in dire straits are not typically incorporated in cost-benefit analysis of health services. Second, it could help consumers and voters clarify what they want from health services and how much they are willing to pay for it. Such clarification could reduce consumer willingness to pay large sums for access to technology-intensive treatments that provide symbolic reassurance or other psychological satisfaction but make little tangible difference in health status. This might push public thinking toward the welfare-maximizing perspective of health economists and others who emphasize measurable improvement in biological functioning.

For the foreseeable future, however, the large gap between aspirations for systemically rational health-related resource use and actual health-spending patterns will remain with us. Any effort to impose a single benefit-cost trade-off threshold for action—applicable to health-related programs in general or to medical care alone—would fly in the face of public and private norms that admit huge differences between the ratios of tangible health benefits to costs necessary to trigger action in different realms. For the time being, we can aspire at best to spheres of rationality—consistency in cost-benefit thinking within, but not across, different realms of activity. We might reasonably hope, for example, for consistency in the cost-benefit judgments that underlie choices between last-ditch,

hopes, and their thinking about disease states and diagnostic and therapeutic options. Psychodynamic inquiry builds on the paradigm of intimate, mostly unconscious linkage between people's elemental fears, anxieties, and hopes and their understandings of life circumstances and choices. *See generally* Roy Schaffer, *THE ANALYTIC ATTITUDE* (1983). Decisions that seem irrational from the expected-utility perspective become understandable as responses to mostly unconscious perceptions of threat or possibility. The richness of this kind of inquiry—the “thick description” it demands and the interpretive depth it entails—is also its greatest limitation. It is individualized, highly subjective, and inherently after-the-fact and ad hoc. It is thus a poor tool for predictive modeling of population-wide deviations from expected-utility thinking.

129. *See* M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 *STAN. L. REV.* 919 (2002) [hereinafter Bloche, *Trust and Betrayal in the Medical Marketplace*]; M. Gregg Bloche, *Clinical Loyalties and the Social Purposes of Medicine*, 281 *JAMA* 268 (1999) (discussing strains on clinical caretakers' loyalty to patients) [hereinafter Bloche, *Clinical Loyalties and the Social Purposes of Medicine*].

life-sustaining measures in cardiac intensive care units. But consistency in the cost-benefit balances struck by intensive care unit physicians, pediatricians who provide well-baby care, and authors of air-pollution regulations is at odds with the human propensity to compartmentalize treatment of risks and costs in different spheres of life. Government initiatives to mandate such consistency across diverse spheres of life would almost certainly meet strong popular opposition.¹³⁰

Recognition of spheres of rationality would substitute for systemic welfare maximization a "federalist" model for the management of health risks and benefits in different substantive domains. It would leave room for health-plan managers, environmental regulators, and other decision makers to strike very different balances in different realms. Such differences themselves add a dynamic element to the model, by creating opportunities for advocates of reform to point to inconsistencies as evidence of unfairness, injustice, or waste. Effective advocacy along such lines can change not only the cost-benefit balances society strikes but also the boundaries society implicitly recognizes between domains of activity in which consistency is sought. These boundaries themselves have moral content, and they will surely shift with time. But we should not mistake such shifts for movement toward society-wide economic rationalization of health-related resource use. Systemwide cost-benefit trade-off triggers for health care provision, in particular, are beyond our practical and moral reach.¹³¹

II

LEGAL CONFLICT AND THE QUEST FOR EFFICIENCY

Welfare-economics reasoning has made large inroads into the law of health care provision. Courts rely upon it when interpreting tort and contract rules. Legislators and administrative agencies invoke efficiency as a rationale for regulatory interventions.¹³² But to the extent that what is

130. Cf. Hornstein, *supra* note 119, at 611-16 (predicting public opposition to efforts to systematize the making of cost-benefit trade-offs for purposes of environmental regulation).

131. From a utilitarian perspective, one might prefer such systemic triggers; I do not mean here to contest their desirability in the abstract. My intent here is to be pragmatic. For the reasons discussed in the text, I am of the view that we are not capable as individuals—and as a democratic society—of the degree of systemic rationality such triggers demand. This incapability is cognitive, affective, and moral. Our bounded rationality and emotional engagement with particular people and experiences preclude the requisite systemwide perspective and judgment. More speculatively, the influence of our particularized emotional engagements upon our moral judgment may restrain us from systemic thinking run amok and thereby bestow evolutionary advantage and moral benefits. Pol Pot and Mao thought systematically, without restraint. Cf. RICHARD RORTY, *CONTINGENCY, IRONY, AND SOLIDARITY* (1989) (reconceiving liberalism as a solidarity-driven commitment to avoiding cruelty).

132. I refer here to the declared goals of regulatory programs and do not mean to deny that regulatory statutes and agencies are often disproportionately responsive to the concerns of politically potent interest groups. Also, regulatory programs sometimes subordinate systemic rationality to redistributive concerns. In addition, more often than they acknowledge, regulators pursue conceptions

efficient or welfare maximizing is uncertain and contested in the health sphere, legal decision makers cannot employ economic reasoning to yield predictable, coherent answers to the questions they confront.

Indeterminacy about what maximizes welfare pervades medical practice and health care policy. This indeterminacy is both empirical and normative. It arises from our scientific uncertainty, our limited cognitive capacities, and our collective indecision about the answers to myriad moral questions. It furnishes many opportunities for parties with conflicting goals and interests to contest the question of what efficiency requires. Legal authorities can impose answers in particular cases. But so long as underlying empirical uncertainties and normative differences linger, these answers will be open to challenge. Furthermore, the answers that judges and regulators decree are inconsistent across jurisdictions and incoherent across substantive areas of the law.¹³³ This incoherence and inconsistency is hardly surprising, given the breadth of empirical and normative indeterminacy in the health sphere.

Legal inconsistency and incoherence are not unique to health care.¹³⁴ Yet the health sphere is virtually unique in its multiplicity of legal and regulatory actors—federal, state, and local; and judicial, administrative, and legislative—each with its own incomplete understandings and parochial aims.¹³⁵ No single public entity, akin to the Environmental Protection Agency or the Federal Communications Commission, exercises sweeping regulatory authority.¹³⁶ Indeterminacy—and ensuing possibilities for inconsistency and incoherence in matters of governance—increases exponentially with complexity and the multiplicity of actors in political and social

of systemic rationality that make sense only if we paternalistically interpret the interests of some affected individuals.

133. Clark C. Havighurst, *American Health Care and the Law: We Need to Talk*, HEALTH AFF., July-Aug. 2000, at 84.

134. "Critical Legal Studies" scholars have for a generation played leading roles in illuminating inconsistencies and incoherence in many areas of law. See, e.g., MARK KELMAN, A GUIDE TO CRITICAL LEGAL STUDIES (1987). Some scholars from both within and outside the Critical Legal Studies movement suggest that the quest for systemic rationality in public policy is inspired by our emotional need for a sense of control, more than by real prospects for success. See Donald C. Langevoort, *Behavioral Theories of Judgment and Decision Making in Legal Scholarship: A Literature Review*, 51 VAND. L. REV. 1499, 1504 (1998).

135. Havighurst, *supra* note 133.

136. One might argue in response that I am merely making the case for why there ought to be such a health-policy agency, to empower us to come closer to achieving systemic rationality. A full response is beyond my scope here, but I strongly suspect that the passion and energy behind our parochial concerns and partial understandings in the health sphere preclude the formation and effective functioning of such an agency. The American history of repeated failed attempts at systematized regulatory governance of medicine, most recently the Clinton administration's health care reform proposal, is consistent with this suspicion. On the more mundane level, my frame of reference for this Article is the array of governance institutions as it (more or less) currently exists, not as it might someday be radically transformed.

systems.¹³⁷ The multiplicity of legal institutions affecting health care is, in turn, layered on top of the biological and psychological complexities I have discussed. Thus, whatever the obstacles that human cognitive limitations and institutional complexity pose for systemic legal governance more generally, these obstacles are much greater in the health sphere than in other policy areas.

To suggest the breadth of the legal challenge posed by this indeterminacy and the magnitude of the resulting instability and incoherence in health law, I will highlight the role of ideas about efficiency in a number of areas of law bearing on the duties and rights of doctors and hospitals, payers, and patients. I will not try to review or even to summarize these areas of law. To do so would require a treatise. Rather, I will focus on the welfare maximization principle's inability to yield clear, coherent, and stable answers to contested questions within several areas—medical tort law, disputes over medical coverage, legal safeguards for medical professionalism, health care antitrust law, and regulation of capital investment.

A. *Medical Tort Law*

As first-year law students quickly learn, the law of negligence instructs persons (and organizations) to take "reasonable care." Whether or not, as Chicagoan law-and-economics scholars have famously argued, courts have long treated this duty as a call to take precautions when benefits outweigh costs, reasonableness in negligence law is today almost universally understood in these utilitarian terms. Thus the question of what is rational in the cost-benefit balancing sense is at the heart of tort law's treatment of medical decision and action. Clinical judgments and interventions that yield probabilistic benefits in excess of financial and health costs are appropriate, indeed required, under the reasonable-care standard. Medical action (and inaction) that fails this test should, in theory, lead to liability for any harm that results.

As it does in other technically complex fields, tort law finesses the problem of determining what constitutes reasonable care in the medical sphere by looking to industry practice and to experts—the medical profession—to specify standards of care in particular cases.¹³⁸ The utilitarian case for such deference rests on standard free-market assumptions, including the sovereignty of revealed preferences as measures of benefit. In an adequately functioning market, industry practice strikes an acceptable balance between producers' costs and consumers' benefits, and the law looks to

137. Indeterminacy increases exponentially with complexity in physical and biological systems as well, to the point that meaningful prediction, which requires artful simplification of situations involving multiple interactions, becomes impossible. RICHARD C. LEWONTIN, *THE TRIPLE HELIX: GENE, ORGANISM, AND ENVIRONMENT* 82-87 (2000).

138. See William Schwartz & Neil Komesar, *Doctors, Damages and Deterrence: An Economic View of Medical Malpractice*, 298 NEW ENG. J. MED. 1282, 1283 (1978).

industry experts to say what that practice is. This paradigm “works”—yielding consistency and predictability—to the extent that there is (1) clarity about what industry practice is and (2) agreement that industry practice strikes an acceptable balance between costs and benefits. Both are lacking in the medical sphere. The great diversity of medical-practice styles, both within and between health plans, offers litigants many opportunities to contest the question of what constitutes industry practice. This virtually guarantees inconsistent, unpredictable adjudicative outcomes. For the reasons discussed above, we lack the empirical and normative certainty necessary to agree on “correct” outcomes. To the extent that industry practices can be specified, the multiple failings of the medical marketplace raise widely held doubts about the appropriateness of the cost-benefit trade-offs built into these practices. These doubts have sown the seeds for challenges to medical tort law’s traditional deference to professional standards of care.¹³⁹

An alternative approach to specifying standards of clinical care for tort law looks to medical and other experts, armed with empirical data, to make the necessary cost-benefit trade-offs and to set evidence-based practice standards.¹⁴⁰ This approach founders on the problems of scientific uncertainty, limited cognitive capacity, and moral irresolution discussed herein. Any set of cost-benefit trade-offs and resulting practice standards is open to plausible challenges, rooted in alternative empirical assumptions, cognitive predispositions, and normative premises. Without an independent basis for treating particular practice standards as authoritative in particular contexts, legal indeterminacy and intractable conflicts inevitably ensue.

B. *Disputes Over Medical Coverage*

In theory, contract law permits the parties to medical transactions to choose the practice standards by which they will be bound, or at least to narrow the range of clinical alternatives by agreeing to general cost-benefit trade-off guidelines.¹⁴¹ However, courts have not allowed health care providers to contract out of the tort system’s approach to setting standards of care. Insurance coverage for clinical services is a different matter, although the managed care revolution has blurred the line between coverage and provision of services. The courts have tended to treat coverage disputes as questions of contract law, albeit subject to the specialized, almost tort-like

139. See, e.g., *Kennedy v. Murphy*, 640 N.E.2d 764, 767 n.6 (Ind. Ct. App. 1994) (stating that local custom is only one of several factors in determining standard of care); see also Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, LAW & CONTEMP. PROBS., Winter-Spring 1991, at 87, 116-17.

140. See Sackett & Rosenberg, *supra* note 56; Richard E. Leahy, Comment, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CALIF. L. REV. 1483 (1989).

141. See HAVIGHURST, *supra* note 29, at 22.

interpretive principles that judges classically apply to insurance contracts. Actions against insurers for injunctive relief (to compel provision of denied benefits) and breach of contract traditionally benefit from canons of construction that favor insureds when insurance-contract provisions are ambiguous or complex.¹⁴² On the other hand, the law gives effect to unambiguous, clearly drafted insurance coverage exclusions¹⁴³ and, as Clark Havighurst has observed, would probably permit the contractual grant of authority to health plans to make coverage decisions based on clearly stated cost-benefit trade-off principles.¹⁴⁴ To the consternation of Havighurst and other advocates of explicit rationing via ex ante contractual consent, health plans have not explicitly asserted this authority in their subscriber agreements. Rather, they have stuck to the traditional standard for coverage decisions, the opaque "medical necessity" test.

Like the tort standard of reasonable care, medical-necessity clauses in health-plan contracts derive their specific content from external sources. Before the 1980s, courts tended to treat medical-necessity provisions as contractual commitments to pay for all services judged appropriate by treating physicians, so long as these judgments were consonant with professional standards of care.¹⁴⁵ To constrain treating physicians' power to spend, insurers began adding contractual provisions reserving for themselves the authority to determine medical necessity. Courts have accepted the general idea of such constraints, but they have closely scrutinized the fairness of insurers' internal appeal procedures,¹⁴⁶ the adequacy of notice to subscribers concerning appeal rights and plans' power to decide medical necessity,¹⁴⁷ and the reasonableness of insurers' medical-necessity determinations.¹⁴⁸ Legal disputes over coverage have tended to play out in these areas.¹⁴⁹ Although judicial examination of plans' notice and appeals

142. These include the principles that courts should construe ambiguous contract language (1) in favor of the "reasonable expectations of the insured" and (2) against the interests of the drafters. *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) (criticizing judicial use of these doctrines to expand insurance coverage after-the-fact).

143. *See, e.g.,* *Lewis v. Trustmark Ins. Co.*, No. 98-2493, 1999 U.S. App. LEXIS 15746 (4th Cir. July 12, 1999) (per curiam) (holding that the plan administrator did not abuse its discretion by finding a treatment "experimental" as defined by the plan, then subsequently denying coverage); *Martin v. Blue Cross & Blue Shield of Va., Inc.*, 115 F.3d 1201 (4th Cir. 1997).

144. HAVIGHURST, *supra* note 29, at 113.

145. *E.g.,* *Van Vactor v. Blue Cross Ass'n*, 365 N.E.2d 638 (Ill. App. Ct. 1977).

146. *See* *Engalla v. Permanente Med. Group*, 938 P.2d 903 (Cal. 1997).

147. *See* *Sarchett v. Blue Shield of Cal.*, 729 P.2d 267 (Cal. 1987).

148. *See, e.g.,* *Aetna Life Ins. Co. v. Lavoie*, 470 So. 2d 1060 (Ala. 1984); *Tudor v. Metro. Life Ins. Co.*, 539 N.Y.S.2d 690 (N.Y. Dist. Ct. 1989).

149. Contractual exclusions for experimental or investigational treatment have been another nidus of legal conflict over coverage. Construing such provisions pursuant to ERISA, federal district courts in Minnesota and New Jersey ordered payment for bone-marrow transplants for multiple myeloma. *Leonhardt v. Holden Bus. Forms Co.*, 828 F. Supp. 657 (D. Minn. 1993); *Dozza v. Crum & Forster Ins.*

procedures takes some account of dignitary and other nonutilitarian, due process concerns, reliance on contract law as the basis for judicial review of insurers' coverage decisions has encouraged courts to consider coverage issues in economics-oriented terms.

When the meaning of ambiguous contract language is at issue, "black letter" contract doctrine frames the question for the courts as an inquiry into what the parties—insurers and insureds—mutually intended.¹⁵⁰ Such mutual intent is, in truth, absent for the vast majority of medical-necessity determinations, since insurance purchasers (subscribers or their employers) cannot anticipate and plan for the almost infinite range of clinical circumstances they might someday confront. Contract law treats the problem of absence of mutual intent by searching for the most reasonable way to fill the gap,¹⁵¹ and contemporary contract jurisprudence defines reasonableness in utilitarian terms. Thus, judicial review of medical-necessity determinations under contract law principles is largely an inquiry into the economic rationality of insurers' decisions—an inquiry subject to all of the cognitive constraints and empirical and normative indeterminacies discussed in this Article.

Some subscriber contracts seek to cabin this inquiry through language requiring that medical necessity be determined in accordance with health plans' clinical-practice and payment protocols. But health plans rarely make these protocols available to consumers. To the contrary, plans often insist that their payment rules are proprietary.¹⁵² Since contract law does not permit enforcement of terms known or accessible only to one party, health plans' efforts to preempt disputes over medical-necessity determination by invoking such protocols stand on weak legal ground. Were health plans to put even general language in their contracts setting forth system-wide cost-benefit trade-off policies, courts might tolerate detailed payment protocols that aim to give these policies rough effect. But, health plans have so far shied away from doing so. The opaque medical-necessity provisions in almost all health-insurance contracts do not acknowledge, let alone ordain the weighing of benefits against costs.

Were some bold health-plan managers to offer contracts with explicit cost-benefit balancing principles, the pervasive empirical and normative indeterminacies discussed above would preclude a single, definitive

Co., 716 F. Supp. 131, 140 (D.N.J. 1989). Addressing the same issue, however, a district court in Arizona denied payment. *See Lehman v. Mutual of Omaha Ins. Co.*, 806 F. Supp. 859 (D. Ariz. 1992).

150. "Black letter" contract law calls for interpretation of ambiguous terms such as "medical necessity" through inquiry into the parties' shared intent. RESTATEMENT (SECOND) OF CONTRACTS § 201 (1979) (rules in aid of interpretation).

151. This gap-filling approach is sometimes explicit and other times implicit in the legal fiction of an inquiry into what the parties would have intended.

152. *See Contract Issues and Quality Standards for Managed Care: Hearings Before the Subcomm. on Health and Env't of the House Comm. on Commerce*, 104th Cong., (1996) (statement of Karen Ignani, President and CEO, Am. Ass'n of Health Plans).

translation of these principles into comprehensive protocols for treatment and payment. These indeterminacies would leave much room for unsatisfied patients and providers to contest denials of benefits and little guidance for judges, arbitrators, or others faced with such disputes. The result would be case-by-case incoherence and unpredictability and a high degree of legal conflict over denials of coverage.

Absent any contract language constraining the assessment of medical need, the space for conflict over health plans' medical-necessity determinations is even wider. Both contract and tort law principles prescribe open-ended inquiry into a coverage decision's reasonableness—inquiry bounded only by the ability of the opposing parties to marshal expert testimony on behalf of one or another purported standard of appropriate care.¹⁵³ The current explosion of litigation in this area and the emergence of medical-coverage disputes as a front-and-center political issue¹⁵⁴ are thus hardly surprising. Nor is it surprising that managed health plans have devoted considerable resources¹⁵⁵ to the campaign to preserve their immunity, under the federal Employees Retirement Income Security Act ("ERISA"), from suits for compensatory damages arising from denial of coverage.¹⁵⁶ Were

153. Federal and state rules of evidence have been applied to permit the admission of such medical testimony without regard for its scientific basis. Even under the Federal Rules, which have been construed to require judges to screen proffered scientific evidence for scientific validity, *see Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), medical testimony material to an issue of fact is admitted without judicial assessment of its scientific foundation, so long as the proffered expert qualifies on the basis of her professional credentials. However, medical testimony offered in toxic-tort cases is subjected to Daubert review. *See, e.g., Moore v. Ashland Chem., Inc.*, 126 F.3d 679 (5th Cir. 1997).

154. *See, e.g., Ceci Connolly, Gore Outlines Proposal on Health Care; Guaranteed Coverage for Children is Pledged*, WASH. POST, Sept. 8, 1999, at A4; Amy Goldstein & David S. Broder, *Health Care Growing as 2000 Issue*, WASH. POST, July 11, 1999, at A1. Through the summer of 2001, as both houses of Congress debated, then passed, versions of the so-called Patients' Bill of Rights, legal remedies for denial of coverage remained a front-burner political issue. September eleventh and its political aftermath pushed this issue at least temporarily to the periphery of the congressional agenda.

155. The Health Insurance Association of America contributed \$114,862 to federal candidates during the 1997-98 election cycle. The American Association of Health Plans contributed \$43,075 during the same period. These contributions from the two major health-insurance and managed care trade associations do not include donations made by individual companies or their employees. *See The Center for Responsive Politics, Political Action Committees*, at <http://www.opensecrets.org/pacs> (last visited Nov. 7, 2002).

156. ERISA's preemption of state regulation of employee benefit plans, 29 U.S.C. § 514 (1997), was construed by courts during the early and mid-1990s to bar state tort and contract actions against employer-provided health plans for denial of coverage, whether or not such plans are self-insured. *E.g., Corcoran v. United HealthCare, Inc.*, 965 F.2d 1321 (5th Cir. 1992). More recently, the U.S. Supreme Court and some lower courts have signaled a cutback of this immunity. *See supra* note 9. But ERISA preemption's ultimate fate remains to be determined. Approximately 160 million Americans obtain their medical coverage through the workplace and thus face the possibility of ERISA preemption of state law claims against health plans for negligent administration of plan benefits. Consumers with employment-based medical coverage cannot pursue federal actions against their health plans for compensatory damages. ERISA has been construed to permit them to sue in federal court only for the value of coverage denied. *See Corcoran*, 965 F.2d at 1334-38.

health plans to lose this immunity, the threat of a new surge of litigation would put great pressure on them to be more generous in their medical-necessity determinations, which would in turn increase their costs in a fiercely competitive environment. Resolution of disputes over medical necessity requires answers to scientific mysteries that the medical community has not yet solved and normative questions that American society is not close to putting to rest.

C. *Legal Safeguards for Medical Professionalism*

The law insulates professional authority in a number of ways from market and political pressures. Organized medicine's response to the managed care industry's rising power has focused on preserving and enlarging these protections. Proscriptions against medical practice by corporations,¹⁵⁷ professional control of state medical licensing and disciplinary bodies,¹⁵⁸ and federal and state reliance on credentialing decisions made by private-sector professional organizations¹⁵⁹ are examples of existing patterns of protection and deference to professional authority. Efforts to expand such protection include lobbying of state legislatures to limit health plans' power to contract selectively with providers (by enacting "any willing provider" statutes and restrictions on physician "deselection") and the campaign to win exemption from antitrust and other restrictions on medical unionization.¹⁶⁰

Not surprisingly, the managed care industry has vigorously resisted these efforts, warning that medical unionization and restrictions on selective contracting would seriously weaken the industry's ability to harness market forces on behalf of more cost conscious, and thus more rational, use of medical resources.¹⁶¹ Organized medicine counters with variations on the traditional claim that consumer ignorance about health care and

157. Although corporations, primarily health plans and hospitals, exercise considerable influence on clinical judgment, it remains the case in most jurisdictions that only physicians can make (and be held personally accountable for) medical decisions. *Physicians and Surgeons*, 61 AM. JUR. 2D, at § 54 (1981). Of course, to the extent that health plans and hospitals, through coverage protocols and other policies, set the parameters within which physicians must act, the prohibition on corporate practice of medicine is a formalism without bite.

158. See Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANN. HEALTH L. 201 (1999).

159. Such diverse matters as institutional licensing, participation in publicly funded programs, and courtroom admission of expert testimony are tied to credentials issued by medical-specialty societies and boards.

160. E.g., *Legal Scope of Proposed Antitrust Waiver for Physicians Debated Before House Panel*, HEALTH L. REP. (BNA) No. 25, June 24, 1999, at 1017; *Doctors Drawn to Unions by Abuses in Health Care System, Conference Told*, HEALTH L. REP. (BNA) No. 39, Oct. 7, 1999, at 1624.

161. See *Quality Health-Care Coalition Act of 1999: Hearing Before the House Comm. on the Judiciary*, 104th Cong. (June 22, 1999) (airing views strongly opposed to collective bargaining by physicians).

physicians' expertise and ethical commitment to patients¹⁶² make medical judgment, insulated from market pressures, the preferable basis for allocating clinical resources. In legislatures, regulatory bodies, and the public arena more generally, the common currency of the debate over the place of professionalism in health care and of legal protections for it has been the comparative efficacy of market forces and professional judgment from a social welfare-maximizing perspective. To be sure, proponents of insulating professional judgment from market pressures tend to stress the benefits for patients rather than for society as a whole. But this patient-centered perspective is tied to a particular conception of social welfare—and of rationality and efficiency—that puts a premium on the concerns of the sick over the preferences of consumers in general.

Thus the debate over the role of professional judgment and authority in health care is, at the core, a contest between understandings of what efficiency requires. The empirical uncertainties and normative disagreements considered in this Article translate into conflict between these understandings. Competing interest groups, especially the medical profession and the managed care industry, drive this conflict, and shifting balances of political influence may settle particular legislative and regulatory questions (at least for a time). But our underlying empirical and normative irresolution creates the climate for this conflict. Claims contrary to settled empirical or normative consensus could not gain political traction. The absence of consensus makes space for sharply differing views about the appropriate place of professional judgment and authority in health care provision.

D. Health Care Antitrust Law

Maximization of consumer welfare is the animating principle of contemporary antitrust law,¹⁶³ thus antitrust enforcement in the health sector

162. See Arrow, *supra* note 54.

163. Strictly speaking, antitrust law targets anticompetitive trade practices without reference to consumer welfare. But when confronting "market failure" and "rule of reason" defenses to allegations of anticompetitive behavior, courts have looked for guidance to the ideal of the perfectly competitive, welfare-maximizing marketplace. When they have found market failures that cause competitive behavior to reduce social welfare, courts have permitted private restraints on this behavior, reasoning that such restraints improve social welfare in a manner akin to a better-functioning marketplace. See, e.g., *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999) (upholding dental association's restrictions on advertising of fees as "procompetitive," and therefore acceptable under "rule of reason" analysis, on the ground that the restrictions reduced the possibility of consumer misunderstandings). This approach preserves, in form, the antitrust ideal of the competitive marketplace, while transforming much of antitrust law, in practice, into open-ended inquiry into the efficiency of the conduct at issue. Critics of this approach contend that it turns the antitrust inquiry into whether a practice is "procompetitive" or "anticompetitive" on its face by empowering judges to attach the "procompetitive" label to restrictions on competition that they believe further social welfare. Peter Carstensen & Bette Roth, *The Per Se Legality of Some Naked Restraints: A (Re)conceptualization of the Antitrust Analysis of Cartelistic Organizations*, ANTITRUST BULL., Summer 2000, at 349, 415. Proponents of greater reliance on markets in health care matters warn that this approach opens a door "much wider than is prudent" to physicians' self-serving restraints on competition. Havighurst, *supra* note 17, at 952.

unabashedly pursues efficiency. In passing on mergers, acquisitions, and collaborative arrangements, enforcement agencies and courts look to whether the combinations at issue produce consumer welfare loss.¹⁶⁴ Per se proscriptions against some arrangements rest on generalized, categorical judgments about their effects on consumer welfare. So-called “rule of reason” inquiries into combinations not prohibited per se involve individualized, case-by-case consideration of consumer-welfare effects. Resolution of health care antitrust law disputes thus requires choices between competing conceptions of efficiency in medicine.

The most bitterly contested questions in medical antitrust law today involve combinations of physicians and other health care providers in response to the market pressures of the managed care revolution.¹⁶⁵ Antitrust-enforcement guidelines adopted jointly by the U.S. Department of Justice and the Federal Trade Commission¹⁶⁶ put great weight on financial risk-bearing as a measure of whether collaborative arrangements among providers enhance or undermine consumer welfare. The guidelines’ strong preference for risk bearing by providers is rooted in the premise that, for any given degree of market power, integration of health care financing and provision yields clinical resource use closer to the optimum than do fee-for-service payment arrangements. Undergirding this premise are many contestable empirical claims and normative judgments. They involve such matters as: the comparative degree to which at-risk and fee-for-service providers consider the costs of tests and treatments and the clinical consequences of foregoing them, the comparative extent to which these differently paid providers weigh the benefits of preventive services, the inclinations of at-risk and fee-for-service providers to practice evidence-based medicine and to value clinical results in accordance with consumer preferences, the privileging of consumer preferences at the point of health-plan subscription versus the moment of clinical decision, and the import of role conflict (and potential patient mistrust) engendered by financial incentives to withhold beneficial care.¹⁶⁷

The empirical uncertainties and normative disagreements that have been this Article’s focus suffuse these and other underlying questions. We have good reason to believe that fee-for-service practice and coverage is wasteful—that, in general, it engenders overspending relative to clinical benefits achieved. However, we lack analytic tools for quantifying this

164. See Peter J. Hammer, *Medical Antitrust Arrangements: Coase and the Changing Structure of the Firm*, in *THE PRIVATIZATION OF HEALTH CARE REFORM: LEGAL AND REGULATORY PERSPECTIVES*, 113-57 (M. Gregg Bloche ed., 2003).

165. *Id.*

166. U.S. DEP’T. OF JUSTICE & FED. TRADE COMM’N, *STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE* (1996), available at <http://www.usdoj.gov:80/atr/public/guidelines/0000.pdf>.

167. See David Mechanic & Mark Schlesinger, *The Impact of Managed Care on Patients’ Trust in Medical Care and Their Physicians*, 275 JAMA 1693 (1996).

waste. The concept of moral hazard is central to contemporary economic thinking about clinical waste. Yet, as I argued above, moral hazard cannot yield measures of waste unless supplemented by speculative resolution of empirical unknowns and by agreement on normative matters that remain fervently contested. We are thus hardly in a position to opine with confidence, as do the antitrust-enforcement agencies, that putting providers at insurance risk is more efficient or rational than third-party, fee-for-service payment, with all its flaws. Neither, for that matter, is there sound basis for the competing claim, pressed in the political arena by doctors and hospitals,¹⁶⁸ that exempting providers from antitrust restrictions on non-risk bearing combinations will enhance consumer welfare. In antitrust, as in other areas of health law, efficiency is insufficiently determinate to yield clear, durable answers to the most contested questions.

E. Regulation of Capital Investment

Efforts to contain medical spending through regulatory constraints on health care providers' capital spending reached a peak in the 1970s and have been on the wane since. Once required by federal law,¹⁶⁹ so-called Certificate of Need ("CON") regulation of spending on new construction and large-scale technology purchases now persists in fewer than half of the states.¹⁷⁰ The CON approach entails, in essence, the use of medical-practice protocols at the macro level. State regulators' decisions to issue or deny CONs for new construction or technology are supposed to be made by

168. Hammer, *supra* note 164.

169. National Health Planning and Resources Development Act of 1974 ("NHPDA"), 42 U.S.C. § 300m(d), 300m-2(a)(4)(B) (1976) (repealed 1993). The repealed sections of NHPDA required states to designate agencies to perform "Certificate of Need" review of health facilities and services or else lose federal funds for development, expansion, and support of health resources.

170. Twenty-six states and territories have some form of Certificate of Need regulation for hospitals or home health care facilities. ALA. CODE. §§ 22-21-260 to 22-21-278 (1994); ALASKA STAT. §§ 18.07.011-18.07.021 (Michie 1995); CONN. GEN. STAT. §§ 19a-633 to 19a-645 (1994) (licensing and state budget review); FLA. STAT. ch. 408 (1993 & Supp. 1994); GA. CODE ANN. §§ 31-6-1 to 31-6-70 (1994); HAW. REV. STAT. §§ 323d-1 to 323d-54 (1989); KY. REV. STAT. ANN. §§ 216B.010-216B.030 (Banks-Baldwin 1994); ME. REV. STAT. ANN. tit. 22, §§ 301-324 (West 1994); MD. CODE ANN., HEALTH-GEN. II, §§ 19-101 to 19-222 (1994); MICH. COMP. LAWS §§ 222.22201-222.22260 (1995); MISS. CODE ANN. §§ 41-7-171 to 41-7-209 (1995); MO. REV. STAT. §§ 197.300-197.366 (1995); MONT. CODE ANN. §§ 50-5-301 to 50-5-316 (1994); NEB. REV. STAT. §§ 71-5801 to 71-5870 (1994); N.H. REV. STAT. ANN. §§ 151-C:1 to 151-C:15 (1994); N.J. STAT. ANN. §§ 26:2H-1 to 26:2I-39 (West 1994); N.C. GEN. STAT. §§ 131E-175 to 131E-190 (1995); OHIO REV. CODE ANN. §§ 3702.51 to 3702.60 (Anderson 1995); OKLA. STAT. ANN. tit. 63, §§ 1-850 to 1-858 (West 1995); 35 PA. CONS. STAT. §§ 448.701-448.712 (2000); S.C. CODE ANN. §§ 44-7-320 to 44-7-460 (Law. Co-op. 1976); TENN. CODE ANN. §§ 68-11-101 to 68-11-125 (1994); VA. CODE ANN. §§ 32.1-102.1 to 32.1-102.11 (Michie 1994); 19 V.I. CODE ANN. § 223 (1994); WASH. REV. CODE §§ 70.38.015-70.38.920 (1995); W. VA. CODE §§ 16-2D-1 to 16-2D-15 (1995). Cf. Patrick John McGinley, Comment, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a "Managed Competition" System*, 23 FLA. ST. U. L. REV. 141 (1995); J. Duncan Moore, Jr., *CON Survival Struggle*, MOD. HEALTHCARE, Aug. 11, 1997, at 32; Thom Wilder, *Ohio Law Highlights Sweeping Changes for State CON Programs*, 4 HEALTH L. REP. (BNA) No. 4, June 1, 1995, at 829.

reference to guidelines detailing optimal ratios of different types of hospital beds, diagnostic-imaging machines, outpatient facilities, and so on to numbers of people in the geographic area served. To the extent that CON regulation succeeds in holding the supply of some services below (insurance-driven) demand, allocation among patients with competing needs is negotiated by attending physicians and hospital or clinic administrators.¹⁷¹

Thus the CON strategy entails a quest for systemic efficiency at several stages—development of protocols specifying optimal ratios of plant and equipment to people, case-by-case regulatory decision making based on these protocols, and allocation of scarce facilities and technology among individual patients. At all of these levels, the indeterminacies discussed in this Article come into play. Absent scientific evidence for the efficacy of most clinical interventions and society-wide agreement on how to value multitudinous states of health and illness, promulgation of protocols specifying optimal levels of plant-and-equipment is speculative to the point of arbitrariness. Application of such protocols to particular capital projects is bedeviled by difficulties involved in defining populations served by proposed and preexisting facilities and evaluating these populations' preferences and states of health. Allocation at the micro level, among individual patients, is vexed by our inability to project clinical outcomes and to agree on how to value and compare states of health and illness in individual cases.

The result is indeterminacy that engenders intractable conflict at all three levels. State regulators' CON decisions have often been the subject of paralytic litigation¹⁷² over both the content of population-wide protocols specifying ratios of plant and equipment to people and the application of such protocols to individual cases. At the clinical level, the politics of personal influence among attending physicians and administrators mediate the tensions that build as patients queue up for services when demand exceeds supply.¹⁷³ To the extent that this politics becomes visible to patients, it erodes confidence in the fairness of allocative decisions.¹⁷⁴ It also raises the troubling prospect of systemic bias against members of disadvantaged

171. See Harris, *supra* note 27.

172. See Payton & Powsner, *supra* note 25.

173. See Harris, *supra* note 27.

174. Large, widespread supply-demand mismatches in clinical settings invite corruption in the form of bribes to physicians and clinical administrators in exchange for preferred access to services. The potential for such corruption was dramatically illustrated by the bribes routinely demanded and paid within the Soviet Union's health care system, which promised state-financed universal access but was, in practice, grossly undercapitalized (and understaffed) relative to population-wide demand. Mark G. Field, *The Health Crisis in the Former Soviet Union: A Report from the 'Post-War' Zone*, 41 SOC. SCI. & MED. 1469 (1995).

groups, who are less likely on average to be attended by those physicians with the most influence in clinical settings.¹⁷⁵

III

THE LAW OF HEALTH CARE PROVISION, RECONCEIVED

Welfare maximization as an organizing principle for the law of health care provision founders upon pervasive indeterminacy. This indeterminacy leaves broad scope for legal conflict. The result is instability, inconsistency, and unpredictability in health law. An unsavory byproduct is a wide opening for the politics of interest group and personal influence. At the macro level, health plans, providers, and employers spend large amounts to lobby Congress and state legislatures, finance friendly candidates' campaigns, and make their cases to courts and regulatory agencies. At the patient-care level, the lack of clear, uncontested guideposts enlarges the role of personal relationships and persuasion when clinical caretakers and administrators make allocative choices in individual cases. An ironic consequence is that commitment to social-welfare maximization as a harmonizing principle for health law risks undermining confidence in health law as a reasoned, consistent scheme of governance. Pervasive unpredictability also frustrates the law's crucial function as a set of reliable baseline or default rules and principles that create a foundation for private ordering via contract.

Moreover, the language of welfare maximization risks diverting legal decision makers' attention from the underlying substance of health policy disagreements. By collapsing diverse substantive concerns onto a single metaphorical yardstick—efficiency—for the disposition of health law and policy disputes, talk of welfare maximization discourages consideration of the disparate empirical uncertainties and moral tensions that animate these disputes. This has serious practical consequences. Inattention to underlying substantive concerns fosters inconsistent, unpredictable resolution of legal disputes, undermining the quest for more rational health policy. And the low profile of underlying substantive concerns in the language of health law makes deliberative, democratic choice in health-policy matters less likely.

A. Citizens' Expectations and the Purposes of Medicine

There is an urgent need to reconceive the law of health care provision in a manner that avoids these failings. If this diverse body of law is to govern the managed care revolution in accord with our values, needs, and cognitive constraints—if it is to cabin destructive conflict and foster

175. See RAYMOND S. DUFF & AUGUST B. HOLLINGSHEAD, *SICKNESS AND SOCIETY* (1968) (discussing links between patients' social status and access to physicians able to assert influence in hospital settings on their patients' behalf).

confidence in legal governance as reasoned, consistent, and reliable to the extent possible—it must pursue more manageable aims. These aims should emerge, in a democracy, from our hopes and expectations for the health care system, both as individuals and as public-regarding citizens.¹⁷⁶ Were we to insist on one or another idealized conception of health law's aims, divorced from our actual hopes and expectations, the resulting legal design could not sustain public acceptance.¹⁷⁷ Inevitably, these hopes and expectations will clash, just as our perspectives as patients, friends and family of the sick, and public-regarding citizens often conflict. Thus a principal function of the law of health care provision must be to manage such conflict as it arises.

The law of health care provision must also be tailored to the peculiar organizational, economic, cultural, and scientific features of contemporary medical care. The high value that legal culture puts on consistency of legal interpretation within doctrinal realms¹⁷⁸ discourages custom tailoring of the law to the unique characteristics of different human endeavors. Applied to health law's disparate doctrinal bases, the lawyer's ideal of doctrinal consistency across diverse spheres of human activity not only discourages law's pragmatic adaptation to health care's particularities; it furthers the fragmentation of the health system's regulatory and legal governance¹⁷⁹ by encouraging the uncoordinated development of legal doctrines that send contradictory signals to the system's actors.¹⁸⁰ Judicial self-restraint deserves its due. The courts' legitimacy in the public's eye rests heavily on their reluctance to engage in the wholesale policymaking that is the province of elected officials.¹⁸¹ But this legitimacy is at risk when judges' pursuit of formal consistency yields confusing and contradictory substantive messages to those who must follow the law. Legitimacy requires a balance

176. To be sure, there need to be limits to such democratic deference. A thorough exploration of how to set these limits is beyond this Article's scope, but in general I would argue that these limits should comport with reigning conceptions of fundamental human rights. This approach, of course, has its share of indeterminacy, but it clearly rules out some legal practices, such as race and gender discrimination, that might arise from unconstrained democratic deference.

177. I break self-consciously here with scholars who ground their approaches to the law and policy of health care provision upon one or another idealized philosophic model. *E.g.*, EPSTEIN, *supra* note 28 (libertarian paradigm); NORMAN DANIELS, *JUST HEALTH CARE* 42-48 (1985) (Rawlsian model). These idealized models enrich public and scholarly debate but cannot ultimately prevail over impassioned human expectations.

178. See RONALD DWORKIN, *LAW'S EMPIRE* 225-75 (1986).

179. Havighurst, *supra* note 133.

180. M. Gregg Bloche, *The Managed Care Revolution and Patients' Rights: Potential Institute of Medicine Initiatives* (1999) (unpublished background paper, on file with the National Academy of Sciences, Institute of Medicine). Whether, as a general matter, one inclines toward legal formalism or to a species of realism, the health system's peculiarities and health law's fragmented doctrinal bases and jurisdictional origins make a compelling case for a realist approach to the legal governance of medicine.

181. See Hammer, *supra* note 9 (discussing judicial misgivings about engaging overtly in policymaking in the health sphere).

between judicial self-restraint and substantive coherence. Legislative inaction in an area as fraught with conflict as is health care merits heightened judicial emphasis on substantive coherence.¹⁸²

Last June, the Supreme Court showed a new sensitivity to the need to take substance seriously in the health sphere. Confronting the convolutions of ERISA preemption¹⁸³ in a case involving state-mandated, independent review of HMO coverage denials, the Court considered the institutional means by which HMOs meld health care financing and service provision.¹⁸⁴ The Court based its holding—that ERISA does not preempt such mandates—on its finding that HMOs both bear financial risk and provide medical care.¹⁸⁵ Such attention to “facts on the ground” will be essential if health law is to send coherent regulatory messages.

It is far beyond the scope of this Article to specify aims in detail for health law and to determine the implications of these aims for the resolution of health law’s many controversies. Rather, I attempt in a general way to identify health law’s major, conflicting aims¹⁸⁶—aims democratically rooted in people’s expectations and hopes for the health system. I then offer some preliminary suggestions about how this understanding of legal aims might contribute to the management of conflict in the health sphere.

B. *The Aims of Health Law*

Courts should refashion health law, within its disparate doctrinal realms, to spotlight the substantive empirical and normative questions that animate legal disputes. Health law cannot finesse or do away with disagreements that neither our society nor our politics have been able to resolve. However, when disputes between parties arise, health law can and should make underlying empirical and normative questions explicit. And,

182. Cf. GUIDO CALABRESI, *A COMMON LAW FOR THE AGE OF STATUTES* (1982) (arguing for aggressive judicial reinterpretation, and on occasion, judicial repeal of outmoded and obsolete statutes).

183. See *supra* notes 3-9 and accompanying text.

184. See *Rush Prudential HMO v. Moran*, 122 S. Ct. 2151, 2160-62 (2002) (reviewing the diverse organizational and contractual mechanisms by which HMOs and other managed health plans combine financial risk-bearing and health care provision). The Court’s review of organizational and contractual mechanisms drew upon (albeit not extensively) health care financing and health policy literature of the sort rarely cited in judicial opinions.

185. The appellant HMO had contested this proposition on the ground that the managed care industry is evolving in ways that increasingly separate financial risk-bearing and medical care provision. The Court concluded, however, that combination of risk-bearing and service provision remains a “dominant feature” of managed care. See *id.* at 2161 (holding that HMOs’ financial risk-bearing brings their coverage decision-making within the scope of ERISA’s so-called “insurance savings” clause, which shields state insurance regulation from ERISA preemption). The appellant, Justice Souter wrote for the Court, “cannot checkmate common sense by trying to submerge HMOs’ insurance features beneath an exclusive characterization of HMOs as providers of health care.” *Id.* at 2162.

186. My choice of the word “aims” here over the term “principles” is intentional. It reflects the diffuse, even inchoate, quality of democratically set goals, in contrast to the more fully defined quality of principles.

when courts must answer these questions, they should do so candidly. Doing so would clear a path toward substantive coherence and predictability, both within and across doctrinal settings. It would enable actors in the health sphere to draw consistent messages from the law, to conform their conduct accordingly, and to question these messages cogently in both the legal and political arenas. It would empower the public and enrich the democratic process by making health law's choices more visible. It would thereby render legislative action more responsive to public values and less open to special-interest-group influence.

Beyond this, courts should encourage health insurers and care providers to present consumers with care and coverage options in a manner that makes cost-benefit trade-offs explicit. Legal rules should reward contractual candor about painful trade-offs, so as to encourage consumers to understand and reflect upon these trade-offs. Health law should take a dim view of contractual efforts to submerge hard substantive choices in euphemism, as occurs, for example, when insurers promise all "medically necessary" care, then seek, *sub rosa*, to ration care.¹⁸⁷

The vision of legal dispute resolution I have in mind does not dispense with rationality; rather, it aspires to rationality in a more incremental form,¹⁸⁸ adaptable to complexity and indeterminacy. For the most part, I dispense with the language of economics and the characterization of regulatory and legal decision making as cost-benefit calculus. I do not view this discourse as either inherently inhumane, as do some commentators,¹⁸⁹ or as

187. The Supreme Court sent a signal to this effect in *Rush Prudential HMO v. Moran*, 122 S. Ct. 2151 (2002), by rejecting Rush Prudential's characterization of state-mandated independent "medical necessity" review as a matter of contract interpretation. Instead, the Justices treated "medical necessity" review as akin to a requirement that insurers obtain (and abide by) a second medical opinion, based on "independent medical judgment," *id.* at 2168-69. In so doing, the Court construed the "medical necessity" test for coverage as an indicator of contractual deference to professional standards of care—standards made mandatory by state laws requiring independent medical review. But the Court noted that health insurance contracts need not employ the "medical necessity" test. *Id.* at 2167, n.10. To the extent that insurance contracts limit coverage on other than "medical necessity" grounds, state laws requiring independent "medical necessity" review do not apply, and insurers can hold patients and providers to contractual standards. *Id.* The Court's opinion in *Rush Prudential HMO* thus invites health plan designers and contract drafters to be explicit about cost-benefit trade-off rules and other coverage exclusions. By doing so, health plans can avoid giving trump authority to physician-reviewers (and the medical profession) in coverage matters.

188. See JON ELSTER, *SOLOMONIC JUDGEMENTS: STUDIES IN THE LIMITATIONS OF RATIONALITY* 175-216 (1989) (reviewing constraints on rationality in public policy formulation); see also Colin S. Diver, *Policymaking Paradigms in Administrative Law*, 95 HARV. L. REV. 393 (1981) (defending Herbert Simon's bounded-rationality paradigm as a pragmatic model for public policymaking); Charles Lindblom, *Still Muddling, Not Yet Through*, 39 PUB. ADMIN. REV. 517 (1979); Charles Lindblom, *The Science of "Muddling Through"*, 19 PUB. ADMIN. REV. 79 (1959).

189. See, e.g., Arthur Leff, *Economic Analysis of Law: Some Realism About Nominalism*, 60 VA. L. REV. 451 (1974); George Annas, *Reframing the Debate on Health Care Reform by Replacing Our Metaphors*, 332 NEW ENG. J. MED. 745 (1995); Rashi Fein, *What Is Wrong with the Language of Medicine*, 306 NEW ENG. J. MED. 863 (1982). Cf. Margaret Radin, *Market-Inalienability*, 100 HARV. L.

incapable of characterizing decision analysis under conditions of bounded rationality and normative controversy. To the contrary, as Guido Calabresi has shown,¹⁹⁰ the language of economics and utility can be employed in an empathic, morally rich fashion to explore our most passionately felt concerns and the conflicts between them. Economics methodologies, moreover, have been ingeniously adapted to characterize complex and uncertain decision scenarios.¹⁹¹

I depart from the language of economics and utility for strictly pragmatic reasons. Speaking of our many deeply felt health-related concerns in terms of a linear scale of costs and benefits adds nothing to our understanding of these concerns and little to our thinking about how to balance these concerns in particular cases. These concerns cannot be translated into dollar or other numeric terms without prior moral or other normative judgments, and the language of economics and utility is mute about how to make these judgments. This language underscores the point that comparative decisions must be made, within resource constraints, when concerns conflict. But economics language is not needed to make this point, and collapsing all competing concerns onto a single metric of cost and benefit¹⁹² risks diverting legal decision makers' attention from the task of better understanding them.¹⁹³

My effort to identify health law's aims starts with the uncontroversial premise that promoting and restoring people's health matters greatly. Not only is health a near-universal human want; good health is morally desirable as a prerequisite for pursuing work opportunities,¹⁹⁴ nurturing the young and sustaining the family, and enjoying a rich range of recreational

REV. 1849 (1987) (arguing that market exchange of things closely tied to our ideals of "human flourishing" degrades the persons who trade these things away).

190. See GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* (1978).

191. Measures that are incrementally rational, as opposed to systemically welfare maximizing, can be modeled as a climb toward local, rather than global, maxima. ELSTER, *supra* note 84.

192. The idea of a single metric is particularly problematic when decision makers must think about both the ultimate outcomes of alternative courses of action and the paths by which these outcomes are to be achieved. The Nobel-Prize-winning economist (and critic of economics) Amartya Sen distinguishes between "culmination outcomes" (ultimate outcomes) and "comprehensive outcomes," which include both culmination outcomes and the effects of the processes by which culmination outcomes occur. Amartya Kumar Sen, *Maximization and the Act of Choice*, 65 *ECONOMETRICA* 745 (1997). Collapsing culmination outcomes and these process effects onto a single metric reduces the visibility of all that is unique, or incommensurable, about these process effects. Welfare economics typically limits its focus to the utility of culmination outcomes. The focus of health care economists on the measurable outcomes of medical treatment is illustrative. However, I presently argue, the processes by which medical outcomes come about matter at least as much as do culmination outcomes in health care.

193. To the extent that conflict over what is "efficient" in health care law reflects unappreciated differences between understandings of the aims of health care provision, language that reveals these understandings is a necessary tool for management of such conflict. The reductionism inherent in economics language is a barrier to rich, empathic discussions of these understandings.

194. See DANIELS, *supra* note 177, at 33-34 (making Rawlsian case for universal access to medical care as a means for pursuing fair equality of opportunity).

opportunities. Moreover, in some religious traditions, regard and care for the body is itself a spiritual obligation.¹⁹⁵ I depart, however, from the assumption in most health law and bioethics commentary that attaining health is the sole or even dominant purpose of medicine. Were pursuit of health medicine's lone or dominant function, much that clinical caretakers do—and that the law accepts, even insists upon—would make no sense. Our health system commits vast resources to technologies that yield, at best, small improvements in health status or prospects for prolonged life, while it (and we as patients) forgoes opportunities to achieve larger health gains at lower cost through more robust health promotion, disease prevention, and early diagnosis and treatment. Ample evidence shows that such measures—as well as society-wide efforts to protect the environment, make workplaces safer, and alleviate poverty—yield larger health benefits at lower cost than much of what clinicians do in intensive care units, organ-transplant teams, and other high-technology settings. Some argue that this disconnect between apparent cost-benefit thresholds for technology-intensive medical services and for health-promoting clinical and social programs represents a large public policy failure, and that policymakers should redirect resources from the former to the latter. Yet it is difficult to imagine public acceptance for policies that would rechannel resources on a huge scale from the technology-intensive care that holds out hope to people in dire medical straits. Public policies that demanded such a profound shift in spending on behalf of some abstract conception of population-wide health improvement would surely meet strong popular resistance.¹⁹⁶

An understanding of health law's aims that builds democratically on people's hopes and expectations for the health care system cannot dismiss such feelings; rather, it must connect empathically with them. Though I will not argue the point in depth,¹⁹⁷ I submit that the emotional and moral imperatives of rescue drive much of our resistance to pursuit of

195. See, e.g., CATECHISM OF THE CATHOLIC CHURCH, para. 2288-91 (Libreria Editrice Vaticana trans., 2d ed. 1997) ("Life and physical health are precious gifts entrusted to us by God. We must take reasonable care of them, taking into account the needs of others and the common good.").

196. Tamer proposals for the shifting of resources from high-technology care to other programs yielding greater aggregate health or other benefits have in the past encountered fierce resistance. A notable example is former Colorado Governor Richard Lamm's 1984 proposal to limit the elderly's use of costly clinical technology, which ignited a media firestorm. See Editorial, *Life, Death and Governor Lamm*, N.Y. TIMES, Mar. 31, 1984, at 22.

197. Commentators on environmental policy and tort law often note differences in our regard for identified and statistical lives. See, e.g., BREYER, *supra* note 118, at 33-39; THOMAS C. SCHELLING, *The Life You Save May Be Your Own*, in CHOICE AND CONSEQUENCE 113 (1984). Such commentary is usually unsympathetic, typically dismissing these differences as the product of cognitive error or other forms of irrationality. Some have even tried to explain these differences as evolutionary residue—ways of thinking adaptive to our forest and cave-dwelling ancestors and thus biologically selected over a long period, but maladaptive for people in present-day technological societies. E. Donald Elliott, *The Evolutionary Tradition in Jurisprudence*, 85 COLUM. L. REV. 38 (1985). The possibility that they may still be adaptive, in unrecognized ways, is not taken seriously in this literature.

population-wide health maximization. Rescue, or at least nonabandonment, of people struck by medical misfortune overlaps with promotion and restoration of health, yet it is distinct in its rootedness in the value of standing by people in distress, even at the expense of some abstract greater good. The iconography of devotion to individuals at the expense of larger purpose appears throughout our culture.¹⁹⁸ The recent surge of popular anger toward managed care stems in part from its compromises between the plight of individuals in distress and the requisites of population-wide resource management. To the extent that our intensive care units, bone-marrow transplants, magnetic resonance imagers, and the like symbolically express our commitment to stand by individuals in dire straits, their cost-effectiveness at promoting health, compared with less-heroic clinical and social interventions, seem beside the point. In a society as enthralled by technology as ours, costly clinical measures that bring leading-edge technology to bear are potent expressions of this commitment, quite apart from their biological efficacy.

This powerful emotional and moral imperative goes underrecognized in commentary on the law of health care provision. Within the standard story of waste, this imperative has no role except as a source of inefficiency. But a humane, pragmatic conception of health law's aims must make room for it. To be sure, it may be a luxury in the economic sense: it seems probable that societies with higher per capita incomes spend larger fractions of their incomes on technology-intensive, rescue-oriented medical care than do poorer societies.¹⁹⁹ Yet so long as we treat the moral and policy problems of medical resource allocation as matters to be addressed within national boundaries, the moral import of the rescue imperative ought to be weighed from a Western, postindustrial perspective.²⁰⁰

198. Recent examples include the films *SAVING PRIVATE RYAN* (DreamWorks SKG 1998) and *BLACKHAWK DOWN* (Columbia Pictures 2001), in which many people risk their lives to save one or a few, and a costly and dangerous winter 1999 flight over the South Pole to drop medical supplies for a researcher with a lump in her breast. Denise Grady, *Trapped at the South Pole, Doctor Becomes a Patient*, N.Y. TIMES, July 13, 1999, at A1; *Ailing Doctor at South Pole Is Evacuated at Last*, N.Y. TIMES, Oct. 16, 1999, at A9. Rescue, courageously attempted, is an elemental dramatic theme in literature and film and part of the moral learning we draw from our culture beginning in early childhood.

199. In general, the poorer the country, the lower its medical spending as a proportion of gross domestic product. Organization for Economic Cooperation and Development, OECD Health Data 99 (1999), available at <http://www.oecd.org/els/health/software99.htm> (last visited May 2, 2000). The bitter controversy in postapartheid South Africa over government efforts to make large budgetary shifts from tertiary medical services to primary care and health promotion programs in largely Black areas, see Gabrielle Murphy, *South African Health Care in Black and White*, 351 LANCET 1421 (1998), highlights the tension between health spending priorities for people living at subsistence levels and those living in postindustrial upper- and middle-class comfort.

200. I concede that this is troubling from an international social- and economic-rights perspective, and that a powerful case can be made for allocating health resources based on a transnational conception of justice that compels a large shift of resources from tertiary services in industrialized states to health-promotion programs for the world's poorer nations. See HEALTH CARE REFORM: A

Inevitably, the imperative of rescue will at times clash with the imperatives of health promotion and restoration; moreover, the rescue imperative will itself often be open to differing interpretations. It is not my purpose here to resolve such differences in the abstract. Although a deeper exploration of the moral idea of rescue could clarify and enrich our theoretical understanding,²⁰¹ these differences will appear in concrete circumstances that demand particularized resolutions. My limited purpose here is to enter a plea for the recognition of rescue as one of health care's (and health law's) legitimate aims. Such recognition would not end legal and regulatory disagreement over management of clinical resources, but it would cabin such disputes by discouraging arguments that accord population-wide health maximization trump value over the anguish of identified persons.²⁰²

An overlapping psychological imperative, also arising from the anguish of identified persons but meriting recognition as a distinct aim of health care law, is support and comfort at the bedside and clinic, whether or not rescue or restoration of health are possible. The recent proliferation of research and commentary on end-of-life care has increased awareness of this clinical purpose, but our needs for support and comfort are not restricted to such dire circumstances. The anxieties of a new mother insecure about breast-feeding, a healthy twenty-something awaiting a herpes culture, or a fit forty-something with marginally high blood cholesterol also merit support, requiring caring health professionals to strike awkward, nonutilitarian balances between these nonurgent needs and other patients' more pressing circumstances.²⁰³ Effective clinical support is protean in its expression, encompassing soothing voice tones and words, physical presence and touching, pain relief, biological and other explanation, and even laboratory testing as both a demonstration of concern²⁰⁴ and a means of

HUMAN RIGHTS APPROACH 149 (Audrey R. Chapman ed., 1994). But such a shift of health resources across national boundaries seems exceedingly unlikely in the foreseeable future; thus, treatment of health-resource allocation as an intranational matter makes practical sense.

201. Among the many open questions not addressed herein are the relative moral import of rescue's efficacy versus rescuers' feelings of commitment, rescuees' experiences of fear and vulnerability, and the risks and costs of the rescue effort (risk and cost weigh, paradoxically and simultaneously, in favor of a rescue endeavor's nobility and against its practicality).

202. Proponents of tightly managed care as a tool for rationalizing medical practice from a population-wide outcomes perspective would prefer to see the law do exactly the opposite. See, e.g., David M. Eddy, *Performance Measurement: Problems and Solutions*, 17 HEALTH AFF., July-Aug. 1998, at 7.

203. A body of psychological research supports the conclusion that the intensity of subjectively experienced need does not vary greatly along the continuum from comparatively minor (as seen objectively) to dire needs. See generally A.H. MASLOW, *MOTIVATION AND PERSONALITY* (1987). That we experience need in this objectively irrational manner should be intuitively apparent to anyone who has ever felt momentarily furious over some trivial failure in, say, airline beverage service or a consumer product.

204. M. Gregg Bloche & Kevin P. Quinn, *Professionalism and Personhood*, in PERSONHOOD IN HEALTH CARE, 347-54 (David C. Thomasma et al. eds., 2001).

rendering biological explanation more credible and comforting.²⁰⁵ All have in common the commitment of resources not wholly justifiable in terms of rescue or health promotion and restoration.²⁰⁶ The standard story of waste that animates most scholarship on the law of health care provision makes little or no allowance for such resource use.

A related moral imperative, respect for the dignity of people rendered vulnerable by medical misfortune or fear, deserves recognition as a separate aim of health law. For a generation, the bioethics movement has emphasized this imperative, and the law has come to recognize it, albeit to a lesser degree than some bioethics commentators would prefer. The law affirms this imperative with protections for patient self-determination in clinical and research settings²⁰⁷ and safeguards for medical information privacy,²⁰⁸ even when this imperative clashes with the exigencies of population-wide health promotion.²⁰⁹ The older, Hippocratic tradition in medical ethics affords protection for personal dignity in another fashion, through a professional duty of undivided loyalty to patients.²¹⁰ This duty safeguards sick, vulnerable people from the indignity of exploitation by doctors with conflicts of interest and loyalty.²¹¹ Unfortunately, the law has not generally recognized such a duty. For example, in cases involving financial rewards to physicians for withholding care, courts have treated the conflict of interest involved as either unproblematic if the care provided does not constitute malpractice²¹² or as manageable through disclosure of and consent to the financial incentives at issue.²¹³

The paradigm of disclosure and consent has recently been stretched to a point that raises doubts about its ability to protect personal dignity.

205. Different personality styles and cultural norms predispose people to varying patterns of responsiveness to these protean expressions of comfort and support. An emotional, even histrionic person might respond best to soothing words and a gentle tone, while a more obsessive, abstractly logical patient (especially one with a technical background) might do best with a biologically detailed explanation (whether or not scientifically validated), buttressed by laboratory data. People with strong religious backgrounds or faith might take more comfort from faith-based narratives of illness and reason for hope.

206. This distinction is perhaps too sharply drawn. To the extent that clinical expressions of support and comfort increase compliance with effective treatment or potentiate a prescribed treatment's efficacy (through a placebo effect), they contribute to rescue and health promotion and restoration.

207. See RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 151-86 (1986); see also text accompanying notes 73-74.

208. See Lawrence O. Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451 (1995).

209. See LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 113-42 (2000) (discussing tensions in law between medical privacy concerns and community-wide health promotion).

210. See Edmund D. Pellegrino, *Societal Duty and Moral Complicity: The Physician's Dilemma of Divided Loyalty*, 16 INT'L J.L. & PSYCHIATRY 371 (1993).

211. See, e.g., TALCOTT PARSONS, *THE SOCIAL SYSTEM* 428-47 (1951); Bloche, *Clinical Loyalties and the Social Purposes of Medicine*, *supra* note 129.

212. See *Pegram v. Herdrich*, 530 U.S. 211 (2000).

213. See *Shea v. Esensten*, 107 F.3d 625 (8th Cir. 1997).

Financial incentives for withholding care,²¹⁴ release of personal health information to insurers, employers, governments, and even direct mail marketers,²¹⁵ and administrative constraints on access to covered services are among the policies that have been defended by reference to disclosure and consent. Greater regard for personal dignity as a health law aim would raise the bar to such promiscuous use of consent, especially when given in a pro forma rather than a reflective, deliberative manner. Greater legal emphasis on the dignity of the sick should also imply heightened protection for the Hippocratic precept of undivided professional loyalty to patients and lower tolerance for financial and organizational arrangements that align clinical caretakers with health care payers.²¹⁶

A system of health care provision that fared well in terms of the four aims just discussed—health promotion and restoration, rescue, support and comfort, and personal dignity—would nevertheless be a moral failure, indeed a national embarrassment, were some among us unable to access it. Whether such access should be considered an individual right²¹⁷ or a social obligation²¹⁸ is a question beyond my scope here. But the American failure to achieve universal access to medical care is at odds with the standard set by the rest of the industrialized world.²¹⁹ This standard expresses a global consensus around the notion of health care as a need so basic that belonging to a society that entitles a person to its provision.²²⁰ By failing to provide some among us with care that meets our society's conception of what constitutes a decent minimum,²²¹ we send them and others a troubling

214. E.g., Tracy E. Miller & William M. Sage, *Disclosing Physician Financial Incentives*, 281 JAMA 1424 (1999); E. Haavi Morreim, *To Tell the Truth: Disclosing the Incentives and Limits of Managed Care*, 3 AM. J. MANAGED CARE 35 (1997). Disclosure and consent to such incentives can occur via contract, when consumers subscribe to health plans, or later on, in doctors' offices, when patients choose primary care or other providers. The proliferation of different methods of physician payment within single health plans has led some proponents of this extension of the consent paradigm to prefer the doctor's office as the locus for this type of disclosure and consent.

215. See M. Gregg Bloche, *Managed Care, Medical Privacy, and the Paradigm of Consent*, 7 KENNEDY INST. ETHICS J. 381 (1997).

216. See Bloche, *Trust and Betrayal in the Medical Marketplace*, *supra* note 129.

217. See John D. Arras, *Retreat from the Right to Health Care: The President's Commission and Access to Health Care*, 6 CARDOZO L. REV. 321 (1984); see also T. Patrick Hill, *Health Care: A Social Contract in Transition*, 43 SOC. SCI. & MED. 783 (1996).

218. THE PEPPER COMMISSION; U.S. BIPARTISAN COMM'N ON COMPREHENSIVE HEALTH CARE, 101ST CONG., A CALL FOR ACTION (2d Sess. 1990).

219. Proponents of universal access used to note acidly that the United States and South Africa were the only industrialized nations that did not provide it. But postapartheid South Africa instituted a program of universal access, leaving the United States with no peer in this regard.

220. See MICHAEL WALZER, *SPHERES OF JUSTICE: A DEFENSE OF PLURALIST EQUALITY* 68 (1983) (arguing that every society somehow defines its own set of basic human needs, then ensures their provision to all whom it recognizes as members).

221. Although there is much room for debate over what level of assured access to care constitutes a decent minimum, American law's guarantee of emergency services only to our country's forty-two million uninsured, the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd

message of social exclusion²²² and nonrecognition of our common humanity. If one postulates that this is morally unacceptable in the twenty-first century, then a fifth aim of the law of health care provision should be to universalize access to basic medical services. To be sure, courts and regulatory agencies have little leeway here: Congress and state legislatures determine the scope of public provision of medical coverage and services to those unable to afford them. But where courts or agencies can make a difference, for example, by construing ambiguous statutory provisions, recognition of this fifth aim favors interpretations that expand access to services.

IV

PRELIMINARY APPLICATIONS

How might this account of medicine's conflicting purposes and health law's aims contribute to resolution of legal disputes in the health sphere? Here, I suggest some parameters for an ordered approach. My intent is not to persuade readers that my approach is "right." The importance of democratic deliberation for the further formulation of health law's aims—and for choices between aims when they conflict—renders it impossible, in the abstract, to specify a "right" approach. My more modest objective here is to offer a starting point for reflective legal and regulatory choice that takes richer, more open account of our expectations of medicine than can the language of systemic efficiency. But I make a less modest claim. By spotlighting the substantive disagreements that efficiency talk suppresses, legal decision makers can resolve them more consistently and predictably. The law can thereby send clearer, more coherent behavioral signals to health care actors, fostering their ability to innovate in socially useful ways. And, by rendering controversial substantive choices more visible, the law can promote popular engagement, through politics, in the making of these choices.

I begin with American health law's embarrassing moral backdrop: our national failure to make basic medical care available to all. Universal access to care is morally urgent, not primarily on promotion-of-health grounds (since other social programs can promote population-wide health more cheaply), but as expression of our common humanity and community. Until we make basic health services accessible to all, debate about how the law should treat the concerns of those financially able to obtain care leaves a disturbing moral aftertaste. Thus the imperative of expanding access favors legal interpretations that tend toward this end,

(2000) [hereinafter EMTALA], surely falls short. It does not compare to the comprehensive packages of basic services available to all in every other industrialized nation.

222. The message of social exclusion is sometimes explicit, as it was in the 1996 federal legislation that authorized states and localities to bar noncitizens from publicly funded health services. See Personal Responsibility and Work Opportunity Act of 1996, 8 U.S.C. § 1611-1614 (2000).

even at the expense of such concerns as the progressivity of public financing,²²³ preservation of the tort system's panoply of rights and remedies,²²⁴ and maintenance of a broad range of choice between health care providers.

Beyond this, courts and agencies ought to treat the law of health care provision not as a tool for maximizing the aggregate medical benefits that clinical dollars buy, but as an expression of the awkward coexistence of health promotion and less-tangible aims—those I have tried to capture through the categories of rescue, support and comfort, and regard for the dignity of the vulnerable. We cannot hope to calibrate precisely the import of each of these aims in all of the circumstances that spawn legal conflict. The law should therefore avoid grand, systemic efforts to determine what is most rational or efficient. Whether the imperatives of rescue, comfort, or regard for dignity should prevail over population-wide health promotion and restoration should be decided case-by-case, even as the law grounds its choices on precedent and aspires to consistency. Reactions of the heart,²²⁵ social norms,²²⁶ and public values all have roles in this decision making, as does analysis of financial costs and health benefits. How might this strategy apply to the fields of law I considered earlier as illustrations of welfare maximization's failings? Review of the many questions that concern health law decision makers is beyond this Article's scope, but I propose some analytic starting points.

A. Medical Tort Law

The setting of standards of care in medical-malpractice cases should reflect the priority of rescue over population-wide efficiency, especially when treatment that a plaintiff says should have been provided would have stood a serious chance of making a life-saving or life-changing difference. We honor the ethic of rescue, and our feelings of solidarity with people in

223. EMTALA, *supra* note 221, and other federal and state laws require hospitals to provide "free" emergency and other services that are in fact cross-subsidized from health-insurance premiums paid by consumers and their employers, then transferred to hospitals as compensation for services. Such financing is regressive, like a sales tax, in that it takes generally higher percentages of household income from less-well-off consumers (so long as they are insured). Robert A. Carolina & M. Gregg Bloche, *Paying for Undercompensated Hospital Care: The Regressive Profile of a "Hidden Tax"*, 2 HEALTH MATRIX 141 (1992). Thus, expansive constructions of EMTALA and other "free" care requirements both enlarge access and selectively burden the least prosperous insureds.

224. Were it to be proven, for example, that caps on punitive damages or awards for pain and suffering translate into lower health coverage costs and expanded access to care, such limits would merit serious consideration.

225. *Cf.* NUSSBAUM, *supra* note 85, at 40-43 (considering the reflective, deliberative use of our impassioned reactions as instruments of ethical and moral reasoning).

226. To a degree insufficiently acknowledged, except among the small number of economics-oriented scholars who have begun to study the welfare-enhancing functions of specialized social norms, social and professional mores can be understood in neoclassical economics terms. *See* ROBERT C. ELLICKSON, *ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES* 123-239 (1991). Health-economics scholarship and research, so often critical of the mores of physicians and other clinical actors, have been slow to explore such possibilities.

anguish, by requiring that the best of generally available medical technology²²⁷ be employed on behalf of the sick, especially the very sick, unless we have good scientific reasons to believe that the intervention at issue is futile or of minimal benefit. Proposals to require the converse—to make scientific proof of a technique's efficacy a prerequisite for treating it as a legal standard of care—founder on the awkward fact that most diagnostic and therapeutic interventions are ill supported by scientific evidence.²²⁸ Taken literally, this prerequisite would bar the adoption of most clinical techniques as legal standards of care. So long as patients retain some confidence in medical judgment absent scientific data,²²⁹ refusal by the legal system to hold straying practitioners to professional standards might be understood by patients as license for professional abandonment.

One might object that this rescue-oriented approach indulges social waste, and that tort law should not “lock in” clinical practices that are the product of insurance-induced market distortion. My answer is that priority for the ethic of rescue over population-wide efficiency in health promotion is not wasteful if it accurately reflects our values. Moreover, as I presently suggest, the law governing medical insurance can, in conjunction with innovative insurance-coverage design, nudge clinical practice away from ever-more-costly interventions of low or uncertain biological value without unduly compromising the ethic of rescue.

The imperatives of rescue and respect for the dignity of people made vulnerable by medical misfortune weigh against retreat from the requirement of full disclosure of therapeutic options to sick patients. Proponents of such a retreat argue that sick patients' clinical self-determination deserves less scope because insurance desensitizes patients to cost.²³⁰ Such a retreat might permit a health plan's physicians to refrain from disclosing

227. Large variations in clinical practice, both between and within localities, make the setting of legal standards of care problematic even after one accepts this approach, due to the paucity of scientific evidence establishing the best treatment alternatives. This indeterminacy can be narrowed to some degree by giving priority to local clinical standards. From a rescue-oriented perspective, which calls for use of all available medical means, failure to provide a therapy that is rarely or never offered to patients in a given locality (and thus is not part of local expectations) seems less troublesome than failure to provide a treatment that is often employed locally.

228. This is not to say that most interventions have been scientifically shown to be ineffective. It says only that we lack good scientific answers, either pro or con, to the question of their efficacy. See *supra* text accompanying notes 54-72.

229. The prevailing view, sometimes tacit and other times explicit, in the medical outcomes research and health economics literature is that clinical judgment without scientific proof is at best of little informational value and at worst laden with distortions and misperceptions arising from cognitive errors and each physician's small lifetime clinical sample size. An alternative view holds that clinical judgment absent scientific proof has at least modest validity of its own. See FED. JUD. CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2d ed. 2000) (reviewing admissibility of medical testimony under the Federal Rules of Evidence); cf. DONALD A. SCHON, THE REFLECTIVE PRACTITIONER: HOW PROFESSIONALS THINK IN ACTION (1983) (analyzing clinical problem solving).

230. See, e.g., Clark C. Havighurst, *Prospective Self-Denial: Can Consumers Contract Today to Accept Health Care Rationing Tomorrow?*, 140 U. PA. L. REV. 1755, 1758-59 (1992).

more costly clinical alternatives that the plan would prefer not to cover.²³¹ Were systemwide efficiency in health promotion and restoration the law's primary aim, this retreat might be justified, though it would present risks of exploitation by plans and providers.²³² The imperatives of rescue and regard for personal dignity, however, lend countervailing force to preservation of sick patients' autonomy. The detailed contours of informed-consent doctrine in the era of managed care are beyond my scope here. But the overarching approach I urge is that informed-consent law continue to reflect the viewpoint of individual patients in need, and sometimes in anguish, and that it refrain from population-wide thinking about health promotion and the sparing of resources.²³³

Medical tort law should further safeguard patients from the indignity of betrayal by moving from inchoate suggestion²³⁴ to adoption of the principle that physicians have a duty of undivided loyalty to their patients.²³⁵ The law has been peculiarly slow to impose on clinical caretakers the same fiduciary obligations it insists upon for lawyers, financial advisors, and other professionals.²³⁶ It has relied instead upon the paradigm of informed consent to protect patients against exploitation by the doctor with a double agenda.²³⁷ But the rise of vertically and horizontally integrated health plans and other contractual arrangements that put physicians at risk for the costs of care²³⁸ is putting unprecedented financial and other pressure on doctors to depart from the ethic of undivided loyalty to patients.²³⁹ To be sure, some argue that financial incentives to withhold services are a cheaper, easier-to-administer cost-control method than is arms length, prospective

231. It might do so either by simply cutting back on the informed-consent doctrine's disclosure obligations or by allowing health plans and subscribers to contract out of current bedside-disclosure requirements.

232. If providers failed to disclose "efficient" clinical alternatives, patients would typically not learn about them, enabling health plans to reduce their costs and increase their profits in a socially wasteful manner.

233. I do not mean to suggest here that population-wide reasoning has no place in health law (it should, as I argue below), but only that the law's protection for patient self-determination at the moment of medical decision should not be rolled back out of regard for population-wide concerns.

234. See *Wickline v. State*, 239 Cal. Rptr. 810 (Ct. App. 1986) (asserting in dictum that treating physicians should be advocates for their patients vis-a-vis health plans).

235. Bloche, *Clinical Loyalties and the Social Purposes of Medicine*, *supra* note 129.

236. MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST* (1993).

237. In this, the law has taken its cue from the bioethics movement, which for the last thirty years or more has given primacy to informed consent as an instrument for protecting patients and has relegated the problem of multiple loyalties to the philosophic background. M. Gregg Bloche, *Beyond Consent*, in *RESEARCH ON HUMAN SUBJECTS: ETHICS, LAW, AND SOCIAL POLICY* 44 (David N. Weisstub ed., 1998).

238. Thomas Rice, *Physician Payment Policies: Impacts and Implications*, 18 ANN. REV. PUB. HEALTH 549 (1997).

239. Daniel Sulmasy et al., *Physicians' Ethical Beliefs About Cost-Control Arrangements*, 160 ARCHIVES INTERNAL MED. 649 (2000).

utilization review.²⁴⁰ But to the extent that physician fidelity to patients fosters their sense of dignity (by shielding them from the experience of betrayal) and reassures them that, in time of need, their caretakers will attempt rescue, incentives to withhold services impose intangible emotional and moral costs. Proponents of financial rewards for frugal practice rarely acknowledge these costs.

One might argue in response that advance disclosure of such incentives to patients²⁴¹ should suffice.²⁴² Patients sufficiently concerned about these incentives will avoid health plans that offer them and providers who accept them, this argument holds; thus we can look to the medical marketplace to resolve the question of their social desirability. This argument privileges the health care choices that consumers or their employers make before the onset of illness. The argument neglects the vulnerability and dependence they experience when medical crisis or need arises. To the extent that consumers, when choosing among plans and providers, fail to focus on provider payment arrangements or to anticipate their feelings of vulnerability and dependence when illness strikes, this privileging of the *ex ante* (pre-illness) perspective is at odds with human experience. Empirical research into consumers' thinking about doctors' financial incentives might better illuminate their *ex ante* understandings. But it is doubtful that the typical health-plan subscriber, after at most a few hours spent reading plan descriptions and interviewing doctors, focuses meaningfully on these incentives or anticipates the fear and dependence that come with the threat of serious illness. I thus submit that advance disclosure is an inadequate response to financial or other incentives to doctors to limit treatment. It is inadequate, that is, if the law of health care provision is to be rooted in human experience, hopes, and expectations, as I have urged here.

A detailed account of how the law might formulate a duty of loyalty that responds to these concerns is beyond my scope here, but I suggest some general principles. First, this duty should apply both to physicians who accept incentives that create conflicts of interest and to health plans or other actors that offer these incentives.²⁴³ Second, the duty should

240. See generally MARK V. PAULY ET AL., *PAYING PHYSICIANS: OPTIONS FOR CONTROLLING COST, VOLUME, AND INTENSITY OF SERVICES* (1992); Jerome R. Gardner & Roxy Maroney, *Positioning for Capitation by Redesigning Internal Processes*, HEALTHCARE FIN. MGMT., July 1995, at 40, 42.

241. Such disclosure could occur when patients choose employment, subscribe to health plans, or enter into doctor-patient relationships with particular providers. See Wolf, *supra* note 77.

242. Deven C. McGraw, *Financial Incentives to Limit Services: Should Physicians Be Required to Disclose These to Patients?*, 83 GEO. L.J. 1821 (1995) (arguing that physician disclosure should satisfy doctrine of informed consent); see also *Shea v. Esenstein*, 107 F.3d 625 (8th Cir. 1997) (holding that health-insurance providers for employer-sponsored health plans have a fiduciary duty, under ERISA, to disclose physicians' financial incentives to withhold services).

243. The U.S. Supreme Court's decision two years ago, in *Pegram v. Herdrich*, 530 U.S. 211 (2000), was dismaying for its failure to read ERISA's fiduciary duty language to limit HMOs' economic rewards to physicians for withholding care, see *supra* note 14, and for its refusal to

encompass arrangements that reward clinicians for ordering more services or for making referrals.²⁴⁴ Third, financial and other influences on clinical decision making are unavoidable, and the duty should be formulated realistically. The goal is to avoid incentives that too strongly tempt physicians to break faith with their patients. Drawing lines and setting limits is a complex endeavor, more appropriately undertaken by a specialized regulatory agency than by the courts. Among the complexities that beset such limit-setting are lack of empirical evidence regarding the links between clinical judgment and levels of physician risk for the cost of care and the difficulty of determining individual doctors' incentives.²⁴⁵ But if legislators and regulators fail to act on this front, courts should not shy from intervening, as best they can, with the aid of expert witnesses and other oft-used judicial tools for coping with technical complexity.

Some urge a more restrictive approach to physicians' financial incentives, proposing that doctors be paid pre-set salaries.²⁴⁶ This would put health plans and physicians into employment relationships, limiting the flexibility of both to respond to patients' and health care purchasers' changing needs. Employment relations create powerful influences on physician judgment, arising from lines of supervisory authority and from the development of corporate cultures responsive to employers' needs. These influences may put more pressure on medical judgment than do strong financial incentives. Neither the law nor governing ethical principles require that other professionals with analogous fiduciary responsibilities be compensated without regard for the volume of services rendered. Lawyers' hourly billing and investment professionals' transaction-based compensation are typically treated as consistent with their fiduciary obligations. Payment of physicians in rough proportion to the time they put in on their patients' behalf should be similarly accepted. Financial rewards for adherence to widely accepted patterns of best, frugal practice, such as strategic sequencing of diagnostic work-ups to gather a given level of information at minimum costs, should also be accepted.²⁴⁷ But financial rewards for referrals to specialists, clinical laboratories, hospitals, and so on are

acknowledge divided loyalty at the bedside as a concern in itself, apart from its influence upon levels of care. On the other hand, *Pegram* left the door open to state law challenges to monetary rewards for withholding treatment.

244. See M. Gregg Bloche, Editorial, *Cutting Waste and Keeping Faith*, 128 ANNALS INTERNAL MED. 688 (1998).

245. Most physicians participate in multiple health plans, each with different payment schemes, and many doctors are part of group practices. These practices receive revenues from numerous health plans and then distribute this money to doctors based on these practices' own internal incentive schemes.

246. Arnold S. Relman, *Salaried Physicians and Economic Incentives*, 319 NEW ENG. J. MED. 784 (1988).

247. Sensible reward systems along such lines could be developed and updated in consultation with panels of leading physicians possessing state-of-the-art knowledge of relevant research data and areas of clinical consensus.

problematic, as are large premiums for time spent performing invasive procedures as opposed to evaluating and talking with patients or developing diagnostic or therapeutic plans.²⁴⁸

The clinician's fiduciary duty should also oblige physicians to appeal health care payers' refusals to authorize services if the physician believes such refusals are unfounded.²⁴⁹ In practice, liability arising from breach of fiduciary obligations would be unusual, since causal links between such breach and legally cognizable damages would be difficult to establish.²⁵⁰ Yet the prospect of this liability would affirm, at least symbolically, the physician's duty and commitment to stand by patients in need.

B. Disputes Over Medical Coverage

So long as health plans employ the vacuous term "medical necessity" to define their contractual coverage obligations, legal decision makers must look to external sources to impute content to these obligations. In so doing, they should sustain the priority of rescue over population-wide efficiency by requiring, as I have urged for the setting of tort standards, that the best of generally available medical technology be covered, absent good scientific reason for believing it to be futile or only minimally beneficial. To require less by way of coverage would be to permit plans to breach the promise of attempted rescue that a commitment to meet medical need implies. Rescuers do not act half heartedly; they make their best efforts using the best available means, which is what the socially constructed concept of need calls for when a person is in difficult straits.²⁵¹ Rescue makes this

248. Physicians in many specialties can earn upwards of ten times more per hour performing technology-intensive procedures than by engaging in such "cognitive" activities as interviewing patients and planning diagnostic work-ups. See, e.g., James V. Maloney, Jr., *A Critical Analysis of the Resource-Based Relative Value Scale*, 266 JAMA 3453 (1991). The result is a set of perverse and pervasive incentives to invade the body in a costly fashion, with little planning or reflection.

249. To avoid obliging the clinician to function, without pay or expertise, in a lawyer-like mode, this duty to appeal should perhaps be limited to use of the health plan's internal, administrative appeals process, though the clinician should also cooperate with legal counsel retained by the patient if the clinician's internal appeals fail. See Bloche, *supra* note 70. But cf. William M. Sage, *Physicians as Advocates*, 35 Hous. L. Rev. 1529 (1999) (arguing against lawyer-like advocacy duties for physicians *vis-a-vis* health plans).

250. A plaintiff would need to prove that absent the breach of fiduciary duty, she would have received care that would probably have prevented the harm alleged. She would thus have to show not only that an alternative, superior course of treatment would have avoided the harm, but that had the defendant abided by its fiduciary duty, she would have received the better treatment.

251. It is said, for example, that the climber stranded on a mountain precipice "needs" a helicopter rescue—even if her own recklessness created her predicament and even if the resources spent on such a rescue could save more lives if otherwise employed—so long as a helicopter is present and can reach the precipice without grave risk to its crew. Readers, I am sure, can come up with many similar examples of this cognitive construct and moral intuition, an intuition I treat in this Article as worthy of respect rather than a thing to be dismissed as error.

moral demand, and rescuers who fall short in this regard are subject to moral reproach.²⁵²

Subscribing to a health plan, on the other hand, is an act of choice, albeit experienced as more or less "voluntary" depending on the chooser's financial circumstances, range of medical coverage options, and other life parameters. Regard for the dignity of individuals requires that the law honor subscribers' choices to accept less than the conventional promise of medically necessary care, so long as agreed-upon moral prerequisites for "voluntariness"²⁵³ are met. Thus the law should permit health plans to offer prospective subscribers less than this promise and to hold patients to the terms of the deal when unfortunate medical conditions arise. The imperative of population-wide health promotion supports such deference to contractual choice, since consumers' decisions to economize on costly medical services may facilitate movement of resources to activities that promote health more cheaply. But the imperatives of rescue, regard for dignity, and universalization (or at least expansion) of access to medical services weigh in favor of a cautious approach to enforcement of contractual terms that offer less than the conventional commitment to medically necessary care.

To bind themselves and their families to such terms, plan subscribers should choose them clearly and deliberately from among affordable contractual options that include conventional medical-necessity language. It is not enough for the proverbial "small print" in the plan description to clearly explain coverage limits and exclusions. Employers and health plans need to develop subscription procedures that ensure high-visibility disclosure of coverage limits and careful consumer consideration of their potential clinical implications before signing up. Consumers should be aware, for example, of the kinds of treatments, for instance organ transplants, that a plan specifically excludes. In the case of contract language allowing plans to refrain from covering scientifically unproven therapies, consumers should be told that most medical interventions lack clear scientific proof of efficacy and that such language therefore gives plans broad discretion to deny coverage for accepted treatments. Contract terms authorizing plans to weigh clinical benefits against costs should clearly state cost-benefit trade-off principles and policies toward medical uncertainty. These general principles should be made concrete for prospective subscribers (and future legal decision makers) through particular examples of therapies covered and foregone. This kind of clarity of disclosure and of subscriber understanding should be a moral prerequisite for "voluntary" opting out from the

252. See Eric Mack, *Bad Samaritanism and the Causation of Harm*, 9 PHIL. & PUB. AFF. 230 (1980).

253. Whether consciously or otherwise, we characterize choices as "voluntary" when we believe that the circumstances and pressures under which they were made are sufficiently acceptable, morally, to support holding the chooser responsible for the consequences. Bloche, *supra* note 76.

conventional coverage of medically necessary care; moreover, for opting out to be deemed "voluntary," conventional coverage should be affordable (through public subsidies if necessary).²⁵⁴

C. Legal Safeguards for Medical Professionalism

If maximizing health promotion per clinical dollar spent were the sole aim of American health care law, the Hippocratic ethic of undivided professional loyalty to patients would often stand in the way of sensible resource management. But the imperatives of rescue, support and comfort, and regard for the dignity of people in medical distress favor robust protection for the Hippocratic norm of clinical fidelity to the point that infringement on this ethic should be rare. Failure to buffer the medical profession from contemporary market pressures could eviscerate this ethic, both as a constraint on behavior and as a moral ideal,²⁵⁵ by putting physicians under the authority of health-plan managers and others with cross-cutting goals. Cognitive dissonance between this institutional reality and the Hippocratic ideal could prove unsustainable, collapsing the fiduciary ideal as a cognitive structure capable of restraining self-interest.²⁵⁶ Recognition in tort law of a duty of loyalty along the lines described above would both reinforce Hippocratic fidelity as a behavioral constraint and empower physicians to resist contrary pressures from payers and others. Additional legal constraints aimed at bolstering professional loyalty to patients include prohibition of health plans' efforts to discourage physicians from telling patients about accepted but costly therapies and limits on health plans' power to choose providers based on their clinical spending patterns.

254. What is "voluntary" and what is otherwise is, of course, not clear cut: such line drawing requires difficult moral and political judgments about the acceptability of the chooser's decision-making circumstances and range of alternatives. M. Gregg Bloche, *Beyond Autonomy: Coercion and Morality in Clinical Relationships*, 6 HEALTH MATRIX 229 (1996). But the questions of voluntariness and affordability at least frame the inquiry and signal that ex ante, contractual consent to limits beyond the "medical necessity" baseline should not be taken at face value, without examining the conditions that give rise to consent. Cf. David B. Goodwin, *Disputing Insurance Coverage Disputes*, 43 STAN. L. REV. 779 (1991) (discussing strong propensity of courts to treat insureds as lacking bargaining power and to apply "contract of adhesion" doctrine in coverage disputes).

255. Professional commitment to this ethic may already be eroding. A 1996 survey of more than 1500 practicing physicians found that 80% believed that the medical profession's commitment to the ethic of undivided loyalty to patients had decreased during the previous ten years. Sulmasy et al., *supra* note 239.

256. It is a rarely observed irony that some of the most vigorous proponents of managerial use of financial incentives to reduce physicians' clinical spending look to the fiduciary ethic to keep physicians from taking frugality too far, even as they discount the corrosive effect of such incentives on the profession's fiduciary commitment. See Brief of Amicus Curiae American Association of Health Plans at 18, *Pegram v. Herdrich*, 530 U.S. 211 (2000) (No. 98-1949) (asserting that financial incentives will not "motivate physicians to cast aside their professional and ethical obligations"). See also G. Khushf, *A Radical Rupture in the Paradigm of Modern Medicine: Conflicts of Interest, Fiduciary Obligations, and the Scientific Ideal*, 23 J. MED. PHIL. 98 (1998).

The case for deference to professional self-governance as a way to promote the efficacy of clinical care has been much undermined over the past few decades by mounting evidence of professional ignorance about the effectiveness of medical interventions. Further study of the content of medical expertise, the nature of medical self-governance, and what each may contribute to quality of care when scientific evidence is lacking might prove valuable.²⁵⁷ Meanwhile, it may make sense, from a risk-averse perspective, for regulators and private accreditors to continue to defer to the credentialing authority of professional organizations in the various specialties and to require that health plans and hospitals do the same.

Such deference, however, should not extend to professional organizations' efforts to use their cultural and moral authority as leverage for the pursuit of economic advantages that serve no public purpose. Such efforts include advocacy of exemptions from state financial-reserve requirements for physician-sponsored health plans, attempts to set fees collectively, and pursuit of regulatory "safe harbors" for referral of patients to laboratory and other facilities in which the referring clinician has an interest. So-called patient-protection bills, now being pushed in many state legislatures by medical societies, contain some provisions that would strengthen the fiduciary ethic and professional self-governance along the lines urged above. But they contain others—for example, "any willing provider" clauses²⁵⁸—that would limit health plans' ability to choose providers based on defensible quality²⁵⁹ and price²⁶⁰ concerns. Some of these provisions would also bar health plans from contracting with subscribers for less than the conventional promise of "medically necessary" care.

D. Health Care Antitrust Law

Robust policing of health care markets for price-fixing activity and for combinations that create troublesome market power, as market power is

257. Among health care economists in particular, there is a strong tendency to doubt the value of clinical judgments that are not well supported by scientific evidence. The impressions, training, and past experiences that support such judgment are often dismissed as little more than accumulations of heuristic bias and error. The validity of this sort of professional expertise should neither be reflexively denied nor presumed, and it is a question of much import for the future of health care law and policy.

258. See *Ky. Ass'n of Health Plans v. Nichols*, 227 F.3d 352 (6th Cir. 2000), *cert. granted*, 122 S. Ct. 2657 (2002) (holding state "any willing provider" statute, requiring health plans to accept all qualified physicians, to be "saved" from ERISA preemption).

259. Defensible quality concerns might include educational credentials (beyond those minimally necessary to enter professional practice), research and publication records, and evidence of adherence to accepted patterns of best, frugal practice.

260. By limiting the size of their provider panels, health plans can channel their bulk purchasing power to obtain lower prices for their subscribers. See generally JOHN R. GRIFFITH, *THE WELL-MANAGED HEALTH CARE ORGANIZATION* 515-58 (3d ed. 1995).

conventionally measured,²⁶¹ should remain the centerpiece of medical anti-trust enforcement. Congress and the enforcement agencies should reject physicians' efforts to win antitrust exemption for collective bargaining over fees. These unexceptional propositions further the imperatives of population-wide health promotion and expanded access to medical services by holding down costs to purchasers. Over the long haul, moreover, vigorous price competition could slow increases in spending on high-technology, low-benefit services by trimming the windfalls available to providers of cutting-edge technologies. Reducing these windfalls would moderate the cycle of ambitious technology-oriented research and development, large financial rewards (from health care payers) for sellers and practitioners of new technologies, and resulting high incentives for new research and development.²⁶² Robust price competition presents no obstacle to the imperatives of rescue, support and comfort, and respect for the dignity of the sick. And, by restraining low-benefit spending, it could shift resources to public programs and economic development activities that more effectively promote health.

On the other hand, efficiency grounds do not clearly support the anti-trust-enforcement agencies' current preference for economic risk bearing by providers,²⁶³ and this policy fosters physician payment schemes that put patients' trust at risk. Antitrust decision makers should therefore decline to treat provider risk-bearing as a safe harbor for collective price setting. However, collective action by physicians on nonprice matters that affect professional trustworthiness and judgment should be evaluated under the antitrust "rule of reason" and, in some cases, permitted. Such matters include so-called gag rules and other efforts to keep physicians from telling patients about costly treatment options, implementation of clinical-practice protocols, and the handling of appeals when insurers decline to authorize care. The U.S. Supreme Court's opinion in *California Dental Association v. FTC*²⁶⁴ opened the way for this approach. Upholding the association's disclosure requirements for discount advertising, the Court said, in essence, that collective action by professionals in defense of ethical norms is allowable under the "rule of reason" when such action furthers consumer

261. Herfindal-Hirschman Index ("HHI") definition of relevant geographic and product markets will remain especially complicated in the health care field due to overlapping and uncertain geographic patterns of service use and the myriad services and bundles of services offered by providers.

262. My focus here is on investment in new, low-benefit technologies—those that Lewis Thomas famously termed "half-way technologies," because they do not target basic biological mechanisms of disease and consequently tend toward unimpressive biological results. LEWIS THOMAS, *THE LIVES OF A CELL: NOTES OF A BIOLOGY WATCHER* 33-36 (1974). As Thomas argued, we may be overinvesting in "half-way technologies" and underinvesting in the basic biological research necessary to build foundations for more decisive therapeutic advances.

263. See *supra* text accompanying notes 165-68.

264. 526 U.S. 756 (1999).

welfare.²⁶⁵ By construing consumer welfare to incorporate the purposes of medicine I have discussed, including intangibles like trustworthiness, anti-trust decision makers can and should give health care providers safe harbor to act collectively on nonprice matters of concern to consumers. To be sure, perfect agency by providers on their patients' behalf in such matters is unattainable: to some degree, providers pursue self-interest. But the norm of Hippocratic commitment to patients, which itself can be explained in terms of the medical profession's long-term interest in its own credibility,²⁶⁶ is likely to channel providers' advocacy in such matters along lines that parallel patients' concerns.²⁶⁷

E. Regulation of Capital Investment

Assessed in terms of the aims of health care law that I have identified, regulatory constraints on capital investment are a bad idea. The indeterminacies that plague regulators' attempts to specify optimal ratios of clinical plant and equipment to people and to apply these ratios case-by-case to proposed capital projects²⁶⁸ make the CON paradigm an unpromising tool for the cost-effective promotion of health. The paralytic conflict that these indeterminacies engender virtually ensures enormous waste, particularly when competing applicants vie before agencies and courts for authorization to initiate services. To the extent that constraints on capital investment succeed in holding the supply of clinical services below the demand, friction within health care institutions over allocation of these services to patients engenders additional waste. Moreover, the politics of personal influence often substitutes for agreed upon means of determining patients' relative needs.²⁶⁹

The supply-demand mismatches that are the goal of CON regulation also operate at cross purposes with the imperative of rescue. The imperative of rescue implies access to technology that is widely available and that might make a difference for people in difficult medical straits. Assessed in terms of the imperative of support and comfort, the case for the CON paradigm is at best equivocal. Constraints on capital investment might nudge physicians toward more humane, less technology-oriented engagement with patients. But diminished access to diagnostic technology could reduce physicians' ability to offer detailed, plausible, and thus comforting clinical

265. To be precise, the Court said that collective professional action passes muster under the "rule of reason" if the action is "procompetitive." *Id.* at 779-80. But, as critics of *California Dental* have pointed out, the Court used the term "procompetitive" loosely, as synonymous with promotion of social welfare. *See supra* note 163.

266. *See* Arrow, *supra* note 54.

267. M. Gregg Bloche, *The Market for Medical Ethics*, 26 J. HEALTH POL'Y, POL. & L. 1099 (2001).

268. *See supra* text accompanying notes 171-72.

269. *See supra* text accompanying notes 173-75.

explanations. The CON paradigm's implications for the dignity of the sick are negative, at least to the extent that supply-demand mismatches expose patients to the politics of personal influence. Finally, to the extent that this politics disfavors the least advantaged among us,²⁷⁰ the supply-demand mismatches that "successful" CON regulation induces undercut the imperative of universal access and the ideal of social inclusion.

CONCLUSION

The law of health care provision is a chaotic, dysfunctional patchwork. It is thus understandable that many commentators and some courts now look to the logic of social-welfare maximization to harmonize health law. But the welfare-maximization premise is not up to the task. Our cognitive limitations and moral disagreements make its logic too blurry in practice. We cannot ask economics—or health law—for clear answers to scientific and moral questions about medical care's efficacy and value that our society has not been able to resolve.

The alternative approach to health care law that I have urged here begins by conceding our cognitive failings and moral differences. It acknowledges that we want many contradictory things from medicine. The oft-stated aim of promotion and restoration of health fails to capture this untidy complexity. Rather than settling for the false simplicity of some reductionist formula, legal decision makers should wrestle with the often poignant, incommensurable concerns that animate health law disputes. These concerns lie beneath health law's euphemistic terms—its references to reasonable care, medical need, consumer welfare, and the like. Judges should bring these concerns into the open. Transparency is vital if courts are to align their health-policy judgments over time, across different doctrinal settings. And candid discussion of the values at stake might more deeply engage citizens in debates about what health policy should be. Rather than usurping the role of legislators in health policy, courts could revitalize it, by drawing attention to hard questions now submerged in legal euphemism.

I have proposed some normative starting points for the courts in several doctrinal areas critical to the governance of managed care. But my larger aim is to change the way that courts "do" health law. Courts should pay less heed to formal, doctrinal consistency and closer attention to the coherence of the messages they send to actors in the health sphere. Courts should resist the allure of a single yardstick of cost and benefit. And when judges choose, as they must, between competing priorities, they should make the normative basis for their choices explicit. By so doing, courts can increase the likelihood that their decisions, over time, will produce wise health

270. See *supra* text accompanying notes 174-75.

policy, responsive to the revolutionary changes American medicine is undergoing.