

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

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

As a response to specific events, Dr. Drazen has a legitimate gripe. His complaint was provoked by two highly political government decisions: federal legislation banning “partial birth” abortion, and Congress’s attempt, at the eleventh hour, to prevent life support from being withdrawn from Terri Schiavo. Dr. Drazen was also carrying the torch for editors past in defense of medical professionalism. A similar piece by his predecessor at the helm of America’s most prestigious medical journal, Dr. Jerome Kassirer, berated Congress for enacting the “partial birth” abortion ban in the first place, as well as for mandating 48 hours of post-partum insurance coverage and for publicly endorsing mammography for all women in their forties.² To Dr. Drazen, the Supreme Court’s decision to uphold the Congressional ban shows that “the judicial branch has regrettably joined the legislative branch in practicing medicine without a license.”³

As a blanket statement, however, Dr. Drazen’s objection to government regulation is (to put it mildly) problematic. The United States spends roughly \$2 trillion annually on

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¹ Jeffrey M. Drazen, Government in Medicine, 356 *New Engl. J. Med.* 2195 (2007).

² Jerome P. Kassirer, Practicing Medicine Without a License – The New Intrusions by Congress, 336 *New Eng. J. Med.* 1747 (1997).

³ Drazen, *supra* note __, at 2195.

health care, about half of that taxpayers' money. Health care comprises 15% of gross domestic product, and provides approximately one in ten jobs, more than any other industry. Along with education, health is a building block of community and a primary determinant of both personal liberty and economic productivity. Yet some 15% of Americans lack health insurance (25% in Texas, where I live), and with it access to basic medical care. If regulation has no place in medicine, how can a modern health care system function? Without government, as less patrician New Englanders have been reputed to say, "You can't get there from here."

Dr. Drazen's standard for ethically acceptable health policy has two prongs, one relating to expertise and the other to orientation. Through most of its history, health care regulation has contended with some version of Dr. Drazen's preference for oversight and discussion (he does not say "decision") by "informed and knowledgeable people." As Jay Gold wrote twenty years ago, a major challenge in health law is how to hold experts accountable to non-experts.⁴ The complexity of health care puts it beyond the ken of most mortals, and ignorance is a bad basis for government. Because of its informational advantages, the medical profession claims it should retain primary responsibility for the public policy of health care (leaving aside for the moment any moral ones it may also possess).

This is nothing new. Professional (i.e., physician) control over health care has a long, checkered history of both public-mindedness and protectionism. As Ron Gilson has noted, "a necessary condition for professionalism is market power."⁵ Unsurprisingly, the public message of organized medicine has been more than *noblesse oblige*. *Après moi le*

⁴ Jay A. Gold, *Wiser than the Laws?: The Legal Accountability of the Medical Profession*, 7 *Am. J.L. & Med.* 145 (1981).

⁵ Ronald J. Gilson, *The Devolution of the Legal Profession: A Demand Side Perspective*, 49 *Md. L. Rev.* 869, 916 (1990).

deluge better captures the disaster that looms, the AMA often has argued, should society stray far from physician authority.⁶

There are alternative defenses against ignorance. What generalist legislators and courts lack in knowledge, for example, expert administrative agencies can readily supply.

Though Dr. Drazen does not inveigh directly against the executive branch, bureaucratic control seldom appeals to the medical profession, which prefers that government delegate authority to self-regulatory bodies such as the Joint Commission on Accreditation of Healthcare Organizations. As a matter of information policy, of course, we could also leave as many “discussions” as possible to the market, which has well-established advantages over central planning in its ability to communicate signals that coordinate complex activity through the “miracle” of competitive pricing.⁷

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

A “specific patient” refers to more than a specific diagnosis or treatment. Part of the charge against policymakers for “practicing medicine” indeed involves substitution of political for clinical judgment in technical areas. Narrowly tailored legislation – mandated health insurance coverage for hospitalization following childbirth (“drive-through delivery” laws) and breast cancer surgery (“drive-through mastectomy” laws), and explicit informed consent requirements for patients undergoing mastectomy, sterilization, abortion, or other surgical intervention – can be criticized for kowtowing to

⁶ See generally PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1982) (casting the history of American medicine in terms of physicians’ successful collective opposition to both corporate and governmental control).

⁷ Frederick A. Hayek, *The Use of Knowledge in Society*, 35 *Am. Econ. Rev.* 519 (1945) (arguing that free markets are informationally superior to Communist central planning, in large part because of price signaling).

narrow interest groups, resisting subsequent modification in light of new evidence, and abdicating responsibility for dealing with larger problems. But the problem of patient specificity, although present in these laws, is not just a matter of keeping medical textbooks out of politicians' hands.

A "specific patient" is an identifiable person, often someone afflicted with a serious disease that we can imagine ourselves suffering from but are grateful we do not actually have to endure. Occasionally, as with Terri Schiavo, the political process indeed intrudes on the private medical decisions of named individuals.⁸ Usually, however, politicians and policymakers apply the mental construct of the specific patient, and that patient's therapeutic relationship with a specific physician, to problems of collective costs and benefits for which such a starting point, I will argue, is not appropriate. In other words, I come not to praise Dr. Drazen's second criterion for health care regulation, but to recommend its interment.

The distinction I want to draw is between legal obligations to discrete parties and legal regimes that serve abstract goals or broad collectives. What I call a "relational duty" is generally owed to an individual, one on one, though it may be owed to a legal entity other than a person, or to a well-defined group of persons or entities. In health care, the obligation of physician to patient constitutes the paradigm case of relational duty. Law often approaches relational duties as problems of legal agency: the agent (the physician) serves the principal party (the patient).⁹

Not all laws, of course, address relational duties. Many laws are primarily intended to advance collective goals such as public safety, economic growth, and the general welfare,

⁸ See generally *The Schiavo Case: A Symposium*, 22 *Const. Commentary* 383 (2005) (collecting articles about the case).

⁹ For purposes of this Essay, the legal term of art that attaches to the physician-patient relationship is not important. Strict definitions of agency may not capture all of what physicians do for patients. And commentators differ on whether the physician-patient relationship should be considered "fiduciary" or merely "confidential." Compare Tamar Frankel, *Fiduciary Law*, 71 *Cal. L. Rev.* 795, 796 n.6 (physician-patient relationship is fiduciary) to Restatement (Second) of Trusts § 2 cmt. B (1950) (confidential relationship between physician and patient does not create an absolute duty of loyalty).

and affect individuals only insofar as they may have contact with regulated activities. An obligation to further the interest of a something rather than a someone – perhaps an aggregate of persons, perhaps an ideal – I call a “regulatory duty.” The thesis of this Essay is that far more legal issues in health care are approached as relational than as regulatory problems, making it very difficult for law to serve truly “public” policy. The Essay begins by speculating about sources of health law’s relational bias, and ends by discussing four areas of contemporary health policy that, in my view, require a more regulatory approach.

It is an apt time to consider these issues. Key constituencies are clamoring for comprehensive national health reform following the 2008 presidential election much as they did when President Bill Clinton took office in 1993, and the issue has again moved to the front of the domestic policy agenda in public opinion polls. Many of the same arguments are being made today as fifteen years ago. But many of the same obstacles exist as well, including the relational orientation of prevailing law. This Essay therefore uses experiences from that earlier, unsuccessful effort to illustrate current tensions in public policy and to draw lessons for the future.

Sources of Health Law’s Relational Bias

A relational perspective, particularly where the delivery of medical services is concerned, is a defining characteristic of American health law. This is inescapable and to a considerable degree desirable, because the product of health care, as Kenneth Arrow once wrote, is inseparable from the process of providing it.¹⁰ The healing professions are based on intimacy, with good care requiring a combination of compassion, competence, and confidentiality.¹¹ The U.S. health care system has retained this flavor despite its massive scope and scale. As a result, over a period of decades, sometimes because of

¹⁰ Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 949 (1963). For a comprehensive updating and analysis of Arrow’s seminal article, see *Uncertain Times: Kenneth Arrow and the Changing Economics of Health Care* (Peter J. Hammer et al., eds.) (2003).

¹¹ Hippocratic Oath, in Taber’s *Cyclopedic Medical Dictionary* 662 (14th ed. 1981).

direct pressure and sometimes because of lack of countervailing force, most health regulatory problems have been framed in relational terms. The following merit brief discussion as continuing sources of relational bias: lack of distinction between private law and public law, professional ethics and bioethics, budgetary and general politics, and health care consumerism.

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

In the early 19th century, a serious attempt in American medical schools to create a public-minded field of “medical jurisprudence” similar to that thriving in the centralized bureaucracies of Western Europe was thwarted in the United States by local politics and courtroom processes.¹² Instead, much of what we now call “health law” developed around discrete interactions between one patient and one physician, such as medical malpractice, in which private legal accountability both drew from and criticized the established ethics of personal medical care. Subsequent legislation and administrative law, whether associated with government health insurance programs such as Medicare, with private health care financing, or with assuring the safety and quality of medical care, layered atop this foundation of private legal governance. Considerable attention has been paid to whether contract principles or tort principles should guide legal judgments about medical care and health insurance coverage,¹³ but the decision to frame the choice as

¹² See JAMES C. MOHR, *DOCTORS AND THE LAW: MEDICAL JURISPRUDENCE IN NINETEENTH-CENTURY AMERICA* (1993) (describing how the legal and medical professions grew apart in small towns with locally appointed coroners and high-profile lawsuits in which physicians lost face as witnesses and defendants)

¹³ Wendy K. Mariner, *Slouching Toward Managed Care Liability: Reflections on Doctrinal Boundaries, Paradigm Shifts, and Incremental Reform*, 29 *J.L. Med. & Ethics* 253 (2001) (arguing that little hangs on the tort-contract distinction).

being between these two private law regimes and not a public law regime is rarely questioned. Attempts to reform the law of medical malpractice to improve collective safety and provide equitable compensation for injury, for example, are still criticized for ignoring fundamental values of individual justice.¹⁴ “Public” health law evolved separately as “public health law,” but – as discussed below – has had little connection to the medical profession or to the large and expensive institutions that supply and fund it.

Professional ethics and bioethics. The relationship between a single patient and a single physician is at the heart of medical ethics. When physicians provided mainly comfort and solace to families, plus guidance regarding *materia medica* that could be both used and misused, not causing harm and valuing the patient’s interest above all else were sufficient, and sensible, ethical precepts. As the ability of physicians to diagnose and treat improved, and the revenues associated with doing so grew, the medical profession reconstituted its authority under formal codes of ethics that also conveyed the profession’s collective importance to society.¹⁵ As Paul Starr and others have explained, these increasingly political documents invoked relational values – such as free choice of physician by patient and of patient by physician, direct payment for services rendered, unfettered clinical decision-making, and secrecy regarding the details of care – in order to protect the medical profession’s economic position and forestall both government and corporate control.¹⁶

¹⁴ See, e.g., John C.P. Goldberg, *The Constitutional Status of Tort Law: Due Process and the Right to a Law for the Redress of Wrongs*, 115 *YALE L.J.* 524 (2005); John C.P. Goldberg, *Tort Law for Federalists (and the Rest of Us): Private Law in Disguise*, 28 *HARV. J.L. & PUB. POL’Y* 3 (2004). But see Samuel Issacharoff & John Fabian Witt, *The Inevitability of Aggregate Settlement: An Institutional Account of American Tort Law*, 57 *Vand. L. Rev.* 1571 (2004) (arguing that aggregate resolution of tort claims, albeit through private institutions, has served as a pragmatic counterpoint to the notion of “individualized justice” throughout modern American history).

¹⁵ See Starr, *supra* note __, at 79-144 (discussion physicians’ “consolidation of authority” between 1850 and 1930). Starr describes the AMA’s initial code of ethics at mid-century as an attempt by mainstream physicians to exclude unconventional practitioners, *id.* at 90-91, and notes that professional self-regulation was ineffective until decades later when, because of medical advances, “[t]he public granted the legitimate complexity of medicine and the need for institutionalized professional authority.” *Id.* at 141.

¹⁶ See Starr, *supra* note __, at 299-301 (describing physician resistance to health insurance innovations).

The bioethics revolution of the late twentieth century helped the medical profession understand the ethical implications of changing technology, but did not alter its relational orientation. Anglo-American bioethics expresses itself in individualistic terms that reflect its classical liberal heritage, emphasizing personal liberty and freedom of choice more than collective obligation or community cohesiveness. Since the 1950s, for example, the principal project of bioethics has been to convert the tradition of professional beneficence into a commitment to patient autonomy, ethical impulses that could nearly as easily have been channeled into social responsibility.¹⁷ Bioethicists' regulatory mission – mediating the mutual obligations of individuals and society – has remained inchoate, subsumed (and often invisible) within the relational mission of mediating interactions between health professionals and specific patients.

This emphasis reflects in part an inversion of the original relationship between bioethics and government. The founding document of modern bioethics is the Nuremberg Code, which was a response to Nazi wartime atrocities masquerading as scientific experimentation.¹⁸ Its basic purpose was to remind individual scientists that they were both professionals and human beings with moral obligations to other human beings, regardless of government direction to the contrary. The Belmont Report issued in reaction to the U.S. government's notorious Tuskegee Syphilis Study had a similar character.¹⁹ By contrast, research ethics today consists of dense regulations issued by government that are enforced against individual researchers on pain of withholding their funding. The historical threat to research subjects, state power, has become their chief protector.

¹⁷ See, e.g., Ruth R. Faden & Tom L. Beauchamp, *A History and Theory of Informed Consent* (1986).

¹⁸ Nuremberg Code, *in* 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW, No. 10, at 182 (1949), *available at* http://www.ushmm.org/research/doctors/Nuremberg_Code.htm.

¹⁹ The Belmont Report emphasizes beneficence, and prohibits "brutal or inhumane treatment" regardless of consent. THE NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMED. & BEHAV. RES., U.S. DEP'T OF HEALTH, EDUC. & WELFARE, THE BELMONT REPORT: ETHICAL PRINCIPALS & GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 17 (1978). This is similar to the Nuremberg Code's ban on experimentation where possible death or disabling injury can be expected.

Also supporting the relational emphasis of bioethics is that, notwithstanding the Bush administration's aggressive national security agenda, money rather than renewed government power is the *bête noire* of today's medical ethicists. Because it involves private conduct rather than state action, the commercialization of medicine tends to be seen by commentators as a threat to individual patients and corresponding professional values rather than as a perversion of collective interest.²⁰ This places bioethics in a difficult position, because it must reconcile resistance to commercial exploitation of patients by profit-seeking corporations with overall support for patient autonomy, including freedom to participate in the marketplace. The result has been an ethics of consumer protection, with various precepts adopted to provide patients and research subjects with complete information and prevent fraud, coercion, or duress.²¹ Consumer protection, however, focuses on individual decision-making and therefore gives bioethics few opportunities to articulate collective, social goals.

A retreat to relational bioethics is also pragmatic. Although ethicists have long believed that the proper allocation of society's scarce resources is a key question solidly within their purview, their opinions about social responsibility and redistribution tend not to be as well received by the political process as their opinions about individual liberty. The bioethicists who were invited to the White House to work on health reform in 1993, for example, expected rationing to be their most important agenda item. To their surprise, they were explicitly forbidden from mentioning the word by the administration's reform czar, Ira Magaziner, and were instructed instead to craft a lofty preamble for the Clinton administration's universal coverage legislation and then to work on familiar relational issues such as advance directives.²²

²⁰ See, e.g., Marc A. Rodwin, *Medicine, Money, and Morals: Physicians' Conflicts of Interest* (1993) (describing the dangers to patients of marketizing medicine and changing the financial incentives of physicians).

²¹ See, e.g., E. Haavi Morreim, *Holding Health Care Accountable: Law and the New Medical Marketplace* (2001) (dividing quality problems in medical markets into expertise issues and resource issues, and proposing corresponding duties involving tort, agency, and contract).

²² These pressures have been bipartisan. It has been suggested, for example, that the first President Bush rejected the state of Oregon's Medicaid waiver application because he did not want to be known as the "rationing president." See Thomas Bodenheimer, *The Oregon Health Plan - Lessons for the Nation (First of Two Parts)*, 337 *New Eng. J. Med.* 651, 652 (1997).

Politics, especially budgetary politics. Political dynamics reinforce relational governance. Although some commentators criticize the notion of a “statistical” life,²³ regulatory policies that increase the risk of physical injury or death in tangential ways for faceless persons (e.g., raising speed limits or relaxing environmental controls) are easier for politicians to adopt and maintain than policies that cost more immediate lives (e.g., not paying for organ transplantation). Health care regulation is uniquely amenable to portrayal in terms of identified lives. For example, Jacobs and colleagues credit Oregon’s controversial Medicaid rationing plan with increasing public budgeting for health care by forcing state legislators to cast votes on coverage of specific treatments that have direct implications for identifiable people.²⁴

Anecdotes have power in all politics, but especially so in health care.²⁵ Pressure for cost containment, both public and private, has been resisted most successfully when vivid narratives – albeit often exaggerated or misused – can be offered to the public. Examples at the federal level include the Emergency Medical Treatment and Active Labor Act of 1990 (EMTALA),²⁶ and the Newborns’ and Mothers’ Health Protection Act of 1996.²⁷ On the other hand, preventive care is not as compelling politically as treatment of manifest disease because its effects are less salient – a reason why successful prevention campaigns, such as for a polio vaccine, often use “poster children.”²⁸

Even comprehensive health reforms must withstand scrutiny one patient at a time. When I worked in the Clinton White House in 1993, I asked the experts whose work I was

²³ Lisa Heinzerling, *The Rights of Statistical People*, 24 *Harv. Envtl. L. Rev.* 189 (2000).

²⁴ Lawrence Jacobs et al., *The Oregon Health Plan and the Political Paradox of Rationing: What Advocates and Critics Have Claimed and What Oregon Did*, *Journal of Health Politics, Policy & Law* 1999; 24(1): 161-180.

²⁵ See David A. Hyman, *Do Good Stories Make for Good Policy?*, 25 *J. Health Pol. Pol’y & L.* 1149 (2000) (arguing that when atypical or incomplete stories motivate health care “reform,” unsound policies may result).

²⁶ See also David A. Hyman, *Patient Dumping and EMTALA: Past Imperfect/Future Shock*, 8 *Health Matrix* 29 (1998).

²⁷ P.L. 104-204 (1996). See also David A. Hyman, *What Lessons Should We Learn From Drive-Through Deliveries?* 107 *Pediatrics* 406 (2001).

²⁸ DAVID M. OSHINSKY, *POLIO: AN AMERICAN STORY* (2005).

coordinating to construct fictitious profiles of ordinary Americans on whom the effects of their proposed policies could be assessed and described. A few months later, in his first televised appearance promoting the newly released Health Security Act,²⁹ President Clinton stumbled over his initial question, which was from a mother who wanted to know if his plan would have covered experimental treatment for her son, who had died of leukemia.³⁰ The Health Insurance Association of America exploited this relational bias to help defeat the Clinton proposal using the “Harry and Louise” ads, which portrayed an ordinary couple complaining about the government limiting their individual choices.³¹

To avoid the trap of the identified life, politicians usually constrain health care through aggregate financing decisions (which savvy opponents now assiduously convert to children’s lives lost, cancer patients left untreated, etc.), and scrupulously avoid reforms that alter health care delivery even though it is health care delivery that ultimately determines cost, access, and quality. It is ironic that an analysis credited with helping kill the Health Security Act, Betsy McCaughey’s essay “No Exit,” was primarily about how private managed care might compromise health care delivery, an issue with no direct connection to the Clinton proposal that came to the fore more quickly after its defeat than had it passed.³² Financing decisions also fall squarely within Washington’s comfort zone. To tax or not to tax is the critical vote that public officials must defend in re-election campaigns, and handing out money is how politicians win friends and influence people.

²⁹ Health Security Act, H.R. 3600 (1993).

³⁰ U.S. Newswire, October 4, 1993, Remarks by President Clinton During 'A California Town Hall Meeting', White House Office of the Press Secretary.

³¹ See THEDA SKOCPOL, *BOOMERANG* 137-38 (1996) (discussing HIAA's advertising campaign); Raymond L. Goldstein et al., *Harry and Louise and Health Care Reform: Romancing Public Opinion*, 26 *J. Health Politics, Pol’y & L.* 1325 (2001) (suggesting that advertising of this sort can demobilize public support for health policy initiatives that are unfavorable to special interests). When I returned to California the following year, I learned that a local Democratic operative supporting health reform had contacted the actress who played “Louise,” hoping to persuade her to go public with the fact that she herself lacked health insurance and might well benefit from government-sponsored universal coverage. The actress arrived at the meeting wearing a hidden recording device provided by the Republican opposition. Welcome to politics.

³² Elizabeth McCaughey, *No Exit: What the Clinton Plan Will Do For You*, *New Republic*, Feb. 7, 1994, at 21.

The health care delivery system remains politically untouchable. Lawrence Jacobs distinguishes America's politics of health care supply from Europe's politics of health care access, noting how this makes U.S. health policy vulnerable to interest group pressure in support of narrowly defined services and providers.³³ Because innovators tend not to lobby, and because regulatory changes to existing ways of receiving services could be seen as threatening identified lives, government policymakers have been largely powerless to improve the system's collective efficiency, and therefore to make it affordable for more of the population. As Jacobs observes, moreover, access to health care for economically disadvantaged groups has been "fiscalized" as a problem of allocating scarce tax dollars rather than as a source of social solidarity and future stability.³⁴

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

The collective meaning of the Clinton health reform plan was budgetary, not service-oriented. Two major design features of the Health Security Act had as their principal purpose to persuade the Congressional Budget Office (CBO) that universal coverage could be achieved without massive tax increases and that spending would not exceed

³³ Lawrence R. Jacobs, *Politics of America's Supply State: Health Reform and Technology*, HEALTH AFF., Mar./Apr. 1995, at 143.

³⁴ Id. at 149-52.

predetermined limits.³⁵ Nominally private “health alliances” (the forerunner of the “connector” in the recently enacted Massachusetts Health Plan) were created to collect premium dollars and broker health plan enrollment, and “global budgets” were written into law to backstop market competition if aggregate spending continued to rise. CBO bought the this-will-keep-spending-down argument but rejected the this-is-not-a-tax argument, killing health reform as a political matter.³⁶

Health consumerism. Changing language used to describe recipients of medical care – from dependent “patients” to demanding “consumers” – has reinforced the non-collective, relational nature of most health care regulation. Consumerism, like feminism and environmentalism, is often described as a product of the 1960s rebellion against establishment values, but its impact is scattershot almost by definition. In health care, consumerism (assisted by the Internet) has substantially overcome physicians’ monopoly on medical information, but has made insured patients even more insistent in their pursuit of seemingly beneficial treatment. Consumerism (assisted by bioethics) has oriented physicians to goals defined by patients, but has largely freed the medical profession from ethical responsibilities beyond the satisfaction of individual demand.³⁷ Consumerism (assisted by persistent cost inflation) may finally open medical pricing to public scrutiny, but rejects collective negotiation in favor of a decentralized market. As the managed care experience described below illustrates, monetizing medical practice often breeds suspicion of group purchasing because of concern about economic self-interest on the part of employers, health insurers, or other purchasing intermediaries.

³⁵ Viveca Novak, *By The Numbers*, National Journal, February 12, 1994, at 348. “Health alliances” were non-profit bodies that would structure regional health insurance markets, receiving contributions from employers and paying risk-adjusted premiums to the health plans in which beneficiaries had enrolled. “Global budgets” would have limited, as a matter of law, the aggregate amount that could be paid for the statutory package of health benefits, imposing various correctives that (if not revised by a subsequent Congress) would be triggered should the limits be exceeded. For a policy-minded explanation of these and other features of the Clinton Health Plan, see Paul Starr & Walter A. Zelman, *Bridge to Compromise: Competition Under a Budget*, Health Aff., Supp. 1993, at 7.

³⁶ Robert D. Reischauer, Testimony of the Director of the Congressional Budget Office to the House Energy Committee, Subcommittee on Health and the Environment, regarding the Clinton Health Plan, Feb. 10, 1994.

³⁷ See David A. Hyman, *How Law Killed Ethics*, 34 PERSP. BIO. MED. 134 (1990); William M. Sage, *The Lawyerization of Medicine*, 26 J. HEALTH POL. POL’Y & L. 1179, 1184–87 (2001).

Consumerism also assigns government a facilitative rather than constitutive role in health care. President Clinton endorsed this individualistic approach in his Second Inaugural Address, proposing that “a new government for a new century [would be] humble enough not to try to solve all our problems for us but strong enough to give us the tools to solve our problems for ourselves.”³⁸ Largely for this reason, information disclosure has been a mainstay of health care regulation for the last decade, as discussed in detail below.³⁹

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

When consumerism imposes substantive demands on regulation, however, its needs are difficult to accommodate. Consider the Food and Drug Administration (FDA), which in the 1990s turned to industry-paid user fees to help it keep up with increasingly vocal demand for breakthrough drugs while still protecting the public.⁴⁰ High-profile failures of oversight, such as Vioxx, sensitized consumerist voters to the financial self-interest of the pharmaceutical industry, but have not led them to recognize that, in collective terms, medical innovation can never be both quickly available and assuredly safe and effective.

³⁸ Transcript of President Clinton’s Second Inaugural Address to the Nation, *N.Y. Times*, Jan. 21, 1997, at A14.

³⁹ See generally William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 *COLUM. L. REV.* 1701 (1999).

⁴⁰ See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 *Va. L. Rev.* 1753, 1840-44 (1996) (analyzing the adoption of drug user fees).

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

Current Needs for Collective Goals and Regulatory Governance

Relational bias resulting from the factors identified above might simply be an uncomfortable fact of life for health care policymakers were it not for the crushingly high costs that health care imposes on American society and the suboptimal benefits it provides. Far more than social security, Medicare and Medicaid entitlements dominate government budgets and squeeze out discretionary spending on education, infrastructure, and economic development. At the same time, millions of “one patient-one physician” encounters do not really sum to a system, but remain a fragmented collection of inaccessible services with uneven quality, questionable safety, and insufficient impact on the health of the nation.⁴¹

⁴¹ See *World’s Best Medical Care?*, N.Y. Times, Aug. 12, 2007, at WK9 (describing the American health system’s shortcomings compared with other nations); Karen Davis et al., *Mirror, Mirror on the Wall: An International Update on the Comparative Performance of American Health Care* (Commonwealth Fund report, May 2007). Safety and quality problems are catalogued in two landmark reports by the Institute of Medicine); INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 130-39 (2001). INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

Between the debate over national health reform in 1993-94 and today, new challenges for health law and health policy have arisen, and new approaches have been offered.

Unfortunately, little explicit attention is being paid to the tension between individual and collective goals that these trends and ideas present. Without attempting to cover the landscape of policy innovation, this Essay will offer observations about relational and regulatory governance in four areas: conflicts of interest in biomedical research, managed care and pay-for-performance, health care transparency and education, and the “new” public health.

Research “conflicts of interest.” The modern biomedical research enterprise offers an instructive example of how relational governance can confuse and mislead health policy. The medical marketplace encompasses research as well as clinical care, and money changing hands in unaccustomed ways has provoked criticism in both domains.⁴² Specifically, critics of commercialized research have labeled many payments by industry to academic researchers “conflicts of interest,” and have used the same term to question non-financial motivators for research that perturb their moral compass.⁴³ Ethically, a conflict of interest suggests corruption. Legally, it triggers a limited menu of responses: disclosure and consent, partitioning of functions, or outright prohibition.

Indeed, money can compromise things we consider fundamental values of science, particularly in universities. Money might change the direction of scientific agendas. It might threaten the integrity of research. It might harm research subjects. It might delay the dissemination of research results to the scientific community and the public. Finally, it might reduce public trust in medical science, and therefore support for government

⁴² Bud Relman, a highly influential prior editor of the *New England Journal of Medicine* and a vigorous defender of traditional ethics and practices, cautioned physicians in 1991 about medicine’s transition from profession to industry, warning that “our profession faces an ethical and economic crisis of unprecedented proportions, as it struggles to find its bearings in a health care system that has become a vast and highly lucrative marketplace.” Arnold S. Relman, *Shattuck Lecture – The Health Care Industry: Where Is It Taking Us?*, 325 *New Engl. J. Med.* 854, 854 (1991).

⁴³ See, e.g., Troyen A. Brennan et al., *Health Industry Practices that Create Conflicts of Interest*, 295 *JAMA* 429, 429 (2006); Sheldon Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* (2003) (criticizing university-industry relationships, often involving patented technologies).

research funding and willingness to participate in clinical trials. All of these are real risks, with real scandals to illustrate them.⁴⁴

But are they conflicts of interest? When lawyers guard against their own conflicts of interest, as required by the rules of professional responsibility, they define them in clearly relational terms. As legal ethicist Brad Wendel explains: “A conflict of interest arises when a person, the agent [i.e., the lawyer], stands in a relationship of trust with another person, the principal [i.e., the client] which requires the agent to exercise judgment on behalf of the principal and where the agent’s judgment is impaired because of another interest of the agent.”⁴⁵

Critics of new biomedical funding models, by contrast, typically justify their concern by invoking something like the following definition of conflict of interest: “a set of conditions in which professional judgment concerning a primary interest such as a patient’s welfare or the validity of research tends to be unduly influenced by a secondary interest such as financial gain.”⁴⁶ The problem with this definition is that only the first example is individual and relational; a physician who is legally and ethically obligated to be loyal to a specific patient might well be conflicted if paid by another. The second example, the validity of research, is an abstraction with collective, regulatory significance but no relational meaning. One cannot be loyal to research integrity, or to the common

⁴⁴ At the University of Pennsylvania, Jesse Gelsinger died after physicians with a commercial stake in a novel gene therapy ignore warning signs when enrolling research subjects to test the procedure. Sheryl Gay Stolberg, *F.D.A. Officials Fault Penn Team in Gene Therapy Death*, N.Y. Times, Dec. 9, 1999, at A22. In another case, a pharmaceutical company, Apotex, pressured the University of Toronto, to which it had promised a multimillion dollar gift, to demote a hematologist who had published negative findings about its new iron-binding drug. Krista Foss, *Grievance Filed in Drug-Research Controversy at U of T: Doctor in Lengthy Battle with Company Over Freedom to Publish Her Negative Findings*, Globe & Mail (Toronto), Dec. 18, 1998, at A11. The maker of Synthroid, Boots Pharmaceutical, attempted to suppress the publication of research that it sponsored at the University of California, San Francisco, which failed to show its product to be advantageous. See Drummond Rennie, *Thyroid Storm*, 277 JAMA 1238, 1238–39 (1997); see also *In re Synthroid Mktg. Litig.*, 264 F.3d 712, 714 (7th Cir. 2001) (discussing the published study).

⁴⁵ W. Bradley Wendel, *The Deep Structure of Conflicts of Interest*, 16 GEO. J. LEGAL ETHICS 473, 477 (2003) (book review). A general economic definition of an agent is anyone who makes a decision on behalf of another. The law of agency sets its scope more narrowly, defining an agent as a fiduciary subject to the principal’s right of control. Restatement (Second) of Agency § 1 (1958).

⁴⁶ Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 573 (1993).

welfare, or to motherhood and apple pie (though one certainly can be loyal to one's mom).

Unlike lawyers and clients, there is no identifiable party to whom biomedical researchers owe exclusive loyalty, unless it is merely those researchers' academic or corporate employers. The most intuitive relational accusation against researchers who receive outside funding is disloyalty to people who participate in human subjects research. If the researcher-subject relationship, like the physician-patient relationship, demanded such loyalty, conflict of interest discourse would be appropriate. But, as Coleman has explained, no such dominant relational duty exists.⁴⁷ One of the principal insights of modern bioethics is that the proper measure of research is its value to society.⁴⁸ Scientists are ethically and legally obligated to minimize risk of harm to participants, and can never conduct experiments that are likely to cause serious injury. But subjects participate in research, and sometimes even suffer harm, to further a social mission rather than in expectation of personal medical benefit. For this reason, ethicists often worry about the "therapeutic misconception," research subjects' incorrect belief that the white-coated researcher who supervises the experiment has their cure or physical benefit as her primary concern.⁴⁹

Financial flows in biomedical research therefore are less about conflicts of interest – unless a researcher is also a patient's treating physician – and more about getting the regulatory incentives right for productive, ethical research. Moral purity is not the issue;

⁴⁷ Coleman identifies recent litigation against clinical researchers as a pressing reason to define clearly the obligations owed by researchers to subjects because the template for such litigation is the obligation of physician to patient under established laws of medical malpractice and informed consent. Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 388–91 (2005).

⁴⁸ See, e.g., Franklin G. Miller, *Research Ethics and Misguided Moral Intuition*, 32 J.L. Med. & Ethics 111 (2004). Miller notes the curiosity that founding documents in bioethics assume that researchers must act with "therapeutic beneficence" toward human subjects, *id.* at 111, but that recent conceptions of research ethics minimize direct benefit to the subject as the basis for participation, stressing instead altruistic desire to help future sufferers among the general public, or within susceptible subgroups in whose wellbeing the participant has at most an indirect interest. *Id.* at 114.

⁴⁹ Paul S. Applebaum, *Clarifying the Ethics of Clinical Research: A Path Toward Avoiding the Therapeutic Misconception*, Am. J. Bioethics, Spring 2002, at 22, 23 (discussing the substantial prevalence of "therapeutic misconception").

professional effectiveness is. To appreciate this, one need only think beyond money (which seems “conflicting” because it has an identifiable source) to what has been called “non-financial conflicts of interest.”⁵⁰ Human motivation is complex, and indeed biomedical researchers may do what they do for many reasons in addition to payment: publication, promotion, peer recognition, etc. Selecting skilled researchers and giving them the proper incentives to produce useful knowledge is an important social project, but one cannot coherently argue that intellectual curiosity or altruism is always a better motivator than monetary gain or desire for fame.

This is particularly so given the incentive environment the federal government deliberately created for biomedical researchers. The watershed event in this respect was the passage in 1980 of the Bayh-Dole Act, which responded to American industry’s seeming inability (compared, at the time, to the Japanese) to commercialize technologies funded by public research dollars.⁵¹ The Bayh-Dole Act encouraged universities to patent inventions derived from NIH, NSF, or similar funding streams, and then license those patents to private industry for commercial development (at the same time producing a politically attractive off-budget subsidy for universities through licensing fees and royalties). The generation of research scientists that followed the Bayh-Dole Act looks and acts unlike its predecessors.⁵² Earlier university researchers were from relatively homogeneous backgrounds, accepted modest pay, and sought little publicity, but enjoyed prestige and security within their academic communities. For the more diverse generation that followed, achieving success requires entrepreneurship, monetary rewards matter, and it is important to be in the public eye.

⁵⁰ See Norman Levinsky, Nonfinancial Conflicts of Interest in Research, 347 *NEW ENG. J. MED.* 759 (2002).

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

⁵² To illustrate, I recently learned from the chair of biomedical engineering at the University of Texas that most junior faculty joining his department list “starting a company” as one of their five-year career goals. It is hard to imagine that ambition being either offered or accepted as a path to academic success a generation ago.

There may be good reason to refine research incentives as a matter of collective public policy, much as incentive compensation for corporate managers has been recalibrated to better align their interests with those of shareholders without tempting them to commit fraud. However, labeling those incentives “conflicts of interest” – whether from honest concern, misplaced nostalgia, or inability to compete – merely provokes public disapproval and legal scrutiny without solving the problem. In particular, only when one gets past conflict of interest rhetoric do the empirics matter. Instead of leveling moral accusations, society can ask, and determine as a regulatory matter, what incentive structures, informational requirements, and legal remedies produce new knowledge at reasonable cost without unacceptably endangering research subjects.⁵³

The managed care backlash and pay for performance. Another illustration of misguided relational emphasis comes from the country’s first widespread experiment with payer involvement in health care delivery: the managed care expansion of the 1980s and 1990s. Health insurers may not be saints, but the managed care experience primarily spotlights America’s inability to engage affordable access to basic medical care as a collective issue. As Havighurst and Richman observe, American law turns out to be no friend to the have-nots where health coverage is concerned.⁵⁴

Managed care regulation began as a common project to loosen the organized medical profession’s economic grip on the health care system by clearing away self-protective laws, such as prohibitions on selective contracting with hospitals or physicians, thereby freeing up resources for both public and private expansions of access. It ended in a legislative frenzy to keep things exactly as they had been for well-insured individuals with political power.⁵⁵ The language of the backlash legislation, “patient protection,” perfectly captured the (successful) political strategy of managed care’s opponents: frame

⁵³ For a more detailed argument, see William M. Sage, Some Principles Require Principals: Why Banning “Conflicts of Interest” Won’t Solve Incentive Problems in Biomedical Research, 85 *Texas L. Rev.* 1413 (2007).

⁵⁴ Clark C. Havighurst & Barak D. Richman, Distributive Injustice(s) in American Health Care, 69 *Law & Contemp. Probs.* 7 (Autumn 2006).

⁵⁵ See David A. Hyman, Managed Care at the Millennium: Scenes From a Maul, 24 *J. Health, Pol., Pol’y & L.* 1061, 1061 (1999).

the debate in relational terms using the image of someone ill facing restrictions on desired treatment. A collective voice – including potential patients, those for whom the current system is unaffordable – was never heard.

Reactionary legislation was bolstered by the medical profession and the courts. Health insurance is constructed around pre-existing risk pools such as workplaces; physicians, however, fiercely resisted assuming ethical responsibility for “populations” and reasserted the primacy of “advocacy” for individual patients.⁵⁶ The courts, forced to examine managed care because most health plans are governed by the Employer Retirement Income Security Act of 1974 (ERISA), never got beyond the relational perspective. Cases involving patient injury plausibly attributable to managed care restrictions were finessed by most judges to allow equitable results without setting lasting precedents, at least until the Supreme Court articulated a bright-line rule in favor of defendants.⁵⁷ The best judicial opportunity for giving legal meaning to collective obligations in managed care was *Pegram v. Herdrich*, which asked the federal courts to consider how an ERISA plan’s fiduciary duty to groups of beneficiaries might affect the

⁵⁶ See Jerome P. Kassirer, *Managing Care—Should We Adopt a New Ethic?*, 339 NEW ENG. J. MED. 397, 397 (1998) (arguing that a population-based ethic for the provision of health care—“intentionally providing minimally acceptable care to some for the benefit of others”—is wrong); see also William M. Sage, *Physicians As Advocates*, 73 HOUS. L. REV. 1529 (1999) (arguing that a strict duty of physician advocacy on behalf of individual patients would be counterproductive). Among medical practice settings, only a few well-established HMOs seem to have developed cultures that make physicians feel responsible for their colleagues’ patients as well as their own, promoting cost-consciousness without obligating them to “ration at the bedside.” For a revealing portrait of the tension between individual and group health management, see David M. Eddy, *Broadening the Responsibilities of Practitioners: The Team Approach*, 269 JAMA 1849 (1993) (discussing the proper use of expensive radiographic contrast agents).

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

Non-ERISA coverage cases decided under state insurance law have consistently looked to plaintiffs’ treating physicians for the best evidence of medical necessity, downplaying the significance of expertise regarding collective cost-effectiveness or even clinical benefit. See, e.g., *Florence Nightingale Nursing Service, Inc. v. Blue Cross & Blue Shield of Alabama*, 832 F. Supp. 1456 (N.D. Ala. 1993) (ridiculing the defendant health plan’s medical director for being trained “not only in medicine but in ‘cost containment’”).

delivery of services to individuals.⁵⁸ Unfortunately, the Supreme Court found a way to dispose of the case without resolving, or even discussing, that critical question.⁵⁹

To be fair, courts are constituted to hear specific controversies presented by plaintiffs with standing to sue, and only make general law when necessary to the resolution of an individual dispute.⁶⁰ Collective litigation over managed care – several class action suits were filed – dealt either with pedestrian matters, such as delays in physician payment, or with highly speculative ones, such as whether all purchasers of managed health coverage had been defrauded.⁶¹ Other than *Pegram*, which was not litigated expertly by the plaintiff, there were no accessible vehicles for articulating regulatory duties using judicial processes.

Managed care lost the first battle, but continues the war against health care costs because affordability remains a major concern of the Medicare and Medicaid programs, of most employers, and of nearly all individuals who purchase or want to purchase health insurance. Today's care management, however, is kinder and gentler (or, if you prefer, sadder yet wiser) than its prior incarnation. But there is still no indication that policymakers have solved, or even that they recognize, the problem of building collective benefits using relational tools.

Having endured a cycle of both consumer rejection (admittedly during an economic boom) and legal restriction for seeming to interfere with relational obligations to patients, health plans no longer offload capitated risk on financially unsophisticated physicians,

⁵⁸ *Pegram v. Herdrich*, 530 U.S. 211 (2000).

⁵⁹ *Pegram*, 530 U.S. at 231-34 (holding that a mixed eligibility-treatment decision made by an HMO through its employed physicians is not a fiduciary act under ERISA). See also William M. Sage, *UR Here: The Supreme Court's Guide for Managed Care*, HEALTH AFF., Sept./Oct. 2000, at 219.

⁶⁰ William M. Sage, Unfinished Business: How Litigation Relates to Health Care Regulation, 28 J. Health Politics, Pol'y & L. 387 (2003).

⁶¹ See Clark C. Havighurst, Consumers Versus Managed Care: The New Class Actions, 20 Health Aff., July-Aug. 2001, at 8. "Fraud on the market" is another example of the legal system trying to address systemic harms by extrapolating from individual ones. See Sage, *supra* note __, at __ n. 163 [Texas L. Rev.]; John C. Coffee, Jr., *Causation by Presumption? Why the Supreme Court Should Reject Phantom Losses and Reverse Broudo*, 60 BUS. LAW. 533 (2005); Merritt B. Fox, *Demystifying Causation in Fraud-on-the-Market Actions*, 60 BUS. LAW. 507 (2005); *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336 (2005).

rarely limit enrollees to narrow physician panels selected for unrevealed but presumably economic reasons, and seldom exercise unilateral corporate authority to rule physician-recommended treatment “not medically necessary.” Instead, managed care (and Medicare as well) has reinvented its objective as value-based purchasing, is beginning to measure and publicize provider quality, and is attempting to pay physicians and hospitals more for better performance.⁶²

What is nobody explaining? Whether “value,” “quality,” and “performance” are to be judged by individual or by collective criteria.⁶³ The first generation of pay for performance is merely pay for measurement, creating the public good of baseline and trend information that can be justified as pro-consumer but that has primarily collective benefit. Government standards and Medicare-based subsidies for electronic recordkeeping in essence reflect this fact. What will the next generation of pay for performance represent? Pay for physician loyalty to individual patients, based on subjective satisfaction, accessibility of desired treatment, and individual health outcomes? Or pay for compliance with cost-effective best practices and population-based disease prevention and lifestyle modification that improves society’s productivity and reduces its disease burden? If the latter, how will these practices be selected and how will the results be measured? This choice is more than a technical one. It goes to the heart of assessing health care in individual relational versus collective regulatory terms.

Health care transparency and education. Similar problems regarding overemphasis on relational obligations and failure to define collective goals afflict the legion of regulatory mandates that comprise the “health care transparency” movement. Informational asymmetries between physicians and patients have been cited since the 1960s as the principal reason why efficient markets seldom emerge in health care.⁶⁴ These insights

⁶² See, e.g., Michael E. Chernew, Allison B. Rosen, and A. Mark Fendrick, Value-Based Insurance Design, 26 *Health Aff.* W195 (2007) (Web Exclusive); Meredith B. Rosenthal et al., Paying for Quality: Providers’ Incentives for Quality Improvement, 23 *Health Aff.* 127 (2004).

⁶³ William M. Sage, *Pay-for-Performance: Will It Work in Theory?*, 3 *IND. HEALTH L. REV.* 305 (2006).

⁶⁴ Arrow, *supra* note ____.

were used to explain the continued importance of professional ethics, and sometimes to justify broad government involvement in funding and overseeing medical care.⁶⁵

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

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

Although bringing patients’ knowledge closer to physicians’ would seem to benefit both autonomy and competition, the relational dangers of asymmetric information were already old news when these programs were instituted. The real action has involved

⁶⁵ Arrow, *supra* note __ (discussing professional ethics as a non-market social institution that reduces uncertainty in medical markets); Peter J. Hammer, Arrow’s Analysis of Social Institutions: Entering the Marketplace with Giving Hands, in *Uncertain Times: Kenneth Arrow and the Changing Economics of Health Care* (Peter J. Hammer et al., eds.) at 216 (2003) (analyzing Arrow’s thesis regarding social institutions); James C. Robinson, The End of Asymmetric Information, in *Uncertain Times: Kenneth Arrow and the Changing Economics of Health Care* (Peter J. Hammer et al., eds.) at 216 (2003) (criticizing the political use of information asymmetry to justify heavy-handed regulation).

collective information acquisition and processing, addressing problems revealed by Wennberg's small-area variation studies and the Institute of Medicine's scholarly exposés of quality and safety lapses in hospitals.⁶⁶ The hope of wringing substantial cost savings out of this disorganized and wasteful system, while actually enhancing quality of care through incentives and subsidies for data gathering and communication, is what motivates interest in electronic health records, decision support software, and other information technology. Transparency, it now seems, is to a large extent a public good, and should be structured and regulated accordingly.

Transparency intended to support another current marketplace trend, "consumer-directed care,"⁶⁷ similarly combines individual transactional utility with collective benefit. The pragmatic purpose of consumer-directed care among employers and government payers is to reduce third-party financing of health insurance from a comprehensive commitment to a defined contribution in the face of continued medical inflation. But proponents of health savings accounts and similar insurance products also believe that large aggregate savings will be realized once consumers, pursuing financial self-interest, use information about price and quality to make prudent choices.⁶⁸

Ideally, these demand effects of transparency could combine with the collective supply-side effects described above to free health care delivery from its historical tethers and enable it to achieve efficiencies typical of most other modern economic sectors. The

⁶⁶ See JOHN E. WENNBURG, *THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES* 2 (1996); INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 130-39 (2001). INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

⁶⁷ See James C. Robinson, *Consumer-Directed Health Insurance: The Next Generation*, *HEALTH AFF.*, Dec. 13, 2005 (Web Exclusive).

⁶⁸ Phil Gramm, *Why We Need Medical Savings Accounts*, 330 *NEW ENG. J. MED.* 1752-1753 (1994) (claiming that waste in health care is primarily attributable to the moral hazard of costlessness at the point of service); Gerald L. Musgrave et al., *Lunch Insurance*, 15 *REGULATION* 257 (1992) (making the same point by postulating a "lunch system" with subsidies similar to the current health care system). Whether or not one agrees with this assessment of moral hazard, John A. Nyman, *Is "Moral Hazard" Inefficient?: The Policy Implications of a New Theory*, *Health Aff.*, Sept./Oct. 2004, at 194 (arguing that health insurance shifts dollars to more highly valued future uses), the consumer-directed care movement deserves respect in political terms for having a theory and an innovation to support it, something little seen in health care since the Nixon administration's experiment with health maintenance organizations.

“retail medical clinic” movement, for example, associates basic medical care with familiar pharmacy and supermarket brands that offer assurances of price competition and customer service, but are spared the presumption of an adversarial financial relationship that made brand-name managed care organizations unattractive to consumers in the 1990s.⁶⁹

Transparency also has collective meaning in health care through its reinforcement of democratic governance. Near the end of his career, Thomas Jefferson wrote: “I know of no safe depository of the ultimate powers of this society but the people themselves; and if we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion.”⁷⁰

Among other things, the public deserves information to help it approve or reject the massive redistributions of wealth that the health care system facilitates: generational and income-based transfers through Medicare and Medicaid, tax expenditures arising from non-taxability of employer-sponsored coverage, and tax exemptions for hospitals and other non-profit providers. Even information about medical error and compensation for avoidable patient injury has a social dimension – involving collective insurance against misfortune and the value received for public investment in the health care and legal systems – that complements new (and praiseworthy) relational commitments of physicians to reveal and discuss with patients any unanticipated outcomes of medical care.⁷¹

Public health. Public health is a fourth area of current interest in which relational-regulatory balance is important. Traditional public health law focused on protecting society from negative externalities of individual behavior such as transmission of disease through contagion or contamination. As noted previously, public health law represents the paradigm case for a regulatory, collective approach to health policy, but has been

⁶⁹ For a discussion of the public policy implications of retail clinics, see William M. Sage, *The Walmartization of Health Care*, *Journal of Legal Medicine* (forthcoming 2007).

⁷⁰ Thomas Jefferson, Letter to William Charles Jarvis, Sept. 28, 1820.

⁷¹ See William M. Sage et al., *Bridging the Private-Public Divide: A Pragmatic Information Policy for Medical Malpractice and Patient Safety*, 59 *Vand. L. Rev.* 1263 (2006).

marginalized both legally and financially compared with the diagnosis and treatment of individual patients.⁷² From roughly 1950 to 2000, in particular, public health not only was substantially less lucrative for physicians than acute-care medicine, but seemed to have outlived its usefulness (at least domestically) as the great plagues were conquered in rapid succession by sanitary infrastructure, vaccines, and antimicrobial drugs.

This complacency has ended, with globalization, terrorism, and natural disaster resurrecting traditional public health as “biopreparedness” and “biosecurity.”⁷³ At the same time, chronic disease has come to dominate our national medical record, imposing huge social costs in dollars and in reduced quality of life. In response, advocates have articulated a “new” public health agenda that attempts to reduce demand for health care services by instilling individual habits of healthy living, disease prevention, and emotional well-being.⁷⁴

These challenges, and the resource needs that accompany them, can best be met by remarrying the public health and health care systems, both in substance and in legal governance. Doing so requires providing a regulatory rationale for issues that are currently seen through a relational lens.⁷⁵ With respect to controlling obesity, for example, a recent article by Alderman and colleagues laments that “[c]urrent policy and legal analysis are singularly focused on individuals as rational choice makers or on breaking the chain of causation close to the individual and rarely takes [sic] a larger view.

⁷² See Arrow, *supra* note __, at 941 (clarifying immediately for readers that the subject of his economic analysis was “medical care” and not “health”).

⁷³ See Lawrence O. Gostin, *Public Health Law: Power, Duty, Restraint* (2000) (analyzing legal and ethical tradeoffs between public goods and private rights). These threats, and the AIDS pandemic that preceded them, have also reinvigorated and reshaped public health efforts in the international arena. See Jon Cohen, *The New World of Global Health*, 311 *Science* 62 (2006).

⁷⁴ See generally Lawrence O. Gostin & Peter D. Jacobson, *Law and the Health System* 41-76 (considering whether public health law should concern itself with issues such as socioeconomic status and the built environment, and whether state intervention can be justified in the absence of market externalities).

⁷⁵ It is worth acknowledging that utopian visions of managed care also included bringing public health together with clinical medicine based on the assumption that population-based “health maintenance” by prepaid health plans serving broad segments of their communities required such an approach. A detailed ethical framework for governing these organizations based on political rather than market or professional accountability was even proposed. Ezekiel J. Emanuel & Linda L. Emanuel, *Preserving Community in Health Care*, 22 *J. Health Politics, Pol’y & L.* 147 (1997).

Environmental factors and the individual's social context are not considered.”⁷⁶ Another article in the same symposium identifies five promising areas for collective intervention to reduce individual obesity: the school environment, the built environment, community facilities, the point of sale environment, and earmarked taxes and fees.⁷⁷ However, the relational underpinnings of health law do not currently provide a normative roadmap for entering this territory, although some ethicists and legal philosophers have attempted to supply one based on theories of justice and interconnectedness.⁷⁸

Transparency initiatives offer another illustration of how relational approaches tend to crowd out regulatory ones in contemporary public health policy. As noted, the appropriate scope of public health remains a subject for debate. Defenders of the “old” public health argue on ideological grounds that individual liberty should trump paternalism, and emphasize the close historical connection between the role of public health law in fighting communicable disease and constitutional limitations on the state's coercive powers.⁷⁹ Advocates for the “new” public health argue on pragmatic grounds that chronic disease has become a greater risk to individuals than infection, and emphasize that most modern public health measures are non-coercive, with information their principal example.⁸⁰

An unrecognized problem with this response is its retreat from a regulatory to a relational justification. The fact that a public health intervention – even an individually oriented one such as information provision – physically protects an individual from her own

⁷⁶ Jess Alderman et al., Application of Law to the Childhood Obesity Epidemic, 35 J.L. Med. & Ethics 90, 91 (2007) (symposium issue on childhood obesity).

⁷⁷ Marice Ashe et al., Local Venues for Change: Legal Strategies for Healthy Environments, 35 J.L. Med. & Ethics 138 (2007).

⁷⁸ See, e.g., Lawrence O. Gostin & Madison Powers, What Does Social Justice Require for the Public's Health? Public Health Ethics and Policy Imperatives, 25 Health Aff. 1053 (2006) (urging an interventionist approach to the multiple causes of systematic disadvantage in health); Leslie P. Francis et al., How Infectious Disease Got Left Out – and What This Omission Might Have Meant for Bioethics, 19 Bioethics 307 (2005) (speculating on how the historical coincidence of liberal bioethics taking shape at the nadir of concern over infectious disease might have drained bioethics of collective content).

⁷⁹ Richard A. Epstein, *Let the Shoemaker Stick to His Last: A Defense of the "Old" Public Health*, 46(Supp.) Perspectives Biol. Med. S 138 (2003).

⁸⁰ Lawrence O. Gostin & M. Gregg Bloche, *The Politics of Public Health: A Response to Epstein*, 46(Supp.) Perspectives Biol. Med. S 160 (2003).

diseases rather than someone else's does not drain the intervention of collective importance. Transparency and education geared to wellness and prevention of non-communicable disease honor "public" health in several ways: by promoting community cohesiveness, by boosting economic productivity and increasing prosperity, by conserving public funds for non-health care purposes, and by creating a critical mass of voter and consumer demand that can force changes to the built and purchased environment through democratic and market processes. Although these points are sometimes made, public health advocates would do well to stress such collective benefits even for informational and educational programs. Because budgetary politics often dominate health policy, as discussed above, an important specific reform would be to revise government accounting rules and practices to take account of savings outside the health care system generated by investments in the health care system, and to accommodate (with appropriate discount rates and sensitivity analyses) the longer time horizons necessary to realize returns on those investments.

Conclusion

It is sometimes said that the plural of anecdote is not data. One might add that the plural of health law seems not to be health policy. This Essay argues that the modern American health care system cannot be governed effectively using legal standards and methods suited to individual physician-patient encounters, regardless of whether those encounters reflect mainly professional or mainly marketplace behavior. Instead, health law must develop collective meaning that supports health policymakers' efforts to expand access, improve quality, and maintain affordability.⁸¹

As industry and society change, it is not unusual for relational duties that frame individual transactions to be adapted into regulatory duties with collective social

⁸¹ Collective meaning implies shared sacrifice as well as shared benefit, not merely a right to health care (as the "social paradigm" is often portrayed in contrast to professional or market dominance). See, e.g., Rand Rosenblatt, *The Four Ages of Health Law*, 14 *Health Matrix* 155, 166-75 (2004) (describing a version of health law based on an egalitarian social contract).

importance. One can observe the phenomenon not only in health care, but in corporate governance, environmental regulation, and other areas. But it represents a particular challenge for professions such as medicine that, because of their overall success, have become regulated industries. In these settings, it is worth reminding ourselves that collective goals matter, and that a profession can still be valued for its social contribution as well as its technical skill.⁸²

With the future promising still greater technical achievements for medicine, but without a way either to temper demand for those resources or to finance them for ordinary citizens, even the United States must eventually transform its individually oriented health care system into a collective one. Physicians can be a positive force in shaping and achieving collective goals, but only if they can carry both their scientific skills and their humanitarian commitments beyond the “best interests of a specific patient.” Faced with evidence of declining physician influence,⁸³ commentators are beginning to turn in this direction. Cassel and Brennan call a physician-led regulatory approach “managing the commons”;⁸⁴ Stevens calls it a “new public service ethos.”⁸⁵

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

⁸² Steven Brint distinguishes “social trustee” professionals from “expert knowledge” professionals, and asserts a historical trend in favor of the latter group, who tend to provide sophisticated services to paying clients. STEVEN BRINT, *IN AN AGE OF EXPERTS: THE CHANGING ROLE OF PROFESSIONALS IN POLITICS AND PUBLIC LIFE* 7–8 (1994). See also William F. May, *Beleaguered Rulers: The Public Obligation of the Professional* (2001) (arguing that all professions have social as well as technical duties, including to teach virtue to their clients within their fields of expertise).

⁸³ See Mark Schlesinger, *A Loss of Faith: The Sources of Reduced Political Legitimacy for the American Medical Profession*, 80 *Milbank Q.* 185 (2002).

⁸⁴ Christine K. Cassel & Troyen E. Brennan, *Managing Medical Resources: Return to the Commons?* 297 *JAMA* 2518 (2007) (articulating physicians’ duty to attend to collective costs).

⁸⁵ Rosemary A. Stevens, *Public Roles for the Medical Profession in the United States: Beyond Theories of Decline and Fall*, 79 *Milbank Q.* 327, 345–47 (urging the profession to redefine patients as groups, physicians as teams and organization, and science as a “positive joint effort of numerous organizations and interests”).